

Table of Contents

Attachments A	
Attachment A.1: Discussion of COVID-19 Deaths in the United States	1
Attachment A.2: Disease Comparison Chart	18
Attachment A.3: NVSS Guidance for Certifying COVID-19 Deaths	23
Attachment A.4: Medical Examiners' and Coroners Handbook on Death Registration and Fetal Death Reporting, 2003 Revisions	32
Attachment A.5: Senator Scott Jensen, M.D. Documents and Attachments	170
Attachment A.6: The Infection fatality rate of COVID-19 inferred from Seroprevalence data	237
Attachment B: Conclusion Regarding Masks, They Do Not Work	289
Attachments C	
Attachment C.1: Inaccurate Testing	299
Attachment C.2: CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel	318
Attachment D: Governor DeWine August Tweets	377
Attachment E: FOIA Request Documentation	380
Attachment F: Impacts of COVID-19 Mitigation Efforts/Activities	384
Attachment G: Press Release Timeline	398
Attachment H: Open Letter Advocating for an Anti-racist Public Health Response to Demonstrations Against Systemic Injustice Occurring During the COVID-19 Pandemic	407
Attachment I: COVID-19 & Public Health Totalitarianism: Untoward Effects on Individuals, Institutions and Society	425
Attachment J: Plaintiff Affidavits and Declarations	556
Attachment K: Expert Declarations	615

Attachment A.1

Discussion of COVID-19 Deaths in the United States

From February 1, 2020 through March 21, 2020 the CDC reported a total of 665 COVID-19 deaths (CDC Daily Updates of Totals by Week and State, 2020). The following week ending March 28 there were a staggering 3,146 COVID-19 deaths reported. It begs the question; how does the death count increase by nearly five times in one week, which is more than that of the previous seven weeks combined? Concerns over inflated COVID-19 fatality numbers have been prominent for months. Businesses are being shuttered because of these numbers. Paychecks are being furloughed because of these numbers. Children are being denied the opportunity to go to school because of these numbers. Masks are being mandated because of these numbers. So, are they right?

INFECTIOUS DISEASE REPORTING AND CAUSES OF DEATH

Before COVID-19

For the past 17 years, all infectious diseases and causes of death are categorized based on the guidance of the *2003 CDC's Medical Examiners' & Coroners' Handbook on Death Registration and Fetal Death Reporting and the CDC's Physicians' Handbook on Medical Certification of Death*. "The cause-of-death section consists of two parts. Part I is for reporting a chain of events leading directly to death, with the immediate cause of death (the final disease, injury, or complication directly causing death) online (a) and the underlying cause of death (the disease or injury that initiated the chain of events that led directly and inevitably to death) on the lowest used line. Part II is for reporting all other significant diseases, conditions, or injuries that contributed to death but which did not result in the underlying cause of death given in Part I." (Centers for Disease Control and Prevention, 2003).

Unique COVID-19 Reporting and the Impact of Comorbidities on Fatality Data

On March 24, 2020 the National Vital Statistics System (NVSS) released the formal guidance regarding a "newly-introduced ICD code" (U07.1) to "accurately capture mortality data for Coronavirus Disease 2019 (COVID-19) on death certificates" (CDC, 2020e). These guidelines usurped the 2003 data collection guidance that is used for all other infectious diseases and causes of death data and are unique to COVID-19.

Also guiding COVID-19 data collection and reporting is the April 14th CDC adoption of a position paper authored by the Council of State and Territorial Epidemiologist (CSTE position paper). The NVSS guidelines and the CSTE position paper provide that COVID-19 would:

- be recorded as the underlying cause of death "more often than not;"
- be recorded as the cause of death listed in Part 1 of the death certification even in assumed cases;
- be recorded as the primary cause of death even if the decedent had other chronic comorbidities. All comorbidities for COVID-19 would be listed now in Part II, rather than in Part I as they have been since 2003 for all other causes of death.

It is the Part I causes of death that are recorded for public health reporting. Also within these guidelines the instructions were clear to report the cause of death as COVID-19 even without a

confirmed test. “COVID-19 should be reported on the death certificate for all descendants where the disease caused **or is assumed to have caused or contributed to death**. Certifiers should include as much detail as possible based on their knowledge of the case, medical records, laboratory testing, etc.” The guidelines also state, “If the death certification reports terms such as “probable COVID-19” or “likely COVID-19,” these terms would be assigned the new ICD code. It is **not likely that the NCHS will follow up on these cases.**” (National Vital Statistics System, 2020).

The CSTE position paper assists individuals in determining whether a person has possible or probable COVID-19. The criteria for a diagnosis are quoted below:

COVID-19 Death Certificate Guidelines

Clinical Criteria

At least two of the following symptoms: fever (measured or subjective), chills, rigors, myalgia, headache, sore throat, new olfactory and taste disorder(s)

OR

At least one of the following symptoms: cough, shortness of breath, or difficulty breathing

OR

Severe respiratory illness with at least one of the following:

- Clinical or radiographic evidence of pneumonia, OR
- Acute respiratory distress syndrome (ARDS).

AND

No alternative more likely diagnosis.

Laboratory Criteria

Laboratory evidence using a method approved or authorized by the U.S. Food and Drug Administration (FDA) or designated authority:

Confirmatory laboratory evidence:

- Detection of severe acute respiratory syndrome coronavirus 2 ribonucleic acid (SARS-CoV-2 RNA) in a clinical specimen using a molecular amplification detection test

Presumptive laboratory evidence:

- Detection of specific antigen in a clinical specimen
- Detection of specific antibody in serum, plasma, or whole blood indicative of a new or recent infection*

**Serologic methods for diagnosis are currently being defined.*

Epidemiologic Linkage

One or more of the following exposures in the 14 days before onset of symptoms:

- Close contact** with a confirmed or probable case of COVID-19 disease; **OR**
- Close contact** with a person with:
 - clinically compatible illness **AND**
 - linkage to a confirmed case of COVID-19 disease.
- Travel to or residence in an area with sustained, ongoing community transmission of SARS-CoV-2.
- Member of a risk cohort as defined by public health authorities during an outbreak.

***Close contact is defined as being within 6 feet for at least a period of 10 minutes to 30 minutes or more depending upon the exposure. In healthcare settings, this may be defined as exposures of greater than a few minutes or more. Data are insufficient to precisely define the duration of exposure that constitutes prolonged exposure and thus a close contact.*

Case Classification

Probable

- Meets clinical criteria **AND** epidemiologic evidence with no confirmatory laboratory testing performed for COVID-19.
- Meets presumptive laboratory evidence **AND** either clinical criteria **OR** epidemiologic evidence.
- Meets vital records criteria with no confirmatory laboratory testing performed for COVID-19.

Confirmed

- Meets confirmatory laboratory evidence.

Other Criteria

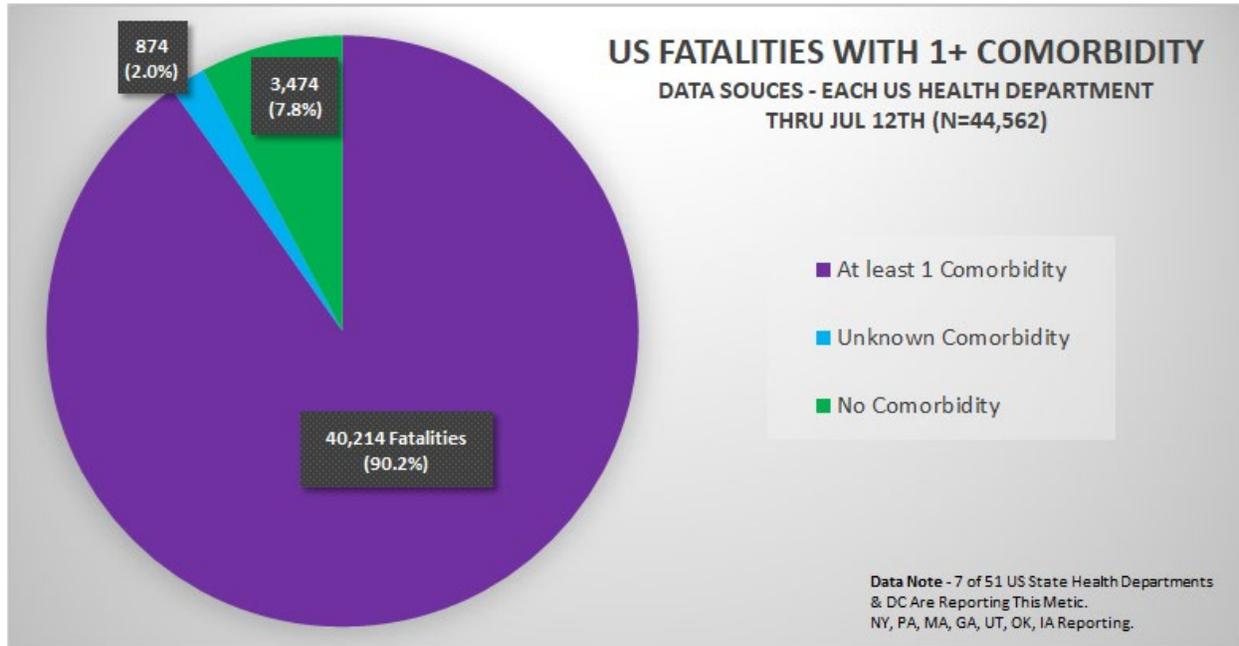
Vital Records Criteria

- A death certificate that lists COVID-19 disease or SARS-CoV-2 as a cause of death or a significant condition contributing to death.

Within the 2003 CDC Handbook guidelines COVID-19—in the presence of an established comorbidity—could be no higher than Part I, line item (d) or lower, or in Part II. To simplify, under the 2003 CDC handbook, COVID-19 fatalities would be listed as a cause of death in Part I only if there were no comorbidities. Furthermore, COVID-19 would have only been permitted to be listed on a death certificate if there had been a positive lab test or confirmation through pathologic autopsy findings.

“If each state were publishing comorbidity data, and if each state used the CDC’s 2003 Revision Handbook as they do for all other death certificates, **the actual COVID-19 fatality totals would be approximately 90.2% LOWER than they currently are based upon an extrapolation of the data that is available.**” (Children’s Health Defense, 2020).

The same article discussed the compiled data from the only seven states that publish analyzable comorbidity data. The researchers found "... that 90.2% of the state fatalities had at least one comorbidity and therefore these fatalities would not be counted as COVID-19 fatalities under the 2003 CDC Handbook, but instead are counted based on upon the NVSS guidelines and CSTE position paper adopted by the CDC on March 24th and April 14th respectively." Below is comorbidity graph presented by Children's Health Defense researchers.



Source: Children's Health Defense, 2020

In April 2020, the Journal of the American Medical Association published a study and reported that 94% of COVID-19 patients in the New York City area suffered from at least one comorbidity (Richardson et al., 2020). The researchers found that 53% of all COVID-19 patients also had hypertension, 42% were categorized as obese, and 32% had diabetes. Karina Davidson, one of the study's authors, stated, "Having serious comorbidities increases your risk. This is a very serious disease with a very poor outcome for those who have severe infections from it."

Comorbidities Kill Millions Each Year

Below is a chart of the top causes of death for the 2018 year, the most recent data available (CDC, 2020a).

Underlying Cause of Death, 1999-2018 Results

Request Form Results Map Chart About

Dataset Documentation Other Data Access Help for Results Printing Tips Help with Exports Save Export Reset

Quick Options More Options Top Notes Citation Query Criteria

Messages:

▶ When you group results by 15 Leading Causes, results are initially ordered by Death counts; also, total rows, zero rows, suppressed rows, and Percent of Total are not available. Click any green up/down arrow to change the order. [More information.](#)

15 Leading Causes of Death ↓	Deaths ↑↓	Population ↑↓	Crude Rate Per 100,000 ↑↓
#Diseases of heart (I00-I09,I11,I13,I20-I51)	655,381	327,167,434	200.3
#Malignant neoplasms (C00-C97)	599,274	327,167,434	183.2
#Accidents (unintentional injuries) (V01-X59,Y85-Y86)	167,127	327,167,434	51.1
#Chronic lower respiratory diseases (J40-J47)	159,486	327,167,434	48.7
#Cerebrovascular diseases (I60-I69)	147,810	327,167,434	45.2
#Alzheimer disease (G30)	122,019	327,167,434	37.3
#Diabetes mellitus (E10-E14)	84,946	327,167,434	26.0
#Influenza and pneumonia (J09-J18)	59,120	327,167,434	18.1
#Nephritis, nephrotic syndrome and nephrosis (N00-N07,N17-N19,N25-N27)	51,386	327,167,434	15.7
#Intentional self-harm (suicide) (*U03,X60-X84,Y87.0)	48,344	327,167,434	14.8
#Chronic liver disease and cirrhosis (K70,K73-K74)	42,838	327,167,434	13.1
#Septicemia (A40-A41)	40,718	327,167,434	12.4
#Essential hypertension and hypertensive renal disease (I10,I12,I15)	35,835	327,167,434	11.0
#Parkinson disease (G20-G21)	33,829	327,167,434	10.3
#Pneumonitis due to solids and liquids (J69)	19,239	327,167,434	5.9

Note: A '#' symbol preceding the label indicates a rankable cause of death. [More information.](#)

Source: <https://wonder.cdc.gov/controller/datarequest/D76jsessionid=77882FF4BD5D3BE7ADC461287433BE6F>

At the top of the list is diseases of the heart: 655,381 individuals died of heart conditions in 2018. Certainly, heart conditions would be a pre-existing condition. What if an individual has COVID-19 and a heart disease and they die, are they going to list it as a COVID-19 death?

Four rows down we see an extremely significant number: 159,000 individuals died from chronic lower respiratory disease in 2018. Diabetes killed nearly 85,000 individuals and 59,120 deaths were caused by influenza and pneumonia. These numbers illustrate the people who have comorbidities with COVID-19.

If we extrapolate those numbers to 2020, that's nearly one million people with comorbidities. According to Statistician Professor Sir David Spiegelhalter, there will be “a substantial overlap” with COVID-19 and “Many people who die of [COVID-19] would have died anyway within a short period.” (Triggle, N., 2020).

The CDC Morbidity and Mortality Weekly Report for February 12–March 28, 2020 also reported that 94% of COVID-19 patients had at least one underlying condition (comorbidity) (CDC, 2020f). Given these massive cause of death numbers, the guidelines for listing cause of death is *critical* in separating out the comorbid vs. the COVID-19 deaths. Unfortunately, given the guidelines discussed, it can be anticipated that a majority of these deaths will be/have been attributed to COVID-19, thus leading to inflated numbers and inaccurate data on which important decisions are being made—even Supreme Court decisions.

In May, in an opinion discussing large gatherings, Chief Justice Roberts mentions that COVID-19 “has killed thousands of people in California and more than 100,000 nationwide.” (S. Bay United Pentecostal Church v. Newsom, 2020). What if, just like in New York, 94% of those 100,000 had co-morbidities that were the actual cause of death. What if 94,000 of those deaths were individuals who died *with* COVID-19, not *from* COVID-19? Even if that is the case for half of them, ignoring the way these statistics have been recorded for the past 17 years and changing it has disastrous implications.

In actuality the COVID-19 death rate could be more like to the severe seasonal flu which are between 12,000 – 61,000 deaths annually, per CDC estimates. (CDC, 2020c). Not the hundreds of thousands which Chief Justice Roberts was lead to believe.

In an editorial in New England Journal of Medicine, Fauci et al. (2020) stated that “If one assumes that the number of asymptomatic or minimally symptomatic cases is several times as high as the number of reported cases, the case fatality rate may be considerably less than 1%. This suggests that the overall clinical consequences of Covid-19 may ultimately be more akin to those of a severe seasonal influenza (which has a case fatality rate of approximately 0.1%) or a pandemic influenza (similar to those in 1957 and 1968) rather than a disease similar to SARS or MERS, which have had case fatality rates of 9 to 10% and 36%, respectively.”

FINANCIAL INCENTIVE FOR FALSE REPORTING

Section 3710 of the CARES (Coronavirus Aid, Relief, and Economic Security) Act increased the amount of payment to hospitals from Medicare by 20% for patients being treated with COVID-19. While there is much discussion on what is actually covered in the treatment of COVID-19 by this Act, the simple fact is that hospitals make 20% more from a COVID-19 patient suffering from acute respiratory distress syndrome or pneumonia than an influenza patient with the same issues. Given the criteria that no testing is required to list COVID-19 as a cause of death there would appear to be a substantial incentive to use a COVID-19 diagnosis whenever possible to obtain the higher reimbursement rate.

MORE EXPERTS EXPRESS CONCERN THAT NUMBERS ARE OVER-INFLATED

Recently, some of the prominent U.S. public health leadership have also speculated on the financial incentive for hospitals classifying deaths as COVID-19. The CDC’s director, Robert Redfield, stated that financial incentives could inflate COVID-19 fatality totals (Satney, 2020).

“I think you’re correct in that we’ve seen this in other disease processes too, really in the HIV epidemic, somebody may have a heart attack, but also have HIV — the hospital would prefer the [classification] for HIV because there’s greater reimbursement.

So I do think there’s some reality to that. When it comes to death reporting, though, ultimately, it’s how the physician defines it in the death certificate and ... we review all of those death certificates.

So I think, probably it is less operable in the cause of death, although I won’t say there are not some cases. I do think though [that] when it comes to hospital reimbursement issues or individuals that get discharged, there could be some play in that for sure.”

This sentiment is also shared by the U.S. Health and Human Services Admiral Giroir who stated that he “acknowledged that the statistics he is getting from the states are over-inflated.” (Satney, 2020).

Additionally, in early May Dr. Deborah Birx, coronavirus task force member, expressed concerns with the possible inflation of COVID-19 fatalities and case counts, stating, “There is nothing from the CDC that I can trust.” According to four people present for a discussion between Dr. Birx and Robert Redfield, Dr. Birx expressed her belief that the death toll may be inflated by up to 25% (Dawsey et al., 2020).

Many states including Colorado, Pennsylvania, and New Jersey face questions concerning COVID-19 patients dying from causes other than the virus. In late April, Pennsylvania removed more than 200 deaths from their COVID-19 reporting. The president of the Pennsylvania Coroners Association and practicing coroner commented that “There’s a discrepancy in the numbers. I’m not saying there’s something going on... I’m not a conspiracy theory guy. But accuracy is important.” (Simon, 2020).

In early May, it was reported that nearly 24% of individuals counted as a COVID-19 fatality in the state of Colorado do not have COVID-19 listed on their death certificate (Ingold and Paul, 2020). And again in May, the San Diego County California supervisor argued that there were only six COVID-19 deaths within the county’s 194 count, that were “pure, solely coronavirus deaths.” (Miller, 2020).

Another example, the Washington State health statistics manager, Dr. Katie Hutchison, confirmed that non-COVID-19 deaths were being recorded at COVID-19 deaths, “We currently do have some deaths that are being reported that are clearly from other causes... We have about five deaths – less than five deaths – that we know of that are related to obvious other cases. In this case, they are from gunshot wounds.” (Duduit, 2020).

EXCESS DEATHS AND THE IMPACT OF COVID-19 MITIGATION/RESPONSE

The COVID-19 mitigation efforts were not aimed a lowering overall suffering and death but instead were blindly focused on “stopping the virus”. There was no clear cost-benefit analysis conducted or presented which would have considered two critical positions: whether the mitigation would work and whether the cost of it working would create more harm, at which point other options should have been considered. As Kristina Kristen (2020), guest editor for the Children’s Health Defense, stated, “If a so-called solution “works” but in doing so creates massive, disproportionate collateral damage and increases overall harm, then clearly it cannot be called a solution, and certainly should never be mandated onto a population.”

One example of a COVID-19 response that had catastrophic impact was that of the mismanagement of nursing homes. In mid-March, several governors issued orders to require COVID-19 patient placement in nursing homes thus exposing the most vulnerable population. On March 25, 2020 New York Governor Andrew Cuomo prohibited nursing homes from requiring incoming patients to be tested for COVID-19 or to inquire as to their COVID-19 status (New York Department of Health, 2020). Five governors (MI, NY, PA, NJ, and CA) ignored protocols and forced COVID-19 patients into nursing homes (Scalise Congress of the United States letter, 2020). Republican Whip Steve Scalise, the Ranking Member of the Select Subcommittee on the Coronavirus Crisis, wrote, “While nursing home residents make up 0.5% of the U.S. population, they account for 42% of nationwide COVID-19 deaths.” These nursing

home deaths were predictable and preventable and come at the hands of governors making poor COVID-19 mitigation policy decisions.

Excess deaths are calculated based on an estimate of how many people are expected to die during any given time period (CDC, 2020d). It goes without saying that no one can predict how many people will die at any given time and that many things impact this number. According to the CDC (2020d), as of August 21, 2020 the total number of deaths involving COVID-19 (which includes all deaths where COVID-19 was present even when it was not the cause of death) was 159,865. The total number of deaths from all causes was 1,737,141 and the percent of expected deaths was 111%. Basic math tells us the following:

- If 1,737,141 is 111% of expected deaths, then the total expected deaths would be 1,564,991.891891
- Given this it can be concluded that there are approximately 172,150 excess deaths as of August 21, 2020
- The difference between the expected deaths and deaths attributed to COVID-19 are the basis for the argument that there is undercounting.

As clearly demonstrated in the sections above, the number of deaths from COVID-19 is nowhere near the number presented by the CDC, so how can we be experiencing so many excess deaths if they are not coming from COVID-19?

When discussing excess deaths, the damage being done by the COVID-19 mitigation efforts must be taken into consideration. The reality is that the true danger to Ohioans and the U.S. public stems not from COVID-19, but from the so-called solution to COVID-19 which has created "...massive, disproportionate collateral damage..." and has increased "overall harm." (Kristen, 2020). An overview of some of the mitigation impacts are presented below.

Nursing Home Catastrophe:

- On March 25, 2020, Governor Andrew Cuomo issued an order prohibiting nursing homes from requiring incoming patients to be tested for COVID-19 or to inquire as to their COVID-19 status.

No resident shall be denied re-admission or admission to the NH solely based on a confirmed or suspected diagnosis of COVID-19. NHs are prohibited from requiring a hospitalized resident who is determined medically stable to be tested for COVID-19 prior to admission or readmission.

https://web.archive.org/web/20200407103413/https://coronavirus.health.ny.gov/system/files/documents/2020/03/doh_covid19-_nhadmissionsreadmissions_-032520.pdf

- In a May 1, 2020 opinion article, *Blame governors for the coronavirus deaths in nursing homes*, Michael Goodwin wrote,

"If they are honest, historians judging the American experience during the coronavirus pandemic will excoriate our barbaric failure to protect the elderly. We think ourselves as civilized, but mindless policies and bureaucratic indifference turned many nursing homes and

rehabilitation centers into killing fields.” <https://nypost.com/2020/05/16/blame-governors-for-coronavirus-deaths-in-nursing-homes-goodwin/>

- A June 2020 Special Report, *Infection Control Surveys at Nursing Facilities: CMS Data are Not Plausible*, from the Center for Medicare Advocacy and an article, *Nursing homes go unchecked as fatalities mount*, discussed how nearly half of the U.S. nursing homes failed to follow standard oversight during COVID-19 which would undoubtedly impact the number of unnecessary and preventable deaths of the most at risk population.

Thousands of nursing homes across the country have not been checked to see if staff are following proper procedures to prevent coronavirus transmission...

Only a little more than half of the nation’s nursing homes had received inspections according to data released earlier this month... <https://www.politico.com/news/2020/06/15/nursing-homes-coronavirus-321220> and Center for Medicare Advocacy report <https://medicareadvocacy.org/wp-content/uploads/2020/06/Infection-Control-Surveys-Report.pdf>

- In an article published on August 13, 2020, *More than 40% of U.S. Coronavirus deaths are linked to Nursing Homes*, there were 68,000 residents and workers in long-term care facilities that had died from COVID-19 and of the seven states with the top COVID-19 mortality, five of them are the states that mismanaged nursing homes.

While 8 percent of the country’s cases have occurred in long-term care facilities, deaths related to Covid-19 in these facilities account for more than 41 percent of the country’s pandemic fatalities.

<https://www.nytimes.com/interactive/2020/us/coronavirus-nursing-homes.html>

Deaths of Despair, Suicide, Overdose, Violence, and Health Impacts:

- An April 15, 2020, article, *Officials worry of potential spike in overdose deaths amid COVID-19 pandemic*, discussed the expected spike in drug overdose deaths amid the COVID-19 mitigation efforts.

With millions of Americans forced into weeks of extended isolation, several communities have reported a spike in drug overdose deaths, prompting health officials to raise concerns about the safety of those suffering from substance use disorders amid the COVID-19 pandemic. <https://abcnews.go.com/US/officials-worry-potential-spike-overdose-deaths-amid-covid/story?id=70149746>

- The article, *Projected Deaths of Despair from COVID-19*, published on May 8, 2020 by the Wellbeing Trust, discusses the estimated 75,000 “deaths of despair.” CBS news also published an article discussing the Wellbeing Trust report and “deaths of despair.”

More Americans could lose their lives to deaths of despair, deaths due to drug, alcohol, and suicide, if we do not do something immediately. Deaths of despair have been on the rise for

the last decade, and in the context of COVID-19, deaths of despair should be seen as the epidemic within the pandemic.

... conditions stemming from the novel coronavirus — rampant unemployment, isolation and an uncertain future — could lead to 75,000 deaths from drug or alcohol abuse and suicide, new research suggests.

Deaths from these causes are known as "deaths of despair." And the COVID-19 pandemic may be accelerating conditions that lead to such deaths. https://wellbeingtrust.org/wp-content/uploads/2020/05/WBT_Deaths-of-Despair_COVID-19-FINAL-FINAL.pdf and <https://www.cbsnews.com/news/coronavirus-deaths-suicides-drugs-alcohol-pandemic-75000>

- On May 12, 2020, the Lancet published an article, *A wake-up call: COVID-19 and its impact on children's health and wellbeing*, discussing the expected 1-2 million child deaths and 56,700 maternal deaths in 188 countries as a result of the mitigation efforts if efforts are not taken.

Building on lessons learned from previous outbreaks of Ebola virus disease and severe acute respiratory syndrome (SARS), the authors estimate a devastating increase in the numbers of maternal and child deaths resulting from reductions in routine health service coverage.

Left unchecked, these reductions (due to, for example, disruptions in medical supply chains or the availability of human and financial resources) along with declines in the uptake of health services by communities fearful of infection will be more catastrophic for mothers and children than COVID-19 itself. The projection of an additional 1.2 million child deaths and 56,700 maternal deaths in 118 countries if coverage of essential services drops by around 45% for 6 months is alarming. It is also avoidable if we act now.

[https://www.thelancet.com/pdfs/journals/langlo/PIIS2214-109X\(20\)30238-2.pdf](https://www.thelancet.com/pdfs/journals/langlo/PIIS2214-109X(20)30238-2.pdf)

- Another article, *California doctors say they've seen more deaths from suicide than coronavirus since lockdowns*, published on May 21, 2020 explores the impacts the COVID-19 mitigation has had on suicide.

Doctors in Northern California say they have seen more deaths from suicide than they've seen from the coronavirus during the pandemic.

"The numbers are unprecedented," Dr. Michael deBoisblanc of John Muir Medical Center in Walnut Creek, California, told ABC 7 News about the increase of deaths by suicide, adding that he's seen a "years' worth of suicides" in the last four weeks alone.

DeBoisblanc said he believes it's time for California officials to end the stay-at-home order and let people back out into their communities.

"Personally, I think it's time," he said. "I think, originally, this was put in place to flatten the curve and to make sure hospitals have the resources to take care of COVID patients. We have the current resources to do that, and our other community health is suffering."

<https://www.washingtonexaminer.com/news/california-doctors-say-theyve-seen-more-deaths-from-suicide-than-coronavirus-since-lockdowns>

- A letter sent from 600 physicians on May 22, 2020 to President Trump stated that the lockdowns are a ‘Mass Casualty Incident’ and discussed the estimated this mitigation impacts on suicide, cancer, heart attacks, etc.

“The downstream health effects...are being massively under-estimated and under-reported. This is an order of magnitude error,” according to the letter initiated by Simone Gold, M.D., an emergency medicine specialist in Los Angeles.

“Suicide hotline phone calls have increased 600%,” the letter said. Other silent casualties: “150,000 Americans per month who would have had new cancer detected through routine screening.”

From missed cancer diagnoses to untreated heart attacks and strokes to increased risks of suicides, “We are alarmed at what appears to be a lack of consideration for the future health of our patients.” <https://www.forbes.com/sites/gracemarieturner/2020/05/22/600-physicians-say-lockdowns-are-a-mass-casualty-incident/#33715bc350fa>; letter <https://www.scribd.com/document/462319362/A-Doctor-a-Day-Letter-Signed>

- On June 17, 2020, Everytown Research and Policy published an article, *Gun Violence and COVID-19: Colliding Public Health Crises*, the relationship between increased firearm purchasing, during COVID-19 mitigation, and the higher risks of suicide, homicide, unintentional shoots, and intimate partner violence.

The US has seen the collision of two major public health crises: COVID-19 and gun violence. A comprehensive understanding of how this collision will affect Americans and the factors driving the increase in gun violence during the pandemic is still developing, but there are a few takeaways: While millions of Americans rushed out to purchase new firearms in the middle of a global pandemic, thinking they were buying safety, research shows that they are in fact exposing themselves and their families to higher risks of suicide, homicide, unintentional shootings, and intimate partner violence.

<https://everytownresearch.org/reports/covid-gun-violence/>

- On July 15 and 16, 2020, two articles were published, *In Shadow of Pandemic, U.S. Drug Overdose Deaths Resurge to Record* and *Why are overdose deaths surging amid COVID-19?*, discussing the increased drug deaths linked to the COVID-19 mitigation.

Drug deaths in America, which fell for the first time in 25 years in 2018, rose to record numbers in 2019 and are continuing to climb, a resurgence that is being complicated and perhaps worsened by the coronavirus pandemic.

<https://www.nytimes.com/interactive/2020/07/15/upshot/drug-overdose-deaths.html?referringSource=articleShare&fbclid=IwAR10SY-qZCiwKY3W1b0K8SM8nG1fHNRAI9cYCeXB94hdTalLgclFMCjHsc>

As the global COVID-19 pandemic continues, opioid overdose deaths are surging nationwide.

This increase in opioid overdose deaths is likely linked to COVID-19 restrictions and closures that have hindered access to treatment and recovery services for those suffering from substance use disorder.

The American Medical Association issued a report stating that it's "greatly concerned by an increasing number of reports from national, state and local media suggesting increases in opioid-related mortality—particularly from illicitly manufactured fentanyl and fentanyl analogs." , <https://wexnermedical.osu.edu/blog/why-are-overdose-deaths-surging-amid-covid-19>

- An article published on July 22, 2020, *Highway deaths spike for third-straight month as drivers take advantage of empty roads*, discusses the surge in motor-vehicle crashes and how the COVID-19 mitigation efforts has supported the "surge" of fatalities.

Motor vehicle fatalities surged by 23.5 percent in May, as drivers took advantage of open roads to push to autobahn speeds, a situation made easier by the fact that authorities in many communities were pulling back on enforcement, in part, to avoid risking the possibility of their officers becoming exposed to the coronavirus.

According to the National Safety Council report, the May numbers mark the third-straight month that U.S. motorists were at a higher risk of dying from a crash — and it comes as a setback to safety advocates who had been hoping that the drop in traffic during the coronavirus-induced lockdown would see a decline in highway fatalities.

"At a moment when the country should be reaping a safety benefit from less traffic, the roads are riskier, threatening to reverse traffic safety gains made over the last few years," the NSC said in a statement. <https://www.nbcnews.com/business/autos/highway-deaths-spike-third-straight-month-drivers-take-advantage-empty-n1234651>

- Robert Redfield, CDC director, also acknowledges the COVID-19 impacts. In an article published on July 28, 2020, *CDC Director Compares Rate of Suicide to COVID-19 Deaths*, Director Redfield is quoted discussing the impacts on high school suicide.

Robert Redfield, Centers for Disease Control and Prevention director, stated, "But there has been another cost that we've seen, particularly in high schools... We're seeing, sadly, far greater suicides now than we are deaths from COVID. We're seeing far greater deaths from drug overdose that are above excess that we had as background than we are seeing the deaths from COVID." <https://townhall.com/tipsheet/micaelaburrow/2020/07/28/redfield-says-more-abovebase-suicides-than-covid-deaths-n2573278>

Children and Adolescents

- The April 15, 2020 *Policy Brief: The Impact of COVID-19 on children*, discussing the “hundreds of thousands of additional child deaths” that could occur in 2020 as a result of the COVID-19 mitigation’s impacts on the economy.

Economic hardship experienced by families as a result of the global economic downturn could result in hundreds of thousands of additional child deaths in 2020, reversing the last 2 to 3 years of progress in reducing infant mortality within a single year. And this alarming figure does not even take into account services disrupted due to the crisis – it only reflects the current relationship between economies and mortality, so is likely an under-estimate of the impact. Rising Executive Summary 2 POLICY BRIEF: THE IMPACT OF COVID-19 ON CHILDREN POLICY BRIEF: THE IMPACT OF COVID-19 ON CHILDREN 3 malnutrition is expected as 368.5 million children across 143 countries who normally rely on school meals for a reliable source of daily nutrition must now look to other sources. The risks to child mental health and well being are also considerable. Refugee and internally displaced children as well as those living in detention and situations of active conflict are especially vulnerable.

https://www.un.org/sites/un2.un.org/files/policy_brief_on_covid_impact_on_children_16_april_2020.pdf

Also, worth mentioning, while not causally related to the COVID-19 mitigation, is that during all of this, on May 25, 2020, George Floyd was arrested and died because of the excessive police force used during the arrest. Following the death and subsequent release of the arrest video, the Nation experienced an increase in rioting, movements to defund the police, protesting, and violence. Additionally, there has also been an increase in homicide deaths (Pries, 2020)

Lastly, according to the CDC (2020d) excess deaths data by date, the increase in excess deaths began immediately following the COVID-19 mitigation/response efforts.

CONCLUSION

Had the 2003 CDC Handbook guidelines been used for recording COVID-19 fatalities, as it has for ALL other causes of death in 2020, the COVID-19 fatality count would be significantly lower. Based on the comorbidity data published by New York, Massachusetts, Georgia, Oklahoma, Utah, Pennsylvania, and Iowa the COVID-19 fatality rate could drop by approximately 90.2%. Additionally, because of the inaccuracies with the available information it is not clear exactly how many people have died as a direct cause of COVID-19. It is clear that large number of the reported COVID-19 deaths may not have correlated to COVID-19 at all. Instead, it appears that most of these individuals only died *with* COVID-19 but not *from* COVID-19. Lastly, the COVID-19 mitigation such as isolation, social distancing, and masks, etc. are proving to be far deadlier and damaging than the virus. The long-term effects of the mitigation have yet to be fully revealed but as we continue to see suicides, “deaths of despair”, overdose, etc. increase it can be assumed that the effects will be devastating and last longer than the virus itself.

REFERENCES

Bendavid et al. (2020) “COVID-19 Antibody Seroprevalence in Santa Clara County, California”, medRxiv 2020.04.14.20062463; doi: <https://doi.org/10.1101/2020.04.14.20062463>
<https://www.medrxiv.org/content/10.1101/2020.04.14.20062463v2>

Burrow, M. (2020, July 28). *CDC Director Compares Rate of Suicides to COVID-19 Deaths*. Townhall. <https://townhall.com/tipsheet/micaelaburrow/2020/07/28/redfield-says-more-abovebase-suicides-than-covid-deaths-n2573278>

Centers for Disease Control and Prevention. (2003). *CDC: Medical Examiners’ and Coroners’ Handbook on Death Registration and Fetal Death Reporting, 2003 Revision*. Retrieved from https://www.cdc.gov/nchs/data/misc/hb_cod.pdf

Centers for Disease Control and Prevention. (2020a). CDC Wonder: Underlying Cause of Death. Retrieved from <https://wonder.cdc.gov/controller/datarequest/D76;jsessionid=77882FF4BD5D3BE7ADC461287433BE6F>

Centers for Disease Control and Prevention. (2020b). Daily Updates of Totals by Week and State. Retrieved from <https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm>

Centers for Disease Control and Prevention. (2020c). Disease Burden of Influenza. Retrieved from <https://www.cdc.gov/flu/about/burden/index.html>

Centers for Disease Control and Prevention. (2020d). Excess Deaths Associated with COVID-19. Retrieved from https://www.cdc.gov/nchs/nvss/vsrr/covid19/excess_deaths.htm

Centers for Disease Control and Prevention. (2020e). *NVSS: National Vital Statistics System COVID-19 Alert No. 2*. <https://www.cdc.gov/nchs/data/nvss/coronavirus/Alert-2-New-ICD-code-introduced-for-COVID-19-deaths.pdf>

Centers for Disease Control and Prevention. (2020f). *Preliminary Estimates of the Prevalence of Selected Underlying Health Conditions Among Patients with Coronavirus Disease 2019—United States, February 12-March 28, 2020*. <https://www.cdc.gov/mmwr/volumes/69/wr/mm6913e2.htm>

Center for Medicare Advocacy. (2020). *Special Report. Infection Control Surveys at Nursing Facilities: CMS Data are Not Plausible*. <https://medicareadvocacy.org/wp-content/uploads/2020/06/Infection-Control-Surveys-Report.pdf>

CSTE: Council of State & Territorial Epidemiologists. (2020). *Standardized surveillance case definition and national notification for 2019 novel coronavirus disease (COVID-19)*. https://cdn.ymaws.com/www.cste.org/resource/resmgr/2020ps/Interim-20-ID-01_COVID-19.pdf

Dawsey, J., Parker, A., Rucker, P., and Abutaleb, Y. (2020, May 9). *As deaths mount, Trump tries to convince Americans it's safe to inch back to normal*. The Washington Post. https://www.washingtonpost.com/politics/as-deaths-mount-trump-tries-to-convince-americans-its-safe-to-inch-back-to-normal/2020/05/09/bf024fe6-9149-11ea-a9c0-73b93422d691_story.html

Duduit, D. (2020, May 27). *Washington inflates COVID-19 numbers, includes gunshot victims among deaths*. The Western Journal. <https://www.westernjournal.com/washington-inflates-covid-19-numbers-includes-gunshot-victims-among-deaths/>

Eisenstein, P.A. (2020, July 22). *Highway deaths spike for third-straight month as drivers take advantage of empty roads*. NBC News. <https://www.nbcnews.com/business/autos/highway-deaths-spike-third-straight-month-drivers-take-advantage-empty-n1234651>

Everytown Research & Policy. (2020). *Report: Gun Violence and COVID-19. Colliding Public Health Crises*. <https://everytownresearch.org/report/gun-violence-and-covid-19-colliding-public-health-crises/>

Fauci, A.S, Lane, H.C., Redfield, R.R. (2020). Covid-19 — Navigating the Uncharted. *New England Journal of Medicine*, 382, 1268-1269. <https://www.nejm.org/doi/full/10.1056/NEJMe2002387>

Goodwin, Michael. (2020, May 16). *Blame governors for coronavirus deaths in nursing homes: Goodwin*. New York Post. <https://nypost.com/2020/05/16/blame-governors-for-coronavirus-deaths-in-nursing-homes-goodwin/>

If COVID fatalities were 90.2% Lower, how would you feel about schools reopening? (2020, July 24). Children's Health Defense. Retrieved from <https://childrenshealthdefense.org/news/if-covid-fatalities-were-90-2-lower-how-would-you-feel-about-schools-reopening/>

Ingold, J. and Paul, J. (2020, May 15). *Nearly a quarter of the people Colorado said died from coronavirus don't have COVID-19 on their death certificate*. The Colorado Sun. <https://coloradosun.com/2020/05/15/colorado-coronavirus-death-certificate/>

Katz, J., Goodnough, A., and Sanger-Katz, M. (2020, July 15). *In shadow of pandemic, U.S. drug overdose deaths resurge to record*. The New York Times. <https://www.nytimes.com/interactive/2020/07/15/upshot/drug-overdose-deaths.html?referringSource=articleShare&fbclid=IwAR10SY-qZCiwKY3W1b0K8SM8nG1fHNRAI9cYCeXB94hdTalLglclFMCjHsc>

Kristen, K. (2020, August 20). *COVID Response Is All Cost, No Benefit*. Children's Health Defense. https://childrenshealthdefense.org/news/covid-response-is-all-cost-no-benefit/?utm_source=salsa&eType=EmailBlastContent&eld=c4b8e232-2fa3-4416-a49b-c368044c395d

Letter to President Trump. (2020). Retrieved from <https://www.scribd.com/document/462319362/A-Doctor-a-Day-Letter-Signed>

Mallin, A. (2020, April 15). *Officials worry of potential spike in overdose deaths amid COVID-19 pandemic*. ABS News. <https://abcnews.go.com/US/officials-worry-potential-spike-overdose-deaths-amid-covid/story?id=70149746>

Miller, A.M. (2020, May 15). *San Diego County supervisor says six of 194 confirmed deaths are 'pure, solely coronavirus' deaths*. Washington Examiner. <https://www.washingtonexaminer.com/news/san-diego-county-supervisor-says-six-of-194-confirmed-deaths-are-pure-solely-coronavirus-deaths>

Miller, A.M. (2020, May 21). *California doctors say they've seen more deaths from suicide than from coronavirus since lockdowns*. Washington Examiner. <https://www.washingtonexaminer.com/news/california-doctors-say-theyve-seen-more-deaths-from-suicide-than-coronavirus-since-lockdowns>

New York Department of Health. (2020). *Advisory: Hospital Discharges and Admissions to Nursing Homes*, https://web.archive.org/web/20200407103413/https://coronavirus.health.ny.gov/system/files/documents/2020/03/doh_covid19-_nhadmissionsreadmissions_-032520.pdf

New York Times. (2020, August 13). *More than 40% of U.S. coronavirus deaths are linked to nursing homes*. <https://www.nytimes.com/interactive/2020/us/coronavirus-nursing-homes.html>

Petterson, S., Westfall, J.M., and Miller, B.F. (2020). *Projected Deaths of Despair During the Coronavirus Recession*. *Well Being Trust*. https://wellbeingtrust.org/wp-content/uploads/2020/05/WBT_Deaths-of-Despair_COVID-19-FINAL-FINAL.pdf

Pries, A. (2020, May 30, updated 2020, June 2). *These are all the cities where protests and riots have erupted over George Floyd's death*. NJ Advance Media for NJ.com. <https://www.nj.com/news/2020/05/these-are-all-the-cities-where-protests-and-riots-have-erupted-over-george-floyds-death.html>

Richardson, S., Hirsh, J.S., Narasimhan, M., Crawford, J.M., McGinn, T., Davidson, K.W., and the Northwell COVID-19 Research Consortium. (2020). *Presenting characteristics, comorbidities, and outcomes among 5700 patients hospitalized with COVID-19 in the New York City area*. *The Journal of the American Medical Association*, 323(20), 2052-2059. <https://jamanetwork.com/journals/jama/fullarticle/2765184>

S. Bay United Pentecostal Church v. Newsom, U.S., 140 S.Ct. 1613, 207 L.Ed.2d 154 (2020).

Satney, J. (2020, August 2). *CDC chief confirms COVID-19 deaths overinflated*. PrepForThat Survivor News. https://prepforthat.com/cdc-chief-confirms-covid-19-deaths-overinflated/?fbclid=IwAR1PTFQZ9qYH3WQghLij_uhhwBXgpTFhpc46gbONG0ESuh9mF_V2W7w9oaM

Scalise Congress of the United States letter. (2020). Retrieved from <https://twitter.com/SteveScalise/status/1272661471382700032>

Simon, S. (2020, April 23). *Pa. removes more than 200 deaths from official coronavirus count as questions mount about reporting process, data accuracy*. The Philadelphia Inquirer. <https://www.inquirer.com/health/coronavirus/spl/pennsylvania-death-count-changes-confusion-coronavirus-20200423.html>

The Lancet. (2020). *A wake-up call: COVID-19 and its impact on children's health and wellbeing*. [https://www.thelancet.com/pdfs/journals/langlo/PIIS2214-109X\(20\)30238-2.pdf](https://www.thelancet.com/pdfs/journals/langlo/PIIS2214-109X(20)30238-2.pdf)

Triggle, N. (2020, April 16). *Coronavirus: How to understand the death toll*. BBC News. <https://www.bbc.com/news/health-51979654>

United Nations. (2020). *Policy Brief: The Impact of COVID-19 on Children*. https://www.un.org/sites/un2.un.org/files/policy_brief_on_covid_impact_on_children_16_april_2020.pdf

“WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020”, <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>

Williams, M. (2020, July 16). *Why are overdose deaths surging amid COVID-19?* The Ohio State University Wexner Medical Center. <https://wexnermedical.osu.edu/blog/why-are-overdose-deaths-surging-amid-covid-19>

Attachment A.2

Disease Comparison Chart

On March 22, 2020 Amy Acton, the Ohio Department of Health issued the order that shut down Ohio and placed all citizens into house arrest (the “shelter in place” order) without due process.

Below is a breakdown of some vital statistics related to this order:

Disease	Case Fatality Rate	Reproduction Rate
COVID-19 (Current)	0.26%	0.87 - 2.5 (Ohio specific) 0.7 - 1.9 (Globally)
MERS (2012)	34.3%	2-5
SARS-CoV (2002)	9.6%	2-5
2017-2018 Seasonal Flu	0.14%	1.53
Ebola (2014)	25%	1.51
1957-1960 Flu Pandemic	0.28%	1.65
1918-1920 Flu Pandemic	2.25%	1.8
Tuberculosis	12.3%	0.24 - 4.3

Case fatality rate: The case-fatality rate is the proportion of persons with a particular condition (cases) who die from that condition. It is a measure of the severity of the condition. (CDC, <https://www.cdc.gov/csels/dsepd/ss1978/lesson3/section3.html>)

Reproduction rate: The basic reproduction number (R_0), also called the basic reproduction ratio or rate or the basic reproductive rate, is an epidemiologic metric used to describe the contagiousness or transmissibility of infectious agents. (CDC, https://wwwnc.cdc.gov/eid/article/25/1/17-1901_article)

Specifically, the number of COVID-19 deaths is divided by the number of infections to calculate the case-fatality rate. The average CFR of the antibody studies shown on the table is 0.26%.

COVID-19: Location	Infections (% of population)	Deaths	Case-Fatality Rate (CFR)
Los Angeles County, CA	367,000 (4.65%) ¹⁰	423 ¹¹	0.12%
Santa Clara County, CA	54,000 (2.8%) ¹²	94 ¹²	0.17%
Miami-Dade County, FL	165,000 (6%) ¹³	374 ¹⁴	0.23%
Arizona	226,000 (3.1%) ¹⁵	549 ¹⁶	0.24%
New York City, NY	2.075 million (24.7%) ¹⁷	10,746 ¹⁸	0.52%
Average CFR			0.26%

Table 1: Estimated CFR from antibody studies of SARS-CoV-2 conducted by several public health departments and research institutions.

Furthermore, on May 22, 2020, two months into the “shelter in place” order, PJ Media published an article titled, *The CDC Just Gave Us the Biggest Reason to End the Coronavirus Lockdowns* stating,

But, now here’s what the CDC is saying about the fatality rate the coronavirus:

0-49 years old: .05%

50-64 years old: .2%

65+ years old: 1.3%

Overall ages: .4%

According to the CDC’s current best estimate, the case fatality rate of the coronavirus is .4 percent. And that’s just amongst symptomatic cases, which, the CDC estimates, is 65 percent of all cases. This means the CDC estimates that the fatality rate for all infections across all age groups, symptomatic as well as asymptomatic, is approximately .26 percent.

Lastly, in an editorial in *New England Journal of Medicine*, Fauci et al. (2020) stated that “If one assumes that the number of asymptomatic or minimally symptomatic cases is several times as high as the number of reported cases, the case fatality rate may be considerably less than 1%. This suggests that the overall clinical consequences of Covid-19 may ultimately be more akin to those of a severe seasonal influenza (which has a case fatality rate of approximately 0.1%) or a pandemic influenza (similar to those in 1957 and 1968) rather than a disease similar to SARS or MERS, which have had case fatality rates of 9 to 10% and 36%, respectively.” (Fauci, A.S, et al., 2020).

References:

COVID-19 Current:

- Case Fatality - https://wwwnc.cdc.gov/eid/article/26/6/20-0320_article
- Reproductions Rate -
 - Ohio - <https://coronavirus.ohio.gov/wps/portal/gov/covid-19/resources/news-releases-news-you-can-use/basic-reproduction-number-pop-up-sites>
 - Globally - <https://epiforecasts.io/covid/posts/global/>

MERS:

- Case Fatality - <http://www.emro.who.int/health-topics/mers-cov/mers-outbreaks.html>
- Reproduction Rate - <https://pubmed.ncbi.nlm.nih.gov/28958834/>

SARS-CoV:

- Case fatality - https://www.who.int/csr/sars/country/table2003_09_23/en/
- Reproduction Rate - <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7074654/>

Ebola:

- Case Fatality - <https://www.who.int/news-room/fact-sheets/detail/ebola-virus-disease>
- Reproduction rate - <http://currents.plos.org/outbreaks/index.html%3Fp=40381.html>

Yearly Influenza:

- Case Fatality - <https://physiciansforinformedconsent.org/COVID-19/>
 - Centers for Disease Control and Prevention. Washington, D.C.: U.S. Department of Health and Human Services. Disease burden of influenza; [cited 2020 May 14]. <https://www.cdc.gov/flu/about/burden/index.html>.
 - Davis LE, Caldwell GG, Lynch RE, Bailey RE, Chin TD. Hong Kong influenza: the epidemiologic features of a high school family study analyzed and compared with a similar study during the 1957 Asian influenza epidemic. *Am J Epidemiol*. 1970 Oct;92(4):240-7.
 - Glezen WP. Emerging infections: pandemic influenza. *Epidemiol Rev*. 1996;18(1):64-76.
- Reproduction Rate -
 - https://journals.lww.com/imd/Fulltext/2019/09000/A_Severe_Seasonal_Influenza_Epidemic_During.4.aspx
 - <https://bmcinfectdis.biomedcentral.com/articles/10.1186/1471-2334-14-480>
 - <https://www.cambridge.org/core/journals/epidemiology-and-infection/article/seasonal-influenza-in-the-united-states-france-and-australia-transmission-and-prospects-for-control/CE0D31575579C69D9693890FA0F7C806>

TB:

- Case Fatality - <https://bmcinfectdis.biomedcentral.com/articles/10.1186/1471-2334-14-5>
- Reproduction Rate - <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6092233/>

Table:

- Sood N, Simon P, Ebner P, Eichner D, Reynolds J, Bendavid E, Bhattacharya J. Seroprevalence of SARS-CoV-2-specific antibodies among adults in Los Angeles County, California, on April 10-11, 2020. *JAMA*. 2020 May 18;e208279.
- Los Angeles County Department of Public Health. Los Angeles (CA): Los Angeles County Department of Public Health. COVID-19 surveillance dashboard; [cited 2020 May 24]. http://dashboard.publichealth.lacounty.gov/covid19_surveillance_dashboard/; because the infection percentage from Table 1 was calculated by dividing the cumulative sum of positive specimens by the number of total specimens collected between April 10 and April 14, 2020, (i.e., the average infection percentage for the span), the CFR is calculated based on total deaths reported until April 12, the middle day of the span.
- Bendavid E, Mulaney B, Sood N, Shah S, Ling E, Bromley Dulfano R, Lai C, Weissberg Z, Saavedra-Walker R, Tedrow J, Tversky D, Bogan A, Kupiec T, Eichner D, Gupta R, Ioannidis J, Bhattacharya J. COVID-19 antibody seroprevalence in Santa Clara County, California. *Medrxiv* [Preprint]. 2020 Apr 30 [cited 2020 May 19]. <https://www.medrxiv.org/content/10.1101/2020.04.14.20062463v2.full.pdf>; CFR is calculated based on total deaths and antibody results reported in the study.
- Miami-Dade County Office of the Mayor. Second round of COVID-19 community testing completed; Miami-Dade County and the University of Miami Miller School of Medicine announce initial findings. Miami-Dade County news release; 2020 Apr 24 [cited 2020 19 May]. <https://www.miamidade.gov/releases/2020-04-24-sample-testing-results.asp>.

- Florida Division of Emergency Management. Tallahassee (FL): Florida Division of Emergency Management. Coronavirus: summary of persons being monitored, persons under investigation, and cases; 2020 May 18 [cited 2020 May 19]. <https://floridadisaster.org/globalassets/covid19/dailies/covid-daily-report-5.18.20-.pdf> (42-50 p); because the infection percentage from Table 1 was calculated by dividing the cumulative sum of positive specimens by the number of total specimens collected between April 10 and April 24, 2020, (i.e., the average infection percentage for the span), the CFR is calculated based on total deaths reported until April 17, the middle day of the span.
- Arizona Department of Health Services. Phoenix (AZ): Arizona Department of Health Services. Data dashboard; [cited 2020 May 15]. <https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/covid-19/dashboards/index.php> (click on Laboratory Testing); CFR is calculated using antibody tests from specimens collected between April 26 and May 10, 2020.
- Arizona Department of Health Services. Phoenix (AZ): Arizona Department of Health Services. Data dashboard; [cited 2020 May 24]. <https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/covid-19/dashboards/index.php> (click on COVID-19 Deaths); because the infection percentage from Table 1 was calculated by dividing the cumulative sum of positive specimens by the number of total specimens collected between April 26 and May 10, 2020, (i.e., the average infection percentage for the span), the CFR is calculated based on total deaths reported until May 3, the middle day of the span.
- Coronavirus antibodies present in nearly 25% of all NYC residents, Cuomo says; un-pause in certain regions of NY might begin in May. CBS New York; 2020 Apr 27 [cited 2020 May 19]. <https://newyork.cbslocal.com/2020/04/27/coronavirus-antibodies-present-in-nearly-25-of-all-nyc-residents/>.
- New York City Department of Health and Mental Hygiene. New York City: New York City Department of Health and Mental Hygiene. Coronavirus disease 2019 (COVID-19) daily data summary; 2020 Apr 23 [cited 2020 May 19]. <https://www1.nyc.gov/assets/doh/downloads/pdf/imm/covid-19-daily-data-summary-deaths-04242020-1.pdf>; because the infection percentage from Table 1 was calculated by dividing the cumulative sum of positive specimens by the number of total specimens collected between April 20 and April 27, 2020, (i.e., the average infection percentage for the span), the CFR is calculated based on total deaths reported until April 23, the middle day of the span.

Articles/Editorial:

- May 22, 2020, *The CDC Just Gave Us the Biggest Reason to End the Coronavirus Lockdowns*, <https://pjmedia.com/news-and-politics/matt-margolis/2020/05/22/the-cdc-just-gave-us-the-biggest-reason-to-end-the-coronavirus-lockdowns-n417178>

- Fauci, A.S, Lane, H.C., Redfield, R.R. (2020). Covid-19 — Navigating the Uncharted. *New England Journal of Medicine*, 382, 1268-1269.
<https://www.nejm.org/doi/full/10.1056/NEJMe2002387>



Guidance for Certifying COVID-19 Deaths

March 4, 2020

NCHS is receiving questions about how deaths involving the new coronavirus strain should be reported on death certificates. We are working on formal guidance to certifiers to be published as soon as possible. In the meantime, to address the immediate need, here is some basic information that can be shared in advance of the more formal and detailed guidance. It is important to emphasize that **Coronavirus Disease 2019** or **COVID-19** should be reported on the death certificate for all decedents where the disease caused or is assumed to have caused or contributed to death. Other terminology, e.g., SARS-CoV-2, can be used as long as it is clear that it indicates the 2019 coronavirus strain, but we would prefer use of WHO’s standard terminology, e.g., COVID-19. Specification of the causal pathway leading to death in Part I of the certificate is also important. For example, in cases when COVID-19 causes pneumonia and fatal respiratory distress, both pneumonia and respiratory distress should be included along with COVID-19 in Part I. Certifiers should include as much detail as possible based on their knowledge of the case, medical records, laboratory testing, etc. If the decedent had other chronic conditions such as COPD or asthma that may have also contributed, these conditions can be reported in Part II. Here is an example:

CAUSE OF DEATH (See instructions and examples)		Approximate interval: Onset to death
<p>32. PART I. Enter the <u>chain of events</u>—diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition resulting in death) →</p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST</p>		2 days
a. <u>Acute respiratory distress syndrome</u> Due to (or as a consequence of):		10 days
b. <u>Pneumonia</u> Due to (or as a consequence of):		10 days
c. <u>COVID-19</u> Due to (or as a consequence of):		
d. _____ Due to (or as a consequence of):		
<p>PART II. Enter other <u>significant conditions contributing to death</u> but not resulting in the underlying cause given in PART I.</p>		<p>33. WAS AN AUTOPSY PERFORMED? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown</p>	<p>36. IF FEMALE: <input checked="" type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year</p>	<p>37. MANNER OF DEATH <input checked="" type="checkbox"/> Natural <input type="checkbox"/> Homicide <input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>

For more general guidance and training on cause-of-death reporting, certifiers can be referred to the Cause of Death mobile app available through <https://www.cdc.gov/nchs/nvss/mobile-app.htm> and the Improving Cause of Death Reporting online training module, which can be found at https://www.cdc.gov/nchs/nvss/improving_cause_of_death_reporting.htm.

Steven Schwartz, PhD
 Director – Division of Vital Statistics
 National Center for Health Statistics
 3311 Toledo Rd | Hyattsville, MD 20782



COVID-19 Alert No. 2
March 24, 2020

New ICD code introduced for COVID-19 deaths

This email is to alert you that a newly-introduced ICD code has been implemented to accurately capture mortality data for Coronavirus Disease 2019 (COVID-19) on death certificates.

Please read carefully and forward this email to the state statistical staff in your office who are involved in the preparation of mortality data, as well as others who may receive questions when the data are released.

What is the new code?

The new ICD code for Coronavirus Disease 2019 (COVID-19) is U07.1, and below is how it will appear in formal tabular list format.

U07.1 COVID-19

Excludes: Coronavirus infection, unspecified site (B34.2)
 Severe acute respiratory syndrome [SARS], unspecified (U04.9)

The WHO has provided a second code, **U07.2**, for clinical or epidemiological diagnosis of COVID-19 where a laboratory confirmation is inconclusive or not available. Because laboratory test results are not typically reported on death certificates in the U.S., NCHS is not planning to implement U07.2 for mortality statistics.

When will it be implemented?

Immediately.

Will COVID-19 be the underlying cause?

The underlying cause depends upon what and where conditions are reported on the death certificate. However, the rules for coding and selection of the underlying cause of death are expected to result in COVID-19 being the underlying cause more often than not.

What happens if certifiers report terms other than the suggested terms?

If a death certificate reports coronavirus without identifying a specific strain or explicitly specifying that it is not COVID-19, NCHS will ask the states to follow up to verify whether or not the coronavirus was COVID-19. As long as the phrase used indicates the 2019 coronavirus strain, NCHS expects to assign the new code. However, it is preferable and more straightforward for certifiers to use the standard terminology (COVID-19).

What happens if the terms reported on the death certificate indicate uncertainty?

If the death certificate reports terms such as “probable COVID-19” or “likely COVID-19,” these terms would be assigned the new ICD code. It is not likely that NCHS will follow up on these cases. If “pending COVID-19 testing” is reported on the death certificate, this would be considered a pending record. In this scenario, NCHS would expect to receive an updated record, since the code will likely result in R99. In this case, NCHS will ask the states to follow up to verify if test results confirmed that the decedent had COVID-19.

Do I need to make any changes at the jurisdictional level to accommodate the new ICD code?

Not necessarily, but you will want to confirm that your systems and programs do not behave as if U07.1 is an unknown code.

Should “COVID-19” be reported on the death certificate only with a confirmed test?

COVID-19 should be reported on the death certificate for all decedents where the disease caused **or is assumed to have caused or contributed to death**. Certifiers should include as much detail as possible based on their knowledge of the case, medical records, laboratory testing, etc. If the decedent had other chronic conditions such as COPD or asthma that may have also contributed, these conditions can be reported in Part II. (See attached Guidance for Certifying COVID-19 Deaths)

Steven Schwartz, PhD
Director – Division of Vital Statistics
National Center for Health Statistics
3311 Toledo Rd | Hyattsville, MD 20782



Guidance for Certifying Deaths Due to Coronavirus Disease 2019 (COVID–19)

Introduction

In December 2019, an outbreak of a respiratory disease associated with a novel coronavirus was reported in the city of Wuhan in the Hubei province of the People's Republic of China (1). The virus has spread worldwide and on March 11, 2020, the World Health Organization declared Coronavirus Disease 2019 (COVID–19) a pandemic (2). The first case of COVID–19 in the United States was reported in January 2020 (3) and the first death in February 2020 (4), both in Washington State. Since then, the number of reported cases in the United States has increased and is expected to continue to rise (5).

In public health emergencies, mortality surveillance provides crucial information about population-level disease progression, as well as guides the development of public health interventions and assessment of their impact. Monitoring and analysis of mortality data allow dissemination of critical information to the public and key stakeholders. One of the most important methods of mortality surveillance is through monitoring causes of death as reported on death certificates. Death certificates are registered for every death occurring in the United States, offering a complete picture of mortality nationwide. The death certificate provides essential information about the deceased and the cause(s) and circumstances of death. Appropriate completion of death certificates yields accurate and reliable data for use in epidemiologic analyses and public health reporting. A notable example of the utility of death certificates for public health surveillance is the ongoing monitoring of pneumonia and influenza deaths. Accurate and timely death certificate data are integral to detecting elevated levels of influenza activity in real time (<https://www.cdc.gov/flu/weekly/index.htm>).

Monitoring the emergence of COVID–19 in the United States and guiding public health response will also require accurate and timely death reporting. The purpose of this report is to provide guidance to death certifiers on proper cause-of-death certification for cases where confirmed or suspected COVID–19 infection resulted in death. As clinical guidance on COVID–19 evolves, this guidance may be updated, if necessary. When COVID–19 is determined to be a cause of death, it is important that it be reported on the death certificate to assess accurately the effects of this pandemic and appropriately direct public health response.

Cause-of-Death Reporting

When reporting cause of death on a death certificate, use any information available, such as medical history, medical records, laboratory tests, an autopsy report, or other sources of relevant information. Similar to many other diagnoses, a cause-of-death statement is an informed medical opinion that should be based on sound medical judgment drawn from clinical training and experience, as well as knowledge of current disease states and local trends (6).

Part I

This section on the death certificate is for reporting the sequence of conditions that led directly to death. The immediate cause of death, which is the disease or condition that directly preceded death and is not necessarily the underlying cause of death (UCOD), should be reported on line a. The conditions that led to the immediate cause of death should be reported in a logical sequence in terms of time and etiology below it.

The UCOD, which is “(a) the disease or injury which initiated the train of morbid events leading directly to death or (b) the circumstances of the accident or violence which produced the fatal injury” (7), should be reported on the lowest line used in Part I.

Approximate interval: Onset to death

For each condition reported in Part I, the time interval between the presumed onset of the condition, not the diagnosis, and death should be reported. It is acceptable to approximate the intervals or use general terms, such as hours, days, weeks, or years.

Part II

Other significant conditions that contributed to the death, but are not a part of the sequence in Part I, should be reported in Part II. Not all conditions present at the time of death have to be reported—only those conditions that actually contributed to death.

Certifying deaths due to COVID-19

If COVID-19 played a role in the death, this condition should be specified on the death certificate. In many cases, it is likely that it will be the UCOD, as it can lead to various life-threatening conditions, such as pneumonia and acute respiratory distress syndrome (ARDS). In these cases, COVID-19 should be reported on the lowest line used in Part I with the other conditions to which it gave rise listed on the lines above it.

Generally, it is best to avoid abbreviations and acronyms, but COVID-19 is unambiguous, so it is acceptable to report on the death certificate.

In some cases, survival from COVID-19 can be complicated by pre-existing chronic conditions, especially those that result in diminished lung capacity, such as chronic obstructive pulmonary disease (COPD) or asthma. These medical conditions do not cause COVID-19, but can increase the risk of contracting a respiratory infection and death, so these conditions should be reported in Part II and not in Part I.

When determining whether COVID-19 played a role in the cause of death, follow the CDC clinical criteria for evaluating a person under investigation for COVID-19 and, where possible, conduct appropriate laboratory testing using guidance provided by CDC or local health authorities. More information on CDC recommendations for reporting, testing, and specimen collection, including postmortem testing, is available from: <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html> and <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-postmortem-specimens.html>. It is important to remember that death certificate reporting may not meet mandatory reporting requirements for reportable diseases; contact the local health department regarding regulations specific to the jurisdiction.

In cases where a definite diagnosis of COVID-19 cannot be made, but it is suspected or likely (e.g., the circumstances are compelling within a reasonable degree of certainty), it is acceptable to report COVID-19 on a death certificate as “probable” or “presumed.” In these instances, certifiers should use their best clinical judgement in determining if a COVID-19 infection was likely. However, please note that testing for COVID-19 should be conducted whenever possible.

Common problems

Common problems in cause-of-death certification include:

1. reporting intermediate causes as the UCOD (i.e., on the lowest line used in Part I),
2. lack of specificity, and
3. illogical sequences.

Intermediate causes are those conditions that typically have multiple possible underlying etiologies and thus, a UCOD must

be specified on a line below in Part I. For example, pneumonia is an intermediate cause of death since it can be caused by a variety of infectious agents or by inhaling a liquid or chemical. Pneumonia is important to report in a cause-of-death statement but, generally, it is not the UCOD. The cause of pneumonia, such as COVID-19, needs to be stated on the lowest line used in Part I.

Additionally, the reported UCOD should be specific enough to be useful for public health and research purposes. For example, a “viral infection” can be a UCOD, but it is not specific. A more specific UCOD in this instance could be “COVID-19.”

All causal sequences reported in Part I should be logical in terms of time and pathology. For example, reporting “COVID-19” due to “chronic obstructive pulmonary disease” in Part I would be an illogical sequence as COPD cannot cause an infection, although it may increase susceptibility to or exacerbate an infection. In this instance, COVID-19 would be reported in Part I as the UCOD and the COPD in Part II. While there can be reasonable differences in medical opinion concerning a sequence that led to a particular death, the causes should always be provided in a logical sequence from the immediate cause on line a. back to the UCOD on the lowest line used in Part I.

Manner of death

The manner of death, sometimes referred to as circumstances of death, is also reported on death certificates. Natural deaths are due solely or almost entirely to disease or the aging process (8). In the case of death due to a COVID-19 infection, the manner of death will almost always be natural.

When to Refer to a Medical Examiner or Coroner

Some jurisdictions have requirements for referring deaths involving threats to public health to the medical examiner or coroner, so certifiers should follow the regulations in the jurisdiction in which the death occurred. As always, if a death involved an injury, poisoning, or complications thereof, then the case should be referred. The local medical examiner or coroner should be consulted with questions on referral requirements.

Conclusion

An accurate count of the number of deaths due to COVID-19 infection, which depends in part on proper death certification, is critical to ongoing public health surveillance and response. When a death is due to COVID-19, it is likely the UCOD and thus, it should be reported on the lowest line used in Part I of the death certificate. Ideally, testing for COVID-19 should be

Vital Statistics Reporting Guidance

conducted, but it is acceptable to report COVID–19 on a death certificate without this confirmation if the circumstances are compelling within a reasonable degree of certainty.

For more guidance and training on cause-of-death reporting in general, see the Cause of Death mobile app available from: <https://www.cdc.gov/nchs/nvss/mobile-app.htm> and the Improving Cause of Death Reporting online training module available from: https://www.cdc.gov/nchs/nvss/improving_cause_of_death_reporting.htm (free Continuing Medical Education credits and Continuing Nursing Education credits available). For current information on the COVID–19 outbreak, see the CDC website at: <https://www.cdc.gov/coronavirus/2019-nCoV/index.html>.

References

1. World Health Organization. Novel coronavirus—China. Geneva, Switzerland. 2020. Available from: <https://www.who.int/csr/don/12-january-2020-novel-coronavirus-china/en/>.
2. World Health Organization. WHO Director-General’s opening remarks at the media briefing on COVID–19—11 March 2020. Geneva, Switzerland. 2020. Available from: <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>.
3. Holshue ML, DeBolt C, Lindquist S, Lofy KH, Wiesman J, Bruce H, et al. First case of 2019 novel coronavirus in the United States. *N Engl J Med*. 382(10):929–36. 2020. Available from: <https://www.nejm.org/doi/full/10.1056/NEJMoa2001191>.
4. Centers for Disease Control and Prevention. CDC, Washington state report first COVID–19 death [press release]. 2020. Available from: <https://www.cdc.gov/media/releases/2020/s0229-COVID-19-first-death.html>.
5. Centers for Disease Control and Prevention. CDC confirms possible instance of community spread of COVID–19 in U.S. [press release]. 2020. Available from: <https://www.cdc.gov/media/releases/2020/s0226-Covid-19-spread.html>.
6. National Center for Health Statistics. Physician’s handbook on medical certification of death. Hyattsville, MD: National Center for Health Statistics. 2003.
7. World Health Organization. International statistical classification of diseases and related health problems, 10th revision (ICD–10), Volume 2. 5th ed. Geneva, Switzerland. 2016.
8. National Center for Health Statistics. Medical examiner’s and coroner’s handbook on death registration and fetal death reporting. Hyattsville, MD: National Center for Health Statistics. 2003.

Appendix. Scenarios and Example Certifications for Deaths Due to COVID-19

Scenario I: A 77-year-old male with a history of hypertension and chronic obstructive pulmonary disease

A 77-year-old male with a 10-year history of hypertension and chronic obstructive pulmonary disease (COPD) presented to a local emergency department complaining of 4 days of fever, cough, and increasing shortness of breath. He reported recent exposure to a neighbor with flu-like symptoms. He stated that his wheezing was not improving with his usual bronchodilator therapy. Upon examination, he was febrile, hypoxic, and in

moderate respiratory distress. His chest x-ray demonstrated hyperinflation and his arterial blood gas was consistent with severe respiratory acidosis. Testing of respiratory specimens indicated COVID-19. He was admitted to the ICU and despite aggressive treatment, he developed worsening respiratory acidosis and sustained a cardiac arrest on day 3 of admission.

Comment: In this case, the acute respiratory acidosis was the immediate cause of death, so it was reported on line a. Acute respiratory acidosis was precipitated by the COVID-19 infection, which was reported below it on line b. in Part I. The COPD and hypertension were contributing causes but were not a part of the causal sequence in Part I, so those conditions were reported in Part II.

Scenario I

<p align="center">CAUSE OF DEATH (See instructions and examples)</p> <p>32. PART I. Enter the <u>chain of events</u>--diseases, injuries, or complications--that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition -----> resulting in death)</p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST</p>		<p>Approximate interval: Onset to death</p>
<p>a. Acute respiratory acidosis Due to (or as a consequence of):</p>	<p>b. COVID-19 Due to (or as a consequence of):</p>	<p>3 days</p>
<p>c. _____ Due to (or as a consequence of):</p>	<p>d. _____ Due to (or as a consequence of):</p>	<p>1 week</p>
<p>PART II. Enter other <u>significant conditions contributing to death</u> but not resulting in the underlying cause given in PART I</p> <p align="center">Chronic obstructive pulmonary disease, hypertension</p>		<p>33. WAS AN AUTOPSY PERFORMED? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> Probably</p> <p><input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown</p>	<p>36. IF FEMALE:</p> <p><input type="checkbox"/> Not pregnant within past year</p> <p><input type="checkbox"/> Pregnant at time of death</p> <p><input type="checkbox"/> Not pregnant, but pregnant within 42 days of death</p> <p><input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death</p> <p><input type="checkbox"/> Unknown if pregnant within the past year</p>	<p>37. MANNER OF DEATH</p> <p><input checked="" type="checkbox"/> Natural <input type="checkbox"/> Homicide</p> <p><input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation</p> <p><input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>

Vital Statistics Reporting Guidance

Scenario II: A 34-year-old female with no significant past medical history

A 34-year-old female with no significant past medical history presented to her primary care physician complaining of 6 days of fever, cough, and myalgias. She was found to be febrile, hypotensive, and hypoxic. She was admitted to the hospital and underwent a CT scan of the chest, which revealed diffuse ground-glass opacification indicative of viral pneumonia. Respiratory specimens were sent for testing and rRT-PCR confirmed COVID-19. Her condition deteriorated over the next

2 days and she developed acute respiratory distress syndrome (ARDS). She was transferred to the ICU and started on positive pressure ventilation. Despite aggressive resuscitation, the patient expired on hospital day 4.

Comment: In this case, the immediate cause of death was ARDS, so it was reported on line a. as a consequence of pneumonia, which was reported on line b. The underlying cause of death (UCOD) was COVID-19 so it was reported on line c., the lowest line used in Part I.

Scenario II

CAUSE OF DEATH (See instructions and examples)		Approximate interval: Onset to death
<p>32. PART I. Enter the <u>chain of events</u>--diseases, injuries, or complications--that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p>		
<p>IMMEDIATE CAUSE (Final disease or condition -----> resulting in death)</p>	<p>a. <u>Acute respiratory distress syndrome</u> Due to (or as a consequence of): _____</p>	<p>2 days</p>
<p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST</p>	<p>b. <u>Pneumonia</u> Due to (or as a consequence of): _____</p>	<p>10 days</p>
	<p>c. <u>COVID-19</u> Due to (or as a consequence of): _____</p>	<p>10 days</p>
	<p>d. _____ Due to (or as a consequence of): _____</p>	
<p>PART II. Enter other <u>significant conditions contributing to death</u> but not resulting in the underlying cause given in PART I</p>		<p>33. WAS AN AUTOPSY PERFORMED? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>
		<p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> Probably</p> <p><input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown</p>	<p>36. IF FEMALE:</p> <p><input checked="" type="checkbox"/> Not pregnant within past year</p> <p><input type="checkbox"/> Pregnant at time of death</p> <p><input type="checkbox"/> Not pregnant, but pregnant within 42 days of death</p> <p><input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death</p> <p><input type="checkbox"/> Unknown if pregnant within the past year</p>	<p>37. MANNER OF DEATH</p> <p><input checked="" type="checkbox"/> Natural <input type="checkbox"/> Homicide</p> <p><input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation</p> <p><input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>

Vital Statistics Reporting Guidance

Scenario III: An 86-year-old female with an unconfirmed case of COVID-19

An 86-year-old female passed away at home. Her husband reported that she was nonambulatory after suffering an ischemic stroke 3 years ago. He stated that 5 days prior, she developed a high fever and severe cough after being exposed to an ill family member who subsequently was diagnosed with COVID-19. Despite his urging, she refused to go to the hospital, even when her breathing became more labored and temperature escalated. She was unresponsive that morning and her husband phoned emergency medical services (EMS). Upon EMS arrival, the

patient was pulseless and apneic. Her husband stated that he and his wife had advanced directives and that she was not to be resuscitated. After consulting with medical command, she was pronounced dead and the coroner was notified.

Comment: Although no testing was done, the coroner determined that the likely UCOD was COVID-19 given the patient’s symptoms and exposure to an infected individual. Therefore, COVID-19 was reported on the lowest line used in Part I. Her ischemic stroke was considered a factor that contributed to her death but was not a part of the direct causal sequence in Part I, so it was reported in Part II.

Scenario III

CAUSE OF DEATH (See instructions and examples)		Approximate interval: Onset to death
<p>32. PART I. Enter the <u>chain of events</u>--diseases, injuries, or complications--that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition -----> resulting in death)</p> <p>a. <u>Acute respiratory illness</u></p> <p>Due to (or as a consequence of): _____</p> <p>b. <u>Probable COVID-19</u></p> <p>Due to (or as a consequence of): _____</p> <p>c. _____</p> <p>Due to (or as a consequence of): _____</p> <p>d. _____</p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST</p>		<p>1 day</p> <p>5 days</p>
<p>PART II. Enter other <u>significant conditions contributing to death</u> but not resulting in the underlying cause given in PART I</p> <p><u>Ischemic stroke</u></p>		<p>33. WAS AN AUTOPSY PERFORMED? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> Probably</p> <p><input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown</p>	<p>36. IF FEMALE:</p> <p><input checked="" type="checkbox"/> Not pregnant within past year</p> <p><input type="checkbox"/> Pregnant at time of death</p> <p><input type="checkbox"/> Not pregnant, but pregnant within 42 days of death</p> <p><input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death</p> <p><input type="checkbox"/> Unknown if pregnant within the past year</p>	<p>37. MANNER OF DEATH</p> <p><input checked="" type="checkbox"/> Natural <input type="checkbox"/> Homicide</p> <p><input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation</p> <p><input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>

**U.S. DEPARTMENT OF
HEALTH & HUMAN SERVICES**

Centers for Disease Control and Prevention
National Center for Health Statistics
3311 Toledo Road, Room 4551, MS P08
Hyattsville, MD 20782–2064

FIRST CLASS MAIL
POSTAGE & FEES PAID
CDC/NCHS
PERMIT NO. G-284

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, \$300

Vital Statistics Reporting Guidance

Contents

Introduction.....	1
Cause-of-Death Reporting	1
Part I	1
Approximate interval: Onset to death	1
Part II	1
Certifying deaths due to COVID–19	2
Common problems	2
Manner of death	2
When to Refer to a Medical Examiner or Coroner.....	2
Conclusion	2
References.....	3
Appendix. Scenarios and Example Certifications for Deaths Due to COVID–19	4
Scenario I: A 77-year-old male with a history of hypertension and chronic obstructive pulmonary disease.....	4
Scenario II: A 34-year-old female with no significant past medical history	5
Scenario III: An 86-year-old female with an unconfirmed case of COVID–19	6

Acknowledgments

NCHS would like to acknowledge Marcus Nashelsky, M.D., for his contributions to the guidance and example certifications.

Suggested citation

National Center for Health Statistics. Guidance for certifying deaths due to COVID–19. Hyattsville, MD. 2020.

Copyright information

All material appearing in this report is in the public domain and may be reproduced or copied without permission; citation as to source, however, is appreciated.

National Center for Health Statistics

Jennifer H. Madans, Ph.D., *Acting Director*

Amy M. Branum, Ph.D., *Acting Associate Director for Science*

Division of Vital Statistics

Steven Schwartz, Ph.D., *Director*

Isabelle Horon, Dr.P.H., *Acting Associate Director for Science*

For e-mail updates on NCHS publication releases, subscribe online at:

<https://www.cdc.gov/nchs/govdelivery.htm>.

For questions or general information about NCHS: Tel: 1–800–CDC–INFO (1–800–232–4636) • TTY: 1–888–232–6348

Internet: <https://www.cdc.gov/nchs>

Online request form: <https://www.cdc.gov/info>

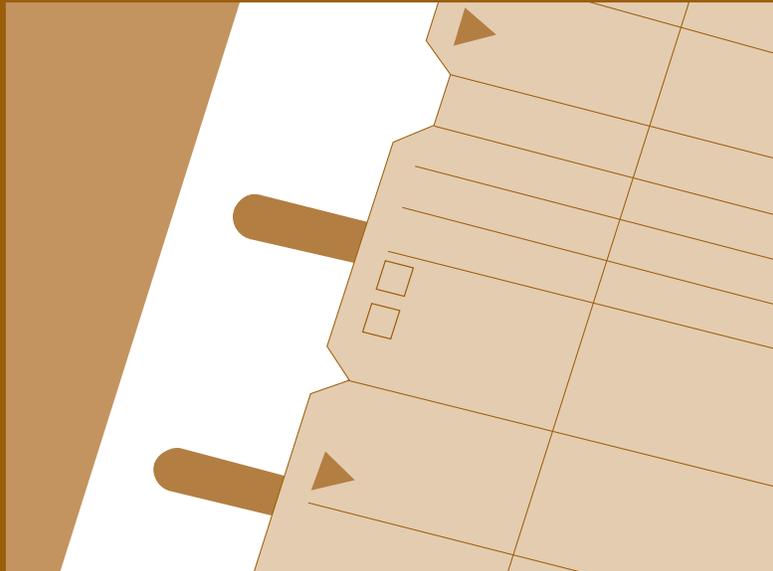
DHHS Publication No. 2020–1126 • CS316264



SAFER • HEALTHIER • PEOPLE™

Medical Examiners' and Coroners' Handbook on Death Registration and Fetal Death Reporting

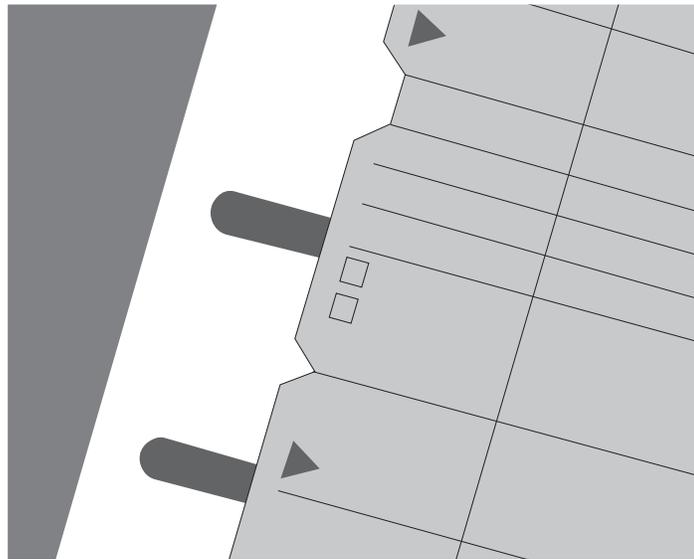
2003 Revision



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Center for Health Statistics

Medical Examiners' and Coroners' Handbook on Death Registration and Fetal Death Reporting

2003 Revision



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Center for Health Statistics

Hyattsville, Maryland
April 2003

DHHS Publication No. (PHS) 2003-1110

National Center for Health Statistics

Edward J. Sondik, Ph.D., *Director*

Jack R. Anderson, *Deputy Director*

Jack R. Anderson, *Acting Associate Director for International Statistics*

Jennifer H. Madans, Ph.D., *Associate Director for Science*

Lawrence H. Cox, Ph.D., *Associate Director for Research and Methodology*

Diane M. Makuc, Dr.P.H., *Acting Associate Director for Analysis, Epidemiology, and Health Promotion*

P. Douglas Williams, *Acting Associate Director for Data Standards, Program Development, and Extramural Programs*

Edward L. Hunter, *Associate Director for Planning, Budget, and Legislation*

Jennifer H. Madans, Ph.D., *Acting Associate Director for Vital and Health Statistics Systems*

Douglas L. Zinn, *Acting Associate Director for Management and Operations*

Charles J. Rothwell, *Associate Director for Information Technology and Services*

Division of Vital Statistics

James A. Weed, Ph.D., *Acting Director*

James A. Weed, Ph.D., *Acting Chief, Mortality Statistics Branch*

Preface

This handbook contains instructions for medical examiners and coroners on the registration of deaths and the reporting of fetal deaths. It was prepared by the Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics (NCHS). These instructions pertain to the 2003 revisions of the U.S. Standard Certificate of Death and the U.S. Standard Report of Fetal Death and the 1992 revision of the Model State Vital Statistics Act and Regulations. This handbook is intended to serve as a model that can be adapted by any vital statistics registration area.

Other handbooks and references on preparing and registering vital records are mentioned at the end of the section on “Medical Certification of Death” and are listed in the references. For most of these resources, the State vital statistics office or NCHS will be able to provide as many copies as requested.

Acknowledgments

This publication was prepared by staff from the Division of Vital Statistics led by Donna L. Hoyert, Ph.D., and Arialdi M. Minino, M.P.H. Martha L. Munson, M.S., provided content for fetal death items. Robert N. Anderson, Ph.D., also contributed to this handbook. Mary Anne Freedman, M.A., the Director of the Division of Vital Statistics while this publication was being prepared, reviewed and commented on the contents. Expert medical review and comments were provided by Randy Hanzlick, M.D.; Gregory G. Davis, M.D.; and Lillian R. Blackmon, M.D.

This handbook was edited by Kathy Sedgwick, typeset by Jacqueline M. Davis, and the graphics produced by Jarmila G. Ogburn of the Publications Branch, Division of Data Services.

Questions about mortality and cause-of-death issues may be directed to staff in the Mortality Statistics Branch, whereas questions about fetal death issues may be directed to Joyce A. Martin, M.P.H., or other staff in the Reproductive Statistics Branch of the Division of Vital Statistics, the Centers for Disease Control and Prevention's National Center for Health Statistics, Hyattsville, MD 20782.

Contents

Preface	iii
Acknowledgments	v
Introduction	1
Purpose	1
Importance of Death Registration and Fetal Death Reporting	2
U.S. Standard Certificates and Reports	4
Confidentiality of Vital Records	5
Responsibility of Medical Examiner or Coroner	5
Death Registration	5
Fetal Death Reporting	7
General Instructions for Completing Certificates and Reports	9
Medical Certification of Death	11
Certifying the Cause of Death	11
Cause of Death	11
Changes to Cause of Death	14
Instructions	14
Part I of the Cause-of-death section	15
Line (a) Immediate Cause	15
Lines (b), (c), and (d) Due to (or as a Consequence of)	16
Approximate Interval Between Onset and Death	16
Part II of the Cause-of-Death section (Other Significant Conditions)	17
Other Items for Medical Certification	18
Autopsy	18
Circumstances of Injury or Violence	19
Special Problems for the Medical-Legal Officer	20
Precision of Knowledge Required to Complete Death Certificate Items	20
Trauma as a Cause of Death	20
Natural	21
Accident	21
Suicide	21
Homicide	21

Could not be Determined	21
Pending Investigation	21
Determining a Suicide	21
When Cause Cannot be Determined	22
Deferred “Pending Investigation”	22
Certifier Section	24
Examples of Medical Certification	25
Common Problems in Death Certification	40
Additional Resources	42
Completing Other Items on the Death Certificate	43
About the Decedent (Items 1–19, 51–55)	43
Parents (Items 11 and 12)	52
Informant (Items 13a–c)	52
Place of Death (Items 14)	53
Facility (Items 15–17)	54
About the Disposition (Items 18–23)	55
Pronouncement (Items 24 and 25)	57
Pronouncing Physician (Items 26–28)	58
Date of Death (Item 29)	59
Time of Death (Item 30)	60
Medical Examiner or Coroner Contacted (Item 31)	61
Cause of Death (Item 32)	61
Autopsy (Items 33 and 34)	62
Tobacco Use Contribute to Death (Item 35)	63
If Female, Pregnancy Status (Item 36)	63
Manner of Death (Item 37)	63
Accident or Injury (Items 38–44)	64
Certifier (Items 45–49)	67
Decedent’s Education (Item 51)	69
Decedent of Hispanic Origin (Item 52)	69
Race (Item 53)	70
Occupation and Industry of Decedent (Items 54 and 55)	71
Completing the Cause of Fetal Death	74
Cause of Fetal Death	74
Supplemental Report of Cause of Fetal Death	77
Other Items for Medical Certification	77
Examples of Reporting Cause of Fetal Death	78
Common Problems in Fetal Death Certification	81
Completing the Report of Fetal Death	83
FACILITY WORKSHEET	83
CAUSE OF FETAL DEATH	95
PATIENT WORKSHEET	98

References	105
------------------	-----

Appendixes

A. The U.S. Standard Certificate of Death	108
B. Decedent's Educational Level Selection Card	110
C. Race and Hispanic Origin Category Selection Cards	111
D. The U.S. Standard Report of Fetal Death	112
E. Definitions of Live Birth and Fetal Death	114
F. Facility Worksheet for the Report of Fetal Death	115
G. Patient's Worksheet for the Report of Fetal Death	123
H. The Vital Statistics Registration System in the United States ..	128

Introduction

Purpose

This handbook is designed to acquaint medical examiners and coroners with the vital registration system in the United States and to provide instructions for completing and filing death certificates and fetal death reports. Emphasis is directed toward the certification of medical information relating to these events when they come within the jurisdiction of the medical-legal officer (i.e., medical examiner or coroner).

A significant number of the deaths occurring in the United States must be investigated and certified by a medical-legal officer. Although State laws vary in specific requirements, deaths that typically require investigation are those due to unusual or suspicious circumstances, violence (accident, suicide, or homicide), those due to natural disease processes when the death occurred suddenly and without warning, when the decedent was not being treated by a physician, or the death was unattended (1).

In those cases where death is not the result of accident, suicide, or homicide, some States include in their laws a specific time period regarding how recently treatment must have been provided by a physician for that physician to be authorized to complete the medical certification of cause of death. These time limits vary from State to State. In some States where no time limit is specified, it is left to interpretation or local custom to determine whether the cause of death should be completed by a physician or by the medical examiner or coroner. The medical-legal officer should investigate the case and ensure that the medical certification of cause of death is properly completed.

Because State laws, regulations, and customs vary significantly regarding which cases must be investigated by a medical-legal officer, each medical examiner or coroner must become familiar with practices within the officer's area and ensure that all cases falling within his or her jurisdiction are properly investigated. If there is any doubt as to jurisdiction, the medical-legal officer should assume jurisdiction.

Importance of death registration and fetal death reporting

The death certificate is a permanent record of the fact of death, and depending on the State of death, may be needed to get a burial permit. The information in the record is considered as *prima facie* evidence of the fact of death that can be introduced in court as evidence. State law specifies the required time for completing and filing the death certificate.

The death certificate provides important personal information about the decedent and about the circumstances and cause of death. This information has many uses related to the settlement of the estate and provides family members' closure, peace of mind, and documentation of the cause of death.

The death certificate is the source for State and national mortality statistics (figures 1–3) and is used to determine which medical conditions receive research and development funding, to set public health goals, and to measure health status at local, State, national, and international levels. The Centers for Disease Control and Prevention's National Center for Health Statistics (NCHS) publishes summary mortality data in the *National Vital Statistics Report* publication "Deaths: Final data" and on the Internet at <http://www.cdc.gov/nchs> (under vital statistics, mortality).

These mortality data are valuable to physicians indirectly by influencing funding that supports medical and health research (which may alter clinical practice) and directly as a research tool. Research topics include identifying disease etiology, evaluating diagnostic and therapeutic techniques, examining medical or mental health problems that may be found among specific groups of people (2), and indicating areas in which medical research can have the greatest impact on reducing mortality.

Analyses typically focus on a single condition reported on the death certificate, but some analyses do consider all conditions mentioned. Such analyses are important in studying certain diseases and conditions and in investigating relationships between conditions reported on the same death certificate (for example, types of fatal injuries and automobile crashes or types of infections and HIV).

Because statistical data derived from death certificates can be no more accurate than the information provided on the certificate, it is very important that all persons concerned with the registration of deaths strive not only for complete registration, but also for accuracy and promptness in reporting these events. Furthermore, the potential usefulness of detailed specific information is greater than more general information.

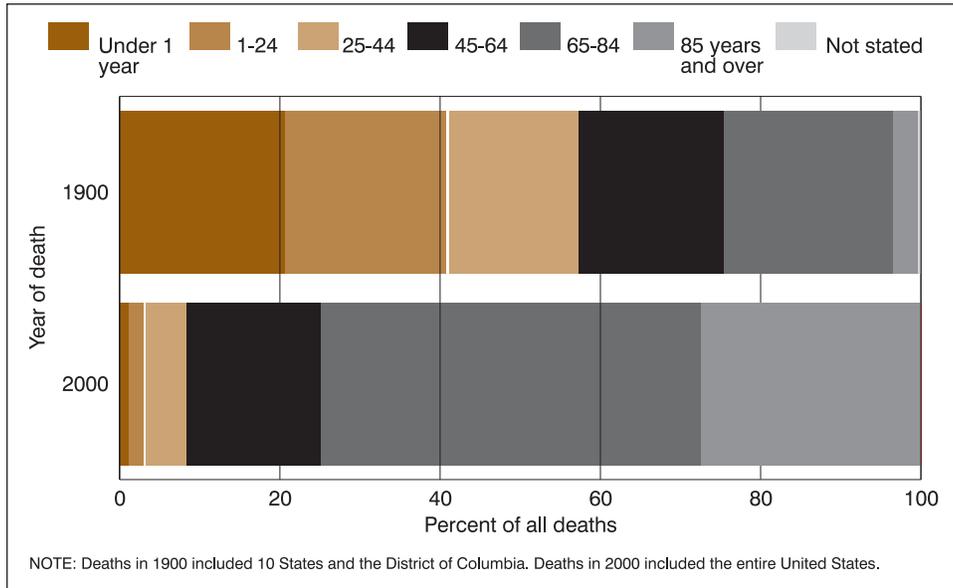


Figure 1. Deaths by age

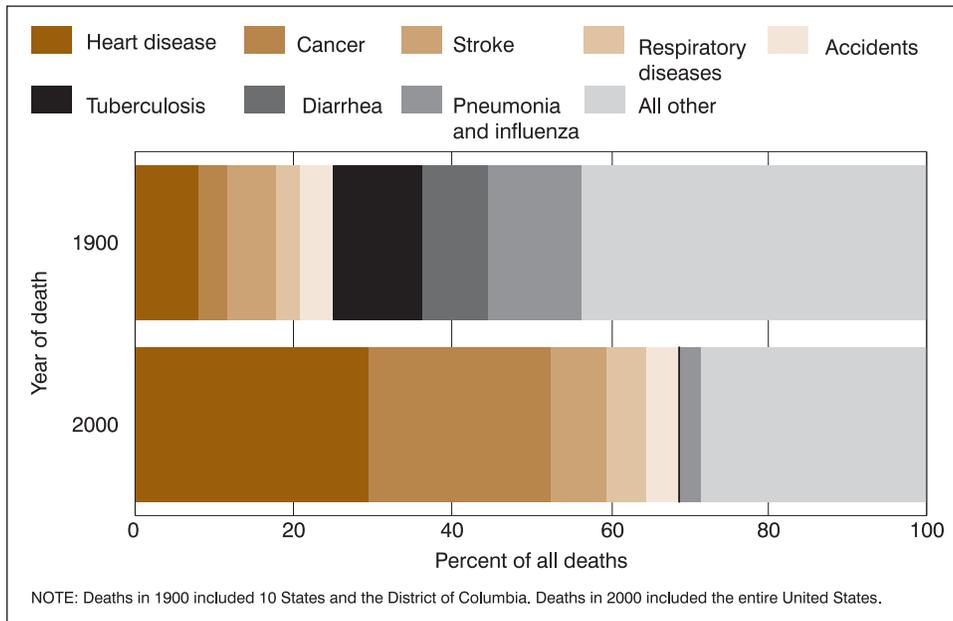


Figure 2. Deaths by cause

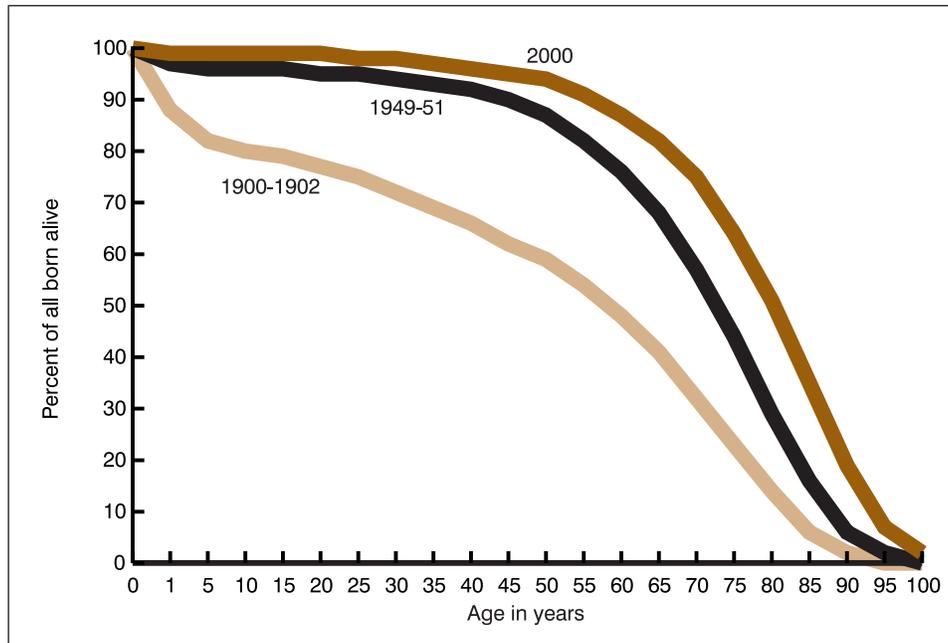


Figure 3. Percent of persons born alive in selected years surviving to specific ages

The fetal death report is recommended as a legally required statistical report designed primarily to collect information for statistical and research purposes. In most States, these reports are not maintained in the official files of the State health department, and certified copies of these reports are rarely issued. However, in a number of States, it remains a legal certificate. The record, whether a certificate or a report, provides valuable health and research data. The information is used to study the causes of poor pregnancy outcome. These data are also essential in planning and evaluating prenatal care services and obstetrical programs. They are also used to examine the consequences of possible environmental and occupational exposures of parents on the fetus.

U.S. Standard Certificates and Reports

The registration of deaths and fetal deaths is a State function supported by individual State laws and regulations. The original certificates are filed in the States and stored in accordance with State practice. Each State has a contract with NCHS that allows the Federal Government to use information from the State records to produce national vital statistics. The national data program is called the National Vital Statistics System (NVSS) (3,4).

To ensure consistency in the NVSS, NCHS provides leadership and coordination in the development of a standard certificate of death for the States to use as a model. The standard certificate is revised periodically to ensure that the data collected relate to current and anticipated needs. In the revision process, stakeholders review and evaluate each item on the standard certificate for its registration, legal, genealogical, statistical, medical, and research value. The associations on the stakeholder panel that recommended the current U.S. Standard Certificate of Death included the American Medical Association, the National Association of Medical Examiners, the College of American Pathologists, and the American Hospital Association (3). For the U.S. Standard Report of Fetal Death, the associations included the American Academy of Pediatrics, American College of Obstetricians and Gynecologists, Association of State and Territorial Health Officers (Maternal and Child Health Affiliate), American Medical Association, and American College of Nurse Midwives (3).

Most State certificates conform closely in content and arrangement to the standard. Minor modifications are sometimes necessary to comply with State laws or regulations or to meet specific information needs. Having similar forms promotes uniformity of data and comparable national statistics. They also allow the comparison of individual State data with national data and data from other States. Uniformity of death certificates among the States also increases their acceptability as legal records.

Confidentiality of vital records

To encourage appropriate access to vital records, NCHS promotes the development of model vital statistics laws concerning confidentiality (1). State laws and supporting regulations define which persons have authorized access to vital records. Some States have few restrictions on access to death certificates. However, there are restrictions on access to death certificates in the majority of States. Legal safeguards to the confidentiality of vital records have been strengthened over time in some States.

The fetal death report is designed primarily to collect information for statistical and research purposes. In many States these records are not maintained in the official files of the State health department. Most States never issue certified copies of these records; the other States issue certified copies very rarely.

Responsibility of the medical examiner or coroner

Death registration

The principal responsibility of the medical examiner or coroner in death registration is to complete the medical part of the death certificate. Before

delivering the death certificate to the funeral director, he or she may add some personal items for proper identification such as name, residence, race, and sex. Under certain circumstances and in some jurisdictions, he or she may provide all the information, medical and personal, required on the certificate.

The funeral director, or other person in charge of interment, will otherwise complete those parts of the death certificate that call for personal information about the decedent. He or she is also responsible for filing the certificate with the registrar where the death occurred. Each State prescribes the time within which the death certificate must be filed with the registrar.

In general, the duties of the medical examiner or coroner are to:

- Complete relevant portions of the death certificate.
- Deliver the signed or electronically authenticated death certificate to the funeral director promptly so that the funeral director can file it with the State or local registrar within the State's prescribed time period.
- Assist the State or local registrar by answering inquiries promptly.
- Deliver a supplemental report of cause of death to the State vital statistics office when autopsy findings or further investigation reveals the cause of death to be different from what was originally reported.

When the cause of death cannot be determined within the statutory time limit, a death certificate should be filed with the notation that the report of cause of death is "deferred pending further investigation." A permit to authorize disposal or removal of the body may then be obtained.

If there are other reasons for a delay in completing the medical portion of the certificate, the registrar should be given written notice of the reason for the delay.

When the circumstances of death (accident, suicide, or homicide) cannot be determined within the statutory time limit, the cause-of-death section should be completed and the manner of death should be shown as "pending investigation."

As soon as the cause of death and circumstances or manner of death are determined, the medical examiner or coroner should file a supplemental report with the registrar or correct or amend the death certificate according to State and local regulations regarding this procedure.

When a body has been found after a long period of time, the medical examiner or coroner should estimate the date and time of death as accurately as possible. If an estimate is made, the information should be entered as “APPROX—date” and/or “APPROX—time.”

If completed properly, the cause of death will communicate the same essential information that a case history would (5). For example, the following cause-of-death statement is complete:

- I a) Septic shock
 - b) Infected decubitus ulcers
 - c) Complications of cerebral infarction
 - d) Cerebral artery atherosclerosis
- II Insulin-dependent diabetes mellitus

If not completed properly, information may be missing from the cause-of-death section, so someone reading the cause of death would not know why the condition on the lowest used line developed. For example:

- I a) Pneumonia
 - b) Malnutrition
- II

This example does not explain what caused malnutrition. A variety of different circumstances could cause malnutrition, so the statement is incomplete and ambiguous.

In some cases, the medical-legal officer will be contacted to verify information reported on a death certificate or to provide additional information to clarify what was meant. The original cause-of-death statement may not be wrong from a clinical standpoint, but may not include sufficient information for assigning codes for statistical purposes. Following guidelines in this handbook should minimize the frequency with which the medical examiner or coroner will need to spend additional time answering follow-up questions about a patient’s cause of death.

Fetal death reporting

In some jurisdictions the medical-legal officer is required to complete reports of fetal death when the fetal death occurred without medical attendance or occurred under strange or unusual circumstances or was a result of an accident, suicide, or homicide. When completing a report of fetal death, the medical examiner or coroner is to:

- Complete the cause-of-fetal-death section.

- Return the fetal death report to the person or institution charged by State law with the responsibility for filing the report.
- If the medical-legal officer is required by State law to fill out a report of fetal death when the fetal death occurs outside a hospital or other institution, complete such a report and send it directly to the local or State registrar.

When an abandoned infant or apparent newborn is found dead, a problem may arise as to whether the event should be registered as a fetal death or an infant death (see [appendix E](#) for definitions). If the infant is considered to have lived, even for a very short time, following delivery, then the medical examiner or coroner will use the death certificate usually employed. He or she must also ensure that the birth of this infant is properly registered. If the infant is considered to be a fetal death or stillborn, then the appropriate fetal death report must be completed.

General Instructions for Completing Certificates and Reports

Aside from the facts related to medical certification, the medical examiner or coroner may need to obtain some or all of the personal information required on the certificate or report.

In some jurisdictions the medical-legal officer is not required to complete all of the personal items. He or she may complete and sign the medical certification section and add a few identifying items, such as name, age, sex, race, and residence. The certificate or report is then given to the funeral director who completes the remainder of the record.

In other jurisdictions the medical-legal officer customarily completes all the personal items. Under such conditions the medical examiner or coroner must obtain the information from an informant who has knowledge of the facts.

The informant is usually a member of the family or a friend of the family. The following individuals can be the informant and are listed in order of preference: spouse, a parent, a child of the decedent, another relative, or other person who has knowledge of the facts. At times the medical examiner or coroner will have to obtain personal information from a physician or a hospital official. In some cases, information will be obtained from the police.

Whatever the source may be, the name, relationship to decedent, and mailing address of the informant must appear on the certificate in the space provided.

It is essential that certificates and reports be prepared as permanent durable records. Completing a death certificate involves the following guidelines:

- Use the current form designated by the State.
- Complete each item, following the specific instructions for that item.
- Take care to make entry legible. Use a computer printer with high resolution, typewriter with good black ribbon and clean keys, or print legibly using permanent **black** ink.

- Do not use abbreviations except those recommended in the specific item instructions.
- Verify with the informant the spelling of names, especially those that have different spellings for the same sound (Smith or Smyth, Gail or Gayle, Wolf or Wolfe, and so forth).
- Refer problems not covered in these instructions to the State office of vital statistics or to the local registrar.
- Obtain all signatures; rubber stamps or other facsimile signatures are not acceptable. If jurisdiction provides, authenticate electronically.
- Do not make alterations or erasures.
- File the original certificate or report with the registrar. Reproductions or duplicates are not acceptable.
- File a supplemental report after investigation is completed for records previously filed as “pending further investigation.”

Medical Certification of Death

Certifying the cause of death

The medical examiner or coroner's primary responsibility in death registration is to complete the medical part of the death certificate. The medical certification includes:

- Date and time pronounced dead;
- Date and time of death;
- Question on whether the case was referred to the medical examiner or coroner;
- Cause-of-death section including cause of death, manner of death, tobacco use, and pregnancy status items;
- Injury items for cases involving injuries;
- Certifier section with signatures.

The proper completion of this section of the certificate is of utmost importance to the efficient working of a medical-legal investigative system.

Cause of death

This section must be completed by the medical examiner or coroner. The cause-of-death section, a facsimile of which is shown on page 12, follows guidelines recommended by the World Health Organization. An important feature is the reported underlying cause of death determined by the medical examiner or coroner and defined as (a) the disease or injury that initiated the train of morbid events leading directly to death, or (b) the circumstances of the accident or violence that produced the fatal injury. In addition to the underlying cause of death, this section provides for reporting the entire sequence of events leading to death as well as other conditions significantly contributing to death (6).

The cause-of-death section is designed to elicit the opinion of the medical certifier. Causes of death on the death certificate represent a medical opinion that might vary among individual medical-legal officers. A properly

completed cause-of-death section provides an etiological explanation of the order, type, and association of events resulting in death. The initial condition that starts the etiological sequence is specific if it does not leave any doubt as to why it developed. For instance, sepsis is not specific because a number of different conditions may have resulted in sepsis, whereas Human immunodeficiency virus infection is specific.

In certifying the cause of death, any disease, abnormality, injury, or poisoning, if believed to have adversely affected the decedent, should be reported. If the use of alcohol and/or other substance, a smoking history, or a recent pregnancy, injury, or surgery was believed to have contributed to death, then this condition should be reported. The conditions present at the time of death may be completely unrelated, arising independently of each other; or they may be causally related to each other, that is, one condition may lead to another which in turn leads to a third condition, and so forth. Death may also result from the combined effect of two or more conditions.

The mechanism of death, such as cardiac or respiratory arrest, should not be reported as it is a statement not specifically related to the disease process, and it merely attests to the fact of death. The mechanism of death therefore provides no additional information on the cause of death.

CAUSE OF DEATH (See instructions and examples)				Approximate interval: Onset to death
<p>32. PART I. Enter the chain of events—diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition resulting in death) -----></p> <p>a. _____ Due to (or as a consequence of):</p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST</p> <p>b. _____ Due to (or as a consequence of):</p> <p>c. _____ Due to (or as a consequence of):</p> <p>d. _____</p>				<p>33. WAS AN AUTOPSY PERFORMED?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I</p>				<p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> Probably</p> <p><input type="checkbox"/> No <input type="checkbox"/> Unknown</p>	<p>36. IF FEMALE:</p> <p><input type="checkbox"/> Not pregnant within past year</p> <p><input type="checkbox"/> Pregnant at time of death</p> <p><input type="checkbox"/> Not pregnant, but pregnant within 42 days of death</p> <p><input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death</p> <p><input type="checkbox"/> Unknown if pregnant within the past year</p>	<p>37. MANNER OF DEATH</p> <p><input type="checkbox"/> Natural <input type="checkbox"/> Homicide</p> <p><input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation</p> <p><input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>		
<p>38. DATE OF INJURY (Mo/Dy/Yr) (Spell Month)</p>	<p>39. TIME OF INJURY</p>	<p>40. PLACE OF INJURY (e.g., Decedent's home; construction site; restaurant; wooded area)</p>	<p>41. INJURY AT WORK? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>42. LOCATION OF INJURY: State: _____ City or Town: _____</p> <p>Street & Number: _____ Apartment No.: _____ Zip Code: _____</p>				
<p>43. DESCRIBE HOW INJURY OCCURRED:</p>			<p>44. IF TRANSPORTATION INJURY, SPECIFY:</p> <p><input type="checkbox"/> Driver/Operator</p> <p><input type="checkbox"/> Passenger</p> <p><input type="checkbox"/> Pedestrian</p> <p><input type="checkbox"/> Other (Specify)</p>	

As can be seen, the cause-of-death section consists of two parts. The first part is for reporting the sequence of events leading to death, proceeding backwards from the final disease or condition resulting in death. So, each condition in Part I should cause the condition above it. A specific cause of death should be reported in the last entry in Part I so there is no ambiguity about the etiology of this cause. Other significant conditions that contributed to the death, but did not lead to the underlying cause, are reported in Part II.

In addition, there are questions relating to autopsy, manner of death (for example, accident), and injury. The cause of death should include information provided by the pathologist if an autopsy or other type of postmortem examination is done. For deaths that have microscopic examinations pending at the time the certificate is filed, the additional information should be reported as soon as it is available. If the medical examiner or coroner has any questions about the procedure for doing this, contact the registrar.

The completion of the cause-of-death section for a medical-legal case requires careful consideration due to special problems that may be involved. The medical-legal case may depend upon toxicological examination for its ultimate cause-of-death certification (a situation not encountered as frequently in ordinary medical practice). Occasionally the medical examiner or coroner must deal with death certifications in which the cause of death is not clear, even after autopsy and toxicological examination. Despite these special problems that the medical examiner or coroner may encounter in dealing with causes of death, it is important that the medical certification be as accurate and complete as circumstances allow.

For statistical and research purposes, it is important that the causes of death and, in particular, the underlying cause of death, be reported as specifically and as precisely as possible. Careful reporting results in statistics for both underlying and multiple causes of death (i.e., all conditions mentioned on a death certificate) reflecting the best medical opinion.

Every cause-of-death statement is coded and tabulated in the statistical offices according to the latest revision of the *International Classification of Diseases* (6). When there is a problem with the reported cause of death (e.g., when a causal sequence is reported in reverse order), the rules provide a consistent way to select the most likely underlying cause. However, it is better when rules designed to compensate for poor reporting are not invoked, so that the rules are confirming the physician's statement rather than imposing assumptions about what the physician meant.

Statistically, mortality research focuses on the underlying cause of death because public health interventions seek to break the sequence of causally

related medical conditions as early as possible. However, all cause information reported on death certificates is important and is analyzed.

In the sections that follow, detailed instructions are given on how to complete Parts I and II. A number of examples of properly completed certificates with case histories are provided in this section to illustrate how the cause of death should be reported. Some common problems are also discussed later in this section.

Changes to cause of death

Should additional medical information or autopsy findings become available that would change the cause or causes of death originally reported, the original death certificate should be amended by the medical-legal officer by **immediately** reporting the revised cause of death to the State vital records office or local registrar.

Instructions

The cause-of-death section consists of two parts. **Part I** is for reporting a chain of events leading directly to death, with the **immediate cause** of death (the final disease, injury, or complication directly causing death) on line (a) and the **underlying cause** of death (the disease or injury that initiated the chain of events that led directly and inevitably to death) on the lowest used line. **Part II** is for reporting all other significant diseases, conditions, or injuries that contributed to death but which did not result in the underlying cause of death given in **Part I**.

The cause-of-death information should be the medical examiner's or coroner's best medical OPINION. Report each disease, abnormality, injury, or poisoning that the medical examiner or coroner believe adversely affected the decedent. A condition can be listed as "probable" even if it has not been definitively diagnosed.

If an organ system failure (such as congestive heart failure, hepatic failure, renal failure, or respiratory failure) is listed as a cause of death, always report its etiology on the line(s) beneath it (for example, renal failure **due to** Type I diabetes mellitus or renal failure **due to** ethylene glycol poisoning).

When indicating neoplasms as a cause of death, include the following: a) primary site or that the primary site is unknown, b) benign or malignant, c) cell type or that the cell type is unknown, d) grade of neoplasm, and e) part or lobe of organ affected (for example, a primary well-differentiated squamous cell carcinoma, lung, left upper lobe).

For each fatal injury (for example, stab wound of chest or gunshot wound) or poisoning, always report the trauma (for example, transection of subclavian vein or perforation of heart or pulmonary hemorrhage), and impairment of function (for example, air embolism or cardiac tamponade) that contributed to death.

Part I of the cause-of-death section

Only one cause is to be entered on each line of Part I. Additional lines should be added between the printed lines when necessary. For each cause, indicate in the space provided the approximate interval between the date of onset (not necessarily the date of diagnosis) and the date of death. For clarity, do not use parenthetical statements and abbreviations when reporting the cause of death. The underlying cause of death should be entered on the LOWEST LINE USED IN PART I. The underlying cause of death is the disease or injury that started the sequence of events leading directly to death or the circumstances of the accident or violence that produced the fatal injury. In the case of a violent death, the form of external violence or accident is antecedent to an injury entered, although the two events may be almost simultaneous.

Conditions in Part I should represent a distinct sequence so that each condition may be regarded as being the consequence of the condition entered immediately below it. When a condition does not seem to fit into such a sequence, consider whether it belongs in Part II.

Line (a) immediate cause

In Part I, the immediate cause of death is reported on line (a). This is the final disease, injury, or complication directly causing the death. An immediate cause of death must always be reported on line (a). It can be the sole entry in the cause-of-death section if that condition is the only condition causing the death.

In the case of a violent death, enter the result of the external cause (for example, fracture of vault of skull, crushed chest).

The immediate cause does not mean the mechanism of death or terminal event (for example, cardiac arrest or respiratory arrest). The mechanism of death (for example, cardiac or respiratory arrest) should not be reported as the immediate cause of death as it is a statement not specifically related to the disease process, and it merely attests to the fact of death. The mechanism of death therefore provides no additional information on the cause of death.

Lines (b), (c), and (d) due to (or as a consequence of)

On line (b) report the disease, injury, or complication, if any, that gave rise to the immediate cause of death reported on line (a). If this, in turn, resulted from a further condition, record that condition on line (c). If this in turn resulted from a further condition, record that condition on line (d). For as many conditions as are involved, write the full sequence, one condition per line, with the most recent condition at the top, and the underlying cause of death reported on the lowest line used in Part I. If more than four lines are needed, add additional lines (writing "due to" between conditions on the same line is the same as drawing an additional line) rather than using space in Part II to continue the sequence. The certification on page 18 is an example in which an additional line was necessary.

The words "due to (or as a consequence of)," which are printed between the lines of Part I, apply not only in sequences with an etiological or pathological basis and usually a chronological time ordering, but also to sequences in which an antecedent condition is believed to have prepared the way for a subsequent cause by damage to tissues or impairment of function.

If the immediate cause of death arose as a complication of or from an error or accident in surgery or other medical procedure or treatment, it is important to report what condition was being treated, what medical procedure was performed, what the complication or error was, and what the result of the complication or error was.

In case of injury, the form of external violence or accident is antecedent to an injury entered although the two events are almost simultaneous (for example, automobile accident or fallen on by tree).

Approximate interval between onset and death

Space is provided to the right of lines (a), (b), (c), and (d) for recording the interval between the presumed onset of the condition (not the diagnosis of the condition) and the date of death. This should be entered for all conditions in Part I. These intervals usually are established by the medical examiner or coroner on the basis of available information. In some cases the interval will have to be estimated. The terms "unknown" or "approximately" may be used. General terms, such as minutes, hours, or days, are acceptable, if necessary. If the time of onset is entirely unknown, state that the interval is "unknown." Do not leave these items blank.

This information is useful in coding certain diseases and also provides a useful check on the accuracy of the reported sequence of conditions.

Part II of the cause-of-death section (other significant conditions)

All other important diseases or conditions that were present at the time of death and that may have contributed to the death, but did not lead to the underlying cause of death listed in Part I or were not reported in the chain of events in Part I, should be recorded on these lines. (More than one condition can be reported per line in Part II.)

For example, a patient who died of alcoholism may also have had a hypertensive heart disease that contributed to the death. In this case, the hypertensive heart disease would be entered in Part II as a contributory cause of death. If a decedent was pregnant, or less than 43 days postpartum at the time of death, and the pregnancy contributed to death, the fact of pregnancy should be indicated here. If the presence of infectious disease has not been noted in Part I, record it here.

Multiple conditions and sequences of conditions resulting in death are common, particularly among the elderly. When there are two or more possible sequences resulting in death, or if two conditions seem to have added together (e.g., stabbing caused both right intrathoracic hemorrhage and air embolism), choose and report in Part I the sequence or condition thought to have had the greatest impact (7). Other conditions or conditions from the other sequence(s) should be reported in Part II. For example, in the case of a diabetic male with chronic ischemic heart disease who dies from pneumonia, the medical examiner or coroner must choose the sequence of conditions that had the greatest impact and report this sequence in Part I. One possible sequence that the certifier might report would be pneumonia due to diabetes mellitus in Part I with chronic ischemic heart disease reported in Part II. Another possibility would be pneumonia due to the chronic ischemic heart disease entered in Part I with diabetes mellitus reported in Part II. Or the certifier might consider the pneumonia to be due to the ischemic heart disease that was due to the diabetes mellitus and report this entire sequence in Part I. Because these three different possibilities would be coded very differently, it is very important for the certifying medical examiner or coroner to decide which sequence most accurately describes the conditions causing death.

For some cases it may not be possible to make a precise determination of interacting causes of death. For these cases a judgment may be made. In cases of doubt, it may be necessary to use qualifying phrases in either Part I or Part II to reflect uncertainty as to which conditions led to death. In cases where the certifier is unable to establish a cause of death based upon reasonable medical certainty or that such a condition was more probably than not the cause of death, he or she should enter "unknown" in

the cause-of-death section. However, “unknown” should be used only after all possible efforts, including an autopsy, have been made to determine the cause.

The following certification is an example in which the cause-of-death section was modified to record all conditions related to the immediate cause of death.

CAUSE OF DEATH (See instructions and examples)			
<p>32. PART I. Enter the chain of events—diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition resulting in death) → a. <u>Asphyxia by vomitus</u> Due to (or as a consequence of): _____</p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST</p> <p>b. <u>Cerebellar hemorrhage</u> Due to (or as a consequence of): _____</p> <p>c. <u>Hypertension</u> Due to (or as a consequence of): _____</p> <p>d. <u>Primary aldosteronism</u></p> <p>e. <u>Adrenal adenoma</u></p>			<p>Approximate interval: Onset to death</p> <p>minutes _____</p> <p>hours _____</p> <p>about 3 years _____</p> <p>3 + years _____</p> <p>3+ years _____</p>
<p>PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I.</p> <p>Congestive heart failure</p>		<p>33. WAS AN AUTOPSY PERFORMED? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown</p>	<p>36. IF FEMALE: <input type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year</p>	<p>37. MANNER OF DEATH <input checked="" type="checkbox"/> Natural <input type="checkbox"/> Homicide <input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>	
<p>38. DATE OF INJURY (Mo/Day/Yr) (Spell Month)</p>	<p>39. TIME OF INJURY</p>	<p>40. PLACE OF INJURY (e.g., Decedent's home; construction site; restaurant; wooded area)</p>	<p>41. INJURY AT WORK? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>
<p>42. LOCATION OF INJURY: State: _____ City or Town: _____</p> <p>Street & Number: _____ Apartment No.: _____ Zip Code: _____</p>			
<p>43. DESCRIBE HOW INJURY OCCURRED:</p>		<p>44. IF TRANSPORTATION INJURY, SPECIFY: <input type="checkbox"/> Driver/Operator <input type="checkbox"/> Passenger <input type="checkbox"/> Pedestrian <input type="checkbox"/> Other (Specify)</p>	

Other items for medical certification

The remaining items that require the medical examiner’s or coroner’s certification relate to autopsy, manner of death, female decedent’s pregnancy status, if tobacco use contributed to death, and injury.

Autopsy—The medical examiner or coroner should indicate whether an autopsy was performed and whether the findings were available to complete the cause of death. A separate report provides case histories and examples of medical certification after autopsy (8).

If additional medical information or autopsy findings are received after the medical examiner or coroner has certified to the cause of death and he or she determines the cause to be different from that originally entered on the death certificate, the original certificate should be amended by filing a

supplemental report of cause of death with the State registrar. Information on the proper form to use and procedure to follow can be obtained from his or her State registrar.

Circumstances of injury or violence—Space is provided on the death certificate for reporting the manner of death; check one of the following boxes: Natural, Accident, Suicide, Homicide, Pending Investigation, or Could not be determined. If “Pending Investigation” is checked, it should be changed after the investigation is completed. The appropriate State amendment procedures should be used to modify this item.

When the death was the result of an external cause, the medical examiner or coroner should specify whether it was an accident, suicide, or homicide and describe the circumstances in items 38–44. In item 43 a clear, brief statement as to how the injury occurred should be made, indicating the circumstances or cause, such as “Burned using gasoline to light stove,” “Slipped and fell while shoveling snow,” “Self-inflicted handgun wound,” or “Stabbed by sharp instrument.”

Bearing in mind that accident prevention programs, assessment of motor vehicle fatalities, and so forth, depend upon the proper wording of this item, the medical examiner or coroner should, in as few words as possible, describe the injury-producing situation. If the death was due to a vehicular accident, be sure to indicate whether the decedent was a driver, passenger, or pedestrian, and the type of vehicle(s) involved.

The medical examiner or coroner should state whether the injury occurred while the deceased was at work at his or her usual occupation and give the specific location where the accident took place.

The National Association of Medical Examiners has put together a guide on how **manner** of death may be determined (9). In certain cases, the manner of death preferred by the medical examiner community and the disease classification differ. As a result, it is important to specify the circumstances (e.g., item 43) involved so that both communities are able to make appropriate use of the information.

In the cases of violent death where the medical examiner or coroner cannot decide which of the terms—accident, suicide, or homicide—best describes the manner of death, “Could not be determined” should be checked. The medical examiner or coroner should bear in mind that “Could not be determined” is intended solely for cases in which it is impossible to establish with reasonable medical certainty the circumstances of death after thorough investigation. This category should not be used for cases “Pending Investigation.”

Special problems for the medical-legal officer

The medical examiner or coroner may experience little difficulty completing most of the items on the death certificate if death occurred under well-defined circumstances. Frequently, however, direct evidence related to cause of death is nonexistent, or there is some doubt concerning facts related to the individual. Under these circumstances, the medical-legal officer should report the facts when they are available, make estimations where such are possible, and where no facts are known and no estimations possible, indicate "Unknown."

Some special problems related to certification by a medical-legal officer are discussed below.

Precision of knowledge required to complete death certificate items

The cause-of-death section in the medical examiner's or coroner's certification is always a medical **opinion**. This opinion is, of course, a synthesis of all information derived from both the investigation into the circumstances surrounding the death and the autopsy, if performed. It represents the best effort of the medical examiner or coroner to reduce to a few words his or her entire synthesis of the cause of death.

In some cases, certain items (such as age or race) may be unknown and the medical examiner or coroner must make his or her best estimate of these items. A best estimate of the manner of death and the time and date of injury may also be required when neither investigation nor examination of the deceased provides definitive information.

The medical examiner or coroner may wish to devote some thought to the degree of "proof" necessary to properly certify deaths that may later be involved in litigation. He or she may wish to consider that the proof required in a criminal proceeding is of a higher degree of positivity than that required in a civil proceeding.

Trauma as a cause of death

It should be noted by all medical-legal officers that if trauma is either the underlying cause of death or a contributing cause of death, the manner of the onset of the trauma must be indicated; that is, the trauma must have been initiated by an accident, a suicidal venture, or a homicidal event. It may be impossible for the certifier to determine which of these three fits the particular case at hand, in which case it may be necessary to state that the manner of death could not be determined. If trauma is listed in Part I or II of item 32, then items 38-44 must be completed.

The National Association of Medical Examiners makes the following distinctions between manners of death (9):

Natural—“due solely or nearly totally to disease and/or the aging process.”

Accident—“there is little or no evidence that the injury or poisoning occurred with intent to harm or cause death. In essence, the fatal outcome was unintentional.”

Suicide—“results from an injury or poisoning as a result of an intentional, self-inflicted act committed to do self-harm or cause the death of one’s self.”

Homicide—“occurs when death results from...” an injury or poisoning or from “...a volitional act committed by another person to cause fear, harm, or death. Intent to cause death is a common element but is not required for classification as homicide.”

Could not be determined—“used when the information pointing to one manner of death is no more compelling than one or more other competing manners of death when all available information is considered.”

Pending investigation—used when determination of manner depends on further information.

One of the more difficult tasks of the medical examiner or coroner is to determine whether a death is an accident or the result of an intent to end life. The medical examiner or coroner must use all information available to make a determination about the death. This may include information from his or her own investigation, police reports, staff investigations, and discussions with the family and friends of the decedent.

Determining a suicide

- There is evidence that death was self-inflicted. Pathological (autopsy), toxicological, investigatory, and psychological evidence, and statements of the decedent or witnesses, may be used for this determination.
- There is evidence (explicit and/or implicit) that at the time of injury the decedent intended to kill self or wished to die and that the decedent understood the probable consequences of his or her actions.
 - Explicit verbal or nonverbal expression of intent to kill self
 - Implicit or indirect evidence of intent to die, such as the following:

- Expression of hopelessness
- Effort to procure or learn about means of death or rehearse fatal behavior
- Preparations for death, inappropriate to or unexpected in the context of the decedent's life
- Expression of farewell or desire to die, or acknowledgment of impending death
- Precautions to avoid rescue
- Evidence that decedent recognized high potential lethality of means of death
- Previous suicide attempt
- Previous suicide threat
- Stressful events or significant losses (actual or threatened)
- Serious depression or mental disorder (10,11)

When cause cannot be determined

It is well known that a professionally competent, searching autopsy and toxicological examination of the body fluids and organs, coupled with the best available bacteriologic, virologic, and immunologic studies, may fail to reveal the cause of death.

If this is the case and if the investigation has been pursued as far as possible, then the medical examiner or coroner will have no recourse but to indicate in one form or another that the cause of death "Could not be determined." One possible phrase is "Cause of death not determined at autopsy and toxicological examination." This is better than the term "Unknown" as it at least indicates the extent of the investigation undertaken.

Deferred "pending investigation"

Most, if not all, medical-legal investigative systems make provisions for cases in which the cause or manner of death cannot be immediately determined. Local laws vary somewhat as to how to handle such cases.

The procedure followed most frequently is to require that the death certificate be completed insofar as possible and filed within the time limits specified by law. Once the cause and/or manner of death are determined, a supplemental report must be prepared and filed by the medical-legal officer. This supplemental report becomes a part of the death certificate that is on file for the decedent.

It should be emphasized that the death certificate that is filed is to be completed insofar as possible. In other words, if the cause of death is known, but it is not known whether it was the result of an accident, suicide, or homicide, the death certificate that is filed should include the cause of death and show the manner of death in item 37 as "Pending Investigation." THE CAUSE OF DEATH SHOULD NEVER BE LEFT BLANK OR SHOWN AS "PENDING" WHEN IT IS KNOWN BUT THE MANNER OF DEATH, ACCIDENT, SUICIDE, OR HOMICIDE IS UNKNOWN.

The concept of "pending investigation" is made more necessary by the gradual increase in the sophistication of toxicological and immunologic methods of investigation. This concept, however, poses some complications. One of these is the proper issuing of certified copies of death certificates when the certificate is not complete. Another is the establishment of the maximum amount of time that may elapse between the time of the issue of the "pending" certificate and the final completion of the certificate. This time interval is established by statute in some jurisdictions, by custom or local arrangements in others. The medical-legal officer must operate within the legal limitations set in his or her area.

Because such cases should be held to a minimum, the following guidelines were recommended by the Subcommittee on the Medical Certification of Medicolegal Cases of the U.S. National Committee on Vital and Health Statistics (12).

1. The term "pending" is intended to apply only to cases in which there is a reasonable expectation that an autopsy, other diagnostic procedure, or investigation may significantly change the diagnosis.
2. Certifications of cause of death should not be deferred merely because "all details" of a case are not available. Thus, for example, if it is clear that a patient died of "cancer of the stomach," reporting of the cause should not be deferred while a determination of the histological type is being carried out. Similarly, if a death is from "influenza," there is no justification for delaying the certification because a virological test is being carried out.
3. In cases where death is known to be from an injury, but the circumstances surrounding the death are not yet established, the injury should be reported immediately. The circumstances of the injury should be noted as "pending investigation" and a supplemental report filed.
4. Lastly, the term "pending" is not intended to apply to cases in which the cause of death is in doubt and for which no further

diagnostic procedures can be carried out. In this case, the “probable” cause should be entered on the basis of the facts available and the certification made in accordance with the best judgment of the certifier.

The medical examiner or coroner must realize that when a death certificate is “pending,” the final settlement of burial expenses, insurance claims, veterans benefits, and so forth, is slowed. Indeed, many such matters will be held open until the certificate is properly completed. Therefore, the use of the term “pending investigation,” or similar deferring terms, should be avoided whenever possible.

Certifier section

The medical examiner or coroner certifies that “On the basis of examination and/or investigation, in my opinion, death occurred at the time, date, and place, and due to the cause(s) and manner as stated.”

45. CERTIFIER (Check only one): <input type="checkbox"/> Certifying physician - To the best of my knowledge, death occurred due to the cause(s) and manner stated. <input type="checkbox"/> Pronouncing & Certifying physician - To the best of my knowledge, death occurred at the time, date, and place, and due to the cause(s) and manner stated. <input type="checkbox"/> Medical Examiner/Coroner - On the basis of examination, and/or investigation, in my opinion, death occurred at the time, date, and place, and due to the cause(s) and manner stated.			
Signature of certifier: _____			
46. NAME, ADDRESS, AND ZIP CODE OF PERSON COMPLETING CAUSE OF DEATH (Item 32)			
47. TITLE OF CERTIFIER	48. LICENSE NUMBER	49. DATE CERTIFIED (Mo/Day/Yr)	50. FOR REGISTRAR ONLY- DATE FILED (Mo/Day/Yr)

The phrase “in my opinion” is included because it is recognized that in medical-legal cases, it is not always possible to make precise determinations of the date and the cause(s) of death. The date may be obscure in the case of bodies found some time after death occurred, and the relationship between the existing diseases or the sequence in which diseases or injuries occurred is not always clear.

However, except in unusual circumstances, the medical examiner or coroner is in a better position than any other individual to make a judgment as to which of the conditions led directly to death and to state the antecedent conditions, if any, that gave rise to this cause.

Space is provided for the time of death and for the date the decedent was pronounced dead. When the exact time of death is unknown, but there is sufficient basis for the medical examiner or coroner to render an opinion, the approximate time of death as estimated by the medical examiner or coroner will be given. This information should be entered as “APPROX—time.” Local time should be used, recording hours and minutes according to a 24-hour clock (for example, 0725).

The medical examiner or coroner signs the completed statement, adding his or her degree or title and license number. The date of certification and mailing address of the medical examiner or coroner should also be provided.

Examples of medical certification

This section contains several examples of medical certification for the guidance of the medical examiner or coroner.

Case No. 1

On January 2, 2003, a 21-year-old female was critically injured in an automobile accident and died from a fractured skull causing cerebral contusion soon after being brought to the hospital. Police records indicated she was the driver in a two-car collision that occurred at 2:15 a.m. at the corner of 21st Street and Ash Street. The decedent crossed the center line and struck an oncoming car head on. Autopsy showed injuries and blood ethanol of 0.240 grams percent.

CAUSE OF DEATH (See instructions and examples)				Approximate interval: Onset to death
32. PART I. Enter the chain of events--diseases, injuries, or complications--that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.				
IMMEDIATE CAUSE (Final disease or condition resulting in death)	a. Cerebral contusion	Due to (or as a consequence of):		30 minutes
Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST	b. Fractured skull	Due to (or as a consequence of):		30 minutes
	c. Blunt impact to head	Due to (or as a consequence of):		30 minutes
	d. Collision of two motor vehicles	Due to (or as a consequence of):		30 minutes
PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I.			33. WAS AN AUTOPSY PERFORMED? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Acute ethanol intoxication			34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
35. DID TOBACCO USE CONTRIBUTE TO DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown	36. IF FEMALE: <input checked="" type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year	37. MANNER OF DEATH <input type="checkbox"/> Natural <input type="checkbox"/> Homicide <input checked="" type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined		
38. DATE OF INJURY (Mo/Day/Yr) (Spell Month) January 2, 2003	39. TIME OF INJURY 0215	40. PLACE OF INJURY (e.g., Decedent's home; construction site; restaurant; wooded area) City street	41. INJURY AT WORK? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
42. LOCATION OF INJURY: State: Nevada City or Town: Xylene Street & Number: 21 st and Ash Street Apartment No.: Zip Code: 89511-4444				
43. DESCRIBE HOW INJURY OCCURRED: Decedent unrestrained driver in an auto-auto collision. Decedent crossed line and hit oncoming vehicle head on.			44. IF TRANSPORTATION INJURY, SPECIFY: <input checked="" type="checkbox"/> Driver/Operator <input type="checkbox"/> Passenger <input type="checkbox"/> Pedestrian <input type="checkbox"/> Other (Specify)	

Case No. 2

On May 15, 2003, a 49-year-old male gardener was brought to the emergency room with an infected wound of the right foot. Because of repeated convulsions, he was admitted to the hospital. The examining physician made a diagnosis of tetanus. His wife reported that while employed as a gardener on April 1, 2003, he stepped on a garden rake. He treated the laceration himself. Patient died of asphyxia during convulsions May 16, 2003. Autopsy supported diagnosis.

CAUSE OF DEATH (See instructions and examples)				Approximate interval: Onset to death
<p>32. PART I. Enter the chain of events—diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition resulting in death) -----> a. <u>Convulsions</u> Due to (or as a consequence of): _____</p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST</p> <p>b. <u>Clostridium tetanus infection</u> Due to (or as a consequence of): _____</p> <p>c. <u>Infected puncture laceration of foot</u> Due to (or as a consequence of): _____</p> <p>d. _____</p>				<p>2 days _____</p> <p>6 weeks _____</p> <p>6 weeks _____</p>
<p>PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I.</p>			<p>33. WAS AN AUTOPSY PERFORMED? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown</p>	<p>36. IF FEMALE:</p> <p><input type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year</p>	<p>37. MANNER OF DEATH</p> <p><input type="checkbox"/> Natural <input type="checkbox"/> Homicide <input checked="" type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>		
<p>38. DATE OF INJURY (Not Day/Yr) (Spell Month) April 1, 2003</p>	<p>39. TIME OF INJURY 1500</p>	<p>40. PLACE OF INJURY (e.g., Decedent's home; construction site; restaurant; wooded area) Private yard</p>	<p>41. INJURY AT WORK? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>42. LOCATION OF INJURY: State: Vermont City or Town: Lowell Street & Number: 221 Folk Avenue Apartment No.: Zip Code: 05847-3333</p>				
<p>43. DESCRIBE HOW INJURY OCCURRED: Stepped on rake while gardening in a residential yard</p>			<p>44. IF TRANSPORTATION INJURY, SPECIFY: <input type="checkbox"/> Driver/Operator <input type="checkbox"/> Passenger <input type="checkbox"/> Pedestrian <input type="checkbox"/> Other (Specify)</p>	

Case No. 3

On May 10, 2003, a 25-year-old male was admitted to the hospital with a gunshot wound to the head. He had been at home in his study cleaning his gun when the shot was fired at approximately 9 p.m. He died at 11:05 p.m. on the same day. Autopsy showed contact gunshot wound of right temple.

CAUSE OF DEATH (See instructions and examples)				Approximate interval: Onset to death
<p>32. PART I. Enter the chain of events, diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition resulting in death) → a. <u>Penetration brain injury</u> Due to (or as a consequence of):</p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST b. <u>Gunshot wound to head</u> Due to (or as a consequence of):</p> <p>c. _____ Due to (or as a consequence of):</p> <p>d. _____</p>				<p><u>2 hours</u></p> <p><u>2 hours</u></p>
PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I.			33. WAS AN AUTOPSY PERFORMED? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
			34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
35. DID TOBACCO USE CONTRIBUTE TO DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown	36. IF FEMALE: <input type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year	37. MANNER OF DEATH <input type="checkbox"/> Natural <input type="checkbox"/> Homicide <input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input checked="" type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined		
38. DATE OF INJURY (Mo/Day/Yr) (Spell Month) May 10, 2003	39. TIME OF INJURY 2100	40. PLACE OF INJURY (e.g., Decedent's home; construction site; restaurant; wooded area) Decedent's home		41. INJURY AT WORK? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
42. LOCATION OF INJURY: State: Alabama City or Town: Columbus				
Street & Number: 3129 Discus Avenue			Apartment No.:	Zip Code: 36102-8888
43. DESCRIBE HOW INJURY OCCURRED: Decedent cleaning gun had contact wound to right temple.			44. IF TRANSPORTATION INJURY, SPECIFY: <input type="checkbox"/> Driver/Operator <input type="checkbox"/> Passenger <input type="checkbox"/> Pedestrian <input type="checkbox"/> Other (Specify)	

NOTE: Autopsy findings in this case indicate an intentionally inflicted gunshot wound rather than accidental discharge of a firearm.

Case No. 4

On June 21, 2003, a 39-year-old male had been in a powerboat that capsized after striking an underwater obstruction at about 2 p.m. The body was recovered 2 hours later by the water patrol. Blood alcohol was measured at 0.31 grams percent.

CAUSE OF DEATH (See instructions and examples)				Approximate interval: Onset to death
<p>32. PART I. Enter the chain of events--diseases, injuries, or complications--that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition resulting in death) → a. <u>Asphyxia</u> Due to (or as a consequence of): _____</p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST</p> <p>b. <u>Drowning</u> Due to (or as a consequence of): _____</p> <p>c. _____ Due to (or as a consequence of): _____</p> <p>d. _____</p>				<p>_____ <u>Unknown</u> _____</p> <p>_____ <u>Unknown</u> _____</p> <p>_____</p> <p>_____</p>
<p>PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I.</p> <p>Alcohol intoxication at 0.31 grams percent</p>		<p>33. WAS AN AUTOPSY PERFORMED? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>		
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown</p>	<p>36. IF FEMALE: <input type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year</p>	<p>37. MANNER OF DEATH <input type="checkbox"/> Natural <input type="checkbox"/> Homicide <input checked="" type="checkbox"/> Accident <input type="checkbox"/> Pending investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>		
<p>38. DATE OF INJURY (Mo/Day/Yr) (Spell Month) June 21, 2003</p>	<p>39. TIME OF INJURY 1400</p>	<p>40. PLACE OF INJURY (e.g., Decedent's home; construction site; restaurant; wooded area) Public lake</p>	<p>41. INJURY AT WORK? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	
<p>42. LOCATION OF INJURY: State: Idaho City or Town: Elkton</p> <p>Street & Number: Lake Tarpon Apartment No.: Zip Code: 83722</p>				
<p>43. DESCRIBE HOW INJURY OCCURRED: Boat operator fell in lake from powerboat when it hit underwater obstruction</p>		<p>44. IF TRANSPORTATION INJURY, SPECIFY: <input checked="" type="checkbox"/> Driver/Operator <input type="checkbox"/> Passenger <input type="checkbox"/> Pedestrian <input type="checkbox"/> Other (Specify)</p>		

Case No. 5

On January 12, 2003, a 2-year-old female was admitted to the hospital with salicylate poisoning. She had been under treatment for tonsillitis and upper respiratory infection. She had been given multiple excessive doses of aspirin (adult rather than baby tablets). She died on January 13, 2003.

CAUSE OF DEATH (See instructions and examples)				Approximate interval: Onset to death
<p>32. PART I. Enter the chain of events--diseases, injuries, or complications--that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition resulting in death) -----> a. <u>Acute salicylate poisoning</u> Due to (or as a consequence of): _____ <u>23 hours</u></p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST b. <u>Overdose of aspirin</u> Due to (or as a consequence of): _____ <u>23 hours</u></p> <p>c. <u>Treatment for acute tonsillitis</u> Due to (or as a consequence of): _____ <u>2 days</u></p> <p>d. _____</p>				
<p>PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I.</p> <p>Upper respiratory infection</p>			<p>33. WAS AN AUTOPSY PERFORMED? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown</p>		<p>36. IF FEMALE: <input checked="" type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year</p>		<p>37. MANNER OF DEATH <input type="checkbox"/> Natural <input type="checkbox"/> Homicide <input checked="" type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>
<p>38. DATE OF INJURY (Mo/Day/Yr) (Spell Month) January 12, 2003</p>	<p>39. TIME OF INJURY 0705</p>	<p>40. PLACE OF INJURY (e.g., Decedent's home, construction site, restaurant, wooded area) Own home</p>		<p>41. INJURY AT WORK? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>
<p>42. LOCATION OF INJURY: State: Oregon City or Town: New Haven Street & Number: 2139 Carlton Avenue Apartment No.: 12 Zip Code: 97323-9999</p>				<p>43. DESCRIBE HOW INJURY OCCURRED: Overdose of aspirin given</p>
				<p>44. IF TRANSPORTATION INJURY, SPECIFY: <input type="checkbox"/> Driver/Operator <input type="checkbox"/> Passenger <input type="checkbox"/> Pedestrian <input type="checkbox"/> Other (Specify)</p>

Case No. 6

On May 5, 2003, a 54-year-old male was found dead from carbon monoxide poisoning in an automobile in a closed garage. A hose, running into the passenger compartment of the car, was attached to the exhaust pipe. The deceased had been dependent for some time as a result of a malignancy, and letters found in the car indicated intent to take his own life.

CAUSE OF DEATH (See instructions and examples)				Approximate interval: Onset to death
<p>32. PART I. Enter the chain of events—diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition resulting in death) -----> a. <u>Carbon monoxide poisoning</u></p> <p>Due to (or as a consequence of): _____</p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST</p> <p>b. <u>Inhaled auto fumes</u></p> <p>Due to (or as a consequence of): _____</p> <p>c. _____</p> <p>Due to (or as a consequence of): _____</p> <p>d. _____</p>				<p>Unknown</p> <p>Unknown</p>
<p>PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I.</p> <p>Cancer of stomach</p>			<p>33. WAS AN AUTOPSY PERFORMED? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> Probably <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown</p>		<p>36. IF FEMALE:</p> <p><input type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year</p>		<p>37. MANNER OF DEATH</p> <p><input type="checkbox"/> Natural <input type="checkbox"/> Homicide <input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input checked="" type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>
<p>38. DATE OF INJURY (Mo/Day/Yr) (Spell Month)</p> <p>May 5, 2003</p>	<p>39. TIME OF INJURY</p> <p>Unknown</p>	<p>40. PLACE OF INJURY (e.g., Decedent's home; construction site; restaurant; wooded area)</p> <p>Own home garage</p>	<p>41. INJURY AT WORK? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	
<p>42. LOCATION OF INJURY: State: Missouri City or Town: Alexandria</p> <p>Street & Number: 898 Sylvan Road Apartment No.: Zip Code: 65100-1234</p>				
<p>43. DESCRIBE HOW INJURY OCCURRED:</p> <p>Inhaled carbon monoxide from auto exhaust through hose in an enclosed garage</p>			<p>44. IF TRANSPORTATION INJURY, SPECIFY:</p> <p><input type="checkbox"/> Driver/Operator <input type="checkbox"/> Passenger <input type="checkbox"/> Pedestrian <input type="checkbox"/> Other (Specify)</p>	

Case No. 7

A 32-year-old male was admitted to the hospital on August 23, 2003, with several stab wounds. He had been found in an alley off Smith Street at 4 a.m. by the police. No weapon was discovered. He died at 6:30 p.m. on the same day. Autopsy revealed that the intrathoracic hemorrhage due to the stab wound of the lung could be considered fatal.

CAUSE OF DEATH (See instructions and examples)				Approximate interval: Onset to death
<p>32. PART I. Enter the chain of events—diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition resulting in death) → a. <u>Intrathoracic hemorrhage</u> Due to (or as a consequence of):</p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST</p> <p>b. <u>Stab wound of lung</u> Due to (or as a consequence of):</p> <p>c. _____ Due to (or as a consequence of):</p> <p>d. _____ Due to (or as a consequence of):</p>				<p><u>15 hours</u></p> <p><u>15 hours</u></p>
<p>PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I.</p> <p>Several stab wounds of abdomen and extremities</p>			<p>33. WAS AN AUTOPSY PERFORMED? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown</p>		<p>36. IF FEMALE: <input type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year</p>		<p>37. MANNER OF DEATH <input type="checkbox"/> Natural <input checked="" type="checkbox"/> Homicide <input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>
<p>38. DATE OF INJURY (Mo/Day/Yr) (Spell Month) August 23, 2003</p>	<p>39. TIME OF INJURY 0330</p>	<p>40. PLACE OF INJURY (e.g., Decedent's home; construction site; restaurant; wooded area) Alley</p>	<p>41. INJURY AT WORK? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	
<p>42. LOCATION OF INJURY: State: Maryland City or Town: Davidsonville Street & Number: Alley between 331 and 333 Smith Street Apartment No.: Zip Code: 21035-3333</p>				
<p>43. DESCRIBE HOW INJURY OCCURRED: Stabbed by a sharp instrument</p>			<p>44. IF TRANSPORTATION INJURY, SPECIFY: <input type="checkbox"/> Driver/Operator <input type="checkbox"/> Passenger <input type="checkbox"/> Pedestrian <input type="checkbox"/> Other (Specify)</p>	

Case No. 8

On July 4, 2003, a 56-year-old male was found dead in a hotel. Autopsy revealed no anatomic cause of death. Blood alcohol level was 0.450 grams percent.

CAUSE OF DEATH (See instructions and examples)				Approximate interval: Onset to death
<p>32. PART I. Enter the chain of events—diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition resulting in death) → a. <u>Acute alcohol poisoning</u> Due to (or as a consequence of):</p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST</p> <p>b. _____ Due to (or as a consequence of):</p> <p>c. _____ Due to (or as a consequence of):</p> <p>d. _____</p>				<p>Unknown</p>
<p>PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I.</p> <p>Alcoholic cirrhosis</p>			<p>33. WAS AN AUTOPSY PERFORMED? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown</p>	<p>36. IF FEMALE:</p> <p><input type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year</p>	<p>37. MANNER OF DEATH</p> <p><input type="checkbox"/> Natural <input type="checkbox"/> Homicide <input checked="" type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>		
<p>38. DATE OF INJURY (Mo/Day/Yr) (Spell Month) July 4, 2003</p>	<p>39. TIME OF INJURY Unknown</p>	<p>40. PLACE OF INJURY (e.g., Decedent's home; construction site; restaurant; wooded area) In bed in a hotel room</p>	<p>41. INJURY AT WORK? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	
<p>42. LOCATION OF INJURY: State: <u>Hawaii</u> City or Town: <u>Haiku</u></p> <p>Street & Number: <u>666 Beach Highway</u> Apartment No.: <u>301</u> Zip Code: <u>96899</u></p>				
<p>43. DESCRIBE HOW INJURY OCCURRED: Over ingested ethanolic beverages. Decedent's blood alcohol level was 0.450 grams percent.</p>			<p>44. IF TRANSPORTATION INJURY, SPECIFY:</p> <p><input type="checkbox"/> Driver/Operator <input type="checkbox"/> Passenger <input type="checkbox"/> Pedestrian <input type="checkbox"/> Other (Specify)</p>	

Case No. 9

On March 18, 2003, a 2-month-old male was found dead in his crib. There was no previous illness, and, although autopsy revealed congestion of the lungs, the medical examiner determined that this did not cause the death. Because no other condition could be found that could have led to the death of the infant, the cause of death was determined to be sudden infant death syndrome.

CAUSE OF DEATH (See instructions and examples)				Approximate interval: Onset to death
<p>32. PART I. Enter the <u>chain of events</u>—diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition -----> resulting in death)</p> <p>a. <u>Sudden infant death syndrome</u> Due to (or as a consequence of):</p> <p>b. _____ Due to (or as a consequence of):</p> <p>c. _____ Due to (or as a consequence of):</p> <p>d. _____ Due to (or as a consequence of):</p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST.</p>				<p>Unknown</p>
<p>PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I.</p>			<p>33. WAS AN AUTOPSY PERFORMED? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown</p>		<p>36. IF FEMALE: <input type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year</p>		<p>37. MANNER OF DEATH <input checked="" type="checkbox"/> Natural <input type="checkbox"/> Homicide <input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>
<p>38. DATE OF INJURY (Mo/Day/Yr) (Spell Month)</p>	<p>39. TIME OF INJURY</p>	<p>40. PLACE OF INJURY (e.g., Decedent's home; construction site; restaurant; wooded area)</p>		<p>41. INJURY AT WORK? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>42. LOCATION OF INJURY: State: _____ City or Town: _____ Apartment No.: _____ Zip Code: _____</p>				
<p>43. DESCRIBE HOW INJURY OCCURRED:</p>				<p>44. IF TRANSPORTATION INJURY, SPECIFY: <input type="checkbox"/> Driver/Operator <input type="checkbox"/> Passenger <input type="checkbox"/> Pedestrian <input type="checkbox"/> Other (Specify)</p>

NOTE: There are established protocols for investigating possible SIDS deaths and criteria for distinguishing between SIDS, consistent with SIDS, and unexpected and undetermined causes. This will be discussed in greater detail in a later section.

Case No. 10

On August 18, 2003, a 32-year-old female was found dead at home. Initial investigation did not reveal cause of death; neither did autopsy or toxicological examination.

CAUSE OF DEATH (See instructions and examples)				Approximate interval: Onset to death
<p>32. PART I. Enter the chain of events—diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition resulting in death) -----></p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST</p>				<p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
<p>a. <u>Cause of death not determined upon autopsy and toxicologic examination</u></p> <p>Due to (or as a consequence of): _____</p>				<p><u>Unknown</u></p>
<p>b. _____</p> <p>Due to (or as a consequence of): _____</p>				
<p>c. _____</p> <p>Due to (or as a consequence of): _____</p>				
<p>d. _____</p>				
<p>PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I.</p>			<p>33. WAS AN AUTOPSY PERFORMED?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	
			<p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> Probably</p> <p><input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown</p>		<p>36. IF FEMALE:</p> <p><input checked="" type="checkbox"/> Not pregnant within past year</p> <p><input type="checkbox"/> Pregnant at time of death</p> <p><input type="checkbox"/> Not pregnant, but pregnant within 42 days of death</p> <p><input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death</p> <p><input type="checkbox"/> Unknown if pregnant within the past year</p>		<p>37. MANNER OF DEATH</p> <p><input type="checkbox"/> Natural <input type="checkbox"/> Homicide</p> <p><input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation</p> <p><input type="checkbox"/> Suicide <input checked="" type="checkbox"/> Could not be determined</p>
<p>38. DATE OF INJURY (Mo/Day/Yr) (Spell Month)</p>	<p>39. TIME OF INJURY</p>	<p>40. PLACE OF INJURY (e.g., Decedent's home; construction site; restaurant; wooded area)</p>		<p>41. INJURY AT WORK?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>42. LOCATION OF INJURY: State: _____ City or Town: _____</p> <p>Street & Number: _____ Apartment No.: _____ Zip Code: _____</p>				
<p>43. DESCRIBE HOW INJURY OCCURRED:</p>			<p>44. IF TRANSPORTATION INJURY, SPECIFY:</p> <p><input type="checkbox"/> Driver/Operator</p> <p><input type="checkbox"/> Passenger</p> <p><input type="checkbox"/> Pedestrian</p> <p><input type="checkbox"/> Other (Specify)</p>	

NOTE: This example is one way in which the medical-legal officer, after reasonable investigation, can indicate that the cause has not been determined. Presumably, such a death certificate would have been initially issued with the term "Pending Investigation" checked in item 37 and, at a later time, the phrase "Could not be determined" substituted.

Case No. 11

On September 4, 2003, a 50-year-old alcoholic male was found unconscious in an abandoned house at 4 a.m. by police. He was admitted to the hospital where he died at 10 a.m. on the same day. Examination on admission to the hospital revealed a large subdural hematoma causing intracerebral hemorrhage. There was a large subgaleal hemorrhage over the area of the subdural hematoma.

CAUSE OF DEATH (See instructions and examples)				Approximate interval: Onset to death
<p>32. PART I. Enter the chain of events—diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition resulting in death) →</p> <p>a. <u>Subdural hematoma</u> Due to (or as a consequence of): _____</p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST</p> <p>b. <u>Blunt force impact to head</u> Due to (or as a consequence of): _____</p> <p>c. _____ Due to (or as a consequence of): _____</p> <p>d. _____</p>				<p>Unknown</p> <p>Unknown</p>
<p>PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I.</p>			<p>33. WAS AN AUTOPSY PERFORMED? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown</p>		<p>36. IF FEMALE:</p> <p><input type="checkbox"/> Not pregnant within past year</p> <p><input type="checkbox"/> Pregnant at time of death</p> <p><input type="checkbox"/> Not pregnant, but pregnant within 42 days of death</p> <p><input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death</p> <p><input type="checkbox"/> Unknown if pregnant within the past year</p>		<p>37. MANNER OF DEATH</p> <p><input type="checkbox"/> Natural <input type="checkbox"/> Homicide</p> <p><input type="checkbox"/> Accident <input checked="" type="checkbox"/> Pending Investigation</p> <p><input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>
<p>38. DATE OF INJURY (Mo/Day/Yr) (Spell Month)</p> <p>September 4, 2003</p>	<p>39. TIME OF INJURY</p> <p>Unknown</p>	<p>40. PLACE OF INJURY (e.g., Decedent's home, construction site, restaurant, wooded area)</p> <p>Abandoned house</p>	<p>41. INJURY AT WORK? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	
<p>42. LOCATION OF INJURY: State: Florida City or Town: Miami</p> <p>Street & Number: 3131 Smith Street Apartment No.: _____ Zip Code: 33109-1233</p>				
<p>43. DESCRIBE HOW INJURY OCCURRED:</p> <p>Unknown</p>			<p>44. IF TRANSPORTATION INJURY, SPECIFY:</p> <p><input type="checkbox"/> Driver/Operator</p> <p><input type="checkbox"/> Passenger</p> <p><input type="checkbox"/> Pedestrian</p> <p><input type="checkbox"/> Other (Specify)</p>	

NOTE: The above certificate was issued before police investigation was completed. After a thorough investigation, the legal-medical officer made the judgment that the decedent probably fell down the stairs next to which the body was found. The certificate should be amended in item 37 to "Accident."

CAUSE OF DEATH (See instructions and examples)				Approximate interval: Onset to death
<p>32. PART I. Enter the <u>chain of events</u>--diseases, injuries, or complications--that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition resulting in death) → a. <u>Subdural hematoma</u> Due to (or as a consequence of): _____</p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST b. <u>Blunt force injury to top of head</u> Due to (or as a consequence of): _____</p> <p>c. <u>Probable fall</u> Due to (or as a consequence of): _____</p> <p>d. _____</p>				<p>Unknown</p> <p>Unknown</p> <p>Unknown</p>
<p>PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I.</p>			<p>33. WAS AN AUTOPSY PERFORMED? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown</p>	<p>36. IF FEMALE: <input checked="" type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year</p>	<p>37. MANNER OF DEATH <input type="checkbox"/> Natural <input type="checkbox"/> Homicide <input checked="" type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>		
<p>38. DATE OF INJURY (Mo/Day/Yr) (Spell Month) September 4, 2003</p>	<p>39. TIME OF INJURY Unknown</p>	<p>40. PLACE OF INJURY (e.g., Decedent's home; construction site; restaurant; wooded area) Abandoned house</p>	<p>41. INJURY AT WORK? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	
<p>42. LOCATION OF INJURY: State: Florida City or Town: Miami Street & Number: 3131 Smith Street Apartment No.: Zip Code: 33109-1233</p>				
<p>43. DESCRIBE HOW INJURY OCCURRED: Decedent probably fell down stairs in abandoned house</p>			<p>44. IF TRANSPORTATION INJURY, SPECIFY: <input type="checkbox"/> Driver/Operator <input type="checkbox"/> Passenger <input type="checkbox"/> Pedestrian <input type="checkbox"/> Other (Specify)</p>	

Case No. 12

On March 4, 2003, a 40-year-old male collapsed at a swimming pool. He had no history of heart problems but had complained 2 days earlier of chest pains and indigestion. Autopsy revealed an acute myocardial infarction due to severe coronary artery disease. The serum was milky. A family history of hyperlipidemia was identified.

CAUSE OF DEATH (See instructions and examples)				Approximate interval: Onset to death	
32. PART I. Enter the chain of events--diseases, injuries, or complications--that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.				_____ minutes	
IMMEDIATE CAUSE (Final disease or condition resulting in death) a. <u>Acute myocardial infarction</u> <small>Due to (or as a consequence of):</small>				_____ years	
Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST					
b. <u>Severe coronary artery disease</u> <small>Due to (or as a consequence of):</small>					
c. _____ <small>Due to (or as a consequence of):</small>					
d. _____ <small>Due to (or as a consequence of):</small>					
PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I. Familial hyperlipidemia			33. WAS AN AUTOPSY PERFORMED? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
			34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
35. DID TOBACCO USE CONTRIBUTE TO DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> Probably <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown		36. IF FEMALE: <input type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year		37. MANNER OF DEATH <input checked="" type="checkbox"/> Natural <input type="checkbox"/> Homicide <input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined	
38. DATE OF INJURY (Mo/Day/Yr) (Spell Month)		39. TIME OF INJURY	40. PLACE OF INJURY (e.g., Decedent's home; construction site; restaurant; wooded area)		41. INJURY AT WORK? <input type="checkbox"/> Yes <input type="checkbox"/> No
42. LOCATION OF INJURY: State: _____ City or Town: _____ Apartment No.: _____ Zip Code: _____					
43. DESCRIBE HOW INJURY OCCURRED:			44. IF TRANSPORTATION INJURY, SPECIFY: <input type="checkbox"/> Driver/Operator <input type="checkbox"/> Passenger <input type="checkbox"/> Pedestrian <input type="checkbox"/> Other (Specify)		

Case No. 13

On July 26, 2003, a 32-year-old male was found along a roadway lying in some brambles. He was thrashing about and grinding his teeth. His body temperature was 103° F. He steadily went into full arrest and later died in the emergency room at a medical center. He had a history of cocaine and cannabis abuse. Toxicological examination revealed that he died of cocaine toxicity.

CAUSE OF DEATH (See instructions and examples)				Approximate interval: Onset to death
<p>32. PART I. Enter the chain of events—diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition resulting in death) → a. <u>Agitated delirium</u> Due to (or as a consequence of):</p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST.</p> <p>b. <u>Cocaine toxicity with cocaine level of 2150 nanograms per milliliter</u> Due to (or as a consequence of):</p> <p>c. _____ Due to (or as a consequence of):</p> <p>d. _____</p>				<p>_____ minutes</p> <p>_____ minutes</p> <p>_____ minutes</p>
<p>PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I.</p> <p>History of cocaine and cannabis abuse</p>			<p>33. WAS AN AUTOPSY PERFORMED? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown</p>		<p>36. IF FEMALE:</p> <p><input type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year</p>		<p>37. MANNER OF DEATH</p> <p><input type="checkbox"/> Natural <input type="checkbox"/> Homicide <input checked="" type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>
<p>38. DATE OF INJURY (Mo/Day/Yr) (Spell Month) July 26, 2003</p>	<p>39. TIME OF INJURY Unknown evening</p>	<p>40. PLACE OF INJURY (e.g., Decedent's home; construction site; restaurant; wooded area) Unknown</p>		<p>41. INJURY AT WORK? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>
<p>42. LOCATION OF INJURY: State: Illinois City or Town: Morton Street and Number: Elm Street Apartment No.: _____ Zip Code: 61550</p>				
<p>43. DESCRIBE HOW INJURY OCCURRED: When found, the decedent was experiencing an adverse reaction to cocaine. Decedent had a history of substance abuse.</p>			<p>44. IF TRANSPORTATION INJURY, SPECIFY: <input type="checkbox"/> Driver/Operator <input type="checkbox"/> Passenger <input type="checkbox"/> Pedestrian <input type="checkbox"/> Other (Specify)</p>	

Case No. 14

On October 1, 2003, at 2:30 p.m., a 22-year-old male was found hanging by the neck in the garage at the rear of his residence. He had a history of dependency and drug abuse and was last seen by his mother 30 minutes earlier.

CAUSE OF DEATH (See instructions and examples)				Approximate interval: Onset to death
<p>32. PART I. Enter the chain of events—diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p> <p>IMMEDIATE CAUSE (Final disease or condition resulting in death) -----> a. <u>Asphyxia</u> Due to (or as a consequence of): _____</p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST</p> <p>b. <u>Hanging by the neck</u> Due to (or as a consequence of): _____</p> <p>c. _____ Due to (or as a consequence of): _____</p> <p>d. _____</p>				<p>_____ minutes</p> <p>_____ minutes</p> <p>_____ minutes</p>
<p>PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I.</p> <p>Substance abuse, depression</p>			<p>33. WAS AN AUTOPSY PERFORMED? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown</p>		<p>36. IF FEMALE: <input type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year</p>		<p>37. MANNER OF DEATH <input type="checkbox"/> Natural <input type="checkbox"/> Homicide <input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input checked="" type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>
<p>38. DATE OF INJURY (Mo/Day/Yr) (Spell Month) October 1, 2003</p>	<p>39. TIME OF INJURY 1430</p>	<p>40. PLACE OF INJURY (e.g., Decedent's home; construction site; restaurant; wooded area) Garage at decedent's home</p>		<p>41. INJURY AT WORK? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>
<p>42. LOCATION OF INJURY: State: <u>Kansas</u> Street & Number: <u>217 Kirk Avenue</u> City or Town: <u>Wichita</u> Apartment No.: _____ Zip Code: <u>67204-6666</u></p>				<p>43. DESCRIBE HOW INJURY OCCURRED: Hanging by rope from rafters</p>
				<p>44. IF TRANSPORTATION INJURY, SPECIFY: <input type="checkbox"/> Driver/Operator <input type="checkbox"/> Passenger <input type="checkbox"/> Pedestrian <input type="checkbox"/> Other (Specify)</p>

Common problems in death certification

Often several acceptable ways of writing a cause-of-death statement exist. Optimally, a certifier will be able to provide a simple description of the process leading to death that is etiologically clear and be confident that this is the correct sequence of causes. However, realistically, description of the process is sometimes difficult because the certifier is **not certain**.

In this case, the certifier should think through the causes about which he/she is confident and what possible etiologies could have resulted in these conditions. The certifier should select the causes that are suspected to have been involved and use words such as “probable” or “presumed” to indicate that the description provided is not completely certain. If the initiating condition reported on the death certificate could have arisen from a pre-existing condition but the certifier cannot determine the etiology, he/she should state that the etiology is unknown, undetermined, or unspecified, so it is clear that the certifier did not have enough information to provide even a qualified etiology. Reporting a cause of death as unknown should be a last resort.

The **elderly decedent** should have a clear and distinct etiological sequence for cause of death, if possible. Terms such as senescence, infirmity, old age, and advanced age have little value for public health or medical research. Age is recorded elsewhere on the certificate. When a number of conditions resulted in death, the medical examiner or coroner should choose the single sequence that, in his or her opinion, best describes the process leading to death, and place any other pertinent conditions in Part II. “Multiple system failure” could be included in Part II, but the systems need to be specified to ensure that the information is captured.

The **infant decedent** should have a clear and distinct etiological sequence for cause of death, if possible. “Prematurity” should not be entered without explaining the etiology of prematurity. Maternal conditions may have initiated or affected the sequence that resulted in infant death, and such maternal causes should be reported in addition to the infant causes on the infant’s death certificate (e.g., Hyaline membrane disease **due to** prematurity, 28 weeks **due to** placental abruption **due to** blunt trauma to mother’s abdomen).

When **SIDS** is suspected, a complete investigation should be conducted, typically by a medical examiner or coroner. Issues relating to pathology, role of injury, and concern about forms of abuse have influenced certification practices for SIDS and other deaths for which cause is difficult to determine (9).

Protocols exist for determining if an infant death under 1 year of age is a SIDS death including thorough scene investigation, review of clinical history, and a complete autopsy (9,13). The investigation results usually fit within one of the following (9):

- Disease or injury—Investigation identifies a cause of death such as pneumonia, meningitis, overlaying, head trauma, asphyxia from plastic bag, or other cause. The disease condition or conditions should be reported on the death certificate.
- Sudden Infant Death Syndrome—Investigation finds no reason to question the preliminary diagnosis of SIDS. That is, toxicology tests and histology are negative, there are no unusual scene findings or sleeping conditions, there is no medical/clinical history that would predispose the baby to die, and the autopsy did not reveal any other explanation.
- Consistent with Sudden Infant Death Syndrome but with disease condition—Investigation results are consistent with a diagnosis of SIDS; however, a disease or other condition (e.g., focal bronchiolitis) is identified. If the role of the condition in causing or contributing to death is not known or is difficult to ascertain, this finding would not preclude reporting “Consistent with Sudden Infant Death Syndrome” in Part I and the disease conditions in Part II of the death certificate.
- Consistent with Sudden Infant Death Syndrome but risk factor exists—Investigation results are consistent with a diagnosis of SIDS; however, a risk factor or external condition (e.g., bed sharing or sleeping on a soft pillow) is identified. If the role of the external condition or risk factor in causing or contributing to death is not known or is difficult to prove, this finding would not preclude reporting “Consistent with Sudden Infant Death Syndrome” in Part I and the risk factor or external conditions in Part II of the death certificate.
- Unexpected and undetermined cause—Investigation results rule out Sudden Infant Death Syndrome but the cause is not determined. Other possible findings that are found but for which the role is unclear may be reported in Part II.

Most certifiers will find themselves, at some point, in the circumstance in which they are **unable to provide a simple description of the process of death**. In this situation, the certifier should try to provide a clear sequence, qualify the causes about which he/she is uncertain, and be able to explain the certification chosen.

When processes such as the following are reported, additional information about the etiology should be reported:

Abscess	Cellulitis	Gastrointestinal hemorrhage	Pancytopenia
Abdominal hemorrhage	Cerebral edema	Heart failure	Paralysis
Adhesions	Cerebrovascular accident	Hemothorax	Perforated gallbladder
Adult respiratory distress syndrome	Cerebellar tonsillar herniation	Hepatic failure	Peritonitis
Acute myocardial infarction	Chronic bedridden state	Hepatitis	Pleural effusions
Altered mental status	Cirrhosis	Hepatorenal syndrome	Pneumonia
Anemia	Coagulopathy	Hyperglycemia	Pulmonary arrest
Anoxia	Compression fracture	Hyperkalemia	Pulmonary edema
Anoxic encephalopathy	Congestive heart failure	Hypovolemic shock	Pulmonary embolism
Arrhythmia	Convulsions	Hyponatremia	Pulmonary insufficiency
Ascites	Decubiti	Hypotension	Renal failure
Aspiration	Dehydration	Immunosuppression	Respiratory arrest
Atrial fibrillation	Dementia (when not otherwise specified)	Increased intracranial pressure	Seizures
Bacteremia	Diarrhea	Intracranial hemorrhage	Sepsis
Bedridden	Disseminated intravascular coagulopathy	Malnutrition	Septic shock
Biliary obstruction	Dysrhythmia	Metabolic encephalopathy	Shock
Bowel obstruction	End-stage liver disease	Multi-organ failure	Starvation
Brain injury	End-stage renal disease	Multi-system organ failure	Subarachnoid hemorrhage
Brain stem herniation	Epidural hematoma	Myocardial infarction	Subdural hematoma
Carcinogenesis	Exsanguination	Necrotizing soft-tissue infection	Sudden death
Carcinomatosis	Failure to thrive	Old age	Thrombocytopenia
Cardiac arrest	Fracture	Open (or closed) head injury	Uncal herniation
Cardiac dysrhythmia	Gangrene		Urinary tract infection
Cardiomyopathy			Ventricular fibrillation
Cardiopulmonary arrest			Ventricular tachycardia
			Volume depletion

If the certifier is unable to determine the etiology of a process such as those shown above, the process must be qualified as being of an unknown, undetermined, probable, presumed, or unspecified etiology so it is clear that a distinct etiology was not inadvertently or carelessly omitted.

The following conditions and types of death might seem to be specific or natural, but when the medical history is examined further, may be found to be complications of an injury or poisoning (possibly occurring long ago):

Asphyxia	Epidural hematoma	Hyperthermia	Sepsis
Bolus	Exsanguination	Hypothermia	Subarachnoid hemorrhage
Choking	Fall	Open reduction of fracture	Subdural hematoma
Drug or alcohol overdose/drug or alcohol abuse	Fracture	Pulmonary emboli	Surgery
	Hip fracture	Seizure disorder	Thermal burns/chemical burns

Additional resources

In addition to the series of handbooks, additional resources include manuals, guidelines, and Web sites (5,7,8,14–20). Resources on completing death certificates should be kept with or near blank death certificates for easy reference. Additional copies of government-produced resources are available from the State vital statistics offices, the National Center for Health Statistics (8,14–16), and the Internet at <http://www.cdc.gov/nchs> (look under vital statistics, mortality, writing cause-of-death statements).

Several resources (5,7) are available for purchase from the College of American Pathologists. These resources have more examples of cause-of-death certification and address some situations such as peri-procedural deaths that are not as straightforward as many deaths.

Completing Other Items on the Death Certificate

These instructions pertain to the 2003 revision of the U.S. Standard Certificate of Death. Usually the funeral director completes items 1–23 and 51–55. Another physician may have completed some of the medical items, but under certain circumstances the medical examiner or coroner may be responsible for completing the entire certificate. Therefore, instructions for completing all items on the certificate are included.

NAME OF DECEDENT: For use by physician or institution

The left-hand margin of the certificate contains a line where the physician or hospital can write in the name of the decedent. This allows the hospital to assist in completing the death certificate before the body is removed by the funeral director. However, because the funeral director is responsible for completing the personal information about the decedent and because the hospital frequently does not have the complete legal name of the decedent, the hospital or physician should enter the name they have for the decedent in this item, and the funeral director will then enter the full legal name in item 1.

1. DECEDENT'S LEGAL NAME (Include AKAs if any)(First, Middle, Last)

Enter the full first, middle, and last names of the decedent. Do not abbreviate. Do not copy any name from the left-hand margin of the certificate into item 1 on the certificate; the name in the margin may be incomplete or incorrect.

It is suggested that the medical examiner or coroner print the name as provided to him or her by the informant and have the informant check the spelling and order of names before entering the name on the certificate.

If there appears to be more than one spelling of any name provided, and the correct spelling cannot be verified, use the most common spelling. The name must consist of English alphabetic characters and punctuation marks.

If the medical examiner or coroner cannot determine the name of a found body, enter “Unknown” in the name field. Do not enter names such as “John Doe” or “Jane Doe.”

Multiple first or middle names

If the informant indicates two first names separated by a space, such as “Mary Louise Carter,” verify that “Louise” is part of the first name and is not a middle name. Enter the two first names with a blank space between them. If several middle names are given, enter all with a space between the names.

Initials

If the informant indicates that the person uses a first initial such as “E. Charles Jones,” try to obtain the whole first name.

If the first name can be obtained, enter the whole first name. If not, enter just the initial followed by a period.

If the informant indicates two initials and a surname such as “H.S. Green,” determine if these are a first and middle initial, or two first initials with no middle name or initial. Try to obtain the whole name(s).

If the names can be obtained, enter the whole names in the appropriate spaces. If there are no whole names, then enter the initials in the appropriate spaces. Each initial should be followed by a period.

Religious names and titles

If there is a title preceding the name, such as “Doctor,” do not enter the title in any of the name fields.

For religious names such as “Sister Mary Lawrence,” enter “Sister Mary” in the first name field.

No first or middle names (infants)

If a name such as “Baby Boy Watts” is obtained from medical records for the death of a newborn, check with the parents or other informant to see if the child had a given name.

If the child had not been given a name, leave the first and middle name fields blank and enter only the surname.

Alias(es)

Complete the current legal name before entering any other names (**alias** or AKA, “also known as,” names such as AKA Smith) the decedent used or was known as. The alias should be listed if it is substantially different from the decedent’s legal name (e.g., Samuel Langhorne Clemens AKA Mark Twain, but not Jonathon Doe AKA John Doe). Record the alias name with AKA preceding the name (e.g., AKA Smith). Repeat until there are no other names provided.

The State may enter the full alias rather than just the part of the name that differs from the legal name.

AKA does not include:

- Nicknames, unless used for legal purposes or at the family’s request
- Spelling variations of the first name
- Presence or absence of middle initial
- Presence or absence of punctuation marks or spaces
- Variations in spelling of common elements of the surname, such as “Mc” and “Mac” or “St.” and “Saint”

This item is used to identify the decedent. This is the most important item on the certificate for legal and personal use by the family. There are alternate spellings to many names, and it is critical for the family to have the name spelled correctly.

2. SEX

Enter male or female based on observation. Do not abbreviate or use other symbols. If sex cannot be determined after verification with medical records, inspection of the body, or other sources, enter “Unknown.” Do not leave this item blank.

This item aids in the identification of the decedent. It is also used in research and statistical analysis to determine sex-specific death rates.

3. SOCIAL SECURITY NUMBER (SSN)

Enter the decedent’s 9-digit **social security number** (SSN). Read the number back to the informant or check against the document from which it is being copied before moving to the next item.

If the informant does not know the decedent's SSN at the time of the interview, leave the item blank until the informant can supply the number.

If the decedent has no social security number, for example, a recent immigrant or a person from a foreign country visiting the United States, enter "None."

If the deceased's social security number is not known, enter "Unknown."

If the decedent's SSN is not obtainable, enter "Not Obtainable."

This item is useful in identifying the decedent and facilitates the filing of social security claims.

4a-c. AGE

Make one entry only in either 4a, 4b, or 4c depending on the age of the decedent.

4a. AGE—Last Birthday (Years)

Enter the decedent's exact age in years at his or her last birthday.

If the decedent was under 1 year of age, leave this item blank.

Drop all fractions, such as "75 and a half years"; record as "75."

For responses such as "about 90 years," enter "90" in the Years box.

4b. UNDER 1 YEAR—Months, Days

Enter the exact age in either months or days at time of death for infants surviving at least 1 month.

If the infant was 1-11 months of age inclusive, enter the age in completed months.

If the infant was less than 1 month old, enter the age in completed days.

If the infant was over 1 year or under 1 day of age, leave this item blank.

For responses such as "almost 4 months," enter "3" in the Months box.

4c. UNDER 1 DAY—Hours, Minutes

Enter the exact number of hours or minutes the infant lived for infants who did not survive for an entire day.

If the infant lived 1–23 hours inclusive, enter the age in completed hours.

If the infant was less than 1 hour old, enter the age in minutes.

If the infant was more than 1 day old, leave this item blank.

If the informant gives an unspecified answer such as several hours or a few minutes, ASK—Can you give me a number? If a range is given, use the lower number. If the informant cannot give a number, be sure to identify the units, if possible, by entering a “?” in the appropriate unit box.

If the informant does not know and cannot obtain the age, record “Unknown” in box 4a.

Information from this item is used to study differences in age-specific mortality and in planning and evaluating public health programs.

5. DATE OF BIRTH (Month, Day, Year)

Enter the full name of the month (January, February, March, etc.), day, and 4-digit year that decedent was born. Do not use a number or abbreviation to designate the month.

If the date of birth is unknown, then enter “Unknown.” If part of date of birth is unknown, then enter the known parts and leave the remaining parts blank.

For example, for a person who is born in 1913, but the month and day are not known, enter 1913. If the month and year are known and the day is not known, enter February, “blank,” 1913.

This item is useful in identification of the decedent for legal purposes. It also helps verify the accuracy of the “age” item.

6. BIRTHPLACE (City and State or Foreign Country)

If the decedent was born in the United States, enter the name of the city and State.

(NOTE: Canadian provinces and Canadian territories are not collected for decedent’s place of birth.)

If the decedent was not born in the United States, enter the name of the country of birth whether or not the decedent was a U.S. citizen at the time of death.

If the decedent was born in the United States but the city is unknown, enter the name of the State only. If the State is unknown, enter “U.S.—unknown.”

If the decedent was born in a foreign country but the country is unknown, enter “Foreign—unknown.”

If no information is available regarding place of birth, enter “Unknown.”

This item is used to match birth and death certificates of a deceased individual. Matching these records provides information from the birth certificate that is not contained on the death certificate and may give insight into which conditions led to death. Information from the birth certificate is especially important in examining the causes of infant mortality.

7a–g Residence of Decedent

The residence of the decedent (State, county, city, and street address) is the place where his or her household is located, the place where the decedent actually resided, or where the person lives and sleeps most of the time. This is not necessarily the same as “home State,” “voting residence,” “mailing address,” or “legal residence.”

Do not enter addresses that are post office boxes or rural route numbers. Get the building number and “street” name for the residence address rather than the postal address.

Temporary residence

Never enter a temporary residence, such as one used during a visit, business trip, or a vacation. However, usual onshore place of residence during a tour of military duty is not considered temporary and should be entered as the place of residence on the certificate. Similarly, usual place of residence during attendance at college is not considered temporary and should be entered as the place of residence on the certificate.

Multiple residences

If the decedent lived in more than one residence (parent living in a child’s household, children in joint custody, person owning more than one residence, or commuters living elsewhere while working), enter the residence lived in most of the year. If a child lives an equal amount of time in each residence, report the residence staying at when death occurred.

Institutions or group homes

If a decedent had been living in a facility where an individual usually resides for a long period of time, such as a group home, mental institution, nursing home, penitentiary, hospital for the chronically ill, long-term care facility, congregate care facility, foster home, or board and care home, this facility should be entered as the place of residence in items 7a through 7g.

Children

If the decedent was a child, residence is the same as that of the parent(s), legal guardian, or custodian unless the child was living in an institution where individuals usually reside for long periods of time, as indicated above. In those instances the residence of the child is shown as the facility. Children residing at a boarding school are considered to live at a parent's residence. Residence for foster children is the place they live most of the time.

Infants

If the decedent was an infant who never resided at home, the place of residence is that of the mother or legal guardian. Do not use an acute care hospital as the place of residence for any infant.

7a. RESIDENCE—STATE

Enter the name of the State in which the decedent lived. This may differ from the State in the mailing address. If the decedent was not a resident of the United States, enter the name of the country and the name of the unit of government that is the nearest equivalent of a State.

This item is where the U.S. States and territories and the Canadian provinces are recorded.

If a Canadian province or territory, enter the name of the province or territory followed by “/ Canada.” If resident of any other country, enter the name of the country in the space for State.

If the decedent's residence is unknown, enter “Unknown.”

7b. RESIDENCE—COUNTY

Enter the name of the county in which the decedent lived.

If the decedent resided in any country other than the United States and its territories, leave this item blank.

7c. RESIDENCE—CITY OR TOWN

Enter the name of the city, town, or location in which the decedent lived. This may differ from the city, town, or location used in the mailing address.

7d. RESIDENCE—STREET AND NUMBER

Enter the number and street name of the place where the decedent lived.

If the “street” name has a direction as a prefix, enter the prefix in front of the street name. If the “street name” has a direction after the name, enter the direction after the name (e.g., South Main Street or Florida Avenue NW). Report the “street” designator (Street, Road, Avenue, Court, etc.).

Enter the building number assigned to the decedent’s residence. If the number is unknown, enter “Unknown.”

7e. RESIDENCE—APARTMENT NUMBER

Enter the apartment or room number associated with the residence.

If there is no apartment or room number associated with this residence, leave the item blank.

7f. RESIDENCE—ZIP CODE

Enter the ZIP Code of the place where the decedent lived. This may differ from the ZIP Code used in the mailing address.

The 9-digit ZIP Code is preferred over the 5-digit ZIP Code. If only the 5-digit ZIP code is known, report that.

If the decedent was not a resident of the United States or its territories, leave this item blank.

7g. RESIDENCE—INSIDE CITY LIMITS?

Enter “Yes” if the location entered in 7c is incorporated and if the decedent’s residence is inside its boundaries. Otherwise enter “No.”

If it is not known if the residence is inside the city or town limits, enter “Unknown” in the space.

Mortality data by residence are used with population data to compute death rates for detailed geographic areas. These data are important in environmental studies. Data on deaths by place of residence of the decedent are

also used to prepare population estimates and projections. Local officials use this information to evaluate the availability and use of services in their area. Information on residence inside city limits is used to properly assign events within a county. Information on ZIP Code and whether the decedent lived inside city limits is valuable for studies of deaths for small areas.

8. EVER IN U.S. ARMED FORCES?

If the decedent ever served in the U.S. Armed Forces, enter “Yes.” If not, enter “No.” If the medical examiner or coroner cannot determine whether the decedent served in the U.S. Armed Forces, enter “Unknown.” Do not leave this item blank.

This item is used to identify decedents who were veterans. This information is of interest to veteran groups.

9. MARITAL STATUS AT TIME OF DEATH

Enter the marital status of the decedent at time of death. Specify one of the following: Married; Married, but separated; Never married; Widowed; or Divorced. Just because a spouse may be the informant does not preclude the possibility of “Married, but separated.” A person is legally married even if separated. A person is no longer legally married when the divorce papers are signed by a judge.

- “Annulled and not remarried” and “never previously married” are considered “Never Married.”
- “Annulled and not remarried” and “married previously” are classified as how the previous marriage terminated (Widowed, Divorced).
- “Common Law marriage” is considered “Married.”
- “Indian marriage” is considered “Married.”

If marital status cannot be determined, enter “Unknown.” Do not leave this item blank.

This information is used in determining differences in mortality by marital status.

10. SURVIVING SPOUSE’S NAME (If wife, give name prior to first marriage)

If the decedent was married at the time of death, enter the full name of the surviving spouse.

If the surviving spouse is the wife, enter her name prior to first marriage (e.g., maiden name).

This item is used in genealogical studies and in establishing proper insurance settlements and other survivor benefits.

11 and 12 PARENTS

11. FATHER'S NAME (First, Middle, Last)

Enter the first, middle, and last name of the father of the decedent.

It is suggested that the medical examiner or coroner print the name as provided to him or her by the informant and have the informant check the spelling before entering the name on the certificate.

If there appears to be more than one spelling of any name provided, and the correct spelling cannot be verified, use the most common spelling. The name must consist of English alphabetic characters and punctuation marks.

If the father's name cannot be determined, enter "Unknown" in the name field.

12. MOTHER'S NAME PRIOR TO FIRST MARRIAGE (First, Middle, Last)

Enter the name (first, middle, and surname) of the mother of the decedent used prior to first marriage, commonly known as the maiden name. This is the name given at birth or adoption, not a name acquired by marriage. This name is useful because it remains constant throughout life.

The names of the decedent's mother and father aid in identification of the decedent's record. The mother's name prior to first marriage or maiden surname is important for matching the record with other records because it remains constant throughout a lifetime in contrast to other names which may change because of marriage or divorce. These items are also of importance in genealogical studies.

13a-c INFORMANT

13a. INFORMANT'S NAME

Enter the name of the person who supplied the personal facts about the decedent and his or her family.

13b. RELATIONSHIP TO DECEDENT

Enter the relationship of the informant to the decedent. For example, this may be a husband, wife, parent, son, daughter, brother, sister, or friend.

13c. MAILING ADDRESS (Street and Number, City, State, ZIP Code)

Enter the complete mailing address of the informant whose name appears in item 13a. Be sure to include the ZIP Code.

The name and mailing address of the informant are used to contact the informant when inquiries must be made to correct or complete any items on the death certificate.

14. PLACE OF DEATH (Check only one; see instructions)

14. PLACE OF DEATH (Check only one; see instructions)	
IF DEATH OCCURRED IN A HOSPITAL: <input type="checkbox"/> Inpatient <input type="checkbox"/> Emergency Room/Outpatient <input type="checkbox"/> Dead on Arrival	IF DEATH OCCURRED SOMEWHERE OTHER THAN A HOSPITAL: <input type="checkbox"/> Hospice facility <input type="checkbox"/> Nursing home/Long term care facility <input type="checkbox"/> Decedent's home <input type="checkbox"/> Other (Specify):

Check the type of place where the decedent was pronounced dead.

Hospital deaths

If the decedent was pronounced dead in a hospital, check the box indicating the decedent's status at the hospital: Inpatient, Emergency Room/Outpatient (ER), or Dead on Arrival (DOA). Hospitals are licensed institutions with medical staff providing diagnostic and therapeutic services to patients.

Nonhospital deaths

If the decedent was pronounced dead somewhere else, check the box indicating whether pronouncement occurred at a Hospice facility, Nursing home/Long term care facility, Decedent's home, or Other location.

Hospice facility refers to a licensed institution providing hospice care (e.g., palliative and supportive care for the dying), not to hospice care that might be provided in a number of different settings, including a patient's home.

If death was pronounced at a licensed long-term care facility, check the "Nursing home/Long term care facility" box. A long-term care facility is not a hospital, but provides patient care beyond custodial care (e.g., nursing home, skilled nursing facility, long-term care facilities, convalescent care facility, extended care facility, intermediate care facility, residential care facility, congregate care facility).

If death was pronounced in the decedent's home, check the box that indicates decedent's home. A decedent's home includes independent living units such as private homes, apartments, bungalows, and cottages.

If death was pronounced at a licensed ambulatory/surgical center, orphanage, prison ward, public building, birthing center, facilities offering housing and custodial care, but not patient care (e.g., board and care home, group home, custodial care facility, foster home), check "Other (Specify)." If "Other (Specify)" is checked, specify where death was legally pronounced, such as prison ward, physician's office, the highway where a traffic accident occurred, a vessel, orphanage, group home, or at work.

If the place of death is unknown but the body is found in a State, enter the place where the body is found as the place of death.

15. FACILITY NAME (If not institution, give street & number)

Institution deaths

If the death occurred in a hospital, enter the full name of the hospital.

If death occurred en route to or on arrival at a hospital, enter the full name of the hospital. Deaths that occur in an ambulance or emergency squad vehicle en route to a hospital fall in this category.

If the death occurred in another type of institution such as a nursing home, enter the name of the institution where the decedent died.

Noninstitution deaths

If the death occurred at home, enter the house number and street name.

If the death occurred at some place other than those described above, enter the number and street name of the place or building (if at a building) where the decedent died.

If the death occurred on a moving conveyance, enter the name of the vessel, for example, *S.S. Olive Seas* (at sea) or *Eastern Airlines Flight 296* (in flight).

16. CITY OR TOWN, STATE, AND ZIP CODE

Enter the name of the city, town, village, or location, State, and ZIP code where death occurred.

17. COUNTY OF DEATH

Enter the name of the county of the institution or address given in item 15 for where death occurred. If the death occurred on a moving conveyance in the United States and the body is first removed from the conveyance in this State, complete a death certificate and enter as the place of death the address where the body was first removed from the conveyance.

If the death occurred on a moving conveyance in international waters, international airspace, or in a foreign country or its airspace, and the body is first removed from the conveyance in this State, register the death in this State, but enter the actual place of death insofar as can be determined.

These items are used to identify the place of death which is needed to determine who has jurisdiction for deaths that legally require investigation by a medical examiner or coroner. These items are also used for research and statistics comparing hospital and nonhospital deaths. Valuable information is also provided for health planning and on the utilization of health facilities.

18–20 DISPOSITION

18. METHOD OF DISPOSITION

18. METHOD OF DISPOSITION: <input type="checkbox"/> Burial <input type="checkbox"/> Cremation <input type="checkbox"/> Donation <input type="checkbox"/> Entombment <input type="checkbox"/> Removal from State <input type="checkbox"/> Other (Specify): _____

Check the box corresponding to the method of disposition of the decedent’s body. If the body is to be used by a hospital or a medical or mortuary school for scientific or educational purposes, enter “Donation” and specify the name and location of the institution in items 19 and 20. “Donation” refers only to the entire body, not to individual organs. If “Other (Specify)” is checked, enter the method of disposition on the line provided.

The response reflects the wishes of the next of kin or informant.

19. PLACE OF DISPOSITION (Name of cemetery, crematory, other place)

Enter the name of the cemetery, crematory, or other place of disposition. If the body is removed from the State, specify the name of the cemetery, crematory, or other place of disposition to which the body is removed.

If the body is to be used by a hospital or medical or mortuary school for scientific or educational purposes, give the name of that institution.

20. LOCATION—CITY, TOWN, AND STATE

Enter the name of the city, town, or village and the State where the place of disposition is located.

If the body of the decedent is to be used by a hospital or medical or mortuary school for scientific or educational purposes, enter the name of the city, town, or village and the State where the institution is located.

If there is any question about how to record the place of disposition, contact the State or local registrar.

This information indicates whether the body was properly disposed of as required by law. It also serves to locate the body in case exhumation, autopsy, or transfer is required later.

21–23 FUNERAL FACILITY

21. NAME AND COMPLETE ADDRESS OF FUNERAL FACILITY

Enter the name and complete address (including ZIP Code) of the facility handling the body prior to burial or other disposition.

These items assist in quality control in filling out and filing death certificates. They identify the person who is responsible for filing the certificate with the registrar.

22. SIGNATURE OF FUNERAL SERVICE LICENSEE OR OTHER AGENT

The funeral service licensee or other person first assuming custody of the body and charged with responsibility for completing the death certificate should sign in permanent black ink. If jurisdiction permits, authenticate electronically. Rubber stamps or facsimile signatures are not permitted.

23. LICENSE NUMBER (Of Licensee)

Enter the personal State license number of the funeral service licensee. If some other person who is not a licensed funeral director assumes custody of the body, identify the category of the license and corresponding State license number, or, if the individual possesses no license at all, enter "None."

ITEMS ON WHEN DEATH OCCURRED

Items 24 and 25 and 29–31 should always be completed. If the facility uses a separate pronouncer or other person to indicate that death has taken place and another person more familiar with the case completes the remainder of the medical portion of the death certificate, the *pronouncer* completes items 24–28. In all other cases, the certifier completes items 24 and 25, 29–37, and 45–49, and items 26–28 are left blank.

24. DATE PRONOUNCED DEAD (Month, Day, Year)

Enter the exact month, day, and 4-digit year that the decedent was pronounced dead. Complete this item even when it is the same as item 29, the actual or presumed date.

Enter the full name of the month—January, February, March, etc. Do not use a number or abbreviation to designate the month.

This is used to identify the date the decedent was legally pronounced dead. This information is very helpful in those cases where a body of a person who has been dead for some time is found and the death is pronounced by a medical examiner or coroner.

25. TIME PRONOUNCED DEAD

Enter the exact time (hour and minute using a 24-hour clock) the decedent was pronounced dead according to local time. If daylight saving time is the official prevailing time where death occurs, it should be used to record the time of death. Be sure to indicate the time using a 24-hour clock.

24-hour clock	12-hour clock
0000 (medical facilities); 2400 (military facilities)	12 midnight
0100	1:00 a.m.
0200	2:00 a.m.
0300	3:00 a.m.
0400	4:00 a.m.
0500	5:00 a.m.
0600	6:00 a.m.
0700	7:00 a.m.
0800	8:00 a.m.
0900	9:00 a.m.
1000	10:00 a.m.
1100	11:00 a.m.
1200	12 noon
1300	1:00 p.m.
1400	2:00 p.m.
1500	3:00 p.m.
1600	4:00 p.m.
1700	5:00 p.m.
1800	6:00 p.m.
1900	7:00 p.m.
2000	8:00 p.m.
2100	9:00 p.m.
2200	10:00 p.m.
2300	11:00 p.m.

A death that occurs at 2400 or 0000 midnight belongs to the start of the new day. One minute after 12 midnight is entered as 0001 of the new day.

If the exact time of death is unknown, the time should be approximated by the person who pronounces the body dead. “Approx” should be placed before the time.

26–28 PRONOUNCING PHYSICIAN ONLY

Items 26–28 are to be completed only when the physician responsible for completing the medical certification of cause of death is not available at the time of death to certify the cause of death and the State has a law providing for a pronouncing physician. In this situation, a pronouncing physician is the person who determines that the decedent is legally dead but who was not in charge of the patient’s care for the illness or condition that resulted in death. This hospital physician certifies to the fact and time of death (items 24 and 25) and signs and dates the death certificate (items 26–28) so the body can be released. The attending physician is normally responsible for completing the cause-of-death section (item 32), but in medical examiner cases, the medical examiner may complete the cause of death. See section on medical certification of death in this handbook for a more detailed discussion of the completion of item 32.

COMPLETE ITEMS 26–28 ONLY WHEN CERTIFYING PHYSICIAN IS NOT AVAILABLE AT TIME OF DEATH TO CERTIFY CAUSE OF DEATH.

26. SIGNATURE OF PERSON PRONOUNCING DEATH (Only when applicable)

Obtain the signature in ink and the degree or title of the physician who pronounces death. This physician certifies to the time, date, and place of death only. Rubber stamps or facsimile signatures are not permitted on paper certificates. Jurisdictions with electronic death certificates may have other ways to authenticate the certification than by using a signature.

27. LICENSE NUMBER (Only when applicable)

Enter the State license number of the physician who pronounces death.

28. DATE SIGNED (Month, Day, Year) (Only when applicable)

Enter the exact month, day, and year that the pronouncing physician signs the certificate. Do not use a number to designate the month.

This information is useful for the quality control program by indicating that the medical certification was provided by the attending physician.

Items 24 and 25 must be completed by the person who pronounces death—the pronouncing physician, pronouncing/certifying physician, or medical examiner/coroner.

29. ACTUAL OR PRESUMED DATE OF DEATH (Month, Day, Year)

Enter the exact month, day, and year that death occurred.

Enter the full name of the month—January, February, March, etc. Do not use a number or abbreviation to designate the month.

Pay particular attention to the entry of month, day, or year when a death occurs around midnight or December 31. Consider a death at midnight to have occurred at the beginning of the next day rather than the end of the previous day. For instance, the date for a death that occurs at 11:59 p.m. or 2359 on December 31 should be recorded as December 31 while those occurring the next minute 0000 should be recorded as January 1.

If the exact date of death is unknown, it should be approximated by the person completing the medical certification. "Approx—" should be placed before the date. If date cannot be determined by approximating, the date found should be entered and identified as such.

This item is used in conjunction with the hour of death to establish the exact time of death of the decedent. Epidemiologists also use date of death in conjunction with the cause-of-death section for research on intervals between injuries, onset of conditions, and death.

30. ACTUAL OR PRESUMED TIME OF DEATH

Enter the exact time (hour and minute using a 24-hour clock) of death according to local time. If daylight saving time is the official prevailing time where death occurs, it should be used to record the time of death. Be sure to indicate the time using a 24-hour clock.

24-hour clock	12-hour clock
0000 (medical facilities); 2400 (military facilities)	12 midnight
0100	1:00 a.m.
0200	2:00 a.m.
0300	3:00 a.m.
0400	4:00 a.m.
0500	5:00 a.m.
0600	6:00 a.m.
0700	7:00 a.m.
0800	8:00 a.m.
0900	9:00 a.m.
1000	10:00 a.m.
1100	11:00 a.m.
1200	12 noon
1300	1:00 p.m.
1400	2:00 p.m.
1500	3:00 p.m.
1600	4:00 p.m.
1700	5:00 p.m.
1800	6:00 p.m.
1900	7:00 p.m.
2000	8:00 p.m.
2100	9:00 p.m.
2200	10:00 p.m.
2300	11:00 p.m.

A death that occurs at 2400 or 0000 midnight belongs to the start of the new day. One minute after 12 midnight is entered as 0001 of the new day.

If the exact time of death is unknown, the time should be approximated by the person who certifies the death. "Approx—" should be placed before the time.

This item establishes the exact time of death which is important in inheritance cases when there is a question of who died first. This is often important in the case of multiple deaths in the same family.

31. WAS MEDICAL EXAMINER OR CORONER CONTACTED?

31. WAS MEDICAL EXAMINER OR CORONER CONTACTED? <input type="checkbox"/> Yes <input type="checkbox"/> No
--

Enter “Yes” if the medical examiner or coroner was contacted in reference to this case. Otherwise enter “No.” Do not leave this item blank.

In cases of accident, suicide, or homicide, the medical examiner or coroner must be notified.

This item records whether the medical examiner or coroner was informed when the circumstances require such action. In such cases, the physician must ensure that this is done.

32. CAUSE OF DEATH

Detailed instructions for this item, together with case records, are contained in the section on Medical Certification of Death in this handbook.

These items are to be completed by the attending physician or medical examiner/coroner certifying or reporting his or her opinion on the cause of death.

Part I. Enter the chain of events—diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.

The cause of death means the disease, abnormality, injury, or poisoning that caused the death, not the mechanism of death, such as cardiac or respiratory arrest, shock, or heart failure.

In Part I, the immediate cause of death (final disease or condition resulting in death) is reported on line (a). Antecedent conditions, if any, that gave rise to the cause are reported on lines (b), (c), and (d). The underlying cause (disease or injury that initiated events resulting in death) should be reported on the last line used in Part I. No entry is necessary on lines (b), (c), and (d) if the immediate cause of death on line (a) describes completely the sequence of events. ONLY ONE CAUSE SHOULD BE ENTERED ON A LINE.

Provide the best estimate of the interval between the onset of each condition and death. Do not leave the space for the interval blank; if unknown, so specify.

Part II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in Part I.

In Part II, enter other important diseases or conditions that contributed to death but did not result in the underlying cause of death given in Part I.

Cause of death is the most important statistical research item on the death certificate. It provides medical information that serves as a basis for describing trends in human health and mortality and for analyzing the conditions leading to death. Mortality statistics provide a basis for epidemiological studies that focus on leading causes of death by age, race, or sex (for example, AIDS, heart disease, and cancer). They also provide a basis for research in disease etiology and evaluation of diagnostic techniques, which in turn lead to improvements in patient care.

All conditions reported are important and are analyzed. For example, analyses may examine associations between conditions reported on the same death certificates such as types of conditions reported in combination with hepatitis.

33. WAS AN AUTOPSY PERFORMED?

33. WAS AN AUTOPSY PERFORMED? <input type="checkbox"/> Yes <input type="checkbox"/> No

Enter "Yes" if a partial or complete autopsy was performed. Otherwise enter "No."

An autopsy is important in giving additional insight into the conditions that lead to death. This additional information is particularly important in arriving at the immediate and underlying causes when the cause is not immediately clear.

34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH?

34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> No

Enter "Yes," if the autopsy findings were available at the time that cause of death was determined. Otherwise enter "No." Leave this item blank if no autopsy was performed.

This information assists in determining whether, for the 9 percent of cases for which an autopsy is done, the information was available to assist in determining the cause of death. Knowing whether the autopsy results were available for determining the cause of death gives insight into the quality of the cause-of-death data.

35. DID TOBACCO USE CONTRIBUTE TO DEATH?

Check "Yes" if, in the medical examiner's or coroner's opinion, any use of tobacco or tobacco exposure contributed to death. Tobacco use may contribute to deaths due to a wide variety of diseases; for example, tobacco use contributes to many deaths due to emphysema or lung cancer and some heart disease and cancers of the head and neck. Check "No" if, in his or her opinion, the use of tobacco did not contribute to death.

36. IF FEMALE, WAS DECEDENT PREGNANT AT TIME OF DEATH OR WITHIN PAST YEAR?

If the decedent is a female, check the appropriate box in item 36. If the decedent is a male, leave the item blank. If the female is either too old or too young to be fecund, check the not pregnant within the past year box.

This information is important in determining the scale of mortality among this population and will be of assistance with maternal mortality review programs.

37. MANNER OF DEATH

37. MANNER OF DEATH
<input type="checkbox"/> Natural <input type="checkbox"/> Homicide
<input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation
<input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined

Complete this item for all deaths. Check the box corresponding to the manner of death. Deaths not due to external causes should be identified as “Natural.” Usually, these are the only types of deaths a physician will certify.

Indicate “Pending Investigation” if the manner of death cannot be determined to be accident, homicide, or suicide within the statutory time limit for filing the death certificate. This should be changed later to one of the other terms.

Indicate “Could not be determined” ONLY when it is impossible to determine the manner of death.

In cases of accidental death this information is used to justify the payment of double indemnity on life insurance policies. It is also used to obtain a more accurate determination of cause of death.

All deaths due to external causes must be referred to the medical examiner or coroner. If the manner of death checked in item 37 was anything other than natural, items 38–44 must be completed.

The National Association of Medical Examiners has put together a guide on how manner of death should be determined (9). In certain cases, the manner of death preferred by the medical examiner community and the disease classification conflict. As a result, it is important to specify the circumstances involved so that both communities are able to make use of the information.

38–44 ACCIDENT OR INJURY—to be filled out in all cases of deaths due to injury or poisoning

Complete these items in cases where injury caused or contributed to the death. All deaths resulting from injury must be reported to a medical examiner or coroner, who will usually certify to the cause of death.

38. DATE OF INJURY (Month, Day, Year)

Enter the exact month, day, and year that the injury occurred. Enter the full name of the month—January, February, March, etc. Do not use a number or abbreviation to designate the month.

The date of injury may not necessarily be the same as the date of death.

Estimates may be provided with “Approx—” placed before the date.

39. TIME OF INJURY

Enter the exact time (hour and minute using a 24-hour clock) when the injury occurred, according to local time. If daylight saving time is the official prevailing time where death occurs, it should be used to record the time of death. Be sure to indicate the time using a 24-hour clock.

24-hour clock	12-hour clock
0000 (medical facilities); 2400 (military facilities)	12 midnight
0100	1:00 a.m.
0200	2:00 a.m.
0300	3:00 a.m.
0400	4:00 a.m.
0500	5:00 a.m.
0600	6:00 a.m.
0700	7:00 a.m.
0800	8:00 a.m.
0900	9:00 a.m.
1000	10:00 a.m.
1100	11:00 a.m.
1200	12 noon
1300	1:00 p.m.
1400	2:00 p.m.
1500	3:00 p.m.
1600	4:00 p.m.
1700	5:00 p.m.
1800	6:00 p.m.
1900	7:00 p.m.
2000	8:00 p.m.
2100	9:00 p.m.
2200	10:00 p.m.
2300	11:00 p.m.

If the exact time of death is unknown, the time should be approximated by the person who certifies the death. “Approx—” should be placed before the time.

The date of injury may differ from the date of death.

40. PLACE OF INJURY (e.g., Decedent’s home; construction site; restaurant; wooded area)

Enter the general type of place (such as restaurant, vacant lot, baseball field, construction site, office building, or decedent’s home) where the injury occurred. DO NOT enter firm or organization names. (For example, enter “factory,” not “Standard Manufacturing, Inc.”)

41. INJURY AT WORK?

41. INJURY AT WORK? <input type="checkbox"/> Yes <input type="checkbox"/> No

Complete if anything other than natural disease is mentioned in Part I or Part II of the medical certification (item 32), including homicides, suicides, and accidents or if anything other than natural is checked for manner of death (item 37). This includes all motor vehicle deaths. The item must be completed for decedents ages 14 years or over and may be completed for those less than 14 years of age if warranted.

Enter "Yes" if the injury occurred at work. Otherwise enter "No." An injury may occur at work regardless of whether the injury occurred in the course of the decedent's "usual" occupation.

Examples of injury at work and injury not at work follow:

Injury at work

Injury while working or in vocational training on job premises
Injury while on break or at lunch or in parking lot on job premises
Injury while working for pay or compensation, including at home
Injury while working as a volunteer law enforcement official, etc.
Injury while traveling on business, including to or from business contacts

Injury not at work

Injury while engaged in personal recreational activity on job premises
Injury while a visitor (not on official work business) to job premises
Homemaker working at homemaking activities
Student in school
Working for self for no profit (mowing yard, repairing own roof, hobby)
Commuting to or from work

These guidelines were developed jointly by: The National Association for Public Health Statistics and Information Systems (NAPHSIS), the National Institute of Occupational Safety and Health (NIOSH), the National Center for Health Statistics (NCHS), and the National Center for Environmental Health and Injury Control (NCEHIC). For questions contact the State Vital Statistics Office.

42. LOCATION OF INJURY (Street and Number, City or Town, State, Apartment No., Zip Code)

Enter the complete address where the injury took place including ZIP Code. Fill in as many of the items as is known.

43. DESCRIBE HOW INJURY OCCURRED

Enter, in narrative form, a brief but specific and clear description of how the injury occurred. Explain the circumstances or cause of the injury, such as "fell off ladder while painting house," "driver of car ran off roadway," or "passenger in car in car-truck collision." Specify **type of gun** (e.g., handgun, hunting rifle) or **type of vehicle** (e.g., car, bulldozer, train, etc.)

when it is relevant to circumstances. Indicate if more than one vehicle is involved; specify type of vehicle decedent was in. For motor vehicle accidents, indicate whether the decedent was a driver, passenger, or pedestrian.

If known, indicate what activity the decedent was engaged in when the injury occurred (e.g., playing a sport, working for income, hanging out at a bar).

In cases of accidental death, items 38–43 are used in justifying the payment of double indemnity on life insurance policies. They are also needed for a more accurate determination of causes of death. Information from these items forms the basis of statistical studies of occupational injuries.

44. IF TRANSPORTATION INJURY, SPECIFY:

44. IF TRANSPORTATION INJURY, SPECIFY: <input type="checkbox"/> Driver/Operator <input type="checkbox"/> Passenger <input type="checkbox"/> Pedestrian <input type="checkbox"/> Other (Specify)

Specify role of decedent (e.g., driver, passenger) in the transportation accident. Driver/operator and passenger should be designated for modes other than motor vehicles such as bicycles. “Other” applies to watercraft, aircraft, animal, or people attached to outside of vehicles (e.g., “surfers”) who are not bonafide passengers or drivers.

Details will help assign deaths to categories that may be used to assess trends and effectiveness of safety programs.

45–49 CERTIFIER

45. CERTIFIER (Check only one)

45. CERTIFIER (Check only one): <input type="checkbox"/> Certifying physician-To the best of my knowledge, death occurred due to the cause(s) and manner stated. <input type="checkbox"/> Pronouncing & Certifying physician-To the best of my knowledge, death occurred at the time, date, and place, and due to the cause(s) and manner stated. <input type="checkbox"/> Medical Examiner/Coroner-On the basis of examination, and/or investigation, in my opinion, death occurred at the time, date, and place, and due to the cause(s) and manner stated. Signature of certifier: _____

The CERTIFYING PHYSICIAN box should be checked only in those cases when the person who is completing the medical certification of cause of death (item 32) is not the person who pronounced death (items 24 and 25). The certifying physician is responsible for completing items 32–49.

The PRONOUNCING & CERTIFYING PHYSICIAN box should be checked when the same person is responsible for completing items 24–49, that is, when the same physician has both pronounced death and certified the cause of death. If this box is checked, items 26–28 should be left blank.

The MEDICAL EXAMINER/CORONER box should be checked when investigation is required by the Post Mortem Examination Act and the cause of death is completed by a medical examiner or coroner. The medical examiner/coroner is responsible for completing items 24–49.

SIGNATURE OF CERTIFIER

The medical-legal officer who certifies the cause of death in item 32 signs the certificate in permanent black ink. Jurisdictions with an electronic death certificate may allow electronic authentication. The degree or title of the medical-legal officer should also be indicated. Rubber stamps or facsimile signatures are not permitted.

46. NAME, ADDRESS, AND ZIP CODE OF PERSON COMPLETING CAUSE OF DEATH (Item 32)

Enter the full name and address of the person whose signature or authentication appears in item 45.

This information is used by the State office of vital statistics for querying the certifier when a question about cause of death arises.

48. LICENSE NUMBER

Enter the State license number of the medical-legal officer who signs or authenticates the certificate in item 45.

This number assists in State quality control programs when it is necessary to contact the certifier for additional information concerning the death.

49. DATE CERTIFIED (Month, Day, Year)

Enter the exact month, day, and year that the certifier signed the certificate.

Enter the full name of the month—January, February, March, etc. Do not use a number or an abbreviation to designate the month.

These items are of legal value in attesting that the medical certification was completed and signed within the time limit required by statute.

51. DECEDENT'S EDUCATION

Check the box that corresponds to the highest level of education that the decedent completed.

Show the informant the education level categories on a card (see [appendix B](#)), and ask the informant to choose the category that, to the best of his or her knowledge, describes the highest education level completed by the decedent.

- 8th grade or less
- 9th–12th grade; no diploma
- High School Graduate or GED completed
- Some college credit; but no degree
- Associate Degree (e.g., AA, AS)
- Bachelor's Degree (e.g., BA, AB, BS)
- Master's Degree (e.g., MA, MS, MEng, MEd, MSW, MBA)
- Doctorate (e.g., PhD, EdD) or Professional degree (e.g., MD, DDS, DVM, LLB, JD)

If the decedent was currently enrolled, mark the previous grade of highest degree received. If the respondent does not know or is not sure, select "Unknown." If the respondent refuses, enter "Refused." If there is no informant or for some other reason the information is not available, enter "Not obtainable."

If the respondent indicates that the decedent has a degree that is not listed on the card, enter "Not classifiable."

This information is used to study the relationship between mortality and education (which roughly corresponds with socioeconomic status). This information is valuable in medical studies of causes of death and in programs to prevent illness and death.

52. DECEDENT OF HISPANIC ORIGIN?

Based on the informant's response, check the box (see card in [appendix C](#)) that best corresponds with the decedent's ethnic identity as given by the informant. The response should reflect what the decedent considered himself or herself to be. The informant is encouraged to select only one response. If the informant is unable to select a single response, mark all boxes that apply; for example "Mexican" and "Cuban," enter both responses. If the respondent indicates an ethnic origin not on the list, it should be recorded in the "Specify" space. Enter the informant's response even if it is not a Hispanic origin.

The choices are as follows:

- No, Not Spanish/Hispanic/Latino
- Yes, Mexican, Mexican American, Chicano
- Yes, Puerto Rican
- Yes, Cuban
- Yes, Other Spanish/Hispanic/Latino
(Specify) _____

Each question, Race and Hispanic Origin, should be asked independently. “Hispanic” is not a race, and a decedent of Hispanic origin may be of any race. Do not leave item 52 blank. “Hispanic” is a self-designated classification for people whose origins are from Spain, the Spanish-speaking countries of Central or South America, the Caribbean, or those identifying themselves generally as Spanish or Spanish-American. Origin can be viewed as ancestry, nationality, or country of birth of the person or person’s parents or ancestors prior to their arrival in the United States. Although the prompts include the major Hispanic groups, other groups may be specified under “Other.”

If the informant does not know, enter “Unknown.”

If there is no informant, enter “Not obtainable.”

If respondent refuses, enter “Refused.”

Hispanics comprise a substantial population group within this country. Reliable data are needed to identify and assess public health problems of Hispanics. Information from item 52 will permit the production of mortality data for the Hispanic community. Identifying health problems will make it possible to target public health resources to this important segment of our population.

53. DECEDENT’S RACE

Ask the informant to look at the card (see [appendix C](#)) and indicate the race or races of the decedent. Enter the race or races of the decedent as stated by the informant. Each question, Race and Hispanic origin, should be asked independently. Do not leave item 53 blank. If there is no box for the informant’s response for one or more race, check the box “Other” and enter the informant’s literal (written) response even if the response is not a race or race(s).

Check one or more of the following choices to indicate what the decedent considered himself/herself to be:

- White
- Black or African American
- American Indian or Alaska Native
(Name of the enrolled or principal tribe) _____
- Asian Indian
- Chinese
- Filipino
- Japanese
- Korean
- Vietnamese
- Other Asian (Specify) _____
- Native Hawaiian
- Guamanian or Chamorro
- Samoan
- Other Pacific Islander (Specify) _____
- Other (Specify) _____

American Indian and Alaska Native refer only to those native to North and South America (including Central America) and does not include Asian Indian. Please specify the name of enrolled or principal tribe (e.g., Navajo, Cheyenne, etc.) for the American Indian or Alaska Native.

For Asians and Pacific Islanders, enter the national origin of the decedent. For Asians check Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, or specify other Asian group; for Pacific Islanders check Native Hawaiian, Guamanian or Chamorro, Samoan, or specify Other Pacific Islander.

If more than one race is indicated, enter each race (e.g., Samoan-Chinese-Filipino or White, American Indian).

If there is no informant or other reliable source of this information, enter "Not obtainable." If the respondent does not know, enter "Unknown." If the respondent refuses, enter "Refused."

Race is essential for identifying specific mortality patterns and leading causes of death among different racial groups. It is also used to determine if specific health programs are needed in particular areas and to make population estimates.

54 and 55 OCCUPATION AND INDUSTRY OF DECEDENT

These items are to be completed for all decedents 14 years of age and over. Enter the information even if the decedent was retired, disabled, or institutionalized at the time of death.

This information is useful in studying deaths related to jobs and in identifying any new risks. For example, the link between lung disease and lung cancer and asbestos exposure in jobs such as shipbuilding or construction was discovered by analyzing this sort of information on death certificates.

54. DECEDENT'S USUAL OCCUPATION (Indicate type of work done during most of working life. DO NOT USE RETIRED.)

Enter the usual occupation of the decedent. This means the type of job the individual was engaged in for most of his or her working life. It is not necessarily the highest paid job nor the job considered the most prestigious, but the one occupation, of perhaps several, that accounted for the greatest number of working years. For example, usual occupation may include claim adjuster, farmhand, coal miner, janitor, store manager, college professor, or civil engineer. Never enter "Retired."

If the decedent was a homemaker at the time of death but had worked outside the household during his or her working life, enter that occupation. If the decedent was a "homemaker" during most of his or her working life, or never worked outside the household, enter "Homemaker." Enter "Student" if the decedent was a student at the time of death and was never regularly employed or employed full time during his or her working life.

If not known, enter "Unknown."

55. KIND OF BUSINESS/INDUSTRY

Enter the kind of business or industry to which the occupation listed in item 54 is related, such as insurance, farming, coal mining, hardware store, retail clothing, university, or government. Do not enter firm or organization names.

If the decedent was a homemaker during his or her working life, and "Homemaker" is entered as the decedent's usual occupation in item 54, enter "Own home" or "Someone else's home," whichever is appropriate.

If the decedent was a student at the time of death and "Student" is entered as the decedent's usual occupation in item 54, enter the type of school, such as high school or college, in item 55.

These items are useful in studying occupationally related mortality and in identifying job-related risk areas. For example, correlating asbestos used in particular occupations in the shipbuilding industry to respiratory cancer was possible with this information. If the medical examiner or coroner have

questions about what classification to use for a decedent's occupation or industry, refer to the handbook "Guidelines for Reporting Occupation and Industry on Death Certificates (21)."

If not known, enter "Unknown."

Completing the Cause of Fetal Death

The primary responsibility of the medical examiner or coroner whose name appears in item 14 of the Fetal Death Report is to complete the cause-of-fetal-death section (items 18a and b, e–h on the report which are collected using items 33–38 on the facility worksheet).

Cause of fetal death

A facsimile of the section on cause of fetal death of the Fetal Death Report is shown on the following page. It is designed to facilitate the reporting of the causes of fetal death and places upon the medical examiner or coroner the responsibility for indicating the conditions and events resulting in the fetal death.

The cause-of-death section consists of two parts. The initiating cause/condition (item 18a) is for reporting a single condition that most likely began the sequence of events resulting in the death of the fetus. Other significant causes or conditions (item 18b) include all other conditions contributing to death. These conditions may be conditions that are triggered by the initiating cause (item 18a) or causes that are not among the sequence of events triggered by the initiating cause (item 18a).

The cause-of-death information should be the medical examiner's or coroner's best medical opinion. Report a specific condition in the space most appropriate to the given situation. A condition can be listed as "probable" if it has not been definitively diagnosed. In reporting the causes of fetal death, conditions in the fetus or mother, or of the placenta, cord, or membranes, should be reported if they are believed to have adversely affected the fetus.

The American College of Obstetrics and Gynecology Technical bulletin number 176 provides guidelines on a full investigation of a fetal death. Cause of fetal death should include information provided by the pathologist if tissue analysis, autopsy, or another type of postmortem exam was done. If microscopic exams for a fetal death are still pending at the time the report is filed, the additional information should be reported to the registrar as soon as it is available.

For statistical and research purposes, it is important that the reporting of the medical information on the fetal death report be specified as precisely as possible. Cause of death is used for medical and epidemiological research on disease etiology and to evaluate the effectiveness of diagnostic and therapeutic techniques. It is a measure of health status at local, State, national, and international levels.

Responsibility of medical examiner or coroner

When a death occurs without medical attendance at or immediately after the delivery, or when further investigation is required by State regulations, a medical examiner or coroner may investigate the fetal death. The death should be reported to the medical examiner or coroner as required by State law.

18. CAUSE/CONDITIONS CONTRIBUTING TO FETAL DEATH		
CAUSE OF FETAL DEATH Mother's Name _____ Mother's Medical Record No. _____	18a. INITIATING CAUSE/CONDITION (AMONG THE CHOICES BELOW, PLEASE SELECT THE ONE WHICH MOST LIKELY BEGAN THE SEQUENCE OF EVENTS RESULTING IN THE DEATH OF THE FETUS) Maternal Conditions/Diseases (Specify) _____ Complications of Placenta, Cord, or Membranes <input type="checkbox"/> Rupture of membranes prior to onset of labor <input checked="" type="checkbox"/> Abruption placenta <input type="checkbox"/> Placental insufficiency <input type="checkbox"/> Prolapsed cord <input type="checkbox"/> Chorioamnionitis <input type="checkbox"/> Other (Specify) _____ Other Obstetrical or Pregnancy Complications (Specify) _____ Fetal Anomaly (Specify) _____ Fetal Injury (Specify) _____ Fetal Infection (Specify) _____ Other Fetal Conditions/Disorders (Specify) _____ <input type="checkbox"/> Unknown	18b. OTHER SIGNIFICANT CAUSES OR CONDITIONS (SELECT OR SPECIFY ALL OTHER CONDITIONS CONTRIBUTING TO DEATH IN ITEM 18a) Maternal Conditions/Diseases (Specify) _____ Complications of Placenta, Cord, or Membranes <input type="checkbox"/> Rupture of membranes prior to onset of labor <input type="checkbox"/> Abruption placenta <input type="checkbox"/> Placental insufficiency <input type="checkbox"/> Prolapsed cord <input type="checkbox"/> Chorioamnionitis <input type="checkbox"/> Other (Specify) _____ Other Obstetrical or Pregnancy Complications (Specify) _____ <u>Intrauterine anoxia</u> Fetal Anomaly (Specify) _____ Fetal Injury (Specify) _____ Fetal Infection (Specify) _____ Other Fetal Conditions/Disorders (Specify) _____ <input type="checkbox"/> Unknown
	18c. WEIGHT OF FETUS (grams preferred, specify unit) _____ 1,550 <input checked="" type="checkbox"/> grams <input type="checkbox"/> lb/oz	18e. ESTIMATED TIME OF FETAL DEATH <input checked="" type="checkbox"/> Dead at time of first assessment, no labor ongoing <input type="checkbox"/> Dead at time of first assessment, labor ongoing <input type="checkbox"/> Died during labor, after first assessment <input type="checkbox"/> Unknown time of fetal death
18d. OBSTETRIC ESTIMATE OF GESTATION AT DELIVERY _____ 36 (completed weeks)		

Instructions for completing cause of fetal death

Cause-of-death information should be the medical examiner's or coroner's best medical opinion. Abbreviations and parenthetical statements should be avoided in reporting causes of death. The terminal event should not be used. The medical examiner or coroner should report the initiating cause of the terminal event in 18a.

If two or more possible sequences resulted in death, or if two conditions seem to have an interactive effect, the condition that most directly caused death, in the opinion of the certifier, should be reported in 18a.

If an organ system failure is listed as a cause of death, always report its etiology. Always report the fatal injury (e.g., stab wound of mother's abdomen), the trauma, and impairment of function.

In 18b, report all diseases or conditions contributing to death that were not reported in 18a and that did not result in the initiating cause of death.

The original fetal death report should be amended if additional medical information or autopsy or histological placental findings become available that would change the cause of death originally reported.

Specify conditions as fetal or maternal

The conditions are set up to facilitate reporting maternal conditions on the "Maternal Conditions/Diseases (Specify)" lines and fetal conditions and obstetrical or pregnancy complications on the remaining lines.

For example, the completed cause of fetal death below indicates asphyxia to the fetus due to a homicide by stabbing of the mother.

CAUSE OF FETAL DEATH		18. CAUSE/CONDITIONS CONTRIBUTING TO FETAL DEATH			
		18a. INITIATING CAUSE/CONDITION (AMONG THE CHOICES BELOW, PLEASE SELECT THE ONE WHICH MOST LIKELY BEGAN THE SEQUENCE OF EVENTS RESULTING IN THE DEATH OF THE FETUS)	18b. OTHER SIGNIFICANT CAUSES OR CONDITIONS (SELECT OR SPECIFY ALL OTHER CONDITIONS CONTRIBUTING TO DEATH IN ITEM 18a)		
Mother's Name Mother's Medical Record No.	Maternal Conditions/Diseases (Specify) <u>Mother stabbed to death in a homicide</u>	Maternal Conditions/Diseases (Specify) _____			
	Complications of Placenta, Cord, or Membranes <input type="checkbox"/> Rupture of membranes prior to onset of labor <input type="checkbox"/> Abruptio placenta <input type="checkbox"/> Placental insufficiency <input type="checkbox"/> Prolapsed cord <input type="checkbox"/> Chorioamnionitis <input type="checkbox"/> Other (Specify) _____ Other Obstetrical or Pregnancy Complications (Specify) _____ Fetal Anomaly (Specify) _____ Fetal Injury (Specify) _____ Fetal Infection (Specify) _____ Other Fetal Conditions/Disorders (Specify) _____ <input type="checkbox"/> Unknown	Complications of Placenta, Cord, or Membranes <input type="checkbox"/> Rupture of membranes prior to onset of labor <input type="checkbox"/> Abruptio placenta <input type="checkbox"/> Placental insufficiency <input type="checkbox"/> Prolapsed cord <input type="checkbox"/> Chorioamnionitis <input type="checkbox"/> Other (Specify) _____ Other Obstetrical or Pregnancy Complications (Specify) _____ Fetal Anomaly (Specify) _____ Fetal Injury (Specify) _____ Fetal Infection (Specify) _____ Other Fetal Conditions/Disorders (Specify) <u>Asphyxia</u> <input type="checkbox"/> Unknown			
	18c. WEIGHT OF FETUS (grams preferred, specify unit) <u>1,550</u> <input checked="" type="checkbox"/> grams <input type="checkbox"/> lb/oz	18e. ESTIMATED TIME OF FETAL DEATH <input checked="" type="checkbox"/> Dead at time of first assessment, no labor ongoing <input type="checkbox"/> Dead at time of first assessment, labor ongoing <input type="checkbox"/> Died during labor, after first assessment <input type="checkbox"/> Unknown time of fetal death	18f. WAS AN AUTOPSY PERFORMED? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Planned	18g. WAS A HISTOLOGICAL PLACENTAL EXAMINATION PERFORMED? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Planned	
	18d. OBSTETRIC ESTIMATE OF GESTATION AT DELIVERY <u>36</u> (completed weeks)		18h. WERE AUTOPSY OR HISTOLOGICAL PLACENTAL EXAMINATION RESULTS USED IN DETERMINING THE CAUSE OF FETAL DEATH? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

Supplemental report of cause of fetal death

In many instances, information on the cause of fetal death may be pending further study of tissue or autopsy results, cytogenetic study, or a pathology report. When additional information is obtained, the medical examiner or coroner should file a supplemental report of cause of fetal death.

Other items for medical certification

Additional information required from the medical examiner or coroner includes estimated time of fetal death (item 18e), was an autopsy performed? (item 18f), was a histological placental examination performed? (item 18g), and were autopsy or histological placental examination results used in determining the cause of fetal death? (item 18h).

Examples of reporting cause of fetal death

Case History No. 1

The mother was a 29-year-old gravida 1, para 0 woman with a history of drug abuse. She had a normal pregnancy until 28 weeks' gestation when hydramnios was noted. Ultrasonography suggested anencephaly. No fetal movement was noted, nor were fetal heart sounds audible. Labor was induced, and a stillborn anencephalic fetus weighing 1,100 grams was delivered.

18. CAUSE/CONDITIONS CONTRIBUTING TO FETAL DEATH		
Mother's Name _____ Mother's Medical Record No. _____	CAUSE OF FETAL DEATH 18a. INITIATING CAUSE/CONDITION (AMONG THE CHOICES BELOW, PLEASE SELECT THE ONE WHICH MOST LIKELY BEGAN THE SEQUENCE OF EVENTS RESULTING IN THE DEATH OF THE FETUS) Maternal Conditions/Diseases (Specify) _____ _____ Complications of Placenta, Cord, or Membranes <input type="checkbox"/> Rupture of membranes prior to onset of labor <input type="checkbox"/> Abruptio placenta <input type="checkbox"/> Placental insufficiency <input type="checkbox"/> Prolapsed cord <input type="checkbox"/> Chorioamnionitis <input type="checkbox"/> Other (Specify) _____ Other Obstetrical or Pregnancy Complications (Specify) _____ _____ Fetal Anomaly (Specify) <u>Anencephaly</u> _____ Fetal Injury (Specify) _____ _____ Fetal Infection (Specify) _____ _____ Other Fetal Conditions/Disorders (Specify) _____ _____ <input type="checkbox"/> Unknown	18b. OTHER SIGNIFICANT CAUSES OR CONDITIONS (SELECT OR SPECIFY ALL OTHER CONDITIONS CONTRIBUTING TO DEATH IN ITEM 18a) Maternal Conditions/Diseases (Specify) <u>Maternal drug use</u> _____ Complications of Placenta, Cord, or Membranes <input type="checkbox"/> Rupture of membranes prior to onset of labor <input type="checkbox"/> Abruptio placenta <input type="checkbox"/> Placental insufficiency <input type="checkbox"/> Prolapsed cord <input type="checkbox"/> Chorioamnionitis <input type="checkbox"/> Other (Specify) _____ Other Obstetrical or Pregnancy Complications (Specify) _____ _____ <u>Intrauterine anoxia</u> Fetal Anomaly (Specify) _____ _____ Fetal Injury (Specify) _____ _____ Fetal Infection (Specify) _____ _____ Other Fetal Conditions/Disorders (Specify) _____ _____ <input type="checkbox"/> Unknown
	18c. WEIGHT OF FETUS (grams preferred, specify unit) _____ <u>1,100</u> <input checked="" type="checkbox"/> grams <input type="checkbox"/> lb/oz	18a. ESTIMATED TIME OF FETAL DEATH <input checked="" type="checkbox"/> Dead at time of first assessment, no labor ongoing <input type="checkbox"/> Dead at time of first assessment, labor ongoing <input type="checkbox"/> Died during labor, after first assessment <input type="checkbox"/> Unknown time of fetal death
18d. OBSTETRIC ESTIMATE OF GESTATION AT DELIVERY _____ <u>28</u> (completed weeks)		

Note: The drug(s) should be specified when known.

Case History No. 2

The mother had a normal pregnancy until 28 weeks' gestation when she noticed the absence of fetal movement, which was confirmed by ultrasound. There were no audible fetal heart sounds. Labor was induced and the mother was delivered of a 900-gram fetus, apparently female, delivered after prostaglandin.

The facies was abnormal with depressed nasal bridge, anteverted nostrils, small mouth, small posteriorly rotated ears, and midline frontal bossing. There was an umbilical hernia and a sacral neural tube defect (meningocele).

18. CAUSE/CONDITIONS CONTRIBUTING TO FETAL DEATH		
CAUSE OF FETAL DEATH Mother's Name _____ Mother's Medical Record No. _____	18a. INITIATING CAUSE/CONDITION (AMONG THE CHOICES BELOW, PLEASE SELECT THE ONE WHICH MOST LIKELY BEGAN THE SEQUENCE OF EVENTS RESULTING IN THE DEATH OF THE FETUS)	18b. OTHER SIGNIFICANT CAUSES OR CONDITIONS (SELECT OR SPECIFY ALL OTHER CONDITIONS CONTRIBUTING TO DEATH IN ITEM 18a)
	Maternal Conditions/Diseases (Specify) _____ Complications of Placenta, Cord, or Membranes <input type="checkbox"/> Rupture of membranes prior to onset of labor <input type="checkbox"/> Abruptio placenta <input type="checkbox"/> Placental insufficiency <input type="checkbox"/> Prolapsed cord <input type="checkbox"/> Chorioamnionitis <input type="checkbox"/> Other (Specify) _____ Other Obstetrical or Pregnancy Complications (Specify) _____ Fetal Anomaly (Specify) <u>Probable chromosome anomaly-pending</u> <u>cytogenetics report</u> Fetal Injury (Specify) _____ Fetal Infection (Specify) _____ Other Fetal Conditions/Disorders (Specify) _____ <input type="checkbox"/> Unknown	Maternal Conditions/Diseases (Specify) _____ Complications of Placenta, Cord, or Membranes <input type="checkbox"/> Rupture of membranes prior to onset of labor <input type="checkbox"/> Abruptio placenta <input type="checkbox"/> Placental insufficiency <input type="checkbox"/> Prolapsed cord <input type="checkbox"/> Chorioamnionitis <input type="checkbox"/> Other (Specify) _____ Other Obstetrical or Pregnancy Complications (Specify) _____ Fetal Anomaly (Specify) <u>Multiple congenital anomaly syndrome</u> Fetal Injury (Specify) _____ Fetal Infection (Specify) _____ Other Fetal Conditions/Disorders (Specify) _____ <input type="checkbox"/> Unknown
18c. WEIGHT OF FETUS (grams preferred, specify unit) <u>900</u> <input checked="" type="checkbox"/> grams <input type="checkbox"/> lb/oz	18d. ESTIMATED TIME OF FETAL DEATH <input checked="" type="checkbox"/> Dead at time of first assessment, no labor ongoing <input type="checkbox"/> Dead at time of first assessment, labor ongoing <input type="checkbox"/> Died during labor, after first assessment <input type="checkbox"/> Unknown time of fetal death	18e. WAS AN AUTOPSY PERFORMED? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Planned 18f. WAS A HISTOLOGICAL PLACENTAL EXAMINATION PERFORMED? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Planned 18g. WERE AUTOPSY OR HISTOLOGICAL PLACENTAL EXAMINATION RESULTS USED IN DETERMINING THE CAUSE OF FETAL DEATH? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
18a. OBSTETRIC ESTIMATE OF GESTATION AT DELIVERY <u>28</u> (completed weeks)		

The external genitalia were ambiguous. There was syndactyly of toes two and three, and rockerbottom feet bilaterally. The fingers were short and edematous; there were no flexion creases on the palms of either hand.

Gross autopsy revealed internally that the genitalia were those of a normal male. The adrenals were small. There were several accessory spleens, partial malrotation of the gut, and an atrial septal defect. The placenta had trophoblastic cysts. Tissues (muscle and fetal membranes) were taken for future chromosome analysis.

Two weeks later a chromosome analysis report became available that provided a diagnosis of triploidy, karyotype XXY. A supplemental report of cause of fetal death was filed with the registrar of vital statistics.

CAUSE OF FETAL DEATH		18. CAUSE/CONDITIONS CONTRIBUTING TO FETAL DEATH		
		18a. INITIATING CAUSE/CONDITION (AMONG THE CHOICES BELOW, PLEASE SELECT THE ONE WHICH MOST LIKELY BEGAN THE SEQUENCE OF EVENTS RESULTING IN THE DEATH OF THE FETUS)	18b. OTHER SIGNIFICANT CAUSES OR CONDITIONS (SELECT OR SPECIFY ALL OTHER CONDITIONS CONTRIBUTING TO DEATH IN ITEM 18b)	
Mother's Name _____	Mother's Medical Record No. _____	Maternal Conditions/Diseases (Specify) _____	Maternal Conditions/Diseases (Specify) _____	
		Complications of Placenta, Cord, or Membranes <input type="checkbox"/> Rupture of membranes prior to onset of labor <input type="checkbox"/> Abruptio placenta <input type="checkbox"/> Placental insufficiency <input type="checkbox"/> Prolapsed cord <input type="checkbox"/> Chorioamnionitis <input type="checkbox"/> Other (Specify) _____	Complications of Placenta, Cord, or Membranes <input type="checkbox"/> Rupture of membranes prior to onset of labor <input type="checkbox"/> Abruptio placenta <input type="checkbox"/> Placental insufficiency <input type="checkbox"/> Prolapsed cord <input type="checkbox"/> Chorioamnionitis <input type="checkbox"/> Other (Specify) _____	
		Other Obstetrical or Pregnancy Complications (Specify) _____	Other Obstetrical or Pregnancy Complications (Specify) _____	
		Fetal Anomaly (Specify) <u>Triploidy syndrome XXY</u>	Fetal Anomaly (Specify) <u>Multiple congenital anomaly syndrome</u>	
	Fetal Injury (Specify) _____	Fetal Injury (Specify) _____		
	Fetal Infection (Specify) _____	Fetal Infection (Specify) _____		
	Other Fetal Conditions/Disorders (Specify) _____	Other Fetal Conditions/Disorders (Specify) _____		
	<input type="checkbox"/> Unknown	<input type="checkbox"/> Unknown		
	18c. WEIGHT OF FETUS (grams preferred, specify unit) <u>900</u> <input checked="" type="checkbox"/> grams <input type="checkbox"/> lb/oz	18e. ESTIMATED TIME OF FETAL DEATH <input checked="" type="checkbox"/> Dead at time of first assessment, no labor ongoing <input type="checkbox"/> Dead at time of first assessment, labor ongoing <input type="checkbox"/> Died during labor, after first assessment <input type="checkbox"/> Unknown time of fetal death	18f. WAS AN AUTOPSY PERFORMED? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Planned	
	18d. OBSTETRIC ESTIMATE OF GESTATION AT DELIVERY <u>28</u> (completed weeks)		18g. WAS A HISTOLOGICAL PLACENTAL EXAMINATION PERFORMED? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Planned	
			18h. WERE AUTOPSY OR HISTOLOGICAL PLACENTAL EXAMINATION RESULTS USED IN DETERMINING THE CAUSE OF FETAL DEATH? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Common problems in fetal death certification

Uncertainty

Often several acceptable ways of writing a cause-of-death statement exist. Optimally, a certifier will be able to provide a simple description of the initiating cause and other contributing causes that is etiologically clear and to be confident that this is correct. However, realistically, description of the process is sometimes difficult because the certifier is not certain.

In this case, the certifier should think through the causes about which he/she is confident and what possible etiologies could have resulted in these conditions. The certifier should select the causes that are suspected to have been involved and use words such as “probable” or “presumed” to indicate that the description provided is not completely certain. Causes of death on the fetal death report should not include terms such as “prematurity” without explaining the etiology because they have little value for public health or medical research.

Reporting a cause of fetal death as unknown should be a last resort.

When a number of conditions or multiple organ/system failure resulted in death, the physician, medical examiner, or coroner should choose a single condition which most likely began the sequence of events resulting in the fetal death and list the other conditions in 18b of the certification section. “Multiple system failure” could be included as an “other significant cause or condition,” but also specify the systems involved to ensure that the detailed information is captured. Maternal conditions may have initiated or affected the sequence that resulted in a fetal death. These maternal conditions should be reported in the cause-of-death statement in addition to the fetal causes.

Avoid ambiguity

Most certifiers will find themselves, at some point, unable to provide a simple description of the process of death. In this situation, the certifier should try to provide an initiating condition, qualify the causes about which he/she is uncertain, and be able to explain the certification chosen.

When conditions such as the following are reported, information about the etiology should be reported if possible:

Unknown	Low birthweight
Prematurity	Intrauterine hypoxia
Immaturity	

If the certifier is unable to determine the etiology of a process such as those shown above, the process must be qualified as being of an unknown, undetermined, probable, presumed, or unspecified etiology so it is clear that a distinct etiology was not inadvertently or carelessly omitted.

Mechanisms of death

Mechanistic terminal events such as respiratory failure preferably should not be the initiating cause in a cause-of-death statement. Please enter the condition that triggered the events resulting in this terminal event as the initiating cause.

Completing the Report of Fetal Death

These instructions pertain to the 2003 revision of the U.S. Standard Report of Fetal Death. Information for the U.S. Standard Report of Fetal Death is collected using worksheets (see [appendixes D and E](#)). Although the hospital usually completes the facility worksheet and the mother completes the patient's worksheet, under certain circumstances the medical examiner or coroner may be responsible for completing them (22). Therefore, instructions for completing all items on the worksheets are included; information on the worksheets subsequently is transferred to the report form.

FACILITY WORKSHEET

These instructions pertain to the 2003 revision of the U.S. Standard Report of Fetal Death. Information needed to complete the facility worksheet should come from the medical records. Please see the "Guide to Completing the Facility Worksheets for the Certificate of Live Birth and Report of Fetal Death" for more detailed instructions (21).

1. Facility name (If not institution, give street and number)

Type or print the name of the facility where the fetal death occurred. If this fetal death did not occur in a hospital or freestanding birthing center, type or print the street and number of the place where the fetal death occurred. If the fetal death occurred en route, (that is, in a moving conveyance), type or print the city, town, village, or location where the fetus was first removed from the conveyance. If the fetal death occurs in international airspace or waters, enter "plane" or "boat."

2. Facility I.D.

Print the facility's National Provider Identification Number (NPI) or, if no NPI, the State hospital code.

3. City, Town, or Location of delivery

Type or print the name of the city, township, village or other location where the fetal death occurred. If the fetal death occurred in international waters or airspace, enter the location where the fetus was first removed from the boat or plane.

4. County of delivery

Type or print the name of the county where the fetal death occurred. If the fetal death occurred in international waters or airspace, enter the name of the county where the fetus was first removed from the boat or plane.

5. Place of delivery

Check the box that best describes the type of place where the fetal death occurred. If the type of place is not known, type or print “unknown” in the space.

- Hospital
- Freestanding birthing center
- Home delivery
- Planned to deliver at home Yes No
- Clinic/Doctor’s Office
- Other (specify) _____

Items 1–5 identify the place of delivery, which is used to study relationships of hospital and nonhospital pregnancy terminations. It is also used by many States to produce statistical data by specific facility. Information on place of delivery, together with residence information, provides data to evaluate the utilization and distribution of health services.

6a. Date of first prenatal care visit (Prenatal care begins when a physician or other health professional first examines and/or counsels the pregnant woman as part of an ongoing program of care for the pregnancy)

Print or type the month, day, and year of the first prenatal care visit. Complete all parts of the date that are available; leave the rest blank.

If it is not known whether the patient had prenatal care, or if she had care but the date of the first visit is not known, write “unknown.”

If the patient had no prenatal care, check the “no prenatal care” box and leave the date blank.

This item identifies when during the pregnancy the patient entered prenatal care and is needed as the basis for measures of how soon patients initiate prenatal care and for measures of the appropriate utilization of services. This information is also used to study the impact of prenatal care on pregnancy outcome.

6b. Date of last prenatal care visit (Enter the date of the last visit recorded in the patient's prenatal records)

Print or type the month, day, and year of the last prenatal care visit recorded in the records. Complete all parts of the date that are available; leave the rest blank.

If it is not known whether the patient had prenatal care, or if she had care but the date of the last visit is not known, write "unknown."

If the patient had no prenatal care, check the "no prenatal care" box and leave the date blank.

7. Total number of prenatal care visits for this pregnancy (Count only those visits in the record. If none, enter "0.")

If the patient had no prenatal care, type or print "0" in the space. Note: the "no prenatal care" box should also be checked in items 6a and 6b.

If the patient had prenatal care but the number of visits is not known, type or print "unknown" in the space.

Type or print the total number of prenatal care visits for this pregnancy in this space.

This item is needed as the basis for measures of utilization of prenatal care services. It is also used in conjunction with "Date of First Prenatal Care Visit" to assess the adequacy of prenatal care.

8. Date last normal menses began

Print or type all parts of the date that the patient's last normal menses began.

If no parts of the date are known, write in "unknown."

This item provides information on the length of gestation, which can be associated with weight of fetus to determine the maturity of the fetus at delivery. It is also associated with infant morbidity and mortality, and is important in medical research.

9. Number previous live births now living (For multiple deliveries, includes live born infants born before this fetus in the multiple set)

When completing this item, do not include this fetal death; include all previous live-born infants. For multiple deliveries, include all live-born

infants preceding this fetal death in the delivery. If first delivered in a multiple delivery, do not include this fetus. If second delivered, include the first live born, etc.

Type or print the number of previous born infants still living in item 9.

The information in items 9–14 are essential for determining live-birth and total-birth order, which are important in studying trends in childbearing and child spacing. The information is useful in studying health problems associated with birth order. The dates of last live birth and last other pregnancy outcome permit the calculation of intervals between live births and fetal deaths and between pregnancies. This information allows researchers to analyze the relationship of various maternal characteristics and pregnancy outcomes with birth and pregnancy intervals.

10. Number of previous live births now dead (For multiple deliveries, includes live born infants born before this fetus in the multiple set who subsequently died)

When completing this item, do not include this fetal death but include all previous live-born infants who are now dead.

Please type or print the number of infants born alive but now dead in item 10.

11. Date of last live birth

If the date of delivery is not known, type or print “unknown” in the space.

12. Total number of other pregnancy outcomes (Include fetal losses of any gestational age—spontaneous losses, induced losses, and/or ectopic pregnancies. If this was a multiple delivery, include all fetal losses delivered before this fetus in the pregnancy.)

If there were none, check the “none” box. If the number is unknown, type or print “unknown” in the space.

13. Date of last other pregnancy outcome (Date when last pregnancy which did not result in a live birth ended)

If the date of the event is not known, type or print “unknown” in the space.

14. Risk factors in this pregnancy

The patient may have more than one risk factor; check all that apply. If the patient had none of the risk factors, check the “none of the above” box.

If it is unknown whether the patient had any of the risk factors, type or print unknown.

Diabetes - (Glucose intolerance requiring treatment)

Prepregnancy - (Diagnosis prior to this pregnancy)

Gestational - (Diagnosis in this pregnancy)

Hypertension - (Elevation of blood pressure above normal for age, gender, and physiological condition)

Prepregnancy (Chronic) - (Diagnosis prior to this pregnancy)

Gestational - (PIH, preeclampsia) (Diagnosis during this pregnancy)

Eclampsia - (Diagnosis during this pregnancy)

Previous preterm births - (History of pregnancy(ies) terminating in a live birth of less than 37 completed weeks of gestation)

Other previous poor pregnancy outcome - (Includes perinatal death, small for gestational age/intrauterine growth restricted birth) (History of pregnancies continuing into the 20th week of gestation and resulting in any of the listed outcomes. Perinatal death includes fetal and neonatal deaths.)

Pregnancy resulted from infertility treatment - (Any assisted reproduction treatment whether artificial insemination, drugs (e.g., Clomid, Pergonal) or technical procedures (e.g., in vitro fertilization) used to initiate the pregnancy)

Patient had a previous cesarean delivery - (Previous operative delivery by extraction of the fetus, placenta and membranes through an incision in the maternal abdominal and uterine walls)

If Yes, how many _____

None of the above

The risk factors contribute to the national data set and provide more specific information regarding fetal death events. For example, diabetes information is associated with macrosomia, cesarean delivery, metabolic abnormalities, and congenital anomalies. Management during pregnancy can reduce poor maternal and infant outcomes. Hypertension is associated with increased risk for preterm delivery, intrauterine growth restriction, maternal and perinatal morbidity and mortality. Vaginal bleeding during the pregnancy prior to the onset of labor is associated with increased risk for multiple adverse pregnancy outcomes. Pregnancy resulting from infertility treatment increases the incidence of multiple births.

15. Infections present and/or treated during this pregnancy (Present at start of pregnancy or confirmed diagnosis during pregnancy with or without documentation of treatment)

If the prenatal record is not available and the information is not available from other medical records, write “unknown” in the space. More than one infection may be checked.

- Gonorrhea - (a diagnosis of or positive test for *Neisseria gonorrhoeae*)
- Syphilis - (also called lues - a diagnosis of or positive test for *Treponema pallidum*)
- Chlamydia - (a diagnosis of or positive test for *Chlamydia trachomatis*)
- Listeria (LM) - (a diagnosis of or positive test for *Listeria monocytogenes*)
- Group B Streptococcus (GBS) - (a diagnosis of or positive test for *Streptococcus agalactiae* or group B streptococcus)
- Cytomegalovirus (CMV) - (a diagnosis of or positive test for *cytomegalovirus*)
- Parvo virus (B19) - (a diagnosis of or positive test for parvovirus B19)
- Toxoplasmosis (Toxo) - (a diagnosis of or positive test for *Toxoplasma gondii*)
- None of the above
- Other (specify) _____

All of the listed infections are known to cause concomitant fetal and/or subsequent neonatal infection and thus have significant public health implications. In addition, there is no current national reporting system for these infections that focuses on the prevalence of perinatal transmission.

16. Date of delivery

Print or type the month, day, and 4-digit year. Standard numeric abbreviations are acceptable.

This item is used in conjunction with the date the last normal menses began to calculate the length of gestation, which is an essential element in the study of low birth weight deliveries.

17. Time of delivery

Print or type the hour and minute of birth using a 24-hour clock. If the time of delivery is not known, enter “unknown” in the space. The time recorded should be the exact time when the delivery is complete.

This item documents the exact time of delivery for various legal uses, such as the order of delivery in plural deliveries. When the delivery occurs around

midnight, the exact hour and minute may affect the date of death. For deliveries occurring at the end of the year, the hour and minute affect not only the day but also the year of death.

18. Name and title of person completing report

This item is to be completed by the facility. If the delivery did not occur in a facility, it is to be completed by the attendant or certifier.

Please print or type the name of the person who attended the delivery and their National Provider Identification (NPI) number.

If the attendant does not have an NPI number, type or print “none.” If the attendant should have an NPI number but it is unknown, type or print “unknown.”

19. Date report completed

Print or type the month, day, and 4-digit year. Standard numeric abbreviations are acceptable.

20. Was the mother transferred to this facility for maternal medical or fetal indications for delivery? (Transfers include hospital to hospital, birth facility to hospital, etc.)

Check “Yes” if the patient was transferred from another facility to this one, and enter the name of the facility. If the name of the facility is not known, print or type “unknown.”

21. Attendant’s name, title, and NPI

The attendant at delivery is the individual physically present at the delivery who is responsible for the delivery. For example, if an intern or nurse-midwife delivers a fetus under the supervision of an obstetrician who is present in the delivery room, the obstetrician is to be reported as the attendant.

Please print or type the name of the person who attended the delivery and their NPI number.

If the attendant does not have an NPI number, type or print “none.” If the attendant should have an NPI number but it is unknown, type or print “unknown.”

Check one box to specify the attendant's title. If the "Other (Specify)" box is checked, please print or type the title of the attendant. Examples include: nurse, father, police officer, EMS technician, etc.

- M.D.
- D.O.
- CNM/CM - (Certified Nurse Midwife/Certified Midwife)
- Other Midwife - (Midwife other than CNM/CM)
- Other (specify) _____

22. Mother's weight at delivery

If the patient delivery weight is unknown, print or type "unknown" in the item's space.

Record weight in whole pounds only. Do not include fractions.

23a–e. METHOD OF DELIVERY (The physical process by which the complete delivery of the fetus was effected) (Complete 23a, b, c, d, and e)

A response to each section is required.

If any of the information for an individual section is not known at this time, print or type "unknown" in the space for that particular section.

23a. Was delivery with forceps attempted but unsuccessful? (Obstetric forceps were applied to the fetal head in an unsuccessful attempt at vaginal delivery.)

- Yes No

23b. Was delivery with vacuum extraction attempted but unsuccessful? (Ventouse or vacuum cup was applied to the fetal head in an unsuccessful attempt at vaginal delivery.)

- Yes No

23c. FETAL PRESENTATION AT DELIVERY (Check one)

- Cephalic - (Presenting part of the fetus as vertex, occiput anterior (OA), occiput posterior (OP))
- Breech - (Presenting part of the fetus as breech, complete breech, frank breech, footling breech)
- Other - (Any other presentation not listed above)

23d. Final route and method of delivery (Check one)

- Vaginal/Spontaneous - (Delivery of the entire fetus through the vagina by the natural force of labor with or without manual assistance from the delivery attendant.)
- Vaginal/Forceps -(Delivery of the fetal head through the vagina by application of obstetrical forceps to the fetal head.)
- Vaginal/Vacuum - (Delivery of the fetal head through the vagina by application of a vacuum cup or ventouse to the fetal head.)
- Cesarean - (Extraction of the fetus, placenta and membranes through an incision in the maternal abdominal and uterine walls.)
If cesarean, was a trial of labor attempted? (Labor was allowed, augmented or induced with plans for a vaginal delivery.)
 Yes No

23e. Hysterotomy/Hysterectomy

A hysterotomy is an incision into the uterus extending into the uterine cavity. It may be performed vaginally or transabdominally. A hysterotomy is applicable to fetal deaths only.

A hysterectomy is the surgical removal of the uterus, which may be performed abdominally or vaginally.

- Yes No

The data collected in items 23a–e provide information on current obstetric practices and outcomes. Attempted forceps/attempted vacuum data are needed to evaluate indications for cesarean delivery and for correlation with reported adverse neonatal outcomes. The final route and method of delivery portion will allow for a more complete report of the obstetric intervention used to effect delivery. Cesarean data are needed to evaluate the impact of the current emphasis on vaginal delivery in pregnancies subsequent to a cesarean delivery.

24. Maternal morbidity (Serious complications experienced by the patient associated with labor and delivery) (Check all that apply)

- Maternal transfusion - (Includes infusion of whole blood or packed red blood cells associated with labor and delivery.)
- Third or fourth degree perineal laceration - (3° laceration extends completely through the perineal skin, vaginal mucosa, perineal body and anal sphincter. 4° laceration is all of the above with extension through the rectal mucosa.)
- Ruptured uterus - (Tearing of the uterine wall.)
- Unplanned hysterectomy - (Surgical removal of the uterus that was not planned prior to admission. Includes anticipated but not definitively planned hysterectomy.)
- Admission to intensive care unit - (Any admission of the patient to a facility/unit designated as providing intensive care.)

- Unplanned operating room procedure following delivery - (Any transfer of the patient back to surgical area for an operative procedure that was not planned prior to admission for delivery. Excludes postpartum tubal ligations.)
- None of the above

This item has been added to the report because there is currently no national system of data collection on maternal morbidity and thus no easy mechanism for correlating pregnancy factors on a national basis. Several of the elements included are currently used as clinical quality indicators in various accreditation systems. Having a national database expands the information for assessing perinatal health care delivery systems. Third or fourth degree perineal laceration information may have implications for future problems with anal incontinence—especially for older patients. Ruptured uterus data may indicate whether there are increases in incidences related to vaginal birth after previous c-section. Unplanned hysterectomy, admission to intensive care unit, and unplanned procedure following delivery data are useful for quality assurance purposes.

25. Weight of fetus (Grams) (Do not convert lb/oz to grams)

Wherever possible, weigh and report the fetus' weight in grams. Report weight in pounds and ounces (lb/oz) only if weight in grams is not available. DO NOT convert weight from lb/oz to grams. Please specify whether grams or lb/oz are used.

If the birthweight is not known, print or type “unknown” in the space.

This is the single most important characteristic associated with the viability of the fetus. It is also related to prenatal care, marital status, socioeconomic status, and other factors associated with the delivery of the fetus. It is useful in evaluating the effectiveness of health care.

26. Obstetric estimate of gestation at delivery (Completed weeks)

Please enter the obstetric estimate of the fetus' gestation.

If the obstetric estimate of gestation is unknown, print or type “unknown” in the space. Do not complete this item based on the fetus' date of delivery and the patient's date of LMP.

This item is intended to provide an alternate estimate of gestational age when the date last normal menses began is missing or apparently incompatible with the weight of the fetus.

27. Sex

Print or type whether the fetus is male, female, or if the sex of the fetus is not yet determined. If the sex is unknown print or type “unknown” in the space.

This information is used to measure fetal and perinatal mortality by sex. This information helps identify differences in the impact of environmental and biological factors between the sexes.

28. Plurality

Print or type the plurality of this pregnancy (e.g., single, twin, triplet, etc.). Include all products of the pregnancy, that is, all live births and fetal deaths delivered at any point during the pregnancy. ("Reabsorbed" fetuses, those which are not "delivered"—expulsed or extracted from the patient—should not be counted.)

29. Set order (IF NOT SINGLE DELIVERY)

If this is a singleton delivery, leave this item blank. For multiple deliveries, print the order that this fetus was delivered in the set, e.g., first, second, third, etc. Count all live births and fetal deaths at any point in the pregnancy.

30. If not single delivery, specify number of fetal deaths in this delivery

If this is a singleton delivery, leave this item blank. For multiple deliveries, print or type the number of fetal deaths in this delivery.

The information from items 28–30 is used to study survival differences for multiple births based on order of delivery.

31. Congenital anomalies of the fetus (Malformations of the fetus diagnosed prenatally or after delivery) (Check all that apply)

Anomalies diagnosed should be recorded regardless of whether they contributed to fetal death.

- Anencephaly - (Partial or complete absence of the brain and skull. Also called anencephalus, acrania, or absent brain. Also includes fetuses with craniorachischisis (anencephaly with a contiguous spine defect).)
- Meningomyelocele/Spina bifida - (Spina bifida is herniation of the meninges and/or spinal cord tissue through a bony defect of spine closure. Meningomyelocele is herniation of meninges and spinal cord tissue. Meningocele (herniation of the meninges without spinal cord tissue) should also be included in this category. Both open and closed (covered with skin) lesions should be included. Do not include Spina bifida occulta (a midline bony spine defect without protrusion of the spinal cord or meninges).)
- Cyanotic congenital heart disease - (Congenital heart defects which cause cyanosis. Includes but is not limited to: transposition of the great arteries (vessels), tetralogy of Fallot, pulmonary or pulmonic valvular atresia, truncus arteriosus, total/partial anomalous pulmonary venous return with or without obstruction.)
- Congenital diaphragmatic hernia - (Defect in the formation of the diaphragm allowing herniation of abdominal organs into the thoracic cavity.)

- Omphalocele - (A defect in the anterior abdominal wall, accompanied by herniation of some abdominal organs through a widened umbilical ring into the umbilical stalk. The defect is covered by a membrane (different from gastroschisis, see below), although this sac may rupture. Also called exomphalos. Do not include umbilical hernia (completely covered by skin) in this category.)
- Gastroschisis - (An abnormality of the anterior abdominal wall, lateral to the umbilicus, resulting in herniation of the abdominal contents directly into the amniotic cavity. Differentiated from omphalocele by the location of the defect and absence of a protective membrane.)
- Limb reduction defect (excluding congenital amputation and dwarfing syndromes) - (Complete or partial absence of a portion of an extremity associated with failure to develop.)
- Cleft Lip with or without Cleft Palate - (Incomplete closure of the lip. May be unilateral, bilateral, or median.)
- Cleft Palate alone - (Incomplete fusion of the palatal shelves. May be limited to the soft palate or may extend into the hard palate. Cleft palate in the presence of cleft lip should be included in the "Cleft Lip with or without Cleft Palate" category above.)
- Downs Syndrome (Trisomy 21)
 - Karyotype confirmed
 - Karyotype pending
- Suspected chromosomal disorder - (Includes any constellation of congenital malformations resulting from or compatible with known syndromes caused by detectable defects in chromosome structure.)
 - Karyotype confirmed
 - Karyotype pending
- Hypospadias - (Incomplete closure of the male urethra resulting in the urethral meatus opening on the ventral surface of the penis. Includes first degree on the glans ventral to the tip, second degree in the coronal sulcus, and third degree on the penile shaft.)
- None of the anomalies listed above.

The items selected for this section will provide more specific information regarding fetal death events. Identifying the conditions and contributing causes of fetal death is necessary to understanding why they occur and may lead to possible prevention of fetal loss in the future.

32. Method of disposition

- Burial
- Cremation
- Hospital Disposition
- Donation
- Removal from State
- Other (Specify) _____

Check the box corresponding to the method of disposition of the fetus.

This information indicates whether the fetus was disposed of as required by law. It also serves to help locate the fetus in case exhumation, autopsy, or transfer is required later.

33–34. CAUSE OF FETAL DEATH

Detailed instructions for the cause of fetal death section, together with examples of properly completed records, are contained in the section on completing the cause of fetal death. These items are to be completed by the person whose name appears in item 21.

The cause-of-death section consists of two parts. The initiating cause/condition (item 33) is for reporting a single condition that most likely began the sequence of events resulting in the death of the fetus. Other significant causes or conditions (item 34) include all other conditions contributing to death. These conditions may be triggered by the initiating cause (item 33) or causes that are not among the sequence of events triggered by the initiating cause (item 33).

The cause-of-death information should be the certifier's best medical opinion. Report a specific condition in the space most appropriate to the given situation. A condition can be listed as "probable" if it has not been definitively diagnosed. In reporting the causes of fetal death, conditions in the fetus or mother, or of the placenta, cord, or membranes, should be reported if they are believed to have adversely affected the fetus.

Cause of fetal death should include information provided by the pathologist if an autopsy or other type of postmortem examination was done. If microscopic examinations for a fetal death are still pending at the time the report is filed, the medical examiner or coroner should report the additional information as soon as it is available.

This item provides medical information for ranking causes of fetal death and for analyzing the conditions leading to fetal death. Information on cause of fetal death is correlated with information from other items on the report, such as length of gestation and prenatal care.

35. Was an autopsy performed?

Enter "Yes" if a partial or complete autopsy was performed. Otherwise, enter "No."

An autopsy is important in giving additional insight into the conditions that led to death. This additional information is particularly important when the cause is not immediately clear.

36. Was a histological placental examination performed?

Enter “Yes” if any histological placental examination was performed. Otherwise, enter “No.”

A histological placental examination provides additional information about the conditions that led to death. This may provide insight into the appropriate causes of death to report.

37. Were autopsy or histological placental examination results used in determining the cause of fetal death?

If “No” is checked for both 35 and 36, leave 37 blank. If “Yes” is checked for either 35 or 36, complete item 37.

This information assists in determining whether information was available to assist in ascertaining the cause of death. Knowing whether the exam results were available gives insight into the quality of the cause-of-death data.

38. Estimated time of fetal death

Indicate when the fetus died by specifying one choice:

- Dead at time of first assessment, no labor ongoing
- Dead at time of first assessment, labor ongoing
- Died during labor, after first assessment
- Unknown time of fetal death

This item is used as a check to ensure that the delivery was properly reported as a fetal death and was not a live birth. It also gives information on care.

PATIENT'S WORKSHEET FOR THE REPORT OF FETAL DEATH

1. NAME OF INFANT/FETUS (OPTIONAL) First, Middle, Last, Suffix

2. CURRENT LEGAL NAME OF PATIENT

Type or print the first, middle, and last name of the patient. This is the patient's current legal name.

3. USUAL LOCATION OF PATIENT'S HOUSEHOLD/RESIDENCE

These items refer to the patient's residence address, not her postal address. Do not include post office boxes or rural route numbers.

If the patient is a U.S. resident, print the U.S. State or territory where the patient lives. If the patient is a U.S. resident, do not record "U.S."

If the patient is a Canadian resident, print the name of the province or territory followed by "/ Canada."

If the patient is not a resident of the United States, its territories, or Canada, print the name of the patient's country of residence.

Print the county, city or town or location where the patient lives. If the patient is not a U.S. resident, leave these items blank.

Print the patient's street name and number, apartment or room number, and ZIP Code. If the patient is not a U.S. resident, leave these items blank. For the street name, be sure to include any prefixes, directions, and apartment numbers.

Examples: South Main Street
 Walker Street NW

4. INSIDE CITY LIMITS?

Check whether the patient's residence is inside of city or town limits. If it is not known if the residence is inside the city limits, print "unknown."

If the patient is not a U.S. resident, leave this item blank.

5. PATIENT'S MAILING ADDRESS

This item refers to the patient's postal address. Be sure to include post office boxes or rural route numbers.

If the patient is a U.S. resident, print the U.S. State or territory where the patient gets her mail. If the address is in the United States, do not record "U.S."

If the patient is a Canadian resident, print the name of the province or territory followed by "/ Canada."

If the patient is not a resident of the United States, its territories, or Canada, print the name of the patient's country of residence.

Print the county, city or town, or location where the patient lives. If the patient is not a U.S. resident, leave these items blank.

Print the patient's street name and number, apartment or room number, and ZIP Code. If the patient is not a U.S. resident, leave these items blank.

For the street name, be sure to include any prefixes, directions, and apartment numbers.

Examples: South Main Street
 Walker Street NW

6. PATIENT'S BIRTHDATE

Print or type the month, day, and 4-digit year of birth. Standard numeric abbreviations are acceptable.

7. PATIENT'S BIRTHPLACE

Print or type the name of the U.S. State or territory in which the patient was born. If she was born outside of the United States, print or type the name of the country in which she was born. United States territories are Puerto Rico, U.S. Virgin Islands, Guam, American Samoa, and Northern Marianas. If the patient's birthplace is not known, print or type "unknown" in the space. (NOTE: Canadian provinces and territories are not individually identified for place of birth.)

8. PATIENT'S EDUCATION

Check the box that best describes the highest degree or level of schooling completed at the time of delivery. If no box is checked, write "unknown" in the space.

- 8th grade or less
- 9th–12th grade; no diploma
- High school graduate or GED completed
- Some college credit, but no degree
- Associate degree (eg., AA, AS)
- Bachelor's degree (eg., BA, AB, BS)
- Master's degree (eg., MA, MS, MEng, MEd, MSW, MBA)
- Doctorate (e.g., PhD, EdD) or Professional degree (e.g., MD, DDS, DVM, LLB, JD)

Education is highly related to fertility, health practices, and pregnancy outcome. It is also used as an indicator of socioeconomic status.

9. HISPANIC ORIGIN

Based on the patient's response, enter all the corresponding boxes and fill in any literal (written) responses on the worksheet. The patient is encouraged to select only one response. If the patient has chosen more than one response, check all that she has selected. For example, if both Mexican and Cuban are selected, check both responses. If the patient indicates an ethnic origin not on the list, record it in the "Specify" space. Enter the patient's response in this space even if it is not a Hispanic origin. If the patient did not respond, type or print "unknown." Check the "No" box if the patient is not Spanish/Hispanic/Latina.

- No, not Spanish/Hispanic/Latina
- Yes, Mexican, Mexican American, Chicana
- Yes, Puerto Rican
- Yes, Cuban
- Yes, Other Spanish/Hispanic/Latina (e.g., Spaniard, Salvadoran, Dominican, Columbian) (Specify) _____

Each question, Race and Hispanic origin, should be asked independently. "Hispanic" is not a race, and a decedent of Hispanic origin may be of any race. Do not leave item 9 blank. "Hispanic" is a self-designated classification for people whose origins are from Spain, the Spanish-speaking countries of Central or South America, the Caribbean, or those identifying themselves generally as Spanish or Spanish American. Origin can be viewed as ancestry, nationality, or country of birth of the person or person's parents or ancestors prior to their arrival in the United States. Although the prompts include the major Hispanic groups, other groups may be specified under "Other."

10. RACE

Based on the patient's response, select all the corresponding boxes on the worksheet and fill in any literal (written) responses exactly as given

regardless of whether or not any boxes are marked. If more than one response has been chosen, check all selected; for example, if both “Black” and “Chinese” are checked, select both responses. If there is no response, type or print “unknown.”

- White
- Black or African American
- American Indian or Alaskan Native
(name of enrolled or principal tribe) _____
- Asian Indian
- Chinese
- Filipino
- Japanese
- Korean
- Vietnamese
- Other Asian (specify) _____
- Native Hawaiian
- Guamanian or Chamorro
- Samoan
- Other Pacific Islander (specify) _____
- Other (specify) _____

Each question, Race and Hispanic origin, should be answered independently. Do not leave item 10 blank. If there is no box for the response, check the “Other” box, and enter the response even if it is not a race.

American Indian and Alaska Native refer only to those native to North and South America (including Central America) and does not include Asian Indian. Please specify the name of enrolled or principal tribe (e.g., Navajo, Cheyenne, etc.) for the American Indian or Alaska Native.

For Asians and Pacific Islanders, enter the national origin of the patient. For Asians check Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, or specify other Asian group; for Pacific Islanders check Native Hawaiian, Guamanian or Chamorro, Samoan, or specify Other Pacific Islander.

If more than one race is indicated, enter each race (e.g., Samoan-Chinese-Filipino or White, American Indian).

11. PATIENT EVER MARRIED?

- Yes
- No

12. PATIENT’S NAME PRIOR TO FIRST MARRIAGE

First, Middle, Last, Suffix

13. WAS PATIENT MARRIED DURING PREGNANCY?

- Yes
- No

If the patient is currently married or married at time of conception or any time between conception and the fetal death, check the “Yes” box.

If the patient is not currently married or was not married at the time of conception or any time between conception and the fetal death, check the “No” box.

The information on marital status in items 11–13 is used to monitor the substantial differences in fertility patterns and pregnancy outcomes for married and unmarried women. This information can help to identify the need for additional supportive public health and other services.

14. LEGAL NAME OF BABY’S FATHER

First, Middle, Last, Suffix

15. FATHER’S DATE OF BIRTH

Print or type the month, day, and 4-digit year of birth.

If the father’s Date of Birth is unknown, print “unknown.” If part of the Date of Birth is unknown, enter the known parts and leave the remaining parts blank.

16. FATHER’S BIRTHPLACE

Print or type the name of the U.S. State or territory in which the father was born. If he was born outside of the United States, print or type the name of the country in which he was born. U.S. territories are Puerto Rico, U.S. Virgin Islands, Guam, American Samoa, and Northern Marianas. If the father’s birthplace is not known, print or type “unknown” in the space. (NOTE: Canadian provinces and territories are not individually identified for his place of birth.)

17. DID PATIENT RECEIVE WIC (WOMEN, INFANTS and CHILDREN) FOOD FOR HERSELF DURING THIS PREGNANCY?

This item is to be completed based on information obtained from the patient. Either the “Yes” or “No” box must be checked.

If the patient's worksheet indicates "unknown," print or type "unknown."

This item was added as an indicator of program participation as well as socioeconomic status. WIC is the nutrition program for Women, Infants, and Children and gives pregnant women and/or their children food, checks, or vouchers for food.

18. PATIENT'S HEIGHT

Enter the patient's height in feet and inches. If the record indicates height in fractions such as 5 feet 6 and one-half inches, truncate and enter 5 feet, 6 inches.

If the patient's height is unknown, print or type "unknown" in the space.

19. PATIENT'S PREPREGNANCY WEIGHT

If the patient's prepregnancy weight is unknown, print or type "unknown" in the item's space.

Record weight in whole pounds only; do not include fractions.

20. CIGARETTE SMOKING BEFORE AND DURING PREGNANCY

This item is to be completed by the facility based on information obtained from the patient. If the delivery did not occur in a facility, it is to be completed by the attendant or certifier based on information obtained from the patient.

If the patient's worksheet indicates "unknown" or "refused," print or type "unknown." Enter either the average number of cigarettes or the average number of packs of cigarettes smoked for each time period. If none, enter "0."

	# of cigarettes		# of packs
3 months before pregnancy	_____	OR	_____
first 3 months of pregnancy	_____	OR	_____
second 3 months of pregnancy	_____	OR	_____
last 3 months of pregnancy	_____	OR	_____

This item provides information on changes in tobacco use before and during pregnancy, which has an important impact on pregnancy outcome.

Any use of trade names in this handbook is for identification purposes only and does not imply endorsement by the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics.

References

1. National Center for Health Statistics. Model State vital statistics act and regulations: 1992 revision. Hyattsville, Maryland: Public Health Service. 1995.
2. Pates RD, Scully KW, Einbinder JS, et al. Adding value to clinical data by linkage to a public death registry. Medinfo 2001. London, 2001.
3. National Center for Health Statistics. Report of the panel to evaluate the U.S. standard certificates. Hyattsville, Maryland: Public Health Service. 2000. (Addenda, 2001).
4. Hetzel AM. History and organization of the vital statistics system. Hyattsville, Maryland: National Center for Health Statistics. 1997.
5. Hanzlick R, ed. The medical cause of death manual. Northfield, Illinois: College of American Pathologists. 1994.
6. World Health Organization. International statistical classification of diseases and related health problems, tenth revision. Geneva: World Health Organization. 1992.
7. Hanzlick R, ed. Cause-of-Death statements and certification of natural and unnatural deaths. Northfield, Illinois: College of American Pathologists. 1997.
8. Hoyert D. The autopsy, medicine, and mortality statistics. National Center for Health Statistics. Vital Health Stat 3(32). 2001.
9. Hanzlick R, Hunsaker JH III, Davis GJ. A guide for manner of death classification. St. Louis, Missouri: National Association of Medical Examiners. 2002. <http://www.thename.org/Library/MannerRev.pdf>. Jan 6, 2003.
10. Rosenberg ML, Davidson LE, Smith JC, et al. Operational criteria for the determination of suicide. J Forensic Sci 33(6):1445-56. 1988.
11. Donohue ER, Lifschultz BD. Letter to editor: Discussion of operational criteria for the determination of suicide. J Forensic Sci 34(5):1056-8. 1989.
12. U.S. National Committee on Vital and Health Statistics. Medical certification of medicolegal cases. Washington: Public Health Service. 1960.
13. American Academy of Pediatrics, Committee on Child Abuse and Neglect and Committee on Community Health Services. Investigation and review of unexpected infant and child deaths. Pediatrics. 104(5):1158-60. 1999. <http://www.aap.org/policy/re9921.html>. May 15, 2002.
14. National Center for Health Statistics. Instructions for completing the cause-of-death section of the death certificate. Hyattsville, Maryland: National Center for Health Statistics. <http://www.cdc.gov/nchs/data/dvs/cod.pdf>. Jan 6, 2003.

15. National Center for Health Statistics. Instructions for completing the cause-of-death section of the death certificate for injury and poisoning. Hyattsville, Maryland: National Center for Health Statistics. <http://www.cdc.gov/nchs/data/dvs/inj.pdf>. Jan 6, 2003.
16. National Center for Health Statistics. Possible solutions to common problems in death certification. Hyattsville, Maryland: National Center for Health Statistics. <http://www.cdc.gov/nchs/about/major/dvs/brief.htm>. Jan 6, 2003.
17. Hanzlick R. Writing cause-of-death statements. St. Louis, Missouri: National Association of Medical Examiners. http://www.thename.org/CauseDeath/COD_main_page.htm. Jan 9, 2003.
18. Texas Department of Health. Online CME medical certification of cause and manual of death. http://www.tdh.state.tx.us/phpep/cme/cme_dc/default.html. Apr 20, 2002.
19. National Center for Health Statistics. Cause-of-death module. Hyattsville, Maryland: National Center for Health Statistics. <http://www.cdc.gov/nchs/data/dvs/edc6.pdf>. Apr 20, 2002.
20. National Center for Health Statistics. Mortality Web Page. Hyattsville, Maryland: National Center for Health Statistics. <http://www.cdc.gov/nchs/about/major/dvs/mortdata.htm>. Apr 20, 2002.
21. National Center for Health Statistics. Guidelines for reporting occupation and industry on death certificates. Hyattsville, Maryland: National Center for Health Statistics. http://www.cdc.gov/nchs/data/misc/hb_occup.pdf. Jan 3, 2003.
22. National Center for Health Statistics. Guide to completing facility worksheet for live birth/fetal death. Hyattsville, Maryland: Public Health Service. <http://www.cdc.gov/nchs/data/dvs/GuidetoCompleteFacilityWks.pdf>. Jan 6, 2003.

Appendixes

A.	U.S. Standard Certificate of Death	107
B.	Education Category Selection Card	109
C.	Race and Hispanic Origin Category Selection Cards	110
D.	The U.S. Standard Report of Fetal Death	111
E.	Definitions of Live Birth and Fetal Death	113
F.	Facility Worksheet for the Report of Fetal Death	114
G.	Patient's Worksheet for the Report of Fetal Death	122
H.	The Vital Statistics Registration System in the United States ..	127

Appendix A

U.S. Standard Certificate of Death

U.S. STANDARD CERTIFICATE OF DEATH

LOCAL FILE NO.				STATE FILE NO.			
1. DECEDENT'S LEGAL NAME (Include AKA's if any) (First, Middle, Last) John Leonard Palmer				2. SEX Male		3. SOCIAL SECURITY NUMBER 123-45-6789	
4a. AGE-Last Birthday (Years) 92		4b. UNDER 1 YEAR Months: Days: Hours: Minutes:		5. DATE OF BIRTH (Mo/Day/Yr) April 23, 1911		6. BIRTHPLACE (City and State or Foreign Country) San Francisco, CA	
7a. RESIDENCE-STATE Maryland		7b. COUNTY Frederick		7c. CITY OR TOWN Thurmont			
7d. STREET AND NUMBER 245 Lone View Road				7e. APT. NO.		7f. ZIP CODE 20212-1234	
7g. INSIDE CITY LIMITS? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No							
8. EVER IN US ARMED FORCES? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		9. MARITAL STATUS AT TIME OF DEATH <input checked="" type="checkbox"/> Married <input type="checkbox"/> Married, but separated <input type="checkbox"/> Widowed <input type="checkbox"/> Divorced <input type="checkbox"/> Never Married <input type="checkbox"/> Unknown		10. SURVIVING SPOUSE'S NAME (If wife, give name prior to first marriage) Sheila Marie Sonner			
11. FATHER'S NAME (First, Middle, Last) Stanley Leonard Palmer				12. MOTHER'S NAME PRIOR TO FIRST MARRIAGE (First, Middle, Last) Lorraine Ellen Russell			
13a. INFORMANT'S NAME Sheila Marie Palmer		13b. RELATIONSHIP TO DECEDENT Wife		13c. MAILING ADDRESS (Street and Number, City, State, Zip Code) 245 Lone View Road, Thurmont, MD 20212-1234			
14. PLACE OF DEATH (Check only one; see instructions) <input checked="" type="checkbox"/> Inpatient <input type="checkbox"/> Emergency Room/Outpatient <input type="checkbox"/> Dead on Arrival <input type="checkbox"/> Hospice facility <input type="checkbox"/> Nursing home/Long term care facility <input type="checkbox"/> Decedent's home <input type="checkbox"/> Other (Specify): Mountain Memorial Hospital				15. FACILITY NAME (If not institution, give street & number) Frederick			
16. CITY OR TOWN, STATE, AND ZIP CODE Frederick		17. COUNTY OF DEATH Frederick					
18. METHOD OF DISPOSITION: <input checked="" type="checkbox"/> Burial <input type="checkbox"/> Cremation <input type="checkbox"/> Donation <input type="checkbox"/> Entombment <input type="checkbox"/> Removal from State <input type="checkbox"/> Other (Specify):				19. PLACE OF DISPOSITION (Name of cemetery, crematory, other place) Wesley Memorial Cemetery			
20. LOCATION-CITY, TOWN, AND STATE Frederick				21. NAME AND COMPLETE ADDRESS OF FUNERAL FACILITY Boone and Sons Funeral Home, 475 E. Main Street, Frederick, Maryland 20216-3456			
22. SIGNATURE OF FUNERAL SERVICE LICENSEE OR OTHER AGENT Robert J. Boone				23. LICENSE NUMBER (Of Licensee) 2569114			
24. DATE PRONOUNCED DEAD (Mo/Day/Yr) June 20, 2003				25. TIME PRONOUNCED DEAD 0310			
26. SIGNATURE OF PERSON PRONOUNCING DEATH (Only when applicable) Julia R. Kovar, M.D.				27. LICENSE NUMBER 624998075		28. DATE SIGNED (Mo/Day/Yr) June 20, 2003	
29. ACTUAL OR PRESUMED DATE OF DEATH (Mo/Day/Yr) (Spell Month) June 20, 2003		30. ACTUAL OR PRESUMED TIME OF DEATH 0300		31. WAS MEDICAL EXAMINER OR CORONER CONTACTED? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
32. CAUSE OF DEATH (See instructions and examples) PART I. Enter the chain of events—diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary. IMMEDIATE CAUSE (Final disease or condition resulting in death) a. <u>Pulmonary embolism</u> Due to (or as a consequence of): Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST b. <u>Congestive heart failure</u> Due to (or as a consequence of): c. <u>Acute myocardial infarction</u> Due to (or as a consequence of): d. <u>Chronic ischemic heart disease</u> Approximate interval: Onset to death Minutes: _____ 4 days: _____ 7 days: _____ 8 years: _____							
33. WAS AN AUTOPSY PERFORMED? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No				34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
35. DID TOBACCO USE CONTRIBUTE TO DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> Probably <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown		36. IF FEMALE: <input type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year		37. MANNER OF DEATH <input checked="" type="checkbox"/> Natural <input type="checkbox"/> Homicide <input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined			
38. DATE OF INJURY (Mo/Day/Yr) (Spell Month)		39. TIME OF INJURY		40. PLACE OF INJURY (e.g., Decedent's home, construction site, restaurant, wooded area)		41. INJURY AT WORK? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
42. LOCATION OF INJURY: State: _____ City or Town: _____ Apartment No.: _____ Zip Code: _____							
43. DESCRIBE HOW INJURY OCCURRED:				44. IF TRANSPORTATION INJURY, SPECIFY: <input type="checkbox"/> Driver/Operator <input type="checkbox"/> Passenger <input type="checkbox"/> Pedestrian <input type="checkbox"/> Other (Specify):			
45. CERTIFIER (Check only one): <input checked="" type="checkbox"/> Certifying physician: To the best of my knowledge, death occurred due to the cause(s) and manner stated. <input type="checkbox"/> Postmortem & certifying physician: To the best of my knowledge, death occurred at the time, date, and place, and due to the cause(s) and manner stated. <input type="checkbox"/> Medical Examiner/Coroner: On the basis of examination, autopsy investigation, or my opinion, death occurred at the time, date, and place, and due to the cause(s) and manner stated. Signature of certifier: <u>Edward M. Stone, M.D.</u>							
46. NAME, ADDRESS, AND ZIP CODE OF PERSON COMPLETING CAUSE OF DEATH (Form 30) Edward Matthew Stone, M.D., 23 Porter Drive, Frederick, Maryland 29885-6789							

For use by physician or institution

To Be Completed/Verified By:
FUNERAL DIRECTOR

To Be Completed By:
MEDICAL CERTIFIER

	47. TITLE OF CERTIFIER M.D.	48. LICENSE NUMBER 1299654	49. DATE CERTIFIED (Mo/Day/Yr) June 22, 2003	50. FOR REGISTRAR ONLY- DATE FILED (Mo/Day/Yr) June 23, 2003
To Be Completed By: FUNERAL DIRECTOR	51. DECEDENT'S EDUCATION-Check the box that best describes the highest degree or level of school completed at the time of death.			
	<input type="checkbox"/> 8th grade or less <input type="checkbox"/> 9th - 12th grade; no diploma <input type="checkbox"/> High school graduate or GED completed <input type="checkbox"/> Some college credit, but no degree <input type="checkbox"/> Associate degree (e.g., AA, AS) <input checked="" type="checkbox"/> Bachelor's degree (e.g., BA, AB, BS) <input type="checkbox"/> Master's degree (e.g., MA, MS, MEng, MEd, MSW, MBA) <input type="checkbox"/> Doctorate (e.g., PhD, EdD) or Professional degree (e.g., MD, DDS, DVM, LLB, JD)			
		52. DECEDENT OF HISPANIC ORIGIN? Check the box that best describes whether the decedent is Spanish/Hispanic/Latino. Check the "No" box if decedent is not Spanish/Hispanic/Latino.		53. DECEDENT'S RACE (Check one or more races to indicate what the decedent considered himself or herself to be)
		<input checked="" type="checkbox"/> No, not Spanish/Hispanic/Latino <input type="checkbox"/> Yes, Mexican, Mexican American, Chicano <input type="checkbox"/> Yes, Puerto Rican <input type="checkbox"/> Yes, Cuban <input type="checkbox"/> Yes, other Spanish/Hispanic/Latino (Specify) _____		<input checked="" type="checkbox"/> White <input type="checkbox"/> Black or African American <input checked="" type="checkbox"/> American Indian or Alaska Native (Name of the enrolled or principal tribe) <u>Cherokee</u> <input type="checkbox"/> Asian Indian <input type="checkbox"/> Chinese <input type="checkbox"/> Filipino <input type="checkbox"/> Japanese <input type="checkbox"/> Korean <input type="checkbox"/> Vietnamese <input type="checkbox"/> Other Asian (Specify) _____ <input type="checkbox"/> Native Hawaiian <input type="checkbox"/> Guamanian or Chamorro <input type="checkbox"/> Samoan <input type="checkbox"/> Other Pacific Islander (Specify) _____ <input type="checkbox"/> Other (Specify) _____
54. DECEDENT'S USUAL OCCUPATION (Indicate type of work done during most of working life. DO NOT USE RETIRED).				
Public accountant				
55. KIND OF BUSINESS/INDUSTRY				
Self-employed				

Appendix B

Decedent's Educational Level Selection Card

Decedent's Formal Education Level

What was the highest degree or level of school the decedent COMPLETED? Choose only ONE. If the decedent is currently enrolled, mark the previous grade or highest degree received.

- A.** 8th grade or less
- B.** 9th–12th grade; no diploma
- C.** High School Graduate or GED completed
- D.** Some college credit, but no degree
- E.** Associate Degree (e.g., AA, AS)
- F.** Bachelor's Degree (e.g., BA, AB, BS)
- G.** Master's Degree (e.g., MA, MS, MEng, MEd, MSW, MBA)
- H.** Doctorate (e.g., PhD, EdD) or Professional degree (e.g., MD, DDS, DVM, LLB, JD)

Appendix C

Race and Hispanic Origin Selection Cards

Decedent's Hispanic Origin Selection Card

Please review all the responses below. Please pick the response that best describes whether the decedent is Spanish/Hispanic/Latino. Choose the NO response if the decedent is not Spanish/Hispanic/Latino.

- A.** No, Not Spanish/Hispanic/Latino
- B.** Yes, Mexican, Mexican American, Chicano
- C.** Yes, Puerto Rican
- D.** Yes, Cuban
- E.** Yes, Other Spanish/Hispanic/Latino

If your choice is E. (Other Spanish/Hispanic/Latino) please specify.

Decedent's Race(s) Selection Card

Decedent's Race(s)

Which item(s) below best describe what race(s) the decedent considered himself/herself to be? Select all that apply.

- A.** White
- B.** Black or African American
- C.** American Indian or Alaska Native
(Name of the enrolled or principal tribe)
- D.** Asian Indian
- E.** Chinese
- F.** Filipino
- G.** Japanese
- H.** Korean
- I.** Vietnamese
- J.** Other Asian—(Specify) _____
- K.** Native Hawaiian
- L.** Guamanian or Chamorro
- M.** Samoan
- N.** Other Pacific Islander—(Specify) _____
- O.** Other—(Specify) _____

Appendix D

U.S. Standard Report of Fetal Death

U.S. STANDARD REPORT OF FETAL DEATH

LOCAL FILE NO.		STATE FILE NUMBER			
MOTHER		1. NAME OF FETUS (optional-at the discretion of the parents)	2. TIME OF DELIVERY 0725 (24hr)	3. SEX (M/F/A/unk) Male	4. DATE OF DELIVERY (Mo/Day/Yr) December 31, 2003
5a. CITY, TOWN, OR LOCATION OF DELIVERY El Paso	7. PLACE WHERE DELIVERY OCCURRED (Check one) <input checked="" type="checkbox"/> Hospital <input type="checkbox"/> Freestanding birthing center <input type="checkbox"/> Home Delivery: Planned to deliver at home? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Clinic/Doctor's office <input type="checkbox"/> Other (Specify)	8. FACILITY NAME (if not institution, give street and number) Amsterdam Hospital			
5b. ZIP CODE OF DELIVERY 49205-3633	6. COUNTY OF DELIVERY El Paso		9. FACILITY ID. (NPI)		
10a. MOTHER'S CURRENT LEGAL NAME (First, Middle, Last, Suffix) Carmen Marie Ravoldo		10b. DATE OF BIRTH (Mo/Day/Yr) July 26, 1980			
10c. MOTHER'S NAME PRIOR TO FIRST MARRIAGE (First, Middle, Last, Suffix) Carmen Marie Sanchez		10d. BIRTHPLACE (State, Territory, or Foreign Country) New York City			
11a. RESIDENCE OF MOTHER-STATE Texas	11b. COUNTY El Paso	11c. CITY, TOWN, OR LOCATION El Paso			
11d. STREET AND NUMBER 2277 Gunpowder Drive	11e. APT. NO. 315	11f. ZIP CODE 49205-3630	11g. INSIDE CITY LIMITS? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
FATHER		12a. FATHER'S CURRENT LEGAL NAME (First, Middle, Last, Suffix) Jose Manuel Ravoldo	12b. DATE OF BIRTH (Mo/Day/Yr) September 9, 1974	12c. BIRTHPLACE (State, Territory, or Foreign Country) Texas	
13. METHOD OF DISPOSITION: <input checked="" type="checkbox"/> Burial <input type="checkbox"/> Cremation <input type="checkbox"/> Hospital Disposition <input type="checkbox"/> Donation <input type="checkbox"/> Removal from State <input type="checkbox"/> Other (Specify)					
ATTENDANT AND REGISTRATION INFORMATION		14. ATTENDANT'S NAME, TITLE, AND NPI NAME: Edmund Matthew Stone, M.D. NPI: TITLE: <input checked="" type="checkbox"/> MD <input type="checkbox"/> DO <input type="checkbox"/> CNM/CM <input type="checkbox"/> OTHER MIDWIFE <input type="checkbox"/> OTHER (Specify)	15. NAME AND TITLE OF PERSON COMPLETING REPORT Name: Julia Lynn Gonzalez Title: ART	16. DATE REPORT COMPLETED 12 / 31 / 2003 MM / DD / YYYY	17. DATE RECEIVED BY REGISTRAR 01 / 01 / 2004 MM / DD / YYYY
18. CAUSE/CONDITIONS CONTRIBUTING TO FETAL DEATH					
18a. INITIATING CAUSE/CONDITION (AMONG THE CHOICES BELOW, PLEASE SELECT THE ONE WHICH MOST LIKELY BEGAN THE SEQUENCE OF EVENTS RESULTING IN THE DEATH OF THE FETUS) Maternal Conditions/Diseases (Specify) <u>Severe pre-eclampsia</u>			18b. OTHER SIGNIFICANT CAUSES OR CONDITIONS (SELECT OR SPECIFY ALL OTHER CONDITIONS CONTRIBUTING TO DEATH IN ITEM 18a) Maternal Conditions/Diseases (Specify)		
Complications of Placenta, Cord, or Membranes <input type="checkbox"/> Rupture of membranes prior to onset of labor <input type="checkbox"/> Abruptio placentae <input type="checkbox"/> Placental insufficiency <input type="checkbox"/> Prolapsed cord <input type="checkbox"/> Chorioamnionitis <input type="checkbox"/> Other (Specify)			Complications of Placenta, Cord, or Membranes <input type="checkbox"/> Rupture of membranes prior to onset of labor <input checked="" type="checkbox"/> Abruptio placentae <input type="checkbox"/> Placental insufficiency <input type="checkbox"/> Prolapsed cord <input type="checkbox"/> Chorioamnionitis <input type="checkbox"/> Other (Specify)		
Other Obstetrical or Pregnancy Complications (Specify)			Other Obstetrical or Pregnancy Complications (Specify)		
Fetal Anomaly (Specify)			Fetal Anomaly (Specify)		
Fetal Injury (Specify)			Fetal Injury (Specify)		
Fetal Infection (Specify)			Fetal Infection (Specify)		
Other Fetal Conditions/Disorders (Specify)			Other Fetal Conditions/Disorders (Specify) <u>Intrauterine anoxia</u>		
<input type="checkbox"/> Unknown			<input type="checkbox"/> Unknown		
18c. WEIGHT OF FETUS (grams preferred, specify unit) <u>400</u> <input checked="" type="checkbox"/> grams <input type="checkbox"/> lb/oz		18e. ESTIMATED TIME OF FETAL DEATH <input type="checkbox"/> Dead at time of first assessment, no labor ongoing <input type="checkbox"/> Dead at time of first assessment, labor ongoing <input checked="" type="checkbox"/> Died during labor, after first assessment <input type="checkbox"/> Unknown time of fetal death		18f. WAS AN AUTOPSY PERFORMED? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Planned	
18d. OBSTETRIC ESTIMATE OF GESTATION AT DELIVERY <u>24</u> (completed weeks)				18g. WAS A HISTOLOGICAL PLACENTAL EXAMINATION PERFORMED? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Planned	
				18h. WERE AUTOPSY OR HISTOLOGICAL PLACENTAL EXAMINATION RESULTS USED IN DETERMINING THE CAUSE OF FETAL DEATH? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Mother's Name
 Mother's Medical Record No.

DRAFT 03/11/2003

Mother	19. MOTHER'S EDUCATION (Check the box that best describes the highest degree or level of school completed at the time of delivery)			20. MOTHER OF HISPANIC ORIGIN? (Check the box that best describes whether the mother is Spanish/Hispanic/Latina. Check the "No" box if mother is not Spanish/Hispanic/Latina)			21. MOTHER'S RACE (Check one or more races to indicate what the mother considers herself to be)							
	<input type="checkbox"/> 8th grade or less <input type="checkbox"/> 9th - 12th grade, no diploma <input checked="" type="checkbox"/> High school graduate or GED completed <input type="checkbox"/> Some college credit but no degree <input type="checkbox"/> Associate degree (e.g., AA, AS) <input type="checkbox"/> Bachelor's degree (e.g., BA, AB, BS) <input type="checkbox"/> Master's degree (e.g., MA, MS, MEd, MEd, MSW, MBA) <input type="checkbox"/> Doctorate (e.g., PhD, EdD) or Professional degree (e.g., MD, DDS, DVM, LLB, JD)			<input type="checkbox"/> No, not Spanish/Hispanic/Latina <input type="checkbox"/> Yes, Mexican, Mexican American, Chicana <input checked="" type="checkbox"/> Yes, Puerto Rican <input type="checkbox"/> Yes, Cuban <input type="checkbox"/> Yes, other Spanish/Hispanic/Latina (Specify) _____			<input checked="" type="checkbox"/> White <input type="checkbox"/> Black or African American <input type="checkbox"/> American Indian or Alaska Native (Name of the enrolled or principal tribe) _____ <input type="checkbox"/> Asian Indian <input type="checkbox"/> Chinese <input type="checkbox"/> Filipino <input type="checkbox"/> Japanese <input type="checkbox"/> Korean <input type="checkbox"/> Vietnamese <input type="checkbox"/> Other Asian (Specify) _____ <input type="checkbox"/> Native Hawaiian <input type="checkbox"/> Guamanian or Chamorro <input type="checkbox"/> Samoan <input type="checkbox"/> Other Pacific Islander (Specify) _____ <input type="checkbox"/> Other (Specify) _____							
22. MOTHER MARRIED? (At delivery, conception, or anytime between) <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			23a. DATE OF FIRST PRENATAL CARE VISIT (At delivery, conception, or anytime between) <input type="checkbox"/> No Prenatal Care MM / DD / YYYY			23b. DATE OF LAST PRENATAL CARE VISIT MM / DD / YYYY			24. TOTAL NUMBER OF PRENATAL VISITS FOR THIS PREGNANCY ____ 5 ____ (If none, enter "0")					
25. MOTHER'S HEIGHT ____ 5 foot 3 inches ____ (feet/inches)			26. MOTHER'S PREPREGNANCY WEIGHT ____ 120 ____ (pounds)			27. MOTHER'S WEIGHT AT DELIVERY ____ 133 ____ (pounds)			28. DID MOTHER GET WIC FOOD FOR HERSELF DURING THIS PREGNANCY? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No					
29. NUMBER OF PREVIOUS LIVE BIRTHS			30. NUMBER OF OTHER PREGNANCY OUTCOMES (spontaneous or induced losses or ectopic pregnancies)			31. CIGARETTE SMOKING BEFORE AND DURING PREGNANCY For each time period, enter either the number of cigarettes or the number of packs of cigarettes smoked. IF NONE, ENTER "0". Average number of cigarettes or packs of cigarettes smoked per day.								
29a. Now Living Number ____ 1 ____ <input type="checkbox"/> None			29b. Now Dead Number ____ <input checked="" type="checkbox"/> None			30a. Other Outcomes Number (Do not include this fetus) ____ <input checked="" type="checkbox"/> None			# of cigarettes # of packs Three Months Before Pregnancy OR ____ 1 ____ First Three Months of Pregnancy OR ____ 1 ____ Second Three Months of Pregnancy OR ____ 18 ____ Last Three Months of Pregnancy OR ____ 1 ____					
29c. DATE OF LAST LIVE BIRTH ____ 12 / ____ / 2000 MM YY YY			30b. DATE OF LAST OTHER PREGNANCY OUTCOME ____ / ____ / ____ MM YY YY			32. DATE LAST NORMAL MENSES BEGAN ____ 07 / 21 / ____ 2003 M M D D Y Y Y Y			33. PLURALITY - Single, Twin, Triplet, etc. (Specify) ____ Single ____			34. IF NOT SINGLE BIRTH - Born First, Second, Third, etc. (Specify) _____		
35. MOTHER TRANSFERRED FOR MATERNAL MEDICAL OR FETAL INDICATIONS FOR DELIVERY? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No														
Medical and Health Information	36. RISK FACTORS IN THIS PREGNANCY (Check all that apply):						37. INFECTIONS PRESENT AND/OR TREATED DURING THIS PREGNANCY (Check all that apply)							
	<input type="checkbox"/> Diabetes <input type="checkbox"/> Prepregnancy (Diagnosis prior to this pregnancy) <input type="checkbox"/> Gestational (Diagnosis in this pregnancy) <input type="checkbox"/> Hypertension <input type="checkbox"/> Prepregnancy (Chronic) <input checked="" type="checkbox"/> Gestational (PIH, preeclampsia, eclampsia) <input type="checkbox"/> Previous preterm birth <input type="checkbox"/> Other previous poor pregnancy outcome (Includes perinatal death, small-for-gestational age/ intrauterine growth restricted birth) <input checked="" type="checkbox"/> Vaginal bleeding during this pregnancy prior to the onset of labor <input type="checkbox"/> Pregnancy resulted from infertility treatment <input type="checkbox"/> Mother had a previous cesarean delivery If yes, how many ____ <input type="checkbox"/> None of the above						<input type="checkbox"/> Gonorrhea <input type="checkbox"/> Syphilis <input type="checkbox"/> Herpes Simplex Virus (HSV) <input type="checkbox"/> Chlamydia <input type="checkbox"/> Listeria <input type="checkbox"/> Group B Streptococcus <input type="checkbox"/> Cytomegalovirus <input type="checkbox"/> Parvo virus <input type="checkbox"/> Toxoplasmosis <input type="checkbox"/> None of the above <input type="checkbox"/> Other (Specify) _____							
Mother's Name Mother's Medical Record No.			38. METHOD OF DELIVERY			39. MATERNAL MORBIDITY (Check all that apply) (Complications associated with labor and delivery)			40. CONGENITAL ANOMALIES OF THE FETUS (Check all that apply)					
			A. Was delivery with forceps attempted but unsuccessful? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No B. Was delivery with vacuum extraction attempted but unsuccessful? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No C. Fetal presentation at delivery <input checked="" type="checkbox"/> Cephalic <input type="checkbox"/> Breech <input type="checkbox"/> Other D. Final route and method of delivery (Check one) <input checked="" type="checkbox"/> Vaginal/Spontaneous <input type="checkbox"/> Vaginal/Forceps <input type="checkbox"/> Vaginal/Vacuum <input type="checkbox"/> Cesarean If cesarean, was a trial of labor attempted? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No E. Hysterectomy/Hysterectomy <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			<input checked="" type="checkbox"/> Maternal transfusion <input type="checkbox"/> Third or fourth degree perineal laceration <input type="checkbox"/> Ruptured uterus <input type="checkbox"/> Unplanned hysterectomy <input type="checkbox"/> Admission to intensive care unit <input type="checkbox"/> Unplanned operating room procedure following delivery <input type="checkbox"/> None of the above			<input type="checkbox"/> Anencephaly <input type="checkbox"/> Meningocele/Spina bifida <input type="checkbox"/> Cyanotic congenital heart disease <input type="checkbox"/> Congenital diaphragmatic hernia <input type="checkbox"/> Omphalocele <input type="checkbox"/> Gastroschisis <input checked="" type="checkbox"/> Limb reduction defect (excluding congenital amputation and dwarfing syndromes) <input type="checkbox"/> Cleft Lip with or without Cleft Palate <input type="checkbox"/> Cleft Palate alone <input type="checkbox"/> Down Syndrome <input type="checkbox"/> Karyotype confirmed <input type="checkbox"/> Karyotype pending <input type="checkbox"/> Suspected chromosomal disorder <input type="checkbox"/> Karyotype confirmed <input type="checkbox"/> Karyotype pending <input type="checkbox"/> Hypospadias <input type="checkbox"/> None of the anomalies listed above					

Appendix E

Definitions of Live Birth and Fetal Death

The following definitions come from the 1992 model law¹ and are based upon World Health Organization definitions and are recommended for use in the United States.

Live birth

Live birth means the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy, which, after such expulsion or extraction, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. Heartbeats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps.

Important—If an infant breathes or shows any other evidence of life after complete delivery, even though it may be only momentary, the birth must be registered as a live birth and a death certificate must also be filed.

Fetal death

Fetal death means death prior to the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy and which is not an induced termination of pregnancy. The death is indicated by the fact that after such expulsion or extraction, the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles. Heartbeats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps.

Important—The States differ with respect to the minimum period of gestation for which a fetal death report is required to be reported. If the medical examiner or coroner has any questions about the requirements used in his or her State, he or she should contact the State office of vital statistics.

1. National Center for Health Statistics. Model State vital statistics act and regulations: 1992 revision. Hyattsville, Maryland: Public Health Service. 1995.

Appendix F

Facility Worksheet for the Report of Fetal Death

Patient's medical record # _____
Patient's name _____

DRAFT (2/6/02)

FACILITY WORKSHEET FOR THE REPORT OF FETAL DEATH

Complete this worksheet for pregnancies resulting in fetal death. The Model State Vital Statistics Act and Regulations recommend the following definition of fetal death. "Fetal death" means death prior to the complete expulsion or extraction from its mother of a production of human conception, irrespective of the duration of the pregnancy and which is not an induced termination of pregnancy. The death is indicated by the fact that after such expulsion or extraction, the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles. Heart beats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps. For detailed definitions, instructions, information on sources, and common key words and abbreviations for many of the items included in the worksheet please see "The Guide to Completing Facility Worksheets for the Certificate of Live Birth."

1. Facility name:* _____
(If not institution, give street and number)
2. Facility I.D. (National Provider Identifier): _____
3. City, Town or Location of delivery: _____ Zip code: _____
4. County of delivery: _____
5. Place of delivery:
 - Hospital
 - Freestanding birthing center (Freestanding birthing center is defined as one which has no direct physical connection with an operative delivery center.)
 - Home delivery
Planned to deliver at home Yes No
 - Clinic/Doctor's Office
 - Other (specify, e.g., taxi cab, train, plane, etc.) _____

*Facilities may wish to have pre-set responses (hard-copy and/or electronic) to questions 1-5 for deaths which occur at their institutions.

Prenatal

Sources: Prenatal care records, patient's medical records, labor and delivery records

Information for the following items should come from the patient's prenatal care records and from other medical reports in the patient's chart. If the patient's prenatal care record is not in her hospital chart, please contact her prenatal care provider to obtain the record, or a copy of the prenatal care information. Preferred and acceptable sources are given before each section. Please do not provide information from sources other than those listed.

6(a). Date of first prenatal care visit (Prenatal care begins when a physician or other health professional first examines and/or counsels the pregnant woman as part of an ongoing program of care for the pregnancy):

____M____M____D____D____Y____Y____Y____Y____

No prenatal care (The mother did not receive prenatal care at any time during the pregnancy. If this box is checked skip 6(b))

6(b). Date of last prenatal care visit (Enter the date of the last visit recorded in the mother's prenatal records):

____M____M____D____D____Y____Y____Y____Y____

7. Total number of prenatal care visits for this pregnancy (Count only those visits recorded in the record.

If none enter "0"): _____

8. Date last normal menses began:

____M____M____D____D____Y____Y____Y____Y____

9. Number of previous live births now living (For multiple deliveries, includes live born infants born before this fetus in the multiple set.):

____ Number None

10. Number of previous live births now dead (For multiple deliveries, includes live born infants born before this fetus in the multiple set who subsequently died):

____ Number None

11. Date of last live birth:

____M____M____Y____Y____Y____Y____

12. Total number of other pregnancy outcomes (Include fetal losses of any gestational age- spontaneous losses, induced losses, and/or ectopic pregnancies. If this was a multiple delivery, include all fetal losses delivered before this fetus in the pregnancy):

____ Number None

13. Date of last other pregnancy outcome (Date when last pregnancy which did not result in a live birth ended):

____M____M____Y____Y____Y____Y____

14. Risk factors in this pregnancy (Check all that apply):

Diabetes - (Glucose intolerance requiring treatment)

- Prepregnancy - (Diagnosis prior to this pregnancy)
 Gestational - (Diagnosis in this pregnancy)

Hypertension - (Elevation of blood pressure above normal for age, gender, and physiological condition.)

- Prepregnancy - (Chronic) (Diagnosis prior to this pregnancy)
 Gestational - (PIH, preeclampsia, eclampsia) (Diagnosis during this pregnancy)

Previous preterm births - (History of pregnancy(ies) terminating in a live birth of less than 37 completed weeks of gestation)

Other previous poor pregnancy outcome - (Includes perinatal death, small for gestational age/intrauterine growth restricted birth) - (History of pregnancies continuing into the 20th week of gestation and resulting in any of the listed outcomes. Perinatal death includes fetal and neonatal deaths.)

Vaginal bleeding during this pregnancy prior to the onset of labor - (Any vaginal bleeding occurring any time in the pregnancy prior to the onset of labor.)

Pregnancy resulted from infertility treatment - (Any assisted reproduction treatment whether artificial insemination, drugs (e.g., Clomid, Pergonal) or technical procedures (e.g., in-vitro fertilization) used to initiate the pregnancy.)

- Patient had a previous cesarean delivery - (Previous operative delivery by extraction of the fetus, placenta and membranes through an incision in the maternal abdominal and uterine walls.)
If Yes, how many _____
- None of the above

15. Infections present and/or treated during this pregnancy - (Present at start of pregnancy or confirmed diagnosis during pregnancy with or without documentation of treatment.) (Check all that apply):

- Gonorrhea - (a diagnosis of or positive test for *Neisseria gonorrhoeae*)
- Syphilis - (also called lues - a diagnosis of or positive test for *Treponema pallidum*)
- Herpes Simplex Virus (HSV) - (a diagnosis of or positive test for the herpes simplex virus)
- Chlamydia - (a diagnosis of or positive test for *Chlamydia trachomatis*)
- Listeria (LM) - (a diagnosis of or positive test for *Listeria monocytogenes*)
- Group B Streptococcus (GBS) - (a diagnosis of or positive test for *Streptococcus agalactiae* or group B streptococcus)
- Cytomegalovirus (CMV) - (a diagnosis of or positive test for the *cytomegalovirus*)
- Parvovirus (B19) - (a diagnosis of or positive test for parvovirus B19)
- Toxoplasmosis (Toxo) - (a diagnosis of or positive test for *Toxoplasma gondii*)
- None of the above
- Other (specify) _____

Labor and Delivery

Sources: Labor and delivery records, patient's medical records

16. Date of delivery:
 M M D D Y Y Y Y

17. Time of delivery: _____ 24 hour clock

18. Name and title of person completing report:

(May be, but need not be, the same as the attendant at delivery.)

Name: _____

Title: _____

19. Date report completed:
 M M D D Y Y Y Y

20. Was the mother transferred to this facility for maternal medical or fetal indications for delivery?

(Transfers include hospital to hospital, birth facility to hospital, etc.)

- Yes No

If Yes, enter the name of the facility mother transferred from:

21. Attendant's name, title, and N.P.I. (National Provider Identifier) (The attendant at delivery is the individual physically present at the delivery who is responsible for the delivery. For example, if an intern or nurse-midwife delivers a fetus under the supervision of an obstetrician who is present in the delivery room, the obstetrician is to be reported as the attendant):

Attendant's name

N.P.I.

Attendant's title:

- M.D.
 D.O.
 CNM/CM - (Certified Nurse Midwife/Certified Midwife)
 Other Midwife - (Midwife other than CNM/CM)
 Other specify): _____

22. Mother's weight at delivery (pounds): _____

23. Method of delivery (The physical process by which the complete delivery was effected)
(Complete A, B, C, D, and E):

- A. Was delivery with forceps attempted but unsuccessful? - (Obstetric forceps was applied to the fetal head in an unsuccessful attempt at vaginal delivery.)
 Yes No
- B. Was delivery with vacuum extraction attempted but unsuccessful? - (Ventouse or vacuum cup was applied to the fetal head in an unsuccessful attempt at vaginal delivery.)
 Yes No
- C. Fetal presentation at delivery (Check one):
 Cephalic - (Presenting part of the fetus listed as vertex, occiput anterior (OA), occiput posterior (OP))
 Breech - (Presenting part of the fetus listed as breech, complete breech, frank breech, footling breech)
 Other - (Any other presentation not listed above)
- D. Final route and method of delivery (Check one):
 Vaginal/Spontaneous - (Delivery of the entire fetus through the vagina by the natural force of labor with or without manual assistance from the delivery attendant)
 Vaginal/Forceps - (Delivery of the fetal head through the vagina by application of obstetrical forceps to the fetal head.)
 Vaginal/Vacuum - (Delivery of the fetal head through the vagina by application of a vacuum cup or ventouse to the fetal head.)
 Cesarean - (Extraction of the fetus, placenta and membranes through an incision in the maternal abdominal and uterine walls)
- If cesarean, was a trial of labor attempted? - (Labor was allowed, augmented or induced with plans for a vaginal delivery.)
 Yes No
- E. Hysterotomy/Hysterectomy
 Yes No

24. Maternal morbidity (Serious complications experienced by the patient associated with labor and delivery)
(Check all that apply):

- Maternal transfusion - (Includes infusion of whole blood or packed red blood cells associated with labor and delivery.)
- Third or fourth degree perineal laceration - (3° laceration extends completely through the perineal skin, vaginal mucosa, perineal body and anal sphincter. 4° laceration is all of the above with extension through the rectal mucosa.)
- Ruptured uterus - (Tearing of the uterine wall.)
- Unplanned hysterectomy - (Surgical removal of the uterus that was not planned prior to the admission. Includes anticipated but not definitively planned hysterectomy.)
- Admission to intensive care unit - (Any admission of the mother to a facility/unit designated as providing intensive care.)
- Unplanned operating room procedure following delivery - (Any transfer of the patient back to a surgical area for an operative procedure that was not planned prior to the admission for delivery. Excludes postpartum tubal ligations.)
- None of the above

25. Weight of fetus: _____(grams) (Do not convert lb/oz to grams)
If weight in grams is not available, weight of fetus: _____(lb/oz)

26. Obstetric estimate of gestation at delivery (completed weeks): _____
(The delivery attendant's final estimate of gestation based on all perinatal factors and assessments. Do not compute based on date of the last menstrual period and the date of delivery.)

27. Sex (Male, Female, or Unknown): _____

28. Plurality (Specify 1 (single), 2 (twin), 3 (triplet), 4 (quadruplet), 5 (quintuplet), 6 (sextuplet), 7 (septuplet), etc.)
(Include all live births and fetal losses resulting from this pregnancy.): _____

29. If not single delivery (Order delivered in the pregnancy, specify 1st, 2nd, 3rd, 4th, 5th, 6th, 7th, etc.) (Include all live births and fetal losses resulting from this pregnancy): _____

30. If not single delivery, specify number of fetal deaths in this delivery: _____

31. Congenital anomalies of the fetus (Malformations of the fetus diagnosed prenatally or after delivery.)
(Check all that apply):

- Anencephaly - (Partial or complete absence of the brain and skull. Also called anencephalus, acrania, or absent brain. Also includes fetuses with craniorachischisis (anencephaly with a contiguous spine defect).)
- Meningomyelocele/Spina bifida - (Spina bifida is herniation of the meninges and/or spinal cord tissue through a bony defect of spine closure. Meningomyelocele is herniation of meninges and spinal cord tissue. Meningocele (herniation of meninges without spinal cord tissue) should also be included in this category. Both open and closed (covered with skin) lesions should be included. Do not include Spina bifida occulta (a midline bony spinal defect without protrusion of the spinal cord or meninges).)
- Cyanotic congenital heart disease - (Congenital heart defects which cause cyanosis. Includes but is not limited to: transposition of the great arteries (vessels), tetralogy of Fallot, pulmonary or pulmonic valvular atresia, tricuspid atresia, truncus arteriosus, total/partial anomalous pulmonary venous return with or without obstruction.)
- Congenital diaphragmatic hernia - (Defect in the formation of the diaphragm allowing herniation of abdominal organs into the thoracic cavity.)
- Omphalocele - (A defect in the anterior abdominal wall, accompanied by herniation of some abdominal organs through a widened umbilical ring into the umbilical stalk. The defect is covered by a membrane (different from gastroschisis, see below), although this sac may rupture. Also called exomphalos. Do not include umbilical hernia (completely covered by skin) in this category.)
- Gastroschisis - (An abnormality of the anterior abdominal wall, lateral to the umbilicus, resulting in herniation of the abdominal contents directly into the amniotic cavity. Differentiated from omphalocele by the location of the defect and absence of a protective membrane.)
- Limb reduction defect (excluding congenital amputation and dwarfing syndromes) - (Complete or partial absence of a portion of an extremity associated with failure to develop.)

- Cleft Lip with or without Cleft Palate - (Incomplete closure of the lip. May be unilateral, bilateral or median.)
- Cleft Palate alone - (Incomplete fusion of the palatal shelves. May be limited to the soft palate or may extend into the hard palate. Cleft palate in the presence of cleft lip should be included in the "Cleft Lip with or without Cleft Palate" category above.)
- Down Syndrome - (Trisomy 21)
 - Karyotype confirmed
 - Karyotype pending
- Suspected chromosomal disorder - (Includes any constellation of congenital malformations resulting from or compatible with known syndromes caused by detectable defects in chromosome structure.)
 - Karyotype confirmed
 - Karyotype pending
- Hypospadias - (Incomplete closure of the male urethra resulting in the urethral meatus opening on the ventral surface of the penis. Includes first degree - on the glans ventral to the tip, second degree - in the coronal sulcus, and third degree - on the penile shaft.)
- None of the anomalies listed above

32. Method of Disposition

- Burial
- Cremation
- Hospital Disposition
- Donation
- Removal from State
- Other (Specify) _____

Cause-of-Death Section

Causes/Conditions Contributing to Fetal Death

Previous questions collected details on anomalies, morbidities, and risk factors known to be present for this patient and the fetus. The purpose of the next section is to get a description of those conditions that, in your opinion, **contributed** to the fetal death. Please report any condition judged to be a cause of death even if it has been reported elsewhere on the worksheet.

33. Initiating Cause/Condition

Among the choices below, please select the **ONE** which most likely began the sequence of events resulting in the death of the fetus. If it is not clear to you where to report a condition, write it on the "(Specify)" line that seems most appropriate.

Maternal Conditions/Diseases (Specify) _____
Complications of Placenta, Cord or Membranes
<input type="checkbox"/> Rupture of membranes prior to onset of labor
<input type="checkbox"/> Abruptio placenta
<input type="checkbox"/> Placental insufficiency
<input type="checkbox"/> Prolapsed cord
<input type="checkbox"/> Chorioamnionitis
<input type="checkbox"/> Other (Specify) _____
Other Obstetrical or Pregnancy Complications (Specify) _____
Fetal Anomaly (Specify) _____
Fetal Injury (Specify) _____
Fetal Infection (Specify) _____
Other Fetal Conditions/Disorders (Specify) _____
<input type="checkbox"/> Unknown

34. Other Significant Causes or Conditions

Select or Specify All Other Conditions Contributing to Death in Item 34.

Maternal Conditions/Diseases (Specify) _____
Complications of Placenta, Cord or Membranes <input type="checkbox"/> Rupture of membranes prior to onset of labor <input type="checkbox"/> Abruptio placenta <input type="checkbox"/> Placental insufficiency <input type="checkbox"/> Prolapsed cord <input type="checkbox"/> Chorioamnionitis <input type="checkbox"/> Other (Specify) _____
Other Obstetrical or Pregnancy Complications (Specify) _____
Fetal Anomaly (Specify) _____
Fetal Injury (Specify) _____
Fetal Infection (Specify) _____
Other Fetal Conditions/Disorders (Specify) _____
<input type="checkbox"/> Unknown

35. Was an autopsy performed?

- Yes No Planned

36. Was a histological placental examination performed?

- Yes No Planned

37. Were autopsy or histological placental examination results used in determining the cause of fetal death?

- Yes No

38. Estimated time of fetal death

- Dead at time of first assessment, no labor ongoing
 Dead at time of first assessment, labor ongoing
 Died during labor, after first assessment
 Unknown time of fetal death

Appendix G

Patient's Worksheet for the Report of Fetal Death

Patient's Medical Record # _____	
FOR HOSPITAL USE ONLY	
DRAFT (2/6/02)	Patient's Name _____

Patient's Worksheet for the Report of Fetal Death

We are truly sorry about the loss you have experienced. We understand that this is a difficult time for you and your loved ones. We need to ask you a few questions to assist in the completion of the official report of fetal death. State laws provide protection against the unauthorized release of identifying information from the report of fetal death to ensure confidentiality of the parents. This information may also help researchers understand some of the factors that are related to miscarriage and stillbirth. Your assistance in providing complete and accurate information is very important. We appreciate your help, especially during this very difficult time.

PLEASE PRINT CLEARLY

1. Would you like to name the child? This is entirely optional.

First Middle Last Suffix (Jr, III, etc.)

2. What is your current legal name?

First Middle Last Suffix (Jr, III, etc.)

3. Where do you usually live—that is—where is your household/residence located?

Complete number and street: _____ Apartment Number: _____
(Do not enter rural route numbers)

City, Town, or Location: _____

County: _____ State: _____

Zip Code: _____ (or U.S. Territory, Canadian Province)

If not United States, *country* _____

4. Is this household inside city limits (inside the incorporated limits of the city, town, or location where you live)?

Yes

No

Don't know

Patient's Name _____

5. What is your mailing address?

Same as residence [Go to next question]

Complete number and street: _____

Apartment Number: _____ P. O. Box: _____

City, Town, or Location: _____

State: _____ Zip Code: _____

(or U.S. Territory, Canadian Province)

If not in the United States, *country* _____

6. What is your date of birth? (Example: 3 - 4 - 1977)

Month Day Year

7. In what State, U.S. territory, or foreign country were you born?

Please specify one of the following:

State _____

or

U.S. territory, i.e., Puerto Rico, U.S. Virgin Islands, Guam, American Samoa or Northern Marianas

or

Foreign country _____

8. What is the highest level of schooling that you have completed at the time of delivery? (Check the box that best describes your education. If you are currently enrolled, check the box that indicates the previous grade or highest degree received).

- 8th grade or less
- 9th - 12th grade, no diploma
- High school graduate or GED completed
- Some college credit, but no degree
- Associate degree (e.g. AA, AS)
- Bachelor's degree (e.g. BA, AB, BS)
- Master's degree (e.g. MA, MS, MEng, MEd, MSW, MBA)
- Doctorate (e.g. PhD, EdD) or Professional degree (e.g. MD, DDS, DVM, LLB, JD)

Patient's Name _____

9. Are you Spanish/Hispanic/Latina? If not Spanish/Hispanic/Latina, check the "No" box. If Spanish/Hispanic/Latina, check the appropriate box.

- No, not Spanish/Hispanic/Latina
- Yes, Mexican, Mexican American, Chicana
- Yes, Puerto Rican
- Yes, Cuban
- Yes, other Spanish/Hispanic/Latina (e.g. Spaniard, Salvadoran, Dominican, Columbian)(specify) _____

10. What is your race? (Please check one or more races to indicate what you consider yourself to be).

- White
- Black or African American
- American Indian or Alaska Native (name of enrolled or principal tribe) _____
- Asian Indian
- Chinese
- Filipino
- Japanese
- Korean
- Vietnamese
- Other Asian (specify) _____
- Native Hawaiian
- Guamanian or Chamorro
- Samoan
- Other Pacific Islander (specify) _____
- Other (specify) _____

11. Have you ever been married?

- Yes [Please go to question 12]
- No [Please go to question 14]

12. What name did you use prior to your first marriage?

First Middle Last Suffix(Jr., III, etc.)

Patient's Name

13. Were you married at the time you conceived this child, at the time of delivery, or at any time between conception and delivery?

- Yes
- No

14. What is the current legal name of your baby's father?

First Middle Last Suffix(Jr., III, etc.)

15. What is the father's date of birth? (Example: 3 - 4 - 1976)

Month Day Year

- Don't know

16. In what State, U.S. territory, or foreign country was the father born?
Please specify one of the following:

State _____

or

U.S. territory, i.e., Puerto Rico, U.S. Virgin Islands, Guam, American Samoa or Northern Marianas

or

Foreign country _____

17. Did you receive WIC (Women, Infants & Children) food for yourself during this pregnancy?

- No
- Yes
- Don't know

Patient Name _____

18. What is your height?

_____ feet _____ inches

19. What was your prepregnancy weight, that is, your weight immediately before you became pregnant with this child?

_____ lbs

14. How many cigarettes OR packs of cigarettes did you smoke on an average day during each of the following time periods? If you NEVER smoked, enter zero for each time period.

	# of cigarettes	OR	# of packs
Three months before pregnancy	_____	OR	_____
First three months of pregnancy	_____	OR	_____
Second three months of pregnancy	_____	OR	_____
Last three months of pregnancy	_____	OR	_____

Thank you for completing this worksheet at this very difficult time. The information you have provided is very important; it will be used by researchers to better understand factors related to miscarriage and stillbirth and lead to improved prevention strategies for the future.

Appendix H

The Vital Statistics Registration System in the United States

The registration of births, deaths, fetal deaths, and other vital events in the United States is a State and local function¹. The civil laws of every State provide for a continuous, permanent, and compulsory vital registration system. Each system depends to a very great extent upon the conscientious efforts of the physicians, hospital personnel, funeral directors, coroners, and medical examiners in preparing or certifying information needed to complete the original records. For a graphic presentation of the registration system, see the accompanying chart, "The Vital Statistics Registration System in the United States."

Most States are divided geographically into local registration districts or units to facilitate the collection of vital records. A district may be a township, village, town, city, county, or other geographic area or a combination of two or more of these areas. In some States, however, the law provides that records of birth, death, and/or fetal death be sent directly from the reporting source (hospital, physician, or funeral director) to the State vital statistics office. In this system, functions normally performed by a local registration official are assumed by the staff of the State office.

In States with a local registrar system, the local registrar collects the records of events occurring in his or her area and transmits them to the State vital statistics office. The local registrar is required to see that a complete certificate is filed for each event occurring in that district. In many States this official also has the duty of issuing burial-transit permits to authorize the disposition of dead human bodies. In many States this official is also required to keep a file of all events occurring within his or her district and, if authorized by State law and subject to the restrictions on issuance of copies as specified by the law, may be permitted to issue copies of these records.

The State vital statistics office inspects each record for promptness of filing, completeness, and accuracy of information; queries for missing or

¹Vital events are defined as live births, deaths, fetal deaths, marriages, divorces, and induced terminations of pregnancy, together with any change in civil status that may occur during an individual's lifetime.

inconsistent information; numbers the records; prepares indexes; processes the records; and stores the documents for permanent reference and safe-keeping. Statistical information from the records is tabulated for use by State and local health departments, other governmental agencies, and various private and voluntary organizations. The data are used to evaluate health problems and to plan programs and services for the public. An important function of the State office is to issue certified copies of the certificates to individuals in need of such records and to verify the facts of birth and death for agencies requiring legal evidence of such facts.

The Centers for Disease Control and Prevention's National Center for Health Statistics (NCHS) is vested with the authority for administering the vital statistics functions at the national level². Electronic data files derived from individual records registered in the State offices or, in a few cases, copies of the individual records themselves are transmitted to NCHS. From these data, monthly, annual, and special statistical reports are prepared for the United States as a whole and for the component parts—cities, counties, States, and regions—by various characteristics such as sex, race, and cause of death. These statistics are essential in the fields of social welfare, public health, and demography. They are also used for various administrative purposes, in both business and government. NCHS serves as a focal point, exercising leadership in establishing uniform practices through model laws, standard certificate forms, handbooks, and other instructional materials for the continued improvement of the vital statistics system in the United States.

²Hetzel AM. History and organization of the vital statistics system. Hyattsville, Maryland: National Center for Health Statistics. 1997.

The Vital Statistics Registration System in the United States

<i>Responsible Person or Agency</i>	<i>Birth Certificate</i>	<i>Death Certificate</i>	<i>Fetal Death Report</i>
Hospital authority	<ol style="list-style-type: none"> 1. Completes entire certificate using mother and facility worksheets. 2. Files certificate with local office or State office per State law. 	<p>When death occurs in hospital, may initiate preparation of certificate: Completes information on name, date, and place of death; obtains certification of cause of death from physician; and gives certificate to funeral director.</p> <p>NOTE: If the attending physician is unavailable to certify to the cause of death, some States allow a hospital physician to certify to only the fact and time of death. With legal pronouncement of the death and permission of the attending physician, the body can then be released to the funeral director. The attending physician still must complete the cause-of-death section prior to final disposition of the body.</p>	<ol style="list-style-type: none"> 1. Completes entire report using patient and facility worksheets. 2. Obtains cause of fetal death from physician. 3. Obtains authorization for final disposition of fetus. 4. Files report with local office or State office per State law.
Funeral director		<ol style="list-style-type: none"> 1. Obtains personal facts about decedent and completes certificate. 2. Obtains certification of cause of death from attending physician or medical examiner or coroner. 3. Obtains authorization for final disposition per State law. 4. Files certificate with local office or State office per State law. 	<p>If fetus is to be buried, the funeral director is responsible for obtaining authorization for final disposition.</p> <p>NOTE: In some States, the funeral director, or person acting as such, is responsible for all duties shown under hospital authority.</p>
Physician or other professional attendant	For inhospital birth, verifies accuracy of medical information and signs certificate. For out-of-hospital birth, duties are same as those for hospital authority, shown above.	Completes certification of cause of death and signs certificate.	Provides cause of fetal death and information not available from the medical records.

Local office* (may be local registrar or city or county health department)	<ol style="list-style-type: none"> 1. Verifies completeness and accuracy of certificate and queries incomplete or inconsistent certificates. 2. If authorized by State law, makes copy or index for local use. 3. Sends certificates to State registrar. 	<ol style="list-style-type: none"> 1. Verifies completeness and accuracy of certificate and queries incomplete or inconsistent certificates. 2. If authorized by State law, makes copy or index for local use. 3. If authorized by State law, issues authorization for final disposition on receipt of completed certificate. 4. Sends certificates to State registrar. 	If State law requires routing of fetal death reports through local office, performs the same functions as shown for the birth and death certificate.
City and county health departments	<ol style="list-style-type: none"> 1. Use data derived from these records in allocating medical and nursing services. 2. Follow up on infectious diseases. 3. Plan programs. 4. Measure effectiveness of services. 5. Conduct research studies. 		
State registrar, office of vital statistics	<ol style="list-style-type: none"> 1. Queries incomplete or inconsistent information. 2. Maintains files for permanent reference and is the source of certified copies. 3. Develops vital statistics for use in planning, evaluating, and administering State and local health activities and for research studies. 4. Compiles health-related statistics for State and civil divisions of State for use of the health department and other agencies and groups interested in the fields of medical science, public health, demography, and social welfare. 5. Sends data for all events filed to the National Center for Health Statistics. 		
Centers for Disease Control and Prevention, National Center for Health Statistics	<ol style="list-style-type: none"> 1. Evaluates quality of State vital statistics data and works with States to assure quality. 2. Compiles national statistical data file and runs edits to fully process data. 3. Prepares and publishes national statistics of births, deaths, and fetal deaths; constructs the official U.S. life tables and related actuarial tables. 4. Conducts health and social research studies based on vital records and on sampling surveys linked to records. 5. Conducts research and methodological studies in vital statistics methods, including the technical, administrative, and legal aspects of vital records registration and administration. 6. Maintains a continuing technical assistance program to improve the quality and usefulness of vital statistics. 7. Provides leadership and coordination in the development of standard certificates and report and model laws. 		

* Some States do not have local vital registration offices. In these States, the certificates or reports are transmitted directly to the State office of vital statistics.

Attachment A.5

July 2, 2020

Minnesota Board of Medical Practice

I am aware that under Minnesota law, the Board of Medical Practice has an obligation to make inquiries into complaints and reports of alleged violations of the Minnesota Medical Practice Act. I received your request for information, and pertinent documents and videos necessary for the board to address these allegations are attached.

I would like to begin by stating that as a physician who has practiced medicine in Minnesota for nearly forty years, and as an outspoken physician legislator in Minnesota, I believe the stated complaints and allegations in your letter are derived from politically motivated persons, but I respect your committee's responsibilities to conduct appropriate due diligence. Your correspondence referenced concerns regarding public statements, and I found it noteworthy that your concerns did not involve any actual patient care issues or complaints.

I want to make it very clear that because I was the chief senate author of the two major legislative health care policy bills over the last two years (Pharmacy Benefit Manager licensure and regulation; Insulin safety net program), and because I am vice-chair of the Senate Health and Human Services Committee, I certainly have been in the crosshairs of many politically energized people.

During the COVID-19 pandemic I have been both critical and complimentary of various actions by the Center for Disease Control (CDC), the Minnesota Department of Health, and the State of Minnesota. I take my role as one of the few physician-legislators in the State of Minnesota very seriously, and I firmly believe that I have an obligation to my patients, constituents, and all Minnesotans to use my medical expertise and senate experience to further an understanding of the pandemic situation by "connecting the dots" for citizens and patients who choose to consider a perspective other than what mainstream legacy news sources might choose to provide.

While serving as a legislator, I have been criticized and abused via social media, e-mail, voicemails and phone calls. Death threats have become for my wife and I an occasional "fact of life." Some of the same folks who exuberantly applauded my candid and nonpartisan communication efforts in February of 2020 regarding an insulin safety net program are the same people who now express disdain and ridicule for my "maverick" willingness to "go against the grain" regarding the current COVID-19 conventional media narratives. I have thought long and hard about what potential legal remedies might be available to me when I encounter blatant efforts to slander and harass me for expressing thoughts which don't match up with the "current" perspective.

For months now, people I have never met, never spoken to, and never treated medically have threatened to "report" me to various agencies and boards in an effort to stop me from applying what I believe to be appropriate medical and scientific scrutiny to the current events, treatments, and responses to COVID-19. I view the current allegations you are inquiring about as possible attempts by those who wish to discourage me from voicing alternative or contrarian points of view which may call into question certain governmental actions.

In the last few months, I have made hundreds of statements and comments on the floor of the Minnesota Senate, in various committee meetings, and in local and regional meetings. I have participated in local, national, and international television and radio shows to discuss the current COVID-19 circumstances. I

have said, “YES,” to virtually any request I could accommodate because I believe that is my job as an elected official. To my dismay I have been chastised for not knowing in advance if a hosting media event was conservative or liberal regarding biases – I never thought it should matter. It has become more than clear to me that the American political scene has truly become “blood sport.” Virtually all my public statements, comments, and opinions are available via YouTube, Facebook, Twitter, as well as various news and media outlets.

In responding to the two allegations outlined in your letter dated June 22, 2020, my intention is to respond in my own words and also provide attachments to help reveal the rationale informing my perspectives. I do believe these allegations evolved from an emotional and changing intersection of healthcare, public policy, and partisan politics such that information shared two months ago may no longer represent current perspectives. I have found in my last four years of serving in the Minnesota Senate that when people disagree with me politically, there is almost no telling what type of action or retaliation may occur.

Allegation #1. It is alleged that you were “spreading misinformation [regarding COVID-19] on a regional tv station [i.e. KXJB-TV], “claiming that the Minnesota Department of Health instructed providers to list COVID-19 as the cause of death on death certificates regardless of whether a patient died of COVID-19.

Response:

An allegation of “spreading misinformation” is nebulous and quite broad.

I did not claim that the Minnesota Department of Health (MDH) instructed providers to list COVID-19 as the cause of death regardless of whether a patient died of COVID-19.

But the fact of the matter is that on April 3, 2020 the Minnesota Department of Health emailed information to medical certifiers involved with cause of death certification responsibilities which did advise “physicians, physician assistants, and advanced practice registered nurses who certify deaths to ... report Coronavirus Disease 2019 or COVID-19 on death certificates for all decedents where the disease caused, is assumed to have caused, or contributed, to death.” (ATTACHMENT 1_MDH_4.3.20_initial email)

The language in this email contradicts CDC instructions which state that “significant conditions contributing to death” should not be assumed to be the CAUSE OF DEATH, but rather listed in Part II of the death certificate as a contributing condition. The CDC manual for completing death certificates specifically provides instructions that the UNDERLYING CAUSE OF DEATH (UCOD) should be “defined as the disease or injury that initiated the train of morbid events leading directly to death.” For example, a patient placed in hospice care with end-stage heart failure or cancer who is rapidly approaching death but in the last 24 hours of life is identified as having a positive COVID-19 test or exposure should have the UCOD determined to be the underlying problem which prompted the initiation of hospice care. Any other determination – such as COVID-19 per the advice in the April 3 email from MDH – contradicts CDC manuals, standard physician practices regarding the establishment of a causation sequence with the UCOD identified as the initiating event leading to the patient’s demise, and Minnesota’s own death certification instructions compiled by coroners and medical examiners. (ATTACHMENT 2_CDC Manual_pgs. 9-11; full manual available at: https://www.cdc.gov/nchs/data/misc/hb_cod.pdf)

Another example would be the following: an HIV patient develops AIDS, then contracts overwhelming Pneumocystis pneumonia, then decides to utilize supportive care hospice services. In the last days of his life he develops a taste disturbance and PCR test for COVID-19 is positive. The appropriate UNDERLYING CAUSE OF DEATH (UCOD) is NOT COVID-19 but rather HIV leading to AIDS leading to Pneumocystis pneumonia with COVID-19 possibly involved in the sequence of death as the immediate cause. If the physician believed that COVID-19 did not play a role as the immediate cause of death, she/he could place it in Part II as a contributing condition. It is critical to understand that the UCOD is placed on the bottom line of Part I of the death certificate and is considered the cause of death when tallying causes of death and prevalence of various diseases.

The triggering MDH email stated that COVID-19 should be reported for all decedents where COVID19 caused, is assumed to have caused, or contributed, to death. It also linked certifiers to a CDC seven-page document which on page 3 states that it is acceptable to report COVID-19 as the cause of death without laboratory confirmation if the circumstances are "within a reasonable degree of certainty." (ATTACHMENT 3_CDC_4.3.20_Guidance for Certifying Deaths Due to Coronavirus Disease 2019)

But unfortunately, the CDC reporting guidance went on to declare that in cases where a definite diagnosis of COVID-19 could not be made, but was suspected or likely, it was declared acceptable to report COVID-19 on a death certificate as "probable" or "presumed." This contradicted the following: (i) CDC's own instruction manual for physician completion of death certificates, (ii) standard medical procedures, (iii) WHO coding recommendations, and (iv) Minnesota death certification manual. (ATTACHMENT 4_MN Death Certificate Manual_pgs 48, 60-63; full manual available at: <https://www.health.state.mn.us/people/vitalrecords/physician-me/docs/capcodbook.pdf>)

Frankly the MDH email allowing or even encouraging the use of COVID-19 as a cause of death in the instance of being merely a contributing element was astounding to many physicians including myself – the initiating disease in the train of events leading to death has long been the basis for data and statistical compilation so as to inform public health policy, legislation, and even funding for disease control initiatives.

Both the MDH email and the CDC reporting guidance packet contributed to confusion. The CDC guidance packet was interpreted by many that if COVID-19 played a possible role in the death of a patient, this was enough to identify it as a cause of death. This led to remarkable situations in which no testing was done or even considered but death certificates still called out COVID-19 as the UCOD. The CDC guidance packet did indicate that, where possible, laboratory testing should be done through local health authorities. This "soft" recommendation opened the door for uncertainty and misunderstanding which unfortunately had subsequent impact throughout the world simply because a COVID-19 death was not held to the standard of being involved in the sequential train of causation leading to a patient's death.

I was disturbed by the guidance MDH and CDC promulgated and asserted publicly that the sequence-of-causation protocol traditionally used in determining the all-important UNDERLYING CAUSE OF DEATH (UCOD) was being undermined by the Minnesota Department of Health's invitation to establish COVID-19 as the UCOD regardless of whether or not a laboratory test confirmed the diagnosis of COVID-19 or regardless of the fact that such a test was even considered by a physician. I was alarmed that the nature of the April 3 MDH email seemed to "coach physicians" to complete death certificates in a manner outside standard practices and protocols. I believe that MDH potentially compromised the integrity of death certificate data by inviting the inclusion of "assumed" or "contributed" as a basis to code a death certificate as COVID-19 for the UCOD. I believe this represented a significant and noteworthy change

regarding the recommended practice for death certification which could easily reduce the number of deaths related to heart disease, cancer, stroke, emphysema, etc. in favor of exaggerating the COVID-19 death counts. With this less rigorous process for determining COVID-19 as the UCOD, even annual influenza patient counts would, at some level, be altered since the annual flu outbreak was still in process. (ATTACHMENT 5_AAFP_Editorial on Death Certificates)

I believe the origin of this allegation relates to an interview I participated in on April 7, 2020. I encourage you to watch the seven minute video (LINK BELOW) and would ask in advance that you be mindful of the difference linguistically between the words, “instructed” and “coached.”

<https://www.powerlineblog.com/archives/2020/04/how-honest-is-the-covid-fatality-count.php>

As part of a response to any health crisis or pandemic, clear and verifiable information is key to addressing the situation, preparing a response, implementing preventative measures when possible, and providing treatment to the afflicted. All over Minnesota, the nation, and the world, there has been ongoing discussion related to how COVID-19 deaths are being reported. This is not misinformation; this is fact. (ATTACHMENTS 6,7,and 8_ Pennsylvania, Denver, New York)

In April of this year, the Illinois Director of Public Health, Dr. Ngozi Ezike stated the following:

"I just want to be clear in terms of the definition of people dying of COVID. The case definition is very simplistic. It means at the time of death it was a COVID positive diagnosis. So that means if you were in hospice and had already been given a few weeks to live, and then you also were found to have COVID, that would be counted as a COVID death. It means technically even if you died of a clear alternate cause, but you had COVID at the same time, it's still listed as a COVID death. So, everyone who's listed as a COVID death doesn't mean that that was the cause of the death, but they had COVID at the time of the death."

Dr. Deborah Birx, part of the White House medical team, made the famous statement which has become nearly memorialized:

"If someone dies with COVID-19, we are counting that as a COVID-19 death."

Her outlandish presumption that - no one died WITH COVID-19, rather they died FROM it - was “gas on the fire,” and people around the world were quickly outraged. Any information, guidance, or publication which had the potential to skew, camouflage, or muddy the waters regarding an actual cause of death needed to be intensely scrutinized, in part because the recorded data in 2020 would shape future public policies which would have immense and lasting impact with potentially devastating unintended consequences.

In today’s world of instant communication, any action taken by a governmental body or agency which does not provide clear, concise, and trustworthy information to the general public does nothing to further the public trust, and harms the reputation of such body or agency.

In summary the Minnesota Department of Health distributed instruction and guidance to providers to report COVID-19 on death certificates without precisely distinguishing between causation or correlation

or contribution to the UCOD. I have completed hundreds of death certificates over the last 40 years, and I vehemently disagree with this advice because it is absolutely contrary to past standard practice, created havoc and perverse incentives, and undermined quality data collection. New York, Pennsylvania, California, and many other states chose different paths to determine how to count COVID-19 deaths and each has undergone public scrutiny regarding such decisions.

The issue of laboratory confirmed cases not being segregated from presumed cases presents huge challenges which will require some level of uniformity in coding. (ATTACHMENT 9_COVID-19_ICD-10 Official Guidelines, specifically Chapter 1 (g)(1)(a), paragraph 3)

The notion that a contributing acute viral condition or test result could casually be inserted in place of a chronic progressive life-draining medical problem - such as cancer or heart failure - which was clearly the initiating condition sapping a patient's lifeblood to the point where death was closing in seemed ludicrous. I announced my concern publicly that the confounding communications by MDH and the CDC were problematic – but this assertion was not saying that MDH was “instructing providers to list COVID-19 as the cause of death regardless of whether a patient died of COVID-19.” Rather I expressed piercing alarms that public agencies were unilaterally moving in a dangerous direction that would potentially undermine the public trust just when policymakers needed that trust more than ever if citizens were to be expected to comply with earthshaking public policy decisions. The angst caused by such challenging considerations took root throughout the country, and Americans in every state have proven that they are worthy participants in this crucial conversation regarding the determination of death counts which will obviously impact on case fatality rates, comparisons with influenza epidemics, and state and federal funding decisions to help all Americans get through this crisis.

I hope every physician in Minnesota shares my concern that a paradigm shift in establishing the UCOD has taken place if the cause of death can now be established without regard for a precise sequence of causation or even ordering a simple lab test to bring science into the realm of determining the real cause of death. At the very least there should have been a conversation about this approach, but this did not occur. I reached out to dozens of physicians experienced in the completion of death certificates, and found no disagreement with my concerns. I suspect many physicians lacking ongoing experience with death certificate completion might see my concerns as more esoteric than real. I cannot fix that.

I protested what I perceived to be a counterproductive paradigm shift regarding death certificate completion, but I was gratified to see MDH and CDC distribute clarifying language to remedy the problem. MDH sent out two additional communications in the following weeks to clarify what had become very murky and also announced that it would count only laboratory test confirmed COVID-19 deaths in their tabulations and would sequester death certificates listing COVID-19 without laboratory confirmed tests until further research could be done (these fatalities are now identified with an asterisk on the MDH dashboard.) Numerous states reduced their official death counts in response to the national public outcry and debate regarding questionable cause of death determinations.

On April 9, I received an email from MDH containing clarifying guidance from the Office of Vital Records calling for accuracy, clarity, and confirmation of COVID-19 deaths. This April 9 guidance also reiterated that the UNDERLYING CAUSE OF DEATH meant “the disease or injury which initiated the train of morbid events leading directly to death.” It did not allow for a contributing condition to be the UCOD. (ATTACHMENT 10 and 11_MDH Final Guidance_4.9.20_AND_MDH Certifying Deaths Due to COVID-19_4.9.20)

On May 7, I received an additional MDH email with a link to video guidance for certifying COVID-19 deaths released by the National Center for Health Statistics (NCHS), and this video emphasized the need for the UCOD to represent best clinical judgement in identifying the most logical sequence of causation resulting in death. (ATTACHMENT 12_Video Guidance_5.7.20)

I did not claim that MDH instructed providers to list COVID-19 as the cause of death on death certificates regardless of whether a patient died of COVID-19. Rather I raised some questions:

- Should we be diagnosing COVID-19 in the absence of a laboratory confirmed test of COVID-19?
- If a laboratory confirmed test of COVID-19 is not obtained in a patient who dies, should death certificates be allowed to declare the UNDERLYING CAUSE OF DEATH as COVID-19? If so, in what circumstances?
- Does it matter if testing capability is readily available but not utilized in making the diagnosis of COVID-19? If the patient dies, does this change the diagnostic threshold?

Allegation #2. It is alleged that you also provided “reckless advice [regarding COVID-19] over social media,” stating that COVID-19 “is nothing more than the flu.”

Response:

Over the last few months, in my role as a citizen-physician-legislator, I have made numerous statements and comments in video clips, on the floor of the Minnesota Senate, in various committee meetings, and in local and regional meetings. I have made numerous appearances on local, national, and international television and radio shows. I cannot possibly respond with precision to an allegation that I have provided “reckless advice over social media,” as such an allegation is overly broad, and no specific instance of any such “reckless advice” is provided. Further, what someone who disagrees with a viewpoint I have expressed may deem “reckless advice,” another may deem quite sensible.

In regard to a statement that COVID-19 is “nothing more than a flu,” I have stated that the underlying COVID-19 virus has many similarities to other viruses: it is similar to the 2002 SARS Corona epidemic in regards to physiologic systems involved; it is similar to influenza viruses in that it is a single-stranded respiratory RNA virus with presenting symptoms of fever, cough, shortness of breath, malaise, headaches, muscle aches and GI disturbances. All three of these viruses – Covid-19, SARS, influenza - can kill thousands of people during an outbreak. I have provided specific contextual comparisons between influenza outbreaks and COVID-19 in regard to mortality, testing, latency and incubation periods, modelling uses and shortcomings, treatment protocols, and the unique ‘attack mode’ every virus has the potential to exhibit. Certainly, COVID-19 viruses are far more comparable to influenza viruses than to herpes viruses, Ebola viruses, or gastroenteritis viruses. .

The CDC reported the following on June 14, 2020:

“COVID-19 can look different in different people. For many people, being sick with COVID-19 would be a little bit like having the flu. People can get a fever, cough, or have a hard time taking deep breaths. Most people who have gotten COVID-19 have not gotten very sick. Only a small group of people who get it have had more serious problems.”

Dr. Anthony Fauci stated in a New England Journal of Medicine Editorial on March 26, 2020:

“This suggests that the overall clinical consequences of Covid-19 may ultimately be more akin to those of a severe seasonal influenza (which has a case fatality rate of approximately 0.1%) ...”

(ATTACHMENT 13_New England Journal of Medicine – COVID-19-Navigating the Uncharted).

Dr. Michael Osterholm told Beret Leone of Fox 47 Duluth News on March 14, 2020:

“Deadly strains of Influenza or the flu have been around for centuries. The flu has become a pandemic more than once and killed millions of people. It still exists today, but modern health experts are discussing what would happen if a new influenza virus showed up today, in world of 8-billion people. Unfortunately, we now have on our hands, but it’s caused by a coronavirus which is acting very much like influenza.”

(ATTACHMENT 14_National Infectious Disease Expert Talks COVID-19 in Duluth)

I have compared and opined on case fatality rates, incidence, and death totals between COVID-19 and influenza, which I believe to be eminently reasonable. I have called into question certain reporting metrics which fail to take into account the context of a given perspective, e.g. in 2018 influenza was reported to have caused ~80,000 deaths in the U.S. and the 1918 pandemic caused possibly 50 million deaths worldwide, albeit without the benefit of antibiotics. I have utilized numerous resources - MDH, DHS, CIDRAP, IHME – to inform my opinions. I have interviewed world experts on epidemiology and participated in BBC news programs, Tony Robbins podcasts (with an expert panel featuring world renowned authorities including a Nobel laureate).

I have commented on whether past treatments used for influenza syndromes (as well as other viruses/illnesses) could be beneficial in dealing with COVID-19. Most importantly I have shared with thousands of people through many platforms that a contextual understanding of the similarities and differences between COVID-19 and influenza is one of the most pertinent comprehensions Americans can strive for. I have tried to convey a message centering on scientifically established facts and teachings, personal responsibility, and hopefulness.

I do not recall ever saying specifically that COVID-19 “is nothing more than the flu.” Please direct me to a specific source if you have information to the contrary. (Worldwide there are hundreds of media articles and videos which include comments I have made over the last four months, many without my awareness or permission.)

I do realize that some of my words have been taken out of context and used to fuel perspectives I do not share. In this world of social media, I do not know how to prevent this. I have erected increased safety and privacy guardrails on my social media pages. I have restricted others from posting and tagging on my pages. I have limited administrator access to my platforms. I have recruited numerous persons to scan media and promptly report any concerns to me.

As a Senator receiving thousands of inputs every week, I have diligently reached out to many detractors inviting conversation – some have accepted, most have not. Clearly politics and COVID-19 have become incredibly intertwined and dramatically divisive. For an outspoken and often skeptical physician legislator such as I am, the full exercising of freedom of speech has pushed me into a realm I previously have not explored. Rest assured, I am immensely frustrated by some of the antics that go on in social media, but I

have had to come to the unhappy conclusion that when the worlds of politics intersects with health care, selective use of news sources leads to amazing distortion, division, and discord.

These are critical times. These are hard times. More folks have died alone in long term care facilities than at any other time in my medical career. There will be a new normal emerging and it is still evolving. The resources physicians and patients depend on have become unnecessarily political. I am angry that my patients suffered, often unnecessarily. But I must say that your request for information has helped me process what has gone before us, and I am reinvigorated to do my part in helping Minnesota move through this dramatically difficult and bizarre time with grace and dignity and kindness to others.

Both of the allegations in question are false. Certainly, I might have been able to do some things differently to prevent the misuse of my words on social media sites of which I had never heard of. However, I know of no sure-fire way to do this, and daily I see message content from leaders in education, ministers, doctors, and politicians twisted and turned into something not in any way resembling original intent. Understanding this reality and ruminating on this lesson will be useful for me in the future.

I thank you for doing the work you do as I respectfully submit this response with attachments.

Senator Scott Jensen, M.D.

ATTACHMENT 1

OVR Operations and COVID-19 Death Certification Information

Minnesota Department of Health <mdh@public.govdelivery.com>

Fri, Apr 3, 2020 at 10:13 AM

Reply-To: mdh@public.govdelivery.com

To: smj2203@gmail.com

To our colleagues involved with death registration and certification:

Thank you for providing essential services during the COVID-19 pandemic. Especially now during this uncertain health situation, we appreciate your efforts to certify deaths and provide families the support they need. We want you to know that MDH and the Office of Vital Records (OVR) are here to support you and assure that death records are accurate and that timely registration and certification activities continue. Vital records are essential and we are following the Governor's orders and MDH's plan.

OVR is open and MR&C is available

- Minnesota Registration and Certification (MR&C) is a priority IT system—MR&C is available and is fully operational.
- MR&C and general support and service are available to you and all of our partners. Representatives are available from 8 a.m. to 4:30 p.m., Monday through Friday. Contact the OVR Help Desk at health.vitalrecords@state.mn.us or 651-201-5970. Please leave a voicemail message afterhours and OVR will call you back the next business day.
- OVR makes MR&C access a priority for medical certifiers who are ready to provide information about the cause and manner of death. Sign up to certify online by completing the Medical Certifier and Designated Staff User Agreement (PDF) found on the [MR&C for Medical Certifiers](#) webpage.
- Log in to MR&C from anywhere. MR&C is a web-based system that is available 24/7 from any internet connection.

Advice for physicians, physician assistants, and advanced practice registered nurses who certify deaths

- Take immediate action when you become aware that a patient has died and you need to provide a cause of death statement—timely certification of all deaths is critical during the pandemic. MR&C will send an email and the record will appear in your MR&C cause of death work queue.
 - Consider designating staff to enter your cause of death statements into MR&C on your behalf if you are out of the office, working remotely, or if operations in your clinic or facility are temporarily irregular.
 - Work out coverage with other medical certifiers who have access to your patients' medical records.
- Provide the date you last saw the decedent; **a telemedicine appointment is acceptable** as the date a decedent was last seen
- Provide cause of death information based on your best medical opinion using the information available to you. For guidance on how to enter cause of death information into MR&C, see the [MR&C for Medical Certifiers](#) webpage.
- Know that your cause of death statement is necessary for medical examiners and coroners to authorize cremation. Timely disposition is critical during the pandemic.
- Respond to medical examiners and coroners if they contact you about a death record.
- You can request that OVR correct information about the cause of death anytime, even after

issuance of certificates.

- **NEW!** Find the *Request to Change Cause or Manner of Death* (PDF) on the [OVR Forms for Medical Certifiers](#) webpage.
- Report **Coronavirus Disease 2019 or COVID-19** on death certificates for all decedents where the disease caused, is assumed to have caused, or contributed, to death. Include as much detail as possible based on your knowledge of the patient, medical records, laboratory testing, etc. If the decedent had other chronic conditions such as COPD or asthma that may have also contributed, report the conditions in Part II.
- Find guidance for certifying COVID-19 deaths on the [Additional Resources for Medical Certifiers](#) webpage.

Please protect yourselves and stay healthy. Information about [Coronavirus Disease 2019 \(COVID-19\)](#) is on the Minnesota Department of Health website.

You can update or cancel your subscription at any time by [editing your personal profile](#). All you will need are your email address and your password (if you have selected one).

P.S. If you have any questions or problems please contact subscriberhelp.govdelivery.com for assistance.

STAY CONNECTED:



[MDH on Twitter](#)

[MDH on Facebook](#)

[MDH on LinkedIn](#)

This email was sent to smj2203@gmail.com using GovDelivery Communications Cloud on behalf of: Minnesota Department of Health · [625 Robert Street North · St. Paul MN 55155](#) · 651-201-5000

GOVDELIVERY

ATTACHMENT 2

Medical Certification of Death

The physician's primary responsibility in death registration is pronouncing the death and, when he or she is the attending physician, reporting cause of death. The medical part of the certificate includes:

- Date and time pronounced dead
- Date and time of death
- Question on whether the case was referred to the medical examiner or coroner
- Cause-of-death section including cause of death, manner of death, tobacco use, and females' pregnancy status items
- Injury items for cases involving injuries
- Certifier section with signatures

In most cases, a physician will both pronounce death and certify or report the cause of death. A different physician will pronounce death only when the attending physician is unavailable to certify the cause of death at the time of death and if State law provides for this option. If an inquiry is required by a State Post-Mortem Examinations Act, a medical examiner or coroner is responsible for determining cause of death (4).

Pronouncing date and time of death

Items 24 and 25 must be completed by the person who pronounces death. This may be the pronouncing physician, pronouncing/certifying physician, or the medical examiner or coroner. For cases involving a pronouncing physician different from the certifying physician, the pronouncing physician must also complete items 26–28.

Cause of death

This section must be completed by either the attending physician, the medical examiner, or the coroner. The cause-of-death section, a facsimile of which is shown below, follows guidelines recommended by the World Health Organization. An important feature is the reported underlying cause

of death determined by the certifying physician and defined as (a) the disease or injury that initiated the train of morbid events leading directly to death, or (b) the circumstances of the accident or violence that produced the fatal injury. In addition to the underlying cause of death, this section provides for reporting the entire sequence of events leading to death as well as other conditions significantly contributing to death (5).

The cause-of-death section is designed to elicit the opinion of the medical certifier. Causes of death on the death certificate represent a medical opinion that might vary among individual physicians. A properly completed cause-of-death section provides an etiologic explanation of the order, type, and association of events resulting in death. The initial condition that starts the etiologic sequence is specific if it does not leave any doubt as to why it developed. For example, sepsis is not specific because a number of different conditions may have resulted in sepsis, whereas human immunodeficiency virus syndrome is specific.

CAUSE OF DEATH (See instructions and examples)			Approximate Interval Onset to death
<p>32. PART I. Enter the <u>chain of events</u>—diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.</p>			
<p>IMMEDIATE CAUSE (Final disease or condition resulting in death)</p> <p>Due to (or as a consequence of):</p>	<p>a. _____</p>	<p>_____</p>	
<p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST</p> <p>Due to (or as a consequence of):</p>	<p>b. _____</p>	<p>_____</p>	
<p>Due to (or as a consequence of):</p>	<p>c. _____</p>	<p>_____</p>	
<p>Due to (or as a consequence of):</p>	<p>d. _____</p>	<p>_____</p>	
<p>PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I.</p>		<p>33. WAS AN AUTOPSY PERFORMED? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
		<p>34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>35. DID TOBACCO USE CONTRIBUTE TO DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> Probably <input type="checkbox"/> No <input type="checkbox"/> Unknown</p>	<p>36. IF FEMALE: <input type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year</p>	<p>37. MANNER OF DEATH <input type="checkbox"/> Natural <input type="checkbox"/> Homicide <input type="checkbox"/> Accident <input type="checkbox"/> Pending investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined</p>	

In certifying the cause of death, any disease, abnormality, injury, or poisoning, if believed to have adversely affected the decedent, should be reported. If the use of alcohol and/or other substance, a smoking history, a recent pregnancy, injury, or surgery was believed to have contributed to death, then this condition should be reported. The conditions present at the time of death may be completely unrelated, arising independently of each other; they may be causally related to each other, that is, one condition may lead to another which in turn leads to a third condition; and so forth. Death may also result from the combined effect of two or more conditions.

As can be seen, the cause-of-death section consists of two parts. The first part is for reporting the sequence of events leading to death, proceeding backwards from the final disease or condition resulting in death. So each condition in Part I should cause the condition above it. A specific cause of death should be reported in the last entry in Part I so there is no ambiguity about the etiology of this cause. Other significant conditions that contributed to the death, but did not lead to the underlying cause, are reported in Part II.

In addition, there are questions relating to autopsy, manner of death (for example, accident), and injury. The cause of death should include information provided by the pathologist if an autopsy or other type of postmortem examination is done. For deaths that have microscopic examinations pending at the time the certificate is filed, the additional information should be reported as soon as it is available. If the physician has any questions about the procedure for doing this, he or she should contact his or her State registrar.

For statistical and research purposes, it is important that the causes of death and, in particular, the underlying cause of death be reported as specifically and as precisely as possible. Careful reporting results in statistics for both underlying and multiple causes of death (i.e., all conditions mentioned on a death certificate) reflecting the best medical opinion.

Every cause-of-death statement is coded and tabulated in the statistical offices according to the latest revision of the *International Classification of Diseases* (5). When there is a problem with the reported cause of death (e.g., when a causal sequence is reported in reverse order), the rules provide a consistent way to select the most likely underlying cause. However, it is better when rules designed to compensate for poor reporting are not invoked so that the rules are confirming the physician's statement rather than imposing assumptions about what the physician meant.

Statistically, mortality research focuses on the underlying cause of death because public health interventions seek to break the sequence of causally related medical conditions as early as possible. However, all cause information reported on death certificates is important and is analyzed.

In the sections that follow, detailed instructions on how to complete Parts I and II are given. A number of examples of properly completed certificates with case histories are provided in this section to illustrate how the cause of death should be reported. Some common problems are also discussed later in this section.

ATTACHMENT 3

Guidance for Certifying Deaths Due to Coronavirus Disease 2019 (COVID–19)

Introduction

In December 2019, an outbreak of a respiratory disease associated with a novel coronavirus was reported in the city of Wuhan in the Hubei province of the People's Republic of China (1). The virus has spread worldwide and on March 11, 2020, the World Health Organization declared Coronavirus Disease 2019 (COVID–19) a pandemic (2). The first case of COVID–19 in the United States was reported in January 2020 (3) and the first death in February 2020 (4), both in Washington State. Since then, the number of reported cases in the United States has increased and is expected to continue to rise (5).

In public health emergencies, mortality surveillance provides crucial information about population-level disease progression, as well as guides the development of public health interventions and assessment of their impact. Monitoring and analysis of mortality data allow dissemination of critical information to the public and key stakeholders. One of the most important methods of mortality surveillance is through monitoring causes of death as reported on death certificates. Death certificates are registered for every death occurring in the United States, offering a complete picture of mortality nationwide. The death certificate provides essential information about the deceased and the cause(s) and circumstances of death. Appropriate completion of death certificates yields accurate and reliable data for use in epidemiologic analyses and public health reporting. A notable example of the utility of death certificates for public health surveillance is the ongoing monitoring of pneumonia and influenza deaths. Accurate and timely death certificate data are integral to detecting elevated levels of influenza activity in real time (<https://www.cdc.gov/flu/weekly/index.htm>).

Monitoring the emergence of COVID–19 in the United States and guiding public health response will also require accurate and timely death reporting. The purpose of this report is to provide guidance to death certifiers on proper cause-of-death certification for cases where confirmed or suspected COVID–19 infection resulted in death. As clinical guidance on COVID–19 evolves, this guidance may be updated, if necessary. When COVID–19 is determined to be a cause of death, it is important that it be reported on the death certificate to assess accurately the effects of this pandemic and appropriately direct public health response.

Cause-of-Death Reporting

When reporting cause of death on a death certificate, use any information available, such as medical history, medical records, laboratory tests, an autopsy report, or other sources of relevant information. Similar to many other diagnoses, a cause-of-death statement is an informed medical opinion that should be based on sound medical judgment drawn from clinical training and experience, as well as knowledge of current disease states and local trends (6).

Part I

This section on the death certificate is for reporting the sequence of conditions that led directly to death. The immediate cause of death, which is the disease or condition that directly preceded death and is not necessarily the underlying cause of death (UCOD), should be reported on line a. The conditions that led to the immediate cause of death should be reported in a logical sequence in terms of time and etiology below it.

The UCOD, which is “(a) the disease or injury which initiated the train of morbid events leading directly to death or (b) the circumstances of the accident or violence which produced the fatal injury” (7), should be reported on the lowest line used in Part I.

Approximate interval: Onset to death

For each condition reported in Part I, the time interval between the presumed onset of the condition, not the diagnosis, and death should be reported. It is acceptable to approximate the intervals or use general terms, such as hours, days, weeks, or years.

Part II

Other significant conditions that contributed to the death, but are not a part of the sequence in Part I, should be reported in Part II. Not all conditions present at the time of death have to be reported—only those conditions that actually contributed to death.

Certifying deaths due to COVID-19

If COVID-19 played a role in the death, this condition should be specified on the death certificate. In many cases, it is likely that it will be the UCOD, as it can lead to various life-threatening conditions, such as pneumonia and acute respiratory distress syndrome (ARDS). In these cases, COVID-19 should be reported on the lowest line used in Part I with the other conditions to which it gave rise listed on the lines above it.

Generally, it is best to avoid abbreviations and acronyms, but COVID-19 is unambiguous, so it is acceptable to report on the death certificate.

In some cases, survival from COVID-19 can be complicated by pre-existing chronic conditions, especially those that result in diminished lung capacity, such as chronic obstructive pulmonary disease (COPD) or asthma. These medical conditions do not cause COVID-19, but can increase the risk of contracting a respiratory infection and death, so these conditions should be reported in Part II and not in Part I.

When determining whether COVID-19 played a role in the cause of death, follow the CDC clinical criteria for evaluating a person under investigation for COVID-19 and, where possible, conduct appropriate laboratory testing using guidance provided by CDC or local health authorities. More information on CDC recommendations for reporting, testing, and specimen collection, including postmortem testing, is available from: <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html> and <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-postmortem-specimens.html>. It is important to remember that death certificate reporting may not meet mandatory reporting requirements for reportable diseases; contact the local health department regarding regulations specific to the jurisdiction.

In cases where a definite diagnosis of COVID-19 cannot be made, but it is suspected or likely (e.g., the circumstances are compelling within a reasonable degree of certainty), it is acceptable to report COVID-19 on a death certificate as “probable” or “presumed.” In these instances, certifiers should use their best clinical judgement in determining if a COVID-19 infection was likely. However, please note that testing for COVID-19 should be conducted whenever possible.

Common problems

Common problems in cause-of-death certification include:

1. reporting intermediate causes as the UCOD (i.e., on the lowest line used in Part I),
2. lack of specificity, and
3. illogical sequences.

Intermediate causes are those conditions that typically have multiple possible underlying etiologies and thus, a UCOD must

be specified on a line below in Part I. For example, pneumonia is an intermediate cause of death since it can be caused by a variety of infectious agents or by inhaling a liquid or chemical. Pneumonia is important to report in a cause-of-death statement but, generally, it is not the UCOD. The cause of pneumonia, such as COVID-19, needs to be stated on the lowest line used in Part I.

Additionally, the reported UCOD should be specific enough to be useful for public health and research purposes. For example, a “viral infection” can be a UCOD, but it is not specific. A more specific UCOD in this instance could be “COVID-19.”

All causal sequences reported in Part I should be logical in terms of time and pathology. For example, reporting “COVID-19” due to “chronic obstructive pulmonary disease” in Part I would be an illogical sequence as COPD cannot cause an infection, although it may increase susceptibility to or exacerbate an infection. In this instance, COVID-19 would be reported in Part I as the UCOD and the COPD in Part II. While there can be reasonable differences in medical opinion concerning a sequence that led to a particular death, the causes should always be provided in a logical sequence from the immediate cause on line a. back to the UCOD on the lowest line used in Part I.

Manner of death

The manner of death, sometimes referred to as circumstances of death, is also reported on death certificates. Natural deaths are due solely or almost entirely to disease or the aging process (8). In the case of death due to a COVID-19 infection, the manner of death will almost always be natural.

When to Refer to a Medical Examiner or Coroner

Some jurisdictions have requirements for referring deaths involving threats to public health to the medical examiner or coroner, so certifiers should follow the regulations in the jurisdiction in which the death occurred. As always, if a death involved an injury, poisoning, or complications thereof, then the case should be referred. The local medical examiner or coroner should be consulted with questions on referral requirements.

Conclusion

An accurate count of the number of deaths due to COVID-19 infection, which depends in part on proper death certification, is critical to ongoing public health surveillance and response. When a death is due to COVID-19, it is likely the UCOD and thus, it should be reported on the lowest line used in Part I of the death certificate. Ideally, testing for COVID-19 should be

Vital Statistics Reporting Guidance

conducted, but it is acceptable to report COVID–19 on a death certificate without this confirmation if the circumstances are compelling within a reasonable degree of certainty.

For more guidance and training on cause-of-death reporting in general, see the Cause of Death mobile app available from: <https://www.cdc.gov/nchs/nvss/mobile-app.htm> and the Improving Cause of Death Reporting online training module available from: https://www.cdc.gov/nchs/nvss/improving_cause_of_death_reporting.htm (free Continuing Medical Education credits and Continuing Nursing Education credits available). For current information on the COVID–19 outbreak, see the CDC website at: <https://www.cdc.gov/coronavirus/2019-nCoV/index.html>.

References

1. World Health Organization. Novel coronavirus—China. Geneva, Switzerland. 2020. Available from: <https://www.who.int/csr/don/12-january-2020-novel-coronavirus-china/en/>.
2. World Health Organization. WHO Director-General’s opening remarks at the media briefing on COVID–19—11 March 2020. Geneva, Switzerland. 2020. Available from: <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>.
3. Holshue ML, DeBolt C, Lindquist S, Lofy KH, Wiesman J, Bruce H, et al. First case of 2019 novel coronavirus in the United States. *N Engl J Med*. 382(10):929–36. 2020. Available from: <https://www.nejm.org/doi/full/10.1056/NEJMoa2001191>.
4. Centers for Disease Control and Prevention. CDC, Washington state report first COVID–19 death [press release]. 2020. Available from: <https://www.cdc.gov/media/releases/2020/s0229-COVID-19-first-death.html>.
5. Centers for Disease Control and Prevention. CDC confirms possible instance of community spread of COVID–19 in U.S. [press release]. 2020. Available from: <https://www.cdc.gov/media/releases/2020/s0226-Covid-19-spread.html>.
6. National Center for Health Statistics. Physician’s handbook on medical certification of death. Hyattsville, MD: National Center for Health Statistics. 2003.
7. World Health Organization. International statistical classification of diseases and related health problems, 10th revision (ICD–10), Volume 2. 5th ed. Geneva, Switzerland. 2016.
8. National Center for Health Statistics. Medical examiner’s and coroner’s handbook on death registration and fetal death reporting. Hyattsville, MD: National Center for Health Statistics. 2003.

Vital Statistics Reporting Guidance

Appendix. Scenarios and Example Certifications for Deaths Due to COVID-19

Scenario I: A 77-year-old male with a history of hypertension and chronic obstructive pulmonary disease

A 77-year-old male with a 10-year history of hypertension and chronic obstructive pulmonary disease (COPD) presented to a local emergency department complaining of 4 days of fever, cough, and increasing shortness of breath. He reported recent exposure to a neighbor with flu-like symptoms. He stated that his wheezing was not improving with his usual bronchodilator therapy. Upon examination, he was febrile, hypoxic, and in

moderate respiratory distress. His chest x-ray demonstrated hyperinflation and his arterial blood gas was consistent with severe respiratory acidosis. Testing of respiratory specimens indicated COVID-19. He was admitted to the ICU and despite aggressive treatment, he developed worsening respiratory acidosis and sustained a cardiac arrest on day 3 of admission.

Comment: In this case, the acute respiratory acidosis was the immediate cause of death, so it was reported on line a. Acute respiratory acidosis was precipitated by the COVID-19 infection, which was reported below it on line b. in Part I. The COPD and hypertension were contributing causes but were not a part of the causal sequence in Part I, so those conditions were reported in Part II.

Scenario I

CAUSE OF DEATH (See instructions and examples)		Approximate interval: Onset to death
32. PART I. Enter the <u>chain of events</u> —diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.		
IMMEDIATE CAUSE (Final disease or condition resulting in death) →	a. Acute respiratory acidosis Due to (or as a consequence of):	3 days
Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST	b. COVID-19 Due to (or as a consequence of):	1 week
	c. _____ Due to (or as a consequence of):	
	d. _____ Due to (or as a consequence of):	
PART II. Enter other <u>significant conditions contributing to death</u> but not resulting in the underlying cause given in PART I		33. WAS AN AUTOPSY PERFORMED? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Chronic obstructive pulmonary disease, hypertension		34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
35. DID TOBACCO USE CONTRIBUTE TO DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown	36. IF FEMALE: <input type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year	37. MANNER OF DEATH <input checked="" type="checkbox"/> Natural <input type="checkbox"/> Homicide <input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined

Vital Statistics Reporting Guidance

Scenario II: A 34-year-old female with no significant past medical history

A 34-year-old female with no significant past medical history presented to her primary care physician complaining of 6 days of fever, cough, and myalgias. She was found to be febrile, hypotensive, and hypoxic. She was admitted to the hospital and underwent a CT scan of the chest, which revealed diffuse ground-glass opacification indicative of viral pneumonia. Respiratory specimens were sent for testing and rRT-PCR confirmed COVID-19. Her condition deteriorated over the next

2 days and she developed acute respiratory distress syndrome (ARDS). She was transferred to the ICU and started on positive pressure ventilation. Despite aggressive resuscitation, the patient expired on hospital day 4.

Comment: In this case, the immediate cause of death was ARDS, so it was reported on line a. as a consequence of pneumonia, which was reported on line b. The underlying cause of death (UCOD) was COVID-19 so it was reported on line c., the lowest line used in Part I.

Scenario II

CAUSE OF DEATH (See instructions and examples)			Approximate interval: Onset to death
32. PART I. Enter the <u>chain of events</u> --diseases, injuries, or complications--that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.			
IMMEDIATE CAUSE (Final disease or condition -----> resulting in death)	a. Acute respiratory distress syndrome	Due to (or as a consequence of):	2 days
Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST	b. Pneumonia	Due to (or as a consequence of):	10 days
	c. COVID-19	Due to (or as a consequence of):	10 days
	d. _____	Due to (or as a consequence of):	_____
PART II. Enter other <u>significant conditions contributing to death</u> but not resulting in the underlying cause given in PART I		33. WAS AN AUTOPSY PERFORMED? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
		34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> No	
35. DID TOBACCO USE CONTRIBUTE TO DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown	36. IF FEMALE: <input checked="" type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year	37. MANNER OF DEATH <input checked="" type="checkbox"/> Natural <input type="checkbox"/> Homicide <input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined	

Vital Statistics Reporting Guidance

Scenario III: An 86-year-old female with an unconfirmed case of COVID-19

An 86-year-old female passed away at home. Her husband reported that she was nonambulatory after suffering an ischemic stroke 3 years ago. He stated that 5 days prior, she developed a high fever and severe cough after being exposed to an ill family member who subsequently was diagnosed with COVID-19. Despite his urging, she refused to go to the hospital, even when her breathing became more labored and temperature escalated. She was unresponsive that morning and her husband phoned emergency medical services (EMS). Upon EMS arrival, the

patient was pulseless and apneic. Her husband stated that he and his wife had advanced directives and that she was not to be resuscitated. After consulting with medical command, she was pronounced dead and the coroner was notified.

Comment: Although no testing was done, the coroner determined that the likely UCOD was COVID-19 given the patient's symptoms and exposure to an infected individual. Therefore, COVID-19 was reported on the lowest line used in Part I. Her ischemic stroke was considered a factor that contributed to her death but was not a part of the direct causal sequence in Part I, so it was reported in Part II.

Scenario III

CAUSE OF DEATH (See instructions and examples)			Approximate interval: Onset to death
32. PART I. Enter the <u>chain of events</u> --diseases, injuries, or complications--that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.			
IMMEDIATE CAUSE (Final disease or condition -----> resulting in death)	a. Acute respiratory illness Due to (or as a consequence of):		1 day
Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST	b. Probable COVID-19 Due to (or as a consequence of):		5 days
	c. _____ Due to (or as a consequence of):		
	d. _____ Due to (or as a consequence of):		
PART II. Enter other <u>significant conditions contributing to death</u> but not resulting in the underlying cause given in PART I		33. WAS AN AUTOPSY PERFORMED? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Ischemic stroke		34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> No	
35. DID TOBACCO USE CONTRIBUTE TO DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown	36. IF FEMALE: <input checked="" type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year	37. MANNER OF DEATH <input checked="" type="checkbox"/> Natural <input type="checkbox"/> Homicide <input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined	

**U.S. DEPARTMENT OF
HEALTH & HUMAN SERVICES**

Centers for Disease Control and Prevention
National Center for Health Statistics
3311 Toledo Road, Room 4551, MS P08
Hyattsville, MD 20782–2064

FIRST CLASS MAIL
POSTAGE & FEES PAID
CDC/NCHS
PERMIT NO. G-284

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, \$300

Vital Statistics Reporting Guidance

Contents

Introduction	1
Cause-of-Death Reporting	1
Part I	1
Approximate interval: Onset to death	1
Part II	1
Certifying deaths due to COVID–19	2
Common problems	2
Manner of death	2
When to Refer to a Medical Examiner or Coroner	2
Conclusion	2
References	3
Appendix. Scenarios and Example Certifications for Deaths Due to COVID–19	4
Scenario I: A 77-year-old male with a history of hypertension and chronic obstructive pulmonary disease	4
Scenario II: A 34-year-old female with no significant past medical history	5
Scenario III: An 86-year-old female with an unconfirmed case of COVID–19	6

Acknowledgments

NCHS would like to acknowledge Marcus Nashelsky, M.D., for his contributions to the guidance and example certifications.

Suggested citation

National Center for Health Statistics. Guidance for certifying deaths due to COVID–19. Hyattsville, MD. 2020.

Copyright information

All material appearing in this report is in the public domain and may be reproduced or copied without permission; citation as to source, however, is appreciated.

National Center for Health Statistics

Jennifer H. Madans, Ph.D., *Acting Director*
Amy M. Branum, Ph.D., *Acting Associate Director for Science*

Division of Vital Statistics

Steven Schwartz, Ph.D., *Director*
Isabelle Horon, Dr.P.H., *Acting Associate Director for Science*

For e-mail updates on NCHS publication releases, subscribe online at:
<https://www.cdc.gov/nchs/govdelivery.htm>.

For questions or general information about NCHS: Tel: 1–800–CDC–INFO
(1–800–232–4636) • TTY: 1–888–232–6348

Internet: <https://www.cdc.gov/nchs>

Online request form: <https://www.cdc.gov/info>

DHHS Publication No. 2020–1126 • CS316264

ATTACHMENT 4

Cause of Death and the Death Certificate

Certifiers should be aware that a vital records registration or processing fee may be charged when an amendment is made, and that additional expense may be incurred by the funeral director or family.

Interval Between Onset of Conditions and Death

For each condition listed in Part I of the cause-of-death statement, a space exists to indicate the approximate time interval between the onset of the condition and death. For each condition, the interval should be indicated as accurately as possible based on the certifier's assessment of available information. It is acceptable to list the interval as unknown or approximate, if such is the case. General intervals are also acceptable, such as seconds, minutes, hours, days, weeks, months, and several years. A range such as seconds to minutes, or other statement such as "Known for six years," may also be used. Stating the interval should not be approached casually—the information may be used to assess pre-existing conditions in some medicolegal settings or when insurance claims are processed. Stating the interval also serves as a check that the immediate, intermediate, and underlying causes of death have been written in the proper order.

The stated interval should be based on consideration of the clinical history, symptomatology, natural disease course, and knowledge of the potential uses of such information, not solely on the interval since diagnosis.

Part I	A. Pneumocystis carinii pneumonia	Approximate interval between onset and death 3 weeks
	Due to, or as a consequence of:	
	B. Acquired immunodeficiency syndrome	3 years
	Due to, or as a consequence of:	
Part I	C. Human immunodeficiency virus infection	5 years
	Due to, or as a consequence of:	
	D.	
Part II	OTHER SIGNIFICANT CONDITIONS: Conditions contributing to death but not resulting in the underlying cause of death in Part I Intravenous drug abuse	

Cause of Death and the Death Certificate

The Sequential Part I Format

Part I of the cause-of-death statement is constructed to allow an indication of a sequence of events where one condition results from another. The most recent condition is placed on the top line (A), then other antecedent conditions (ie, going backward in time) are entered on subsequently lower lines (B, then C, then D), as needed.

Part I	Immediate cause:	Approximate interval between onset and death
	A. Most recent condition (resulting from B)	
	Due to, or as a consequence of: B. An antecedent (older) condition (resulting from C)	
	Due to, or as a consequence of: C. An even older condition (resulting from D)	
	Due to, or as a consequence of: D. The first (oldest) condition causing the others above	
Part II	OTHER SIGNIFICANT CONDITIONS: Conditions contributing to death but not resulting in the underlying cause of death in Part I	

Variations in Part I of the cause-of-death section on the death certificates used in different states relate primarily to the number of lines available for use (there are usually three or four lines). It is not required nor is it always necessary to use all of the lines in Part I.

All conditions listed in Part I have a sequential cause-and-effect relationship when read from the bottom to the top. Variation in the number of lines used does not affect the concept of sequence. The lowest completed line in Part I contains the oldest condition, and the uppermost completed line in Part I contains the most recent condition (the condition occurring closest to the time of death).

Cause of Death and the Death Certificate

The Underlying Cause of Death

For deaths that result from disease (natural conditions), the National Center for Health Statistics defines the underlying cause of death as the disease (condition) that initiated the train of morbid events leading directly to death. The definition becomes clearer when put in the context of completing Part I of the cause-of-death statement.

If Part I is written as ...

Part I	Immediate cause:	Approximate interval between onset and death
	A. Acute myocardial infarct	Hours
	Due to, or as a consequence of:	
	B. Atherosclerotic coronary artery disease	Years
Part I	Due to, or as a consequence of:	
	C.	
	Due to, or as a consequence of:	
D.		
Part II	OTHER SIGNIFICANT CONDITIONS: <small>Conditions contributing to death but not resulting in the underlying cause of death in Part I</small>	

... atherosclerotic coronary artery disease is the underlying cause of death because it is the disease (condition) that initiated the train of morbid events. Note that the underlying cause of death is the lowermost completed line in Part I. The underlying cause of death explains why death and the condition on the line above it (acute myocardial infarction) occurred. The underlying cause of death should be stated as etiologically specifically as possible.

As this example shows, it is not required, nor is it always necessary, to use all of the lines in Part I.

The most important concepts presented have to do with properly indicating the underlying cause of death. In general, the underlying cause of death has the greatest medical, legal, and epidemiologic importance—an easily remembered fact because, as in many important documents, it is the bottom line.

Cause of Death and the Death Certificate

Immediate Cause of Death

For deaths due solely to disease, the National Center for Health Statistics defines the *immediate cause of death* as the final disease or complication directly causing the death. The existence of an antecedent, or underlying cause, is implicit in the definition. Again, it is helpful to consider this definition in the context of completing Part I of the cause-of-death statement.

If more than one line is used when completing Part I, the top line (line A) is referred to as the immediate cause of death, which is the disease (condition) or complication of the underlying cause of death that occurred closest to the time of death (last).

The example from the previous page illustrates this concept:

Part I	Immediate cause:	Approximate interval between onset and death
	A. Acute myocardial infarct	Hours
	Due to, or as a consequence of:	
	B. Atherosclerotic coronary artery disease	Years
Part I	Due to, or as a consequence of:	
	C.	
	Due to, or as a consequence of:	
Part I	D.	
	OTHER SIGNIFICANT CONDITIONS: Conditions contributing to death but not resulting in the underlying cause of death in Part I	
Part II		

Thus, acute myocardial infarction is the immediate cause of death because it is the final complication of atherosclerotic coronary artery disease—the underlying cause of death. The immediate cause of death should be stated as etiologically specifically as possible. For example, in a patient whose underlying cause of death is human immunodeficiency virus infection, pneumocystis pneumonia is preferable to pneumonia as an immediate cause of death if pneumocystis is known to be the etiologic agent for the pneumonia.

Underlying and immediate causes of death are linked in a cause-and-effect relationship when read from bottom to top.

Cause of Death and the Death Certificate

Intermediate (Intermediary) Causes of Death

For deaths due solely to disease, an *intermediate (intermediary) cause of death* is a disease, condition, or complication that occurs somewhere in time between the underlying and immediate causes of death. Again, it is helpful to consider this definition in the context of completing Part I of the cause-of-death statement. If more than two lines are used when completing lines A through D in Part I, each line falling between the top line (the immediate cause of death) and lowermost completed line (the underlying cause of death) contains an intermediate cause of death.

The following example illustrates this concept:

Part I	Immediate cause: A. Pulmonary infarct	Approximate interval between onset and death Hours
	Due to, or as a consequence of: B. Pulmonary thromboembolism	Hours
	Due to, or as a consequence of: C. Deep leg vein thrombosis	Days
	Due to, or as a consequence of: D. Essential thrombocytosis	Months
Part II	OTHER SIGNIFICANT CONDITIONS: Conditions contributing to death but not resulting in the underlying cause of death in Part I	

Thus, pulmonary infarct is the immediate cause of death, pulmonary thromboembolism and deep leg vein thrombosis are each an intermediate cause of death, and essential thrombocytosis is the underlying cause of death. Underlying, intermediate, and immediate causes of death are linked in a sequential cause-and-effect relationship when read from bottom to top.

An intermediate cause of death should be stated as etiologically specifically as possible, realizing that it is not always possible to be completely specific. As illustrated by the example above, thromboembolism is fairly specific and identifies the nature of the embolus (thrombotic) from other types (such as air embolism), and is preferable to the less-specific phrase “pulmonary embolus.”

ATTACHMENT 5

Editorials

Death Certificates: Let's Get It Right

GEOFFREY R. SWAIN, M.D., M.P.H.,

GLORIA K. WARD, B.A.,

PAUL P. HARTLAUB, M.D., M.S.P.H.

University of Wisconsin Medical School and City of Milwaukee Health Department Milwaukee, Wisconsin

Am Fam Physician. 2005 Feb 15;71(4):652-656.

It would be difficult to overstate the importance of death certificates—especially in an era of increasing reliance on evidence-based medicine (EBM)—yet physicians receive inadequate training in this important area, and their performance on this task remains less than ideal.¹⁻³

For small and large populations, the definitive assessment of our success at prolonging life is the age-adjusted mortality rate, and the primary tool for measuring mortality rates is the death certificate. In addition, death certificates serve other essential functions (National Center for Health Statistics, Centers for Disease Control and Prevention [CDC] online at <http://www.cdc.gov/nchs>), including setting national, regional, statewide, and local priorities for funding, research, and interventions⁴; settling estates, closing bank accounts, selling stocks and bonds, and determining insurance and pension benefits; providing evidence in court cases; and providing outcome data for major research studies.

Accurate completion is essential to ensure the usefulness and reliability of the individual death certificate as well as the aggregate mortality statistics derived from it, yet data suggest that cause and manner of death are not reported in a consistent fashion. In one recent survey in which 198 experienced and trained medical examiners determined the manner of death for 23 scenarios, there was more than 90 percent agreement for only four scenarios, 13 scenarios had between 60 and 90 percent agreement, and the remaining six scenarios had less than 60 percent agreement.⁵

While the cause of death may be difficult to agree on sometimes, most problems with death certificates stem from failure to complete them correctly. Yet, these errors are avoidable. Myers and Farquhar showed that major errors on death certificates dropped from 32.9 to 15.7 percent ($P = .01$) after primary care physicians attended a 75-minute educational seminar.⁶ Lakkireddy and colleagues also showed that improved completion of death certificates correlated with specific training in that skill.⁷

Physicians without training in death certificates may not even understand the correct definitions of the following terms:

Manner of Death

The context or circumstances that surround the death; examples include accident, suicide, homicide, and natural causes. Typically, physicians can only certify natural deaths, while the coroner or medical examiner must make the final determination for suicides, homicides, and even accidents as common as drug overdoses or falls.

Immediate Cause of Death

The proximate, most recently developed, final diagnostic entity causing the death. Must be a specific etiology (e.g., *Escherichia coli* sepsis, acute renal failure, hypoxemia), not a general concept such as old age or terms like cardiac arrest or organ system failure that can have multiple etiologies.

Underlying Cause of Death

This is the fundamental, original, foundational diagnosis or condition from which the remainder of the etiologic sequence springs; it is the diagnosis of longest duration in the chain of events leading directly to death. Examples include human immunodeficiency virus infection (the underlying cause of acquired immunodeficiency syndrome), coronary artery atherosclerosis, and metastatic breast cancer. The description must be specific enough to make clear why the intermediate (if any) and immediate causes of death developed.

In almost all cases, a time-linked chain of causation can be established, such that the immediate cause of death was a consequence of a somewhat longer-duration diagnosis, which in turn was a consequence of an even longer-duration diagnosis, and so on through as many or few intermediate causes as necessary until reaching the true underlying cause of death. Other significant, but not directly linked, conditions must be listed separately.

Common errors in completion of death certificates include incorrect attribution of the immediate cause of death, listing causes in an incorrect or illogical order, multiple competing immediate causes of death, poor match between cause and manner of death, and failure to identify the true underlying cause or causes.^{3,9} Consider these examples:

- Manner: Natural. Cause: Ventricular fibrillation, due to acute myocardial infarction, due to coronary artery thrombosis, as a consequence of atherosclerotic coronary artery disease. [Satisfactory: Note plausible chain of causality.]
- Manner: Natural. Cause: Pneumonia, due to a hip fracture, due to chronic obstructive pulmonary disease, as a consequence of diabetes mellitus and hypertension. [Unsatisfactory: No causal chain; possibly competing immediate causes; etiology of pneumonia unspecified; hip fracture is usually accidental, not natural; hypertension (in this case) and other diagnoses not in the direct causal chain should be listed in Part II, Other Significant Conditions.]

- Manner: Natural. Cause: Staphylococcal sepsis, due to methicillin-resistant staphylococcal pneumonitis, due to chronic aspiration, secondary to swallowing dysfunction, as a consequence of Parkinson's disease. [Satisfactory: Note clear and plausible chain of causality.]
- Manner: Natural. Cause: Congestive heart failure, as a consequence of ileostomy. [Unsatisfactory: No chain of causality; no clear underlying cause of the ileostomy or the heart failure.]

State statutes govern physician certification of cause of death and provide penalties for failure to complete in a timely or acceptable fashion. States require, and families depend on, certificates that are legible and clearly reproducible by photocopy and microfilm. Only permanent black ink should be used, erasures and "white-out" are not acceptable, and abbreviations should not be used. The physician who knew the decedent the best, or the attending physician, is responsible for completing the death certificate. A "probable" diagnosis is acceptable, as is listing a metastatic carcinoma of unknown primary site as an underlying cause. However, there is no "uncertain" or "unknown" category for cause of death; such cases should be referred to the medical examiner.

Based on the available data, we call for all medical students and residents to be trained to fill out death certificates correctly; for in-training, licensing, and certification examinations to assess competence in this area; and for practicing physicians to review death certificates as a part of their ongoing commitment to continuing medical education and quality of care. Excellent resources include information at the CDC⁸⁹ and many state and local health department Web sites, online tutorials by the National Association of Medical Examiners (http://www.thename.org/CauseDeath/COD_main_page.htm), and the Texas Department of Health (<http://www.dshs.state.tx.us>), and references 1, 2, and 6 listed below.

GEOFFREY R. SWAIN, M.D., M.P.H., is associate medical director for the City of Milwaukee Health Department. Dr. Swain also is a scientist at the Center for Urban Population Health and visiting associate professor in the Department of Family Medicine at the University of Wisconsin Medical School, Milwaukee Clinical Campus.

GLORIA K. WARD, B.A., is deputy registrar for the City of Milwaukee, and supervisor of the Vital Statistics Section at the City of Milwaukee Health Department.

PAUL P. HARTLAUB, M.D., M.S.P.H., is associate professor in the Department of Family Medicine at the University of Wisconsin Medical School, Milwaukee Clinical Campus. He also is associate medical director for care management and preventive services at Aurora Health Care in Milwaukee.

Address correspondence to Geoffrey R. Swain, M.D., M.P.H., City of Milwaukee Health Dept., 841 N. Broadway, Room 315, Milwaukee, WI 53202 (e-mail: gswain@milwaukee.gov). Reprints are not available from the authors.

ATTACHMENT 6

Pennsylvania Slashes Virus Death Toll; Reopening Explained

The administration of Gov. Tom Wolf is cautioning that a declining case count is just one factor that officials will consider in deciding whether a region of the state is ready to begin emerging from the pandemic.

By [Associated Press](#), Wire Service Content April 23, 2020, at 8:46 p.m.

BY MICHAEL RUBINKAM, MARK SCOLFORO and MARC LEVY,
Associated Press

HARRISBURG, Pa. (AP) — The administration of Gov. Tom Wolf cautioned Thursday that a declining case count is just one factor that officials will consider in deciding whether a region of the state is ready to begin emerging from the pandemic.

Wolf's reopening plan divides counties into six geographic regions, where shutdown rules may be relaxed once fewer than one person in 2,000 has been infected over the past two weeks.

Wolf said he believes two regions — the northcentral and northwest, both of which have seen relatively few cases — will be ready for a limited reopening on May 8, with residents permitted to leave their homes at will, and some retail shops allowed to accept customers.

But the case count isn't the only metric, officials said Thursday. The availability of diagnostic testing, the capacity of the health care system and the ability to quickly identify and contain flareups through what's known as contact tracing will also play a role. The state health department will also use a new modeling tool by Carnegie Mellon University.

A manageable number of new virus infections each day will be "very important, it's something we can measure and put down on paper, but it's not the only measure that we're going to be looking at," said the state health secretary, Dr. Rachel Levine.

Even in areas where some semblance of normalcy returns, Levine said she still wants people to wear masks in public and to keep their distance from each other to help prevent a resurgence of the virus.

Wolf, in a separate briefing, predicted that Pennsylvania's hard-hit southeast region will be the last to emerge from pandemic restrictions.

The Wolf standard is more stringent than reopening guidelines issued by the White House, which only call for a downward trajectory of documented cases over a 14-day period. Wolf, a Democrat, is under pressure from GOP lawmakers to open up more quickly and more broadly.

Other coronavirus-related developments in Pennsylvania:

DEATH TOLL SLASHED

The Pennsylvania Department of Health slashed the state's COVID-19 death toll on Thursday by 201, saying probable deaths it had previously included in the count were eliminated after further investigation.

The overall death toll now stands at 1,421, down from 1,622 reported a day earlier.

The number of deaths confirmed by a positive virus test actually rose overnight by 69, to 1,394. But Levine said Thursday that 270 probable deaths that had been added to the death toll in recent days have been removed after further investigation.

"This verification process is very intensive and under normal circumstances it can take months to complete," she said. "We continue to refine the data that we are collecting to provide everyone this information in as near time as we possibly can. This is really difficult with thousands of reports each day."

State health officials had recently changed the way they count COVID-19 deaths — now including probable deaths along with confirmed deaths — which resulted in a doubling of the state's death toll in just four days. A probable death is one in which a coroner or medical examiner listed COVID-19 as the cause or contributing cause, but the deceased was not tested for the virus.

Officials have said they are trying to reconcile data provided by hospitals, health care systems, county and municipal health departments and long-term care living facilities with the department's own records. Some county coroners have accused the state Department of Health of botching the numbers.

Statewide, more than 1,369 additional people tested positive for the virus that causes COVID-19, bringing the statewide total to more than 37,000, the health department reported Thursday.

Copyright 2020 The [Associated Press](#). All rights reserved. This material may not be published, broadcast, rewritten or redistributed.

ATTACHMENT 7

As coronavirus deaths become political flashpoint, Colorado changes how COVID-19 fatalities are publicly reported

By [JESSICA SEAMAN](#) | jseaman@denverpost.com and [ALEX BURNES](#) | aburness@denverpost.com | The Denver Post

PUBLISHED: May 15, 2020 at 9:45 p.m. | UPDATED: May 16, 2020 at 12:01 p.m.

State representative seeks criminal investigation of Colorado's public health director over allegations of falsified death data

Colorado's health department changed the way it publicly reports coronavirus deaths Friday, introducing a second category of fatalities after its methods came under scrutiny — including by a state representative who's calling for the agency's chief to be investigated.

How COVID-19 deaths are counted has become politically divisive, with critics claiming the numbers are inflated and medical experts saying deaths may actually be undercounted. Still, the number of deaths is a crucial data point that informs public understanding of the pandemic's severity and health officials' response to the crisis.

The Colorado Department of Public Health and Environment is now clarifying that its death tally includes the total number of fatalities among people who had COVID-19, including those deaths in which the respiratory disease was not the cause of death listed on the death certificate.

By the agency's count, there were 1,150 people who had died with COVID-19 in their systems as of Thursday.

Unlike that total, which has been updated daily by the agency since the start of the outbreak, death certificate data only shows 878 deaths were

caused by the new coronavirus between Feb. 1 and May 9 — but that number is expected to increase as there is a several-week lag.

“It’s what we know today as the number of deaths due to COVID based on death certificates,” said Chief Medical Officer Dr. Eric France, adding, “Either way the numbers are too high and there’s more to be done. We should be focusing as much as ever on what we can do to control the spread.”

Rep. Mark Baisley this week alleged the Department of Public Health and Environment has falsified the number of people who have died from COVID-19. The allegation comes amid reports that the health department counted some deaths as having been caused by the new coronavirus despite rulings from physicians and coroners that say otherwise.

“For a state agency to come in and start reclassifying causes of death is unusual and kind of disturbs a whole lot of people,” said Baisley, R-Roxborough Park.

Baisley sent a letter dated Thursday to 18th Judicial District Attorney George Brauchler, requesting an investigation “with the intent of bringing criminal charges against” Jill Hunsaker Ryan, the executive director of the state health department. Baisley’s letter was spurred by what he called a “disturbing” discrepancy in reporting at an Arapahoe County nursing home.

On Friday, Baisley said Brauchler has assigned a senior deputy district attorney to the investigation into potentially altered death certificates.

In a statement released by his office, Brauchler declined to discuss the details of any possible investigation. However, if it is determined that death certificates were altered “it is possible that misdemeanor charges would be filed,” the statement said.

Officials with the Department of Public Health and Environment said Friday they are not altering death certificates, but noted it is difficult to track deaths during such a large public health crisis.

“When COVID-19 is reported as a cause of death on the death certificate, more than likely it will be determined to be the underlying cause of death and contribute to those underlying mortality statistics,” said Kirk Bol,

manager of the vital statistics program, during a news conference. “But again, if COVID-19 was not determined to be part of the cause of death it should not be reported on the death certificate.”

How deaths are counted

Public health and medical experts have said counting deaths caused by the outbreak is tricky given a lack of sufficient testing and lags in reporting death certificate data. The accuracy of tests for COVID-19 also has been thrown into question, especially concerning false negatives.

Officials with the Department of Public Health and Environment said they are required by the U.S. Centers for Disease Control and Prevention to track and report the number of deaths among people with COVID-19, including those in which the coronavirus is not listed as a cause of death on their death certificate.

This information, according to the state agency’s website, is important to public health officials as it tells them about the transmission of the new coronavirus and can identify who is at risk of dying from complications from the disease.

Tracking a broader set of data as it relates to COVID-19 and deaths also enables the health agency to compare the epidemic’s toll in Colorado to that in other states that are following the CDC’s directive, public health officials said.

“On one hand we’re identifying and classifying cause of death by COVID,” France said. “And the other hand, we’re doing the important public health work by identifying cases, who also have died while they had COVID, either from it, or from something else, which is important as we do apples to apples comparisons across the state.”

But there have been questions about the accuracy of how the health department is tracking deaths where the disease is not the direct or partial cause of death.

Montezuma County Coroner George Deavers said he had a case, first reported by 9News, in which a man died with COVID-19 but had a blood-

alcohol level of 550 mg, well above the lethal amount. As a result, Deavers ruled the death was from alcohol poisoning. But, he said, the Department of Public Health and Environment counted it among its broader number of 1,150 COVID-19 deaths.

“I feel the state was wrong,” he said, adding, “If it’s a COVID death, it needs to be reported as a COVID death. If it’s not a COVID death, it doesn’t need to be reported as a COVID death. I’m not trying to pad the deaths one way or another.”

COVID-19 is considered the cause of death when a person dies from a complication from the disease, such as pneumonia or respiratory failure, and would not have died at that time or place without the coronavirus. This includes people with underlying illnesses, such as lung and heart diseases.

But making these decisions on the cause of death can be complex. In La Plata County, Coroner Jann Smith had a case involving a person who had a long history of heart issues and while at the hospital tested positive for COVID-19.

Once the patient went home under hospice care, he tested negative. So when the individual died, Smith determined the heart issues were the cause of death.

“If he would have come back positive again, I might have done something different,” she said, adding, “I won’t say it was an easy decision. That was my decision and I’m comfortable with it.”

Still, the health department included the death in its tally of COVID-19 fatalities.

“They have their guidelines to go by, and I have my decisions,” Smith said. “I respect them for theirs.”

The case of Someren Glen

Baisley’s call for an investigation into the state health director was inspired by an April 17 letter written by Tim Rogers, executive director of the Someren Glen retirement community. The letter, which went to residents and their families, said the Centennial facility was aware of four residents whose deaths were confirmed to be related to COVID-19.

Somer Glen's attending physician, Rogers wrote, determined other recent deaths, including at least one of a resident who tested positive for the virus, were not caused by the coronavirus.

However, he said, the Department of Public Health and Environment counted at least seven resident deaths from the coronavirus — three more than his staff had calculated — and was deciding whether to include a potential eighth death that a physician had ruled was not COVID-related.

“(W)e were informed of their intention to override some of our attendant physician’s rulings and reclassify some resident passings we have experienced in the past few weeks,” Rogers wrote, adding, “We have never seen a situation where the health department overrules a physician’s findings. However, these are unprecedented times and the health department official did not share their motivation for changing physician’s orders.”

Pam Sullivan, spokeswoman for Somer Glen, said the purpose of the letter was to be “transparent.”

“The intention of our letter was to inform residents, families and team members that there would be a change in the numbers we were reporting of residents who had passed directly related to the COVID-19 virus due to re-classifications made by the Colorado Department of Public Health and Environment,” she said in a statement. “We have no involvement in the classification or re-classification of a resident who passes at our communities.”

France, the state’s chief medical officer, said he didn’t have details of the Somer Glen deaths. Cause-of-death determinations on death certificates are medical opinions by the coroner or a medical examiner or physician “and there isn’t a process by which we review and change them at the Department of Public Health,” he said

But Baisley characterized what happened as “government imposition, overreach, in a very intimate way.”

“You don’t mess with people’s families like that,” Baisley said. “Boy, for a state to come in and say, ‘We’re going to change (a cause of death) to

COVID-19,' because of whatever their motivations are, why would you do that?"

ATTACHMENT 8

NEW YORK N.Y.C. Death Toll Soars Past 10,000 in Revised Virus Count

•
•

Death Toll Soars Past 10,000 in Revised Virus Count

The city has added more than 3,700 additional people who were presumed to have died of the coronavirus but had never tested positive.



By J. David Goodman and William K. Rashbaum

• Published April 14, 2020 Updated April 21, 2020b New York Times

○
○

New York City, already a world epicenter of the [coronavirus](#) outbreak, sharply increased its death toll by more than 3,700 victims on Tuesday, after officials said they were now including people who had never tested positive for the virus but were presumed to have died of it.

The new figures, released by the city's Health Department, [drove up the number of people killed in New York City to more than 10,000](#), and appeared to increase the overall United States death count by 17 percent to more than 26,000.

Coronavirus Deaths in New York City

The numbers brought into clearer focus the staggering toll the virus has already taken on the largest city in the United States, where deserted streets are haunted by the near-constant howl of ambulance sirens. Far more people have died in [New York City](#), on a per-capita basis, than in Italy — the hardest-hit country in Europe.

And in a city reeling from the overt danger posed by the virus, top health officials said they had identified another grim reality: The outbreak is likely to have also led indirectly to a spike in [deaths](#) of New Yorkers who may never have been infected.

Three thousand more people died in New York City between March 11 and April 13 than would have been expected during the same time period in an ordinary year, Dr. Oxiris Barbot, the commissioner of the city Health Department, said in an interview. While these so-called excess deaths were not explicitly linked to the virus, they might not have happened had the outbreak not occurred, in part because it overwhelmed the normal health care system.

“This is yet another part of the impact of Covid,” she said, adding that more study was needed. Similar analysis is commonly done after heat waves and was performed [in the wake of Hurricane Maria in Puerto Rico](#).

“What New Yorkers are interested in, and what the country is interested in, is that we have an accurate and complete count,” Dr. Barbot added. “It’s part of the healing process that we’re going to have to go through.”

The revised death toll renewed focus on shortcomings in testing that have hamstrung city and state officials [since the beginning of the outbreak](#). A limited number of tests have been available, and until now, only deaths where a person had tested positive were officially counted among those killed by the virus in New York.

They were not included in the counts given publicly by Mayor Bill de Blasio because no tests had confirmed that the victims had the disease, Covid-19.

Mr. de Blasio decided, after another round of briefings over the weekend, to release the presumptive cases, the people said. Most of the added deaths took place in hospitals,

according to the data. Others occurred in nursing homes or other long-term care facilities and in residences.

“In the heat of battle, our primary focus has been on saving lives,” said Freddi Goldstein, the mayor’s press secretary. “As soon as the issue was raised, the mayor immediately moved to release the data.”

In California and Washington — locations of early cases in the American outbreak — officials said they included deaths as connected to Covid-19 only when the disease was confirmed by testing. Louisiana and Chicago followed the same protocol.

The new numbers in New York cover the weeks between March 11 to April 13, beginning at a time when the virus had already been spreading throughout the city and its surrounding suburbs. Mr. de Blasio and Gov. Andrew M. Cuomo shut down large swaths of the city and state by the third week of March.

New York City has been reporting the probable cases to the federal National Center for Health Statistics for more than a week, health officials said. But Dr. Barbot said that the city would continue reporting only confirmed cases to the Centers for Disease Control and Prevention for its coronavirus tracker, because the agency requested those statistics. “We are more than happy to report on probables,” she said.

The C.D.C., in its guidance to local governments, has recommended that cases of “assumed” coronavirus infection be noted on death certificates since before New York City recorded its first death on March 14.

ATTACHMENT 9

ICD-10-CM Official Coding and Reporting Guidelines
April 1, 2020 through September 30, 2020

1. Chapter 1: Certain Infectious and Parasitic Diseases (A00-B99)

g. Coronavirus Infections

1) COVID-19 Infections (Infections due to SARS-CoV-2)

a) Code only confirmed cases

Code only a confirmed diagnosis of the 2019 novel coronavirus disease (COVID-19) as documented by the provider, documentation of a positive COVID-19 test result, or a presumptive positive COVID-19 test result. For a confirmed diagnosis, assign code U07.1, COVID-19. This is an exception to the hospital inpatient guideline Section II, H. In this context, “confirmation” does not require documentation of the type of test performed; the provider’s documentation that the individual has COVID-19 is sufficient.

Presumptive positive COVID-19 test results should be coded as confirmed. A presumptive positive test result means an individual has tested positive for the virus at a local or state level, but it has not yet been confirmed by the Centers for Disease Control and Prevention (CDC). CDC confirmation of local and state tests for COVID-19 is no longer required.

If the provider documents "suspected," "possible," "probable," or “inconclusive” COVID-19, do not assign code U07.1. Assign a code(s) explaining the reason for encounter (such as fever) or Z20.828, Contact with and (suspected) exposure to other viral communicable diseases.

b) Sequencing of codes

When COVID-19 meets the definition of principal diagnosis, code U07.1, COVID-19, should be sequenced first, followed by the appropriate codes for associated manifestations, except in the case of obstetrics patients as indicated in Section . I.C.15.s. for COVID-19 in pregnancy, childbirth, and the puerperium.

For a COVID-19 infection that progresses to sepsis, see Section I.C.1.d. Sepsis, Severe Sepsis, and Septic Shock

See Section I.C.15.s. for COVID-19 in pregnancy, childbirth, and the puerperium

c) Acute respiratory illness due to COVID-19

(i) Pneumonia

For a pneumonia case confirmed as due to the 2019 novel coronavirus (COVID-19), assign codes U07.1, COVID-19, and J12.89, Other viral pneumonia.

(ii) Acute bronchitis

For a patient with acute bronchitis confirmed as due to COVID-19, assign codes U07.1, and J20.8, Acute bronchitis due to other specified organisms.

Bronchitis not otherwise specified (NOS) due to COVID-19 should be coded using code U07.1 and J40, Bronchitis, not specified as acute or chronic.

(iii) Lower respiratory infection

If the COVID-19 is documented as being associated with a lower respiratory infection, not otherwise specified (NOS), or an acute respiratory infection, NOS, codes U07.1 and J22, Unspecified acute lower respiratory infection, should be assigned.

If the COVID-19 is documented as being associated with a respiratory infection, NOS, codes U07.1 and J98.8, Other specified respiratory disorders, should be assigned.

(iv) Acute respiratory distress syndrome

For acute respiratory distress syndrome (ARDS) due to COVID-19, assign codes U07.1, and J80, Acute respiratory distress syndrome.

d) Exposure to COVID-19

For cases where there is a concern about a possible exposure to COVID-19, but this is ruled out after evaluation, assign code Z03.818, Encounter for observation for suspected exposure to other biological agents ruled out.

For cases where there is an actual exposure to someone who is confirmed or suspected (not ruled out) to have COVID-19, and the exposed individual either tests negative or the test results are unknown, assign code Z20.828, Contact with and (suspected) exposure to other viral communicable diseases. If the exposed individual tests positive for the COVID-19 virus, see guideline a).

e) Screening for COVID-19

For asymptomatic individuals who are being screened for COVID-19 and have no known exposure to the virus, and the test results are either unknown or negative, assign code Z11.59, Encounter for screening for other viral diseases. For individuals who are being screened due to a possible or actual exposure to COVID-19, see guideline d).

If an asymptomatic individual is screened for COVID-19 and tests positive, see guideline g).

f) Signs and symptoms without definitive diagnosis of COVID-19

For patients presenting with any signs/symptoms associated with COVID-19 (such as fever, etc.) but a definitive diagnosis has not been established, assign the appropriate code(s) for each of the presenting signs and symptoms such as:

- R05 Cough
- R06.02 Shortness of breath
- R50.9 Fever, unspecified

If a patient with signs/symptoms associated with COVID-19 also has an actual or suspected contact with or exposure to someone who has COVID-19, assign Z20.828, Contact with and (suspected) exposure to other viral communicable diseases, as an additional code. This is an exception to guideline I.C.21.c.1, Contact/Exposure.

g) Asymptomatic individuals who test positive for COVID-19

For asymptomatic individuals who test positive for COVID-19, assign code U07.1, COVID-19. Although the individual is asymptomatic, the individual has tested positive and is considered to have the COVID-19 infection.

15. Chapter 15: Pregnancy, Childbirth, and the Puerperium (O00-O9A)

s) COVID-19 infection in pregnancy, childbirth, and the puerperium

During pregnancy, childbirth or the puerperium, a patient admitted (or presenting for a health care encounter) because of COVID-19 should receive a principal diagnosis code of O98.5-, Other viral diseases complicating pregnancy, childbirth and the puerperium, followed by code U07.1, COVID-19, and the appropriate codes for associated manifestation(s). Codes from Chapter 15 always take sequencing priority.

ATTACHMENT 10

Final Guidance for Certifying COVID-19 Deaths

Minnesota Department of Health <mdh@public.govdelivery.com>

Thu, Apr 9, 2020 at 3:39 PM

Reply-To: mdh@public.govdelivery.com
To: smj2203@gmail.com

Final Guidance for Certifying COVID-19 Deaths

On April 2, 2020, the National Center for Health Statistics (NCHS) released [Guidance for Certifying Deaths Due to Coronavirus Disease 2019 \(COVID-19\) \(PDF\)](#). This replaces guidance released earlier in March.

For your convenience, we created a two-page version of the NCHS guidance. [Certifying Deaths Due to COVID-19 \(PDF\)](#) is also available on the [Death Registration Information for Medical Certifiers](#) website.

Timely and accurate death registration is important. The MDH Office of Vital Records wants medical certifiers to be aware of the final guidance and ready to report COVID-19 confirmed deaths and COVID-19 related deaths accurately.

Visit the Minnesota [Coronavirus Disease 2019 \(COVID-19\)](#) webpages for situation updates and other information for health professionals, the public, schools, businesses and employers.

- [certcovidthsf.pdf](#)

You can update or cancel your subscription at any time by [editing your personal profile](#). All you will need are your email address and your password (if you have selected one).

P.S. If you have any questions or problems please contact [subscriberhelp.govdelivery.com](#) for assistance.

STAY CONNECTED:



[MDH on Twitter](#)

[MDH on Facebook](#)

[MDH on LinkedIn](#)

This email was sent to [smj2203@gmail.com](#) using GovDelivery Communications Cloud on behalf of: Minnesota Department of Health · [625 Robert Street North · St. Paul MN 55155](#) · 651-201-5000

GOVDELIVERY



certcovidthsf.pdf

179K [View as HTML](#) [Download](#)

ATTACHMENT 11

Certifying Deaths Due to COVID-19

This information is from CDC's [Guidance for Certifying Deaths Due to Coronavirus Disease 2019 \(COVID-19\) \(PDF\)](#). See example certifications for deaths due to COVID-19 on pages 4-6 in the guidance above.

Cause of Death Part I – COVID-19

- If COVID-19 played a role in the death, **specify COVID-19 or Coronavirus Disease 2019**.
 - If a medical certifier reports “coronavirus” alone *without identifying a specific strain or without explicitly excluding COVID-19* the Office of Vital Records will contact the medical certifier.
- In many cases, COVID-19 will be the underlying cause of death (UCOD), as it can lead to pneumonia and acute respiratory distress syndrome (ARDS).
 - Report pneumonia or ARDS (and similar) on the lines *above* COVID-19.
 - Report COVID-19 on the lowest line used in Part I.
- If a diagnosis of COVID-19 is suspected or likely “...it is acceptable to report COVID-19 as ‘probable’ or ‘presumed’.”
- If test results for COVID-19 are pending, file the cause of death as “COVID-19, test results pending.” When the test results come back, whether positive or negative for COVID-19, complete the [Request to Change Cause or Manner of Death \(PDF\)](#) form to update the cause of death statement. The Office of Vital Records sends updated records to the National Center for Health Statistics (NCHS) to make national mortality statistics and Minnesota’s mortality data as accurate as possible.

Cause of Death, Part I – General information

A cause-of-death statement is an informed medical opinion based on sound medical judgment drawn from clinical training and experience, as well as knowledge of current disease states and local trends.

- Report the immediate cause of death on line “a.” The immediate cause of death:
 - Is not necessarily the UCOD.
 - Is not the mechanism of death (for example, cardiac or respiratory arrest).
- Report the sequence of conditions that led directly to death with the most recent condition on line “a.”
- Report the UCOD on the lowest line used in Cause of Death, Part I.
- UCOD means “the disease or injury which initiated the train of morbid events leading directly to death.”

Time interval: Onset to Death

For each condition reported in Part I, report the time interval between the presumed onset of the condition (not the diagnosis), and death.

Cause of Death, Part II

In Part II, report other significant conditions that contributed to the death but are not a part of the sequence in Part I.

- Report only the conditions that actually contributed to death.
- COPD and asthma do not cause COVID-19 “but can increase the risk of contracting a respiratory infection and death.” Report these and similar conditions in Cause of Death, Part II.

Minnesota Department of Health
Office of Vital Records
85 East 7th Place
PO Box 64499
St. Paul, MN 55164-0499
651-201-5970
health.vitalrecords@state.mn.us
www.health.state.mn.us

04/06/2020

To obtain this information in a different format, call 651-201-5970.

ATTACHMENT 12

New Video Guidance for Certification of COVID-19 Deaths and Updated COVID-19 Coding Rules

Minnesota Department of Health <mdh@public.govdelivery.com>

Thu, May 7, 2020 at 7:31 AM

Reply-To: mdh@public.govdelivery.com

To: smj2203@gmail.com

Attention medical certifiers and designated staff:

The Office of Vital Records recently received the following information from the National Vital Statistics System at CDC about certifying COVID-19 deaths.

If you have questions about the material below, please contact health.dataquality@state.mn.us.

COVID-19 Alert No. 5

New Video Guidance for Certification of COVID-19 Deaths and Updated COVID-19 Coding Rules

May 5, 2020

New Video Guidance for Certification of COVID-19 Deaths

To supplement the published guidance on filling out death certificates for deaths related to COVID-19, the National Center for Health Statistics (NCHS) has released a short video on the NCHS YouTube channel. The video runs a little over 3 minutes and can be accessed directly at <https://www.youtube.com/watch?v=oL3VMwieAms>.

Updated COVID-19 Coding Rules

The National Center for Health Statistics (NCHS) is updating how it will be coding the term “COVID” without an indication of the specific strain reported on the death certificate. Previously, “COVID” was treated as a generic abbreviation for Coronavirus Disease and was coded B34.2 (Coronavirus infection, unspecified site). Since NCHS’ original coding rules were issued, “COVID” has become an accepted shorthand for the more precise “COVID-

19.” In response, to this change NCHS is changing its coding rules and will now be coding “COVID” to U07.1 (COVID-19). NCHS will also be reviewing and recoding as necessary all 2020 deaths previously coded B34.2.

Other more general terms (e.g. “Coronavirus”) without an indication of the specific strain will continue to be coded to B34.2. NCHS will query the jurisdiction about B34.2 deaths. If the jurisdiction indicates that COVID-19 caused or contributed to the death the coding will be changed to U07.1

You can update or cancel your subscription at any time by [editing your personal profile](#). All you will need are your email address and your password (if you have selected one).

P.S. If you have any questions or problems please contact subscriberhelp.govdelivery.com for assistance.

STAY CONNECTED:



[MDH on Twitter](#)

[MDH on Facebook](#)

[MDH on LinkedIn](#)

This email was sent to smj2203@gmail.com using GovDelivery Communications Cloud on behalf of: Minnesota Department of Health · (Robert Street North · St. Paul MN 55155 · 651-201-5000

govd

ATTACHMENT 13

EDITORIAL



Covid-19 — Navigating the Uncharted

Anthony S. Fauci, M.D., H. Clifford Lane, M.D., and Robert R. Redfield, M.D.

The latest threat to global health is the ongoing outbreak of the respiratory disease that was recently given the name Coronavirus Disease 2019 (Covid-19). Covid-19 was recognized in December 2019.¹ It was rapidly shown to be caused by a novel coronavirus that is structurally related to the virus that causes severe acute respiratory syndrome (SARS). As in two preceding instances of emergence of coronavirus disease in the past 18 years² — SARS (2002 and 2003) and Middle East respiratory syndrome (MERS) (2012 to the present) — the Covid-19 outbreak has posed critical challenges for the public health, research, and medical communities.

In their *Journal* article, Li and colleagues³ provide a detailed clinical and epidemiologic description of the first 425 cases reported in the epicenter of the outbreak: the city of Wuhan in Hubei province, China. Although this information is critical in informing the appropriate response to this outbreak, as the authors point out, the study faces the limitation associated with reporting in real time the evolution of an emerging pathogen in its earliest stages. Nonetheless, a degree of clarity is emerging from this report. The median age of the patients was 59 years, with higher morbidity and mortality among the elderly and among those with coexisting conditions (similar to the situation with influenza); 56% of the patients were male. Of note, there were no cases in children younger than 15 years of age. Either children are less likely to become infected, which would have important epidemiologic implications, or their symptoms were so mild that their infection escaped detection, which has implications for the size of the denominator of total community infections.

On the basis of a case definition requiring a

diagnosis of pneumonia, the currently reported case fatality rate is approximately 2%.⁴ In another article in the *Journal*, Guan et al.⁵ report mortality of 1.4% among 1099 patients with laboratory-confirmed Covid-19; these patients had a wide spectrum of disease severity. If one assumes that the number of asymptomatic or minimally symptomatic cases is several times as high as the number of reported cases, the case fatality rate may be considerably less than 1%. This suggests that the overall clinical consequences of Covid-19 may ultimately be more akin to those of a severe seasonal influenza (which has a case fatality rate of approximately 0.1%) or a pandemic influenza (similar to those in 1957 and 1968) rather than a disease similar to SARS or MERS, which have had case fatality rates of 9 to 10% and 36%, respectively.²

The efficiency of transmission for any respiratory virus has important implications for containment and mitigation strategies. The current study indicates an estimated basic reproduction number (R_0) of 2.2, which means that, on average, each infected person spreads the infection to an additional two persons. As the authors note, until this number falls below 1.0, it is likely that the outbreak will continue to spread. Recent reports of high titers of virus in the oropharynx early in the course of disease arouse concern about increased infectivity during the period of minimal symptoms.^{6,7}

China, the United States, and several other countries have instituted temporary restrictions on travel with an eye toward slowing the spread of this new disease within China and throughout the rest of the world. The United States has seen a dramatic reduction in the number of travelers from China, especially from Hubei province.

At least on a temporary basis, such restrictions may have helped slow the spread of the virus: whereas 78,191 laboratory-confirmed cases had been identified in China as of February 26, 2020, a total of 2918 cases had been confirmed in 37 other countries or territories.⁴ As of February 26, 2020, there had been 14 cases detected in the United States involving travel to China or close contacts with travelers, 3 cases among U.S. citizens repatriated from China, and 42 cases among U.S. passengers repatriated from a cruise ship where the infection had spread.⁸ However, given the efficiency of transmission as indicated in the current report, we should be prepared for Covid-19 to gain a foothold throughout the world, including in the United States. Community spread in the United States could require a shift from containment to mitigation strategies such as social distancing in order to reduce transmission. Such strategies could include isolating ill persons (including voluntary isolation at home), school closures, and telecommuting where possible.⁹

A robust research effort is currently under way to develop a vaccine against Covid-19.¹⁰ We anticipate that the first candidates will enter phase 1 trials by early spring. Therapy currently consists of supportive care while a variety of investigational approaches are being explored.¹¹ Among these are the antiviral medication lopinavir–ritonavir, interferon-1 β , the RNA polymerase inhibitor remdesivir, chloroquine, and a variety of traditional Chinese medicine products.¹¹ Once available, intravenous hyperimmune globulin from recovered persons and monoclonal antibodies may be attractive candidates to study in early intervention. Critical to moving the field forward, even in the context of an outbreak, is ensuring that investigational products are evaluated in scientifically and ethically sound studies.¹²

Every outbreak provides an opportunity to gain important information, some of which is associated with a limited window of opportunity. For example, Li et al. report a mean interval of 9.1 to 12.5 days between the onset of illness and hospitalization. This finding of a delay in the progression to serious disease may be telling us something important about the pathogenesis of this new virus and may provide a unique window of opportunity for intervention. Achieving a better understanding of the pathogenesis of this disease will be invaluable in navigating our re-

sponses in this uncharted arena. Furthermore, genomic studies could delineate host factors that predispose persons to acquisition of infection and disease progression.

The Covid-19 outbreak is a stark reminder of the ongoing challenge of emerging and reemerging infectious pathogens and the need for constant surveillance, prompt diagnosis, and robust research to understand the basic biology of new organisms and our susceptibilities to them, as well as to develop effective countermeasures.

Disclosure forms provided by the authors are available with the full text of this editorial at NEJM.org.

From the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD (A.S.F., H.C.L.); and the Centers for Disease Control and Prevention, Atlanta (R.R.R.).

This editorial was published on February 28, 2020, at NEJM.org.

1. Pneumonia of unknown cause — China: disease outbreak news. Geneva: World Health Organization, January 5, 2020 (<https://www.who.int/csr/don/05-january-2020-pneumonia-of-unknown-cause-china/en/>).
2. de Wit E, van Doremalen N, Falzarano D, Munster VJ. SARS and MERS: recent insights into emerging coronaviruses. *Nat Rev Microbiol* 2016;14:523-34.
3. Li Q, Guan X, Wu P, et al. Early transmission dynamics in Wuhan, China, of novel coronavirus–infected pneumonia. *N Engl J Med* 2020;382:1199-207.
4. Coronavirus disease 2019 (COVID-19): situation report — 36. Geneva: World Health Organization, February 25, 2020 (https://www.who.int/docs/default-source/coronavirus/situation-reports/20200225-sitrep-36-covid-19.pdf?sfvrsn=2791b4e0_2).
5. Guan W, Ni Z, Hu Y, et al. Clinical characteristics of coronavirus disease 2019 in China. *N Engl J Med*. DOI: 10.1056/NEJMoa2002032.
6. Holshue ML, DeBolt C, Lindquist S, et al. First case of 2019 novel coronavirus in the United States. *N Engl J Med* 2020;382:929-36.
7. Zou L, Ruan F, Huang M, et al. SARS-CoV-2 viral load in upper respiratory specimens of infected patients. *N Engl J Med* 2020;382:1177-9.
8. Coronavirus disease 2019 (COVID-19) in the U.S. Atlanta: Centers for Disease Control and Prevention, February 26, 2020 (<https://www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html>).
9. Fong MW, Gao H, Wong JY, et al. Nonpharmaceutical measures for pandemic influenza in nonhealthcare settings — social distancing measures. *Emerging Infect Dis* 2020;26(5) (Epub ahead of print).
10. DRAFT landscape of COVID-19 candidate vaccines — 18 February 2020. Geneva: World Health Organization (<https://www.who.int/blueprint/priority-diseases/key-action/list-of-candidate-vaccines-developed-against-ncov.pdf>).
11. WHO R&D blueprint: informal consultation on prioritization of candidate therapeutic agents for use in novel coronavirus 2019 infection. Geneva: World Health Organization, January 24, 2020 (<https://apps.who.int/iris/bitstream/handle/10665/330680/WHO-HEO-RDBlueprint%28nCoV%29-2020.1-eng.pdf>).
12. Lane HC, Marston HD, Fauci AS. Conducting clinical trials in outbreak settings: points to consider. *Clin Trials* 2016;13:92-5.

DOI: 10.1056/NEJMe2002387

Copyright © 2020 Massachusetts Medical Society.

ATTACHMENT 14

National infectious disease expert talks COVID-19 in Duluth

March 14, 2020 7:36 pm Beret Leone News, Top Stories

DULUTH, MN (KBJR) -- Dr. Michael Osterholm made a stop in Duluth Friday to discuss the Coronavirus, COVID-19.

"In so many ways we are handling this today as if it was a Minneapolis Blizzard. What we have to do is change that mindset because this is going to be more of a coronavirus winter. An entire season and we're just in the first weeks of it."

Preparing for the long-run with the Coronavirus. That's what the University of Minnesota-Twin Cities infectious disease specialist said about the expected outcome of the pandemic.

Dr. Osterholm is at the forefront of the COVID-19 conversation. Friday he told us what impacts the virus could have long-term.

Deadly strains of Influenza or the flu have been around for centuries.

The flu has become a pandemic more than once and killed millions of people.

It still exists today, but modern health experts are discussing what would happen if a new influenza virus showed up today, in world of 8-billion people

"Unfortunately we now have on our hands, but it's caused by a coronavirus which is acting very much like influenza," said Dr. Osterholm.

The infectious disease expert said the outbreak is bound to have a worse outcome than a bad flu season, which is indicated already.

He said, "problem is this isn't just a couple weeks of illness. And already in this country, we're projecting that the number of deaths from this disease could easily surpass a bad flu season by 20-30 fold."

Osterholm authored 2017 book, *Deadliest Enemy: Our War Against Killer Germs*. In the book, he details the most pressing infectious disease threats of our day.

He said the Coronavirus is transmitted in two ways. "Through just kind of close contact with someone and breathing their air and those droplets that you cough out land on a surface."

Osterholm said people need to take precautions. "We should not be scaring people out of their wits, we should be scaring people into their wits [...] We have to figure out how are we going to exist? Are we going to close down everything for 6-months?"

The Doctor says as a society, social distancing is important during an outbreak, but communities have to find ways to use their limited resources to help those most vulnerable to the infection.

"It's one where we can't change it, but we can sure help people understand what they can do to get throughout and we can get through it"

Doctor Osterholm said he expects the virus to die down in the coming months but we could still see cases until the fall.

He adds, medical professionals hope to create a vaccine that would eliminate the virus but that's still a way out.

Beret Leone

PERSONAL AND CONFIDENTIAL

July 27, 2020

Scott M. Jensen, M.D.
9375 Pierson Lake Drive
Chaska, MN 55318

RE: Complaints regarding COVID-19 public statements
Board File Nos: BFA05200976, BFA05200977

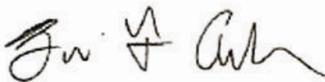
Dear Dr. Jensen:

As you will recall from previous contact, the Board of Medical Practice has conducted an investigation of two complaints that were filed against you in relation to public statements you made regarding COVID-19.

After a thorough review of both the Medical Practice Act and the facts of the situation, including those that you have provided, the Board has decided to dismiss the complaints and close its investigation at this time.

Thank you for your cooperation in this matter. If you have any questions, please feel free to contact me.

Sincerely,



Brian Anderson
Medical Regulations Analyst
612-548-2141
Brian.Anderson@state.mn.us

Attachment A.6

The infection fatality rate of COVID-19 inferred from seroprevalence data

John P.A. Ioannidis

Departments of Medicine, of Epidemiology and Population Health, of Biomedical Data Science,
and of Statistics and Meta-Research Innovation Center at Stanford (METRICS), Stanford

University, Stanford, CA, USA

E-mail: jioannid@stanford.edu

Funding: METRICS has been supported by a grant from the Laura and John Arnold Foundation

Disclosures: I am a co-author (not principal investigator) of one of the 23 seroprevalence studies.

ABSTRACT

Objective To estimate the infection fatality rate of coronavirus disease 2019 (COVID-19) from data of seroprevalence studies.

Methods Population studies with sample size of at least 500 and published as peer-reviewed papers or preprints as of July 11, 2020 were retrieved from PubMed, preprint servers, and communications with experts. Studies on blood donors were included, but studies on healthcare workers were excluded. The studies were assessed for design features and seroprevalence estimates. Infection fatality rate was estimated from each study dividing the number of COVID-19 deaths at a relevant time point by the number of estimated people infected in each relevant region. Correction was also attempted accounting for the types of antibodies assessed. Secondly, results from national studies were also examined from preliminary press releases and reports whenever a country had no other data presented in full papers or preprints.

Results 36 studies (43 estimates) were identified with usable data to enter into calculations and another 7 preliminary national estimates were also considered for a total of 50 estimates. Seroprevalence estimates ranged from 0.222% to 47%. Infection fatality rates ranged from 0.00% to 1.63% and corrected values ranged from 0.00% to 1.31%. Across 32 different locations, the median infection fatality rate was 0.27% (corrected 0.24%). Most studies were done in pandemic epicenters with high death tolls. Median corrected IFR was 0.10% in locations with COVID-19 population mortality rate less than the global average (<73 deaths per million as of July 12, 2020), 0.27% in locations with 73-500 COVID-19 deaths per million, and 0.90% in locations exceeding 500 COVID-19 deaths per million. Among people <70 years old, infection fatality rates ranged from 0.00% to 0.57% with median of 0.05% across the different locations (corrected median of 0.04%).

Conclusions The infection fatality rate of COVID-19 can vary substantially across different locations and this may reflect differences in population age structure and case-mix of infected and deceased patients as well as multiple other factors. Estimates of infection fatality rates inferred from seroprevalence studies tend to be much lower than original speculations made in the early days of the pandemic.

The infection fatality rate (IFR), the probability of dying for a person who is infected, is one of the most critical and most contested features of the coronavirus disease 2019 (COVID-19) pandemic. The expected total mortality burden of COVID-19 is directly related to the IFR. Moreover, justification for various non-pharmacological public health interventions depends crucially on the IFR. Some aggressive interventions that potentially induce also more pronounced collateral harms¹ may be considered appropriate, if IFR is high. Conversely, the same measures may fall short of acceptable risk-benefit thresholds, if the IFR is low.

Early data from China, adopted also by the World Health Organization (WHO),² focused on a crude case fatality rate (CFR) of 3.4%; CFR is the ratio of COVID-19 deaths divided by the number of documented cases, i.e. patients with symptoms who were tested and found to be PCR-positive for the virus. The WHO envoy who visited China also conveyed the message that there are hardly any asymptomatic infections.³ With a dearth of asymptomatic infections, the CFR approximates the IFR. Other mathematical models suggested that 40-70%,⁴ or even⁵ 81% of the global population would be infected. Influential mathematical models^{5,6} eventually dialed back to an IFR of 1.0% or 0.9%, and these numbers long continued to be widely cited and used in both public and scientific circles. The most influential of these models, constructed by Imperial College estimated 2.2 million deaths in the USA and over half a million deaths in the UK in the absence of lockdown measures.⁵ Such grave predictions justifiably led to lockdown measures adopted in many countries. With 0.9% assumed infection fatality rate and 81% assumed proportion of people infected, the prediction would correspond to a global number of deaths comparable with the 1918 influenza, in the range of 50 million fatalities.

Since late March 2020, many studies have tried to estimate the extend of spread of the virus in various locations by evaluating the seroprevalence, i.e. how many people in population samples have developed antibodies for the virus. These studies can be useful because they may

inform about the extent of under-ascertainment of documenting the infection based on PCR testing. Moreover, they can help obtain estimates about the IFR, since one can divide the number of observed deaths by the estimated number of people who are inferred to have been infected.

At the same time, seroprevalence studies may have several caveats in their design, conduct, and analysis that may affect their results and their interpretation. Here, data available as of July 11, 2020 were collected, scrutinized, and used to infer estimates of IFR in different locations where these studies have been conducted.

METHODS

Seroprevalence studies

The input data for the calculations of IFR presented here are studies of seroprevalence of COVID-19 that have been done in the general population, or in samples that might approximate the general population (e.g. with proper reweighting) and that have been published in peer-reviewed journals or have been submitted as preprints as of July 11, 2020. Only studies with at least 500 assessed samples were considered, since smaller datasets would entail extremely large uncertainty for any calculations to be based on them. When studies focused on making seroprevalence assessments at different time intervals, they were eligible if at least one time interval assessment had a sample size of at least 500 participants; among different eligible time points, the one with the highest seroprevalence was selected, since seroprevalence may decrease over time as antibody titers wane. Studies with data collected over more than a month, and that could not be broken into at least one eligible time interval that did not exceed one month in duration were excluded, since it would not be possible to estimate a point seroprevalence with any reliability. Studies were eligible regardless of the exact age range of included participants, but studies including only children were excluded.

Studies where results were only released through press releases were not considered here, since it is very difficult to tell much about their design and analysis, and this is fundamental in making any inferences based on their results. Nevertheless, secondarily, results from national studies were also examined from preliminary press releases and reports whenever a country had no other data presented in full papers of preprints as of July 11, 2020. This allowed these countries to be represented in the collected data, but extra caution is required given the preliminary nature of this information. Preprints should also be seen with caution since they have not been yet fully peer-reviewed (although some of them have already been revised based on very extensive comments from the scientific community). However, in contrast to press releases, preprints typically offer at least a fairly complete paper with information about design and analysis.

Studies done of blood donors were eligible, although it is possible they may underestimate seroprevalence and overestimate IFR due to healthy volunteer effect. Studies done on health care workers were not eligible, since they deal with a group at potentially high exposure risk which may lead to seroprevalence estimates much higher than the general population and thus implausibly low IFR. For a similar reason, studies focused on communities (e.g. shelters or religious or other shared-living communities) were also excluded. Studies were eligible regardless of whether they aimed to evaluate seroprevalence in large or small regions, provided that the population of reference in the region was at least 5000 people.

Searches were made in PubMed (LitCOVID), medRxiv, bioRxiv, and Research Square using the terms “seroprevalence” and “antibodies” with continuous updates (last update July 11, 2020). Communication with colleagues who are field experts sought to ascertain if any major studies might have been missed.

Information was extracted from each study on location, recruitment and sampling strategy, dates of sample collection, sample size, types of antibody used (IgG, IgM, IgA), estimated crude

seroprevalence (positive samples divided by all samples test), and adjusted seroprevalence and features that were considered in the adjustment (sampling process, test performance, presence of symptoms, other).

Calculation of inferred IFR

Information on the population of the relevant location was collected from the papers. Whenever it was missing, it was derived based on recent census data trying to approximate as much as possible the relevant catchment area (e.g. region(s) or county(ies)), whenever the study did not pertain to an entire country. Some studies targeted specific age groups (e.g. excluding elderly people and/or excluding children) and some of them made inferences on number of people infected in the population based on specific age groups. For consistency, the entire population, as well as, separately, only the population with age <70 years were used for estimating the number of infected people. It was assumed that the seroprevalence would be similar in different age groups, but significant differences in seroprevalence according to age strata that had been noted by the original authors were also recorded to examine the validity of this assumption.

The number of infected people was calculated multiplying the relevant population with the adjusted estimate of seroprevalence. Whenever an adjusted seroprevalence estimate had not been obtained, the unadjusted seroprevalence was used instead. When seroprevalence estimates with different adjustments were available, the analysis with maximal adjustment was selected.

For the number of COVID-19 deaths, the number of deaths recorded at the time chosen by the authors of each study was selected, whenever the authors used such a death count up to a specific date to make inferences themselves. If the choice of date had not been done by the authors, the number of deaths accumulated until after 1 week of the mid-point of the study period was chosen. This accounts for the differential delay in developing antibodies versus dying from the infection. It should be acknowledged that this is an averaging approximation, because some

patients may die very soon (within <3 weeks) after infection (and thus are overcounted), and others may die very late (and thus are undercounted due to right censoring).

The inferred IFR was obtained by dividing the number of deaths by the number of infected people for the entire population, and separately for people <70 years old. The proportion of COVID-19 deaths that occurred in people <70 years old was retrieved from situational reports for the respective countries, regions, or counties in searches done in June 3-7 for studies published until June 7 and in July 3-11 for studies published later. A corrected IFR is also presented, trying to account for the fact that only one or two types of antibodies (among IgG, IgM, IgA) might have been used. Correcting seroprevalence upwards (and inferred IFR downwards) by 1.1-fold for not performing IgM measurements and similarly for not performing IgA measurements may be reasonable, based on some early evidence,⁷ although there is uncertainty about the exact correction factor.

Data synthesis considerations

Inspection of the IFR estimates across all locations showed vast heterogeneity with heterogeneity I^2 exceeding 99.9% and thus a meta-analysis would be inappropriate to report across all locations. Quantitative synthesis with meta-analysis across all locations would also be misleading since locations with high seroprevalence would tend to carry more weight than locations with low seroprevalence; locations with more studies (typically those that have attracted more attention because of high death tolls and thus high IFRs) would be represented multiple times in the calculations; and more sloppy studies with fewer adjustments would get more weight, because they would have spuriously tighter confidence intervals than more rigorous studies with more careful adjustments allowing for more uncertainty. Finally, with a highly skewed IFR distribution and with extreme between-study heterogeneity, synthesis with a typical random effects model would tend to produce an erroneously high summary IFR that approximates the

mean of the study-specific estimates (also heavily driven by hotbed high-mortality locations with more studies done), while for a skewed distribution the median is more appropriate.

Therefore, at a first step, IFR estimates from studies done in the same country (or in the US, the same state) were grouped together and a single IFR was obtained for that location, weighting the study-specific IFRs by the sample size of each study. This allowed to avoid giving inappropriately more weight to studies with higher seroprevalence estimates and those with seemingly tighter confidence intervals because of poor or no adjustments, while still giving more weight to larger studies. Then, a single summary estimate was used for each location and the median of the distribution of location-specific IFR estimates was calculated. Finally, it was explored whether the location-specific IFRs were associated with the COVID-19 mortality rate in the population (COVID-19 deaths per million people) in each location as of July 12, 2020; this allowed to assess whether IFR estimates tend to be higher in harder hit locations.

RESULTS

Seroprevalence studies

36 studies with a total of 43 eligible estimates were published either in the peer-reviewed literature or as preprints as of July 11, 2020.⁸⁻⁴³ Dates and processes of sampling and recruitment are summarized in Table 1, sample sizes, antibody types assessed and regional population appear in Table 2, estimated prevalence, and number of people infected in the study region are summarized in Table 3, and number of COVID-19 and inferred IFR estimates are found in Table 4. Several studies performed repeated seroprevalence surveys at different time points, and only the time point with the highest seroprevalence estimate is considered in the calculations. With three exceptions, this is also the latest time point. Furthermore, another 7 preliminary national estimates were also considered (Table 5)⁴⁴⁻⁵⁰ from countries that had no other seroprevalence study published as a full paper or preprint. This yielded a total of 50 eligible estimates.

At least seven studies found some statistically significant, modest differences in seroprevalence rates across some age groups (Oise: decreased seroprevalence in age 0-14, increased in age 15-17; Geneva: decreased seroprevalence in age >50; Netherlands: increased seroprevalence in age 18-30; New York state: decreased seroprevalence in age >55; Brooklyn: decreased seroprevalence in age 0-5, increased in age 16-20; Tokyo: increased seroprevalence in age 18-34, Spain: decreased seroprevalence in age 0-10, Belgium: higher seroprevalence in age >90). The patterns are not strong enough to suggest major differences in extrapolating across age groups, although higher values in adolescents and young adults and lower values in children cannot be excluded.

As shown in Table 1, these studies varied substantially in sampling and recruitment designs. The main issue is whether they can offer a representative picture of the population in the region where they are performed. A generic problem is that vulnerable people who are at high risk of infection and/or death may be more difficult to recruit in survey-type studies. COVID-19 infection seems to be particularly widespread and/or lethal in nursing homes, among homeless people, in prisons, and in disadvantaged minorities. Most of these populations are very difficult, or even impossible to reach and sample from and they are probably under-represented to various degrees (or even entirely missed) in surveys. This would result in an underestimation of seroprevalence and thus overestimation of IFR. Eleven of the 36 studies that are available as full papers (Iran,⁸ Geneva,¹⁰ Gangelt,¹⁶ Rio Grande do Sul,¹⁷ Luxembourg,²⁰ Los Angeles county,²² three Brazil studies,^{25,34,42} Spain,³⁶ and Louisiana³⁷) explicitly aimed for random sampling from the general population. In principle, this is a stronger design. However, even with such designs, people who cannot be reached (e.g. by e-mail or phone or even visiting them at a house location) will not be recruited, and these vulnerable populations are likely to be missed. Moreover, 5 of these 11 studies^{8,10,16,42,37} focused on studying geographical locations that had extreme numbers of

deaths, higher than other locations in the same city or country, and this would tend to select eventually for higher IFR on average.

Seven studies assessed blood donors in Denmark,¹² Netherlands,¹⁵ Scotland,¹⁸ the Bay Area in California,²⁴ Zurich/Lucerne,²⁸ Apulia³¹ and Rio De Janeiro.⁴¹ By definition these studies include people in good health and without symptoms, at least recently, and therefore may markedly underestimate COVID-19 seroprevalence in the general population. A small set of 200 blood donors in Oise, France¹³ showed 3% seroprevalence, while pupils, siblings, parents, teachings and staff at a high school with a cluster of cases in the same area had 25.9% seroprevalence; true population seroprevalence may be between these two values.

For the other studies, healthy volunteer bias may lead to underestimating seroprevalence and this is likely to have been the case in at least one case (the Santa Clara study)¹⁹ where wealthy healthy people were rapidly interested to be recruited when the recruiting Facebook ad was released. The design of the study anticipated correction with adjustment of the sampling weights by zip code, gender, and ethnicity, but it is likely that healthy volunteer bias may still have led to some underestimation of seroprevalence. Conversely, attracting individuals who might have been concerned of having been infected (e.g. because they had symptoms) may lead to overestimation of seroprevalence in surveys. Finally studies of employees, grocery store clients, or patient cohorts (e.g. hospitalized for other reasons, or coming to the emergency room, or studies using residual lab samples) may have sampling bias with unpredictable direction.

As shown in Table 2, all studies have tested for IgG antibodies, but only about half have also assessed IgM, 4 have assessed IgA. Only three studies assessed all three types of antibodies and one more used a pan-Ig antibody. Studies typically considered the results to be “positive” if any tested antibody type was positive, but one study (Luxembourg) that considered the results to be “positive” only if both IgG and IgA were detected. The ratio of people sampled versus the total

population of the region was better than 1:1000 in 11 studies (Idaho,⁹ Denmark blood donors,¹² Gangelt,¹⁶ Santa Clara,¹⁹ Luxembourg,²⁰ Brooklyn,²⁷ Zurich,²⁸ San Francisco,³³ Espirito Santo,³⁴ Spain,³⁶ and Vitacura⁴³).

Seroprevalence estimates

As shown in Table 3, prevalence ranged from as little as 0.222% to as high as 47%. Studies varied a lot on whether they tried or not to adjust their estimates for test performance, sampling (striving to get closer to a more representative sample), and clustering effects (e.g. when including same household members) as well as other factors. The adjusted seroprevalence occasionally differed substantially from the crude, unadjusted value. In principle adjusted values are likely to be closer to the true estimate, but the exercise shows that each study alone may have some unavoidable uncertainty and fluctuation, depending on the analytical choices preferred. In studies that sampled people from multiple locations, large between-location heterogeneity could be seen (e.g. 0-25% across 133 Brazilian cities).²⁵

Inferred IFR

Inferred IFR estimates varied a lot, from 0.00% to 1.63%. Corrected values also varied extensively, from 0.00% to 1.31%. For 10 locations, more than one IFR estimate was available and thus IFR from different studies evaluating the same location could be compared. As shown in figure 1, the IFR estimates tended to be more homogeneous within each location, while they differed a lot across locations. The sample size-weighted summary was used to generate a single estimate to represent each location. Data were available for 32 different locations. The median IFR across all 32 locations was 0.27% (0.24% using the corrected values). Most data came from locations with high death tolls and 23 of the 32 locations had a population mortality rate (deaths per million population) higher than the global average (73 deaths per million population as of July 12) (Figure 2). The uncorrected IFR estimates had a range of 0.01-0.16% (median 0.13%) across

the 9 locations with population mortality rate below the global average, 0.07-0.73% (median 0.27%) across the 15 locations with population mortality rate above the global average but below 500 deaths per million population, and 0.59-1.63% (median 1.12%) across the 8 extreme hotbed locations with over 500 deaths per million population. The corrected IFR estimates had medians of 0.10%, 0.25%, and 0.90%, respectively, for the three groups of locations.

The proportion of COVID-19 deaths that occurred in people <70 years old varied substantially across locations. All deaths in Gangelt were in elderly people while in Wuhan half the deaths occurred in people <70 years old and the proportion might have been higher in Iran, but no data could be retrieved for this country. When limited to people <70 years old, IFR ranged from 0.00% to 0.57% with median of 0.05% (corrected, 0.00-0.46% with median of 0.04%). IFR estimates in people <70 years old were lower than 0.1% in all but 7 locations that were hard-hit hotbeds (Belgium, Wuhan, Italy, Spain, Connecticut, Louisiana, New York).

DISCUSSION

IFR is not a fixed physical constant and it can vary substantially across locations, depending on the population structure, the case-mix of infected and deceased individuals and other, local factors. Inferred IFR values based on emerging seroprevalence studies typically show a much lower fatality than initially speculated in the earlier days of the pandemic.

The studies analyzed here represent 50 different estimates of IFR, but they are not fully representative of all countries and locations around the world. Most of them come from locations with overall COVID-19 mortality rates exceeding the global average (73 deaths per million people as of July 12). The median inferred IFR in locations with COVID-19 mortality rate below the global average is low (0.13%, corrected 0.10%). For hotbed countries with COVID-19 mortality rates above the global average but lower than 500 deaths per million, the median IFR is still not that high (median 0.27%, corrected 0.25%). Very high IFR estimates have been documented

practically in locations that had devastating experiences with COVID-19. Such epicenters are unusual across the globe, but they are overrepresented in the 50 seroprevalence estimates available for this analysis. Therefore, if one could sample equally from all countries and locations around the globe, the median IFR might be even lower than the one observed in the current analysis.

Several studies in hard-hit European countries inferred modestly high IFR estimates for the overall population, but the IFR was still low in people <70 years old. Some of these studies were on blood donors and may have underestimated seroprevalence and overestimated IFR. One study in Germany aimed to test the entire population of a city and thus selection bias is minimal: Gangelt¹⁶ represents a situation with a superspreader event (in a local carnival) and 7 deaths were recorded, all of them in very elderly individuals (average age 81, sd 3.5). COVID-19 has a very steep age gradient of death risk.⁵¹ It is expected therefore that in locations where the infection finds its way into killing predominantly elderly citizens, the overall, age-unadjusted IFR would be higher. However, IFR would still be very low in people <70 in these locations, e.g. in Gangelt IFR is 0.00% in non-elderly people. Similarly, in Switzerland, 69% of deaths occurred in people >80 years old⁵¹ and this explains the relatively high overall IFR in Geneva and Zurich. Similar to Germany, very few deaths in Switzerland have been recorded in non-elderly people, e.g. only 2.5% have occurred in people <60 years old and IFR in that age-group would be ~0.01%. The majority of deaths in most of the hard hit European countries have happened in nursing homes⁵² and a large proportion of deaths also in the US⁵³ also follow this pattern. Moreover, many nursing home deaths have no laboratory confirmation and thus should be seen with extra caution in terms of the causal impact of SARS-CoV-2.

Locations with high burdens of nursing home deaths may have high IFR estimates, but the IFR would still be very low among non-elderly, non-debilitated people. The average length of stay in a nursing home is slightly more than 2 years and people who die in nursing homes die in a

median of 5 months⁵⁴ so many COVID-19 nursing home deaths may have happened in people with life expectancy of only a few months. This needs to be verified in careful assessments of COVID-19 outbreaks in nursing homes with detailed risk profiling of fatalities. If COVID-19 happened in patients with very limited life expectancy, this pattern may even create a dent of less than expected mortality in the next 3-6 months after the coronavirus excess mortality wave. As of July 12 (week 28), preliminary Euromonitor data⁵⁵ indeed already show a substantial dent below baseline mortality in France, and a dent below baseline mortality is seen also for the aggregate European data.

Within China, the much higher IFR estimates in Wuhan versus other areas may reflect the wide spread of the infection to hospital personnel and the substantial contribution of nosocomial infections to a higher death toll in Wuhan;⁵⁶ plus unfamiliarity with how to deal with the infection in the first location where COVID-19 arose. Massive deaths of elderly individuals in nursing homes, nosocomial infections, and overwhelmed hospitals may also explain the very high fatality in specific locations in Italy⁵⁷ and in New York and neighboring states. Seroprevalence studies in health care workers and administrative hospital staff in Lombardy⁵⁸ found 8% seroprevalence in Milan hospitals and 35-43% in Bergamo hospitals, supporting the scenario for widespread nosocomial infections among vulnerable patients. The high IFR values in New York metropolitan area and neighboring states are also not surprising, given the vast death toll witnessed. A very unfortunate decision of the several state governors was to have COVID-19 patients sent to nursing homes. Moreover, some hospitals in New York City hotspots reached maximum capacity and perhaps could not offer optimal care. Use of unnecessarily aggressive management (e.g. mechanical ventilation) and hydroxychloroquine may also have contributed to worse outcomes. Furthermore, New York City has an extremely busy, congested public transport system that may have exposed large segments of the population to high infectious load in close contact

transmission and, thus, perhaps more severe disease. A more aggressive viral clade has also been speculated, but this needs further verification.⁵⁹

IFR may reach very high levels among disadvantaged populations and settings that have the worst combination of factors predisposing to higher fatalities. Importantly, such hotspot locations are rather uncommon exceptions in the global landscape. Moreover, even in these locations, the IFR for non-elderly individuals without predisposing conditions may remain very low. E.g. in New York City only 0.65% of all deaths happened in people <65 years without major underlying conditions.⁵¹ Thus the IFR even in New York City would probably be lower than 0.01% in these people.

Studies with extremely low inferred IFR are also worthwhile discussing. Possible overestimation of seroprevalence and undercounting of deaths need to be considered. E.g., for Kobe, the authors of the study¹¹ raise the question whether COVID-19 deaths have been undercounted in Japan. Both undercounting and overcounting of COVID-19 deaths may be a caveat in different locations and this is difficult to settle in the absence of very careful scrutiny of medical records and autopsies. The Tokyo data,²⁹ nevertheless, also show similarly very low IFR. Moreover, evaluation of all-cause mortality in Japan has shown no excess deaths during the pandemic, consistent with the possibility that somehow the Japanese population was spared. Very low IFRs seem common in Asian countries, including China (excluding Wuhan), Iran, Israel and India. Former immunity from exposure to other coronaviruses, genetic differences, hygienic etiquette, lower infectious load, and other unknown factors may be speculated. IFR seems to be very low also in Singapore where extensive PCR testing was carried out. As of July 12, 2020, in Singapore there were only 26 deaths among 46,283 cases, suggesting an upper bound of 0.06% for IFR, even if no cases had been missed.

Some surveys have also been designed to assess seroprevalence repeatedly spacing out measurements in the same population over time. A typical pattern that seems to emerge is that seroprevalence may increase several fold within a few weeks, but plateau or even decline may follow.^{10,28} A more prominent decline of seropositivity was seen in a study in Wuhan.³² Genuine decrease may be difficult to differentiate from random variation. However, some preliminary data^{60,61} suggest that decrease in antibody titers may be fast. Decrease in seropositivity over time means that the numbers of infected people may be underestimated and IFR overestimated.

The only data from a low-income country among the 23 studies examined here come from Iran⁸ and India⁴⁹ and the IFR estimates appears to be very low. Iran has a young population with only slightly over 1% of the age pyramid at age >80 and India's population is even younger. Similar considerations apply to almost every less developed country around the world. Given the very sharp age gradient and the sparing of children and young adults from death by COVID-19, one may expect IFR to be fairly low in the less developed countries. However, it remains to be seen whether comorbidities, poverty and frailty (e.g. malnutrition) and congested urban living circumstances may have adverse impact on risk and thus increase IFR also in these countries.

One should caution that the extent of validation of the antibody assays against positive and negative controls differs across studies. Specificity has typically exceeded 99.0%, which is reassuring. However, for very low prevalence rates, even 99% specificity may be problematic. Sensitivity also varies from 60-100% in different validation exercises and for different tests, but typically it is closer to the upper than the lower bound. One caveat about sensitivity is that typically the positive controls are patients who had symptoms and thus were tested and found to be PCR-positive. However, it is possible that symptomatic patients may be more likely to develop antibodies than patients who are asymptomatic or have minimal symptoms and thus had not sought PCR testing.⁶¹⁻⁶⁵ For example, one study found that 40% of asymptomatic patients became

seronegative within 8 weeks.⁶¹ Since the seroprevalence studies specifically try to unearth these asymptomatic/mildly symptomatic missed infections, a lower sensitivity for these mild infections could translate to substantial underestimates of the number of infected people and substantial overestimate of the inferred IFR.

The corrected IFR estimates are trying to account for undercounting of infected people when not all 3 antibodies (IgG, IgM, and IgA) are assessed.⁷ However, the magnitude of the correction is uncertain and may also vary in different circumstances. Moreover, it is possible that an unknown proportion of people may have handled the virus using immune mechanisms (mucosal, innate, cellular) that did not generate any serum antibodies.⁶⁶⁻⁶⁹ This may lead to substantial underestimation of the frequency of infection and respective overestimation of the IFR. One study has found indeed that mild SARS-CoV-2 infections may lead to nasal release of IgA, without serum antibody response.⁶⁸ Another study has found that 6 of 8 interfamilial contacts of index cases remained seronegative despite developing symptoms and 6 of 8 developed persisting T cell responses⁶⁹ and the important role of cellular immune responses even in seronegative patients has been documented also by other investigators.⁷⁰

An interesting observation is that even under congested circumstances, like cruise ships, aircraft carriers or homeless shelter, the proportion of people detected positive typically does not get to exceed 20-45%.^{71,72} Similarly, at a wider population level, values ~47% are the maximum values documented to-date and most values are much lower, yet epidemic waves seem to wane. It has been suggested^{73,74} that differences in host susceptibility and behavior can result in herd immunity at much lower prevalence of infection in the population than originally expected. COVID-19 spreads by infecting certain groups more than others because some people have much higher likelihood of exposure. People most likely to be exposed also tend to be those most likely to spread for the same reasons that put them at high exposure risk. In the absence of random

mixing of people, the epidemic wave may be extinguished even with relatively low proportions of people becoming infected. Seasonality may also play a role in the dissipation of the epidemic wave. It has also been observed that many people have CD4 cellular responses to SARS-CoV-2 even without being exposed to this virus, perhaps due to prior exposure to other coronaviruses.⁷⁵ It is unknown whether this proportion varies in different populations around the world and whether this immunity may contribute to SARS-CoV-2 epidemic waves waning without infecting a large share of the population.

A major limitation of the current analysis is that the calculations presented in this paper include several studies that have not yet been fully peer-reviewed. Moreover, there are several studies that are still ongoing. New emerging data may offer more insights and updated estimates. Given that the large majority of studies have been done in locations that were hard hit from COVID-19, it would be useful to do more studies in less hit locations, so as to have a more balanced global perspective.

A comparison of COVID-19 to influenza is often attempted, but many are confused by this comparison unless placed in context. Based on the IFR estimates obtained here, COVID-19 may have infected as of July 12 approximately 300 million people (or more), far more than the ~13 million PCR-documented cases. The global COVID-19 death toll is still evolving, but it is still not much dissimilar to a typical death toll from seasonal influenza (290,000-650,000),⁷⁶ while “bad” influenza years (e.g. 1957-9 and 1968-70) have been associated with 1-4 million deaths.⁷⁷ Notably, influenza devastates low-income countries, but is more tolerant of wealthy nations, probably because of the availability and wider use of vaccination in these countries.⁵⁸ Conversely, in the absence of vaccine and with a clear preference for elderly debilitated individuals, COVID-19 may have an inverse death toll profile, with more deaths in wealthy nations than in low-income countries. However, even in the wealthy nations, COVID-19 seems to affect predominantly the

frail, the disadvantaged, and the marginalized – as shown by high rates of infectious burden in nursing homes, homeless shelters, prisons, meat processing plants, and the strong racial/ethnic inequalities against minorities in terms of the cumulative death risk.^{78,79}

While COVID-19 is a formidable threat, the fact that its IFR is typically much lower than originally feared, is a welcome piece of evidence. The median IFR found in this analysis is very similar to the estimate recently adopted by CDC for planning purposes.⁸⁰ The fact that IFR can vary substantially also based on case-mix and settings involved also creates additional ground for evidence-based, more precise management strategies. Decision-makers can use measures that will try to avert having this lethal virus infect people and settings who are at high risk of severe outcomes. These measures may be possible to be more precise and tailored to specific high-risk individuals and settings than blind lockdown of the entire society. Of course, uncertainty remains about the future evolution of the pandemic, e.g. the presence and height of subsequent waves.⁸¹ However, it is helpful to know that SARS-CoV-2 has relatively modest IFR overall and that possibly IFR can be made even lower with appropriate, precise non-pharmacological choices.

Table 1. Seroprevalence studies on COVID-19 published or depositing preprints as of July 11, 2020: dates, sampling and recruitment process

Location	Dates	Sampling and recruitment
Iran (Guilan) ⁸	April (until April 21)	Population-based cluster random sampling design through phone call invitation, household-based.
Idaho (Boise) ⁹	Late April	People from the Boise, Idaho metropolitan area, part of the Crush the Curve initiative.
Switzerland (Geneva) ¹⁰	April 6-May 9 (5 consecutive weeks)	Randomly selected previous participants of the Bus Santé study with an email (or phone contact, if e-mail unavailable); participants were invited to bring all members of their household, aged 5 years and older.
Japan (Kobe) ¹¹	March 31-April 7	Randomly selected patients who visited outpatient clinics and received blood testing for any reason. Patients who visited the emergency department or the designated fever consultation service were excluded.
Denmark blood donors ¹²	April 6-May 3	All Danish blood donors aged 17-69 years giving blood. Blood donors are healthy and must comply with strict eligibility criteria; they must self-defer for two weeks if they develop fever with upper respiratory symptoms.
France (Oise) ¹³	March 30-April 4	Pupils, their parents and siblings, as well as teachers and non-teaching staff of a high-school.

China (Wuhan) ¹⁴	April 3-15	People applying for a permission of resume (n=1,021) and hospitalized patients during April 3 to 15 (n=381).
Netherlands blood donors ¹⁵	April 1-15	Blood donors. Donors must be completely healthy, but they may have been ill in the past, provided that they recovered at least two weeks before.
Germany (Gangelt) ¹⁶	March 30-April 6	600 adult persons with different surnames in Gangelt were randomly selected, and all household members were asked to participate in the study.
Brazil (Rio Grande do Sul) ¹⁷	May 9-11 (third round, after April 11-13, and 25-27)	Multi-stage probability sampling was used in each of 9 cities to select 500 households, within which one resident was randomly chosen for testing.
Scotland blood donors ¹⁸	March 21-23	Blood donors. Donors should not have felt unwell in the last 14 days, also some other deferrals applied regarding travel and COVID-19 symptoms.
California (Santa Clara) ¹⁹	April 2-3	Facebook ad with additional targeting by zip code.
Luxembourg ²⁰	April 16-May 5	Representative sample (no details how ensured), 1807 of 2000 contacted provided data, were <79 years and had serology results.

Germany (Frankfurt) ²¹	April 6-14	Employees of Infraseriv Höchst, a large industrial site operator in Frankfurt am Main. No exclusion criteria.
California (Los Angeles) ²²	April 10-14	Proprietary database representative of the county. A random sample of these residents was invited, with quotas for enrollment for subgroups based on age, sex, race, and ethnicity distribution.
New York ²³	April 19-28	Convenience sample of patrons ≥ 18 years and residing in New York State, recruited consecutively upon entering 99 grocery stores and via an in-store flyer.
California (Bay Area) ²⁴	March	1,000 blood donors in diverse Bay Area locations (excluding those with self-reported symptoms or abnormal vital signs)
Brazil ²⁵	May 15-22	Sampling from 133 cities (the main city in each region), selecting 25 census tracts with probability proportionate to size in each sentinel city, and 10 households at random in each tract. Aiming for 250 participants per city.
Croatia ²⁶	April 23-28	DIV factory workers in Split and Sibenik-Knin invited for voluntary testing
New York (Brooklyn) ²⁷	Early May	Patients seen in urgent care facility in Brooklyn
Switzerland (Zurich) ²⁸	Prepandemic until June (patients)	Patients at the University Hospital of Zurich and blood donors in Zurich and Lucerne

	and May (blood donors)	
Japan (Tokyo) ²⁹	April 21-May 20	Two community clinics located in the major railway stations in Tokyo (Navitas Clinic Shinjuku and Tachikawa)
Spain (Barcelona) ³⁰	April 14-May 5	Consecutive pregnant women for first trimester screening or delivery in two hospitals
Italy (Apulia) blood donors ³¹	May 1-May 31	Blood donors 18-65 years old free of recent symptoms possibly related to COVID-19, no close contact with confirmed cases, symptoms free during the preceding 14 days, no contacts with suspected cases
China (Wuhan B) ³²	March 26-April 28	Age 16-64, going back to work, with no fever, headache, or other symptoms of COVID-19
California (San Francisco) ³³	April 25-April 28 (and n=40 in May)	U.S. census tract 022901 population-dense area (58% Latinx) in San Francisco Mission district, expanded to neighboring blocks on April 28
Brazil (Espirito Santo) ³⁴	May 13-15	Cross-sectional of major municipalities structured over houses as the sampling units
USA (six states) ³⁵	March 23-April 1 (WA Puget Sound and NYC), April 6-10 (south Florida), April 20-	Convenience samples using residual sera obtained for routine clinical testing (screening or management) by two commercial laboratory companies

	26 (MO), April	
	20-May 3 (UT),	
	April 26-May 3	
	(CT)	
Spain ³⁶	April 27-May 11	35883 households selected from municipal rolls using two-stage random sampling stratified by province and municipality size, with all residents invited to participate (75.1% of all contacted individuals participated)
Louisiana (Orleans and Jefferson Parish) ³⁷	May 9-15	Pool of potential participants reflective of the demographics of the Parishes was based on 50 characteristics, then a randomized subset of 150,000 was selected, then 25,000 were approached with digital apps, and 2640 recruited.
Belgium ³⁸	March 30-April 5 and April 20-26	Residual sera from ten private diagnostic laboratories in Belgium, with fixed numbers per age group, region and periodical sampling, and stratified by sex
France (Crepv-en-Valois) ³⁹	April 28-30	Pupils, their parents and relatives, and staff of primary schools exposed to SARS-CoV-2 in February and March 2020 in a city north of Paris
China (several regions) ^{40*}	March 30-April 10	Voluntary participation by public call for hemodialysis patients (n=979 in Zingzhou, Ubei and n=563 in Guangzhou/Foshun, Guangdong)

		and outpatients in Chingqing (n=993), and community residents in Chengdu, Sichuan (n=9442), and required testing for factory workers in Guangzhou, Guandong (n=442)
Brazil (Rio de Janeiro) blood donors ⁴¹	April 14-27 (eligible: April 24-27)	Blood donors could not have had flulike symptoms within the 30 days before donation; had close contact with suspected or confirmed covid-19 cases in the 30 days before donation; or traveled abroad in the past 30 days.
Brazil (Sao Paulo) ⁴²	May 4-12	Randomly selected adults and their cohabitants sampled from 6 districts of Sao Paulo City with high number of cases
Chile (Vitacura) ⁴³	May 4-19	Classroom stratified sample of children and all staff in a community placed on quarantine after school outbreak

Two of the studies included additional datasets of <500 participants that are not presented here (n=200 blood donors in Oise and n=387 patients in the California (Bay Area) study)
*not considered here are some sub-cohorts from this study, including healthcare workers, and staff from hotel for healthcare workers

Table 2. Sample size, types of antibodies, and population in relevant region

Location	Sample size	Antibody	Population in region*	Population <70 years (%)
Iran (Guilan) ⁸	551	IgG/IgM	2354848	95
Idaho (Boise) ⁹	4856	IgG	481587 (Ada county)	92
Switzerland (Geneva) ¹⁰	577 (4/20-27)	IgG	500000	88
Japan (Kobe) ¹¹	1000	IgG	1518870	79 (Japan)
Denmark blood donors ¹²	20640	IgG/IgM	5771876	86
France (Oise) ¹³	661	IgG	5978000 (Hauts-de-France)	89
China (Wuhan) ¹⁴	1401	IgG/IgM	11080000	93 (China)
Netherlands blood donors ¹⁵	7361	IgG/IgM/IgA	17097123	86
Germany (Gangelt) ¹⁶	919	IgG/IgA	12597	86
Brazil (Rio Grande do Sul) ¹⁷	4500	IgG	11377239	91
Scotland blood donors ¹⁸	500	IgG	5400000	88
California (Santa Clara) ¹⁹	3300	IgG/IgM	1928000	90
Luxembourg ²⁰	1807	IgG/IgA**	615729	90
Germany (Frankfurt) ²¹	1000	IgG	2681000***	84 (Germany)
California (Los Angeles) ²²	863	IgG/IgM	7892000	92
New York ²³	15101	IgG	19450000	90
California (Bay Area) ²⁴	1000	IgG	7753000	90
Brazil (133 cities) ²⁵	24995	IgG/IgM	74656499	94 (Brazil)

Croatia ²⁶	1494	IgG/IgM	4076000	86
New York (Brooklyn) ²⁷	11092	IgG	2559903	91
Switzerland (Zurich) ²⁸	1644 patients (4/1-15)	IgG	1520968 (canton Zurich) 1930525 (Zurich+Lucerne)	88
	1640 blood donors (May)			
Japan (Tokyo) ²⁹	1071	IgG	13902077	79 (Japan)
Spain (Barcelona) ³⁰	874	IgG/IgM/IgA	7566000 (Catalonia)	86
Italy (Apulia) blood donors ³¹	909	IgG/IgM	4029000	84
China (Wuhan B) ³²	1196 (4/4-8)	IgG/IgM	11080000	93 (China)
California (San Francisco) ³³	3953	IgG (also PCR testing)	5174 (census 022901)	95
Brazil (Espirito Santo) ³⁴	4608	IgG/IgM	4018650	94 (Brazil)
USA (six states) ³⁵		Pan-Ig		
WA Puget Sound	3264		4273548	90 (WA)
UT	1132		3282120	92
NYC	2482		9260870	89
MO	1882		6110800	88
South FL	1742		6345345	86 (FL)
CT	1431		3562989	88
Spain ³⁶	61075	IgG	46940000	85
Louisiana (Orleans and Jefferson Parish) ³⁷	2640	IgG	825057	92 (LA)

Belgium ³⁸	3391 (4/20-26)	IgG	11589623	86
France (Crepy-en-Valois) ³⁹	1340	IgG	5978000 (Hauts-de-France)	89
China (several regions) ⁴⁰		IgG/IgM		
Hubei (not Wuhan)	979		48058000	93 (China)
Chongqing	993		31243200	93 (China)
Sichuan	9442		83750000	93 (China)
Guangdong	1005		115210000	93 (China)
Brazil (Rio de Janeiro) blood donors ⁴¹	669 (4/24-27)	IgG/IgM	17264943	94 (Brazil)
Brazil (Sao Paulo) ⁴²	517	IgG/IgM	298240 (6 districts)	94 (Brazil)
Chile (Vitacura) ⁴³	1244	IgG/IgM	85000	92 (Chile)

*The authors of some studies preferred to focus on age-restricted populations: 17-70 years old in the Denmark blood donor study (n=3800000), those 18-79 years old in the Luxembourg study (n=483000); those <70 years old in Netherlands blood donor study (n=13745768); those ≥18 years old in the New York state study (n=15280000); and those >19 years old in the UT population of the six states US study (n=2173082).

**considered positive if both IgG and IgA were positive

***participants were recruited from a large number of districts, but most districts had very few participants; here the population of the 9 districts with >1:10,000 sampling ratio is included (846/1000 participants came from these 9 districts).

Table 3. Prevalence of infection and estimated number of infected people

Location	Seroprevalence (%)		Estimated infected
	Crude	Adjusted (adjustments)	
Iran (Guilan) ⁸	22.0	33.0 (test, sampling)	770000
Idaho (Boise) ⁹	1.79	ND	8620
Switzerland (Geneva) ¹⁰	10.6	10.9 (test, age, sex)	54500
Japan (Kobe) ¹¹	3.3	2.7 (age, sex)	40999
Denmark blood donors ¹²	2.0	1.9 (test)	109665
France (Oise) ¹³	25.9	ND	1548000
China (Wuhan) ¹⁴	10.0	ND	1108000
Netherlands blood donors ¹⁵	2.7	ND	461622
Germany (Gangelt) ¹⁶	15.0	20.0 (test, cluster, sym)	2519
Brazil (Rio Grande do Sul) ¹⁷	0.222	0.222 (sampling)*	25283
Scotland blood donors ¹⁸	1.2	ND	64800
California (Santa Clara) ¹⁹	1.5	2.6 (test, sampling, cluster)	51000
Luxembourg ²⁰	1.9	2.06 (age, sex, district)	12684
Germany (Frankfurt) ²¹	0.6	ND	16086
California (Los Angeles) ²²	4.06	4.65 (test, sex, race/ethnicity, income)	367000
New York ²³	12.5	14.0 (test, sex, age, race/ethnicity, region)	2723000
California (Bay Area) ²⁴	0.4 (blood donors)	0.1 (test/confirmation)	7753

Brazil (133 cities) ²⁵	1.39	1.62 overall, varying from 0 to 25.0 across 133 cities (test, design)	1209435**
Croatia ²⁶	1.27***	ND	51765
New York (Brooklyn) ²⁷	47.0	ND	1203154
Switzerland (Zurich) ²⁸	unclear	1.3 in patients in April 1-15 and 1.6 in blood donors in May (multivariate Gaussian conditioning)	19773 (Zurich) 30888 (Zurich+Lucerne)
Japan (Tokyo) ²⁹	3.83	ND	532450
Spain (Barcelona) ³⁰	14.3	ND	1081938
Italy (Apulia) blood donors ³¹	0.99	ND	39887
China (Wuhan B) ³²	8.36 (3.53 for entire period)	ND (2.80 (age, gender, test) for entire period)	926288
California (San Francisco) ³³	4.3 in the census track	6.1 (age, sex, race/ethnicity, test)	316
Brazil (Espírito Santo) ³⁴	2.1	ND	84391
USA (six states) ³⁵		(age, sex, test)	
WA Puget Sound	1.3	1.13	48291
UT	2.4	2.18	71550
NYC	5.7	6.93	641778
MO	2.9	2.65	161936

South FL	2.2	1.85	117389
CT	4.9	4.94	176012
Spain ³⁶	ND	5.0***** (sampling, age, sex, income)	2347000
Louisiana (Orleans and Jefferson Parish) ³⁷	6.9 (IgG or PCR)	6.9 for IgG (census weighting, demographics)	56578
Belgium ³⁸	5.7	6.0 (sampling, age, sex, province)	695377
France (Crepv-en-Valois) ³⁹	10.4	ND	620105
China (several regions) ⁴⁰			
Hubei (not Wuhan)	3.6	ND	1718110
Chongqing	3.8	ND	11956109
Sichuan	0.6	ND	487847
Guangdong	2.2	ND	2522010
Brazil (Rio de Janeiro) blood donors ⁴¹	6.0	4.7 (age, sex, test)	811452
Brazil (Sao Paulo) ⁴²	5.2	4.7 (sampling design)	14017
Chile (Vitacura) ⁴³	11.2	ND	9500

Among studies with multiple consecutive time points where seroprevalence was evaluated, the seroprevalence estimate was the highest in the most recent time interval with the exception of Switzerland (Geneva) where the highest value was seen two weeks before the last time interval, Switzerland (Zurich) where the highest was seen in April 1-15 for patients at the university hospital and in May for blood donors, and the China (Wuhan B) study where the highest value was seen about 3 weeks before the last time interval.

*an estimate is also provided adjusting for test performance, but the assumed specificity of 99.0% seems inappropriate, since as part of the validation process the authors also found that several of the test-positive individuals had household members who were also infected, thus the estimated specificity was deemed to be at least 99.95%

**the authors calculate 760000 infected in the 90 cities that had 200-250 samples tested, but many of the other 43 cities with <200 samples may be equally or even better represented, since they tended to be smaller than the 90 (mean population 356213 versus 659326)

***1.20% in workers in Split without mobility restrictions, 3.37% in workers in Knin without mobility restrictions, 1.57% for all workers without mobility restrictions; Split and Knin tended to have somewhat higher death rates than nation-wide Croatia, but residence of workers is not given, so the entire population of the country is used in the calculations

**** 5.0% by point of care test, 4.6% with immunoassay, 3.7% by having both tests positive, 6.2% by having at least one test positive

test: test performance; ND: no data available

Table 4. Inferred infection fatality rates

Location	COVID-19 deaths (date)	Inferred IFR (corrected), %	COVID-19 deaths <70 years,*** %	IFR in <70 years (corrected), %
Iran (Guilan) ⁸	617 (4/23)	0.08 (0.07)	No data	No data
Idaho (Boise) ⁹	14 (4/24)	0.16 (0.13)	14 (Idaho)	0.02 (0.02)
Switzerland (Geneva) ¹⁰	243 (4/30)	0.45 (0.36)	8	0.04 (0.03)
Japan (Kobe) ¹¹	10 (mid-April)	0.02 (0.02)	21 (Japan)	0.01 (0.01)
Denmark blood donors ¹²	370 (4/21)	0.34 (0.27)	12	0.05 (0.04)
France (Oise) ¹³	932 (4/7)#	0.06 (0.05)	7 (France, <65 years)	0.01 (0.01)
China (Wuhan) ¹⁴	3869 (5/2)	0.35 (0.31)	50	0.19 (0.15)
Netherlands blood donors ¹⁵	3134 (4/15)	0.68 (0.68)	11	0.09 (0.09)
Germany (Gangelt) ¹⁶	7 (4/15)	0.28 (0.25)	0	0.00 (0.00)
Brazil (Rio Grande do Sul) ¹⁷	124 (5/14)	0.49 (0.39)	31 (Brazil, <60 years)	0.19 (0.15)
Scotland blood donors ¹⁸	47 (4/1)	0.07 (0.06)	9 (<65 years)	0.01 (0.01)
California (Santa Clara) ¹⁹	94 (4/22)	0.18 (0.17)	35	0.07 (0.06)
Luxembourg ²⁰	92 (5/2)	0.73 (0.58)	9	0.07 (0.06)
Germany (Frankfurt) ²¹	42*(4/17)	0.26 (0.21)	14 (Germany)	0.04 (0.03)
California (Los Angeles) ²²	724 (4/19)	0.20 (0.18)	24 (<65 years)	0.06 (0.05)
New York ²³	18610 (4/30)^	0.68 (0.54)^	34	0.26 (0.23)^

California (Bay Area) ²⁴	12 (3/22)	0.15 (0.12)	25	0.04 (0.03)
Brazil (133 cities) ²⁵	**	Median 0.30 (0.27)	31 (<60 years)	0.10 (0.9)
Croatia ²⁶	79 (5/3)	0.15 (0.14)	13	0.02 (0.02)
New York (Brooklyn) ²⁷	4894 (5/19)^	0.41 (0.33)^	34 (NY State)	0.15 (0.14)^
Switzerland (Zurich) ²⁸	107 (4/15 Zurich), 147 (5/22, Zurich+Lucerne)	0.51 (0.41)	8 (Switzerland)	0.05 (0.04)
Japan (Tokyo) ²⁹	189 (5/11)	0.04 (0.03)	21 (Japan)	0.01 (0.01)
Spain (Barcelona) ³⁰	5137 (5/2)	0.48 (0.48)	13 (Spain)	0.07 (0.07)
Italy (Apulia) blood donors ³¹	530 (5/22)	1.33 (1.20)	15 (Italy)	0.24 (0.22)
China (Wuhan B) ³²	3869 (4/13)	0.42 (0.38)	50	0.23 (0.21)
California (San Francisco) ³³	0 (5/4)	0.00 (0.00)	0	0.00 (0.00)
Brazil (Espirito Santo) ³⁴	363 (5/21)	0.43 (0.39)	31 (Brazil, <60 years)	0.14 (0.13)
USA (six states) ³⁵				
WA Puget Sound	207 (4/4)	0.43 (0.43)	10 (WA, <60)	0.05 (0.05)
UT	58 (5/4)	0.08 (0.08)	28 (<65)	0.03 (0.03)
NYC	4146 (4/4)	0.65 (0.65)	34 (NY state)	0.25 (0.25)
MO	329 (4/30)	0.20 (0.20)	23	0.05 (0.05)
South FL	295 (4/15)	0.25 (0.25)	28 (FL)	0.08 (0.08)
CT	2718 (5/6)	1.54 (1.54)	18	0.31 (0.31)

Spain ³⁶	26920 (5/11)	1.15 (0.92)	13	0.18 (0.14)
Louisiana ³⁷	925 (5/16)	1.63 (1.31)	32	0.57 (0.46)
Belgium ³⁸	7594 (4/30)	1.09 (0.87)	10	0.13 (0.10)
France (Crepy-en-Valois) ³⁹	2325 (5/5)#	0.37 (0.30)	7 (France, <65 years)	0.04 (0.03)
China (several regions) ⁴⁰				
Hubei (not Wuhan)	643 (4/12)	0.04 (0.03)	About 50? (if similar to Wuhan)	0.02 (0.02)
Chongqing	6 (4/12)	0.00 (0.00)		0.00 (0.00)
Sichuan	3 (4/12)	0.00 (0.00)		0.00 (0.00)
Guangdong	8 (4/12)	0.00 (0.00)		0.00 (0.00)
Brazil (Rio de Janeiro) blood donors ⁴¹	1019 (5/3)	0.12 (0.11)	31 (Brazil, <60 years)	0.04 (0.04)
Brazil (Sao Paulo) ^{42****}	Unknown (5/15)	Unknown, but likely >0.4	31 (Brazil, <60 years)	Unknown, but likely >0.1
Chile (Vitacura) ^{43****}	Unknown (5/18)	Unknown, but likely <0.2	36 (Chile)	Unknown, but likely <0.1

*approximated from number of deaths in the Hesse province on 4/17 times the proportion of deaths in the 9 districts with key enrollment in the study among all Hesse province deaths.

**data are provided by the authors for deaths per 100,000 population in each city along with inferred IFR in each city, with wide differences across cities; the IFR shown here is the median across the 36 cities with 200-250 samples and at least one positive sample (the interquartile range for the uncorrected IFR is 0.20-0.60 and the full range across all cities is 0-2.4%, but with very wide uncertainty in each city). A higher IFR is alluded in the preprint, but the preprint also shows a scatter diagram for survey-based seroprevalence versus reported deaths per population with a regression slope that agrees with IFR of 0.3.

*** whenever the number/proportion of COVID-19 deaths at age <70 years was not provided in the paper, the proportion of these deaths was retrieved from situational reports of the relevant location; when this was not possible to find for the specific location, a larger geographic entity was used. For Brazil, the closest information that could be found was from a news report

(<https://www.thejakartapost.com/news/2020/05/22/in-brazil-covid-19-hitting-young-people-harder.html>).

For Croatia, data on age for 45/103 deaths were retrieved through Wikipedia.

**** Information on deaths not available for the specific locations. In the Sao Paulo study, the 6 districts were selected as being the most hit of Sao Paulo, but it is not stated which are the districts and one cannot

retrieve what the number of deaths was as of mid-May, but even using data for death rates across all Sao Paulo would lead to IFR >0.4 overall. In the Vitacura study, similarly one can infer from the wider Santiago Metropolitan area that in the Vitacura area the IFR would probably be <0.2 overall.

^Confirmed deaths; inclusion of probable deaths would increase the IFR estimates by about a quarter.

#for France, governmental situational reports provide per region the number of deaths only for in-hospital deaths, therefore the number of in-hospital deaths has been multiplied by a factor equal to the total deaths/in-hospital deaths across France.

IFR: infection fatality rate. The inferred IFR is derived by dividing the number of accumulated deaths (at the time chosen by the authors of each study, or until after 1 week of the mid-point of the study dates, whenever the authors had not arbitrated on a date for the death count) by the estimated number of infected people. The corrected IFR is obtained from the inferred IFR assuming that, as compared with assessing IgG, IgM, and IgA, 20% of the infections are missed when only IgG is assessed, and 10% of the infections are missed when two of the three antibodies are assessed.

Table 5. Additional seroprevalence data from nation-wide studies that have been announced to the press and/or in preliminary reports, but are not presented yet as full articles. Only countries not represented in Tables 1-4 are considered.

Country	Sample size (antibody)	Date	Seroprevalence (%)	Population	Deaths (date)	IFR (corrected)
United Kingdom ⁴⁴	885 (IgG)	April 26-May 24 [^]	6.78	67897000	34636 (5/17)	0.75 (0.60)
Finland ⁴⁵	674 (IgG)	April 20-26 [^]	2.52	5541000	211 (4/30)	0.15 (0.12)
Sweden ⁴⁶	1200 (IgG)	May 18-24	6.3	10101000	4501 (5/28)	0.71 (0.57)
Czechia ⁴⁷	26549 (IgG)	April 23-May 1	0.40	10710000	252 (5/4)	0.59 (0.47)
Israel ⁴⁸	1709 (IgG?)	May 2020	2-3	9198000	299 (6/10)	0.13 (0.10)*
India ⁴⁹	26400 (IgG?)	May 2020	0.73**	1380382000	8107 (6/10)	0.08 (0.06)
Slovenia ⁵⁰	1368 (IgG?)	April 2020	3.1	2079000	92 (5/1)	0.14 (0.11)

[^] slightly lower seroprevalence recorded in subsequent weeks

*Assuming seroprevalence 2.5%. Another ongoing study in Beni Brak (population n=198900, 0 deaths as of mid-June) has shown seroprevalence of 1.4% among the first 2933 samples. A much larger seroprevalence study based on HMOs has also been launched.

**based on data from part of the sample (65 of the 83 districts)

References:

1. Melnick ER, Ioannidis JPA. Head to Head: Should governments continue lockdown to slow the spread of covid-19? *BMJ* 2020;369:m1924. doi: 10.1136/bmj.m1924.
2. <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---3-march-2020>. Accessed May 10, 2020.
3. World Health Organization. Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19) 16-24 February 2020. Published 2020-02-28. Available from: [https://www.who.int/publications-detail/report-of-the-who-china-joint-mission-on-coronavirus-disease-2019-\(covid-19\)](https://www.who.int/publications-detail/report-of-the-who-china-joint-mission-on-coronavirus-disease-2019-(covid-19)). Accessed May 10, 2020.
4. McGinty JC. How many people might one person with coronavirus infect? *Wall Street Journal*. February 14, 2020. <https://www.wsj.com/articles/how-many-people-might-one-person-with-coronavirus-infect-11581676200>. Accessed February 27, 2020.
5. <https://www.imperial.ac.uk/media/imperial-college/medicine/sph/ide/gida-fellowships/Imperial-College-COVID19-NPI-modelling-16-03-2020.pdf>
6. Meyerowitz-Katz G, Merone L 2020 A systematic review and meta-analysis of published research data on COVID-19 infection-fatality rates doi: <https://doi.org/10.1101/2020.05.03.20089854>
7. Garcia-Basteiro AL, Moncunill G, Tortajada M, Vidal M, Guinovart C, Jimenez A, et al. Seroprevalence of antibodies against SARS-CoV-2 among health care workers in a large Spanish reference hospital. *Nature Communications* 2020;11:3500
8. Shakiba M, Nazari S, Mehrabian F, et al. Seroprevalence of COVID-19 virus infection in Guilan province, Iran. medRxiv doi: <https://doi.org/10.1101/2020.04.26.20079244>

9. Bryan A, Pepper G, Wener MH, Fink SL, Morishima C, Chaudhary A, et al. Performance characteristics of the Abbott Architect SARS-CoV-2 IgG assay and seroprevalence testing in Idaho. *J Clin Microbiol.* 2020 doi:10.1128/JCM.00941-20
10. Stringhini S, Wisniak A, Piumatti G, Azman AS, Lauer SA, Baysson H, et al. Seroprevalence of anti-SARS-CoV-2 IgG antibodies in Geneva, Switzerland (SEROCoV-POP): a population-based study. *Lancet* 2020; [https://doi.org/10.1016/S0140-6736\(20\)31304-0](https://doi.org/10.1016/S0140-6736(20)31304-0)
11. Doi A, Iwata Kuroda H, Hasuike T, Nasu S, Kanda A, et al. Seroprevalence of novel coronavirus disease (COVID-19) in Kobe, Japan. *medRxiv* <https://doi.org/10.1101/2020.04.26.20079822>
12. Erikstrup C, Hother CE, Pedersen OB, Mølbak K, Skov RL, Holm DK, et al. Estimation of SARS-CoV-2 infection fatality rate by real-time antibody screening of blood donors. *Clin Infect Dis* 2020; <https://doi.org/10.1093/cid/ciaa849>.
13. Fontanet A, Tondeur L, Madec Y, Grant R, Besombes C, Jolly N, et al. Cluster of COVID-19 in northern France: A retrospective closed cohort study. *medRxiv* 2020 <https://doi.org/10.1101/2020.04.18.20071134>
14. Wu X, Fu B, Chen L, Feng Y. Serological tests facilitate identification of asymptomatic SARS-CoV-2 infection in Wuhan, China. *J Med Virol* 2020 <https://onlinelibrary.wiley.com/doi/10.1002/jmv.25904>
15. Slot E, Hogema BM, Reusken CBEM, Reimerink JH, Molier M, Karregat HM, et al. Herd immunity is not a realistic exit strategy during a COVID-19 outbreak. *Research Square* 2020. <https://dx.doi.org/10.21203/rs.3.rs-25862/v1>

16. Streeck H, Schulte B, Kümmerer BM, Richter E, Höller T, Fuhrmann C, et al. Infection fatality rate of SARS-CoV-2 infection in a German community with a super-spreading event. medRxiv 2020 <https://doi.org/10.1101/2020.05.04.20090076>
17. Silveira MF, Barros AJD, Horta BL, Pellanda LC, Dellagostin O, Struchiner CJ, et al. Repeated population-based surveys of antibodies against SARS2-CoV-2 in Southern Brazil. Nature Medicine 2020 (in press) <https://doi.org/10.1038/s41591-020-0992-3>
18. Thompson C, Grayson N, Paton RS, Lourenco J, Penman BS, Lee L. Neutralising antibodies to SARS coronavirus 2 in Scottish blood donors – a pilot study of the value of serology to determine population exposure. medRxiv <https://doi.org/10.1101/2020.04.13.20060467>
19. Bendavid E, Mulaney B, Sood N, et al. COVID-19 Antibody Seroprevalence in Santa Clara County, California. medRxiv doi: <https://doi.org/10.1101/2020.04.14.20062463>
20. Snoeck CJ, Vaillant M, Abdelrahman T, Satagopam VP, Turner JD, Beaumont K, et al. Prevalence of SARS-CoV-2 infection in the Luxembourgish population: the CON-VINCE study. medRxiv 2020.05.11.20092916; doi: <https://doi.org/10.1101/2020.05.11.20092916>
21. Kraehling V, Kern M, Halwe S, Mueller H, Rohde C, Savini M, et al. Epidemiological study to detect active SARS-CoV-2 infections and seropositive persons in a selected cohort of employees in the Frankfurt am Main metropolitan area. medRxiv 2020.05.20.20107730; doi: <https://doi.org/10.1101/2020.05.20.20107730>
22. Sood N, Simon P, Ebner P, Eichner D, Reynolds J, Bendavid E, Bhattacharya J. Seroprevalence of SARS-CoV-2-Specific Antibodies Among Adults in Los Angeles County, California, on April 10-11, 2020. JAMA. 2020 May 18:e208279.

23. Rosenberg ES, Tesoriero JM, Rosenthal EM, Chung R, Barranco MA, Styer LM, et al. Cumulative incidence and diagnosis of SARS-CoV-2 infection in New York. *Ann Epidemiol* 2020 (in press). DOI: <https://doi.org/10.1016/j.annepidem.2020.06.004>
24. Ng D, Goldgof G, Shy B, Levine A, Balcerak J, Bapat SP, et al. SARS-CoV-2 seroprevalence and neutralizing activity in donor and patient blood from the San Francisco Bay Area. medRxiv 2020.05.19.20107482; doi: <https://doi.org/10.1101/2020.05.19.20107482>
25. Hallal PC, Hartwig FP, Horta BL, Victora GD, Silveira MF, Struchiner CJ, et al. Remarkable variability in SARS-CoV-2 antibodies across Brazilian 1 regions: nationwide serological household survey in 27 states. medRxiv 2020 doi: <https://doi.org/10.1101/2020.05.30.20117531>
26. Jerkovic I, Ljubic T, Basic Z, Kruzic I, Kunac N, Bezic J, et al. SARS-CoV-2 antibody seroprevalence in industry workers in Split-Dalmatia and Sibenik-Knin County, Croatia. medRxiv 2020.05.11.20095158; doi: <https://doi.org/10.1101/2020.05.11.20095158>
27. Reifer J, Hayum N, Heszkel B, Klagsbald I, Strevva VA. SARS-CoV-2 IgG antibody responses in New York City. medRxiv 2020.05.23.20111427; doi: <https://doi.org/10.1101/2020.05.23.20111427>
28. Emmenegger M, De Cecco E, Lamparter D, Jacquat RPB, Ebner D, et al. Early plateau of SARS-CoV-2 seroprevalence identified by tripartite immunoassay in a large population. medRxiv 2020.05.31.20118554; doi: <https://doi.org/10.1101/2020.05.31.20118554>
29. Takita M, Matsumura T, Yamamoto K, Yamashita E, Hosoda K, Hamaki T, Kusumi E. Regional difference in seroprevalence of SARS-CoV-2 in Tokyo: Results from the community point-of-care antibody testing. medRxiv 2020.06.03.20121020; doi: <https://doi.org/10.1101/2020.06.03.20121020>

30. Crovetto F, Crispi F, Llurba E, Figueras F, Gomez-Roig MD, Gratacos E. Seroprevalence and clinical spectrum of SARS-CoV-2 infection in the first versus third trimester of pregnancy. medRxiv 2020; doi: <https://doi.org/10.1101/2020.06.17>.
31. Fiore JR, Centra M, De Carlo A, Granato T, Rosa A, Sarno M, et al. Far away from herd immunity to SARS-CoV-2: results from a survey in healthy blood donors in South Eastern Italy. medRxiv 2020; doi: <https://doi.org/10.1101/2020.06.17.20133678>
32. Ling R, Yu Y, He J, Zhang J, Xu S, Sun R, et al. Seroprevalence and epidemiological characteristics of immunoglobulin M and G antibodies against SARS-CoV-2 in asymptomatic people in Wuhan, China. medRxiv 2020; doi: <https://doi.org/10.1101/2020.06.16.20132423>.
33. Chamie G, Marquez C, Crawford E, Peng J, Petersen M, Schwab D, et al. SARS-CoV-2 community transmission during Shelter-in-place in San Francisco. medRxiv 2020; doi: <https://doi.org/10.1101/2020.06.15.20132233>
34. Gomes CC, Cerutti C, Zandonade E, et al. A population-based study of the prevalence of COVID-19 infection in Espírito Santo, Brazil: methodology and results of the first stage. medRxiv 2020; doi: <https://doi.org/10.1101/2020.06.13.20130559>
35. Havers FP, Reed C, Lim T, Montgomery JM, Klena JD, Hall AJ, et al. Seroprevalence of antibodies to SARS-CoV-2 in six sites in the United States, March 23-May 3, 2020. medRxiv 2020; doi: <https://doi.org/10.1101/2020.06.25.20140384>
36. Pollán M, Pérez-Gómez B, Pastor-Barriuso R, Oteo J, Hernán MA, Pérez-Olmeda M, et al. Prevalence of SARS-CoV-2 in Spain (ENE-COVID): a nationwide, population-based seroepidemiological study. Lancet 2020; [https://doi.org/10.1016/S0140-6736\(20\)31483-5](https://doi.org/10.1016/S0140-6736(20)31483-5)

37. Feehan AK, Fort D, Garcia-Diaz J, et al. Point prevalence of SARS-CoV-2 and infection fatality rate in Orleans and Jefferson Parish, Louisiana, May 9-15, 2020. medRxiv 2020; doi: <https://doi.org/10.1101/2020.06.23.20138321>
38. Herzog S, De Bie J, Abrams S, et al. Seroprevalence of IgG antibodies against SARS coronavirus 2 in Belgium – a prospective cross sectional study of residual samples. medRxiv 2020; doi: <https://doi.org/10.1101/2020.06.08.20125179>
39. Fontanet A, Grant R, Tondeur L, et al. SARS-CoV-2 infection in primary schools in northern France: A retrospective cohort study in an area of high transmission. medRxiv 2020; doi: <https://doi.org/10.1101/2020.06.25.20140178>
40. Xu X, Sun J, Nie S, et al. Seroprevalence of immunoglobulin M and G antibodies against SARS-CoV-2 in China. Nature Medicine 2020; <https://doi.org/10.1038/s41591-020-0949-6>
41. Filhol LA, Scwarcwald CL, Garcia Mateos S, et al. Seroprevalence of anti-SARS-CoV-2 among blood donors in Rio de Janeiro, Brazil. Rev Saude Publica 2020;54:69
42. Tess BH, Granato CFH, Alves MC, et al. SARS-CoV-2 seroprevalence in the municipality of São Paulo, Brazil, ten weeks after the first reported case. medRxiv 2020 doi: <https://doi.org/10.1101/2020.06.29.20142331>
43. Torres JP, Pinera C, De La MAza V, et al. SARS-CoV-2 antibody prevalence in blood in a large school community subject to a Covid-19 outbreak: a cross-sectional study. Clin Infect Dis 2020 (in press)
44. <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/bulletins/coronaviruscovid19infectionsurveyypilot/28may2020>, last accessed July 12, 2020
45. https://www.thl.fi/roko/cov-vaestoserologia/sero_report_weekly.html, last accessed July 20, 2020

46. <https://www.folkhalsomyndigheten.se/nyheter-och-press/nyhetsarkiv/2020/juni/forsta-resultaten-om-antikroppar-efter-genomgangen-covid-19-hos-blodgivare/>, last accessed July 20, 2020
47. <https://covid-imunita.uzis.cz/res/file/prezentace/20200506-dusek.pdf>, last accessed July 20, 2020
48. <https://www.jpost.com/israel-news/coronavirus-herd-immunity-not-in-israel-according-to-a-serological-study-630059>, last accessed July 20, 2020
49. <https://indianexpress.com/article/india/india-not-in-community-transmission-stage-yet-health-ministry-6454183/>, last accessed July 20, 2020
50. <https://www.gov.si/en/news/2020-05-06-first-study-carried-out-on-herd-immunity-of-the-population-in-the-whole-territory-of-slovenia/>, last accessed July 20, 2020
51. Ioannidis JPA, Axfors C, Contopoulos-Ioannidis DG. Population-level COVID-19 mortality risk for non-elderly individuals overall and for non-elderly individuals without underlying diseases in pandemic epicenters. *Environmental Research* 2020 (in press)
52. <https://www.theguardian.com/world/2020/apr/13/half-of-coronavirus-deaths-happen-in-care-homes-data-from-eu-suggests>. Accessed April 27, 2020.
53. American Geriatrics Society. American Geriatrics Society Policy Brief: COVID-19 and Nursing Homes. *J Am Geriatr Soc*. 2020 Apr 8. doi: 10.1111/jgs.16477.
54. Kelly A, Conell-Price J, Covinsky K, Stijacic Cenzer I, Chang A, Boscardin WJ, et al. Lengths of stay for older adults residing in nursing homes at the end of life. *J Am Geriatr Soc*. 2010;58(9):1701-6.
55. EUROMOMO. Graphs and maps: Excess mortality. Updated week 28, 2020. Accessed July 12, 2020. <https://www.euromomo.eu/graphs-and-maps/>

56. Wang D, Hu B, Hu C, et al. Clinical characteristics of 138 hospitalized patients with 2019 novel coronavirus-infected pneumonia in Wuhan, China. *JAMA*. 2020 Feb 7:e201585.
57. Boccia S, Ricciardi W, Ioannidis JPA. What Other Countries Can Learn From Italy During the COVID-19 Pandemic. *JAMA Intern Med*. 2020 Apr 7. doi: 10.1001/jamainternmed.2020.1447.
58. Sandri MT, Azzolini E, Torri V, Carloni S, Tedeschi M, Castoldi M, Mantovani A, Rescigno M. IgG serology in health care and administrative staff populations from 7 hospital representative of different exposures to SARS-CoV-2 in Lombardy, Italy. medRxiv doi: <https://doi.org/10.1101/2020.05.24.20111245>
59. Brofsky A. Distinct clades of SARS-CoV-2: implications for modeling of viral spread. *J Med Virol*. 2020 Apr 20. doi: 10.1002/jmv.25902.
60. Rosado J, Cockram C, Merkling SH, Demeret C, Meola A, Kerneis S, Terrier B, Fafi-Kremer S, et al. Serological signatures of SARS-CoV-2 infection: Implications for antibody-based diagnostics. medRxiv 2020. doi: <https://doi.org/10.1101/2020.05.07.20093963>
61. Long Q, Tang X, Shi Q, et al. Clinical and immunological assessment of asymptomatic SARS-CoV-2 infections. *Nat Med* 2020; <https://doi.org/10.1038/s41591-020-0965-6>
62. Wu F, Wang A, Liu M, et al. Neutralizing antibody responses to SARS-CoV-2 in a COVID-19 recovered patient cohort and their implications. medRxiv 2020;2020.03.30.20047365.
63. Seow J, Graham C, Merrick B, et al. Longitudinal evaluation and decline of antibody responses in SARS-CoV-2 infection. medRxiv 2020; doi: <https://doi.org/10.1101/2020.07.09.20148429>.

64. Edouard S, Colson P, Melenotte C, De Pinto F, Thomas L, La Scola B, et al. Evaluating the serological status of COVID-19 patients using an indirect immunofluorescent assay, France. medRxiv 2020; doi: <https://doi.org/10.1101/2020.05.05.20092064>
65. Solbach W, Schiffner J, Backhaus I, Burger D, Staiger R, Tiemer B, et al. Antibody profiling of COVID-19 patients in an urban low-incidence region in Northern Germany. medRxiv 2020.05.30.20111393; doi: <https://doi.org/10.1101/2020.05.30.20111393>
66. Kikkert M. Innate immune evasion by human respiratory RNA viruses. *J Innate Immun* 2020;12:4–20
67. Krammer F. The human antibody response to influenza A virus infection and vaccination. *Nature Reviews Immunology* 2019;19:1.
68. Cervia C, Nilsson J, Zurbuchen Y, Valaperti A, Schreiner J, Wolfensberger A, et al. Systemic and mucosal antibody secretion specific to SARS-CoV-2 during mild versus severe COVID-19. bioRxiv 2020 doi: <https://doi.org/10.1101/2020.05.21.108308>
69. Gallais F, Velay A, Wendling M-J, Nazon C, Partisani M, Sibia J, et al. Intrafamilial exposure to SARS-CoV-2 induces cellular immune response without seroconversion. medRxiv 2020; doi: <https://doi.org/10.1101/2020.06.21.20132449>
70. Sekine T, Rivera-Ballesteros O, Stralin K, et al. Robust T cell immunity in convalescent individuals with asymptomatic or mild COVID-19. bioRxiv 2020; doi: <https://doi.org/10.1101/2020.06.29.174888>
71. Moriarty LF, Plucinski MM, Marston BJ, Kurbatova EV, Knust B, Murray EL, et al. Public health responses to COVID-19 outbreaks on cruise Ships - Worldwide, February-March 2020. *MMWR Morb Mortal Wkly Rep.* 2020 Mar 27;69(12):347-352.
72. Maxmen A. Coronavirus is spreading under the radar in US homeless shelters. *Nature.* 2020 May;581(7807):129-130.

73. Britton T, Ball F, Trapman P. A mathematical model reveals the influence of population heterogeneity on herd immunity to SARS-CoV-2. *Science* 23 Jun 2020:eabc6810. DOI: 10.1126/science.abc6810
74. Gomes GM, Corder RM, King JG, Langwig KE, Souto-Maior C, Carneiro J, et al. Individual variation in susceptibility or exposure to SARS-CoV-2 lowers the herd immunity threshold. medRxiv <https://doi.org/10.1101/2020.04.27.20081893>
75. Grifoni A, Weiskopf D, Ramirez SI, et al. Targets of T cell responses to SARS-CoV-2 coronavirus in humans with COVID-19 disease and unexposed individuals. *Cell* 2020;181:1-13.
76. Paget J, Spreuwenberg P, Charu V, Taylor RJ, Iuliano AD, Bresee J, et al. Global mortality associated with seasonal influenza epidemics: New burden estimates and predictors from the GLaMOR Project. *J Glob Health*. 2019 Dec; 9(2): 020421.
77. Pandemic Influenza Preparedness and Response: A WHO Guidance Document. Geneva, World Health Organization, 2009.
78. Webb Hooper M, Nápoles AM, Pérez-Stable EJ. COVID-19 and racial/ethnic disparities. *JAMA*. 2020 May 11. doi: 10.1001/jama.2020.8598.
79. Centers for Disease Control and Prevention. COVID-19 in Racial and Ethnic Minority Groups. Updated April 24, 2020. Accessed April 30, 2020. <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html>
80. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html>, Accessed June 6, 2020.

81. Kissler SM, Tedijanto C, Goldstein E, Grad YH, Lipsitch M. Projecting the transmission dynamics of SARS-CoV-2 through the postpandemic period. *Science*. 2020 Apr 14:eabb5793. doi: 10.1126/science.abb5793.

Figure legends

Figure 1. Locations that had two or more IFR estimates from different studies. Locations are defined at the level of countries, except for the USA where they are defined at the level of states and China is separated into Wuhan and non-Wuhan areas. Corrected IFR estimates are shown. Within the same location, IFR estimates tend to have only modest differences, even though it is possible that different areas within the same location may also have genuinely different IFR. France is one exception where differences are large, but both estimates come from population studies of outbreaks from schools and thus may not provide good estimates of population seroprevalence and may lead to underestimated IFR.

Figure 2. Scatterplot of corrected IFR estimates (%) in each location plotted against the COVID-19 mortality rate as of July 12, 2020 in that location (in deaths per million population). Locations are defined at the level of countries, except for the USA where they are defined at the level of states and China is separated into Wuhan and non-Wuhan areas. When several IFR estimates are available from multiple studies for a location, the sample size-weighted mean has been used. Not shown are two locations with >1000 deaths per million population, both of which have high IFR (New York and Connecticut).

Figure 1

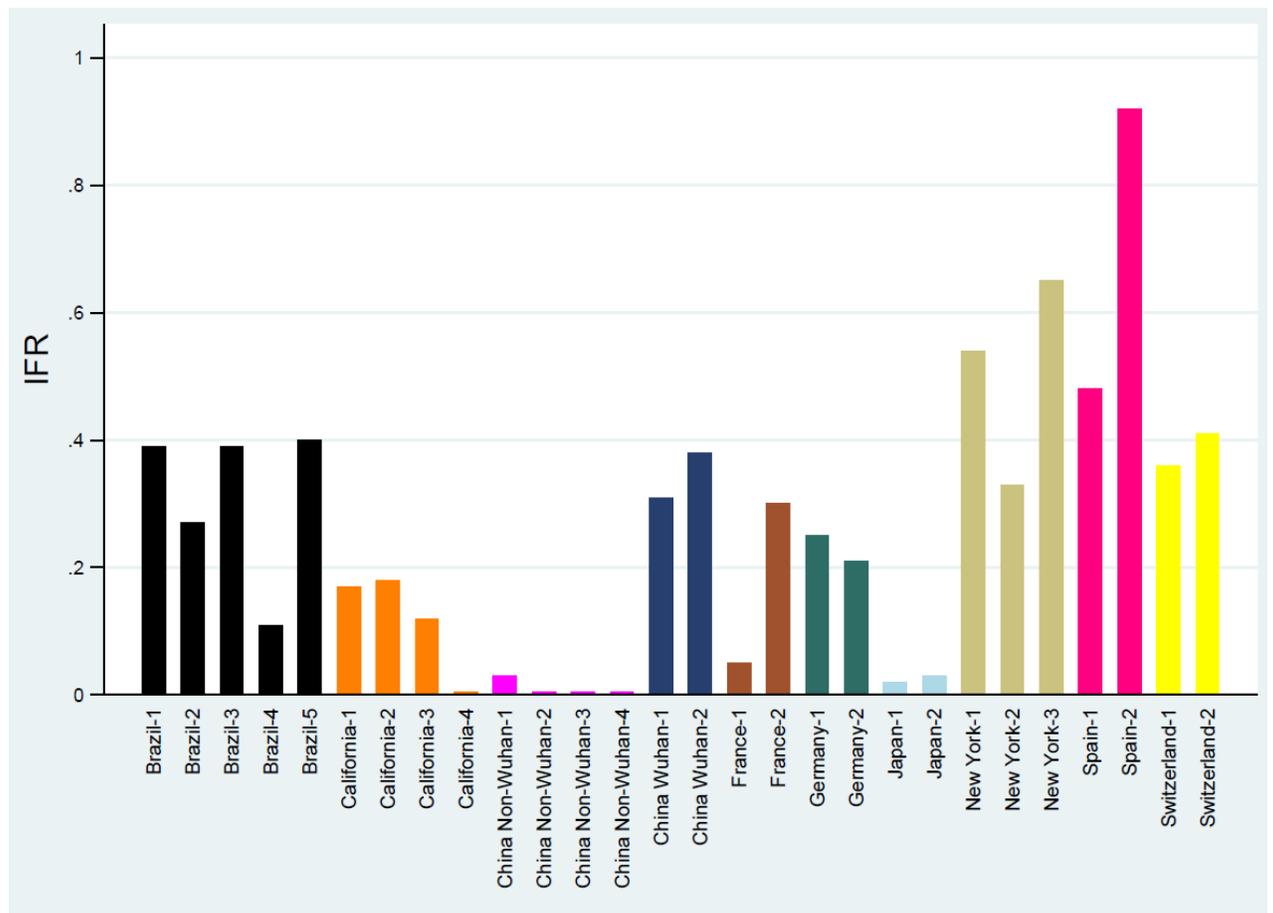
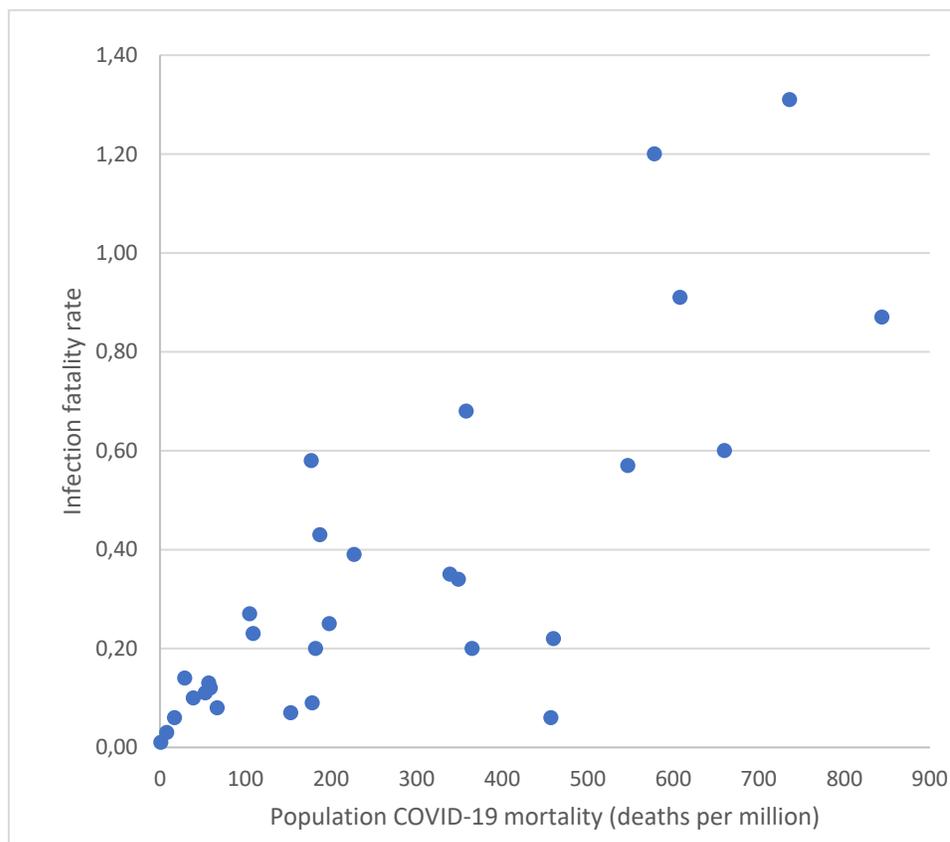


Figure 2



Attachment B

Conclusion Regarding Masks They Do Not Work

By Dr. Sherri Tenpenny, DO, AOBNMM, ABIHM

www.Vaxxter.com

www.Courses4Mastery.com

There are NO randomized, controlled trials (RCT) with verified outcomes that show a benefit to health care workers or community members for wearing a mask or a respirator. There is no such definitive study. Likewise, no study exists that shows a benefit from a broad policy to wear masks in public (documented below).

Furthermore, if there were any benefit to wearing a mask, because of the blocking power against droplets and aerosol particles, then there should be more benefit from wearing a respirator (N95) compared to a surgical mask. There is not. Neither masks nor respirators protect; cloth coverings are essentially worthless.

It should be noted that the surgical masks are primarily designed to protect the environment from the wearer, whereas the respirators are supposed to protect the wearer from the environment. (Balazy, et al).

Coronavirus **particles** are <0.125 microns in size. Masks and respirators filter particles 0.30 to 0.80 microns in size. Masks cannot possibly work. No bias-free study has ever found a benefit from wearing a mask or respirator in this application.

○ Public Health Experts Keep Changing: Mask vs No Mask

- **February 29, 2020:** https://twitter.com/Surgeon_General/status/1233725785283932160
 - “Seriously people – **STOP BUYING MASKS!** They are not effective in preventing general public from catching #Coronavirus, but if healthcare providers can’t get them to care for sick patients, it puts them and our communities at risk!” -Dr. Jerome Adams, US Surgeon General
- **May 10, 2020:** “Don’t Wear a Mask” –Dr. Anthony Fauci
<https://www.youtube.com/watch?v=MOeVkg9P-R8>
- **March 15, 2020: Medical Science News** “Reusing masks may increase your risk of coronavirus infection.” <https://www.news-medical.net/news/20200315/Reusing-masks-may-increase-your-risk-of-coronavirus-infection-expert-says.aspx>
 - Dr. Jenny Harries, England's deputy chief medical officer, has warned that it was **not a good idea for the public to wear facemasks** as the virus can get trapped in the material and causes infection when the wearer breathes in. "For the average member of the public walking down a street, it is not a good idea." Dr. Harries said.
- **March 30, 2020:** WHO Emergencies Press Conference on coronavirus disease
https://www.who.int/docs/default-source/coronaviruse/transcripts/who-audio-emergenciescoronavirus-press-conference-full-30mar2020.pdf?sfvrsn=6b68bc4a_2
 - at 00:22:39: “We **don't generally recommend the wearing to masks in public by otherwise well individuals** because it has not been, up to now, associated with any particular benefit...It does have **benefits psychologically**, socially and there are social norms around that and we don't criticize the wearing of masks, and have not done so, but **there is no specific evidence to suggest that the wearing of masks by the mass population has any particular benefit**. In fact, there's some evidence to suggest the

opposite in the misuse of wearing a mask properly or fitting it properly or taking it off and all the other risks that are otherwise associated with that.

- **March 31, 2020:** <https://www.newsmax.com/us/surgeon-general-adamsmasks/2020/03/31/id/960679/>
 - “You can increase your risk of getting COVID19 by wearing a mask if you are not a health care provider. Folks who don't know how to wear them properly tend to touch their faces a lot and actually **can increase the spread of coronavirus.**” -Dr. Jerome Adams, US Surgeon General
- **April 3, 2020:** <https://time.com/5794729/coronavirus-face-masks/>
 - According to the CDC, wearing a surgical mask **won't stop the wearer from inhaling small airborne particles, which can cause infection.** Nor do these masks form a snug seal around the face.
 - The CDC recommends surgical masks **only for people who *already show symptoms*** of coronavirus and must go outside. Wearing a mask can help prevent spreading the virus by protecting others nearby when you cough or sneeze.
- **May 1, 2020:** Illinois issued an order that a mask will be required in public when social distancing isn't an option.
- **May 27, 2020:** Virginia announced a statewide mask mandate.
-and many more states have followed suit.

○ **Healthy Persons do not Spread Illness**

- **Leung, Nancy., et al. (2020)** “Respiratory virus shedding in exhaled breath and efficacy of face masks.” *Nature Medicine* 26, 676-680. <https://www.nature.com/articles/s41591-020-0843-2>
 - “...Among the samples collected without a face mask, we found that the majority of participants with influenza virus and coronavirus infection **did not shed detectable virus in respiratory droplets or aerosols...** given that each exhaled breath collection was conducted for 30 min, this might imply that **prolonged close contact would be required for transmission to occur**, even if transmission was primarily via aerosols..”
- **Gao, Ming. et al.** “A Study of infectivity of asymptomatic SARS-CoV2 carriers.” *Respiratory Medicine*. 2020. Aug: 169:106026 <https://pubmed.ncbi.nlm.nih.gov/32513410/>
 - 455 contacts who were exposed to the asymptomatic COVID-19 virus carrier: 35 patients, 196 family members and 224 hospital staffs. **NONE of the 455 contacts contracted the SARS-CoV-2 infection**

○ **Mask Mandates as Public Policy is a Disaster**

- **Klompas, Michael., et al. (2020)** “Universal Masking in Hospitals in the COVID-19 Era.” *NEJM* 2020; 382:e63 <https://www.nejm.org/doi/full/10.1056/NEJMp2006372?>
 - **We know that wearing a mask outside health care facilities offers little**, if any, protection from infection. Public health authorities define a significant exposure to Covid-19 as face-to-face contact within 6 feet with a patient with symptomatic Covid-19 that is sustained for at least a few minutes (and some say more than 10 minutes or even 30 minutes). **The chance of catching Covid-19 from a passing interaction in a public space is therefore minimal.** In many cases, the desire for widespread masking is a reflexive reaction to anxiety over the pandemic.

- **Brainard, Julii Suzanne, et al. (2020)** “Facemasks and similar barriers to prevent respiratory illness such as COVID-19: A rapid systematic review.” medRxiv 2020.04.01.20049528
<https://www.medrxiv.org/content/10.1101/2020.04.01.20049528v1>
 - “There were 31 eligible studies (including 12 RCTs). Based on the RCTs we would conclude that wearing facemasks can be very slightly protective against primary infection from casual community contact, and modestly protective against household infections when both infected and uninfected members wear facemasks. **The evidence is not sufficiently strong to support widespread use of facemasks as a protective measure against COVID-19.**
- **Chandrasekaran, Baskaran. (2020)** “Exercise with facemask: Are we handling a devil’s sword?” – a physiological hypothesis. *Med Hypotheses*. Nov; 144:11002. 2020
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7306735/>
 - Exercising with facemasks may reduce available Oxygen and increase air trapping preventing substantial carbon dioxide exchange. The hypercapnic hypoxia may potentially increase acidic environment, cardiac overload, anaerobic metabolism and renal overload, which may substantially aggravate the underlying pathology of established chronic diseases. Further contrary to the earlier thought, **no evidence exists to claim the facemasks during exercise offer additional protection from the droplet transfer of the virus.**
- **Tam, Victor CW et al (2020)** “A reality check on the use of face masks during the COVID 19 outbreak in Hong Kong.” *EClinicalMedicine*. 2020 May; 22:100356
 - In our study, 94.8% wore masks of which 83.7% wore disposable surgical masks. However, 13.0% wore them incorrectly: with 35.5% worn ‘inside-out’ or ‘upside-down’; and 42.5% worn too low, exposing the nostrils or mouth. Packaging of different brands of surgical mask sold locally were examined; very few provided instructions on correct usage. **[NOTE: IF NOT worn correctly, there are doing nothing and should not be worn at all.]**

○ Particle Size: The Key to it All

- **Zhu, Na, et al. (2020).** “A Novel Coronavirus from Patients with Pneumonia in China, 2019” *N Engl J Med* 2020; 382:727-733. <https://www.nejm.org/doi/full/10.1056/nejmoa2001017>
 - Scientists were at a consensus that the diameter of the 2019-nCoV particles were **0.06 to 0.14 microns in size**. Most N95 and N99 face masks can filter out 0.30 microns. **Airborne coronavirus particle (<0.125 micron) will pass directly through a N95 face mask.**
- **Balazy, Anna, et al. (2006).** “Do N95 respirators provide 95% protection level against airborne viruses, and how adequate are surgical masks?” *Am J Infect Control*. 2006 Mar;34(2):51-7.
 - The N95 filtering face piece respirators may not provide the expected protection level **against small virions**. As anticipated, the tested surgical masks showed a much higher particle penetration because they are known to be less efficient than the N95 respirators. **Some surgical masks may let a significant fraction of airborne viruses penetrate through their filters**, providing very low protection against aerosolized infectious agents in the size range of 10 to 80 nm.

○ N95 Respirators

- **Long, Y. et al. (2020).** “Effectiveness of N95 respirators vs surgical masks against influenza: A

systematic review and meta-analysis.” *J Evidence Based Medicine*. 2020;12:93-101.
<https://onlinelibrary.wiley.com/doi/epdf/10.1111/jebm.12381>

- “The current meta-analysis shows the use of N95 respirators compared to surgical masks is **not associated with a lower risk** of laboratory-confirmed influenza.”
- **Randonovich, Lewis, et al. (2019)** “N95 Respirators vs Medical Masks for Preventing Influenza Among Health Care Personnel: A Randomized Clinical Trial”. *JAMA*. 2019 Sept 3; (322(9):824-833. <https://pubmed.ncbi.nlm.nih.gov/31479137/>
 - “Among outpatient health care personnel, N95 respirators vs medical masks as worn by participants in this trial resulted in **no significant difference** in the incidence of laboratory-confirmed influenza.
- **Offeddu, V. et al. (2017)** “Effectiveness of Masks and Respirators Against Respiratory Infections in Healthcare Workers: A Systematic Review and Meta-Analysis,” *Clinical Infectious Diseases*, Volume 65, Issue 11, 1 December 2017, Pages 1934–1942, <https://academic.oup.com/cid/article/65/11/1934/4068747>
 - “Self-reported assessment of clinical outcomes was prone to bias. Evidence of a protective effect of masks or respirators against verified respiratory infection (VRI) was **not statistically significant.**”
- **Chou, Roger, et al. (2020)** “Masks for Prevention of Respiratory Virus Infections, Including SARS-CoV-2, in Health Care and Community Settings.” *Ann Intern Med* June 24:M20-3213. 2020 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7322812/>
 - Randomized trials in community settings found possibly no difference between N95 versus surgical masks and probably **no difference** between surgical versus no mask in risk for influenza or influenza-like illness, but compliance was low. **Bothersome symptoms were common.**
- **Zhu JH, et al.** “Effects of long-duration wearing of N95 respirator and surgical facemask: a pilot study.” *J Lung Pulm Respir Res*. 2014;1(4):97–100. <http://medcraveonline.com/JLPRR/JLPRR-01-00021.pdf>
 - As the protection efficacy and possible effects on nasal functions and subjective sensations of wearing N95 respirator/surgical facemask have been well demonstrated, wearing of respirator and facemask altered the fractions of air components and changed microclimate around the nasal cavity, **which would further affect the function of mucosa** and its transportation rate.
- **Cowling, B. et al. (2010)** “Face masks to prevent transmission of influenza virus: A systematic review.” *Epidemiology and Infection*, 138(4), 449-456. <https://www.cambridge.org/core/journals/epidemiology-and-infection/article/face-masks-to-preventtransmission-of-influenza-virus-a-systematicreview/64D368496EBDE0AFCC6639CCC9D8BC05/core-reader>
 - N95-masked health-care workers (HCW) were significantly more likely to experience headaches. Face mask use in HCW **was not demonstrated to provide benefit** in terms of cold symptoms or getting colds.
- **Smith, Jeffrey, et al. (2016)** “Effectiveness of N95 respirators versus surgical masks in protecting health care workers from acute respiratory infection: a systematic review and meta-analysis.” *CMAJ* 2016 May 17;188(8):567-574 <https://pubmed.ncbi.nlm.nih.gov/26952529/>
 - Although N95 respirators appeared to have a protective advantage over surgical masks

in laboratory settings, our meta-analysis showed that there were **insufficient data to determine definitively whether N95 respirators are superior to surgical masks** in protecting health care workers against transmissible acute respiratory infections in clinical settings.

- **U.S. Food and Drug Administration article (April 2020)**
<https://web.archive.org/web/20200516235249/https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks>
 - If properly fitted, the filtration capabilities of N95 respirators exceed those of face masks. However, **even a properly fitted N95 respirator does not completely eliminate the risk of illness or death.**

○ Surgical Face Masks

- **Isaacs, David, et al. (2020)** “Do Facemasks protect against COVID-19?” *J. of Pediatric and Child Health*, June. 56(6): 976-977. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7323223/>
 - “The **questionable benefits** arguably **do not justify health-care staff wearing surgical masks** when treating low-risk patients and may impede the normal caring relationship between patients, parents and staff. We counsel against such practice, at least at present.”
- **Jacobs, J. L. et al. (2009)** “Use of **surgical face masks** to reduce the incidence of the common cold among health care workers in Japan: A randomized controlled trial,” *American Journal of Infection Control*, Volume 37, Issue 5, 417-419.
<https://www.ncbi.nlm.nih.gov/pubmed/19216002>
 - N95-masked health-care workers (HCW) were significantly more likely to experience headaches. **Face mask use in HCW was not demonstrated to provide benefit in terms of cold symptoms or getting colds.**
- **Smith, J.D. et al. (2016)** “Effectiveness of N95 respirators versus surgical masks in protecting health care workers from acute respiratory infection: a systematic review and meta-analysis,” *CMAJ* Mar 2016 <https://www.cmaj.ca/content/188/8/567>
 - “We identified six clinical studies ...we found **no significant difference** between N95 respirators and surgical masks in associated risk of (a) laboratory-confirmed respiratory infection, (b) influenza-like illness, or (c) reported work-place absenteeism.”
- **Balazy, Anna, et al. (2006)** “Do N95 respirators provide 95% protection level against airborne viruses, and how adequate are surgical masks?” *Am J Infect Control*. 2006 Mar;34(2):51-7.
 - The N95 filtering face piece respirators may not provide the expected protection level **against small virions**. As anticipated, the tested surgical masks showed a much higher particle penetration because they are known to be less efficient than the N95 respirators. **Some surgical masks may let a significant fraction of airborne viruses penetrate through their filters**, providing very low protection against aerosolized infectious agents in the size range of 10 to 80 nm.
- **U.S. Food and Drug Administration article (April 2020)**
<https://web.archive.org/web/20200516235249/https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks>
 - While a surgical mask may be effective in blocking splashes and large-particle droplets, a face mask, by design, **does not filter or block very small particles in the air that may be transmitted by coughs, sneezes**, or certain medical procedures. Surgical masks

also **do not provide complete protection from germs and other contaminants** because of the loose fit between the surface of the face mask and your face.

- **Bader A et al. (2008)** “Preliminary report on surgical mask induced deoxygenation during major surgery. *Neurocirugia* 2008;19:12-126. <https://www.technocracy.news/blaylock-face-masks-pose-serious-risks-to-the-healthy/>

- In this study, researchers examined the blood oxygen levels in 53 surgeons using an oximeter. They measured blood oxygenation before surgery as well as at the end of surgeries. The researchers found that the **mask reduced the blood oxygen levels (paO2) significantly. The longer the duration of wearing the mask, the greater the fall in blood oxygen levels.**

○ Cloth Masks

- **MacIntyre, C Raina, et al.** “A cluster randomized trial of cloth masks compared with medical masks in healthcare workers.” *BMJ Open* 2015; 5:e006577. <https://bmjopen.bmj.com/content/5/4/e006577.full>
 - “Cloth masks also had significantly higher rates of influenza-like illness. Penetration of **viral particles through a cloth mask was almost 97%**”
- **Rengasamy, Samy, et al.** “Simple Respiratory Protection – Evaluation of the filtration performance of cloth masks and common fabric materials against 20-1000nm size particles” *The Annals of Occupational Hygiene*, Vol 54, Issue 7, Oct 2010. Pg 789-798 <https://academic.oup.com/annweh/article/54/7/789/202744>
 - Results obtained show that common fabric materials provide **marginal protection** against nanoparticles including those in the size ranges of virus-containing particles in exhaled breath.
- **Shakya, Kabindra M, et al.** “Evaluating the efficacy of cloth facemasks in reducing particulate matter exposure.” *J Expo Sci Environ Epidemiol.* 2017;27(3):352-357. <https://pubmed.ncbi.nlm.nih.gov/27531371/>
 - “Our results suggest that cloth masks are only marginally beneficial in protecting individuals from particles <2.5 µm (**Note: coronaviruses are between .05 and 0.2 microns**)”
- **MMWR: Weekly** / July 17, 2020 / 69(28);930-932 https://www.cdc.gov/mmwr/volumes/69/wr/mm6928e2.htm?s_cid=mm6928e2_w
 - At salon X in Springfield, Missouri, two stylists with COVID-19 symptoms worked closely with 139 clients before receiving diagnoses of COVID-19, and **none** of their clients developed COVID-19 symptoms. 67 were tested; 67 specimens were positive. Close contacts because ill; apparently everyone recovered uneventfully. **CONCLUSION:** 1) Exposure isn't illness and 2) positive tests isn't illness
- **Angell, Sonia Y., State of California – Health and Human Services Agency article (April 2020)** “Face Coverings Guidance” <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Face-Coverings-Guidance.aspx>
 - “Our best community and individual defense against COVID 19 is washing our hands frequently, avoiding touching our eyes, nose and mouth with unwashed hands, avoiding being around sick people and physical distancing, especially by staying at home.”
“There is limited evidence to suggest that use of cloth face coverings by the public

during a pandemic could help reduce disease transmission.”

○ Wearing a Mask Blocks Oxygen

- Wearing a mask is hazardous to your health.
<https://www.youtube.com/watch?v=ZqRL1GXu5DE>
- **Kao, Tze-Wah, et al. (2004).** The physiological impact of wearing an N95 mask during hemodialysis as a precaution against SARS in patients with end-stage renal disease.” *J Formos Med Asso.* 2004 Aug;103(8):624-8
 - Thirty-nine patients (mean age, 57.2 yrs) in the study. 70% showed a reduction in partial pressure of oxygen (PaO₂), and 19% developed various degrees of hypoxemia. Wearing an N95 mask significantly **reduced the PaO₂ level, increased the respiratory rate, increased chest discomfort, and respiratory distress.** Wearing an N95 mask for **4 hours** during HD significantly reduced PaO₂ and increased respiratory adverse effects in ESRD patients. **[DOES THIS DO THE SAME IN OTHER PATIENTS WITH HEALTH CONDITIONS?]**
- **OSHA documents:** <https://www.osha.gov/laws-regs/standardinterpretations/2007-04-02-0>
 - “People begin to suffer adverse health effects when the oxygen level of their breathing air drops below 19.5 percent oxygen. The rule-making record for the Respiratory Protection Standard clearly justifies adopting the requirement that air breathed by employees must have an **oxygen content of at least 19.5 percent.**”
- **Beder, A et al. (2008)** “Preliminary report on surgical mask induced deoxygenation during major surgery.” *Neurocirugia (Astur)* 2008 Apr;19(2):121-6.
<https://pubmed.ncbi.nlm.nih.gov/18500410/>
 - A study on 53 surgeons using a pulse oximeter pre and postoperatively. **Pulse rates increased and SpO₂ decrease after the first hour.** Since a very small decrease in saturation at this level, reflects a large decrease in PaO₂, our findings may have a clinical value for the health workers and the surgeons. *[NOTE: SpO₂ {O₂ sat} is the saturation of hemoglobin with oxygen measured with a pulse oximeter. PaO₂ is amount of oxygen in the blood, determined by an arterial blood sample. Once the O₂ sat falls below 90%, the PaO₂ drops quickly into the dangerously hypoxic.*
- **Ong JJY et al. (2020)** “Headaches associated with personal protective equipment- A cross-sectional study among frontline healthcare workers during COVID-19.” *Headache* 2020;60(5):864-877. <https://www.technocracy.news/blaylock-face-masks-pose-serious-risks-to-the-healthy/>
 - Study involving 159 healthcare workers aged 21 to 35 years of age found that 81% developed headaches from wearing a face mask.
- **Shehade H et al. Cutting edge:** Hypoxia-Inducible Factor-1 negatively regulates Th1 function. *J Immunol* 2015;195:1372-1376 // **Westendorf AM et al.** Hypoxia enhances immunosuppression by inhibiting CD4⁺ effector T cell function and promoting Treg activity. *Cell Physiol Biochem* 2017;41:1271-84 // **Sceneay J et al.** Hypoxia-driven immunosuppression contributes to the pre-metastatic niche. *Oncoimmunology* 2013;2:1 e22355
<https://www.technocracy.news/blaylock-face-masks-pose-serious-risks-to-the-healthy/>
 - **The importance of these findings is that a drop in oxygen levels (hypoxia) is associated with an impairment in immunity.** Studies have shown that hypoxia can inhibit the type of main immune cells used to fight viral infections called the CD4⁺ T-

lymphocyte. This occurs because the hypoxia increases the level of a compound called hypoxia inducible factor-1 (HIF-1), which inhibits T-lymphocytes and stimulates a powerful immune inhibitor cell called the Tregs. . This sets the stage for contracting any infection, including COVID-19 and making the consequences of that infection much graver. **In essence, your mask may very well put you at an increased risk of infections and if so, having a much worse outcome.**

- **Blaylock RL.** Immunoexcitatory mechanisms in glioma proliferation, invasion and occasional metastasis. *Surg Neurol Inter* 2013;4:15 // **Aggarwal BB.** Nuclear factor-kappaB: The enemy within. *Cancer Cell* 2004;6:203-208 // **Savransky V et al.** Chronic intermittent hypoxia induces atherosclerosis. *Am J Resp Crit Care Med* 2007;175:1290-1297
<https://www.technocracy.news/blaylock-face-masks-pose-serious-risks-to-the-healthy/>

- **People with cancer, especially if the cancer has spread, will be at a further risk from prolonged hypoxia as the cancer grows best in a microenvironment that is low in oxygen.** Low oxygen also promotes inflammation which can promote the growth, invasion and spread of cancers. Repeated episodes of hypoxia has been proposed as a significant factor in atherosclerosis and hence increases all cardiovascular (heart attacks) and cerebrovascular (strokes) diseases

○ Wearing a Mask Increases CO₂ – Leading to Cognitive Dysfunction

- **Zheng, Guo-qing, et al. (2008)** “Chronic hypoxia-hypercapnia influences cognitive function: a possible new model of cognitive dysfunction in COPD.” *Med Hypotheses*. 2008;71(1):111-3
<https://pubmed.ncbi.nlm.nih.gov/18331781/>
 - “We propose that cognitive impairment is strongly related to combination of chronic hypoxia and hypercapnia.”

○ The Psychological Impact of Mask Wearing

- **TIME MAGAZINE (2020)** “Public Health Experts Keep Changing Their Guidance on Whether or Not to Wear Face Masks for Coronavirus.” <https://time.com/5794729/coronavirus-face-masks/>
 - Lynn Bufka, a clinical psychologist and senior director for practice, research and policy at the American Psychological Association, suspects that people are clinging to masks for the same reason they knock on wood or avoid walking under ladders. **“Even if experts are saying it’s really not going to make a difference, a little [part of] people’s brains is thinking, well, it’s not going to hurt. Maybe it’ll cut my risk just a little bit, so it’s worth it to wear a mask,”** she says. In that sense, **wearing a mask is a “superstitious behavior.”** <https://time.com/5794729/coronavirus-face-masks/>
- **Potts, Susan Claire.** “The Cult of the Mask.” <https://remnantnewspaper.com/web/index.php/articles/item/4927-the-cult-of-the-mask>
 - When people hide their faces, they feel they *belong* to something. They can show their solidarity with the whole human race. They can feel *good about themselves*. They can keep people *safe*. They can *make a difference*. **The freedom of the open-faced is seen as a threat to their safety and, more significantly, to their sense of commitment to a great cause.** Currently, the weapons are psychological—shame, ostracism.
- **Klompas, Michael., et al. (2020)** “Universal Masking in Hospitals in the COVID-19 Era.” *NEJM* 2020; 382:e63 <https://www.nejm.org/doi/full/10.1056/NEJMp2006372>
 - One might argue that fear and anxiety are better countered with data and education than

with **a marginally beneficial mask**, particularly in light of the worldwide mask shortage, but it is difficult to get clinicians to hear this message in the heat of the current crisis. **Expanded masking protocols' greatest contribution may be to reduce the transmission of anxiety**, over and above whatever role they may play in reducing transmission of Covid-19.

○ Masks Dehumanize Us

- **Foley, Gretchen N, et al. (2010)** “Nonverbal Communication in Psychotherapy.” *Psychiatry* (Edgmont). June 7(6):38-44 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2898840/>
 - An estimated 60 to 65 percent of interpersonal communication is **conveyed via non-verbal behaviors**.
 - Masks distort the structure of the face. The lower part of their face is disguised. Identity is concealed. No non-verbal cues or emotion is communicated to a fellow human being can be discerned; **all facial communication is hidden under the mask**.
- **Pike, Kathleen M., PhD.** “Why a Mask is Not Just a Mask” https://www.cugmhp.org/five-on-friday/why-a-mask-is-not-just-a-mask/?fbclid=IwAR1_h_ykyuIOzQ9WqA_u_muupA8D8UwOgvnhlwcjoIw_CReHuKSPPmy2wC4
 - “Many young children burst into tears or recoil when someone wearing a mask approaches. One reason for this is that the development of facial recognition is relatively weak in young children. **According to University of Toronto psychologist, Dr. Kang Lee, it is not until kids are about 14 years old that they reach adult skill levels in recognizing faces.** Before then, kids tend to see individual facial features, rather than recognizing the person as a whole. By putting on masks, we take away information that makes it especially difficult for children to recognize others and read emotional signals, which is unsettling and disconcerting. These issues may be especially true for children with autism spectrum disorder, including Asperger’s syndrome, who tend to have particular difficulties reading non-verbal cues.”

+++++

Four Key Reasons Why People Choose to Not Wear a Mask

<https://www.medicalnewstoday.com/articles/covid-19-and-face-masks-to-wear-or-not-to-wear#1.-Masks-offer-no-protection-to-the-wearer>

1. Masks offer no protection to the wearer
 - a. *Masks are not an effective way of protection from the new coronavirus, only N95 are, and masks have disclaimers saying they cannot prevent someone from acquiring the new coronavirus*
2. Evidence is lacking that masks protect anyone: the wearer or the public
 - a. *See the references above*
3. Masks increase the risk of contracting an infection: COVID19 or others
 - a. *Masks can become contaminated very quickly, and every time the wearer breathes in, they inhale contaminants*

4. Masks might harm the wearer
 - a. *Masks limit oxygen intake and increase carbon dioxide (CO₂)*
 - b. *Masks are dangerous for people with certain health conditions (COPD, asthma), as they may restrict breathing*
 - i. The WHO acknowledge that people living with asthma, chronic respiratory conditions, or breathing problems may experience difficulties when wearing face masks.
 - ii. The CDC recommend that anyone who has trouble breathing should not wear a face covering.

+++++

BEST REFERENCES:

1. “No one has died of coronavirus.” <https://www.globalresearch.ca/no-one-has-diedcoronavirus/5717668>
 2. “Masks don’t work.” <https://www.rcreader.com/commentary/masks-dont-work-covid-areview-of-science-relevant-to-covide-19-social-policy>
 3. “Asymptomatic carriers don’t spread infection.” <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7219423/>
 4. “Exposure doesn’t mean death; doesn’t even mean illness.” https://www.cdc.gov/mmwr/volumes/69/wr/mm6928e2.htm?s_cid=mm6928e2_w
 5. “Masks for all not based on sound data.” <https://www.cidrap.umn.edu/newsperspective/2020/04/commentary-masks-all-covid-19-not-based-sound-data>
 6. “COVID19- PCR testing is Scientifically Meaningless” <https://offguardian.org/2020/06/27/covid19-pcr-tests-are-scientifically-meaningless/>
- “Blaylock: Face Masks Pose Serious Risks To The Healthy” <https://www.technocracy.news/blaylock-face-masks-pose-serious-risks-to-the-healthy/>

NOTE: The following articles have many sources you may find helpful to also include/cite:

<https://www.sciencedirect.com/science/article/pii/S1755436516300858#sec0075>

<https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0186217>

Attachment C.1

Inaccurate Testing

From the beginning, COVID-19 testing in the U.S. has been flawed. While the World Health Organization had developed testing specifications for COVID-19 by January 2020, the CDC decided to develop its own test, which was ready by early February. The test was manufactured and distributed by the CDC to health centers throughout the U.S., and within a few days, the tests were found to be inaccurate. In response the FDA insisted that hospitals, academic centers and private companies *should not develop their own tests*. When the agency finally lifted the ban on test development at the end of February, there was a rush to get tests ready for market. Although the FDA provided no standards for how COVID-19 was to be detected. This meant all test makers could decide what standard to use.

Over 100 companies are currently producing tests for COVID-19, and these tests were approved by the FDA under emergency authorization with minimal validation. The test makers only had to show that the tests performed well in test tubes and no real-world demonstration of clinical viability was required.¹ Each vendor established its own and as-yet-unmeasured accuracy. The variations are myriad, with some tests able to detect as few as 100 copies of a viral gene while others require 400 copies for detection.² Additionally, most will show positive results for as long as 6 months, while the actual time a person is contagious is only a few days.

Several issues were never addressed. One is the potential cross-reactivity with other viruses. Another is that the presence of coronavirus is likely to remain for several months after the infectious period has passed. This means the tests are useless for determining who should be quarantined. Yet another is the risk of cross contamination, particularly when testing large numbers of people in crowded settings. Even the tiniest amount of cross contamination can lead to a false positive result, which means people who have never been exposed to COVID-19 could be subjected to unwarranted quarantines.

The accuracy of tests is important since numbers of "cases" is the metric used to determine business closures, event cancellations, lockdowns, withdrawal of civil rights and liberties, whether people can congregate, and if the useless masks are required.

There are two primary processes used to test for the coronavirus. The first method requires a sample of mucus from a person's nose or throat and then attempting to

replicate the RNA through a Polymerase Chain Reaction (PCR) machine. The second is through the antibody test, a blood test that is supposed to determine not if one is infected, but if they have ever been infected. Both tests are flawed.

Biochemist Kary Mullis is the inventor of the PCR test and won the Nobel Prize in chemistry for his invention in 1993. Mullis stated in 2013 that PCR was never designed to diagnose disease. The test finds very small segments of a nucleic acid which are components of a virus. According to Mullis, having an actual infection is quite different than testing positive with PCR. According to Mullis, PCR is best used in medical laboratories and for research purposes.

Dr. David Rasnick, also a biochemist and founder of a lab called Viral Forensics, agrees. "You have to have a whopping amount of any organism to cause symptoms. Huge amounts of it. You don't start with testing; you start with listening to the lungs. I'm skeptical that a PRC test is ever true. It's a great scientific research tool. It's a horrible tool for clinical medicine. 30% of your infected cells have been killed before you show symptoms. By the time you show symptoms...the dead cells are generating the symptoms."

When asked about having a COVID-19 test he stated, "Don't do it, I say, when people ask me. No healthy person should be tested. It means nothing but it can destroy your life, make you absolutely miserable." He went on to say, "Every time somebody takes a swab, a tissue sample of their DNA, it goes into a government database. It's to track us. They're not just looking for the virus. Please put that in your article."³

In fact, PCR testing was already shown to be wildly inaccurate almost 15 years ago. In 2006, massive PCR testing was performed at the Dartmouth Hitchcock Medical Center when it was thought that the medical center was experiencing an epidemic of whooping cough. Almost 1000 healthcare workers were furloughed until their test results were returned. Over 140 employees were told that they had whooping cough, and thousands of others who tested positive were given antibiotics and/or a vaccine for whooping cough.

Almost eight months later, employees received an email from the hospital administration which stated that the entire episode was due to PCR testing error. Not even one case of whooping cough was confirmed with a more reliable follow-up test, and it was determined that the employees just had a common cold, not whooping cough.⁴

Apparently, this history was ignored as incompetent health officials like Mr. Fauci decided that ginning up cases was more important than following the science. Thus, a test that the developer said was not useful for diagnosis and that had been previously shown to be inaccurate 100% of the time was recommended for COVID-19.

A recent meta-analysis published in the *British Medical Journal* looked at the accuracy of PCR testing specifically for COVID-19. The researchers reported that while no test is 100% accurate, the sensitivity and specificity of a test is evaluated by comparison with a gold standard, and there is no gold standard for COVID-19. One of the reasons is that it is impossible to know the false positive rate without having tested people who don't have the virus along with people who do, and this was never done.

The analysis showed that the false negative rate ranges between 2% and 29%. Accuracy of viral RNA swabs was highly variable. In one study, sensitivity was 93% for bronchoalveolar lavage, 72% for sputum, 63% for nasal swab, and only 32% for throat swabs. The researchers stated that results vary for many reasons including stage of disease.⁵ This analysis was published in May, long after Mr. Fauci and his accomplices had succeeded in creating a false pandemic, in part by insisting that more and more people should be tested.

Fortunately, many people are far more diligent than Fauci in checking out facts. Investigators from *OffGuardian* contacted the authors of four papers published in early 2020 in which researchers claimed that they had discovered a new coronavirus. The investigators asked for proof that electron micrographs showed purified virus and all four groups replied that they did not.

Here are the verbatim responses from the four groups:

"The image is the virus budding from an infected cell. It is not purified virus."

"We could not estimate the degree of purification because we do not purify and concentrate the virus cultured in cells."

"[We show] an image of sedimented virus particles, not purified ones."

"We did not obtain an electron micrograph showing the degree of purification."

The investigators also contacted virologist Charles Calisher and asked if he knew of any research group that had isolated and purified SARS-COV-2 and he replied that he did not. They concluded at this time no one knows whether the RNA gene sequences used in the in vitro trials and which were used to calibrate the tests came from SARS-CoV-2.⁶

All of this may explain why some of the testing results from around the world have been so difficult to understand or explain. For example, testing in Guangdong province in China showed that 10% of people who recovered from COVID-19 tested negative and then tested positive again.⁷ Twenty-nine patients tested in Wuhan tested negative, then positive, and then the results were "dubious."⁸

According to Wang Chen, president of the Chinese Academy of Medical Sciences, PCR tests are only 30-50% accurate.⁹

The CDC agrees. A statement in its online instruction manual for PCR testing includes these statements:

Detection of viral RNA may not indicate the presence of infectious virus or that 2019-nCoV is the causative agent for clinical symptoms.”

This test cannot rule out diseases caused by other bacterial or viral pathogens.”¹⁰

The FDA’s online emergency use authorization includes this statement:

“positive results [...] do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.”¹¹

In fact, the manufacturer’s instruction manual for one PCR test includes these statements:

These assays are not intended for use as an aid in the diagnosis of coronavirus infection”

For research use only. Not for use in diagnostic procedures.”¹²

The bottom line is that this test is useless for diagnosing COVID-19. If the error rate is only 5% this could mean that the number of cases worldwide is off by millions. But the error rate is most likely much higher, which means that the world’s population is suffering due to a made-up pandemic.

There Are Other Serious Issues

Some county and state health departments state that the counts for coronavirus are typically reported via a primary care physician or pulmonologist.¹³ Most likely neither of these provider types has an expensive PCR machine at their disposal. Thus, it would appear as though the virus is being diagnosed by physicians the same way they would diagnose any common cold or flu, which is by physical examination and observation of symptoms. The symptoms of COVID-19 are like those of influenza in many ways.

Several Governors in the U.S. requested billions of dollars in federal aid to “assist with the impact of the coronavirus,” the amount of which was based on the infection rate. Collectively, they requested a total of \$500 billion.¹⁴ At this time there is no accountability for exactly how this aid was spent. It is interesting that the states with the worst per capita debt (such as California and New York) have requested the most money.¹⁵ Coincidence? Perhaps not. Naturally, it could make sense to report a higher rate of infection in order to receive a larger piece of the stimulus.

There have been numerous problems with the testing procedures, some political, some scientific. The CDC went against the guidance of the World Health Organization (WHO).¹⁶ The irony, of course, is one corrupt organization ignoring the guidelines of another corrupt organization. Ultimately, the missteps that occurred regarding testing were massive. On April 20, 2020, it was reported that the tests the CDC was using were contaminated with the coronavirus itself.¹⁷ There was no way to know the number of false negatives and false positives.

The Food and Drug Administration (FDA) sent representatives to the CDC and found the primary culprit to be poor laboratory practices. The CDC offered no defense for its decisions.

Testing was not much better in other parts of the world. For example, Spain and the Czech Republic spent millions on a test purchased from a Chinese company called “Shenzhen Bioeasy Technology” and later found that the tests were only 30% accurate. Gordon Chang, who has covered Chinese economics and policy for decades stated “It [China] creates the poison and then sells the cure to it.”¹⁸ How purposeful was this? We will never know, although China had an incentive to keep the world frightened and shut down, both to gain economic advantage and to distract the world while it engaged in practices condemned by many countries.

Even if the test kits are not faulty, more false negatives can result from the swabbing method used to collect samples. The tests typically require a swab to be inserted into the nasal passage. This is a common method used in the “drive-thru” testing sites set up in many cities. In order to be properly detected, the swab must be inserted deep into the nasal passage, causing considerable discomfort. Many of those performing the tests were either not properly trained or tended to withdraw the swab early when the patient exhibited discomfort or resistance.

Dr. Michael Pintella, Director of the State Hygienic Lab in Iowa, stated “Tests involve a multi-step process and each step might lead to a false negative result for any number of reasons, including a poorly collected specimen, a delay in transport of the specimen to the lab, not storing or transporting specimens at the appropriate temperature, problems encountered during testing extraction, analysis errors and more.”¹⁹ In the same news release Dr. Austin Baeth, who was very outspoken about wanting to administer a state lockdown for Iowa, admitted that the tests only have a 63% accuracy rate.

The other common method for testing is the antibody test, which uses a blood sample. The problem with this test is that it does not determine if one has the virus, rather if one has had it before. This is also problematic, as there are many false positives due to detecting antibodies created from other coronaviruses (such as the common cold).²⁰ The methodology is flawed as well. According to a report released in early May, the FDA had to tighten restrictions on the hundreds of companies that were profiting from

selling fraudulent testing kits.²¹ Some of these kits were even being advertised as “do it yourself from home” products. It is widely believed that there are many false negatives arising from these kits as well.

To make matters worse, the CDC had been reporting positive test results from a combination of both the PCR test and the antibody test. Ashish Jha, the K.T. Li Professor of Global Health at Harvard University said, “You’ve got to be kidding me. How could the CDC make that mistake? This is a mess.”²² He further went on to say that mixing the results of the two tests muddies the water. One test is like looking in the rearview mirror and the other just says if one is infected now. He also stated that because of this, the actual amount of cases is and was much higher than reported.

Testing in Tanzania: Apparently Fruit Can Test Positive

The head of Tanzania’s health laboratory in charge of coronavirus was suspended after President John Magufuli of Tanzania had a security detail obtain random samples of Pawpaw, jackfruit, and animals which tested positive for COVID-19.

Samples of fruit were taken from inside the fruit – therefore positive results could not be from someone touching the fruit. The samples were given names and sent to the laboratory.

Here were the results:

Sample of car oil named Jabil Hamza, 30 years old, male - negative

Sample from Jackfruit named Sarah Samuel 45 years old, female - inconclusive test results

Sample of liquid from Pawpaw named Elizabeth Anne 26 years old female - positive

Samples from Kware (type of bird) – positive

Samples from rabbit – undetermined

Goat – positive

Sheep – negative

Magufuli said that this means the Pawpaw named Elizabeth must be placed in isolation, goats should be in isolation, and Jackfruit named Sara should be in isolation. But, he reported, the Pawpaw is not dying it’s just getting ripe. Magufuli says, “a dirty game is being played with these tests,” reported that the tests were imported, and said the WHO should do something about this. He told Reuters that this indicates that some people are testing positive who not have the disease.

The Centers for Disease Control and Prevention says there is no way that fruit can contract COVID-19

As of May 6, 2020, there were 480 cases and 17 deaths in Tanzania, and there was no way to know if the goats, sheep, bird, Pawpaw and jackfruit were included in the count.^{23 24}

But You Must Have COVID-19! You Must!

NBC referred to Dr. Joseph Fair as "...Today's most knowledgeable expert on the coronavirus outbreak." Dr. Fair reported that he was recently diagnosed with COVID-19, and tweeted that he was hospitalized with it.

According to Dr. Fair, he flew home from New York City to New Orleans wearing a mask and gloves, wiped everything down but says he must have contracted it through his eyes. He said that his symptoms were not classic symptoms, but when he developed shortness of breath, he called an ambulance and was admitted to Tulane Medical Center. He had four COVID tests and they were all negative, but he knows he had it and his doctors confirmed that this was the case.

It seems that anyone determined to have COVID-19 will have it – testing does not matter. Apparently, nor does wearing masks and gloves and wiping things down.²⁵

And If All Else Fails, Use "Medical Intuition"

An article in Medscape posted May 16, 2020 describes a patient who arrived at UC San Diego Health medical center with classic COVID-19 symptoms – a history of cough, pneumonia, severe respiratory distress – and required immediate intubation. The patient's back of the throat was swabbed twice and both times was negative for COVID-19. "The two negative tests didn't convince anybody," said Davey Smith, MD, a virologist and chief of the division of infectious diseases and global public health at UC San Diego School of Medicine. It was only on the third test, when they sampled fluid from a bronchial wash, that they were able to find the virus.²⁶ The article was titled "Don't Discount Medical Intuition."

The article went on to say that this is not an isolated incident because there are limitations to current tests and that clinicians report false negative rates as high as 30%. The FDA issued an alert warning of false negatives with Abbott Labs' ID NOW rapid test, one of the most used.²⁷

The authors also cited data in *Annals of Internal Medicine* showing that test accuracy depends on when the person is tested because the false negative results vary during the course of the disease. According to this study, on the day symptoms appear, the false negative rate was 38%; it dropped to 20% on the third day and increased to 66% two weeks later.²⁸

According to Stephen Rawlings, MD PhD, infectious disease fellow at UC San Diego Center for AIDS research, one of the problems is that there is nothing to compare current tests to. He says, "To truly determine false negatives, you need a gold standard test, which is essentially as close to perfect as we can get," Rawlings said. "But there just isn't one yet for coronavirus."

Colin West MD PhD at Mayo Clinic says that the studies that have looked at accuracy of tests currently used have been "filled with flaws," one of which is that the sensitivity estimates are based on testing people who the researchers already knew had COVID-19. This results in significant bias. He says that without control groups of blinded testing it's impossible to determine the magnitude of the inaccuracy.²⁹

The results of an analysis of five studies that included 957 patients and that had yet to be peer-reviewed concluded that "The certainty of the evidence was judged as very low, due to the risk of bias, indirectness, and inconsistency issues. Conclusions: The collected evidence has several limitations, including risk of bias issues, high heterogeneity, and concerns about its applicability."³⁰

Other Countries Inflated Numbers Too

Public health officials in the UK have inflated the number of cases by counting each test twice. When diagnostic tests were used that involved taking both saliva and nasal samples from the same patient, the results were counted as two separate tests. This led to inflated case numbers. Both the Department of Health and Social Care and Public Health England acknowledged that they had engaged in this practice.

This is not the only instance in which the UK government was caught inflating data. In April, public health authorities included thousands of home tests which had been mailed out but not completed in order to make it look like the goal of 100,000 tests was being met.

Apparently using fake numbers to promote a fake pandemic is not limited to the U.S.³¹

The CDC's Strange Definition of a "Case"

As you have seen, the tests were definitely flawed. But the CDC's definition of a "case" did not require any testing at all. The CDC listed over one dozen ways in which a person could be diagnosed with COVID-19.

Here are excerpts from the CDC's "2020 Interim Case Definition"³² (verbatim with commentary)

Clinical Criteria

At least two of the following symptoms: fever (measured or subjective), chills, rigors, myalgia, headache, sore throat, new olfactory and taste disorder(s)

OR

At least one of the following symptoms: cough, shortness of breath, or difficulty breathing

OR

Severe respiratory illness with at least one of the following:

Clinical or radiographic evidence of pneumonia **OR**

Acute respiratory distress syndrome

AND

No alternative more likely diagnosis

Commentary on "Clinical Criteria"

Note that fever can be "subjective."

Headache, sore throat and cough can be symptoms of many things, including the common cold.

"New olfactory and taste disorders" An article published in the *Lancet* referred to COVID testing as "inadequate" and suggests that new symptom profiles be developed to help identify those who should be quarantined.

It suggests that loss of taste and smell are highly predictive of COVID-19 and anyone experiencing these symptoms should self-isolate.³³

In fact, there are many causes of loss of taste and smell. These include:

Aging especially after age 60

Allergies

Nasal and sinus problems like sinusitis or nasal polyps

Medications including beta blockers and ACE inhibitors

Dental problems

Cigarette smoking

Head or facial injury

Alzheimer's disease

Parkinson's disease

Common cold or other viral infections (40%)³⁴

In fact, as much as 20% of the general population has a prolonged smell disorder.³⁵

There are many problems with the *Lancet* article. The basis for the recommendation to use taste and smell as a diagnostic tool is data collected from patients using an online app. Almost 60% of 579 people who reported testing positive said they had lost their

sense of smell and taste; but almost 18% of the 1123 who tested negative also reported loss of taste and smell.³⁶

The researchers acknowledge many limitations which include that these symptoms are non-specific and lack predictive power, and their report relied on self-reported information, which is generally unreliable. Yet, they write, "We believe that having added loss of smell and taste to the list of COVID-19 symptoms is of great value as it will help trace almost 16% of cases that otherwise would have been missed. Loss of smell and taste, together with fever or cough, should now enable us to identify 87.5% of symptomatic COVID-19 cases, although this is likely to be less in the early phases of the infection." This conclusion is hard to fathom in consideration of the facts, although facts have not seemed to matter much these days.

Here's a much more realistic assessment from Eric Holbrook, director of rhinology at Massachusetts Eye and Ear: "Physicians are collecting data so quickly, but a lot of it is subjective data. I haven't seen a careful study that looks at when patients get the diagnosis, and how severe it is, and how long the smell loss lasts."³⁷

Laboratory Criteria

Laboratory evidence using a method approved or authorized by the U.S. Food and Drug Administration (FDA) or designated authority:

Confirmatory laboratory evidence:

- Detection of severe acute respiratory syndrome coronavirus 2 ribonucleic acid (SARS-CoV-2 RNA) in a clinical specimen using a molecular amplification detection test

Presumptive laboratory evidence:

- Detection of specific antigen in a clinical specimen
- Detection of specific antibody in serum, plasma, or whole blood indicative of a new or recent infection*

**Serologic methods for diagnosis are currently being defined*

Commentary on Laboratory Criteria:

Note that these are the tests we proved were inaccurate, and that the CDC admits that the serological methods for diagnosis are currently being defined, but they are ok to use for purposes of diagnosis now.

Epidemiologic Linkage

One or more of the following exposures in the 14 days before onset of symptoms:

- Close contact** with a confirmed or probable case of COVID-19 disease; **OR**
- Close contact** with a person with:
 - clinically compatible illness **AND**
 - linkage to a confirmed case of COVID-19 disease.

- Travel to or residence in an area with sustained, ongoing community transmission of SARS-CoV-2.
- Member of a risk cohort as defined by public health authorities during an outbreak.

***Close contact is defined as being within 6 feet for at least a period of 10 minutes to 30 minutes or more depending upon the exposure. In healthcare settings, this may be defined as exposures of greater than a few minutes or more. Data are insufficient to precisely define the duration of exposure that constitutes prolonged exposure and thus a close contact.*

Commentary on Epidemiologic Linkage:

A person who has been within 6 feet of someone for 10 minutes who may have but is not confirmed to have COVID-19 is now considered a case

A person who has been within 6 feet of a person who has a headache or a sore throat, or has changes in smell or taste is now considered a case

A person who has been in contact with a person who is linked to a person with COVID-19 is now a case.

Travel to an area in which there are COVID-19 cases qualifies a person as a case.

Being a member of a “risk cohort” also qualifies a person as a case. There are no examples, but a statement that health authorities can just name a group as a risk category.

The CDC acknowledges that it is not known the length of exposure required to cause a problem but uses this metric anyway.

Criteria to Distinguish a New Case from an Existing Case

Not applicable (N/A) until more virologic data are available.

Commentary on Criteria to Distinguish a New Case from an Existing Case:

The CDC does not know how to determine a new from an existing case, but when trying to gin up cases, what difference could this make?

Ginning Up the Death Rate

According the CDC’s document titled “Guidance for Certifying Deaths Due to Coronavirus Disease 2019 (COVID–19)”:³⁸

"In cases where a definite diagnosis of COVID cannot be made but is suspected or likely (e.g. the circumstances are compelling with a reasonable degree of

certainty) it is acceptable to report COVID-19 on a death certificate as 'probable' or 'presumed.'"

In other words, when in doubt, classify any death possible as COVID-19, which will serve to inflate the numbers to make it look like the projections are right and keep the hoax alive.

The National Vital Statistics System issued an alert on March 24, 2020 regarding a new ICD code for COVID-19 deaths. According to this document:

The WHO has provided a second code, **U07.2**, for clinical or epidemiological diagnosis of COVID-19 where a laboratory confirmation is inconclusive or not available.

Will COVID-19 be the underlying cause?

The underlying cause depends upon what and where conditions are reported on the death certificate. However, the rules for coding and selection of the underlying cause of death are expected to result in COVID-19 being the underlying cause more often than not.

Should "COVID-19" be reported on the death certificate only with a confirmed test?

COVID-19 should be reported on the death certificate for all decedents where the disease caused **or is assumed to have caused or contributed to death.**³⁹

Again, specific instructions to list the cause of death as COVID-19 as much as possible.

Dr. Deborah Birx, a member of the White House task force, confirmed this. She announced during a press briefing on Tuesday April 7, 2020 that the deaths of all patients who died with coronavirus, even if the cause of death was not due to COVID-19, should list COVID-19 as cause of death on the death certificate. She acknowledged that other countries do not do this. "There are other countries that if you had a pre-existing condition, and let's say the virus caused you to go to the ICU [intensive care unit] and then have a heart or kidney problem...Some countries are recording that as a heart issue or a kidney issue and not a COVID-19 death. The intent is ... if someone dies with COVID-19 we are counting that."⁴⁰

Dr. Scott Jensen, a Minnesota Family practice doctor and state Senator, said that this means that a patient who died after being hit by a bus and tested positive for coronavirus would be listed as having presumed to have died from the virus regardless of whatever damage was caused by the bus.

Dr. Jensen reported receiving a 7-page document from CDC instructing him to do this. As for the motivation? "Fear is a great way to control people," he told a television station.⁴¹

He was notably outspoken about this matter. He cited situations in the past where he had patients who died while having the flu, stating "I've never been encouraged to [notate 'influenza']. I would probably write 'respiratory arrest' to be the top line, and the underlying cause of this disease would be pneumonia ... I might well put emphysema or congestive heart failure, but I would never put influenza down as the underlying cause of death and yet that's what we are being asked to do here."⁴²

When Dr. Anthony Fauci was asked about the number of coronavirus deaths being "padded," he cited the prevalence of "conspiracy theories" during "challenging" times in public health. Dr. Jensen's response to this was "I would remind him that anytime health care intersects with dollars it gets awkward." Dr. Jensen stated that Medicare provides \$13,000 to the hospitals and doctors for each COVID-19 patient, much more than the standard for ailments such as influenza, which has averaged around \$5,000 in recent years. In addition to that, if a ventilator is used for the patient, Medicare provides \$39,000 to the hospital and doctors.⁴³ Although Dr. Jensen did not go as far as saying that physicians are trying to pad their pockets, he is more skeptical of those at higher levels such as hospital administrators.

Other misrepresentations about cause of death were being made almost daily. For example, during a press conference, Connecticut Governor Ned Lamont announced that a 6-week-old baby had died and tested positive for coronavirus, and that this was likely one of the youngest deaths from the disease anywhere.⁴⁴ His tweet read: "It is with heartbreaking sadness today that we can confirm the first pediatric fatality in Connecticut linked to COVID-19. A 6-week-old newborn from the Hartford area was brought unresponsive to a hospital late last week and could not be revived." He went on to say, "This is a virus that attacks our most fragile without mercy. This also stresses the importance of staying home and limiting exposure to other people. Your life and the lives of others could literally depend on it. Our prayers are with the family at this difficult time."⁴⁵

The problem is that this is not what happened at all. In fact, the state's medical examiner refused to certify death from coronavirus. Toxicology tests are pending, and the medical examiner indicated the possibility that the child had an underlying condition or might have died of sudden infant death syndrome or positional asphyxiation.⁴⁶

But the damage was done. Lamont told the public that "...no one is safe from this virus," and issued this warning, "For those young people who think maybe they're a little more invincible, think again."⁴⁷ The public became more frightened, more likely to do as they were told. Stay home, do not congregate, continue to follow directions. He succeeded in scaring people with a false story.

This is not the only example in which a young person was said to have died from COVID-19 when that is not what happened at all. Chloe Middleton, age 21, died from coronavirus, according to her family. She was taken to the hospital after having a heart attack and died shortly after. A coroner said the cause of death was related to COVID-19 because the family reported she had a cough. The hospital had not recorded it as a COVID-19 death because she did not test positive for the disease.

The family took down a Facebook post claiming that Chloe had no underlying health issues and refused to respond to reporters calling for information. Subsequently the coroner's office issued this statement: "Chloe died at Wexham Park Hospital on the 19 March 2020. The case was reported to the Berkshire coroner's office. Her death was very sad but as she had a natural cause of death, involvement by the coroner was not required and the hospital issued a death certificate. There was no postmortem examination or inquest. We must now respect the privacy of her family and cannot provide any further information."⁴⁸

There's More

A study published in April 2020 showed that it is difficult to differentiate between deaths from COVID-19 and Radiation Pneumonitis (RP), which is a common condition that occurs in 15-40% of patients being treated for cancer.⁴⁹ Cancer patients are more susceptible to getting the flu and dying from it. We will never know how many were improperly diagnosed or reported, yet it is important to note.

Inaccurate State Death Reports

The *New York Times* reported on April 14, 2020 that New York City had increased its death toll by 3700 people after officials said they would not include people who never tested positive for COVID-19 but were assumed to have it.

After admitting that the cases were not valid, the *Times* reporters wrote, "The numbers brought into clearer focus the staggering toll the virus has already taken on the largest city in the United States, where deserted streets are haunted by the near-constant howl of ambulance sirens."⁵⁰

In Pennsylvania, death rates were adjusted downward when Health Secretary Rachel Levine said on April 23, 2020 that more information is needed before "probable" cases can be attributed to COVID-19. She said the decision was made in the interest of transparency.

This decision resulted in a reduction of 6 deaths in Lehigh County, and 100 fewer deaths in Philadelphia, 2 fewer in Montgomery County. Bucks county saw a reduction of

10, Monroe county was reduced by 6, and Carbon County was reduced by 2. Total drop was 200 deaths, a significant percentage of the total.⁵¹

On April 20, 2020, Illinois Department of Health Director Dr. Ngozi Ezike explained how her department decides whether a death is due to COVID-19. She said that anyone who dies and has tested positive is categorized as a COVID-19 death.

Here is, verbatim, what she said:

"If you were in hospice and had already been given a few weeks to live, and then you also were found to have COVID, that would be counted as a COVID death. It means technically even if you died of a clear alternate cause, but you had COVID at the same time, it's still listed as a COVID death. So, everyone who's listed as a COVID death doesn't mean that that was the cause of the death, but they had COVID at the time of the death."⁵²

Colorado State representative Mark Baisley has asked for a formal investigation into Jill Ryan, Executive Director of the Colorado Department of Public Health and Environment with the potential for criminal charges to be brought. According to Baisley, Ryan has falsely altered death certificates.

Baisley provided a letter from the Someren Glen senior care facility which was sent to its staff, residents, and families of residents, stating that CPDHE had changed the cause of death recorded by attending physicians in seven cases to reflect COVID-19 instead of the actual cause of death.

The Montezuma County coroner told the same news station that the state overruled the cause of death for a person in his jurisdiction too. The person died of alcohol poisoning, but it was changed to COVID-19.

Eventually the Colorado Department of Health acknowledged that the numbers had been inflated by people who had the virus but died of other causes and adjusted the numbers down from 1150 deaths to 878.⁵³

Dr. Deborah Birx, the task force response coordinator, changed her tune about death counts. During a previous White House daily briefing she stated that death certificates were to state COVID-19 as the cause of death if the person tested positive but died of something else. She said the opposite and asked the CDC to exclude from the death count people who had the virus but died of something else and removed those who were presumed to have the virus but did not have confirmed lab results.

Birx and other health officials take issue with the CDC's system now, claiming that the number of cases and mortality may be inflated as much as 25%. "There is nothing from the CDC that I can trust," she told CDC Director Robert Redfield.⁵⁴

In June 2020, Washington State announced a "phased-in" process which would result in telling the truth about COVID-19 deaths. Apparently just telling the truth all at once would be intolerable. The first phase resulted in several suicides, homicides, and overdose deaths being removed from the death count. Health officials also reported that they would categorize deaths as "confirmed, probable, suspect and not COVID."

The Freedom Foundation investigated and reported on this May 18, 2020 after obtaining written data from Washington State DOH officials. When confronted with it, Washington Governor Inslee responded that it was disgusting and malarkey and accused the Freedom Foundation of "fanning these conspiracy claims from the planet Pluto" and not caring about people who died from COVID.⁵⁵

DOH held a press briefing on May 21, 2020 during which it confirmed that reported deaths were inflated and that "(w)e currently do have some deaths that are being reported that are clearly from other causes" including some "...from gunshot wounds."

Some "Deaths" Were Clearly NOT COVID!

Coal miner Nathan Turner was 30 years old when he was found dead in his home by his fiancé in Queensland, Australia. Queensland Health promptly reported that Turner died of coronavirus and claimed that he was Australia's youngest COVID-19 victim. Local doctors reported that Turner's death baffled them as he had not left his small town since February. They hypothesize that perhaps a nurse from 400 km away who had driven to Blackwater to watch the sunset had infected him.

After all of this, autopsy showed that Turner did not have the virus. The family was furious and called on Premier Annastacia Palaszczuk and health official Jeannette Young to apologize to both the family and to the community for creating "chaos and panic."

"You should be ashamed of yourself and if you had any human decency left then you will apologise for creating trauma to this family whilst you caused panic to our community.

"This is unacceptable behaviour from our leaders in power who forced a family to sit in silence and not to comment about the chaos they were about to inflict on our state."

Queensland Health admits administering additional tests which also were negative for COVID. Apparently, there are many who are intent on making a diagnosis of COVID even when it is not there.

An online petition demanding a truthful apology had gathered 2092 signatures out of 2500 goal within just a few hours.⁵⁶

One of the more insane episodes of deaths categorized as COVID-19 involved a man who was shot by the NYPD after threatening officers with a knife and gun.

Ricardo Cardona called 911 on himself and then repeatedly told officers to kill him when they arrived to find him with the weapons. He later told investigators that he wanted to die by suicide by cop since he had been infected with COVID-19. The officers ultimately fired 11 shots, 7 of which hit him. He died 5 days later, and his death is attributed to COVID-19 with his wounds and underlying health conditions listed as "complicating factors."⁵⁷

¹ Pride D. "Hundreds of different coronavirus tests are being used – which is best?" *The Conversation* April 4 2020

² IBID

³ Farber C. Was the COVID-19 Test Meant to Detect a Virus?" <https://uncoverdc.com/2020/04/07/was-the-covid-19-test-meant-to-detect-a-virus/> accessed 7.2.2020

⁴ Kolata G. "Faith in Quick Test Leads to Epidemic That Wasn't." *New York Times* Jan 22 2007

⁵ Watson J, Whiting PF, Brush JE. "Interpreting a covid-19 test result." *BMJ* 2020 May;369:m1898

⁶ Engelbrecht T, Demeter K. "COVID19 PCR Tests are Scientifically Meaningless." *Off Guardian* Jun 27 2020

⁷ Koop F. "A startling number of coronavirus patients get reinfected." *ZME Science* Feb 26 2020

⁸ Li Y, Yao L, Li J et al. "Stability issues of RT-PCR testing of SARS-CoV-2 for hospitalized patients clinically diagnosed with COVID-19." *J Med Virol* 2020 Mar;92(7)

⁹ Feng C, Hu M. "Race to diagnose coronavirus patients constrained by shortage of reliable detection kits." *South China Morning Post* Feb 11 2020

¹⁰ CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
<https://www.fda.gov/media/134922/download>

¹¹ ACCELERATED EMERGENCY USE AUTHORIZATION (EUA) SUMMARY COVID-19 RT-PCR TEST (LABORATORY CORPORATION OF AMERICA) <https://www.fda.gov/media/136151/download>

¹²

¹³ <https://ttfuture.org/blog/michael/why-coronavirus-will-soon-vanish-overnight>

¹⁴ <https://ctmirror.org/2020/04/16/lamont-other-governors-seek-500-billion-in-new-coronavirus-stimulus-money-for-states/>

¹⁵ https://www.usgovernmentspending.com/compare_state_debt

¹⁶ <https://www.globalresearch.ca/has-covid-19-testing-made-the-problem-worse-confusion-regarding-the-true-health-impacts/5709323>

¹⁷ <https://arstechnica.com/science/2020/04/cdcs-failed-coronavirus-tests-were-tainted-with-coronavirus-feds-confirm/>

¹⁸ <https://www.washingtontimes.com/news/2020/mar/30/china-challenges-the-world-with-flawed-covid-19-te/>

¹⁹ <https://www.kcci.com/article/false-negatives-are-harmful-according-to-medical-professionals/32038917>

²⁰ <https://www.azcentral.com/story/news/local/arizona-health/2020/04/27/questions-linger-covid-19-antibody-tests-even-demand-grows/5170052002/>

²¹ <https://www.nbcnews.com/health/health-news/fda-tightens-rules-antibody-tests-after-false-claims-accuracy-problems-n1199431>

²² <https://www.theatlantic.com/health/archive/2020/05/cdc-and-states-are-misreporting-covid-19-test-data-pennsylvania-georgia-texas/611935/>

²³ Ben Cost "Faulty Coronavirus Kits suspected as goat and fruit test positive in Tanzania"

New York Post May 6 2020

²⁴ Tanzania COVID-19 lab head suspended as president questions data. Al Jazeera May 5 2020

²⁵ Hoffman M. "NBC's Dr. Joseph Fair hospitalized with coronavirus: 'Not out of the woods yet.'" *NBC News* May 14 2020

²⁶ Boerner H. "COVID-19 Test Results: Don't Discount Medical Intuition." *Medscape* May 16 2020

²⁷ FDA News Release. Coronavirus (COVID-19) Update: FDA Informs Public About Possible Accuracy Concerns with Abbott ID NOW Point-of-Care Test.. May 14 2020

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-informs-public-about-possible-accuracy-concerns-abbott-id-now-point>

²⁸ Kucirka LM, Lauer SA, Laeyendecker O, Boon D, Lessler J. "Variation in False-Negative Rate of Reverse Transcript Polymerase Chain Reaction –Based SARS-CoV-2 Tests by Time of Exposure." *Ann Intern Med* 2020 May;M20-1495

²⁹ Boerner H. "COVID-19 Test Results: Don't Discount Medical Intuition." *Medscape* May 16 2020

³⁰ Arevalo-Rodriguez I, Buitrago-Garcia D, Simancas-Racines D et al. "FALSE NEGATIVE RESULTS OF INITIAL RT-PCR ASSAYS FOR COVID-19: A SYSTEMATIC REVIEW." *MedRxiv* doi:

<https://doi.org/10.1101/2020.04.16.20066787>

³¹ Boycott-Owen M, Nuki P. "Tens of thousands of coronavirus tests have been double-counted, officials admit." *The Telegraph* May 21 2020

³² <https://wwwn.cdc.gov/nndss/conditions/coronavirus-disease-2019-covid-19/case-definition/2020/>

³³ Menni C, Sudre CH, Steves CJ, Ourselin S, Spector TD. "Quantifying additional COVID-19 symptoms will save lives." *Lancet* published online June 4 2020

³⁴ Weige-Lussen A, Wolfensberger M. "Olfactory Disorders following Upper Respiratory Tract Infections." In Hummel T, Welge-Lüssen A (eds): Taste and Smell. An Update. *Adv Otorhinolaryngol*. Basel, Karger, 2006, vol 63, pp 125-132

<https://doi.org/10.1159/000093758>

³⁵ Boesveldt S, Postma EM, Boak D et al. "Anosmia – A Clinical Review." *Chem Senses* 2017 Sep 1;42(7):513-523.

³⁶ Menni C, Sudre CH, Steves CJ, Ourselin S, Spector TD. "Quantifying additional COVID-19 symptoms will save lives." *Lancet* published online June 4 2020

³⁷ Richards SE. "Lost your sense of smell? It may not be coronavirus." *Science* April 7 2020

³⁸ <https://www.cdc.gov/nchs/data/nvss/vsrg/vsrg03-508.pdf>

³⁹ <https://d33wjekvz3zs1a.cloudfront.net/wp-content/uploads/2020/04/Alert-2-New-ICD-code-introduced-for-COVID-19-deaths.pdf>

⁴⁰ <https://www.foxnews.com/politics/birx-says-government-is-classifying-all-deaths-of-patients-with-coronavirus-as-covid-19-deaths-regardless-of-cause>

⁴¹ <https://www.youtube.com/watch?v=Pfa4b7T0ZHY>

⁴² <https://www.foxnews.com/media/physician-blasts-cdc-coronavirus-death-count-guidelines>

⁴³ <https://www.usatoday.com/story/news/factcheck/2020/04/24/fact-check-medicare-hospitals-paid-more-covid-19-patients-coronavirus/3000638001/>

⁴⁴ <https://www.cbsnews.com/news/six-week-old-baby-dies-coronavirus-believed-to-be-youngest-fatality/>

⁴⁵ Zilber A. "Coroner refuses to rule COVID-19 as cause of death of six-week-old baby after Connecticut governor claimed toddler was 'youngest coronavirus victim in the world.'" *Daily Mail* April 6 2020

<https://www.dailymail.co.uk/news/article-8193487/Coroner-refuses-rule-COVID-19-cause-death-six-week-old-Connecticut-baby.html>

⁴⁶ Zilber A. "Coroner refuses to rule COVID-19 as cause of death of six-week-old baby after Connecticut governor claimed toddler was 'youngest coronavirus victim in the world.'" *Daily Mail* April 6 2020 <https://www.dailymail.co.uk/news/article-8193487/Coroner-refuses-rule-COVID-19-cause-death-six-week-old-Connecticut-baby.html>

⁴⁷ Zilber A. "Coroner refuses to rule COVID-19 as cause of death of six-week-old baby after Connecticut governor claimed toddler was 'youngest coronavirus victim in the world.'" *Daily Mail* April 6 2020 <https://www.dailymail.co.uk/news/article-8193487/Coroner-refuses-rule-COVID-19-cause-death-six-week-old-Connecticut-baby.html>

⁴⁸ Weaver M. "Chloe Middleton; death of 21-year-old not recorded as Covid-19." *The Guardian* March 27 2020

⁴⁹ [https://www.thegreenjournal.com/article/S0167-8140\(20\)30190-0/fulltext?fbclid=IwAR0dOy2N74mrwd-AeVPjCTGOY-d3dFFM4mTB4JU-Xk7ZjbcXi5hHm-p5VZU#](https://www.thegreenjournal.com/article/S0167-8140(20)30190-0/fulltext?fbclid=IwAR0dOy2N74mrwd-AeVPjCTGOY-d3dFFM4mTB4JU-Xk7ZjbcXi5hHm-p5VZU#)

⁵⁰ Goodman JD, Rashbaum WK. "NYC Death Toll Soars Past 10,000 in Revised Virus Count." *New York Times* April 14 2020

⁵¹ Novak S. "Pa. coronavirus update: New cases, rise, but death toll drops? Here's why, and what it means in the LeHigh Valley." April 23 2020 lehighvalleylive.com

⁵² IDPH Director explains how Covid deaths are classified. April 20 2020

<https://week.com/2020/04/20/idph-director-explains-how-covid-deaths-are-classified/>

⁵³ Clark K. "GOP rep alleges falsified COVID-19 records, calls for indictment of Colorado's top health official" *9News* May 14 2020 <https://www.9news.com/article/news/local/next/gop-rep-alleges-falsified-covid-19-records-calls-for-indictment-of-colorados-top-health-official/73-bf02452f-4615-4efe-9413-a4826a8105b2>

⁵⁴ Guzman J. "Trump administration pushing CDC to change how it counts coronavirus deaths: report." *Changing America* <https://thehill.com/changing-america/well-being/longevity/497602-trump-administration-pushing-cdc-to-change-how-it>

⁵⁵ <https://www.freedomfoundation.com/washington/wa-dept-of-health-to-stop-counting-deaths-improperly-attributed-to-covid-19/>

⁵⁶ Mazzoni A. "Furious family of Nathan Turner, 30, demand an apology after authorities declared the miner was 'Australia's youngest coronavirus victim' - but tests reveal he DIDN'T HAVE the virus." *Daily Mail Australia* June 1 2020

<https://www.dailymail.co.uk/news/article-8376959/Nathan-Turners-family-demand-apology-declared-Australias-youngest-coronavirus-victim.html>

⁵⁷ Sisak MR. "NYPD: Man shot by officers later dies of coronavirus." *ABC News* May 20 2020

Attachment C.2

**CDC 2019-Novel Coronavirus (2019-nCoV)
Real-Time RT-PCR Diagnostic Panel**

For Emergency Use Only

Instructions for Use

**Catalog # 2019-nCoV EUA-01
1000 reactions**

For *In-vitro* Diagnostic (IVD) Use

Rx Only

Centers for Disease Control and Prevention
Division of Viral Diseases
1600 Clifton Rd NE
Atlanta GA 30329



Table of Contents

Intended Use	2
Summary and Explanation.....	2
Principles of the Procedure	3
Materials Required (Provided).....	5
Materials Required (But Not Provided)	6
Warnings and Precautions	10
Reagent Storage, Handling, and Stability.....	11
Specimen Collection, Handling, and Storage.....	12
Specimen Referral to CDC	13
Reagent and Controls Preparation.....	13
General Preparation	14
Nucleic Acid Extraction.....	14
Assay Set Up.....	16
Create a Run Template on the Applied Biosystems 7500 Fast Dx Real-time PCR Instrument (Required if no template exists).....	20
Defining the Instrument Settings	26
Running a Test.....	29
Interpretation of Results and Reporting	34
2019-nCoV rRT-PCR Diagnostic Panel Results Interpretation Guide	36
Quality Control.....	37
Limitations	37
Conditions of Authorization for the Laboratory.....	38
Performance Characteristics	39
Disposal.....	49
References	49
Revision History	50
Contact Information, Ordering, and Product Support	50
Appendix A: Heat Treatment Alternative to Extraction	51

Intended Use

The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet 2019-nCoV clinical and/or epidemiological criteria (for example, clinical signs and symptoms associated with 2019-nCoV infection, contact with a probable or confirmed 2019-nCoV case, history of travel to geographic locations where 2019-nCoV cases were detected, or other epidemiologic links for which 2019-nCoV testing may be indicated as part of a public health investigation). Testing in the United States is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

Results are for the identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in upper and lower respiratory specimens during infection. Positive results are indicative of active infection with 2019-nCoV but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is intended for use by trained laboratory personnel who are proficient in performing real-time RT-PCR assays. The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is only for use under a Food and Drug Administration's Emergency Use Authorization.

Summary and Explanation

An outbreak of pneumonia of unknown etiology in Wuhan City, Hubei Province, China was initially reported to WHO on December 31, 2019. Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in millions of confirmed human infections globally. Cases of asymptomatic infection, mild illness, severe illness, and deaths have been reported.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis 2019-nCoV and is based on widely used nucleic acid amplification technology. The product contains oligonucleotide primers and dual-labeled hydrolysis probes (TaqMan®) and control material used in rRT-PCR for the *in vitro* qualitative detection of 2019-nCoV RNA in respiratory specimens.

The term "qualified laboratories" refers to laboratories in which all users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use.

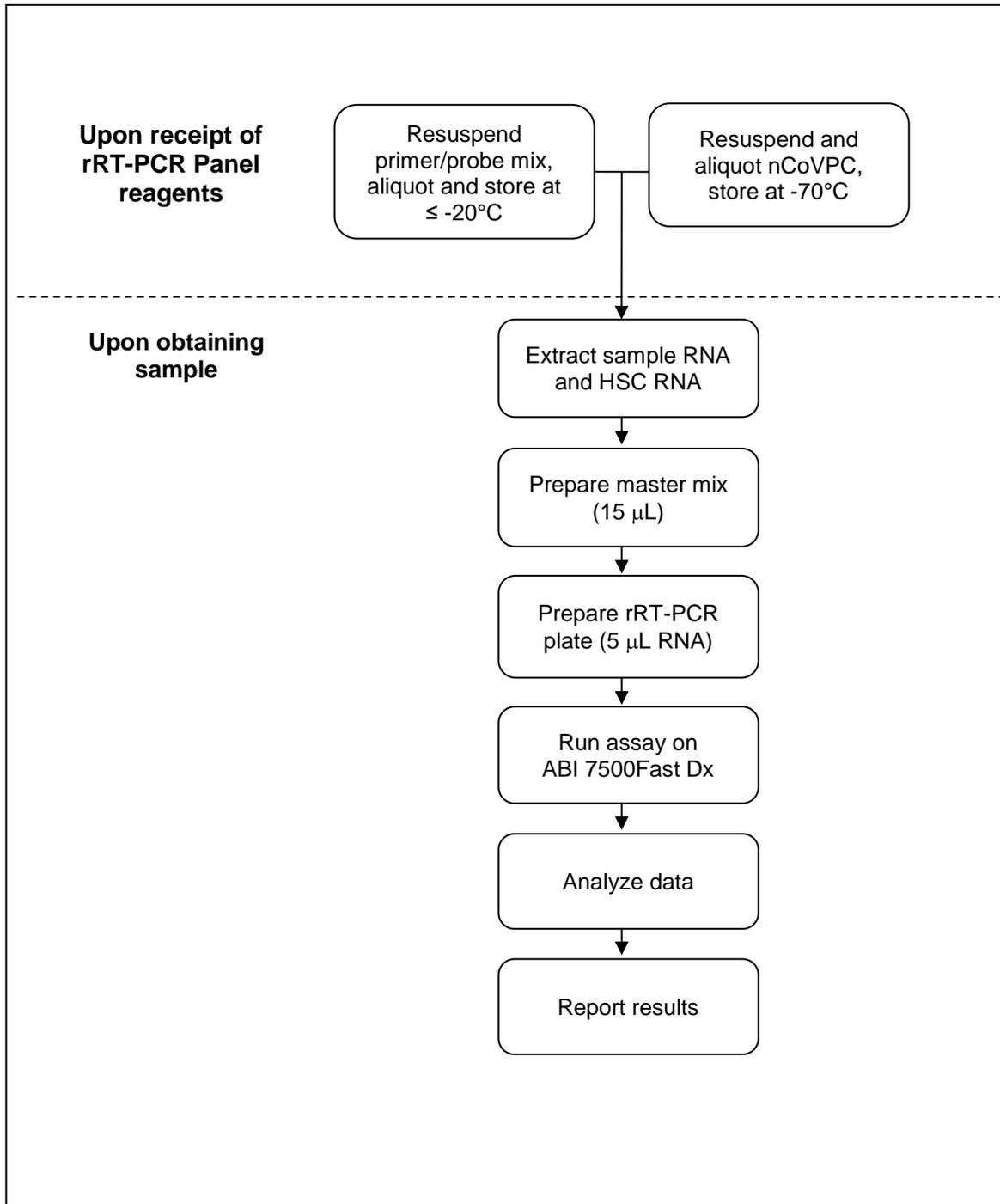
Principles of the Procedure

The oligonucleotide primers and probes for detection of 2019-nCoV were selected from regions of the virus nucleocapsid (N) gene. The panel is designed for specific detection of the 2019-nCoV (two primer/probe sets). An additional primer/probe set to detect the human RNase P gene (RP) in control samples and clinical specimens is also included in the panel.

RNA isolated and purified from upper and lower respiratory specimens is reverse transcribed to cDNA and subsequently amplified in the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with SDS version 1.4 software. In the process, the probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle by Applied Biosystems 7500 Fast Dx Real-Time PCR System with SDS version 1.4 software.

Detection of viral RNA not only aids in the diagnosis of illness but also provides epidemiological and surveillance information.

Summary of Preparation and Testing Process



Materials Required (Provided)

Note: CDC will maintain on its website a list of commercially available lots of primer and probe sets and/or positive control materials that are acceptable alternatives to the CDC primer and probe set and/or positive control included in the Diagnostic Panel. Only material distributed through the CDC International Reagent Resource and specific lots of material posted to the CDC website are acceptable for use with this assay under CDC's Emergency Use Authorization.

This list of acceptable alternative lots of primer and probe materials and/or positive control materials will be available at:

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/virus-requests.html>

Primers and Probes:

Catalog #2019-nCoV EUA-01 Diagnostic Panel Box #1:

<i>Reagent Label</i>	<i>Part #</i>	<i>Description</i>	<i>Quantity / Tube</i>	<i>Reactions / Tube</i>
2019-nCoV_N1	RV202001 RV202015	2019-nCoV_N1 Combined Primer/Probe Mix	22.5 nmol	1000
2019-nCoV_N2	RV202002 RV202016	2019-nCoV_N2 Combined Primer/Probe Mix	22.5 nmol	1000
RP	RV202004 RV202018	Human RNase P Combined Primer/Probe Mix	22.5 nmol	1000

Positive Control (either of the following products are acceptable)

Catalog #2019-nCoV EUA-01 Diagnostic Panel Box #2:

<i>Reagent Label</i>	<i>Part #</i>	<i>Description</i>	<i>Quantity</i>	<i>Notes</i>
nCoVPC	RV202005	2019-nCoV Positive Control (nCoVPC) For use as a positive control with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel procedure. The nCoVPC contains noninfectious positive control material supplied in a dried state and must be resuspended before use. nCoVPC consists of <i>in vitro</i> transcribed RNA. nCoVPC will yield a positive result with each assay in the 2019-nCoV Real-Time RT-PCR Diagnostic Panel including RP.	4 tubes	Provides (800) 5 µL test reactions

Catalog #VTC-04 CDC 2019-nCoV Positive Control (nCoVPC)

<i>Reagent Label</i>	<i>Part #</i>	<i>Description</i>	<i>Quantity</i>	<i>Notes</i>
nCoVPC	RV202005	2019-nCoV Positive Control (nCoVPC) For use as a positive control with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel procedure. The nCoVPC contains noninfectious positive control material supplied in a dried state and must be resuspended before use. nCoVPC consists of <i>in vitro</i> transcribed RNA. nCoVPC will yield a positive result with each assay in the 2019-nCoV Real-Time RT-PCR Diagnostic Panel including RP.	4 tubes	Provides (800) 5 µL test reactions

Materials Required (But Not Provided)

Human Specimen Control (HSC)

<i>Description</i>	<i>Quantity</i>	<i>CDC Catalog No.</i>
Manufactured by CDC. For use as a nucleic acid extraction procedural control to demonstrate successful recovery of nucleic acid as well as extraction reagent integrity. The HSC consists of noninfectious (beta-Propiolactone treated) cultured human cell material supplied as a liquid suspended in 0.01 M PBS at pH 7.2-7.4.	10 vials x 500uL	KT0189

Acceptable alternatives to HSC:

- Negative human specimen material: Laboratories may prepare a volume of human specimen material (e.g., human sera or pooled leftover negative respiratory specimens) to extract and run alongside clinical samples as an extraction control. This material should be prepared in sufficient volume to be used across multiple runs. Material should be tested prior to use as the extraction control to ensure it generates the expected results for the HSC listed in these instructions for use.
- Contrived human specimen material: Laboratories may prepare contrived human specimen materials by suspending any human cell line (e.g., A549, HeLa, or 293) in PBS. This material should be prepared in sufficient volume to be used across multiple runs. Material should be tested prior to use as the extraction control to ensure it generates the expected results for the HSC listed in these instructions for use.

CDC will maintain on its website a list of commercially alternative extraction controls, if applicable, that are acceptable for use with this assay under CDC’s Emergency Use Authorization, at:

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/virus-requests.html>

rRT-PCR Enzyme Mastermix Options

Reagent	Quantity	Catalog No.
Quantabio qScript XLT One-Step RT-qPCR ToughMix	100 x 20 µL rxns (1 x 1 mL)	95132-100
	2000 x 20 µL rxns (1 x 20 mL)	95132-02K
	500 x 20 µL rxns (5 x 1 mL)	95132-500
Quantabio UltraPlex 1-Step ToughMix (4X)	100 x 20 µL rxns (500 µL)	95166-100
	500 x 20 µL rxns (5 x 500 µL)	95166-500
	1000 x 20 µL rxns (1 x 5 mL)	95166-01K
Promega GoTaq® Probe 1- Step RT-qPCR System	200 x 20 µL rxns (2 mL)	A6120
	1250 x 20 µL rxns 12.5 mL	A6121
Thermofisher TaqPath™ 1-Step RT-qPCR Master Mix, CG	1000 reactions	A15299
	2000 reactions	A15300

RNA Extraction Options

For each of the kits listed below, CDC has confirmed that the external lysis buffer is effective for inactivation of SARS-CoV-2.

Instrument/Manufacturer	Extraction Kit	Catalog No.
QIAGEN	² QIAamp DSP Viral RNA Mini Kit	50 extractions (61904)
	² QIAamp Viral RNA Mini Kit	50 extractions (52904) 250 extractions (52906)
QIAGEN EZ1 Advanced XL	² EZ1 DSP Virus Kit	48 extractions (62724) Buffer AVL (19073 or 19089) EZ1 Advanced XL DSP Virus Card (9018703)
	² EZ1 Virus Mini Kit v2.0	48 extractions (955134) Buffer AVL (19073 or 19089) EZ1 Advanced XL Virus Card v2.0 (9018708)
Roche MagNA Pure 24	² MagNA Pure 24 Total NA Isolation Kit	96 extractions (07 658 036 001) External Lysis Buffer (06 374 913 001, 12 239 469 103, 03 246 779 001 or 03 246 752 001)
Roche MagNA Pure 96	² DNA and Viral NA Small Volume Kit	576 extractions (06 543 588 001) External Lysis Buffer (06 374 913 001, 12 239 469 103, 03 246 779 001 or 03 246 752 001)
¹ Roche MagNA Pure LC	² Total Nucleic Acid Kit	192 extractions (03 038 505 001)
¹ Roche MagNA Pure Compact	² Nucleic Acid Isolation Kit I	32 extractions (03 730 964 001)
Promega Maxwell [®] RSC 48	³ Maxwell [®] RSC Viral Total Nucleic Acid Purification Kit	48 extractions (AS1330) 144 extractions (ASB1330)
¹ QIAGEN QIAcube	² QIAamp DSP Viral RNA Mini Kit	50 extractions (61904)
	² QIAamp Viral RNA Mini Kit	50 extractions (52904) 250 extractions (52906)
^{1,3} bioMérieux NucliSENS [®] easyMAG [®] and ^{1,3} bioMérieux EMAG [®] (Automated magnetic extraction reagents sold separately. Both instruments use the same reagents and disposables, with the exception of tips.)		EasyMAG [®] Magnetic Silica (280133) EasyMAG [®] Lysis Buffer (280134) EasyMAG [®] Lysis Buffer, 2 mL (200292) EasyMAG [®] Wash Buffers 1,2, and 3 (280130, 280131, 280132) EasyMAG [®] Disposables (280135) Biohit Pipette Tips (easyMAG [®] only) (280146) EMAG [®] 1000µL Tips (418922)

¹Equivalence and performance of these extraction platforms for extraction of viral RNA were demonstrated with the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (K190302). Performance characteristics of these extraction platforms with 2019-nCoV (SARS CoV-2) have not been demonstrated.

² CDC has confirmed that the external lysis buffer used with this extraction method is effective for inactivation of SARS-CoV-2.

³ CDC has compared the concentration of inactivating agent in the lysis buffer used with this extraction method and has determined the concentration to be within the range of concentrations found effective in inactivation of SARS-CoV-2.

Alternative to Extraction:

If a laboratory cannot access adequate extraction reagents to support testing demand due to the global shortage of reagents, CDC has evaluated a heat treatment procedure for upper respiratory specimens using the Quantabio UltraPlex 1-Step ToughMix (4X), CG. Though performance was comparable, this method has been evaluated with a limited number of clinical specimens and a potential reduction in sensitivity due to carryover of inhibitory substances or RNA degradation cannot be ruled out. It should only be used when a jurisdiction determines that the testing need is great enough to justify the risk of a potential loss of sensitivity. Heat-treated specimens generating inconclusive or invalid results should be extracted with an authorized extraction method prior to retesting. Details and procedure for the heat treatment alternative to extraction may be found in Appendix A.

Equipment and Consumables Required (But Not Provided)

- Vortex mixer
- Microcentrifuge
- Micropipettes (2 or 10 μ L, 200 μ L and 1000 μ L)
- Multichannel micropipettes (5-50 μ l)
- Racks for 1.5 mL microcentrifuge tubes
- 2 x 96-well -20°C cold blocks
- 7500 Fast Dx Real-Time PCR Systems with SDS 1.4 software (Applied Biosystems; catalog #4406985 or #4406984)
- Extraction systems (instruments): QIAGEN EZ1 Advanced XL, QIAGEN QIAcube, Roche MagNA Pure 24, Roche MagNA Pure 96, Promega Maxwell[®] RSC 48, Roche MagNA Pure LC, Roche MagNA Pure Compact, bioMérieux easyMAG, and bioMérieux EMAG
- Molecular grade water, nuclease-free
- 10% bleach (1:10 dilution of commercial 5.25-6.0% hypochlorite bleach)
- DNAzap[™] (Ambion, cat. #AM9890) or equivalent
- RNase AWAY[™] (Fisher Scientific; cat. #21-236-21) or equivalent
- Disposable powder-free gloves and surgical gowns
- Aerosol barrier pipette tips
- 1.5 mL microcentrifuge tubes (DNase/RNase free)
- 0.2 mL PCR reaction plates (Applied Biosystems; catalog #4346906 or #4366932)
- MicroAmp Optical 8-cap Strips (Applied Biosystems; catalog #4323032)

Qualifying Alternative Components:

If a laboratory modifies this test by using unauthorized, alternative components (e.g., extraction methods or PCR instruments), the modified test is not authorized under this EUA. FDA's Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency, updated May 11, 2020, does not change this. As part of this policy, FDA does not intend to object when a laboratory modifies an EUA-authorized test, which could include using unauthorized components, without

obtaining an EUA or EUA amendment, where the modified test is validated using a bridging study to the EUA-authorized test .

Warnings and Precautions

- For *in vitro* diagnostic use (IVD).
 - This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA, 42 U.S.C. § 263a, to perform high complexity tests.
 - This test has been authorized only for the detection of nucleic acid from SARSCoV-2, not for any other viruses or pathogens.
 - This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- Follow standard precautions. All patient specimens and positive controls should be considered potentially infectious and handled accordingly.
- Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
- Handle all specimens as if infectious using safe laboratory procedures. Refer to Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019-nCoV <https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html>.
- Specimen processing should be performed in accordance with national biological safety regulations.
- If infection with 2019-nCoV is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions.
- Performance characteristics have been determined with human upper respiratory specimens and lower respiratory tract specimens from human patients with signs and symptoms of respiratory infection.
- Perform all manipulations of live virus samples within a Class II (or higher) biological safety cabinet (BSC).
- Use personal protective equipment such as (but not limited to) gloves, eye protection, and lab coats when handling kit reagents while performing this assay and handling materials including samples, reagents, pipettes, and other equipment and reagents.
- Amplification technologies such as PCR are sensitive to accidental introduction of PCR product from previous amplifications reactions. Incorrect results could occur if either the clinical specimen or the real-time reagents used in the amplification step become contaminated by accidental introduction of amplification product (amplicon). Workflow in the laboratory should proceed in a unidirectional manner.
 - Maintain separate areas for assay setup and handling of nucleic acids.
 - Always check the expiration date prior to use. Do not use expired reagents. Do not substitute or mix reagents from different kit lots or from other manufacturers.
 - Change aerosol barrier pipette tips between all manual liquid transfers.
 - During preparation of samples, compliance with good laboratory techniques is essential to minimize the risk of cross-contamination between samples and the inadvertent

introduction of nucleases into samples during and after the extraction procedure. Proper aseptic technique should always be used when working with nucleic acids.

- Maintain separate, dedicated equipment (e.g., pipettes, microcentrifuges) and supplies (e.g., microcentrifuge tubes, pipette tips) for assay setup and handling of extracted nucleic acids.
 - Wear a clean lab coat and powder-free disposable gloves (not previously worn) when setting up assays.
 - Change gloves between samples and whenever contamination is suspected.
 - Keep reagent and reaction tubes capped or covered as much as possible.
 - Primers, probes (including aliquots), and enzyme master mix must be thawed and maintained on a cold block at all times during preparation and use.
 - Work surfaces, pipettes, and centrifuges should be cleaned and decontaminated with cleaning products such as 10% bleach, DNAZap™, or RNase AWAY™ to minimize risk of nucleic acid contamination. Residual bleach should be removed using 70% ethanol.
- RNA should be maintained on a cold block or on ice during preparation and use to ensure stability.
 - Dispose of unused kit reagents and human specimens according to local, state, and federal regulations.

Reagent Storage, Handling, and Stability

- Store all dried primers and probes and the positive control, nCoVPC, at 2-8°C until re-hydrated for use. Store liquid HSC control materials at $\leq -20^{\circ}\text{C}$.
Note: Storage information is for CDC primer and probe materials obtained through the International Reagent Resource. If using commercial primers and probes, please refer to the manufacturer's instructions for storage and handling.
- Always check the expiration date prior to use. Do not use expired reagents.
- Protect fluorogenic probes from light.
- Primers, probes (including aliquots), and enzyme master mix must be thawed and kept on a cold block at all times during preparation and use.
- Do not refreeze probes.
- Controls and aliquots of controls must be thawed and kept on ice at all times during preparation and use.

Specimen Collection, Handling, and Storage

Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false test results. Training in specimen collection is highly recommended due to the importance of specimen quality. CLSI MM13-A may be referenced as an appropriate resource.

➤ Collecting the Specimen

- Refer to Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV) <https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html>
- Follow specimen collection device manufacturer instructions for proper collection methods.
- Swab specimens should be collected using only swabs with a synthetic tip, such as nylon or Dacron[®], and an aluminum or plastic shaft. Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended. Place swabs immediately into sterile tubes containing 1-3 ml of appropriate transport media, such as viral transport media (VTM).

➤ Transporting Specimens

- Specimens must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulation. Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential 2019-nCoV specimens. Store specimens at 2-8°C and ship overnight to CDC on ice pack. If a specimen is frozen at -70°C or lower, ship overnight to CDC on dry ice.

➤ Storing Specimens

- Specimens can be stored at 2-8°C for up to 72 hours after collection.
- If a delay in extraction is expected, store specimens at -70°C or lower.
- Extracted nucleic acid should be stored at -70°C or lower.

[Specimen Referral to CDC](#)

For state and local public health laboratories:

- Ship all specimens overnight to CDC.
- Ship frozen specimens on dry ice and non-frozen specimens on cold packs.
- Refer to the International Air Transport Association (IATA - www.iata.org) for requirements for shipment of human or potentially infectious biological specimens. Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential 2019-nCoV specimens.
- Prior to shipping, notify CDC Division of Viral Diseases (see contact information below) that you are sending specimens.
- Send all samples to the following recipient:

Centers for Disease Control and Prevention
c/o STATT
Attention: Unit 66
1600 Clifton Rd., Atlanta, GA 30329-4027
Phone: (404) 639-3931

**The emergency contact number for CDC Emergency Operations Center (EOC) is
770-488-7100.**

All other laboratories that are CLIA certified and meet requirements to perform high complexity testing:

- Please notify your state and/or local public health laboratory for specimen referral and confirmatory testing guidance.

[Reagent and Controls Preparation](#)

NOTE: Storage information is for materials obtained through the CDC International Regent Resource. If using commercial products for testing, please refer to the manufacturer's instructions for storage, handling, and preparation instructions.

Primer and Probe Preparation:

- 1) Upon receipt, store dried primers and probes at 2-8°C.
- 2) Precautions: These reagents should only be handled in a clean area and stored at appropriate temperatures (see below) in the dark. Freeze-thaw cycles should be avoided. Maintain cold when thawed.
- 3) Using aseptic technique, suspend dried reagents in 1.5 mL of nuclease-free water and allow to rehydrate for 15 min at room temperature in the dark.
- 4) Mix gently and aliquot primers/probe in 300 µL volumes into 5 pre-labeled tubes. Store a single, working aliquot of primers/probes at 2-8°C in the dark. Store remaining aliquots at ≤ -20°C in a non-frost-free freezer. Do not refreeze thawed aliquots (stable for up to 4 months at 2-8°C).

2019-nCoV Positive Control (nCoVPC) Preparation:

- 1) Precautions: This reagent should be handled with caution in a dedicated nucleic acid handling area to prevent possible contamination. Freeze-thaw cycles should be avoided. Maintain on ice when thawed.
- 2) Resuspend dried reagent in each tube in 1 mL of nuclease-free water to achieve the proper concentration. Make single use aliquots (approximately 30 μ L) and store at $\leq -70^{\circ}\text{C}$.
- 3) Thaw a single aliquot of diluted positive control for each experiment and hold on ice until adding to plate. Discard any unused portion of the aliquot.

Human Specimen Control (HSC) (not provided)

- 1) Human Specimen Control (HSC) or one of the listed acceptable alternative extraction controls must be extracted and processed with each specimen extraction run.
- 2) Refer to the Human Specimen Control (HSC) package insert for instructions for use.

No Template Control (NTC) (not provided)

- 1) Sterile, nuclease-free water
- 2) Aliquot in small volumes
- 3) Used to check for contamination during specimen extraction and/or plate set-up

General Preparation

Equipment Preparation

Clean and decontaminate all work surfaces, pipettes, centrifuges, and other equipment prior to use. Decontamination agents should be used including 10% bleach, 70% ethanol, and DNAzap™, or RNase AWAY™ to minimize the risk of nucleic acid contamination.

Nucleic Acid Extraction

Performance of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is dependent upon the amount and quality of template RNA purified from human specimens. The following commercially available RNA extraction kits and procedures have been qualified and validated for recovery and purity of RNA for use with the panel:

Qiagen QIAamp® DSP Viral RNA Mini Kit or QIAamp® Viral RNA Mini Kit

Recommendation(s): Utilize 100 μ L of sample and elute with 100 μ L of buffer or utilize 140 μ L of sample and elute with 140 μ L of buffer.

Qiagen EZ1 Advanced XL

Kit: Qiagen EZ1 DSP Virus Kit and Buffer AVL (supplied separately) for offboard lysis

Card: EZ1 Advanced XL DSP Virus Card

Recommendation(s): Add 120 μ L of sample to 280 μ L of pre-aliquoted Buffer AVL (total input sample volume is 400 μ L). Proceed with the extraction on the EZ1 Advanced XL. Elution volume is 120 μ L.

Kit: Qiagen EZ1 Virus Mini Kit v2.0 and Buffer AVL (supplied separately) for offboard lysis

Card: EZ1 Advanced XL Virus Card v2.0

Recommendation(s): Add 120 µL of sample to 280 µL of pre-aliquoted Buffer AVL (total input sample volume is 400 µL). Proceed with the extraction on the EZ1 Advanced XL. Elution volume is 120 µL.

Roche MagNA Pure 96

Kit: Roche MagNA Pure 96 DNA and Viral NA Small Volume Kit

Protocol: Viral NA Plasma Ext LysExt Lys SV 4.0 Protocol or Viral NA Plasma Ext Lys SV Protocol

Recommendation(s): Add 100 µL of sample to 350 µL of pre-aliquoted External Lysis Buffer (supplied separately) (total input sample volume is 450 µL). Proceed with the extraction on the MagNA Pure 96. **(Internal Control = None)**. Elution volume is 100 µL.

Roche MagNA Pure 24

Kit: Roche MagNA Pure 24 Total NA Isolation Kit

Protocol: Pathogen 1000 2.0 Protocol

Recommendation(s): Add 100 µL of sample to 400 µL of pre-aliquoted External Lysis Buffer (supplied separately) (total input sample volume is 500 µL). Proceed with the extraction on the MagNA Pure 24. **(Internal Control = None)**. Elution volume is 100 µL.

Promega Maxwell® RSC 48

Kit: Promega Maxwell® Viral Total Nucleic Acid Purification Kit

Protocol: Viral Total Nucleic Acid

Recommendation(s): Add 120 µL of sample to 330 µL of pre-aliquoted External Lysis Buffer (300 µL Lysis Buffer plus 30 µL Proteinase K; supplied within the kit) (total input volume is 450 µL). Proceed with the extraction on the Maxwell® RSC 48. Elution volume is 75 µL.

Equivalence and performance of the following extraction platforms were demonstrated with the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (K190302) and based on those data are acceptable for use with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

QIAGEN QIAcube

Kit: QIAGEN QIAamp® DSP Viral RNA Mini Kit or QIAamp® Viral RNA Mini Kit

Recommendations: Utilize 140 µL of sample and elute with 100 µL of buffer.

Roche MagNA Pure LC

Kit: Roche MagNA Pure Total Nucleic Acid Kit

Protocol: Total NA External_lysis

Recommendation(s): Add 100 µL of sample to 300 µL of pre-aliquoted TNA isolation kit lysis buffer (total input sample volume is 400 µL). Elution volume is 100 µL.

Roche MagNA Pure Compact

Kit: Roche MagNA Pure Nucleic Acid Isolation Kit I

Protocol: Total_NA_Plasma100_400

Recommendation(s): Add 100 µL of sample to 300 µL of pre-aliquoted TNA isolation kit lysis buffer (total input sample volume is 400 µL). Elution volume is 100 µL.

bioMérieux NucliSENS® easyMAG® Instrument

Protocol: General protocol (not for blood) using “Off-board Lysis” reagent settings.

Recommendation(s): Add 100 µL of sample to 1000 µL of pre-aliquoted easyMAG lysis buffer (total input sample volume is 1100 µL). Incubate for 10 minutes at room temperature. Elution volume is 100 µL.

bioMérieux EMAG® Instrument

Protocol: Custom protocol: **CDC Flu V1** using “Off-board Lysis” reagent settings.

Recommendation(s): Add 100 µL of samples to 2000 µL of pre-aliquoted easyMAG lysis buffer (total input sample volume is 2100 µL). Incubate for 10 minutes at room temperature. Elution volume is 100 µL. The custom protocol, **CDC Flu V1**, is programmed on the bioMérieux EMAG® instrument with the assistance of a bioMérieux service representative. Installation verification is documented at the time of installation. Laboratories are recommended to retain a record of the step-by-step verification of the bioMérieux custom protocol installation procedure.

Manufacturer’s recommended procedures (except as noted in recommendations above) are to be followed for sample extraction. HSC must be included in each extraction batch.

Disclaimer: Names of vendors or manufacturers are provided as examples of suitable product sources. Inclusion does not imply endorsement by the Centers for Disease Control and Prevention.

Assay Set Up

Reaction Master Mix and Plate Set Up

Note: Plate set-up configuration can vary with the number of specimens and workday organization. NTCs and nCoVPCs must be included in each run.

- 1) In the reagent set-up room clean hood, place rRT-PCR buffer, enzyme, and primer/probes on ice or cold-block. Keep cold during preparation and use.
- 2) Mix buffer, enzyme, and primer/probes by inversion 5 times.
- 3) Centrifuge reagents and primers/probes for 5 seconds to collect contents at the bottom of the tube, and then place the tube in a cold rack.
- 4) Label one 1.5 mL microcentrifuge tube for each primer/probe set.
- 5) Determine the number of reactions (N) to set up per assay. It is necessary to make excess reaction mix for the NTC, nCoVPC, HSC (if included in the RT-PCR run), and RP reactions and for pipetting error. Use the following guide to determine N:
 - If number of samples (n) including controls equals 1 through 14, then $N = n + 1$
 - If number of samples (n) including controls is 15 or greater, then $N = n + 2$
- 7) For each primer/probe set, calculate the amount of each reagent to be added for each reaction mixture ($N = \#$ of reactions).

Thermofisher TaqPath™ 1-Step RT-qPCR Master Mix

Step #	Reagent	Vol. of Reagent Added per Reaction
1	Nuclease-free Water	N x 8.5 µL
2	Combined Primer/Probe Mix	N x 1.5 µL
3	TaqPath™ 1-Step RT-qPCR Master Mix (4x)	N x 5.0 µL
	Total Volume	N x 15.0 µL

Promega GoTaq® Probe 1- Step RT-qPCR System

Step #	Reagent	Vol. of Reagent Added per Reaction
1	Nuclease-free Water	N x 3.1 µL
2	Combined Primer/Probe Mix	N x 1.5 µL
3	GoTaq Probe qPCR Master Mix with dUTP	N x 10.0 µL
4	Go Script RT Mix for 1-Step RT-qPCR	N x 0.4 µL
	Total Volume	N x 15.0 µL

Quantabio qScript XLT One-Step RT-qPCR ToughMix

Step #	Reagent	Vol. of Reagent Added per Reaction
1	Nuclease-free Water	N x 3.5 µL
2	Combined Primer/Probe Mix	N x 1.5 µL
3	qScript XLT One-Step RT-qPCR ToughMix (2X)	N x 10.0 µL
	Total Volume	N x 15.0 µL

Quantabio UltraPlex 1-Step ToughMix (4X)

Step #	Reagent	Vol. of Reagent Added per Reaction
1	Nuclease-free Water	N x 8.5 µL
2	Combined Primer/Probe Mix	N x 1.5 µL
3	UltraPlex 1-Step ToughMix (4X)	N x 5.0 µL
	Total Volume	N x 15.0 µL

- 8) Dispense reagents into each respective labeled 1.5 mL microcentrifuge tube. After addition of the reagents, mix reaction mixtures by pipetting up and down. **Do not vortex.**
- 9) Centrifuge for 5 seconds to collect contents at the bottom of the tube, and then place the tube in a cold rack.
- 10) Set up reaction strip tubes or plates in a 96-well cooler rack.
- 11) Dispense 15 μ L of each master mix into the appropriate wells going across the row as shown below (**Figure 1**):

Figure 1: Example of Reaction Master Mix Plate Set-Up

	1	2	3	4	5	6	7	8	9	10	11	12
A	N1											
B	N2											
C	RP											
D												
E												
F												
G												
H												

- 12) Prior to moving to the nucleic acid handling area, prepare the No Template Control (NTC) reactions for column #1 in the assay preparation area.
- 13) Pipette 5 μ L of nuclease-free water into the NTC sample wells (**Figure 2**, column 1). Securely cap NTC wells before proceeding.
- 14) Cover the entire reaction plate and move the reaction plate to the specimen nucleic acid handling area.

Nucleic Acid Template Addition

- 1) Gently vortex nucleic acid sample tubes for approximately 5 seconds.
- 2) Centrifuge for 5 seconds to collect contents at the bottom of the tube.
- 3) After centrifugation, place extracted nucleic acid sample tubes in the cold rack.
- 4) Samples should be added to columns 2-11 (column 1 and 12 are for controls) to the specific assay that is being tested as illustrated in **Figure 2**. Carefully pipette 5.0 μ L of the first sample into all the wells labeled for that sample (i.e. Sample "S1" down column #2). *Keep other sample wells covered during addition. Change tips after each addition.*
- 5) Securely cap the column to which the sample has been added to prevent cross contamination and to ensure sample tracking.
- 6) Change gloves often and when necessary to avoid contamination.
- 7) Repeat steps #4 and #5 for the remaining samples.

- 8) If necessary, add 5 µL of Human Specimen Control (HSC) extracted sample to the HSC wells (**Figure 2**, column 11). Securely cap wells after addition. NOTE: Per CLIA regulations, HSC must be tested at least once per day.
- 9) Cover the entire reaction plate and move the reaction plate to the positive template control handling area.

Assay Control Addition

- 1) Pipette 5 µL of nCoVPC RNA to the sample wells of column 12 (**Figure 2**). Securely cap wells after addition of the control RNA.
NOTE: If using 8-tube strips, label the TAB of each strip to indicate sample position. DO NOT LABEL THE TOPS OF THE REACTION TUBES!
- 2) Briefly centrifuge reaction tube strips for 10-15 seconds. After centrifugation return to cold rack.
NOTE: If using 96-well plates, centrifuge plates for 30 seconds at 500 x g, 4°C.

Figure 2. 2019-nCoV rRT-PCR Diagnostic Panel: Example of Sample and Control Set-up

	1	2	3	4	5	6	7	8	9	10	11 ^a	12
A	NTC	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	nCoV PC
B	NTC	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	nCoV PC
C	NTC	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	nCoV PC
D												
E												
F												
G												
H												

^aReplace the sample in this column with extracted HSC if necessary

Create a Run Template on the Applied Biosystems 7500 Fast Dx Real-time PCR Instrument (Required if no template exists)

If the template already exists on your instrument, please proceed to the **RUNNING A TEST** section.

- 1) Launch the Applied Biosystems 7500 Fast Dx Real-time PCR Instrument by double clicking on the Applied Biosystems 7500 Fast Dx System icon on the desktop.
- 2) A new window should appear, select **Create New Document** from the menu.

Figure 3. New Document Wizard Window

New Document Wizard

Define Document
Select the assay, container, and template for the document, and enter the operator name and comments.

Assay: Standard Curve (Absolute Quantitation) ▼

Container: 96-Well Clear ▼

Template: Blank Document ▼ Browse...

Run Mode: Standard 7500 ▼

Operator: Training User

Comments: SDS v1.4

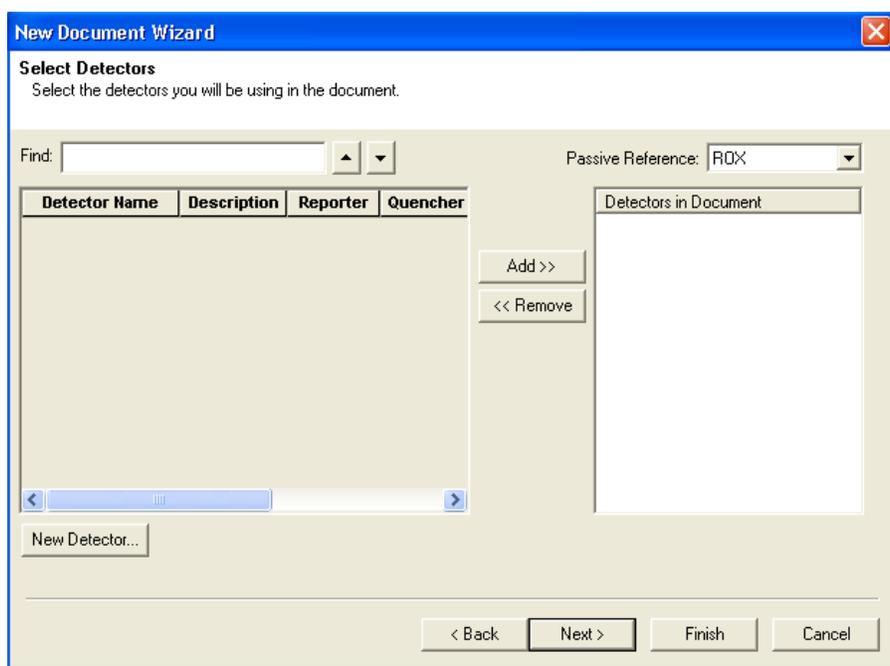
Plate Name: Training Plate

< Back Next > Finish Cancel

Make sure to change Run Mode to **STANDARD 7500**

- 3) The **New Document Wizard** screen in **Figure 3** will appear. Select:
 - a. Assay: **Standard Curve (Absolute Quantitation)**
 - b. Container: **96-Well Clear**
 - c. Template: **Blank Document**
 - d. Run Mode: **Standard 7500**
 - e. Operator: **Your Name**
 - f. Comments: **SDS v1.4**
 - g. Plate Name: **Your Choice**
- 4) After making selections click **Next** at the bottom of the window.

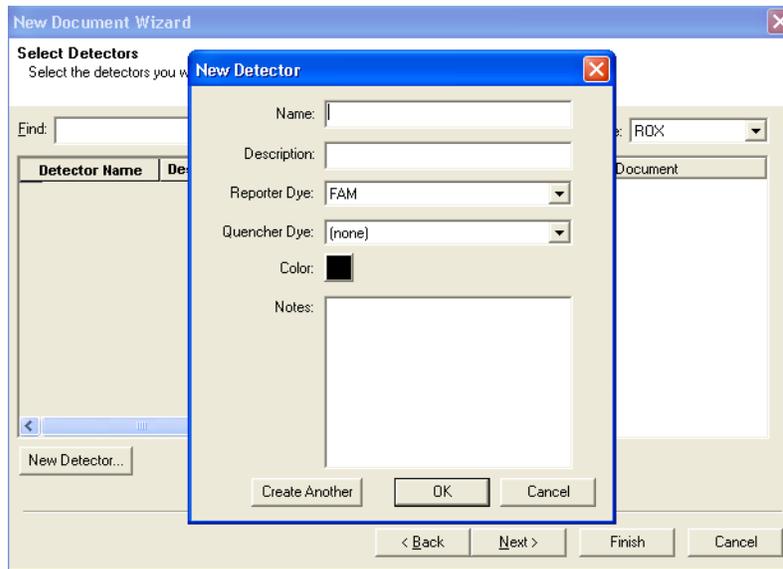
Figure 4. Creating New Detectors



NOTE: ROX is the default passive reference. This will be changed to "none" in step 12.

- 5) After selecting next, the **Select Detectors** screen (**Figure 4**) will appear.
- 6) Click the **New Detector** button (see **Figure 4**).
- 7) The **New Detector** window will appear (**Figure 5**). A new detector will need to be defined for each primer and probe set. Creating these detectors will enable you to analyze each primer and probe set individually at the end of the reaction.

Figure 5. New Detector Window

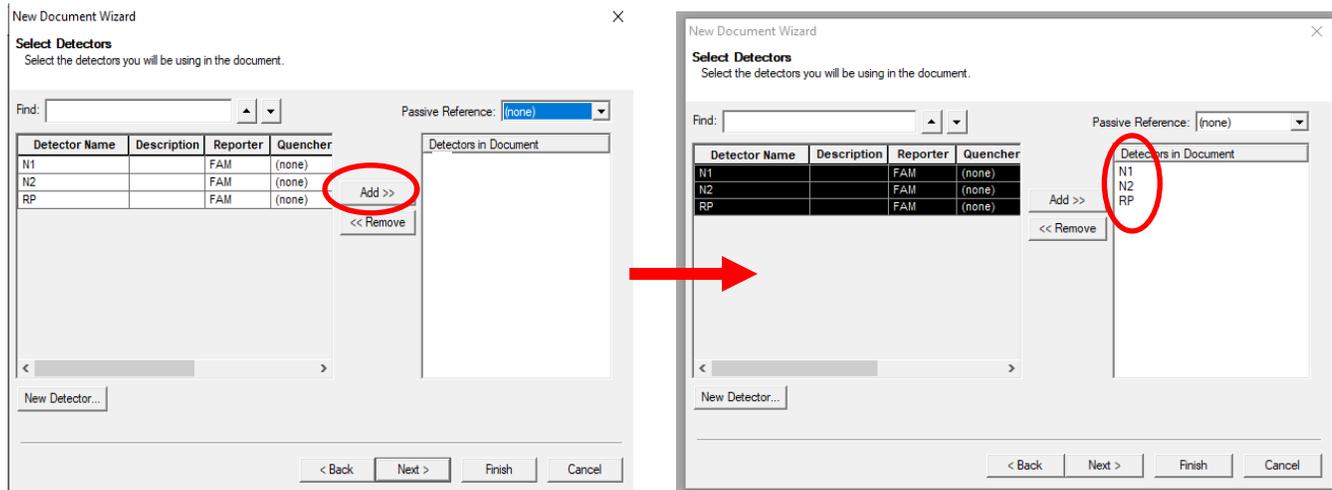


- 8) Start by creating the N1 Detector. Include the following:
 - a. Name: **N1**
 - b. Description: *leave blank*
 - c. Reporter Dye: **FAM**
 - d. Quencher Dye: **(none)**
 - e. Color: *to change the color of the detector indicator do the following:*
 - ⇒ Click on the color square to reveal the color chart
 - ⇒ Select a color by clicking on one of the squares
 - ⇒ After selecting a color click **OK** to return to the New Detector screen
 - f. Click the **OK** button of the New Detector screen to return to the screen shown in **Figure 4**.
- 9) Repeat step 6-8 for each target in the panel.

Name	Reporter Dye	Quencher Dye
N1	FAM	(none)
N2	FAM	(none)
RP	FAM	(none)

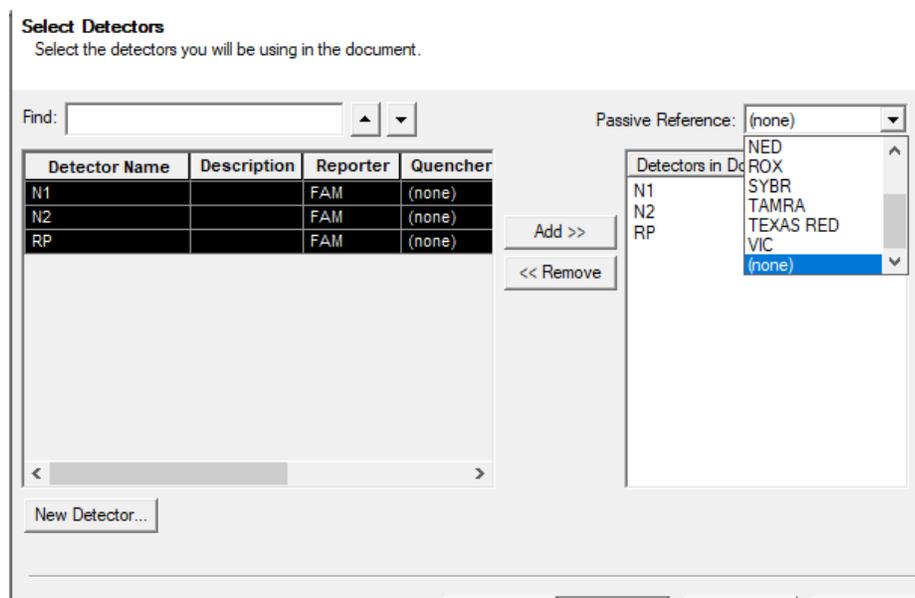
- 10) After each Detector is added, the **Detector Name**, **Description**, **Reporter** and **Quencher** fields will become populated in the **Select Detectors** screen (Figure 6).
- 11) Before proceeding, the newly created detectors must be added to the document. To add the new detectors to the document, click **ADD** (see Figure 6). Detector names will appear on the right-hand side of the **Select Detectors** window (Figure 6).

Figure 6. Adding New Detectors to Document



- 12) Once all detectors have been added, select **(none)** for **Passive Reference** at the top right-hand drop-down menu (Figure 7).

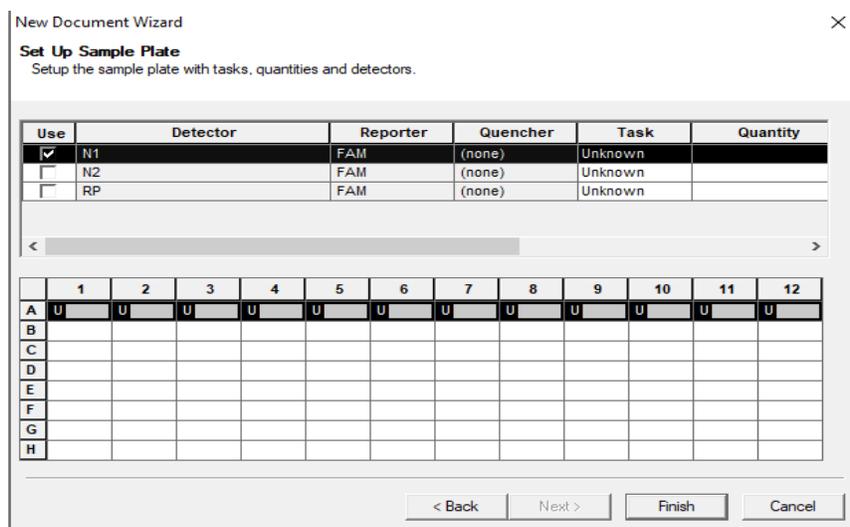
Figure 7. Select Passive Reference



Passive reference should be set to “(none)” as described above.

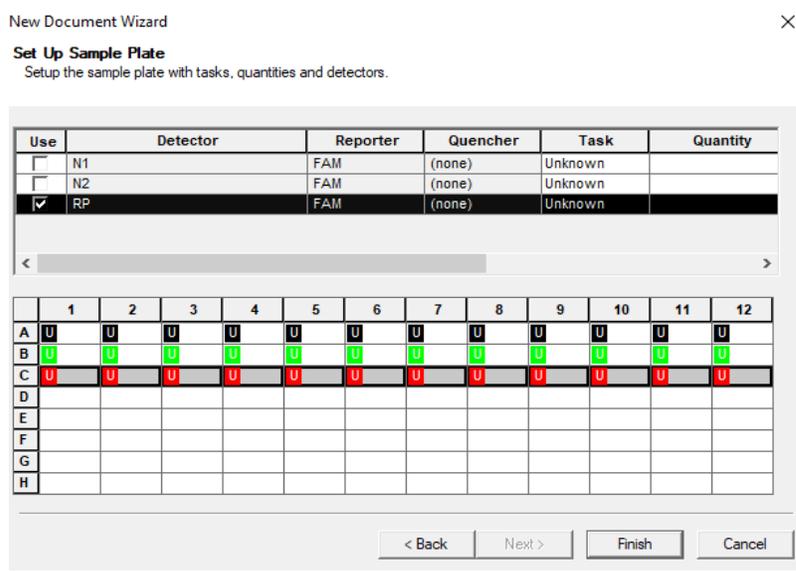
- 13) Click **Next** at the bottom of the **Select Detectors** window to proceed to the **Set Up Sample Plate** window (**Figure 8**).
- 14) In the **Set Up Sample Plate** window (**Figure 8**), use your mouse to select row A from the lower portion of the window, in the spreadsheet (see **Figure 8**).
- 15) In the top portion of the window, select detector **N1**. A check will appear next to the detector you have selected (**Figure 8**). You will also notice the row in the spreadsheet will be populated with a colored "U" icon to indicate which detector you've selected.
- 16) Repeat step 14-15 for each detector that will be used in the assay.

Figure 8. Sample Plate Set-up



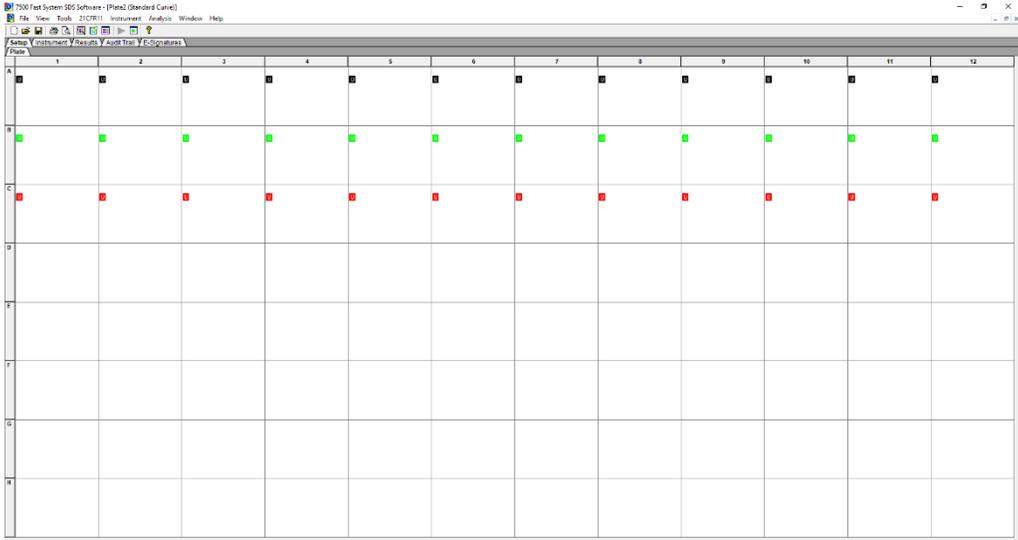
- 17) Select **Finish** after detectors have been assigned to their respective rows. (**Figure 9**).

Figure 9. Finished Plate Set-up



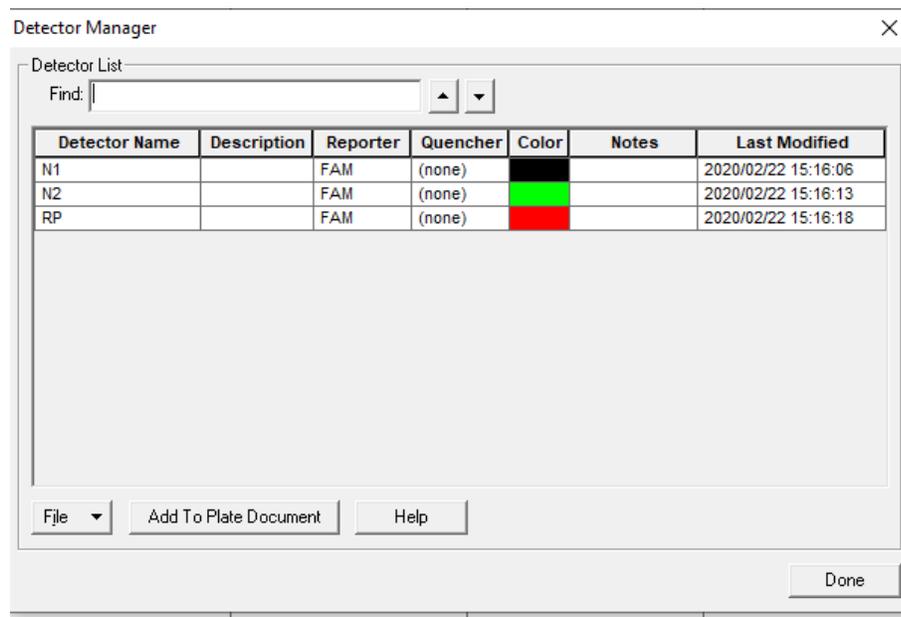
- 18) After clicking “Finish”, there will be a brief pause allowing the Applied Biosystems 7500 Fast Dx to initialize. This initialization is followed by a clicking noise. **Note: The machine must be turned on for initialization.**
- 19) After initialization, the **Plate** tab of the Setup (**Figure 10**) will appear.
- 20) Each well of the plate should contain colored U icons that correspond with the detector labels that were previously chosen. To confirm detector assignments, select **Tools** from the file menu, then select **Detector Manager**.

Figure 10. Plate Set-up Window



21) The Detector Manager window will appear (**Figure 11**).

Figure 11. Detector Manager Window



22) Confirm all detectors are included and that each target has a **Reporter** set to **FAM** and the **Quencher** is set to **(none)**.

23) If all detectors are present, select **Done**. The detector information has been created and assigned to wells on the plate.

[Defining the Instrument Settings](#)

- 1) After detectors have been created and assigned, proceed to instrument set up.
- 2) Select the **Instrument** tab to define thermal cycling conditions.
- 3) Modify the thermal cycling conditions as follows (**Figure 12**):

Thermofisher TaqPath™ 1-Step RT-qPCR Master Mix, CG

- a. In Stage 1, Set to 2 min at **25°C**; **1 Rep.**
- b. In Stage 2, Set to 15 min at **50°C**; **1 Rep.**
- c. In Stage 3, Set to 2 min at **95°C**, **1 Rep.**
- d. In Stage 4, Step 1 set to **3 sec** at **95°C**.
- e. In Stage 4, Step 2 set to **30 sec** at **55.0°C**.
- f. In Stage 4, Reps should be set to **45**.
- g. Under **Settings** (**Figure 12**), bottom left-hand box, change volume to 20 μ L.
- h. Under **Settings**, **Run Mode** selection should be **Standard 7500**.
- i. Step 2 of Stage 4 should be highlighted in yellow to indicate data collection (see **Figure 12**).

OR

Quantabio qScript™ XLT One-Step RT-qPCR ToughMix or UltraPlex 1-Step ToughMix (4X)

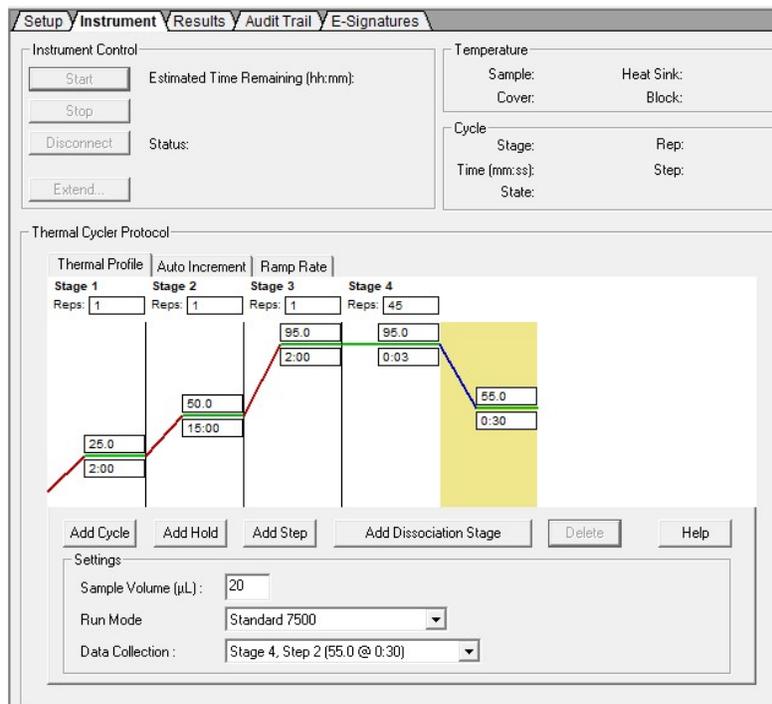
- a. In Stage 1, Set to 10 min at **50°C**; **1 Rep.**
- b. In Stage 2, Set to 3 min at **95°C**, **1 Rep.**
- c. In Stage 3, Step 1 set to **3 sec** at **95°C**.
- d. In Stage 3, Step 2 set to **30 sec** at **55.0°C**.
- e. In Stage 3, Reps should be set to **45**.
- f. Under **Settings (Figure 12)**, bottom left-hand box, change volume to 20 µL.
- g. Under **Settings, Run Mode** selection should be **Standard 7500**.
- h. Step 2 of Stage 3 should be highlighted in yellow to indicate data collection (see **Figure 12**).

OR

Promega GoTaq® Probe 1-Step RT-qPCR System

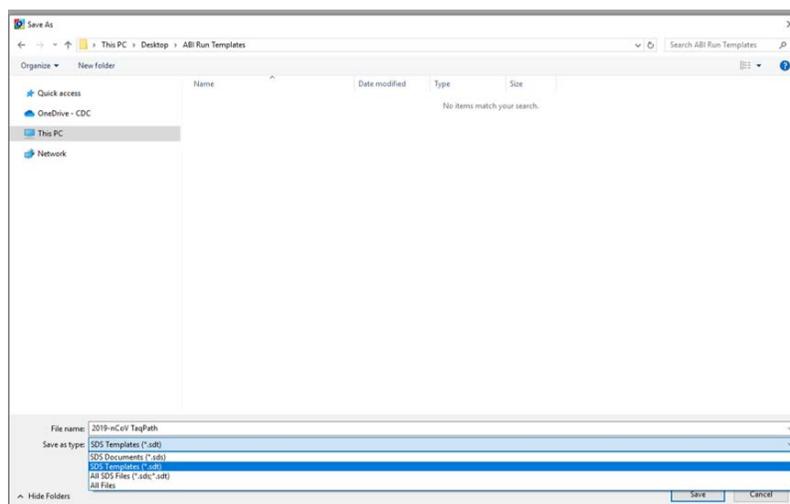
- a. In Stage 1, Set to 15 min at **45°C**; **1 Rep.**
- b. In Stage 2, Set to 2 min at **95°C**, **1 Rep.**
- c. In Stage 3, Step 1 set to **3 sec** at **95°C**.
- d. In Stage 3, Step 2 set to **30 sec** at **55.0°C**.
- e. In Stage 3, Reps should be set to **45**.
- f. Under **Settings (Figure 12)**, bottom left-hand box, change volume to 20 µL.
- g. Under **Settings, Run Mode** selection should be **Standard 7500**.
- h. Step 2 of Stage 3 should be highlighted in yellow to indicate data collection (see **Figure 12**).

Figure 12. Instrument Window



- 4) After making changes to the **Instrument** tab, the template file is ready to be saved. To save the template, select **File** from the top menu, then select **Save As**. Since the enzyme options have different instrument settings, it is recommended that the template be saved with a name indicating the enzyme option.
- 5) Save the template as **2019-nCoV Dx Panel TaqPath** or **2019-nCoV Dx Panel Quanta** or **2019-nCoV Dx Panel Promega** as appropriate in the desktop folder labeled **“ABI Run Templates”** (you must create this folder). Save as type should be SDS Templates (*.sdt) (**Figure 13**).

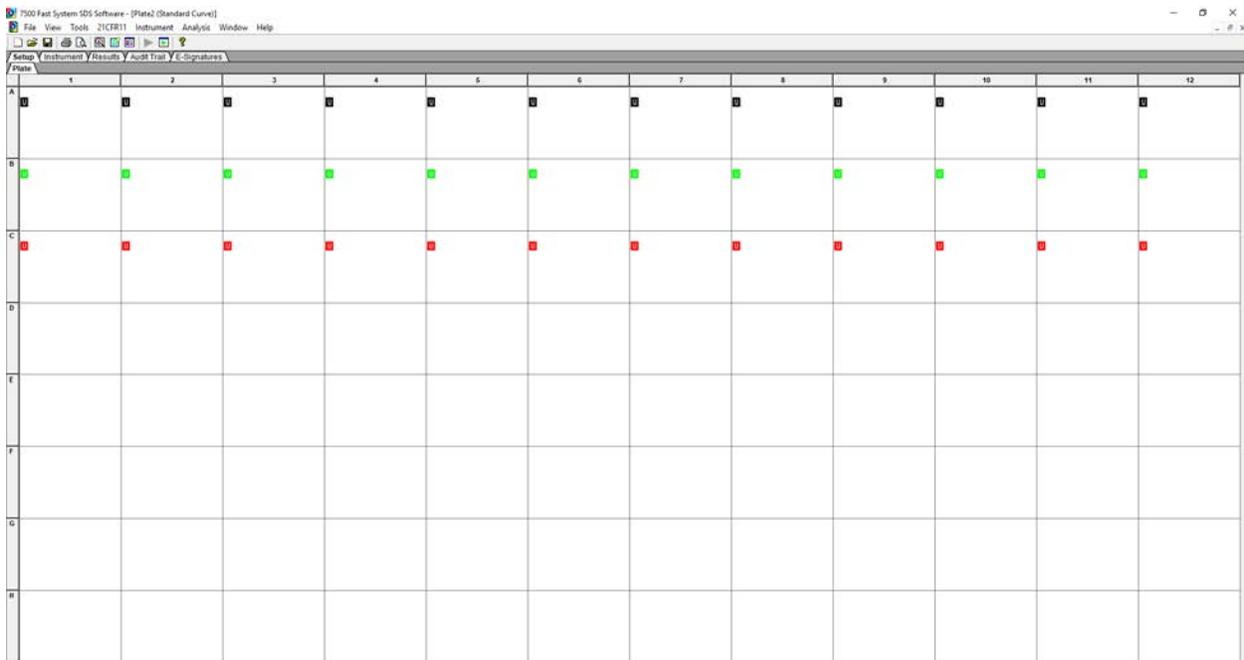
Figure 13. Saving Template



Running a Test

- 1) Turn on the ABI 7500 Fast Dx Real-Time PCR Instrument.
- 2) Launch the Applied Biosystems 7500 Fast Dx Real-time PCR System by double clicking on the 7500 Fast Dx System icon on the desktop.
- 3) A new window should appear, select **Open Existing Document** from the menu.
- 4) Navigate to select your ABI Run Template folder from the desktop.
- 5) Double click on the appropriate template file (**2019-nCoV Dx Panel TaqPath** or **2019-nCoV Dx Panel Quanta** or **2019-nCoV Dx Panel Promega**)
- 6) There will be a brief pause allowing the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument to initialize. This initialization is followed by a clicking noise. **Note: The machine must be turned on for initialization.**

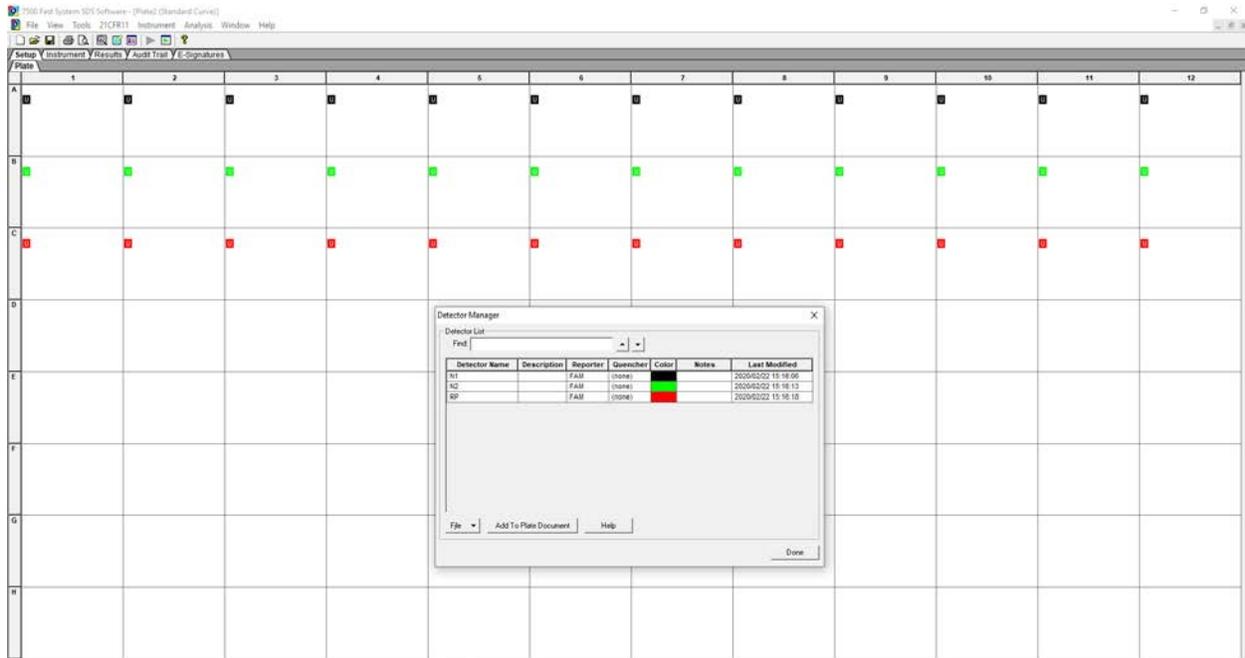
Figure 14. Plate Set-up Window



- 7) After the instrument initializes, a plate map will appear (**Figure 14**). The detectors and controls should already be labeled as they were assigned in the original template.

- 8) Click the **Well Inspector** icon  from the top menu.
- 9) Highlight specimen wells of interest on the plate map.
- 10) Type sample identifiers to **Sample Name** box in the **Well Inspector** window (**Figure 15**).

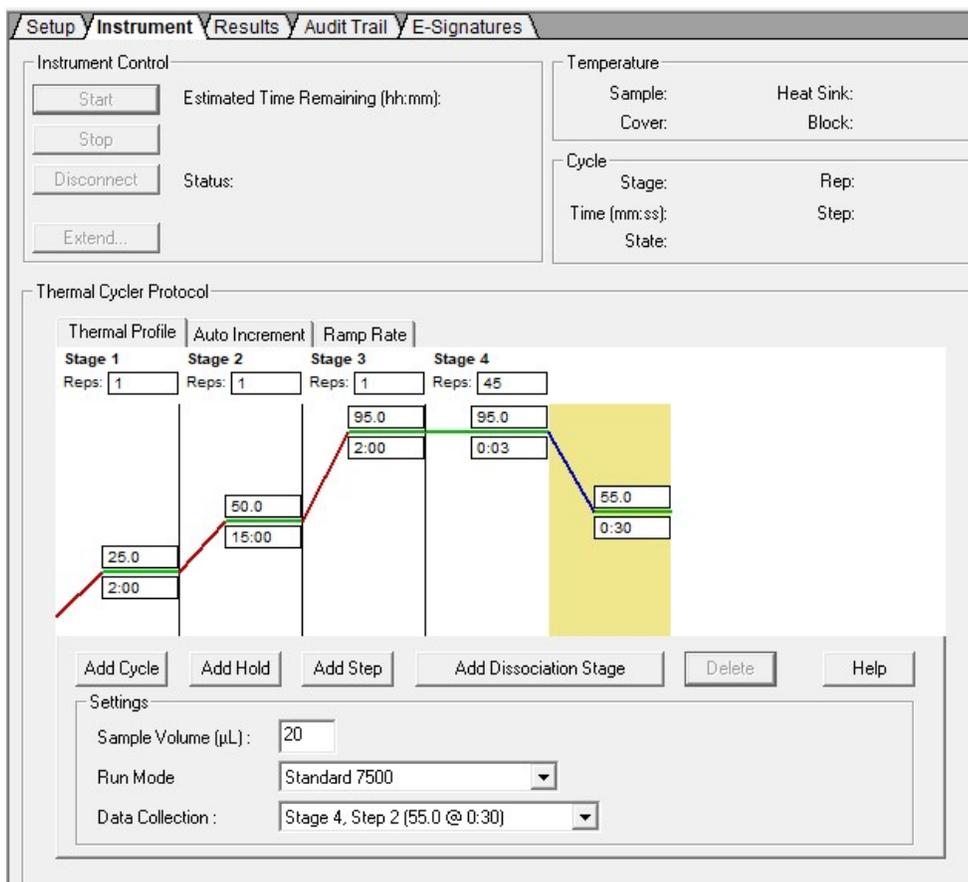
Figure 15. Labeling Wells



- 11) Repeat steps 9-10 until all sample identifiers are added to the plate setup.

- 12) Once all specimen and control identifiers are added click the **Close** button on the **Well Inspector** window to return to the **Plate** set up tab.
- 13) Click the **Instrument** tab at the upper left corner.
- 14) The reaction conditions, volumes, and type of 7500 reaction should already be loaded (**Figure 16**).

Figure 16. Instrument Settings

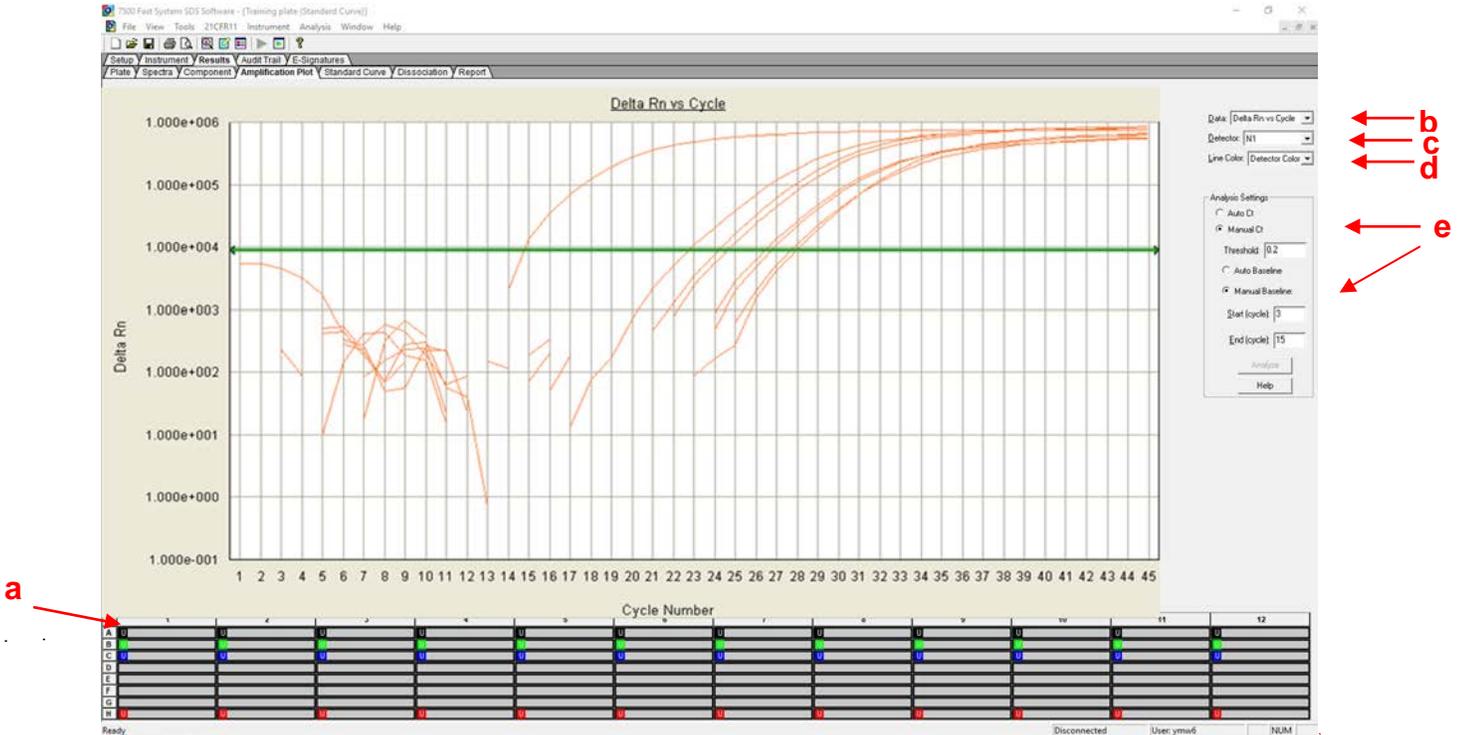


- 15) Ensure settings are correct (refer to the *Defining Instrument Settings*).
- 16) Before proceeding, the run file must be saved; from the main menu, select **File**, then **Save As**. Save in appropriate run folder designation.
- 17) Load the plate into the plate holder in the instrument. Ensure that the plate is properly aligned in the holder.
- 18) Once the run file is saved, click the **Start** button. *Note: The run should take approximately 1 hour and 20 minutes to complete.*

Data Analysis

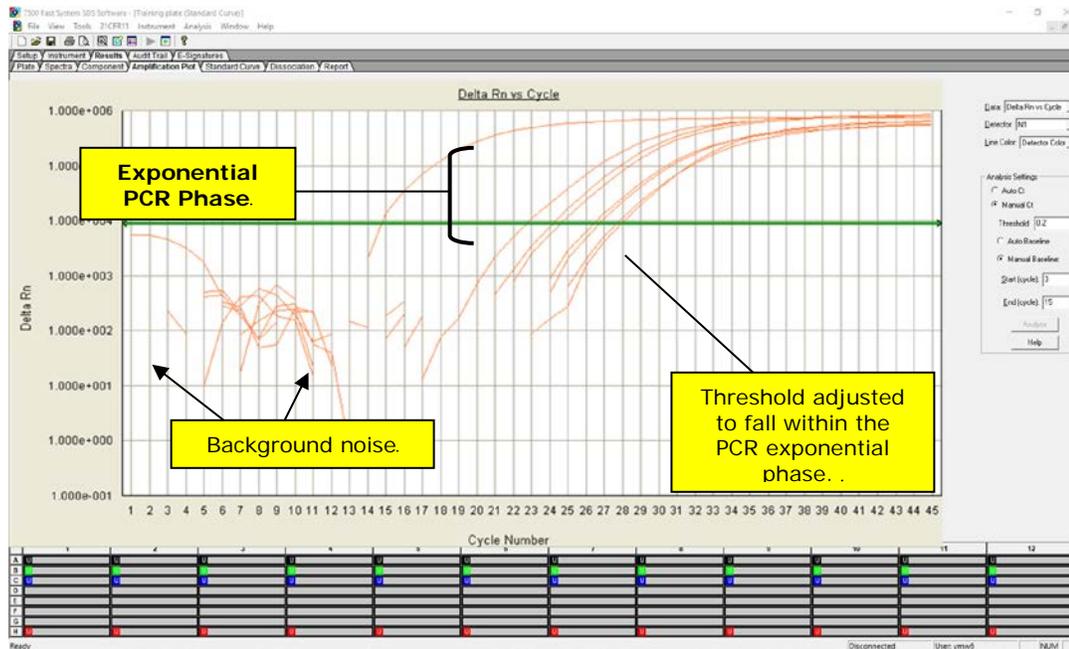
- 1) After the run has completed, select the **Results** tab at the upper left corner of the software.
- 2) Select the **Amplification Plot** tab to view the raw data (**Figure 17**).

Figure 17. Amplification Plot Window



- 3) Start by highlighting all the samples from the run; to do this, click on the upper left-hand box **(a)** of the sample wells (**Figure 17**). All the growth curves should appear on the graph.
- 4) On the right-hand side of the window **(b)**, the **Data** drop down selection should be set to **Delta Rn vs. Cycle**.
- 5) Select **N1** from **(c)**, the **Detector** drop down menu, using the downward arrow.
 - a. Please note that each detector is analyzed individually to reflect different performance profiles of each primer and probe set.
- 6) In the **Line Color** drop down **(d)**, **Detector Color** should be selected.
- 7) Under **Analysis Settings** select **Manual Ct (e)**.
 - b. Do not change the **Manual Baseline** default numbers.
- 8) Using the mouse, click and drag the red threshold line until it lies within the exponential phase of the fluorescence curves and above any background signal (**Figure 18**).

Figure 18. Amplification Plot



- 9) Click the **Analyze** button in the lower right corner of the window. The red threshold line will turn to green, indicating the data has been analyzed.
- 10) Repeat steps 5-9 to analyze results generated for each set of markers (N1, N2, RP).
- 11) Save analysis file by selecting **File** then **Save As** from the main menu.
- 12) After completing analysis for each of the markers, select the **Report** tab above the graph to display the Ct values (**Figure 19**). To filter report by sample name in ascending or descending order, simply click on **Sample Name** in the table.

Figure 19. Report

Well	Sample Name	Detector	Task	Ct	StdDev Ct	Quantity	Mean Qty	StdDev Qty	Filtered	Tm
A1	NTC	N1	Unknown	Unknown						
A2	ncAVRC 1	N1	Unknown	20.2522						
A3	ncAVRC 2	N1	Unknown	20.8418						
A4	ncAVRC 3	N1	Unknown	20.4563						
A5	APC	N1	Unknown	25.4229						
B1	NTC	N2	Unknown	Unknown						
B2	ncAVRC 1	N2	Unknown	20.8181						
B3	ncAVRC 2	N2	Unknown	21.6637						
B4	ncAVRC 3	N2	Unknown	21.2075						
B5	APC	N2	Unknown	26.445						
C1	NTC	RP	Unknown	Unknown						
C2	ncAVRC 1	RP	Unknown	20.9186						
C3	ncAVRC 2	RP	Unknown	21.5687						
C4	ncAVRC 3	RP	Unknown	20.7028						
C5	APC	RP	Unknown	25.9686						

Interpretation of Results and Reporting

Extraction and Positive Control Results and Interpretation

No Template Control (NTC)

The NTC consists of using nuclease-free water in the rRT-PCR reactions instead of RNA. The NTC reactions for all primer and probe sets should not exhibit fluorescence growth curves that cross the threshold line. If any of the NTC reactions exhibit a growth curve that crosses the cycle threshold, sample contamination may have occurred. Invalidate the run and repeat the assay with strict adherence to the guidelines.

2019-nCoV Positive Control (nCoVPC)

The nCoVPC consists of in vitro transcribed RNA. The nCoVPC will yield a positive result with the following primer and probe sets: N1, N2, and RP.

Human Specimen Control (HSC) (Extraction Control)

When HSC is run with the CDC 2019-nCoV rRT-PCR Diagnostic Panel (see previous section on Assay Set Up), the HSC is used as a nucleic acid extraction procedural control to demonstrate successful recovery of nucleic acid as well as extraction reagent integrity. The HSC control consists of noninfectious cultured human cell (A549) material. Purified nucleic acid from the HSC should yield a positive result with the RP primer and probe set and negative results with all 2019-nCoV markers.

Expected Performance of Controls Included in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

Control Type	External Control Name	Used to Monitor	2019 nCoV_N1	2019 nCoV_N2	RP	Expected Ct Values
Positive	nCoVPC	Substantial reagent failure including primer and probe integrity	+	+	+	< 40.00 Ct
Negative	NTC	Reagent and/or environmental contamination	-	-	-	None detected
Extraction	HSC	Failure in lysis and extraction procedure, potential contamination during extraction	-	-	+	< 40.00 Ct

If any of the above controls do not exhibit the expected performance as described, the assay may have been set up and/or executed improperly, or reagent or equipment malfunction could have occurred. Invalidate the run and re-test.

RNase P (Extraction Control)

- All clinical samples should exhibit fluorescence growth curves in the RNase P reaction that cross the threshold line within 40.00 cycles (< 40.00 Ct), thus indicating the presence of the human RNase P gene. Failure to detect RNase P in any clinical specimens may indicate:
 - Improper extraction of nucleic acid from clinical materials resulting in loss of RNA and/or RNA degradation.
 - Absence of sufficient human cellular material due to poor collection or loss of specimen integrity.
 - Improper assay set up and execution.
 - Reagent or equipment malfunction.
- If the RP assay does not produce a positive result for human clinical specimens, interpret as follows:
 - If the 2019-nCoV N1 and N2 are positive even in the absence of a positive RP, the result should be considered valid. It is possible, that some samples may fail to exhibit RNase P growth curves due to low cell numbers in the original clinical sample. A negative RP signal does not preclude the presence of 2019-nCoV virus RNA in a clinical specimen.
 - If all 2019-nCoV markers AND RNase P are negative for the specimen, the result should be considered invalid for the specimen. If residual specimen is available, repeat the extraction procedure and repeat the test. If all markers remain negative after re-test, report the results as invalid and a new specimen should be collected if possible.

2019-nCoV Markers (N1 and N2)

- When all controls exhibit the expected performance, a specimen is considered negative if all 2019-nCoV marker (N1, N2) cycle threshold growth curves DO NOT cross the threshold line within 40.00 cycles (< 40.00 Ct) AND the RNase P growth curve DOES cross the threshold line within 40.00 cycles (< 40.00 Ct).
- When all controls exhibit the expected performance, a specimen is considered positive for 2019-nCoV if all 2019-nCoV marker (N1, N2) cycle threshold growth curves cross the threshold line within 40.00 cycles (< 40.00 Ct). The RNase P may or may not be positive as described above, but the 2019-nCoV result is still valid.
- When all controls exhibit the expected performance and the growth curves for the 2019-nCoV markers (N1, N2) AND the RNase P marker DO NOT cross the cycle threshold growth curve within 40.00 cycles (< 40.00 Ct), the result is invalid. The extracted RNA from the specimen should be re-tested. If residual RNA is not available, re-extract RNA from residual specimen and re-test. If the re-tested sample is negative for all markers and RNase P, the result is invalid and collection of a new specimen from the patient should be considered.
- When all controls exhibit the expected performance and the cycle threshold growth curve for any one marker (N1 or N2, but not both markers) crosses the threshold line within 40.00 cycles (< 40.00 Ct) the result is inconclusive. The extracted RNA should be retested. If residual RNA is not available, re-extract RNA from residual specimen and re-test. If the same result is obtained,

report the inconclusive result. Consult with your state public health laboratory or CDC, as appropriate, to request guidance and/or to coordinate transfer of the specimen for additional analysis.

- If HSC is positive for N1 or N2, then contamination may have occurred during extraction or sample processing. Invalidate all results for specimens extracted alongside the HSC. Re-extract specimens and HSC and re-test.

2019-nCoV rRT-PCR Diagnostic Panel Results Interpretation Guide

The table below lists the expected results for the 2019-nCoV rRT-PCR Diagnostic Panel. If a laboratory obtains unexpected results for assay controls or if inconclusive or invalid results are obtained and cannot be resolved through the recommended re-testing, please contact CDC for consultation and possible specimen referral. See pages 13 and 50 for referral and contact information.

2019 nCoV_N1	2019 nCoV_N2	RP	Result Interpretation ^a	Report	Actions
+	+	±	2019-nCoV detected	Positive 2019-nCoV	Report results to CDC and sender.
If only one of the two targets is positive		±	Inconclusive Result	Inconclusive	Repeat testing of nucleic acid and/or re-extract and repeat rRT-PCR. If the repeated result remains inconclusive, contact your State Public Health Laboratory or CDC for instructions for transfer of the specimen or further guidance.
-	-	+	2019-nCoV not detected	Not Detected	Report results to sender. Consider testing for other respiratory viruses. ^b
-	-	-	Invalid Result	Invalid	Repeat extraction and rRT-PCR. If the repeated result remains invalid, consider collecting a new specimen from the patient.

^aLaboratories should report their diagnostic result as appropriate and in compliance with their specific reporting system.

^bOptimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens from the same patient may be necessary to detect the virus. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation suggest that 2019-nCoV infection is possible, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If 2019-nCoV infection is still suspected, re-testing should be considered in consultation with public health authorities.

Quality Control

- Quality control requirements must be performed in conformance with local, state, and federal regulations or accreditation requirements and the user's laboratory's standard quality control procedures. For further guidance on appropriate quality control practices, refer to 42 CFR 493.1256.
- Quality control procedures are intended to monitor reagent and assay performance.
- Test all positive controls prior to running diagnostic samples with each new kit lot to ensure all reagents and kit components are working properly.
- Good laboratory practice (cGLP) recommends including a positive extraction control in each nucleic acid isolation batch.
- Although HSC is not included with the 2019-nCoV rRT-PCR Diagnostic Panel, the HSC extraction control must proceed through nucleic acid isolation per batch of specimens to be tested.
- Always include a negative template control (NTC) and the appropriate positive control (nCoVPC) in each amplification and detection run. All clinical samples should be tested for human RNase P gene to control for specimen quality and extraction.

Limitations

- All users, analysts, and any person reporting diagnostic results should be trained to perform this procedure by a competent instructor. They should demonstrate their ability to perform the test and interpret the results prior to performing the assay independently.
- Performance of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has only been established in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate).
- Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens (types and time points) from the same patient may be necessary to detect the virus.
- A false-negative result may occur if a specimen is improperly collected, transported or handled. False-negative results may also occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the specimen.
- Positive and negative predictive values are highly dependent on prevalence. False-negative test results are more likely when prevalence of disease is high. False-positive test results are more likely when prevalence is moderate to low.
- Do not use any reagent past the expiration date.
- If the virus mutates in the rRT-PCR target region, 2019-nCoV may not be detected or may be detected less predictably. Inhibitors or other types of interference may produce a false-negative result. An interference study evaluating the effect of common cold medications was not performed.
- Test performance can be affected because the epidemiology and clinical spectrum of infection caused by 2019-nCoV is not fully known. For example, clinicians and laboratories may not know

the optimum types of specimens to collect, and, during the course of infection, when these specimens are most likely to contain levels of viral RNA that can be readily detected.

- Detection of viral RNA may not indicate the presence of infectious virus or that 2019-nCoV is the causative agent for clinical symptoms.
- The performance of this test has not been established for monitoring treatment of 2019-nCoV infection.
- The performance of this test has not been established for screening of blood or blood products for the presence of 2019-nCoV.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.

[Conditions of Authorization for the Laboratory](#)

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website:

<https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm>

Use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel must follow the procedures outlined in these manufacturer's Instructions for Use and the conditions of authorization outlined in the Letter of Authorization. Deviations from the procedures outlined are not permitted under the Emergency Use Authorization (EUA). To assist clinical laboratories running the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, the relevant Conditions of Authorization are listed verbatim below, and are required to be met by laboratories performing the EUA test.

- Authorized laboratories¹ will include with reports of the results of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories will perform the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel as outlined in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use. Deviations from the authorized procedures, including the authorized RT-PCR instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to perform the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel are not permitted.²
- Authorized laboratories that receive the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel must notify the relevant public health authorities of their intent to run the test prior to initiating testing.

¹Authorized Laboratories: For ease of reference, the Letter of Authorization refers to "laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests" as "authorized laboratories."

²If an authorized laboratory is interested in implementing changes to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel that are not in the scope (Section II) of this letter of authorization FDA recommends you discuss with FDA after considering the policy outlined in *Immediately in Effect Guidance for Clinical Laboratories and Food and Drug Administration Staff: Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency* (<https://www.fda.gov/media/135659/download>).

- Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and CDC (respvirus@cdc.gov) any suspected occurrence of false-positive or false-negative results and significant deviations from the established performance characteristics of the test of which they become aware.
- Authorized laboratories will report adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling 1-800-FDA-1088
- All laboratory personnel using the test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit and use the test in accordance with the authorized labeling.
- CDC, IRR, manufacturers and distributors of commercial materials identified as acceptable on the CDC website, and authorized laboratories will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Performance Characteristics

Analytical Performance:

Limit of Detection (LoD):

LoD studies determine the lowest detectable concentration of 2019-nCoV at which approximately 95% of all (true positive) replicates test positive. The LoD was determined by limiting dilution studies using characterized samples.

The analytical sensitivity of the rRT-PCR assays contained in the CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel were determined in Limit of Detection studies. Since no quantified virus isolates of the 2019-nCoV are currently available, assays designed for detection of the 2019-nCoV RNA were tested with characterized stocks of in vitro transcribed full length RNA (N gene; GenBank accession: MN908947.2) of known titer (RNA copies/ μ L) spiked into a diluent consisting of a suspension of human A549 cells and viral transport medium (VTM) to mimic clinical specimen. Samples were extracted using the QIAGEN EZ1 Advanced XL instrument and EZ1 DSP Virus Kit (Cat# 62724) and manually with the QIAGEN DSP Viral RNA Mini Kit (Cat# 61904). Real-Time RT-PCR assays were performed using the ThermoFisher Scientific TaqPath™ 1-Step RT-qPCR Master Mix, CG (Cat# A15299) on the Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument according to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel instructions for use.

A preliminary LoD for each assay was determined testing triplicate samples of RNA purified using each extraction method. The approximate LoD was identified by extracting and testing 10-fold serial dilutions of characterized stocks of in vitro transcribed full-length RNA. A confirmation of the LoD was determined using 3-fold serial dilution RNA samples with 20 extracted replicates. The LoD was determined as the lowest concentration where $\geq 95\%$ (19/20) of the replicates were positive.

Table 4. Limit of Detection Confirmation of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with QIAGEN EZ1 DSP

Targets	2019-nCoV_N1			2019-nCoV_N2		
	$10^{0.5}$	$10^{0.0}$	$10^{-0.5}$	$10^{0.5}$	$10^{0.0}$	$10^{-0.5}$
RNA Concentration ¹	$10^{0.5}$	$10^{0.0}$	$10^{-0.5}$	$10^{0.5}$	$10^{0.0}$	$10^{-0.5}$
Positives/Total	20/20	19/20	13/20	20/20	17/20	9/20
Mean Ct ²	32.5	35.4	NA	35.8	NA	NA
Standard Deviation (Ct)	0.5	0.8	NA	1.3	NA	NA

¹ Concentration is presented in RNA copies/ μ L

² Mean Ct reported for dilutions that are $\geq 95\%$ positive. Calculations only include positive results.

NA not applicable

Table 5. Limit of Detection Confirmation CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with QIAGEN QIAmp DSP Viral RNA Mini Kit

Targets	2019-nCoV_N1			2019-nCoV_N2			
	$10^{0.5}$	$10^{0.0}$	$10^{-0.5}$	$10^{0.5}$	$10^{0.0}$	$10^{-0.5}$	$10^{-1.0}$
RNA Concentration ¹	$10^{0.5}$	$10^{0.0}$	$10^{-0.5}$	$10^{0.5}$	$10^{0.0}$	$10^{-0.5}$	$10^{-1.0}$
Positives/Total	20/20	20/20	6/20	20/20	20/20	20/20	8/20
Mean Ct ²	32.0	32.8	NA	33.0	35.4	36.2	NA
Standard Deviation (Ct)	0.7	0.8	NA	1.4	0.9	1.9	NA

¹ Concentration is presented in RNA copies/ μ L

² Mean Ct reported for dilutions that are $\geq 95\%$ positive. Calculations only include positive results.

NA not applicable

Table 6. Limit of Detection of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

Virus	Material	Limit of Detection (RNA copies/ μ L)	
		QIAGEN EZ1 Advanced XL	QIAGEN DSP Viral RNA Mini Kit
2019 Novel Coronavirus	N Gene RNA Transcript	$10^{0.5}$	10^0

FDA Sensitivity Evaluation: The analytical sensitivity of the test will be further assessed by evaluating an FDA-recommended reference material using an FDA developed protocol if applicable and/or when available.

In Silico Analysis of Primer and Probe Sequences:

The oligonucleotide primer and probe sequences of the CDC 2019 nCoV Real-Time RT-PCR Diagnostic Panel were evaluated against 31,623 sequences available in the Global Initiative on Sharing All Influenza Data (GISAID, <https://www.gisaid.org>) database as of June 20, 2020, to demonstrate the predicted inclusivity of the 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Nucleotide mismatches in the primer/probe regions with frequencies > 0.1% are shown below. With the exception of one nucleotide mismatch with frequency > 1% (2.00%) at the third position of the N1 probe, the frequency of all mismatches was < 1%, indicating that prevalence of the mismatches were sporadic. Only one sequence (0.0032%) had two nucleotide mismatches in the N1 probe, and one other sequence from a different isolate (0.0032%) had two nucleotide mismatches in the N1 reverse primer. No sequences were found to have more than one mismatch in any N2 primer/probe region. The risk of these mismatches resulting in a significant loss in reactivity causing a false negative result is extremely low due to the design of the primers and probes, with melting temperatures > 60°C and with annealing temperature at 55°C that can tolerate up to two mismatches.

Table 7. In Silico Inclusivity Analysis of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Among 31,623 Genome Sequences Available from GISAID as of June 20, 2020

Primer/probe	N1 probe	N1 reverse		N2 probe
Location (5'>3')	3	15	21	13
Mismatch Nucleotide	C>T	G>T	T>C	C>T
Mismatch No.	632	34	71	46
Mismatch Frequency (%)	2.00	0.11	0.22	0.15

Specificity/Exclusivity Testing: In Silico Analysis

BLASTn analysis queries of the 2019-nCoV rRT-PCR assays primers and probes were performed against public domain nucleotide sequences. The database search parameters were as follows: 1) The nucleotide collection consists of GenBank+EMBL+DDBJ+PDB+RefSeq sequences, but excludes EST, STS, GSS, WGS, TSA, patent sequences as well as phase 0, 1, and 2 HTGS sequences and sequences longer than 100Mb; 2) The database is non-redundant. Identical sequences have been merged into one entry, while preserving the accession, GI, title and taxonomy information for each entry; 3) Database was updated on 10/03/2019; 4) The search parameters automatically adjust for short input sequences and the expect threshold is 1000; 5) The match and mismatch scores are 1 and -3, respectively; 6) The penalty to create and extend a gap in an alignment is 5 and 2 respectively.

2019-nCoV_N1 Assay:

Probe sequence of 2019-nCoV rRT-PCR assay N1 showed high sequence homology with SARS coronavirus and Bat SARS-like coronavirus genome. However, forward and reverse primers showed no sequence homology with SARS coronavirus and Bat SARS-like coronavirus genome. Combining primers and probe, there is no significant homologies with human genome, other coronaviruses or human microflora that would predict potential false positive rRT-PCR results.

2019-nCoV_N2 Assay:

The forward primer sequence of 2019-nCoV rRT-PCR assay N2 showed high sequence homology to Bat SARS-like coronaviruses. The reverse primer and probe sequences showed no significant homology with human genome, other coronaviruses or human microflora. Combining primers and probe, there is no prediction of potential false positive rRT-PCR results.

In summary, the 2019-nCoV rRT-PCR assay N1 and N2, designed for the specific detection of 2019-nCoV, showed no significant combined homologies with human genome, other coronaviruses, or human microflora that would predict potential false positive rRT-PCR results.

In addition to the *in silico* analysis, several organisms were extracted and tested with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel to demonstrate analytical specificity and exclusivity. Studies were performed with nucleic acids extracted using the QIAGEN EZ1 Advanced XL instrument and EZ1 DSP Virus Kit. Nucleic acids were extracted from high titer preparations (typically $\geq 10^5$ PFU/mL or $\geq 10^6$ CFU/mL). Testing was performed using the ThermoFisher Scientific TaqPath™ 1-Step RT-qPCR Master Mix, CG on the Applied Biosystems™ 7500 Fast Dx Real-Time PCR instrument. The data demonstrate that the expected results are obtained for each organism when tested with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

Table 8. Specificity/Exclusivity of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

Virus	Strain	Source	2019-nCoV_N1	2019-nCoV_N2	Final Result
Human coronavirus	229E	Isolate	0/3	0/3	Neg.
Human coronavirus	OC43	Isolate	0/3	0/3	Neg.
Human coronavirus	NL63	clinical specimen	0/3	0/3	Neg.
Human coronavirus	HKU1	clinical specimen	0/3	0/3	Neg.
MERS-coronavirus		Isolate	0/3	0/3	Neg.
SARS-coronavirus		Isolate	0/3	0/3	Neg.
bocavirus	-	clinical specimen	0/3	0/3	Neg.
<i>Mycoplasma pneumoniae</i>		Isolate	0/3	0/3	Neg.
<i>Streptococcus</i>		Isolate	0/3	0/3	Neg.
Influenza A(H1N1)		Isolate	0/3	0/3	Neg.
Influenza A(H3N2)		Isolate	0/3	0/3	Neg.
Influenza B		Isolate	0/3	0/3	Neg.
Human adenovirus, type 1	Ad71	Isolate	0/3	0/3	Neg.
Human metapneumovirus	-	Isolate	0/3	0/3	Neg.
respiratory syncytial virus	Long A	Isolate	0/3	0/3	Neg.
rhinovirus		Isolate	0/3	0/3	Neg.
parainfluenza 1	C35	Isolate	0/3	0/3	Neg.
parainfluenza 2	Greer	Isolate	0/3	0/3	Neg.
parainfluenza 3	C-43	Isolate	0/3	0/3	Neg.
parainfluenza 4	M-25	Isolate	0/3	0/3	Neg.

Endogenous Interference Substances Studies:

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel uses conventional well-established nucleic acid extraction methods and based on our experience with CDC's other EUA assays, including the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay for the presumptive detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay for the presumptive detection of novel influenza A (H7N9) virus that are both intended for use with a number of respiratory specimens, we do not anticipate interference from common endogenous substances.

Specimen Stability and Fresh-frozen Testing:

To increase the likelihood of detecting infection, CDC recommends collection of lower respiratory and upper respiratory specimens for testing. If possible, additional specimen types (e.g., stool, urine) should be collected and should be stored initially until decision is made by CDC whether additional specimen sources should be tested. Specimens should be collected as soon as possible once a PUI is identified regardless of symptom onset. Maintain proper infection control when collecting specimens. Store specimens at 2-8°C and ship overnight to CDC on ice pack. Label each specimen container with the patient's ID number (e.g., medical record number), unique specimen ID (e.g., laboratory requisition number), specimen type (e.g., nasal swabs) and the date the sample was collected. Complete a CDC Form 50.34 for each specimen submitted.

Clinical Performance:

As of February 22, 2020, CDC has tested 2071 respiratory specimens from persons under investigation (PUI) in the U.S. using the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Specimen types include bronchial fluid/wash, buccal swab, nasal wash/aspirate, nasopharyngeal swab, nasopharyngeal/throat swab, oral swab, sputum, oropharyngeal (throat) swab, swab (unspecified), and throat swab.

Table 9: Summary of CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Data Generated by Testing Human Respiratory Specimens Collected from PUI Subjects in the U.S.

Specimen Type	2019 nCoV Negative	2019 nCoV Positive	Inconclusive	Invalid	Total
Bronchial fluid/wash	2	0	0	0	2
Buccal swab	5	1	0	0	6
Nasal wash/aspirate	6	0	0	0	6
Nasopharyngeal swab	927	23	0	0	950
Nasopharyngeal swab/throat swab	4	0	0	0	4
Oral swab	476	9	0	0	485
Pharyngeal (throat) swab	363	10	0	1	374
Sputum	165	5	0	0	170
Swab (unspecified)¹	71	1	0	0	72
Tissue (lung)	2	0	0	0	2
Total	2021	49	0	1	2071

¹Actual swab type information was missing from these upper respiratory tract specimens.

Two thousand twenty-one (2021) respiratory specimens of the 2071 respiratory specimens tested negative by the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Forty-nine (49) of the 2071 respiratory specimens tested positive by the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Only one specimen (oropharyngeal (throat) swab) was invalid. Of the 49 respiratory specimens that tested positive by the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, seventeen (17) were confirmed by genetic sequencing and/or virus culture (positive percent agreement = 17/17, 95% CI: 81.6%-100%)

During the early phase of the testing, a total of 117 respiratory specimens collected from 46 PUI subjects were also tested with two analytically validated real-time RT-PCR assays that target separate and independent regions of the nucleocapsid protein gene of the 2019-nCoV, N4 and N5 assays. The nucleocapsid protein gene targets for the N4 and N5 assays are different and independent from the nucleocapsid protein gene targets for the two RT-PCR assays included in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, N1 and N2. Any positive result from the N4 and/or the N5 assay was further investigated by genetic sequencing.

Performance of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel testing these 117 respiratory specimens was estimated against a composite comparator. A specimen was considered comparator negative if both the N4 and the N5 assays were negative. A specimen was considered comparator positive when the N4 and/or the N5 assay generated a positive result, and the comparator positive result(s) were further investigated and confirmed to be 2019-nCoV RNA positive by genetic sequencing.

Table 10: Percent Agreement of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel with the Composite Comparator

CDC 2019-nCoV Panel Result	Composite Comparator Result	
	Positive	Negative
Positive	13 ¹	0
Inconclusive	0	0
Negative	0	104

¹Composite comparator results were available for 13 of 49 CDC 2019-nCoV Panel positive specimens only.

Positive percent agreement = $13/13 = 100\%$ (95% CI: 77.2% - 100%)

Negative percent agreement = $104/104 = 100\%$ (95% CI: 96.4% - 100%)

Enzyme Master Mix Evaluation:

The limit of detection equivalence between the ThermoFisher TaqPath™ 1-Step RT-qPCR Master Mix and the following enzyme master mixes was evaluated: Quantabio qScript XLT One-Step RT-qPCR ToughMix, Quantabio UltraPlex 1-Step ToughMix (4X), and Promega GoTaq® Probe 1- Step RT-qPCR System. Serial dilutions of 2019 novel coronavirus (SARS CoV-2) transcript were tested in triplicate with the CDC 2019-nCoV Real-time RT-PCR Diagnostic Panel using all four enzyme master mixes. Both manufactured versions of oligonucleotide probe, BHQ and ZEN, were used in the comparison. The lowest detectable concentration of transcript at which all replicates tested positive using the Quantabio qScript XLT One-Step RT-qPCR ToughMix and Quantabio UltraPlex 1-Step ToughMix (4X) was similar to that observed for the ThermoFisher TaqPath™ 1-Step RT-qPCR Master Mix. The lowest detectable concentration of transcript when using the Promega GoTaq® Probe 1- Step RT-qPCR System was one dilution above that observed for the other candidates when evaluated with the BHQ version of the CDC assays. The candidate master mixes all performed equivalently or at one dilution below the ThermoFisher TaqPath™ 1-Step RT-qPCR Master Mix when evaluated with the ZEN version of the CDC assays.

Table 11: Limit of Detection Comparison for Enzyme Master Mixes – BHQ Probe Summary Results

Copy Number	ThermoFisher TaqPath™ 1-Step RT-qPCR Master Mix		Quantabio qScript XLT One-Step RT-qPCR ToughMix		Quantabio UltraPlex 1- Step ToughMix (4X)		Promega GoTaq® Probe 1- Step RT-qPCR System	
	2019- nCoV_N1	2019- nCoV_N2	2019- nCoV_N1	2019- nCoV_N2	2019- nCoV_N1	2019- nCoV_N2	2019- nCoV_N1	2019- nCoV_N2
10 ² copies/μL	3/3	3/3	3/3	3/3	3/3	3/3	3/3	3/3
10 ¹ copies/μL	3/3	3/3	3/3	3/3	3/3	3/3	3/3	3/3
10 ⁰ copies/μL	3/3	3/3	3/3	3/3	3/3	3/3	3/3	2/3
10 ⁻¹ copies μL	2/3	0/3	1/3	1/3	1/3	1/3	0/3	0/3

Table 12: Limit of Detection Comparison for Enzyme Master Mixes – ZEN Probe Summary Results

Copy Number	ThermoFisher TaqPath™ 1-Step RT-qPCR Master Mix		Quantabio qScript XLT One-Step RT-qPCR ToughMix		Quantabio UltraPlex 1- Step ToughMix (4X)		Promega GoTaq® Probe 1- Step RT-qPCR System	
	2019- nCoV_N1	2019- nCoV_N2	2019- nCoV_N1	2019- nCoV_N2	2019- nCoV_N1	2019- nCoV_N2	2019- nCoV_N1	2019- nCoV_N2
10 ² copies/μL	3/3	3/3	3/3	3/3	3/3	3/3	3/3	3/3
10 ¹ copies/μL	3/3	3/3	3/3	3/3	3/3	3/3	3/3	3/3
10 ⁰ copies/μL	3/3	2/3	3/3	3/3	3/3	2/3	3/3	3/3
10 ⁻¹ copies μL	1/3	1/3	0/3	0/3	0/3	1/3	1/3	1/3

Retrospective positive (18) and negative (17) clinical respiratory specimens were extracted using the QIAGEN EZ1 Advanced XL instrument and EZ1 DSP Virus Kit and were tested with the CDC 2019-nCoV Real-time RT-PCR Diagnostic Panel using the Quantabio qScript XLT One-Step RT-qPCR ToughMix, Quantabio UltraPlex 1-Step ToughMix (4X), and Promega GoTaq® Probe 1- Step RT-qPCR System master mixes. All three enzyme master mixes performed equivalently, demonstrating 100% positive and 100% negative agreement with expected results and a 95% confidence interval of 82.4%-100% and 81.6%-100%, respectively.

Table 13: Clinical Comparison – Retrospective Study Summary Results

CDC 2019-nCoV Real-time RT- PCR Diagnostic Panel Result	Quantabio qScript XLT One-Step RT-qPCR ToughMix		Quantabio UltraPlex 1-Step ToughMix (4X)		Promega GoTaq® Probe 1- Step RT-qPCR System	
	Positive	Negative	Positive	Negative	Positive	Negative
Positive	18	0	18	0	18	0
Negative	0	17	0	17	0	17

Roche MagNA Pure 24 and MagNA Pure 96 Extraction Platform Evaluation:

Performance of the 2019-CoV Real-time RT-PCR Diagnostic Panel using the Roche MagNA Pure 24 and MagNA Pure 96 extraction platforms was compared to performance with an authorized extraction method. Serial dilutions of quantified inactivated SARS-CoV-2 virus (USA-WA1/2020; 100 RNA copies/ μ L) in lysis buffer were added to pooled negative upper respiratory tract specimen matrix. Five samples of each dilution were extracted in parallel with the QIAGEN EZ1 Advanced XL (EZ1 DSP Virus Kit Cat# 62724) and the Roche MagNA Pure 24 (MagNA Pure 24 Total NA Isolation Kit Cat# 07658036001) and Roche MagNA Pure 96 (MagNA Pure 96 DNA and Viral Nucleic Acid Small Volume Kit Cat# 06543588001) extraction platforms and evaluated using the 2019-nCoV Real-Time RT-PCR Diagnostic Panel and ThermoFisher TaqPath™ 1-Step RT-qPCR Master Mix. The observed LoD was defined as the lowest concentration at which 100% (5 out of 5 total) of all replicates tested positive for both primer/probe sets (N1 and N2) in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. The acceptance criteria for equivalence were defined as demonstrating an observed LoD either at the same endpoint or within a 3-fold dilution. The results showed that both the MagNA Pure 24 and MagNA Pure 96 extraction platforms performed equivalently or within one 3-fold dilution of the LoD observed when using the QIAGEN EZ1 Advanced XL extraction platform.

Table 14. Limit of Detection Comparison between the QIAGEN EZ1 Advanced XL, Roche MagNA Pure 96, and Roche MagNA Pure 24 Extraction Platforms using the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

Platform	Parameter	2019-nCoV_N1 Assay			2019-nCoV_N2 Assay			Observed LoD ¹
		RNA copies/ μ L	# pos./total	Mean Ct ²	Std. Deviation	RNA copies/ μ L	# pos./total	
QIAGEN EZ1 Advanced XL	RNA copies/ μ L	10 ^{1.0}	10 ^{0.5}	10 ^{0.0}	10 ^{1.0}	10 ^{0.5}	10 ^{0.0}	10 ^{0.5}
	# pos./total	5/5	5/5	5/5	5/5	5/5	3/5	
	Mean Ct ²	34.0	35.0	36.3	33.9	36.6	NA	
	Std. Deviation	0.2	0.8	0.2	0.4	0.9	NA	
Roche MagNA Pure 96	RNA copies/ μ L	10 ^{1.0}	10 ^{0.5}	10 ^{0.0}	10 ^{1.0}	10 ^{0.5}	10 ^{0.0}	10 ^{0.5}
	# pos./total	5/5	5/5	5/5	5/5	5/5	2/5	
	Mean Ct ²	33.3	34.6	36.1	33.2	35.7	NA	
	Std. Deviation	0.5	0.5	0.3	0.3	0.4	NA	
Roche MagNA Pure 24	RNA copies/ μ L	10 ^{1.0}	10 ^{0.5}	10 ^{0.0}	10 ^{1.0}	10 ^{0.5}	10 ^{0.0}	10 ^{1.0}
	# pos./total	5/5	3/5	3/5	5/5	5/5	5/5	
	Mean Ct ²	34.4	NA	NA	35.2	36.9	36.2	
	Std. Deviation	0.6	NA	NA	0.5	1.0	0.8	

¹Concentration is presented in RNA copies/ μ L. The observed LoD is the lowest concentration where both assays showed 100% positive detection.

²Mean Ct reported for dilutions that show 100% positivity. Calculations only include positive results.

NA = not applicable

Previously characterized clinical remainder specimens (14 positive and 15 negative) were extracted using both the Roche MagNA Pure 96 and MagNA Pure 24 extraction platforms and evaluated using the 2019-nCoV Real-Time RT-PCR Diagnostic Panel and ThermoFisher TaqPath™ 1-Step RT-qPCR Master Mix. Acceptance criteria for clinical equivalence was defined as demonstrating 100% concurrence with qualitative results shown with the authorized comparator method (QIAGEN EZ1 Advanced XL). Results from this study showed 100% concurrence with the comparator method for both the Roche MagNA Pure

96 and Roche MagNA Pure 24 extraction platforms when used with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic panel.

Table 15. Clinical Comparison Results – Retrospective Study Results

Test Platform	Test Platform Result	QIAGEN EZ1 Advanced XL Result		Positive % Agreement (CI) ¹	Negative % Agreement (CI) ¹
		Positive	Negative		
Roche MagNA Pure 96	Positive	14	0	100.0 (78.5 – 100.0)	100.0 (79.6 – 100.0)
	Negative	0	15		
Roche MagNA Pure 24	Positive	14	0	100.0 (78.5 – 100.0)	100.0 (79.6 – 100.0)
	Negative	0	15		

¹ CI = 95% confidence interval

Promega Maxwell® RSC 48 Extraction Platform Evaluation:

Performance of the 2019-CoV Real-time RT-PCR Diagnostic Panel using the Promega Maxwell® RSC 48 extraction platform was compared to performance with an authorized extraction method. Serial dilutions of quantified inactivated SARS-CoV-2 virus (USA-WA1/2020; 100 RNA copies/μL) in VTM were added to pooled negative upper respiratory tract specimen matrix. Five samples of each dilution were extracted in parallel with the QIAGEN EZ1® Advanced XL (EZ1 DSP Virus Kit Cat# 62724) and the Promega Maxwell® RSC 48 (Promega Maxwell® Viral Total Nucleic Acid Purification Kit Cat# AS1330) extraction platforms and evaluated using the 2019-nCoV Real-Time RT-PCR Diagnostic Panel and ThermoFisher TaqPath™ 1-Step RT-qPCR Master Mix. The observed LoD was defined as the lowest concentration at which 100% (5 out of 5 total) of all replicates tested positive for both primer/probe sets (N1 and N2) in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. The acceptance criteria for equivalence were defined as demonstrating an observed LoD either at the same endpoint or within a 3-fold dilution. The results showed that the performance of the Maxwell® RSC 48 extraction platform performed equivalently or within one 3-fold dilution of the LoD observed when using the QIAGEN EZ1® Advanced XL extraction platform.

Table 16. Limit of Detection Comparison Between the QIAGEN EZ1® Advanced XL and Promega Maxwell® RSC 48 Extraction Platforms Using the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

Platform	Parameter	2019-nCoV_N1 Assay			2019-nCoV_N2 Assay			Observed LoD ¹
QIAGEN EZ1® Advanced XL	RNA copies/μL	10 ^{0.5}	10 ^{0.0}	10 ^{-0.5}	10 ^{0.5}	10 ^{0.0}	10 ^{-0.5}	10 ^{0.0}
	# pos./total	5/5	5/5	0/5	5/5	5/5	3/5	
	Mean Ct ²	32.27	33.80	NA	35.13	36.41	NA	
	Std. Deviation	0.81	0.40	NA	0.81	0.40	NA	
Promega Maxwell® RSC 48	RNA copies/μL	10 ^{0.5}	10 ^{0.0}	10 ^{-0.5}	10 ^{0.5}	10 ^{0.0}	10 ^{-0.5}	10 ^{0.0}
	# pos./total	5/5	5/5	3/5	5/5	5/5	5/5	
	Mean Ct ²	31.11	32.97	NA	31.89	33.95	35.17	
	Std. Deviation	0.24	0.34	NA	0.24	0.35	0.65	

¹Concentration is presented in RNA copies/μL. The observed LoD is the lowest concentration where both assays showed 100% positive detection.

²Mean cycle threshold (Ct) reported for dilutions that show 100% positivity. Calculations only include positive results. NA = not applicable

Previously characterized clinical remainder specimens (15 positive and 15 negative) were extracted using the Promega Maxwell® RSC 48 extraction platform alongside the currently authorized QIAGEN EZ1® Advanced XL extraction platform and evaluated using the 2019-nCoV Real-Time RT-PCR Diagnostic Panel and ThermoFisher TaqPath™ 1-Step RT-qPCR Master Mix. Results from the Maxwell® RSC 48 were compared with the QIAGEN EZ1® Advanced XL extraction performed in parallel showing 100% (15/15) qualitative concurrence on positive samples and 93.3% (14/15) qualitative concurrence on negative samples. This evaluation showed that two originally negative (QIAGEN QIAamp® DSP Viral RNA Mini Kit) specimens (Specimens 16 and 24) yielded an inconclusive result after extraction using the QIAGEN EZ1® Advanced XL. Repeat of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel resolved one of the two specimens (Specimen 24, negative result). The second specimen (Specimen 16) remained inconclusive. Both these specimens yielded a negative result on the Maxwell® RSC 48.

Table 17. Clinical Comparison Results – Retrospective Study Results

Test Platform	Result	Promega Maxwell® RSC 48			Positive % Agreement (CI) ¹	Negative % Agreement (CI) ¹
		Positive	Negative	Inconclusive		
QIAGEN EZ1® Advanced XL	Positive	15	0	0	100.0 (79.6-100.0)	93.3 (70.2-98.9)
	Negative	0	14	0		
	Inconclusive	0	1	0		

¹ CI = 95% confidence interval

Disposal

Dispose of hazardous or biologically contaminated materials according to the practices of your institution.

References

1. Ballew, H. C., *et al.* "Basic Laboratory Methods in Virology," DHHS, Public Health Service 1975 (Revised 1981), Centers for Disease Control and Prevention, Atlanta, Georgia 30333.
2. Clinical Laboratory Standards Institute (CLSI), "Collection, Transport, Preparation and Storage of Specimens for Molecular Methods: Proposed Guideline," MM13-A
3. Lieber, M., *et al.* "A Continuous Tumor Cell Line from a Human Lung Carcinoma with Properties of Type II Alveolar Epithelial Cells." *International Journal of Cancer* 1976, 17(1), 62-70.

Revision History

Revision #	Effective Date	Summary of Revisions
1	February 4, 2020	Original Instructions for Use
2	March 15, 2020	<ul style="list-style-type: none">• Intended use update• Removal of N3 primer and probe set from Diagnostic Panel• Performance data update• Addition of alternative nucleic acid extraction platforms• Addition of acceptable alternatives to HSC and addition of QIAGEN RUO extraction reagents• Positive results no longer presumptive. No confirmation of positive results required
3	March 30, 2020	<ul style="list-style-type: none">• Addition of alternative enzyme master mix options
4	June 12, 2020	<ul style="list-style-type: none">• Addition of MagNA Pure 24 extraction method• Addition of performance data for the MagNA Pure 96 extraction method with SARS-CoV-2• Addition of heat treatment alternative to specimen extraction• Addition of Roche and QIAGEN external lysis buffer alternatives• Acknowledgment of FDA policy permitting end users to qualify alternative components without seeking an EUA or EUA amendment
5	July 13, 2020	<ul style="list-style-type: none">• Addition of Promega Maxwell® RSC 48 extraction method• Update to <i>in silico</i> inclusivity analyses

Contact Information, Ordering, and Product Support

For technical and product support, contact the CDC Division of Viral Diseases directly.

Send email to: respvirus@cdc.gov

Note: If your laboratory is using reagents sourced from someone other than the CDC International Reagent Resource, please refer to the manufacturer's instructions provided with the commercial materials.

Appendix A: Heat Treatment Alternative to Extraction UltraPlex 1-Step ToughMix (4X)

This procedure is only for use by public health laboratories.

Purpose:

In response to a global shortage of nucleic acid extraction reagents causing significant delays in testing, the CDC has investigated the use of a heat treatment method requiring minimal reagents as a specimen processing alternative to nucleic acid extraction for use with the 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

Where possible, laboratories should use qualified RNA or total nucleic acid extraction methods for processing of specimens for subsequent testing by the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. Extraction removes inhibitory substances from specimens that could negatively impact PCR performance.

This procedure for use of heat treatment for specimen processing is only recommended when a shortage of qualified extraction reagents is a limiting factor in a laboratory's ability to meet urgent COVID-19 testing demand.

Precautions/Warnings/Limitations:

- CDC has evaluated this heat treatment process and has determined that this process is effective for inactivation of SARS-CoV-2 in patient specimens.
- Performance was evaluated with only upper respiratory specimens. Heat treatment of lower respiratory specimens for subsequent testing by the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has not been evaluated.
- This procedure for heat treatment of specimens is only for use with the Quantabio UltraPlex 1-Step ToughMix (4X).
- Heat treatment should only be conducted when a lab is ready to test the specimens by PCR. Testing of heat-treated specimens must be conducted the same day.

Acceptable Specimens:

- Upper respiratory specimens
Note: Do not use heat treatment to process specimens that appear bloody or that contain particulate matter. Such specimens should be extracted using a qualified RNA or TNA extraction method prior to testing.

Materials Required (not provided):

- 70% ethanol
- 10% bleach, freshly prepared
- 96-well PCR reaction plates (Applied Biosystems catalog # 4346906, 4366932, 4346907, or equivalent)
- Optical strip caps (Applied Biosystems 4323032, or equivalent)
- 1.5 mL Sarstedt tubes or equivalent

- Aerosol resistant micropipette tips
- Micropipettes
- 96-well cold block
- Cold blocks for 1.5 mL - 2.0 mL tubes
- Vortex mixer
- 96-well plate centrifuge or equivalent
- Thermal cycler or equivalent
- Class II Biological Safety Cabinet (BSC)

Procedure:

Sample Preparation

- 1) Decontaminate BSC with 10% bleach followed by 70% ethanol.
- 2) If samples are frozen, thaw on ice or at 4°C. Wipe the outside of the sample tube with 70% ethanol. Place thawed sample on cold rack or ice in BSC.
- 3) Pulse vortex each sample and briefly spin down in a centrifuge to collect the liquid at the bottom of the tube.

Heat Treatment

- 1) Place a thermal cycler in the BSC, turn on, and program for 95°C for 1 min followed by 4°C hold.
- 2) Place a 96-well PCR plate onto a cold rack or ice in the BSC.
- 3) Transfer 100 µL of each sample to the 96-well PCR plate and securely cap each well using optical strip caps.
NOTE: Ensure that an HSC extraction control is included in each batch run as required under CLIA.
- 4) Place this 96-well PCR plate on the pre-heated thermal cycler and start run. Leave plate on thermal cycler at 4°C, or place on ice or a cold block.
- 5) Remove plate and centrifuge for 1 minute at 500 x g to pellet cellular debris.
- 6) Place plate on a cold rack or ice and proceed to testing the supernatant by rRT-PCR.
- 7) Testing of heat-treated specimens must be conducted the same day heat treatment is performed. For long term storage, keep the original specimen at ≤-70°C.

Special Testing Considerations for Heat Treated Specimens:

- **Enzyme Master Mix**

Testing of specimens that have been processed with heat treatment should be conducted with the **Quantabio UltraPlex 1-Step ToughMix (4X)**, which demonstrated the best performance with heat treated specimens. PCR testing of heat-treated specimens should follow the instructions in the main body of this Instructions for Use document.

- **Resolution of Inconclusive and Invalid Results**

Retesting of heat-treated specimens that generated an inconclusive or invalid result must include extraction of the original specimen with a qualified RNA or total nucleic acid (TNA) extraction method, if available. Do not re-test the heat-treated specimen material to resolve inconclusive or invalid test results.

Verification:

CDC recommends performance of verification studies for the heat treatment method prior to diagnostic use that includes side-by-side preparation of a panel of positive and negative clinical specimens using a qualified extraction method and this heat treatment method with subsequent testing by the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

Performance Characteristics:

Quantabio UltraPlex 1-Step ToughMix (4X)

Limit of Detection Comparison

Serial dilutions of inactivated SARS-CoV-2 [SARS-CoV-2 USA-WA1/2020] were prepared in simulated specimen material (human A549 cells suspended in viral transport medium). Each concentration was prepared side-by-side five times by both EZ1 extraction and by heat treatment. Each extracted or heat-treated sample was subsequently tested by the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel using the Quantabio UltraPlex 1-Step ToughMix (4X) on the Applied Biosystems 7500 Fast Dx instrument. Observed detection was similar between the two specimen preparation methods.

Table B1: UltraPlex Limit of Detection Comparison between QIAGEN EZ1 Advanced XL extraction and heat treatment (95°C for 1 min) method – Summary Results

Enzyme	Platform	Parameter	2019-nCoV_N1 Assay					2019-nCoV_N2 Assay					Observed LoD ¹
Quantabio UltraPlex 1-Step ToughMix (4X) 5 µL Template Addition	QIAGEN EZ1 Advanced XL	RNA copies/µL	10 ^{1.0}	10 ^{0.5}	10 ^{0.0}	10 ^{-0.5}	10 ^{-1.0}	10 ^{1.0}	10 ^{0.5}	10 ^{0.0}	10 ^{-0.5}	10 ^{-1.0}	10 ^{0.5}
		# pos./total	5/5	5/5	4/5	4/5	3/5	5/5	5/5	5/5	2/5	2/5	
		Mean Ct ²	34.11	34.59	NA	NA	NA	32.97	33.76	34.70	NA	NA	
		Std. Deviation	0.75	0.99	NA	NA	NA	0.33	0.72	0.98	NA	NA	
	Heat Treatment 95°C for 1 min	RNA copies/µL	10 ^{1.0}	10 ^{0.5}	10 ^{0.0}	10 ^{-0.5}	10 ^{-1.0}	10 ^{1.0}	10 ^{0.5}	10 ^{0.0}	10 ^{-0.5}	10 ^{-1.0}	10 ^{0.5}
		# pos./total	5/5	5/5	4/5	5/5	1/5	5/5	5/5	4/5	2/5	1/5	
		Mean Ct ²	33.41	34.32	NA	36.73	NA	33.45	35.25	NA	NA	NA	
		Std. Deviation	0.62	0.40	NA	0.82	NA	0.40	0.80	NA	NA	NA	

¹Concentration is presented in RNA copies/µL. The observed LoD is the lowest concentration where both assays showed 100% positive detection.

²Mean Ct reported for dilutions that show 100% positivity. Calculations only include positive results.

NA = not applicable

Clinical Comparison

A panel of 39 upper respiratory specimens were tested side-by-side using extraction with the Qiagen EZ1 extraction instrument and heat treatment. Extracted and heat-treated specimens were subsequently tested with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel using the Quantabio UltraPlex 1-Step ToughMix (4X). Qualitative results were compared to demonstrate agreement.

Table B2: Clinical Comparison Results Summary – Heat Treatment versus QIAGEN EZ1 Advanced XL

	Test Result	Heat Treatment			Total	Positive % Agreement (CI) ¹	Negative % Agreement (CI) ¹
		Positive	Inconclusive	Negative			
QIAGEN EZ1 Advanced XL	Positive	18	1	0	19	94.7 (75.4-99.1)	100 (83.9-100)
	Inconclusive	0	0	0	0		
	Negative	0	0	20	20		
	Total	18	1	20	39		

¹ CI = 95% confidence interval

Questions and Comments:

If you have questions or comments about this procedure, please send by email to: respvirus@cdc.gov

CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel – Verification Requirements

Please consult the following guidance from the Centers for Medicare & Medicaid Services (CMS) regarding diagnostic tests under Emergency Use Authorization (EUA):

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/QSO18-19-CLIA>

INTENDED USE

The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals who meet 2019-nCoV clinical and/or epidemiological criteria (for example, clinical signs and symptoms associated with 2019-nCoV infection, contact with a probable or confirmed 2019-nCoV case, history of travel to a geographic locations where 2019-nCoV cases were detected, or other epidemiologic links for which 2019-nCoV testing may be indicated as part of a public health investigation). Testing in the United States is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

Results are for the identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in upper and lower respiratory specimens during infection. Positive results are indicative of active infection with 2019-nCoV but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is intended for use by trained laboratory personnel who are proficient in performing real-time RT-PCR assays. The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is only for use under a Food and Drug Administration's Emergency Use Authorization.

REQUIRED MATERIALS

The 2019 novel coronavirus positive control (nCoVPC) is provided with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel and should be prepared according to the Instructions for Use. The nCoVPC consists of an RNA transcript of the 2019-nCoV N gene as well as human RNase P gene segment. nCoVPC will yield a positive result with the following primer and probe sets: 2019-nCoV_N1, 2019-nCoV_N2, and RP.

Approximately 2 mL of an upper respiratory specimen (e.g. nasopharyngeal swab (NPS) in transport media) are needed for testing. Specimens may be pooled if less than 2 mL of one specimen is available.

Refer to CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel package insert (manufacturer instructions) for additional reagents, materials, and instructions.

PRECAUTIONS

This reagent should be handled in an approved biosafety level 2 (BSL-2) handling area to avoid contamination of laboratory equipment and reagents that could cause false positive

results. This product is an RNA transcript and is non-infectious. However, the nCoVPC should be handled in accordance with Good Laboratory Practices.

Store reagent at appropriate temperatures (see Instructions for Use) and hold on ice when thawed.

Please use standard precautions when handling respiratory specimens.

INSTRUCTIONS FOR PREPARING SAMPLES BEFORE EXTRACTION WITH THE QIAamp® DSP VIRAL RNA MINI KIT OR THE QIAamp® VIRAL RNA MINI KIT

- Refer to the 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use for reconstitution of the materials for use. RNA should be kept cold during preparation and use.
- Make a 1/10 dilution of nCoVPC by adding 5 µL of nCoVPC into 45 µL of nuclease-free water or 10 mM Tris.
- Aliquot 560 µL of lysis buffer into each of nine tubes labeled 1-9.
- Add 140 µL of upper respiratory specimen (e.g. NPS in viral transport media) into each of the nine labeled tubes with lysis buffer.
- To prepare samples at a moderate concentration, spike 14 µL of undiluted nCoVPC (rehydrated as described in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use) into each tube labeled 1-3 containing lysis buffer and specimen.
- To prepare samples at a low concentration, spike 14 µL of 1/10 dilution of nCoVPC into each tube labeled 4-6 containing lysis buffer and specimen.
- To prepare negative samples, spike 14 µL of nuclease-free water into each tube labeled 7-9 containing lysis buffer and specimen.
- Perform extractions of all nine samples according to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use.

INSTRUCTIONS FOR PREPARING SAMPLES BEFORE EXTRACTION WITH THE QIAGEN EZ1® ADVANCED XL

- Refer to the 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use for reconstitution of the materials for use. RNA should be kept cold during preparation and use.
- Make a 1/10 dilution of nCoVPC by adding 5 µL of nCoVPC into 45 µL of nuclease-free water or 10 mM Tris.
- Aliquot 280 µL of lysis buffer into each of nine tubes labeled 1-9.
- Add 120 µL of upper respiratory specimen (e.g. NPS in viral transport media) into each of the nine labeled tubes with lysis buffer.
- To prepare samples at a moderate concentration, spike 12 µL of undiluted nCoVPC (rehydrated as described in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use) into each tube labeled 1-3 containing lysis buffer and specimen.
- To prepare samples at a low concentration, spike 12 µL of 1/10 dilution of nCoVPC into each tube labeled 4-6 containing lysis buffer and specimen.
- To prepare negative samples, spike 12 µL of nuclease-free water into each tube labeled 7-9 containing lysis buffer and specimen.
- Perform extractions of all nine samples according to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use.

INSTRUCTIONS FOR PREPARING SAMPLES BEFORE EXTRACTION WITH THE ROCHE MagNA PURE TOTAL NUCLEIC ACID KIT OR THE ROCHE MagNA PURE NUCLEIC ACID ISOLATION KIT I

- Refer to the 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use for reconstitution of the materials for use. RNA should be kept cold during preparation and use.
- Make a 1/10 dilution of nCoVPC by adding 5 µL of nCoVPC into 45 µL of nuclease-free water or 10 mM Tris.
- Aliquot 300 µL of lysis buffer into each of nine tubes labeled 1-9.
- Add 100 µL of upper respiratory specimen (e.g. NPS in viral transport media) into each of the nine labeled tubes with lysis buffer.

- To prepare samples at a moderate concentration, spike 12 µL of undiluted nCoVPC (rehydrated as described in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use) into each tube labeled 1-3 containing lysis buffer and specimen.
- To prepare samples at a low concentration, spike 12 µL of 1/10 dilution of nCoVPC into each tube labeled 4-6 containing lysis buffer and specimen.
- To prepare negative samples, spike 12 µL of nuclease-free water into each tube labeled 7-9 containing lysis buffer and specimen.
- Perform extractions of all nine samples according to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use.

INSTRUCTIONS FOR PREPARING SAMPLES BEFORE EXTRACTION WITH THE ROCHE MagNA PURE 24 AND TOTAL NUCLEIC ACID ISOLATION KIT

- Refer to the 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use for reconstitution of the materials for use. RNA should be kept cold during preparation and use.
- Make a 1/10 dilution of nCoVPC by adding 5 µL of nCoVPC into 45 µL of nuclease-free water or 10 mM Tris.
- Aliquot 400 µL of lysis buffer into each of nine tubes labeled 1-9.
- Add 100 µL of upper respiratory specimen (e.g. NPS in viral transport media) into each of the nine labeled tubes with lysis buffer.
- To prepare samples at a moderate concentration, spike 12 µL of undiluted nCoVPC (rehydrated as described in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use) into each tube labeled 1-3 containing lysis buffer and specimen.
- To prepare samples at a low concentration, spike 12 µL of 1/10 dilution of nCoVPC into each tube labeled 4-6 containing lysis buffer and specimen.
- To prepare negative samples, spike 12 µL of nuclease-free water into each tube labeled 7-9 containing lysis buffer and specimen.
- Perform extractions of all nine samples according to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use.

INSTRUCTIONS FOR PREPARING SAMPLES BEFORE EXTRACTION WITH THE ROCHE MagNA PURE 96 DNA AND VIRAL NA SMALL VOLUME KIT

- Refer to the 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use for reconstitution of the materials for use. RNA should be kept cold during preparation and use.
- Make a 1/10 dilution of nCoVPC by adding 5 µL of nCoVPC into 45 µL of nuclease-free water or 10 mM Tris.
- Aliquot 350 µL of lysis buffer into each of nine tubes labeled 1-9.
- Add 100 µL of upper respiratory specimen (e.g. NPS in viral transport media) into each of the nine labeled tubes with lysis buffer.
- To prepare samples at a moderate concentration, spike 12 µL of undiluted nCoVPC (rehydrated as described in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use) into each tube labeled 1-3 containing lysis buffer and specimen.
- To prepare samples at a low concentration, spike 12 µL of 1/10 dilution of nCoVPC into each tube labeled 4-6 containing lysis buffer and specimen.
- To prepare negative samples, spike 12 µL of nuclease-free water into each tube labeled 7-9 containing lysis buffer and specimen.
- Perform extractions of all nine samples according to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use.

INSTRUCTIONS FOR PREPARING SAMPLES BEFORE EXTRACTION WITH THE PROMEGA MAXWELL® RSC 48

- Refer to the 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use for reconstitution of the materials for use. RNA should be kept cold during preparation and use.
- Make a 1/10 dilution of nCoVPC by adding 5 µL of nCoVPC into 45 µL of nuclease-free water or 10 mM Tris.
- Aliquot 330 µL of lysis buffer (300 µL of lysis buffer + 30 µL Proteinase K, included in the kit) into each of nine tubes labeled 1-9.

- Add 120 µL of upper respiratory specimen (e.g. NPS in viral transport media) into each of the nine labeled tubes with lysis buffer.
- To prepare samples at a moderate concentration, spike 12 µL of undiluted nCoVPC (rehydrated as described in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use) into each tube labeled 1-3 containing lysis buffer and specimen.
- To prepare samples at a low concentration, spike 12 µL of 1/10 dilution of nCoVPC into each tube labeled 4-6 containing lysis buffer and specimen.
- To prepare negative samples, spike 12 µL of nuclease-free water into each tube labeled 7-9 containing lysis buffer and specimen.
- Perform extractions of all nine samples according to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use.

INSTRUCTIONS FOR PREPARING SAMPLES BEFORE EXTRACTION WITH THE BIOMÉRIEUX NucliSENS easyMAG OR THE BIOMÉRIEUX EMAG

- Refer to the 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use for reconstitution of the materials for use. RNA should be kept cold during preparation and use.
- Make a 1/10 dilution of nCoVPC by adding 5 µL of nCoVPC into 45 µL of nuclease-free water or 10 mM Tris.
- Aliquot 1000 µL or 2000 µL of pre-aliquoted easyMAG lysis buffer into each of nine tubes labeled 1-9 for the easyMAG or eMAG, respectively.
- Add 100 µL of upper respiratory specimen (e.g. NPS in viral transport media) into each of the nine labeled tubes with lysis buffer.
- To prepare samples at a moderate concentration, spike 12 µL of undiluted nCoVPC (rehydrated as described in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use) into each tube labeled 1-3 containing lysis buffer and specimen.
- To prepare samples at a low concentration, spike 12 µL of 1/10 dilution of nCoVPC into each tube labeled 4-6 containing lysis buffer and specimen.
- To prepare negative samples, spike 12 µL of nuclease-free water into each tube labeled 7-9 containing lysis buffer and specimen.
- Perform extractions of all nine samples according to the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use.

PROCEDURE

Follow the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use for testing the nine extracted samples at least once.

EXPECTED RESULTS

Moderate nCoVPC samples should be positive for 2019-nCoV.

Low nCoVPC samples should be positive for 2019-nCoV.

Negative upper respiratory samples should be negative for 2019-nCoV.

≥90% of test results should be in agreement with the expected results. If test results are <90% in agreement with expected results, contact CDC at respvirus@cdc.gov.

QUESTIONS

Please send questions or comments by email to respvirus@cdc.gov.

DISTRIBUTION

Distributed to qualified laboratories by Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, GA, 30329 USA

Attachment D

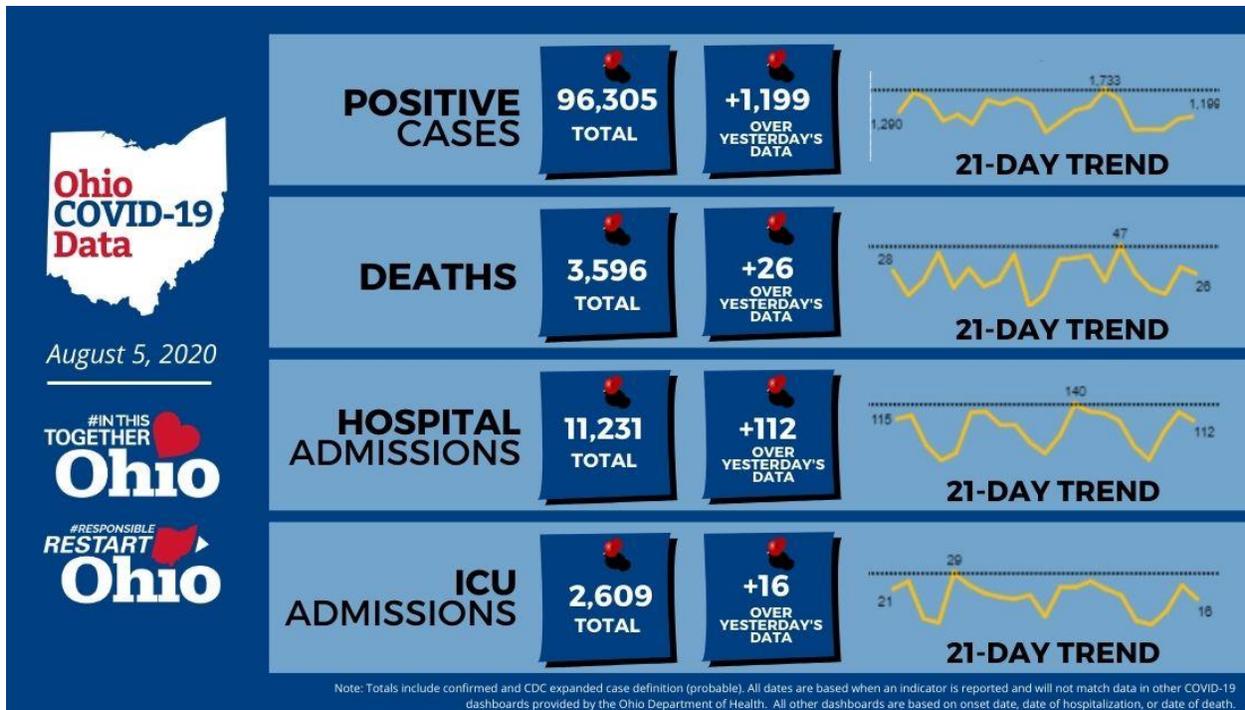
Governor Mike DeWine Tweet

@GovMikeDeWine

#Ohio's #COVID19 data for August 5, 2020.

More in-depth data can be found at <http://coronavirus.ohio.gov>

2:02 PM · Aug 5, 2020



#InThisTogetherOhio

#StaySafeOhio

#MasksOnOhio

Governor Mike DeWine Tweet

@GovMikeDeWine

#Ohio's #COVID19 data for August 11, 2020.

Aug 11, 2020

COVID-19 | Percentage of Cases by Age Group

Age Groups	March	April	May	June	July	August*
0-19	2.4%	3.1%	7.3%	11.2%	11.8%	12.8%
20-29	12.2%	12.7%	16.5%	24.9%	24.5%	19.4%
30-39	13.9%	16.4%	16.9%	18.2%	16.2%	15.2%
40-49	15.7%	16.5%	15.1%	13.7%	13.6%	14.5%
50-59	20.6%	16.7%	14.8%	12.8%	14.1%	14.5%
60-69	18.2%	13.4%	11.2%	8.9%	10.0%	10.5%
70-79	10.4%	9.3%	7.6%	5.6%	5.7%	7.1%
80+	6.6%	11.9%	10.4%	4.7%	4.1%	6.0%

*August data is preliminary through 08-10-2020

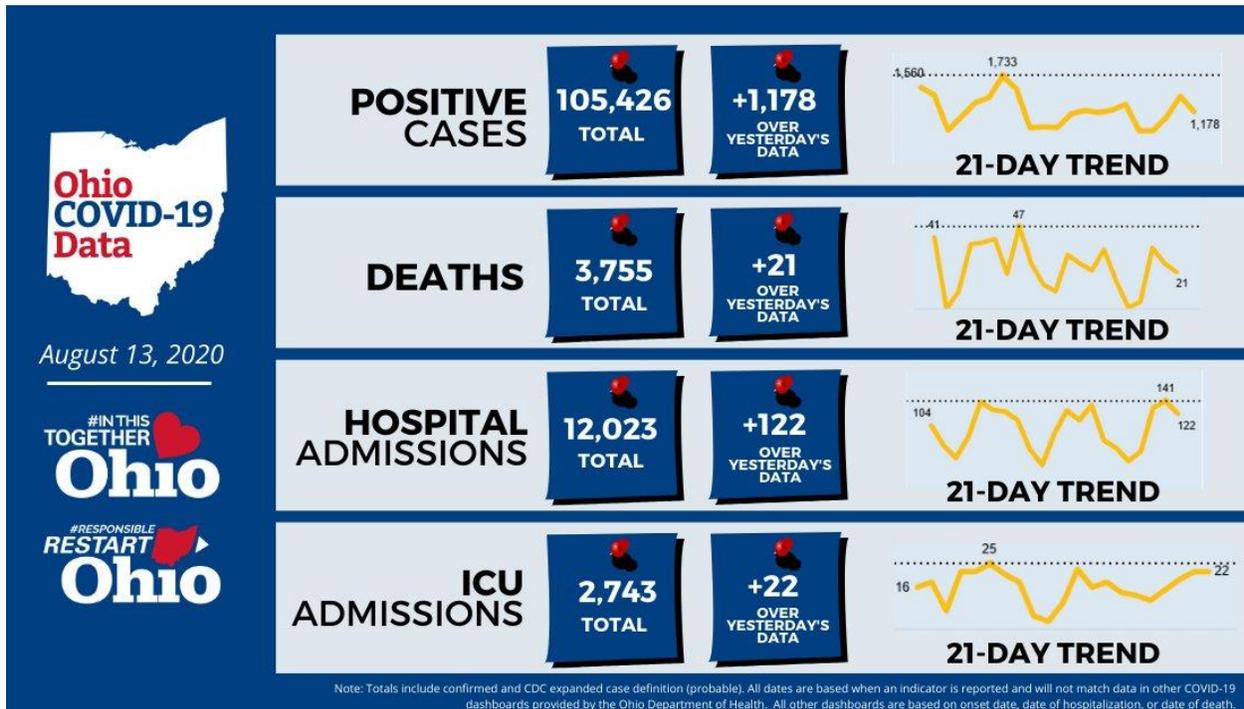


Governor Mike DeWine Tweet

@GovMikeDeWine

#Ohio's #COVID19 data for August 13, 2020.

Aug 13, 2020



Attachment E

	Date Requested	To Whom	Description	Date received?	
#1	26-Apr		Acton's resume, letter of interest, & letter of qualification for her current position as director of ODH.		
#2	26-Apr	ODH	Emails to or from Acton re: covid 3/9 - 3/15/20	no	
#3	26-Apr	ODH	Emails re: masks to or from Acton or Dewine 4/1-4/26	no	
#4	28-Apr	ODH	Emails to or from Acton re: school activities & closures from 1/1/-4/28	no	
#5	Apr-20	ODH	Data from 4/15-4/23 data used to determine & compile the daily reports & data (total tested, number of positive cases, deaths, hospitalizations, ICU, healthcare workers) provided on the ODH website as well as by Acton & DeWine at daily press conferences	no	
#6	2-May	ODH	Documents (such as death certificates) used to determine all covid-19 deaths that are indicated by ODH on their website.	denied on 8/21	Note: waiting 3.5 months for their reply gave me no opportunity to ask questions & revise my request. I continued to request additional records for several months.
#7	11-May	ODH	Resume, job description & records of education (college, continuing education, professional credits, certification) for the State of Ohio's epidemiologist Sietske de Fijter.	yes 5/19	Note: why have none of us ever heard of the ODH state epidemiologist? Why has she never been mentioned or appeared at a press conference?
#8	13-May	ODH	Copies of all emails sent to or from Amy Acton from 3/1/20 to 5/13 regarding lab testing & results of samples for coronavirus/covid-19 that had previously resulted in a negative or positive result for the flu.	no	
#9	13-May	ODH	Documentation from 3/1- 5/13 re: All emails & sent to or from Amy Acton, and other documentation in the possession of ODH, re: Antibody tests/testing that resulted in cases being added to the ODH's daily verbal & online public reports of cases, deaths and/or hospitalization for coronavirus/covid-1.	no	
#10	19-May	ODH	Request for copies of the job description & records of education (college/university, continuing education, professional credits, certification) for Amy Acton. These records would typically be kept in employment/personnel/human resources files.	yes 6/13	Only CV. Although Acton & DeWine claimed 30 years of public health experience, CV shows very little experience in public health or working fulltime. No evidence of education or certifications claimed on her CV.
#11	26-Jun	ODH	Copies of the following information indicated on the copy of Amy Acton's curriculum vitae that recently provided:	yes 8/20	No responsive records except item #17. So no verification of anything claimed by Acton prior to hiring.
			1) ODH's verification of Acton's employment, position & employment dates for The Columbus Foundation, Community research and grants management officer (2017-2018)	no records responsive.	

			2) ODH's verification of Acton's employment, position & employment dates for OSU College of Public Health, Adjunct professor (2011-2017)	no records responsive.	
			3) ODH's verification of Acton's employment, position, & employment dates for Center for Injury Research & Policy, the Research Institute at Nationwide Children's Hospital, Visiting faculty professor (2011-2013)	no records responsive.	
			4) ODH's verification of Acton's employment, position & employment dates for OSU College of Public Health, Adjunct professor (1997-2003)	no records responsive.	
			5) ODH's verification of Acton's employment, position & employment dates, Love our kids, vaccinate early, Director (1998-2000)	no records responsive.	
			6) ODH's verification of Acton's consultancy/position, employment & employment dates, Bexley City Schools. Consultant, preventive medicine (2003-2012)	no records responsive.	
			7) ODH's verification of Acton's consultancy & dates, 1996 Healthy Summit 2000, Akron City Health Dept. Consultant	no records responsive.	
			8) ODH's verification of Acton's employment, position & employment dates, ODH Division of family & community health (1995-1996)	no records responsive.	
			9) ODH's verification of Acton's residency in preventive medicine, OSU (1996)	no records responsive.	
			10) ODH's verification of Acton's Internship/residency training pediatrics, Albert Einstein College of Medicine NYC (1996)	no records responsive.	
			11) ODH's verification of Acton's Internship/residency training pediatrics, Children's Hospital/OSU Columbus (1996)	no records responsive.	
			12) Copy of diploma or transcript for Acton's masters in public health, OSU (1996)	no records responsive.	
			13) Copy of diploma or transcript for	no records responsive.	
			1990 medical school: Northeastern Ohio University College of Medicine, accelerated 6-year program (1990)	no records responsive.	
			14) Copies of Acton's personal references & verification of such.	no records responsive.	

			15) Verification of volunteer experience indicated on Acton's CV, including but not limited to Volunteer @ Children's International Summer Villages (2006-2012)	no records responsive.	
			16) Verification of the "over 30 years of experience in teaching & data analysis, academic & nonprofit administration, government & community service, medical practice, consulting, and healthcare policy & advocacy" as indicated on Acton's CV.	no records responsive.	
			17) Copy of the Director of ODH job description dated 2019 (the predecessor to the May 2020 version you provided in response to my last request).	Yes but was from 2017.	
#12	1-Jul	ODH	Request for copies of the death certificates that ODH used to determine all covid-19 deaths that are indicated by ODH on their covid-19 website from 5/3/20 to the present. Follow-up for 5/2/20 public records request for the same records up to that point as well as for the other 9 pending requests I've sent over the past 2 months but have not received a reply to.	Denied - 8/21	
#13	13-Jul		Request for copies of the death certificates that ODH used to determine all covid-19 deaths that are indicated & reported by ODH on their covid-19 website, at press conferences to the public, & to the media, from 7/1/20 to to 7/13. Follow-up to 5/2/20 & 7/1/20 public records requests for the same records up to that point, & 9 other pending requests over past 3 months.	Denied - 8/21	
#14	21-Aug	ODH	#14 ODH Public Records Request - Procedures involved to obtain covid counts each day for reporting on the ODH website, procedures involved in reconciling determination of death as reported to ODRS with the individual's death certificate, & procedures for updating covid-19 data death data on ODH public website after reconciliation	Pending	
#A	Mar-20	Governor	Request for Acton's resume via online system. No answer to phone calls. No way to leave a message. No Response	No response.	
#B	Apr-20	Governor	Request for emails from 3/9-3/15 mentioning covid keywords	No response.	
#1	30-Apr	Governor	Followup request for Acton's resume, letter of interest, qualifications	7/28 received response to items 1-4.	Appears to be incomplete. Very few records.

#2	30-Apr	Governor	Request for emails mentioning words such as mask, face covering etc.	7/28 received response to items 1-4, appears to be incomplete. Very few records.	Appears to be incomplete. Very few records.
#3	30-Apr	Governor	Request for emails from 3/1-4/30 re: businesses requiring face masks	7/28 received response to items 1-4	Appears to be incomplete. Very few records.
#4	30-Apr	Governor	Request for DeWine emails from 1/2-4/30 regarding school & activity restrictions due to covid-19	7/28 received response to items 1-4.	Appears to be incomplete. Very few records.
	28-Jul	Governor	Emails from #1-#4 received but had redacted email addresses, including DeWine's. He uses a personal email address on a regular basis. Requested them unredacted, cited 2014 OAG DeWine opinion	No response.	

Attachment F

Impacts of COVID-19 Mitigation Efforts/Activities

Kristina Kristen, in a guest editorial for Children’s Health Defense commented that, “Government officials’ interventions for COVID-19 have been strategically one-sided and myopic. Many leaders, in response to the perceived virus threat, completely abandoned rational considerations to lower overall suffering and death. In a blind focus intended to “stop the virus,” officials recklessly locked down billions of people globally with little to no debate, while ignoring the cost factor, an indispensable half of a “cost-benefit” analysis in calculating any solution.

The cost-benefit analysis, the most basic tenet of any decision making process, especially those having to do with life, death and health, must contain two critical data points: whether the intervention will work and whether the cost of it working will create more harm, in which case other alternatives must be considered, including: doing nothing. If a so-called solution “works” but in doing so creates massive, disproportionate collateral damage and increases overall harm, then clearly it cannot be called a solution, and certainly should never be mandated onto a population.” – *Children’s Health Defense*, August 20, 2020, https://childrenshealthdefense.org/news/covid-response-is-all-cost-no-benefit/?utm_source=salsa&eType=EmailBlastContent&eId=c4b8e232-2fa3-4416-a49b-c368044c395d

Additionally, Dr. Katz, president of True Health Initiative and the founding director of the Yale-Griffin Prevention Research Center, stated, “I am deeply concerned that the social, economic and public health consequences of this near total meltdown of normal life — schools and businesses closed, gatherings banned — will be long lasting and calamitous, possibly graver than the direct toll of the virus itself. The stock market will bounce back in time, but many businesses never will. The unemployment, impoverishment and despair likely to result will be public health scourges of the first order.” - *The New York Times*, March 20, 2020, <https://www.nytimes.com/2020/03/20/opinion/coronavirus-pandemic-social-distancing.html>

Impact on Hospitals & Patient Care

- April 9, 2020, *Small-Town Hospitals Are Closing Just As Coronavirus Arrives In Rural America*, <https://www.npr.org/2020/04/09/829753752/small-town-hospitals-are-closing-just-as-coronavirus-arrives-in-rural-america>,

"The loss of revenue over the last few weeks due to the inability to provide non-emergency care is destabilizing core health services in rural America," the NRHA said.

- April 23, 2020, *University Hospitals to temporarily close several ERs in Northeast Ohio*, <https://www.msn.com/en-us/news/us/university-hospitals-to-temporarily-close-several-ers-in-northeast-ohio/ar-BB134Str>,

“The COVID-19 pandemic is requiring University Hospitals to carefully evaluate and align systemwide programs and services to meet evolving patient care needs,” the release says. “An unforeseen consequence of the pandemic has been a sharp decline in the number of patients visiting UH emergency departments systemwide.”

UH says patient visits are down 50% at hospital-based emergency departments and more than 70% at freestanding ERs.

- April 7, 2020, *Major reductions in the number of patients undergoing critical artery-clearing procedures,*

<https://www.onlinejacc.org/content/accj/early/2020/04/07/j.jacc.2020.04.011.full.pdf>,

Our preliminary analysis during the early phase of the COVID pandemic shows an estimated 38% reduction in US cardiac catheterization laboratory STEMI activations, similar to the 40% reduction noticed in Spain (4). A priori, given potential heightened environmental and psychosocial stressors, and a higher case of STEMI induced by viral illness (e.g. similar to influenza) (5) or mimickers such as COVID-19 myopericarditis an increase in STEMI activations would have been expected. Potential etiologies for the decrease in STEMI PPCI activations include avoidance of medical care due to social distancing or concerns of contracting COVID-19 in the hospital, STEMI misdiagnosis, and increased use of pharmacological reperfusion due to COVID-19.

- April 22, 2020, *'Where are the strokes and the heart attacks?' Doctors worry as patients avoid ERs,* <https://www.latimes.com/california/story/2020-04-22/coronavirus-emergency-rooms-numbers-decline>,

Before the coronavirus hit, tens of thousands of people across the state sought emergency help each day. But in the weeks since the virus began its spread throughout the U.S., those numbers have plummeted by a third to a half, according to physicians overseeing emergency departments in hospitals across Los Angeles County and elsewhere in California.

Physicians and health officials are amending their urgent warnings about the virus to stress that emergency departments are not overrun and can treat people safely. The full effect of what Stock dubbed "corona collateral damage syndrome," and what another emergency physician called "a virus of fear," has not yet been tallied as hospitals and state agencies begin to gather comprehensive figures.

- May 4, 2020, *Organ Transplants Plummet During COVID-19 Pandemic,*

<https://www.usnews.com/news/healthiest-communities/articles/2020-05-11/organ-transplants-plummet-during-coronavirus-pandemic>,

"We noted a strong temporal association between the increase in COVID-19 infections and a striking reduction in overall solid-organ transplantation procedures," researchers wrote. "The effect was seen in France and confirmed in the USA."

In the U.S. specifically, the number of such organs recovered from a deceased donor for a transplant dropped from around 110 a day on March 6 to closer to 60 by early April, the study shows. During that same period, kidney transplants from deceased donors fell from around 65 a day to about 35 per day.

- May 4, 2020, *Non-Emergency Procedure Volumes in the Wake of COVID-19,*

<https://ehrn.org/non-emergency-procedure-volumes-in-the-wake-of-covid-19/>,

When compared to 2018-2019 averages, our analysis found a dramatic—but temporary—decrease in procedures for cardiac arrhythmia and coronary artery disease, as well as procedures for all of the major organ cancers we examined. At their lowest point, these procedure volumes were 49-88% below their historical weekly averages.

- May 22, 2020, *600 Physicians Say Lockdowns Are A 'Mass Casualty Incident'*,
<https://www.forbes.com/sites/gracemarieturner/2020/05/22/600-physicians-say-lockdowns-are-a-mass-casualty-incident/#33715bc350fa>,

“The downstream health effects...are being massively under-estimated and under-reported. This is an order of magnitude error,” according to the letter initiated by Simone Gold, M.D., an emergency medicine specialist in Los Angeles.

“Suicide hotline phone calls have increased 600%,” the letter said. Other silent casualties: “150,000 Americans per month who would have had new cancer detected through routine screening.”

From missed cancer diagnoses to untreated heart attacks and strokes to increased risks of suicides, “We are alarmed at what appears to be a lack of consideration for the future health of our patients.”

- July 31, 2020, *Local hospitals experiencing surge of non-COVID patients, deaths*,
<https://www.kget.com/news/local-news/local-hospitals-experiencing-surge-of-non-covid-patients-and-deaths/>,

Sharlet Briggs, CEO of Adventist Hospital Bakersfield, observed in March, “people that would normally come into the emergency room to be checked out, they’re delaying that care because they’re afraid of coming into the hospital or they’re thinking that we’re so busy with COVID patients that they don’t want to bother us.”

Now, four months into the pandemic, it’s the reverse. There’s been a recent surge in non-COVID patients who put off treatment until it was too late.

“We have seen people who have waited for too long and come with a heart attack, and then have lingering damage to the heart that compromises the quality of their life going forward,” said Dr. Brij Bhambi, the Chief Medical Officer at Bakersfield Heart Hospital.

Dr. Hemmal Kothary, Chief Medical Officer at Dignity Health, added, “we’re also seeing more strokes at home. These are time-sensitive illnesses that if you don’t get them taken care of immediately, it could cause more damage.”

Impact on Health

- April 8, 2020, *Unprecedented disruption of lives and work: Health, distress and life satisfaction of working adults in China one month into the COVID-19 outbreak*,
<https://www.sciencedirect.com/science/article/pii/S0165178120306521>,

The preliminary results reveal adults in locations more affected by COVID-19 had distress, and lower physical and mental health, and life satisfaction.

- May 12, 2020, *A wake-up call: COVID-19 and its impact on children's health and wellbeing*, [https://www.thelancet.com/pdfs/journals/langlo/PIIS2214-109X\(20\)30238-2.pdf](https://www.thelancet.com/pdfs/journals/langlo/PIIS2214-109X(20)30238-2.pdf),

Building on lessons learned from previous outbreaks of Ebola virus disease and severe acute respiratory syndrome (SARS), the authors estimate a devastating increase in the numbers of maternal and child deaths resulting from reductions in routine health service coverage.

Left unchecked, these reductions (due to, for example, disruptions in medical supply chains or the availability of human and financial resources) along with declines in the uptake of health services by communities fearful of infection will be more catastrophic for mothers and children than COVID-19 itself. The projection of an additional 1.2 million child deaths and 56700 maternal deaths in 118 countries if coverage of essential services drops by around 45% for 6 months is alarming. It is also avoidable if we act now.

- June 27, 2020, *Lockdown and social distancing could make our immune system weaker, says scientist*, <https://www.msn.com/en-gb/news/coronavirus/lockdown-and-social-distancing-could-make-our-immune-system-weaker-says-scientist/ar-BB162J0W?fbclid=IwAR3w6XmnPL79-uxnrTFIX8LRooKJBKZh3N5Ib9oEo9xjgi5OIISA7SZBerk>,

Prolonged periods of lockdown cocooning the public from germs could leave people dangerously vulnerable to new viruses, a leading epidemiologist has warned.

Sunetra Gupta, professor of theoretical epidemiology at the University of Oxford, fears intense social distancing could actually weaken immune systems because people are not exposed to germs and so do not develop defences that could protect them against future pandemics.

- August 7, 2020, *Dentists say 'mask mouth' can cause serious health complications, including strokes*, <https://www.washingtonexaminer.com/news/mask-mouth-dentists-warn-prolonged-use-of-masks-leading-to-poor-oral-hygiene>,

Dentists are warning about the health issues tied to prolonged use of a mask to stop the spread of the coronavirus.

They said dental problems associated with "mask mouth," including gum disease, could lead to serious complications.

"Gum disease — or periodontal disease — will eventually lead to strokes and an increased risk of heart attacks," Marc Sclafani, a dentist and co-founder of One Manhattan Dental, told the New York Post about "mask mouth," which is increasingly causing inflammation and gum disease among patients.

Another dentist and co-founder at One Manhattan Dental, Rob Ramondi, said 50% of his patients are suffering from negative health issues due to mask-wearing.

"We're seeing inflammation in people's gums that have been healthy forever, and cavities in people who have never had them before," Ramondi said. "About 50% of our

patients are being impacted by this, [so] we decided to name it ‘mask mouth’ — after ‘meth mouth.’”

Impacts on Substance Abuse, Violence, Suicide, & Deaths of Despair

- April 7, 2020, *Coronavirus In Ohio: Domestic Violence Shelters Expect Boom Of Crisis Calls*, <https://radio.wosu.org/post/coronavirus-ohio-domestic-violence-shelters-expect-boom-crisis-calls#stream/0>,

Columbus City Attorney Zach Klein says there were 60 domestic violence arrests in the last week of March, which is about average for the city.

“When you backdrop that against the fact that we’ve had three domestic violence-related homicides in the past three weeks, you look at the fact of high economic anxiety, high COVID-19 anxiety, folks quarantined in their own houses, this is an unstable situation in any household,” Klein says.

Those three homicides sounded alarms for Klein because there were only seven in all of 2019.

“We never want to think that a victim of domestic violence or their family has to wait out the COVID-19 crisis in their own home with an abuser,” Klein says. “You do not have to do that. There are resources that are open.”

- April 10, 2020, *The COVID-19 pandemic and mental health impacts*, <https://onlinelibrary.wiley.com/doi/full/10.1111/inm.12726>,

The current state of the COVID-19 illness already paints a picture of inevitable and large-scale quarantine – some of which are already occurring. In the case of mass quarantine, experiencing social isolation and an inability to tolerate distress escalate anxiety and fear of being trapped and loss of control, and the spread of rumours (Rubin & Wessely 2020). Rumours fuel feelings of uncertainty and are extricably linked to issues such as panic buying and hoarding behaviour. Anxiety related to this pandemic is also compounded by people being reminded of their own mortality that can lead to an ‘urge to splurge’, that is an increase in spending as a means to curb fear and regain control (Arndt et al. 2004).

- April 15, 2020, *Officials worry of potential spike in overdose deaths amid COVID-19 pandemic*, <https://abcnews.go.com/US/officials-worry-potential-spike-overdose-deaths-amid-covid/story?id=70149746>,

With millions of Americans forced into weeks of extended isolation, several communities have reported a spike in drug overdose deaths, prompting health officials to raise concerns about the safety of those suffering from substance use disorders amid the COVID-19 pandemic.

- May 8, 2020, *Projected Deaths of Despair from COVID-19*, https://wellbeingtrust.org/wp-content/uploads/2020/05/WBT_Deaths-of-Despair_COVID-19-FINAL-FINAL.pdf,

More Americans could lose their lives to deaths of despair, deaths due to drug, alcohol, and suicide, if we do not do something immediately. Deaths of despair have been on the

rise for the last decade, and in the context of COVID-19, deaths of despair should be seen as the epidemic within the pandemic.

- May 8, 2020, *Coronavirus pandemic may lead to 75,000 "deaths of despair" from suicide, drug and alcohol abuse, study says*, <https://www.cbsnews.com/news/coronavirus-deaths-suicides-drugs-alcohol-pandemic-75000/>, Full report <https://wellbeingtrust.org/areas-of-focus/policy-and-advocacy/reports/projected-deaths-of-despair-during-covid-19/>

COVID-19 has directly claimed tens of thousands of U.S. lives, but conditions stemming from the novel coronavirus — rampant unemployment, isolation and an uncertain future — could lead to 75,000 deaths from drug or alcohol abuse and suicide, new research suggests.

Deaths from these causes are known as "deaths of despair." And the COVID-19 pandemic may be accelerating conditions that lead to such deaths.

- May 8, 2020, *'Children at risk of lasting psychological distress from coronavirus lockdown': Save the Children* <https://reliefweb.int/report/world/children-risk-lasting-psychological-distress-coronavirus-lockdown-save-children>,

Almost one in four children living under COVID-19 lockdowns, social restrictions and school closures are dealing with feelings of anxiety, with many at risk of lasting psychological distress, including depression. In recent surveys by Save the Children of over 6000 children and parents in the US, Germany, Finland, Spain and the UK, up to 65 per cent of the children struggled with boredom and feelings of isolation.

- May 9, 2020, *Why the Increase in Domestic Violence During COVID-19?*, <https://www.psychologytoday.com/us/blog/making-sense-chaos/202005/why-the-increase-in-domestic-violence-during-covid-19>,

Among all of the horrors that COVID-19 has wrought, domestic violence is a growing scourge that lurks in the shadows. Indeed, a stark uptick in reports of domestic violence and abuse (more commonly referred to in clinical settings as “intimate partner violence” or “IPV”) has recently received national (and even global) attention. New estimates from the United Nations Population Fund suggest that three months of quarantine will result in a 20 percent rise in IPV throughout the world. In total, the report predicts at least 15 million additional cases of IPV will occur as a result of COVID-19 lockdowns.

- May 21, 2020, *California doctors say they've seen more deaths from suicide than coronavirus since lockdowns*, <https://www.washingtonexaminer.com/news/california-doctors-say-theyve-seen-more-deaths-from-suicide-than-coronavirus-since-lockdowns>,

Doctors in Northern California say they have seen more deaths from suicide than they've seen from the coronavirus during the pandemic.

“The numbers are unprecedented,” Dr. Michael deBoisblanc of John Muir Medical Center in Walnut Creek, California, told ABC 7 News about the increase of deaths by suicide, adding that he’s seen a “year’s worth of suicides” in the last four weeks alone.

DeBoisblanc said he believes it's time for California officials to end the stay-at-home order and let people back out into their communities.

"Personally, I think it's time," he said. "I think, originally, this was put in place to flatten the curve and to make sure hospitals have the resources to take care of COVID patients. We have the current resources to do that, and our other community health is suffering."

- May 22, 2020, *600 Physicians Say Lockdowns Are A 'Mass Casualty Incident'*, <https://www.forbes.com/sites/gracemarieturner/2020/05/22/600-physicians-say-lockdowns-are-a-mass-casualty-incident/#33715bc350fa>,

"The downstream health effects...are being massively under-estimated and under-reported. This is an order of magnitude error," according to the letter initiated by Simone Gold, M.D., an emergency medicine specialist in Los Angeles.

"Suicide hotline phone calls have increased 600%," the letter said. Other silent casualties: "150,000 Americans per month who would have had new cancer detected through routine screening."

From missed cancer diagnoses to untreated heart attacks and strokes to increased risks of suicides, "We are alarmed at what appears to be a lack of consideration for the future health of our patients."

- June 17, 2020, *Gun Violence and COVID-19: Colliding Public Health Crises*, <https://everytownresearch.org/reports/covid-gun-violence/>,

The US has seen the collision of two major public health crises: COVID-19 and gun violence. A comprehensive understanding of how this collision will affect Americans and the factors driving the increase in gun violence during the pandemic is still developing, but there are a few takeaways: While millions of Americans rushed out to purchase new firearms in the middle of a global pandemic, thinking they were buying safety, research shows that they are in fact exposing themselves and their families to higher risks of suicide, homicide, unintentional shootings, and intimate partner violence.

- July 10, 2020, *Cleveland Clinic study: Rise in broken-heart syndrome caused by increased stress of coronavirus pandemic*, <https://www.cleveland.com/healthfit/2020/07/cleveland-clinic-study-rise-in-broken-heart-syndrome-caused-by-increased-stress-of-coronavirus-pandemic.html>,

Cleveland Clinic cardiologists have seen a notable increase in cases of broken-heart syndrome during the coronavirus pandemic, indicating the psychological and emotional stress of the crisis is adversely affecting physical health.

- July 15, 2020, *In Shadow of Pandemic, U.S. Drug Overdose Deaths Resurge to Record*, <https://www.nytimes.com/interactive/2020/07/15/upshot/drug-overdose-deaths.html?referringSource=articleShare&fbclid=IwAR10SY-qZCiwKY3W1b0K8SM8nG1fHNRAI9cYCeXB94hdTalLgIcIFMCjHsc>,

Drug deaths in America, which fell for the first time in 25 years in 2018, rose to record numbers in 2019 and are continuing to climb, a resurgence that is being complicated and perhaps worsened by the coronavirus pandemic.

- July 16, 2020, *Why are overdose deaths surging amid COVID-19?*, <https://wexnermedical.osu.edu/blog/why-are-overdose-deaths-surging-amid-covid-19>,
As the global COVID-19 pandemic continues, opioid overdose deaths are surging nationwide.

This increase in opioid overdose deaths is likely linked to COVID-19 restrictions and closures that have hindered access to treatment and recovery services for those suffering from substance use disorder.

The American Medical Association issued a report stating that it's "greatly concerned by an increasing number of reports from national, state and local media suggesting increases in opioid-related mortality—particularly from illicitly manufactured fentanyl and fentanyl analogs."

- July 22, 2020, *Highway deaths spike for third-straight month as drivers take advantage of empty roads*, <https://www.nbcnews.com/business/autos/highway-deaths-spike-third-straight-month-drivers-take-advantage-empty-n1234651>,

Motor vehicle fatalities surged by 23.5 percent in May, as drivers took advantage of open roads to push to autobahn speeds, a situation made easier by the fact that authorities in many communities were pulling back on enforcement, in part, to avoid risking the possibility of their officers becoming exposed to the coronavirus.

According to the National Safety Council report, the May numbers mark the third-straight month that U.S. motorists were at a higher risk of dying from a crash — and it comes as a setback to safety advocates who had been hoping that the drop in traffic during the coronavirus-induced lockdown would see a decline in highway fatalities.

"At a moment when the country should be reaping a safety benefit from less traffic, the roads are riskier, threatening to reverse traffic safety gains made over the last few years," the NSC said in a statement.

- July 28, 2020, *CDC Director Compares Rate of Suicides to COVID-19 Deaths*, <https://townhall.com/tipsheet/micaelaburrow/2020/07/28/redfield-says-more-abovebase-suicides-than-covid-deaths-n2573278>,

Robert Redfield, Centers for Disease Control and Prevention director, stated, "But there has been another cost that we've seen, particularly in high schools... We're seeing, sadly, far greater suicides now than we are deaths from COVID. We're seeing far greater deaths from drug overdose that are above excess that we had as background than we are seeing the deaths from COVID."

Impacts on Human Trafficking

- April 2020, *Human Trafficking During the Pandemic*, <https://polarisproject.org/wp-content/uploads/2020/06/Crisis-in-Human-Trafficking-During-the-Pandemic.pdf>,

When comparing post-shelter-in-place time with pre-shelter-in-place time in 2019 and 2020, the number of crisis trafficking situations increased by more than 40 percent – from

approximately 60 in a 30-day period to 90. Crisis situations are those in which some assistance - such as shelter, transportation, or law enforcement involvement - is needed within 24 hours.

The number of situations in which people needed immediate emergency shelter nearly doubled (from around 29 in pre-shelter-in-place periods to 54 in April 2020).

- June 24, 2020, *The Dynamics of Human Trafficking: Before & After COVID-19*, <https://www.domesticpreparedness.com/resilience/the-dynamics-of-human-trafficking-before-after-covid-19/>,

According to the Global Protection Cluster (GPC), approximately 75% of humanitarian operations worldwide have stopped due to international lockdowns, curfews, and other measures taken in response to COVID-19. Among the emerging trends resulting from the reduction of worldwide humanitarian operations, the GPC reports, “boys, girls, young women and men are reported as being more exposed to violence, sale, trafficking, sexual abuse and exploitation during the COVID-19 pandemic.” As governments divert assets to mitigating the spread of COVID-19, human traffickers are emboldened to exploit an increase in new potential victims – vulnerable populations – and slower responses from law enforcement.

- July 28, 2020, *COVID-19 Has Led to an Increase in Human Trafficking, Experts Say*, <https://www.dailysignal.com/2020/07/28/covid-19-has-led-to-an-increase-in-human-trafficking-expert-say/>,

Beiser said the coronavirus actually has created a climate for human traffickers to exploit the most vulnerable. A recent study, conducted by his group, found that crisis trafficking situations rose by 40% in April of this year compared with the numbers for April 2019.

“The real concern for most anti-trafficking professionals is, when people are out of work or unable to work, when they are not stably housed, when they don’t feel that they can get safety when they need it, that is when trafficking flourishes,” he said.

Impacts on Children/Adolescents

- April 15, 2020, *Policy Brief: The Impact of COVID-19 on children*, https://www.un.org/sites/un2.un.org/files/policy_brief_on_covid_impact_on_children_16_april_2020.pdf,

Economic hardship experienced by families as a result of the global economic downturn could result in hundreds of thousands of additional child deaths in 2020, reversing the last 2 to 3 years of progress in reducing infant mortality within a single year. And this alarming figure does not even take into account services disrupted due to the crisis – it only reflects the current relationship between economies and mortality, so is likely an under-estimate of the impact. Rising Executive Summary 2 POLICY BRIEF: THE IMPACT OF COVID-19 ON CHILDREN POLICY BRIEF: THE IMPACT OF COVID-19 ON CHILDREN 3 malnutrition is expected as 368.5 million children across 143 countries who normally rely on school meals for a reliable source of daily nutrition must now look to other sources. The risks to child mental health and well being are also

considerable. Refugee and internally displaced children as well as those living in detention and situations of active conflict are especially vulnerable.

- April 16, 2020, *U.N. warns economic downturn could kill hundreds of thousands of children in 2020*, <https://www.reuters.com/article/us-health-coronavirus-children-un-idUSKBN21Y2X7>,

Hundreds of thousands of children could die this year due to the global economic downturn sparked by the coronavirus pandemic and tens of millions more could fall into extreme poverty as a result of the crisis, the United Nations warned on Thursday.

The world body also said in a risk report that nearly 369 million children across 143 countries who normally rely on school meals for a reliable source of daily nutrition have now been forced to look elsewhere.

- May 12, 2020, *A wake-up call: COVID-19 and its impact on children's health and wellbeing*, [https://www.thelancet.com/pdfs/journals/langlo/PIIS2214-109X\(20\)30238-2.pdf](https://www.thelancet.com/pdfs/journals/langlo/PIIS2214-109X(20)30238-2.pdf),

Building on lessons learned from previous outbreaks of Ebola virus disease and severe acute respiratory syndrome (SARS), the authors estimate a devastating increase in the numbers of maternal and child deaths resulting from reductions in routine health service coverage.

Left unchecked, these reductions (due to, for example, disruptions in medical supply chains or the availability of human and financial resources) along with declines in the uptake of health services by communities fearful of infection will be more catastrophic for mothers and children than COVID-19 itself. The projection of an additional 1.2 million child deaths and 56700 maternal deaths in 118 countries if coverage of essential services drops by around 45% for 6 months is alarming. It is also avoidable if we act now.

- June 3, 2020, *COVID-19 lockdowns worsen childhood obesity, study finds*, https://www.sciencedaily.com/releases/2020/06/200603194444.htm?fbclid=IwAR1NDusT76f2vJAoxHdHPwnbZ_9GYSzgWCHX4h4UyTWlcxxqLvzs4H39_IY,

"The tragic COVID-19 pandemic has collateral effects extending beyond direct viral infection," says Myles Faith, PhD, UB childhood obesity expert and co-author on the study. "Children and teens struggling with obesity are placed in an unfortunate position of isolation that appears to create an unfavorable environment for maintaining healthy lifestyle behaviors."

- June 19, 2020, *COVID-19 pandemic and mitigation strategies: implications for maternal and child health and nutrition*, <https://academic.oup.com/ajcn/article/112/2/251/5860091>,

Although there has been focus on rising rates of childhood wasting in the short term, maternal and child undernutrition rates are also likely to increase as a consequence of COVID-19 and its impacts on poverty, coverage of essential interventions, and access to appropriate nutritious foods. Key sectors at particular risk of collapse or reduced efficiency in the wake of COVID-19 include food systems, incomes, and social protection, health care services for women and children, and services and access to clean water and sanitation.

- July 27, 2020, *Child malnutrition and COVID-19: the time to act is now*,
[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31648-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31648-2/fulltext),

The estimated increase in child wasting is only the tip of the iceberg. The COVID-19 pandemic is also expected to increase other forms of child malnutrition, including stunting, micronutrient deficiencies, and overweight. The global community's failure to act now will have devastating long-term consequences for children, human capital, and national economies.

Impacts on Hunger

- April 16, 2020, *Poverty and food insecurity could grow dramatically as COVID-19 spreads*,
<https://www.ifpri.org/blog/poverty-and-food-insecurity-could-grow-dramatically-covid-19-spreads>,

As the COVID-19 pandemic spreads, social and economic relief measures—including fiscal stimulus and expansion of social safety nets—are crucial to prevent poverty and hunger from rising dramatically in developing countries. Rob Vos, David Laborde and Will Martin estimate this impact globally, finding that over 140 million additional people could fall into extreme poverty in 2020, including 80 million in Africa and 42 million in South Asia. Food insecurity would rise along with poverty. Without support, this global health crisis could thus cause a major poverty and food crisis.

- April 22, 2020, *UN food agency chief: World could see famines of "biblical proportions" within months*,
<https://www.cbsnews.com/news/coronavirus-famines-united-nations-warning/>,

David Beasley, director of the United Nations World Food Program, warned Tuesday that the world is on "the brink of a hunger pandemic" as it grapples with the global coronavirus crisis.

- May 1, 2020, *We Can't Ignore the Harms of Social Distancing*,
<https://www.medscape.com/viewarticle/929765>,

While uncertainty prevails, I worry that hard questions are being avoided. I will strive not to be tone-deaf, but in the same way we discuss prognosis with patients with cancer or heart failure, we must also address difficult questions concerning the COVID-19 crisis.

The social distancing policies are harming people—not potential harms, but real harms. Economic harm is a euphemism because the economy is people.

- July 20, 2020, *6 million people enrolled for food stamps in the first 3 months of the US coronavirus outbreak as America's superrich kept getting wealthier*,
<https://www.businessinsider.com/us-coronavirus-outbreak-6m-enrolled-food-stamps-superrich-wealthier-2020-7>,

The first three months of the coronavirus pandemic saw six million people sign up to receive food stamps, while the wealth of America's superrich grew by almost 20%, according to multiple reports.

- July 21, 2020, *1 in 10 Americans don't have enough food, double pre-pandemic rates*, <https://www.msn.com/en-us/money/markets/1-in-10-americans-dont-have-enough-food-double-pre-pandemic-rates/ar-BB171jEd>,

Financial hardship has spiked during the coronavirus pandemic with more than 1 in 10 adults telling a Census survey during the first week of July that they sometimes or often didn't have enough to eat, a rate that is two-and-a-half times higher than before the crisis.

- July 27, 2020, *Impacts of COVID-19 on childhood malnutrition and nutrition-related mortality*, [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31647-0/fulltext?fbclid=IwAR1HQCA_VMDyK-yPRQEdUM6HghHR0YrSX3Vh11VSYrMzG6vJsTqd5GT4gyM](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31647-0/fulltext?fbclid=IwAR1HQCA_VMDyK-yPRQEdUM6HghHR0YrSX3Vh11VSYrMzG6vJsTqd5GT4gyM),

The unprecedented global social and economic crisis triggered by the COVID-19 pandemic poses grave risks to the nutritional status and survival of young children in low-income and middle-income countries (LMICs).

- July 27, 2020, *Child malnutrition and COVID-19: the time to act is now*, [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31648-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31648-2/fulltext),

The estimated increase in child wasting is only the tip of the iceberg. The COVID-19 pandemic is also expected to increase other forms of child malnutrition, including stunting, micronutrient deficiencies, and overweight. The global community's failure to act now will have devastating long-term consequences for children, human capital, and national economies.

Impacts on the Economy

- April 2020, *COVID-Induced Economic Uncertainty*, <https://www.nber.org/papers/w26983>,

The COVID-19 pandemic has created an enormous uncertainty shock – larger than the one associated with the financial crisis of 2008-09 and more similar in magnitude to the rise in uncertainty during the Great Depression of 1929-1933.

- April 2, 2020, *America's stunning unemployment surge during coronavirus, visualized*, <https://www.nbcnews.com/business/economy/america-s-stunning-unemployment-surge-during-coronavirus-visualized-n1174801>,

The ranks of the unemployed are swelling in ways not seen before since the coronavirus crisis. Another 1.5 million Americans filed jobless claims last week, bringing the total to 45.4 million since the March 14. Numbers began surging as state-ordered coronavirus lockdowns brought huge swaths of the economy to a halt.

- April 16, 2020, *Poverty and food insecurity could grow dramatically as COVID-19 spreads*, <https://www.ifpri.org/blog/poverty-and-food-insecurity-could-grow-dramatically-covid-19-spreads>,

As the COVID-19 pandemic spreads, social and economic relief measures—including fiscal stimulus and expansion of social safety nets—are crucial to prevent poverty and hunger from rising dramatically in developing countries. Rob Vos, David Laborde and Will Martin estimate this impact globally, finding that over 140 million additional people could fall into extreme poverty in 2020, including 80 million in Africa and 42 million in

South Asia. Food insecurity would rise along with poverty. Without support, this global health crisis could thus cause a major poverty and food crisis.

- June 2020, *Situation tracking for COVID-19 socioeconomic impacts*, <https://data.unicef.org/resources/rapid-situation-tracking-covid-19-socioeconomic-impacts-data-viz/>,

To date, children have been spared from the direct health effects of the COVID-19 virus. They are the hidden victims of the pandemic rather than the face of it. Yet children around the world have had their lives upended because of actions taken to contain the disease. Families are facing heightened stress under lockdown with many experiencing financial insecurity. And children are missing out on life-saving vaccines and much-needed free meals because of the suspension of services. While others experience increasing threats to their safety and wellbeing as services that prevent and respond to violence, abuse and neglect are suspended. Many children, especially the most vulnerable, even risk losing their lives to preventable diseases because access to healthcare is disrupted. Measures taken by governments to contain and mitigate the pandemic are having persistent and far-reaching impacts on children's lives.

- June 8, 2020, *COVID-19 to Plunge Global Economy into Worst Recession since World War II*, <https://www.worldbank.org/en/news/press-release/2020/06/08/covid-19-to-plunge-global-economy-into-worst-recession-since-world-war-ii>,

Economic activity among advanced economies is anticipated to shrink 7% in 2020 as domestic demand and supply, trade, and finance have been severely disrupted. Emerging market and developing economies (EMDEs) are expected to shrink by 2.5% this year, their first contraction as a group in at least sixty years. Per capita incomes are expected to decline by 3.6%, which will tip millions of people into extreme poverty this year.

The blow is hitting hardest in countries where the pandemic has been the most severe and where there is heavy reliance on global trade, tourism, commodity exports, and external financing. While the magnitude of disruption will vary from region to region, all EMDEs have vulnerabilities that are magnified by external shocks. Moreover, interruptions in schooling and primary healthcare access are likely to have lasting impacts on human capital development.

- June 22, 2020, *Coronavirus rent freezes are ending — and a wave of evictions will sweep America*, <https://www.nbcnews.com/think/opinion/coronavirus-rent-freezes-are-ending-wave-evictions-will-sweep-america-ncna1230916>,

Underscoring the pandemic's immense toll, researchers at the University of California, Berkeley Turner Center for Housing Innovation estimate that 50 million renters live in households that suffered COVID-19-related job or income loss, with almost 40 percent occurring in low-income households. The demand for financial assistance is at an all-time high, with a 92 percent increase in daily rental assistance requests and food pantry requests increasing by as much as 2,000 percent in some states. In Houston, a \$15 million rent relief fund was depleted within 90 minutes of opening. Renters are stretched threadbare and are taking on credit card and loan debt just to keep their housing. It's not

surprising, then, that over 31 percent of renters have slight or no confidence in their ability to pay next month's rent.

- July 7, 2020, *Unemployment Expected to Reach Highest Level Since Great Depression*, <https://www.wsj.com/articles/unemployment-expected-to-reach-highest-level-since-great-depression-11594112400>,

Unemployment rates in the world's advanced economies will end the year higher than at any time since the Great Depression and not return to their pre-pandemic levels until 2022 at the earliest, the Organization for Economic and Cooperation and Development said Tuesday.

- July 31, 2020, *US economy posts its worst drop on record*, <https://www.cnn.com/2020/07/30/economy/us-economy-2020-second-quarter/index.html>,

The US economy contracted at a 32.9% annual rate from April through June, its worst drop on record, the Bureau of Economic Analysis said Thursday.

Business ground to a halt during the pandemic lockdown in the spring of this year, and America plunged into its first recession in 11 years, putting an end to the longest economic expansion in US history and wiping out five years of economic gains in just a few months.

- August 7, 2020, *The COVID-19 Eviction Crisis: An Estimated 30-40 Million People in America are at Risk*, <https://www.aspeninstitute.org/blog-posts/the-covid-19-eviction-crisis-an-estimated-30-40-million-people-in-america-are-at-risk/>,

The United States may be facing the most severe housing crisis in its history. According to the latest analysis of weekly U.S. Census data, as federal, state and local protections and resources expire and in the absence of robust and swift intervention, an estimated 30–40 million people in America could be at risk of eviction in the next several months. Many property owners, who lack the credit or financial ability to cover rental payment arrears, will struggle to pay their mortgages and property taxes, and maintain properties. The COVID-19 housing crisis has sharply increased the risk of foreclosure and bankruptcy, especially among small property owners; long-term harm to renter families and individuals; disruption of the affordable housing market; and destabilization of communities across the United States.

Attachment G

Press release Timeline

https://ema.ohio.gov/COVID19_PressReleases.aspx

ODPS Ohio Emergency Management Agency COVID-19 Releases

coronavirus.ohio.gov

COVID-19 News

08.18.2020: COVID-19 Update: Sports Health Order, Georgetown Veterans Home, Ohio Governor's Imagination Library, Women's Suffrage Centennial

08.13.2020: COVID-19 Update: Improving Minority Health, Updated County Risk Levels

08.11.2020: COVID-19 Update: Return to School, Increase in Cases in Younger Populations

08.07.2020: COVID-19 Update: School Broadband Connectivity

08.04.2020: COVID-19 Update: Masks in Schools, Rapid Testing, Community Spread and Spread from Faith-Based Settings, Dr. Amy Acton

07.30.2020: Health Order Signed Limiting County Fairs to Junior Fair Activities

07.30.2020: COVID-19 Update: Liquor Sale and On-Premises Consumption Limits, Mass Gathering Order, Updated Risk Levels

07.28.2020: COVID-19 Update: Child Care Ratios to be Lifted, Additional Restrictions Announced for Local Fairs

07.23.2020: COVID-19 Update: Eight Counties Increase to Red Alert Level Three, Importance of Self-Quarantines, Broadband Expansion

07.23.2020: Statewide Facial Covering Order Signed

07.22.2020: Governor DeWine Issues Statewide Mask Order, Travel Warning

07.16.2020: COVID-19 Update - 19 Red Alert Level 3 Counties, Executive Order, PPE Manufacturing Grants

07.15.2020: Gov. DeWine Implores Ohioans to Unite to Prevent Spread of COVID-19

07.09.2020: COVID-19 Update - New Risk Levels, Higher Education Guidance, Funding for Schools, Homelessness Grant, IMAP Launch, SharedWork Program, Plasma Donation

07.08.2020: Director's Orders Signed for Facial Coverings

07.07.2020: COVID-19 Update - Face Coverings To Be Required in High-Risk Counties

07.07.2020: Lt. Gov. Husted Announces Short-Term "Return to Play" Guidelines for Sports, Launches Campaign to Engage Young Ohioans

07.02.2020: COVID-19 Update - School Guidelines, Public Health Advisory System

06.29.2020: COVID-19 Update - Increases in Hospitalizations and Positivity Rate, Counties of Concern, Nursing Home Visitation, Order Extension

06.25.2020: COVID-19 Update: Increase in Positive Cases, 2-1-1

06.23.2020: COVID-19 Update: Public Awareness Campaigns, Fireworks, Criminal Justice Grants

06.16.2020: COVID-19 UPDATE: Basic Reproduction Number, Pop-Up Sites, Multi-System Youth Grant

06.12.2020: COVID-19 UPDATE: Testing Expansion, R0 in Ohio, Place of Worship Best Practices, New Role for Dr. Acton, ODJFS Employment/Training Grant

06.09.2020: UPDATE: Mass Protest Standard, Office of Law Enforcement Recruitment, PPE Update, GOJO Expansion

06.05.2020: UPDATE: Additional Reopening Dates, Order Signed, Ohio National Guard

06.02.2020: UPDATE: Disparity, K-12 Reopening, Medical Procedures, Funding Opportunities for Businesses

05.28.2020: COVID-19 Update: Testing, Assisted Living Visitation, Premium Deferrals, Fairs

05.26.2020: COVID-19 Update: Congregate Care Unified Response Teams

05.22.2020: Governor Announces New Health Orders Signed May 22

05.21.2020: COVID-19 Update - Efforts to Improve Minority Health, New Sector Openings

05.20.2020: Governor Announces New Health Orders Signed

05.19.2020: COVID-19 Update: Ohioans Protecting Ohioans Urgent Health Advisory

05.18.2020: COVID-19 Update: Safety Checks, Twin Valley Update, Veterans Home Update

05.14.2020: COVID-19 Update: New Responsible RestartOhio Opening Dates

05.13.2020: Ohio Receives Remdesivir to be Distributed Statewide

05.12.2020: COVID-19 Update: Pandemic EBT, Additional Services to Reopen, Staying Connected

05.07.2020: COVID-19 Update: Reopening of Restaurants, Bars, and Personal Care Services

05.05.2020: COVID-19 Update: State Budget Impact

05.04.2020: COVID-19 Update: Testing Priority, Ohio BMVs

05.01.2020: Governor DeWine Announces 'Stay Safe Ohio' Order

04.30.2020: COVID-19 Update: Prison PPE, ODRC Update

04.29.2020: PPE Delivery, Employee Face-Covering Exceptions, Criminal Justice Grants, Class of 2020 Graduation

04.28.2020: Face Coverings, Advisory Groups on Restaurants, Barbershops & Salons

04.27.2020: Gov. DeWine Announces Details of Ohio's Responsible RestartOhio Plan

04.24.2020: COVID-19 Update: Reagent and Testing Swabs, Contact Tracing, Foster Care

04.23.2020: COVID-19 Update - How Environmental Changes Impact Health Risk

04.22.2020: COVID-19 Update: Elective Surgery Order, Mental Health CareLine

04.21.2020: COVID-19 Update: FDA Reagent Approval, Testing Strike Team, Fair Wavier, JobsOhio Banking Partnership, Dividend Checks

04.20.2020: K-12 Schools to Remain Closed, Minority Health Strike Force, Data Collection, Private Lab Testing

04.17.2020: COVID-19 Update: Recovery Phase, Inmate Testing

04.16.2020: COVID-19 Update: Governor DeWine Discussed State's Plan for Reopening Businesses, Regional Coalition Formed

04.15.2020: COVID-19 Update: Deferred Elective Procedures, CARES Act Payments, 1099 Unemployment Claims, First Responder PPE, Testing Partnership, Prison Update, Census 2020

04.13.2020: COVID-19 Update: Nursing Home Order, Liquor Sales, TANF Funding, Rapid Testing, Prison Update

04.10.2020: COVID-19 Update: Eased Medicaid Restrictions, N95 Sterilization, Distillery-Made Hand Sanitizer, Food Trucks at Rest Areas, New Data Reporting

04.09.2020: COVID-19 Update: PPE Manufacturing, Convalescent Plasma

04.08.2020: COVID-19 Update: Continue Staying Home, Correction Officer Death, PPE Sterilization, Child Abuse Reports, Proposed \$1.6 Billion Dividend for Employers

04.07.2020: COVID-19 Update: Liquor Sales, Office of Small Business Relief, Ohio Prisons, SNAP Payments

04.06.2020: Sites Selected for Enhanced Hospital Capacity; ONG to Assist Federal Prison; Dispute Resolution Commission Now Active

04.04.2020: Ohioans Encouraged to Wear Cloth Masks in Public; Governor Signs Telehealth EO; New WiFi Hotspot Locator

04.03.2020: COVID-19 Update: Testing Supplies; PPE Sanitizing; Inmate Release Recommendation; Remote Learning Guide

04.02.2020: Ohio Stay at Home Order Extended Through May 1

04.01.2020: COVID-19 Update: PPE Manufacturing, Testing Order, Click Connect, Foreclosure Prevention

03.31.2020: Ohio Dept. of Health Receives All Allocated PPE from Strategic National Stockpile

03.31.2020: Ohio Takes Inventory of Ventilators; Issues Emergency Connection Order; Extends Telework Order

03.30.2020: Gov. DeWine Extends School Closure Order

03.30.2020: Ohio EMA Warns about Scam Phone Calls

03.29.2020: Governor, Lt. Governor Thank FDA for Approval of Use of Battelle Technology

03.29.2020: Gov. DeWine, Lt. Gov. Husted express disappointment in FDA's decision to limit use of Battelle Technology

03.28.2020: Gov. DeWine makes plea to FDA; Releases list of needed PPE

03.27.2020: Gov. DeWine signs House Bill 197

03.26.2020: Gov. DeWine, Pres. Obhof, Speaker Householder Announce Postponement of State of the State Address

03.26.2020: Personal Protective Equipment Needed; New COVID-19 Data Dashboard Unveiled

03.25.2020: Gov. DeWine's Statement on House Bill 197

03.23.2020: Gov. DeWine Orders Hiring Freeze for State Agencies, Boards and Commissions

03.22.2020: Ohio Issues “Stay at Home” Order; New Restrictions Placed on Child Daycares

03.21.2020: Adult Day Services to Close; BWC Payments Deferred; Trucking Waivers Issued

03.21.2020: Governor, Lt. Governor Statements Honoring State Rep. Dan Manning

03.20.2020: Ohio Records First COVID-19 Death; Senior Centers, Adult Day Cares to Close

03.19.2020: SBA Applications Being Accepted for Economic Injury Disaster Loan Program; DeWine Signs Order Expanding Telehealth Services for Medicaid Recipients

03.19.2020: (SBA NR) SBA Offers Disaster Assistance to Ohio Small Businesses Economically Impacted by COVID-19

03.19.2020: (SBA in Spanish) La SBA Ofrece asistencia en caso de desastre a las pequeñas empresas de Ohio afectadas económicamente por el COVID-19

03.17.2020: Joint Statement from Gov. DeWine and Secretary LaRose (7:31 pm)

03.17.2020: Elective Surgeries Postponed in Ohio Hospitals (7:09 pm)

03.16.2020: Ohio Dept. of Health issues order on closure of polling locations (11 pm)

03.16.2020: Statement from Ohio Governor Mike DeWine on the March 17 Election (10:09 pm)

03.16.2020: Joint Statement from Gov. DeWine and Secretary LaRose on Ohio Primary (9:04 pm)

03.15.2020: EMAO News Release: State Orders Bars, Restaurants Closed during Outbreak

03.15.2020: Gov. News Release: Business, Community Leaders Praise Efforts to Slow Spread of COVID-19

03.15.2020: Gov. DeWine Orders Ohio Bars & Restaurants to Close

03.14.2020: Gov. DeWine Provides COVID-19 Update

03.12.2020: Ohio Bans Mass Gatherings of 100 or More

03.12.2020: Gov. DeWine Announces School Closures

03.11.2020: Gov. DeWine Announces Fourth Confirmed COVID-19 Case; Limits Access to Nursing Homes, Assisted Living Facilities

03.10.2020: Gov. DeWine Recommends Limiting Large Indoor Gatherings

03.09.2020: Gov. DeWine Signs Emergency Order Regarding Coronavirus Response

ODPS Ohio Emergency Management Agency COVID-19 Releases



COVID-19 News

- 04.14.2020 COVID-19 Update: Sports Health Order, Georgetown Veterans Home, Ohio Governor's Immigration Library, Women's Suffrage Centennial
- 04.14.2020 COVID-19 Update: Improving Minority Health, Updated County Risk Levels
- 04.14.2020 COVID-19 Update: Return to School, Increase in Cases in Younger Populations
- 04.14.2020 COVID-19 Update: School Broadband Connectivity
- 04.14.2020 COVID-19 Update: Masks in Schools, Rapid Testing, Community Spread and Spread from Rain-Based Settings, Dr. Jonny Jonn
- 04.14.2020 Health Order Signed Limiting County Fairs to Junior Fair Activities
- 04.14.2020 COVID-19 Update: Liquor Sales and On-Premises Consumption Limits, Mass Gathering Order, Updated Risk Levels
- 04.14.2020 COVID-19 Update: Child Care Rates to be Lifted, Additional Restrictions Announced for Local Fairs
- 04.14.2020 COVID-19 Update: Eight Counties Increase to Red Alert Level Three, Importance of PPE Quarantines, Broadband Expansion
- 04.14.2020 Statewide Facial Covering Order Signed
- 04.14.2020 Governor DeWine Issues Statewide Mask Order, Travel Warning
- 04.14.2020 COVID-19 Update - 19 Red Alert Level 3 Counties, Executive Order, PPE Manufacturing Grants
- 04.14.2020 Gov. DeWine Implores Ohioans to Unite to Prevent Spread of COVID-19
- 04.14.2020 COVID-19 Update - New Risk Levels, Higher Education Guidance, Funding for Schools, Homelessness Grant, MUP Launch, Shared Work Program, Plasma Donation
- 04.14.2020 Director's Orders Signed for Facial Coverings
- 04.14.2020 COVID-19 Update - Face Coverings to be Required in High-Risk Counties
- 04.14.2020 Lt. Gov. Husted Announces Short-Term "Return to Play" Guidelines for Sports, Launches Campaign to Engage Young Ohioans
- 04.14.2020 COVID-19 Update - School Guidelines, Public Health Advisory System
- 04.14.2020 COVID-19 Update - Increases in Hospitalizations and Fatality Rate, Counties of Concern, Nursing Home Visitation, Order Reiteration
- 04.14.2020 COVID-19 Update: Increase in Positive Cases, 2-1-1
- 04.14.2020 COVID-19 Update: Public Awareness Campaign, PPE Grants, Criminal Justice Grants
- 04.14.2020 COVID-19 UPDATE: Basic Reproduction Number, Pop-Up Sites, Multi-System Youth Grant
- 04.14.2020 COVID-19 UPDATE: Testing Expansion, RO in Ohio, Race of Working Bear Practices, New Role for Dr. Jonn, ODPS Employment Training Grant
- 04.14.2020 UPDATE: Mass Procurement, Office of Law Enforcement Recruitment, PPE Updates, COVID Expansion
- 04.14.2020 UPDATE: Additional Reopening Dates, Order Signed, Ohio National Guard
- 04.14.2020 UPDATE: Disparity, K-12 Reopening, Medical Procedures, Funding Opportunities for Businesses
- 04.14.2020 COVID-19 Update: Testing, Isolated Living Visitation, Premium Deferrals, Fairs
- 04.14.2020 COVID-19 Update: Congregate Care Unified Response Teams
- 04.14.2020 Governor Announces New Health Orders Signed May 12
- 04.14.2020 COVID-19 Update - Efforts to Improve Minority Health, New Sector Openings
- 04.14.2020 Governor Announces New Health Orders Signed
- 04.14.2020 COVID-19 Update: Ohioans Proceeding, Ohioans Urgent Health Advisory
- 04.14.2020 COVID-19 Update: Safety, Checks, Twin Valley Update, Veterans Home Update
- 04.14.2020 COVID-19 Update: New Responsible Return Ohio Opening Dates
- 04.14.2020 Ohio Receives Randomly Issued Distributed Statewide
- 04.14.2020 COVID-19 Update: Randomly Issued Additional Services to Reopen, Saying Connected
- 04.14.2020 COVID-19 Update: Reopening of Restaurants, Bars, and Personal Care Services
- 04.14.2020 COVID-19 Update: State Budget Impact
- 04.14.2020 COVID-19 Update: Testing Priority, Ohio Skills
- 04.14.2020 Governor DeWine Announces Stay Safe Ohio Order
- 04.14.2020 COVID-19 Update: Prison PPE, ODR Update
- 04.14.2020 PPE Delivery, Employee Face-Covering Directives, Criminal Justice Grants, Class of 2020 Graduation
- 04.14.2020 Face Coverings, Advisory Groups on Restaurants, Bars, and Salons
- 04.14.2020 Gov. DeWine Announces Details of Ohio's Responsible Return Ohio Plan

- 04.14.2020 COVID-19 Update: Death & Surgery Order, Mental Health Care Line
- 04.14.2020 COVID-19 Update: FDU Reagent Approval, Testing Strike Team, Fair Worker, Jobs Ohio Banking Partnership, Dividend Checks
- 04.14.2020 K-12 Schools to Remain Closed, Minority Health Strike Force, Data Collection, Private Lab Testing
- 04.14.2020 COVID-19 Update: Recovery Phase, Inmate Testing
- 04.14.2020 COVID-19 Update: Governor DeWine Discusses State's Plan for Reopening Businesses, Regional Coalition Formed
- 04.14.2020 COVID-19 Update: Deferred Death Procedures, CURS for Payments, 1000 Unemployment Claims, First Responder PPE, Testing Partnership, Prison Update, Census 2020
- 04.14.2020 COVID-19 Update: Nursing Home Order, Liquor Sales, TANF Funding, Rapid Testing, Prison Update
- 04.14.2020 COVID-19 Update: Beach Medical Restrictions, N95 Sanitization, Dialysis, Mass Hand Sanitizer, Food Trucks at Restaurants, New Data Reporting
- 04.14.2020 COVID-19 Update: PPE Manufacturing, Convalescent Plasma
- 04.14.2020 COVID-19 Update: Continue Saying Home, Correction Officer Death, PPE Sanitization, Child Abuse Reports, Proposed \$1.6 Billion Dividend for Employers
- 04.14.2020 COVID-19 Update: Liquor Sales, Office of Small Business Relief, Ohio Prisons, \$200 Payments
- 04.14.2020 Sites Selected for Enhanced Hospital Capacity, OHG to Assist Federal Prisons, Dispute Resolution Commission Now Active
- 04.14.2020 Ohioans Encouraged to Wear Cloth Masks in Public, Governor Signs Telehealth 20, New WFTH Support Center
- 04.14.2020 COVID-19 Update: Testing Supplies, PPE Sanitizing, Inmate Release Recommendation, Remote Learning Guide
- 04.14.2020 Ohio Stay-at-Home Order Extended Through May 1
- 04.14.2020 COVID-19 Update: PPE Manufacturing, Testing Order, Click Connect, Face Closure Prevention
- 04.14.2020 Ohio Dept of Health Releases 33 Closed PPE from Strategic National Stockpile
- 04.14.2020 Ohio Releases Inventory of Ventilators, Issues Emergency Connection Order, Grants, Network Order
- 04.14.2020 Gov. DeWine Extends School Closure Order
- 04.14.2020 Ohio DDO Warns about Scam Phone Calls
- 04.14.2020 Governor Lt. Governor Thank FDU for Approval of Use of State's Technology
- 04.14.2020 Gov. DeWine Lt. Gov. Husted Express Disappointment in FDU's Decision to Limit Use of State's Technology
- 04.14.2020 Gov. DeWine Makes Plea to FDU, Releases Interim PPE
- 04.14.2020 Gov. DeWine Signs House Bill 197
- 04.14.2020 Gov. DeWine, Pres. Ohiohof Speaker Householder Announce Reopening of State of the State Address
- 04.14.2020 Personal Protective Equipment Headed New COVID-19 Data Dashboard Unleashed
- 04.14.2020 Gov. DeWine's Statement on House Bill 197
- 04.14.2020 Gov. DeWine Orders Giving Peace to State Agencies, Boards and Commissions
- 04.14.2020 Ohio Issues "Stay at Home" Order: New Restrictions Placed on Child Daycares
- 04.14.2020 Adult Day Services to Close, WIC Payments Deferred, Trucking Walkers Issued
- 04.14.2020 Governor Lt. Governor Statements Honoring Sen. Ray, Dan Manning
- 04.14.2020 Ohio Records First COVID-19 Death, Senior Centers, Adult Day Care to Close
- 04.14.2020 Applications Being Accepted for Economic Injury Disaster Loan Program, DeWine Signs Order Expanding Telehealth Services for Medical Providers
- 04.14.2020 (S&N) (S&N) Offers Disaster Assistance to Ohio Small Businesses Economically Impacted by COVID-19
- 04.14.2020 (S&N) (Spanish) La S&N ofrece asistencia en caso de desastre a las pequeñas empresas de Ohio afectadas económicamente por el COVID-19
- 04.14.2020 Joint Statement from Gov. DeWine and Secretary LaRose (7:54 pm)
- 04.14.2020 Death Surgeries Resumed in Ohio Hospitals (7:09 pm)
- 04.14.2020 Ohio Dept of Health Issues Order on Closure of Polling Locations (11 pm)
- 04.14.2020 Statement from Ohio Governor Mike DeWine on 14 March 17 Section (10:09 pm)
- 04.14.2020 Joint Statement from Gov. DeWine and Secretary LaRose on Ohio Primary (8:04 pm)
- 04.14.2020 DDO News Release: State Orders Bars, Restaurants Closed during Outbreak
- 04.14.2020 Gov. News Release: Business, Community Leaders Praise Efforts to Slow Spread of COVID-19
- 04.14.2020 Gov. DeWine Orders Ohio Bars & Restaurants to Close
- 04.14.2020 Gov. DeWine Provides COVID-19 Update
- 04.14.2020 Ohio Bars Mass Gatherings of 50 or More
- 04.14.2020 Gov. DeWine Announces School Closures
- 04.14.2020 Gov. DeWine Announces Fourth Confirmed COVID-19 Case, Units Access to Nursing Homes, Isolated Living Facilities
- 04.14.2020 Gov. DeWine Recommends Limiting Large Indoor Gatherings
- 04.14.2020 Gov. DeWine Signs Emergency Order Regarding Coronavirus Response

Attachment H

Open letter advocating for an anti-racist public health response to demonstrations against systemic injustice occurring during the COVID-19 pandemic

On April 30, heavily armed and predominantly white protesters entered the State Capitol building in Lansing, Michigan, protesting stay-home orders and calls for widespread public masking to prevent the spread of COVID-19. Infectious disease physicians and public health officials publicly condemned these actions and privately mourned the widening rift between leaders in science and a subset of the communities that they serve. As of May 30, we are witnessing continuing demonstrations in response to ongoing, pervasive, and lethal institutional racism set off by the killings of George Floyd and Breonna Taylor, among many other Black lives taken by police. A public health response to these demonstrations is also warranted, but this message must be wholly different from the response to white protesters resisting stay-home orders. Infectious disease and public health narratives adjacent to demonstrations against racism must be consciously anti-racist, and infectious disease experts must be clear and consistent in prioritizing an anti-racist message.

White supremacy is a lethal public health issue that predates and contributes to COVID-19. Black people are twice as likely to be killed by police compared to white people, but the effects of racism are far more pervasive. Black people suffer from dramatic health disparities in life expectancy, maternal and infant mortality, chronic medical conditions, and outcomes from acute illnesses like myocardial infarction and sepsis. Biological determinants are insufficient to explain these disparities. They result from long-standing systems of oppression and bias which have subjected people of color to discrimination in the healthcare setting, decreased access to medical care and healthy food, unsafe working conditions, mass incarceration, exposure to pollution and noise, and the toxic effects of stress. Black people are also more likely to develop COVID-19. Black people with COVID-19 are diagnosed later in the disease course and have a higher rate of hospitalization, mechanical ventilation, and death. COVID-19 among Black patients is yet another lethal manifestation of white supremacy. In addressing demonstrations against white supremacy, our first statement must be one of unwavering support for those who would dismantle, uproot, or reform racist institutions.

Staying at home, social distancing, and public masking are effective at minimizing the spread of COVID-19. To the extent possible, we support the application of these public health best practices during demonstrations that call attention to the pervasive lethal force of white supremacy. However, as public health advocates, we do not condemn these gatherings as risky for COVID-19 transmission. We support them as vital to the national public health and to the threatened health specifically of Black people in the United States. We can show that support by facilitating safest protesting practices without detracting from demonstrators' ability to gather and demand change. This should not be confused with a permissive stance on all gatherings, particularly protests against stay-home orders. Those actions not only oppose public health interventions, but are also rooted in white nationalism and run contrary to respect for Black lives. **Protests against systemic racism, which fosters the disproportionate burden of COVID-19 on Black communities and also perpetuates police violence, must be supported.**

Therefore, we propose the following guidance to support public health:

- Support local and state governments in upholding the right to protest and allow protesters to gather.
- Do not disband protests under the guise of maintaining public health for COVID-19 restrictions.

- Advocate that protesters not be arrested or held in confined spaces, including jails or police vans, which are some of the highest-risk areas for COVID-19 transmission.
- Oppose any use of tear gas, smoke, or other respiratory irritants, which could increase risk for COVID-19 by making the respiratory tract more susceptible to infection, exacerbating existing inflammation, and inducing coughing.
- Demand that law enforcement officials also respect infection prevention recommendations by maintaining distance from protesters and wearing masks.
- Reject messaging that face coverings are motivated by concealment and instead celebrate face coverings as protective of the public's health in the context of COVID-19.
- Prepare for an increased number of infections in the days following a protest. Provide increased access to testing and care for people in the affected communities, *especially* when they or their family members put themselves at risk by attending protests.
- Support the health of protesters by encouraging the following:
 - Use of face coverings.
 - Distance of at least 6 feet between protesters, where possible.
 - Demonstrating consistently alongside close contacts and moving together as a group, rather than extensively intermingling with multiple groups.
 - Staying at home when sick, and using other platforms to oppose racism for high-risk individuals, and those unable or uncomfortable to attend in person.
 -
- Encourage allies who may wish to facilitate safe demonstrations through the following:
 - Providing masks, hand-washing stations, or hand sanitizer to demonstrators.
 - Providing eye protection, such as face shields or goggles, for protection against COVID-19 and chemical irritants used to disperse crowds.
 - Bringing wrapped, single-serving food or beverages to sustain people protesting.
 - Providing chalk markings or other designations to encourage appropriate distancing between protesters.
 - Supplying ropes, which can be knotted at 6-foot intervals, to allow people to march together while maintaining spacing.
 - Donating to bail funds for protesters
- Listen, and prioritize the needs of Black people as expressed by Black voices.

These are strategies for harm reduction. It is our sincere hope that all participants will be able to follow these suggestions for safer public demonstrations, assisted by allies where possible and necessary, but we recognize that this may not always be the case. Even so, we continue to support demonstrators who are tackling the paramount public health problem of pervasive racism. We express solidarity and gratitude toward demonstrators who have already taken on enormous personal risk to advocate for their own health, the health of their communities, and the public health of the United States. We pledge our services as allies who share this goal.

This letter is signed by 1,288 public health professionals, infectious diseases professionals, and community stakeholders.

Aaron Greiner
 Aaron Laviana, MD, MBA_Vanderbilt University Medical Center
 Aaron W Stewart, MS4 UWSOM
 Abharika Sapru, WSU medical student
 Abigail Cartus MPH, University of Pittsburgh Graduate School of Public Health
 Abigail Lee, MPH, The University of Iowa
 Abir Hussein, M.D Infectious Disease Fellow, University of Washington
 Abraham Rice
 Activist
 Adam Cohen
 Adam Tapley, MD, Cambridge Health Alliance, Mass.
 Adam Whalen, MPH Candidate in Epidemiology at Columbia University Mailman School of Public Health
 Aditya S Khanna, PhD. The University of Chicago
 Adriana Dail
 Adriele Fugal
 Adrienne Jones - African American
 Adrienne Shapiro, MD, PhD, Depts. of Global Health and Medicine, University of Washington
 Adrienne Williams
 Agata Bereznicka, MPH Candidate, Boston University
 Agnes Graves MD
 Aileen Navarrete, BUSPH
 Akash Virupakshaiah, CHOP
 Alaina DeKerlegand, Infectious Diseases Pharmacist
 Alan Shu, University of Washington School of Medicine
 Alena Markmann, University of North Carolina
 Alex Junker, Columbia University
 Alexa Pohl MD PhD
 Alexander Lankowski, MD (University of Washington)
 Alexander Tsai, Massachusetts General Hospital
 Alexander Wamboldt, PhD Inside Out Youth Services Manager of Prevention programs
 Alexandra Blair, Postdoctoral Fellow, University of Toronto
 Alexandra Phelan, Georgetown University
 Alexandra Regan, Boston University School of Public Health
 Alexandria Griffin, MPH Candidate UNC Gillings School of Global Public Health
 Alexandria Kragie, MD
 Alexia Rodriguez, MPH
 Alexis Handal, University of Michigan
 Alexis Kushner
 Ali Khan, MD, MPP, Oak Street Health
 Alic Shook, RN, PhD, University of Washington
 Alice Lee
 Alice Murnen, BSN, RN
 Alice Richter Lee
 Alice Williams
 Alicia Burns, University of Washington School of Medicine, MS3
 Alicia Callejo-Black
 Alicia RN, MN
 Alina Kung, MD MS, PGY-1 in Internal Medicine at UCLA
 Alina Schnake-Mahl ScD MPH, Cityblock health
 Alisa Jion Kim, University of Washington medical student
 Alison Roxby MD
 Alison Simmons, University of Toronto
 Alistair Brian Russell, Assistant Professor, UCSD
 Alix Ginsberg, MPH
 Allison Agwu MD ScM (Infectious Diseases Physician, Johns Hopkins University School of Medicine, Baltimore, MD USA)
 Allison Cammisa, medical student at the Frank H. Netter School of Medicine at Quinnipiac University
 Alpha Shrestha, MPH student, UNC Chapel Hill
 Althea M. Hamilton, MD
 Alyssa M. Thomas, Colorado School of Public Health
 Alyssa Patterson, MPH
 Alyssa R. Letourneau, MD, MPH / Mass General Hospital and Harvard Medical School, Boston, MA
 Alyssa Valentine, Master of Public Health Colorado School of Public Health, August 2020 (expected)
 Alysse Wurcel MD
 Amanda Carnes, Family Medicine Physician
 Amanda L., MPH
 Amanda Oropeza, MD
 Amanda Santander, MPH
 Amanda Sekijima, University of Washington School of Medicine
 Amanda Snow, Boston University School of Medicine
 Amber Akemi Piatt, MPH
 Amber Gipson, MPH, Albert Einstein College of Medicine
 Amber Streifel
 Amelia Gifford, Occupational Epidemiologist
 Amelia Knopf, Assistant Professor of Nursing, Indiana University
 Amelia Ziegler
 Amin Bemanian, MD, PhD
 Amina Saqib
 Amisha Parekh de Campos, Middlesex Hospice Homecare
 Amy Baugher, MPH - Epidemiologist
 Amy Blom
 Amy Hamilton
 Amy Pasternack MD, Cambridge Health Alliance
 Ana Weil Acting Assistant Professor
 André Blackman, Founder/CEO Onboard Health
 Andrea Rose Molino, Epidemiologist, Johns Hopkins Bloomberg School of Public Health
 Andreina Orozco
 Andrew Bossick
 Andrew Dey, Public Health Student and Volunteer
 Andrew Finsness
 Andrew H
 Andrew Peace, MD
 Angela Alonzo
 Angela Bengtson
 Angela Budgin University of Colorado
 Angela Song, MD/MPH candidate, Perelman School of Medicine
 Angela Ulrich, PhD MPH Epidemiology Research Fellow, University of Minnesota
 Angela Venegas
 Angela Zhou, Cornell University

Aniruddha Hazra, MD; Assistant Professor; University of Chicago

Anjali Sharma MD, MS Montefiore Medical Center, Bronx NY

Anjani Kolahi, MD UC Irvine Family Medicine

Ann Duerr, MD, PhD, MPH

Ann Kim MD San Francisco department of public health, Redeemer community church

Ann-Claude Rakotoniaina, epidemiology research assistant

Anna Bauer, PhD, University of North Carolina at Chapel Hill

Anna Bianchi - Medical Student

Anna Caudill, incoming MPH class of 2022

Anna Chataginer

Anna Darby, MD/MPH, emergency medicine physician, LAC + USC

Anna Marie Rondon, Dineh Nation, INDIGENOUS Public Health Advocate

Anna Stanley Lee

Anna Warren

Anna Zulema Pollack PhD, MPH, George Mason University

Annabel Consilvio

Anne Boustead, University of Arizona

Anne Marie Darling, PhD

Anne Steele

Anne Whiteside, MSN

Anonymous

Anonymous JD

Anthony Pho, MSN, MPH, ANP-C

Antoinette Sarge, MPH, University of Washington in Seattle

Antonia Beacham, Human

Anupam Somashekar, MD PGY-3 UMMC

Anurag Malani, MD Ann Arbor, MI

April Kaur Randhawa PhD, Fred Hutch, Seattle WA

April Pettit, MD, MPH, Vanderbilt University Medical Center

April Soto MD

April Yang - Lawyer; precious Legal Fellow at USC's Institute on Inequalities in Global Health

Arasi Adkins

Arbor Quist, UNC-Chapel Hill Epidemiology PhD Candidate

Ariana Piacquadio

Ariana Thompson-Lastad, Postdoctoral Fellow, UC San Francisco

Ariane Morrison, UNC Infectious Diseases

Ariel Frey-Vogel, MD, MAT

Arjun Sarkar, M3, Northwestern University Feinberg School of Medicine

Arno Uvin

Art Therapist

Asa Tapley MD MSc (UW School of Medicine)

Ashford Jackson

Ashish D. Parikh, MD, Summit Medical Group

Ashlee Van Schyndel, MPH - University of Illinois-Chicago

Ashley Lara & BUSPH

Ashley Lynes, MS4, UWSOM

Ashley Sand

Ashly Westrick PhD

Ashlyn Lipnicky, University of Kansas

Ashrit Multani, UCLA Health

Asmith Joseph, MPH, MA

Assistant Professor (University of South Florida, Tampa)

Assistant professor LSUHSC

Athena Hsu, University of California - San Diego School of Medicine

Aubrey Hays

Audrey C Cooper

Aumna Iqbal

Austeja Subaciute

Austin Frost

Austin O. Sweat

Axie Acosta, UC Davis Health

Ayden Scheim, PhD, Drexel Dornsife School of Public Health

Ayesha Godil, MPH student, Columbia University Mailman School of Public Health

Ayesha Maharaj MPH BHSc

Başak Çoruh, MD, University of Washington

Beatrice Chen MD MPH, University of Pittsburgh

Benjamin Barrett, ScM

Benjamin S. Avner, MD

Benjamin Snyder, MD/PhD Student, Boston University

Benjamin Todd

Benjamin W Sanders, M.D. M.S.P.H., Pediatrician, Portland, Oregon

Bernadette Venkataraman

Beth Kassler, teacher

Beth Linas, PhD, MHS, Infectious Disease Epidemiologist

Beth Sobba MS4 UWSOM

Betsy Zucker, FNP, nurse practitioner

Betyna Berice

Bikere Ikoba, Master of Public Health student at the University of Iowa

Billie Henry

Bioinformatics Research Fellow, University of Birmingham (UK)

Birgit Brander Rasmussen, Binghamton University-SUNY

Black female that's tired, USAF vet

Black Public Health Researcher/Epidemiologist

Blake Busey

Bohan Xing

Bomi Framroze, Menlo Park, California

Bonnie Snyder, MS1, UWSOM

Bradley Dreifuss, MD FACEP, University of Arizona Colleges of Medicine and Public Health; Arizona College of Emergency Physicians

Braveen Ragunathan

Bree-Ann Owens

Brendan Eappen, medical student, Harvard Medical School

Brendan Pulsifer, Bowdoin College

Brennah Fallon, MPH Candidate, Columbia University Mailman School of Public Health

Brett Jesse

Brian Boursiquot, NYP/Columbia University Medical Center

Brian Cockman

Brian P. Foran, Boston Medical Center, Boston University

Brian Rahmer, PhD, MS

Brian Steely, SLP, CCC, retired educator

Brianna J Scott

Brigid Cakouros, DrPH

Brinn Culver PMHNP
 Brittany Bergam, UWSOM Student
 Brittany Bishop - University of Washington
 Brittany Catucci
 Brittany Gorden, PharmD, BCPS
 Brooke Gallagher - Colorado School of Public Health
 Brooke Spencer, Ragon Institute of Harvard, MGH, and MIT
 BUSM M3 Students
 BVS, Resident
 Byanqa Robinson, RN UCSF Medical Center
 C. Martin Beck, RN
 Caitlin Williams, Gillings School of Global Public Health, UNC
 Chapel Hill
 Caitlyn Nystedt, MPH
 Caleb LoSchiavo, MPH - Rutgers School of Public Health
 Calli Dolloff
 Cameron Bader
 Cameron Nutt, MD (Brigham & Women's Hospital, Boston MA)
 Camille Clefton, MD
 Cara Coogan
 Cara E Saxon, MD (University of Colorado School of Medicine)
 Cara Pennel, DrPH, MPH
 Cardiovascular Researcher
 Caredwen Foley, MPH Student, BU School of Public Health
 Caren Solomon, MD, MPH, Brigham and Women's Hospital
 Carey Farquhar
 Carly Nichols, PhD, Global Health Studies, University of Iowa,
 Carmen Kloer, medical student
 Carmen Yip
 Carmi Orenstein, MPH
 Carole Capper, retired teacher
 Carolina Downie
 Caroline M. Flessa, MPH BUSPH '20
 Caroline McGowan
 Caroline Todd
 Casey Reynolds, RN
 Cassandra Trickett, Aclima Inc.
 Catherine Bisignano MPH, University of Washington
 Catherine R Lucey Executive Vice Dean, UCSF School of
 Medicine
 Catherine Romberger, MPH
 Catherine Voluz, Student
 Catherine Wolff
 Cecilia Culp - Health Equity Policy and Program Analyst
 Celia Wright
 Cerise Brown
 Cesar Lopez, MD-PhD Student at UNC Chapel Hill
 Chandana Golla, UTSW MD/MPH Student '24
 Chang, MD
 Charlene Saulnier FNP-BC
 Charlie Roscoe, Harvard School of Public Health
 Charlotte Cathcart
 Charlotte Marshall, MPH
 Charmaine Lastimoso
 Che Richardson Jung, RN, BSN
 Chelsea Backer, DO
 Chelsea Jones - Senior Medical Student
 Chelsea Lennox, MPH
 Chelsea Marcus
 Chelsey M. Mackenzie, BSN, RN, Birth Doula
 Chemaine Leon
 Cherise Rohr-Allegrini, PhD, MPH, Rohr Consulting.
 Cheryl Dietrich, MPH
 Chrissie Marshall, Gallaudet University
 Chrissy Chard, PhD
 Christian B. Ramers, MD, MPH
 Christian Testa, Statistical Analyst, Harvard School of Public
 Health
 Christina Casas MD
 Christina Chung
 Christina Delnero
 Christine D
 Christine Gwillim, University of Texas
 Christine Johnston, MD, MPH, University of Washington
 Christine Kerr, MD,AAHIVS
 Christopher Harding
 Christopher Lyons, Boston University School of Medicine Class
 of 2023
 Christopher p. Paramedic
 Chrystal Okonta, MSPH, CHES
 Cinthia Leon Lazcano, Public Health Student
 Claire Ogburn
 Claire Richards, PhD, RN
 Claire Rothschild, PhD Candidate, University of Washington
 School of Public Health
 Clara Martin, MPH
 Clare Evans, Assistant Professor, Department of Sociology,
 University of Oregon
 Clark Santee, MD
 Claudia Finkelstein MD Michigan State University
 Colby Sato, Twitter
 Colin Bartz-Overman, Medical Student, University of
 Washington School of Medicine
 Colleen Buckley
 Colleen Kelley MD, MPH, Associate Professor of Medicine,
 Emory University School of Medicine
 Corinne Wiesner, PhD Candidate UNC-Chapel Hill Gillings
 SGPH
 Courtney De La Mater, MPH
 Cressida Madigan
 Cris Craig, retired Manager, Health information Resources,
 Kitsap Public Health
 Crisis and Harm Reduction Specialist
 Crystal Childress
 Cynthia Gay University of North Carolina at Chapel Hill
 D'Aviance M. Harris — Birmingham, AL
 Dan Vekhter, Seton Hall University School of Medicine
 Dana Nordenstrom, MPH
 Dana Paycao, MPH, UCLA
 Daniel Becker, Indiana University
 Daniel Goldstein, Umass Amherst
 Daniel Leung, MD, University of Utah
 Daniel Low
 Daniel Winetsky, MD, Columbia University
 Daniela Coronado, James Madison University
 Daniella Mendoza

Danielle Bloch, MPH
 Danielle Desrosiers
 Danielle Lafond, BUSM
 Danielle McCarty RN
 Danielle Rome MD, NYP-Columbia
 Danielle Zerr, MD, MPH UW/Seattle Children's
 Danniell Zamora, Infectious Diseases, University of Washington
 Daphne Schneider MD, Cambridge Health Alliance
 Darcy Rao, University of Washington
 Darragh Kerr, MPH, University of Washington
 Daryl Nault
 Dashawna Fussell-Ware, MSW, University of Pittsburgh
 Data analyst, New York City Department of Health and Mental Hygiene
 David Charles Mallinson, University of Wisconsin-Madison
 David de Gijzel, MD. Infectious Disease and Addiction Medicine.
 David Joseph Koesters - unaffiliated
 David M. Aronoff, MD, FIDSA, FAAM
 David P. Eisenman, MD MSHS, David Geffen School of Medicine at UCLA, Fielding UCLA School of Public Health
 David Swedler, PhD MPH
 David van Duin, university of North Carolina
 Dawn Fishbein, MD, MedStar Health Research Institute
 DeAnn Rice RN
 Deborah Sarson
 Debra Williams
 Deidre Alessio NP Cambridge Health Alliance
 Delia Pinto Santini, Afrolatina Scientist
 Denise McCulloch, MD, MPH, Infectious Diseases Fellow, University of Washington
 Dental Student
 Derek Prince, UWSOM
 Deryn Isaac
 Devang Amin, Internal Medicine Resident
 Devin English, PhD - Rutgers School of Public Health
 Devin Perez
 Dhruvi Chauhan, MPH Candidate '21, Columbia University, New York, NY
 Diana A
 Diana M. Tordoff, MPH, PhDc, University of Washington, Department of Epidemiology
 Diana Nguyen
 Diana Schlotterbeck
 Diane Kanjilal, RN Beth Israel Deaconess Medical Center
 Dimiter zlatkov
 Divya Prajapati, UCSD
 Divya Subramanian
 Doctor
 Dominic Facciponte
 Dominika Seblova, postdoctoral research fellow Columbia University
 Dominique Cantave, Harvard University
 Dominique Heinke, Epidemiologist
 Donna J. Curtis, MD, MPH, Pediatric Infectious Disease Specialist
 Dr Lee Pfaff
 Dr Miqdad Asaria, Department of Health Policy, London School of Economics and Political Science
 Dr Nicole Christian Brathwaite, MD
 Dr Summaya Zulfiqar, EM
 Dr Swati Chavda, Resident University of Calgary
 Dr. Alex Moulton - Harbor UCLA
 Dr. Andrea d'Aquino, Stanford
 Dr. Ayesha Appa, UCSF
 Dr. Dodie Arnold, CEO Arnold CR
 Dr. Hilary Michel MD
 Dr. Kate Sullenberger — Veterinarian
 Dr. Katherine Muldoon
 Dr. Megan L. Srinivas, University of North Carolina
 Dr. Nahal Nikroo
 Dr. Natalie Marshall, Clinical Microbiology Fellow, PhD in Microbiology & Immunology
 Dr. Sarah Sanders, Cambridge Health Alliance
 Dr. Sheldon Francis, Delaware Veterans Cemetery
 Duane R. Taylor
 Dylan Bickers, former USAF Public Health Technician and Community Health NCOIC
 Earl Adsley
 Ebony Hilton MD
 Edberg Deborah
 Edward Courchaine, PhD
 Eileen Li, University of Washington School of Medicine
 Ekene Nwoye
 Elana Tan MD, Tristar Horizon Medical Center
 Eleanor Murray, Boston University School of Public Health
 Elena Diskin - Virginia Department of Health Epidemiologist
 Elena Hernandez, MPH Candidate at UCLA Fielding School of Public Health
 Elisa Cheng, MD, Clinical Instructor, Cambridge Health Alliance /
 Elisa Pasqual MD PhD (Spain/Italy)
 Elise Moore, ASTHO
 Eliza P Shulman, DO, MPH
 Eliza Pelrine, MD
 Elizabeth Adler, MD
 Elizabeth Ahlers, PsyD
 Elizabeth Christian, MD, Infectious Disease fellow
 Elizabeth Epstein-Tracy
 Elizabeth Gulleen, Research Associate Fred Hutchinson Cancer Research Center
 Elizabeth Hirsch, University of Minnesota
 Elizabeth Jacobs
 Elizabeth Kamai, MSPH; Gillings School of Global Public Health, UNC Chapel Hill
 Elizabeth Lalasz, RN, National Nurses United
 Elizabeth Larson, MPH Candidate
 Elizabeth Morris, Colorado School of Public Health
 Elizabeth Pinsky, MD, Massachusetts General Hospital
 Elizabeth Traub, MPH -- Infectious Disease Epidemiologist
 Ellen Kettler, MS4 at UC San Diego School of Medicine
 Ellen Walker
 Ellie Gladstone, JD, MPH, Public Health Institute, Oakland, CA
 Ellie Grossman MD MPH, Harvard Medical School / Cambridge Health Alliance

Ellie Joo
 Elspeth Fullerton, MS1, University of Washington School of Medicine
 Elspeth Nolen, University of Washington School of Public Health
 Elvira Aronzon
 Emilia Hermann, MD MPH - Montefiore Primary Care and Social Internal Medicine
 Emily A Kendall MD PhD, Johns Hopkins
 Emily Beaudin
 Emily Begnel, MPH - University of Washington
 Emily Boes, MD
 Emily Ciccone, Infectious Diseases Fellow, University of North Carolina at Chapel Hill
 Emily Deichsel, University of Maryland, Baltimore
 Emily DeVoto, PhD, MSPH, epidemiologist
 Emily Fleckenstein
 Emily Gemmell, MPH PhD Student, University of British Columbia
 Emily Herscher
 Emily Malavenda, MD (Cambridge Health Alliance)
 Emily Merchant
 Emily Muller, MS3
 Emily Scott, MD/MPH, University of Colorado
 Emily Sousa, PNP, MPH
 Emily Thorn, Medical Student
 Emily Wong, MD, Africa Health Research Institute and Massachusetts General Hospital
 Emma Ciersk, PHE graduate
 Emma Clark, Public Health Advisor
 Emma Glennon, University of Cambridge
 Emma Kersey, Columbia University Mailman School of Public Health
 Emma Mulligan, BUSM Class of 2022
 Epidemiologist, Centers for Disease Control & Prevention
 Epidemiologist, NIH
 Epidemiologist, Regional Government, Canada
 Eric Hausmann
 Eric Rohr
 Eric Stulberg, University of Utah
 Erica Bass, MD PGY3 Internal Medicine at UCSF
 Erica Chavis, Clinical Specialist Pharmacist
 Erica Lokken, PhD - University of Washington
 Erin Duncan MD MPH
 Erin Flattery, Resident Physician, NYP-Columbia
 Erin Hsu, MD, Infectious Diseases Doctor
 Erin J Aiello Bowles, MPH, Kaiser Permanente Washington Health Research Institute
 Erin James, postdoctoral associate Yale University
 Erin L. Abner, PhD, MPH; Associate Professor of Epidemiology at University of Kentucky
 Erin Mordecai, Assistant Professor, Stanford University
 Erin Philpott, DO
 Ernie-Paul Barrette, MD, Washington University
 Esther Ofei-Asamani, Mphil, MPH, School of Governance
 Gimpa -Ghana
 Ethel Yang, MBA/MPH
 Eva Stein, MD; University of Colorado School of Medicine
 Evan L. Eschliman, Johns Hopkins School of Public Health
 Ezza Khan, MD Hunterdon Medical Center
 Faisal Tan, BUSM
 Faith Price, Community Prevention Coordinator and WSU Doctoral Student in Prevention Science
 Faith Williams
 Family medicine physician, Cambridge health alliance
 Family Medicine resident, University of Nebraska Medical Center
 Fanghua Lou
 Fanny Gonzalez
 Farley R Cleghorn MD MPH, Palladium
 Fatima Al Dhaheri, MD. Infectious disease fellow
 Fausto Gonzalez torres
 Felipe Findley
 Fiorella Guido, MS3, Upstate University
 Flynne Lewis, pediatrician CCHS
 Former Probation Officer
 Frances Oakes
 Francesca Golightly, Boston University School of Public Health
 Frederick L. Altice, M.D., Yale University
 Gabriel Benavidez, PhD student in epidemiology @ The University of South Carolina
 Gabriela Alcalde
 Gabriela Velazquez
 Gabriella Page-Fort
 Gabriella Vargas, University of Virginia
 Gabrielle Chamoun, Medical Student
 Gabrielle Pollack, MS1
 Gail R. Hansen, Hansen Consults
 Gallaudet University Student
 Genevieve Boland
 Genna Braverman
 Genya Shimkin, MPH, University of Washington Department of Family Medicine
 George A. Alba, MD; Massachusetts General Hospital, Harvard Medical School
 George Mekeel RN
 Gerard Coste, MD Cambridge Health Alliance
 Geri Medina, MPH candidate at Boston University School of Public Health
 Ghadeer Hasan RUTGERS RWJMS
 Gillian Isabella Hollerich
 Gillian Tarr, Environmental Health Sciences, School of Public Health, University of Minnesota
 Ginger Johnston, Pastor
 Glenn Stevens
 Grace Mulholland, MSPH, University of North Carolina at Chapel Hill
 Graham Mooney, Johns Hopkins University
 Gregg Gonsalves, Yale School of Public Health
 Gretchen Snoeyenbos Newman
 H. Hunter Handsfield, MD, Professor Emeritus, University of Washington
 Hailey Boudreau
 Hailey Wyatt
 Hala Benmoussa
 Haley Burdge, Upstate College of Medicine student

Hamsa Subramaniam, Doctoral candidate - Department of Epidemiology, UNC-Chapel Hill
Hannah Breakstone, Alumna
Hannah Godlove, NYC Hospital Public Health Advisor
Hannah H Leslie, Harvard TH Chan School of Public Health
Hannah Hall
Hannah Lampert, MS4, University of Washington School of Medicine
Hannah Nam, Northwestern Memorial Hospital
Hannah Newman, MPH, CIC Manager of Epidemiology & Infection Prevention, Lenox Hill Hospital, New York City
Hannah VanBenschoten, PhD Candidate, Department of Bioengineering, University of Washington
Harita Nyalakonda
Harry Hudome
Haya Jamali, University of Washington
Heather Currey, Seattle 500 Women Scientists
Heather Limper, PhD, MPH-Epidemiologist
Heather Martinez, DVM, MPH
Heather Molvik, UWSOM MS4
Hee Joo Ko
Heena Patel
Helen Cole, Universitat Autònoma de Barcelona
Hifzah Malik, Columbia Mailman
Hilary Godwin, PhD
Hilary M Babcock, MD, MPH; Washington University School of Medicine
Hillary Miller
Holly Scheider, MPH, Public Health Advocate
Honor Bixby, McGill University
Ida Shum
Ilana Schlesinger
Ilyssa Moore MD
Inaya Mofiz- College of William and Mary student
India Ornelas, University of Washington School of Public Health
Indira Case
Infectious Disease Physician, Atlanta, GA
Iris S. Delgado, MPH
Isabella Horning, MSN candidate
Ishani Patel, Gillings School of Global Public Health, UNC Chapel Hill
Iyah Romm
J TREES RITTER, DO, FIDSA
J.F.Gamez
Jace
Jacinda C Abdul-Mutakabbir PharmD, AAHIVP
Jacob Dexter-Meldrum
Jacob McNinch, University of Washington Medical Anthropology and Global Health student
Jacopo Leal Pacini
Jacqueline Benson Master of Public Health Candidate
Jacqueline Hodges, MD MPH, Rising Fellow, UVA Infectious Diseases
Jacqueline Johnson
Jacquelyn DeVries, medical student
Jade Baugh
Jade Pagkas-Bather, MD, MPH University of Chicago

Jaime M.
Jake A Kleinmahon, MD
Jamal, PhD. candidate
James Huynh, PhD Student, UCLA Fielding School of Public Health, Center for the Study of Racism, Social Justice, & Health
James P. Lyon, Penn State University
Jamie Rausch, Ph.D., RN
Jan M Risser, retired epidemiologist
Janet Soeprono, MD
Janice Verley MD
Janie Ginocchio, MPA
Jared Baeten, University of Washington
Jasmine Reyes
Jasmine Tomita-Barber
Jasnah Kholin, virologist, Hong Kong
Jaspal Singh Bassi, MD Candidate, UC Irvine
Jay Luthar MD - Cambridge Health Alliance (suggest providing protestors with an N95 and DIY face shields)
Jay White
Jayati Sharma
Jayce Pangilinan, MD
Jehan Budak, MD, University of Washington
Jen Balkus, PhD, MPH - Assistant Professor at the University of Washington School of Public Health
Jen Merk University of Washington School of Medicine MS1 (Spokane)
Jenna Holmen, MD, MPH (Infectious Disease)
Jenna Oelschlegel, MSW (Clinical Social Worker)
Jennifer Chang, MD, Kaiser Permanente at Los Angeles Medical Center
Jennifer Doran
Jennifer Jones, PharmD
Jennifer Schulte, Colorado School of Public Health
Jennifer Scott CNM MSN Licensed Midwife NY
Jennifer Velloza, PhD, MPH, University of Washington
Jennifer Weuve, Boston University School of Public Health
Jerina Carmona, Columbia University Mailman School of Public Health
Jessica Cataldi MD, Pediatric Infectious Diseases physician, Denver, CO
Jessica Ho, MPH, M1 at Columbia University
Jessica Long, PhD MPH, University of Washington
Jessica McMillin, NYMC SoM Medical Candidate
Jessica Mogk MPH
Jessica Plante MPH, Boston University
Jessica Ruff
Jessica Ruglis, PhD, MPH, MAT, Associate Professor, McGill University
Jessica Schmitt, LCSW - University of Chicago
Jessica Xiao, UCSD School of Medicine MS4
Jill Royle, MPH, PhD
Jillian Brelsford, RN CHA
Jim Recht, MD Cambridge Health Alliance/Harvard Medical School
Jimish Mehta
Joanna Schaenman, UCLA
Joanne Park, Student

Jodie Katon
 Joel Blankson MD, PhD Johns Hopkins Medicine
 John Kim MD, Cambridge Health Alliance
 John Lynch, MD, MPH University of Washington
 John Schneider, University of Chicago
 John Stephen Dumler
 Jolie LeBlanc, MD
 Jonathan Colasanti, MD, MSPH, Emory University
 Jonathan Golob. MD PhD
 Jonathan Malagon
 Jonathan Seaman, MD
 Jonathan Wu, D.O., M.P.H.
 Jordan Hoese, MD, MPH
 Jordan Kazakov
 Jorge Rivera-Gonzalez CSU MPH candidate
 Joseph C Gathe Jr MD FACP FIDSA
 Juan Acosta, Medical Student, Upstate Medical University
 Juan C
 Judith Feinberg MD West Virginia University
 Judith Portillo
 Judith Segall, MPH
 Judy Lubin, PhD, MPH, President, Center for Urban and Racial Equity
 Julia Dettinger
 Julia Durrant, MD, OHSU
 Julia Finn, Rollins school of public health
 Julia Marcus, PhD, MPH; Harvard Medical School
 Julia Morrison
 Julia Nash, BU
 Julia P Baker, DVM/PhD student, University of Minnesota, College of Veterinary Medicine
 Julia Raleigh - Medical Student, Upstate Medical University
 Julia Sung, MD, assistant professor of Infectious Diseases
 Julia Swanson (WSU Medical Student)
 Julia Velonjara, MPH; University of Washington
 Juliana Jacangelo
 Julie Baer
 Julie Chiu - JMU Alumna/Public Health Education Major
 Julie M. Petersen, MPH
 Julie Nguyen
 Julie Steinbrink, MD, Duke University
 Julie Vaishampayan, MD, MPH
 Justin Feldman, Assistant Professor, NYU School of Medicine
 Justin O'Hea Our Revolution NJ, HPAE
 Kacey Ernst, Associate Professor and Program Director Epidemiology- University of Arizona
 Kadedrah Parson
 Kaiser Valshon, MS4, UWSOM
 Kali Neil - Epidemiologist
 Kara Cicero MD MPH, Internal Medicine Resident, Rising Hematology/Oncology Fellow, NYP/Columbia
 Karen Bloch, MD MPH Vanderbilt University Medical Center
 Karen Chung, MS4, University of Washington School of Medicine
 Karen Daum
 Karen Fowler DrPH UAB Dept or Pediatrics
 Karen Gruen
 Karen MacDonell, Wayne State University
 Karim Khan, Boston Medical Center Infectious Diseases and Addiction Medicine
 Karina Calderon
 Karla Neugebauer PhD biochemist, Yale University
 Karolina Maciag MD/PhD, UW Infectious Disease Fellow
 Kate Gregory
 Kate Kim
 Kate Liefer, Public Health Nurse
 Kate Nolt
 Katharine Rifken, MS
 Katherine Claire Donfro
 Katherine Greenberg, BU School of Public Health
 Katherine LeMasters - UNC CH
 Katherine Muldoon
 Katherine Pavilonis
 Katherine Walton-Elliott
 Kathleen Tompkins, MD, Infectious Diseases Fellow, The University of North Carolina
 Kathryn Kimpel MS4
 Kathryn Macapagal, PhD, Research Assistant Professor, Northwestern University Feinberg School of Medicine
 Kathryn Schoenauer, UPenn MPH student
 Kathryn Staudinger, ESFCOM
 Katia Bruxvoort, PhD MPH, Kaiser Permanente Southern California
 Katie Judson, MPH Population Health Program Manager
 Katie McCann, MSW, MPH, LCSW
 Katie Shea Barrett
 Katie Witkiewitz, University of New Mexico
 Katrina Ortblad, ScD, MPH, University of Washington
 Kavya Magham
 Kayla Spence
 Kayla Williams, MS, MPH CSPH alumni
 Keely Dennis, MPH candidate, Mailman school of public health
 Keilah A. Jacques
 Kellcey Lesmerises Boston University
 Kelly Danckert, Boston University School of Public Health Student
 Kelly O'Shea, MPH University of Illinois at Chicago
 Kelly Storck, LCSW. Mental Health Therapist
 Kelsey Eccles RN
 Kelsey Murphey
 Ken Rothman
 Kenan Xiao, MD University of Nebraska Medical Center
 Kerri A. Thom, MD, MS, Professor of Epidemiology and Public Health, University of Maryland
 Kerry Dierberg, MD; Bellevue & NYU Hospitals, New York, NY
 Kevin Chung, MS4, University of Washington School of Medicine
 Kevin Downes, MD, Pediatric Infectious Diseases, Children's Hospital of Philadelphia
 Kevin Maloney MPH, Epidemiology PhD Student, Emory Rollins School of Public Health
 Kevin Vu
 Kiara Yoder
 Kieran Todd
 Kim N. June, advocate
 Kimberlee Rossi

Kimberly Baller
 Kimberly Murray RN
 Kira Newman, MD, PhD, University of Washington
 Kiran Salman, MPH Student, Columbia University Mailman School of Public Health
 Kitonga Kiminyo
 Kobina Amoah.
 Koen Tieskens, PhD, Researcher Boston University School of Public Health
 Korinna Straube M.S. Yale University
 Kris Ronsin, GH emergency consultant
 Kristel Hallsson, MS3, University of Washington School of Medicine
 Kristen Pogreba-Brown PhD MPH
 Kristin Andrejko, UC Berkeley School of Public Health Department of Epidemiology
 Kristin Sommerhalter, PhD
 Kristin Vahle, MPH
 Kristin Wunder, MPH, Bannon Consulting Services
 Kristine Madsen, UWSOM, MS4
 Kyle Horonzy
 Kyle Levinger
 Kylie ODonoghue
 L. Parker, BSN, RN
 Lai Wong CCRN: CPMC & UCSF
 Larissa Cruz, MPH
 LaToya Moseley
 Laura C
 Laura Cordova
 Laura Jacobson, MPH OHSU-PSU School of public health
 Laura Landrum
 Laura Marks MD, PhD, Washington University in St Louis
 Laura Marshall, BUSM '22
 Laura Rasmussen-Torvik, PhD MPH Northwestern University Feinberg School of Medicine
 Laura Richman Duke University
 Laura Titkemeyer
 Laura Vercammen, MPH, Boston University School of Public Health
 Lauren A Hittner, MD. Harvard Vanguard Medical Assc
 Lauren Ciszak, MD south end community health center
 Lauren Greenberg, MPH
 Lauren Guerra, Columbia Mailman SPH
 Lauren Lane
 Lauren Marcell, Medical Student at University of Washington
 Lauren McCullough
 Lauren Nguyen, UWSOM MS1
 Lauren Schaeffer
 Lauren Scott, RN
 Lauren Zalla, Department of Epidemiology, University of North Carolina at Chapel Hill
 Laurie Pulver, MD, MPH
 LaWanda Prestage
 Leah Harvey, MD, MPH. Boston Medical Center Infectious Disease
 Leah Hollander, Medical Student, BUSM
 Leah Yoke, University of Washington
 Leanne Berge, community health plan of Washington
 Lee McKoin, University of Washington School of Medicine, MS2
 Leigh Senderowicz, ScD MPH, University of Wisconsin-Madison
 Leila Roumani
 Lein Soltan, Gillings MPH student
 Leon I. Bender MD
 Leslie Frey, LCSW
 Leslie New, Washington State University Vancouver
 Leslie V. Farland, University of Arizona
 Lexie Awiszus
 Liana Bogran
 Lianne Dillon, Public Health Institute
 Lina Rosengren-Hovee, MD, MPH University of North Carolina Infectious Diseases
 Linda Oseso, MPH
 Lindsay P. Carter, Pediatric Hospital Medicine, Boston, MA
 Lindsey J. Butler, Boston University School of Public Health
 Lindsey Kelly, PA-C, Cambridge Health Alliance
 Lindsey M. Filiatreau
 Linh Huynh
 Lisa Callegari
 Lisa Glaskin
 Lisa L. Abuogi, MD,MSc Associate Professor University of Colorado, Denver
 Lisa M. Bodnar, PhD, University of Pittsburgh
 Lisa Suennen
 Lisle Winston MD, NewYork-Presbyterian/Columbia
 Liz K, RN
 Liz Kelly, MSPH, Project Manager, UNC Chapel Hill
 Liza Henry, MPH/MSW Student, University of Minnesota
 Liza Lutzker, UC Berkeley School of Public Health
 Lizzete Alvarado, California Department of Public Health
 Loraxia
 Lori M O'Grady, MSN, RN, APN, WHNP-BC
 Lorky Libaridian, MD (Cambridge Health Alliance, MA, Instructor in Medicine, Harvard Med School)
 Louis A Vontver MD MED
 Louisa Smith, PhD Candidate, Harvard T.H. Chan School of Public Health
 Lucy Brainerd, MPH
 Lucy Dong
 Luke Johnson, UWSOM Medical Student
 Luke Strnad, MD / Assistant professor of Medicine, Oregon Health and Sciences University
 Lydia Hartzell, MPH
 Lynette Phillips, Associate Professor of Epidemiology, Kent State College of Public Health
 M.O. social worker
 Madeleine Harnois - Legal Aid Attorney
 Madeleine Kane, medical student, UCSF-UC Berkeley Joint Medical Program
 Madeleine Witwer-Dukes, MPH
 Madeline DiLorenzo, MD
 Madeline Kaufman
 Madeline Lewis-Epidemiology
 Madeline Stewart, Medical Student, Boston University School of Medicine

Madison Thompson, CSU
 Magdalena Cerdá, NYU Grossman School of Medicine
 Maggie Collison, MD
 Mai Tuyet Pho, MD MPH, Section of Infectious Diseases and
 Global Health, University of Chicago
 Maisa Morrar, PA-C
 Maisha Davis
 Malkit K. Singh MD MPA
 Mallika Iyer, MS1, UW School of Medicine
 Mallory Harris, Stanford University PhD Student
 Mandavi Kulkarni, M.D.
 Manu Vikram Venkat MD, Columbia University
 Mara Abera
 Mara Hansen Staples, Impact for Health
 Marc Emerson, UNC-CH
 Marcia Luke-van Dijk, Avalon Housing
 Maren Batalden, MD MPH, Chief Quality Officer, Cambridge
 Health Alliance, Cambridge, MA
 Maret Maliniak, Emory University
 Margarita Triguero-Mas, PhD MPH; postdoctoral researcher at
 Barcelona Lab for Urban Environmental Justice and
 Sustainability (BCNUEJ), Hospital del Mar Medical Research
 Institute (IMIM); Institute for Environmental Science and
 Technology - Universitat Autònoma de Barcelona (ICTA-UAB)
 Margot Hedlin, MD
 Mari Kitahata MD, MPH Professor University of Washington
 Maria G. Lozano-Diaz RN, CNM MS
 Maria Gomez
 Maria Montes Arvizu, Undergrad at University of California,
 San Diego
 Maria Pyra, University of Chicago
 Maria Terra, Nurse Practitioner, Cambridge Health Alliance
 Marie Finkbeiner, University of Washington MS3
 Marie Stoner
 Marielle Bugayong, Johns Hopkins Bloomberg School of Public
 Health
 Mariko Cantley
 Mariko K Wong, MD Cambridge Health Alliance, Harvard
 Medical School
 Marilena Caldarusa
 Marin Mazeres, BUSM class of 2023
 Marisol Jimenez, Tepeyac Consultinh
 Marisol Valenzuela-Lara, MD/MPH PhD in Epidemiology
 student at Emory University
 Marissa Miller, PA-C
 Mark A Swancutt, MD, PhD, DTM&H, Fulton County Board of
 Health, Atlanta
 Mark ODonnell
 Marlee Fischer, MPH
 Marley Williams, Health Equity Manager, Public Health Alliance
 Martha Kaufman, retired health professional
 Martin Kuchar
 Marwan Haddad MD MPH
 Mary Burgess UAMS
 Mary Mathison, MS1, UWSOM Seattle campus
 Mary Montgomery MD, Brigham and Women's Hospital
 Mary Noble MD, Clinical Associate Professor, University of
 Washington School of Medicine
 Matthew C Hall
 Matthew Fox, Boston University
 Matthew J Kuehnert, MD
 Matthew Kronman, MD; University of Washington
 Matthew Stolman, Columbia University Mailman School of
 Public Health
 Maya Adler, MPH
 Maya J. Carter, MD
 McMahan, public health professional
 Meaghan Bransfield, BUSPH, BUSSW
 Medical Student
 Medical Student
 Medical Student, UC San Diego
 Meditating for Black Lives
 Meera Nagarsheth
 Megan C. Visotski, MS, PA-C
 Megan Davis - Boston University School of Medicine
 Megan Gaydos, MPH, Human Impact Partners
 Megan Jones
 Megan Jula, MPH
 Megan Lasure, MPH, Wisconsin State Laboratory of Hygiene
 Megan Pospisil, University of Iowa College of Public Health
 Graduate Student
 Megan Tusler, contingent faculty, U Chicago
 Megha L Mehrotra, University of California, Berkeley
 Megha Shah, MD MPH MS
 Meghan R. Shea, MPH, Epidemiologist, Columbus Public
 Health, Columbus Ohio
 Melanie A. Fisher MD - West Virginia University
 Melanie Brunt MD, MPH
 Melanie Langa, Medical Student University of Washington
 School of Medicine
 Melanie Martinsen
 Melanie Thompson MD, AIDS Research Consortium of Atlanta,
 Principal Investigator
 Melissa McPheeters, Vanderbilt University
 Melissa Milfort
 MELISSA VEGA, FHCSO
 Meltem Karatepe, M.D.
 Meredith Clement, MD, Louisiana State University Health
 Sciences Center, New Orleans, LA
 Merline Jacques
 Mia Haddad, MPH Candidate at Boston University School of
 Public Health
 Michael Maranda, Michigan (no affiliation)
 Michael Seibert, MD
 Michael T. Melia, MD - Johns Hopkins
 Michalina Montañó, University of Washington
 Michela Blain, MD, University of Washington
 Michele Andrasik PhD, Senior Staff Scientist, Vaccine and
 Infectious Disease Division, Fred Hutch and University of
 Washington
 Michelle Brescia
 Michelle Floris-Moore, MD, MS. Infectious Diseases physician
 and clinical investigator, UNC School of Medicine
 Michelle Moore, AGPCNP-BC, University of Chicago Medical
 Center, Section of Infectious Diseases & Global Health

Michelle R. Caunca, PhD, University of Miami Miller School of Medicine
Michelle R. Jacobs, Department of Sociology, Wayne State University
Michelle Rattinger
Michelle Stephens
Mike Dolan Fliss, PhD Epidemiology, MPS, MSW
Mike Hunt
Miko Robertson, RN
Milena Casamassima
Mili Parikh, UCSD School of Medicine
Miquelle Marin
Miranda Caggy
Mitchell Dumais, UWSOM
Mitchell Lee, Rollins School of Public Health
Moira Palumbo
Molly Levine, 4th Year Medical Student, University of Washington
Molly Miller-Petrie, University of Washington
Mona Rigaud, MD; MPH (Pediatric Infectious Dis)
Monica Gandhi, Professor of Medicine, UCSF
Monica Martinez, MPH
Monica Sierra, PhD. Epidemiology
Morgan Pothast
Morgan Warren
MPH grad- Yale School of Public Health
MPH, Tri-County Health Department
Mukta Baweja MD
N.K.
Nabiha Nuruzzaman, MPH (Columbia Public Health Alumni, Medical Student at Frank H Netter MD SOM)
Naeha Haridasa, The George Washington University School of Medicine and Health Sciences, Medical Student
Najla Aljaberi. Pediatric rheumatologist.
Nakul Vyas, Medical Student, Boston University School of Medicine
Namita Arunkumar, BUSM
Namita Raghavan, VCU SOM
Nancy Miles, MS1, UW School of Medicine
Nancy Skehan, MD
Nancy Warren, RTI International
Nandita Mani, MD, Infectious Diseases Fellow, University of Washington
Natalie Bowman
Natalie Foster
Natalie Mourra, Kaiser Permanente Los Angeles Medical Center
Natasha Hongsermeier-Graves, medical student at University of Nebraska Medical Center
Natasha Jhala, MPH (Columbia University)
Natasha Kumar, MD; Northwestern University
Natasha Sanchez, MPH candidate, Boston University
Nathalie Phillips, PA-C
Nathaniel Matthews-Trigg, MPH - Washington Physicians for Social Responsibility & Radical Public Health
Nellie Landon Kassebaum, CSU MPH Student
Nephrologist
Nicholas DesLauriers, University of Minnesota

Nicholas hansen
Nicholas Locke, MPH
Nicholas Van Wagoner
Nicholas Varunok MD MSc
Nicky Tettamanti, MPH Student at Mailman School of Public Health, Columbia University
Nicolas Cortes-Penfield, MD
Nicole Ayd Klein, Professor of Public Health, Southern Illinois University Edwardsville
Nicole Brescia (physician)
Nicole Iriarte, MPH candidate at the University of Virginia
Nicole Kester
Nicole Kitten, MPH Candidate, BUSPH
Nicole Oslance, medical student
Nicole Roselli, MD, MBA - Bellevue Hospital NYC
Nicole Theodoropoulos, MD, UMass Memorial Medical Center
Nicolette Slaughter
Niha Mamillapalli
Nikkiya M Fraser, MD; infectious disease specialist, Fort Wayne, IN
Nikolaos Mavrogiorgos, MD, University of North Carolina
Nina Nguyen
Nisha Puri-BUSPH student
Nita Bharti, Penn State University, Center for Infectious Disease Dynamics
Nitya Dhanaraj Cooper Medical School of Rowan University
Noah Segal, MPH, University of Iowa - College of Public Health
Noam Harris
Noelle Brescia
Nongnooch Poowanawittayakom
Nonprofit Program Manager
Northeastern Student
Nusheen Ameenuddin, MD, MOH, MPA, FAAP
Nyka Osteen, Public Health Practitioner
Occupational Therapist
Ofole Mgbako, MD ID Fellow, Columbia University Medical Center
Olivia Kates MD, Senior Fellow, Division of Allergy and Infectious Diseases, University of Washington
Olivia Teter
Pamela Knight
Pamela Koehler JD MPH
Pat Hollingsworth
Patricia Morton, PhD, Wayne State University
Paul Valente, Clinical Social Work
Paula Strassle, PhD, UNC School of Medicine
Pauline Kwong Bridgeman, M.D.
Pedro Gullón MD, PhD - Universidad de Alcalá
Penny Viater. Nurse Practitioner University of Chicago Medical Center
Peter Chin-Hong MD UCSF
Peter F. Bornstein, MD, MBA; St. Paul Infectious Disease Associates, Ltd.
Peter Young
Phanih Touch, MS3, University of Washington School of Medicine
Pharmacist

Phoebe Dembs, LMSW, SUNY Upstate
Physician
Physician assistant
Pooja Mehta MD MSHP, Cityblock Health
Pooja Patel, University of Michigan SPH
Prachi Priyam, MD, MPH
Pranatharthi Chandrasekar
Pranav Reddy, MD, MPA, Resident Physician, Yale School of
Medicine Department of Obstetrics and Gynecology
Pranav
Pratik Lakhani
Premal Patel
Price Nyland, Bowdoin College '20
Priest
Prithvi Addepalli, MHA
Priya Midha, MS (Clinical Epidemiology), PhD Student (Public
Health, Epidemiology concentration), Kent State University
Priya Raghavan, MD
Priyokti Rana, BUSPH
Psychologist
Public Health Advisor - CDC
Public Health Analyst
Public Health Expert
Public Health Officer/ Research
Public Health Official, Rhode Island
Public Health Professional - USC
Public Health Sanitarian
Punit Matta, BUSM
Queen Escalante, James Madison University Student
Qumber Ali - Medical Student
Quratulain Syed
Ra Amen
Raaka Kumbhakar, PGY3 IM Resident/rising ID fellow,
Columbia
Rachael Cohen, BS in Global Health Studies (Allegheny
College) MS Candidate* in Global Health (Georgetown
University)
Rachael Groh, MD Candidate, Netter SOM
Rachael Kfare
Rachana Tank, University of Glasgow
Rachel Bender Ignacio MD MPH, Assistant Professor of
Infectious Diseases, University of Washington
Rachel Berkowitz, DrPH, MPH - Postdoctoral Research Fellow,
University of California, Berkeley
Rachel Dutton, UCSD
Rachel Garcia, MPH
Rachel Hathaway, MD, Harvard Medical School
Rachel Ingraham
Rachel Nation, MPH
Rachel Rinehart, University of Washington School of Medicine
Rachel Scott MD/MPH
Rachel Silverman, PhD, ScM, Research Scientist, Virginia
Tech
Rachel Tao - Mailman School of Public Health student
Rachel Tsong, Columbia Mailman School of Public Health
Rachel Viqueira, Epidemiologist and Program Evaluator
Rachel Witt, MD
Radhika Dhingra, Professor, Gillings School of Public health,
University of North Carolina at Chapel Hill
Radhika Sharma, MPH Health Educator & NEIU Instructor
Raeven Clockston
Raj Panjabi, Assistant Professor, Harvard Medical School
Ramya Dronamraju MPH
Rana Shaheen
Rashmi Baragi
Ravi Kalhan, Professor of Medicine, Northwestern University,
Feinberg School of Medicine
Rebeca Huebner, MLS (ASCP), MPH
Rebecca Miller, MPH
Rebecca Reece, MD, IDSA member
Rebecca Rogers, MD, Cambridge Health Alliance
Rebecca Schulte
Rebecca Sharar, MPH, MS4 University of Washington School
of Medicine
Rebecca Smith, University of Illinois
Rebecca Spence, JD, MPH
Rebecca Stebbins, MSPH, UNC-Chapel Hill
Rebekah K. Puddington
Rechel Geiger, medical student
Regina C. Ortiz Nieves, MS (Puerto Rico Mental Health and
Anti-Addiction Services Administration)
Regina LaRocque, MD MPH, Harvard Medical School
Regina Wittaker
Rena Li
Renee Nelson
Renslow Sherer MD, University of Chicago
Research Assistant Professor, University of Illinois, Chicago
Research Associate
Researcher in Health Economics
Researcher, MPH, UCSF
Rhea Mathew, MS, MD candidate Drexel University College of
Medicine
Richard A. Loftus, M.D. Associate Program Director, Internal
Medicine Residency Program, Eisenhower Health, Rancho
Mirage CA
Richard Armenta, California State University, San Marcos,
Assistant Professor
Richard Greendyk, MD, Columbia University Medical Center-
NYP
Richard Harris
Richard Rodgers
Richard Winn MD, professor of medicine
Rishi Singhal
Robbie Christian Infectious Diseases Pharmacist
Robert Eagle, MS4, UWSOM
Robert T. Fairman, MPH, CHES, Georgia State University
School of Public Health
Robert W Comer, MD
Roberts Bartholow, Good Samaritan Hospital Cincinnati
Robin Nokes
Ronke Akinkugbe; VCU
Rosemarie Corral
Ruby Barnard-Mayers
Rupali Jain
Russell Buhr MD, PhD; Assistant Professor of Medicine, UCLA
Ruth Aminu

Ruth Wang, M.Ed., MD Candidate [MS4] at UC San Diego
 School of Medicine
 Ruvandhi Nathavitharana MD MPH, Harvard Medical School
 Ryan Muir - pharmacist
 S.A.
 Saba Khan
 Sabeen Rokerya, Columbia University Mailman School of
 Public Health
 Sabina Gonzalez, RN
 Sacharitha Bowers, MD
 Sade Perkins
 Sahit Menon - UCSD School of Medicine, Medical Student
 Saimrunali Dadigala
 Saleena Subaiya
 Sam Packard, MPH, University of Arizona
 Samantha Calderazzo, Medical Student
 Samantha Cox, Medical Student, Nebraska
 Samantha Hall, MPH candidate Boston University School of
 Public Health
 Samantha Lee MD, Cardiology Fellow, Icahn School of
 Medicine at Mount Sinai
 Samantha Loh, MPH, Colorado School of Public Health
 Samantha Moulton
 Samantha Schnall
 Samara Khan, MPH student at the CUNY School of Public
 Health and Health Policy
 Samsara Davalos Reyes
 Sana Abbasi
 Sanda Vujnic MD
 Sandra Springer, MD , Yale School of Medicine
 Santiago Neme, MD MPH, UWMC-NW Medical Director
 Santiago Ripoll, Postdoctoral Researcher, University of Sussex
 Saparja Nag, M1 at University of Connecticut SOM
 Sara Atlas, Columbia University Mailman School of Public
 Health
 Sara Benham, PhD candidate, Old Dominion University
 Sara Drescher, MD
 Sara Gomez
 Sara Hurtado Bares, MD
 Sara Kass-Gergi, MD, NYP-Columbia Medical Center
 Sara Knauff, University of Washington School of Medicine
 Sara Shashaani
 Saraf Salim, MPH
 Sarah Ames, MPH candidate at Boston University School of
 Public Health
 Sarah B. Andrea, PhD, MPH, University of Washington School
 of Public Health
 Sarah Bansen APRN
 Sarah Case, MS1, University of Washington
 Sarah Corley, BUSPH alum
 Sarah Cullum
 Sarah E. Hawkins
 Sarah Frank, RN
 Sarah Gitterman, Colorado School of Public Health
 Sarah Gramm, teacher
 Sarah Jergenson, MPH candidate, University of Minnesota
 Sarah Kipperman- public school teacher in Virginia
 Sarah Leong
 Sarah Lorraine
 Sarah Ney. Educator
 Sarah Renaud
 Sarah Rossi - MPH candidate at Boston University
 Sarah Stein Family Medicine PA
 Sarah Wolfarth-Davis
 Sasha Sommerfeldt
 Scientist and Free Clinic Volunteer
 Sedem Adiabu Rollins School of Public Health
 Seth J. Prins PhD MPH, Assistant Professor of Epidemiology
 and Sociomedical Sciences
 Shaelin Nauta
 Shahbaz Hasan, Infectious Care, Dallas
 Shahera Ranjha
 Shaina Coogan, MPH
 Shamia Robinson
 Shana Geary, MPH, CPH
 Shana Kagan MPH, MN, RN, PHN
 Shannon Limjuco, MPH
 Shannon Vance, MPH, George Washington University
 Shaoli Chaudhuri
 Sharon Wang
 Sharrelle Barber, ScD MPH, Drexel University Dornsife School
 of Public Health
 Sheela Lewis
 Shenandoah University Student
 Shibani Chettri, MPH, Epidemiology PhD Student @ The Ohio
 State University
 Shira Shafir, PhD, MPH UCLA Fielding School of Public Health
 Shivanjali Shankaran
 Shradha Biradar, MPH, Medical Student Touro University CA
 Shreela Sharma, PhD, Professor of Epidemiology, University
 of Texas School of Public Health
 Shrita Pendekanti, UC San Diego School of Medicine
 Siobhan Callaghan MD
 Skye Fishbein
 Sminu Bose, MD
 Smriti Karwa, MPH
 Social Worker
 Sofie Pedersen
 Sonia Midha
 Sonya Neal -UCSD
 Sora Chee, Upstate Medical University
 Spencer Septien
 Stacie Smith
 Stanford, Graduate Student, Epidemiology and Clinical
 Research
 Stanley PA-S
 Stephanie Mayne, PhD, MHS - CHOP
 Stephanie Wagner, MD/MPH
 Steven C. Hatch, MD, MSc, University of Massachusetts
 Medical School
 Steven Pergam, MD, MPH
 Steven Ridini, Health Resources in Action
 Steven Rodriguez Columbia University
 Steven Rothman, MD; SUNY Upstate Medical University
 Student
 Suhair Bhatti, MPH

Sujatha Srinivasan, PhD. Senior Staff Scientist, Vaccine and Infectious Disease Division, Fred Hutch, Seattle
 Sukhmani Bal, MPH - BUSPH/MGH CCCSEW
 Suliman Ghafary, MPH
 Sumedh Mankar, physician, primary care and public health
 Supriya Rani Jain (Brandeis University)
 Surabhi Nirkhe, Internal Medicine resident, UCSF
 Susan Bolick RN, retired public health nurse
 Susan Caisse
 Susan Watson, LCSW, MPA, MHS
 Sydney Perlotto, FP/RH Policy Advocacy
 Sydney Pomenti, MD NYP - Columbia - New York Presbyterian
 Sylvia Coleman, MD
 Sylvia Czuppon
 Sylvia Kang, Yale School of Nursing
 Sylvia Romm
 Talia H. Swartz, MD, PhD, Icahn School of Medicine at Mount Sinai
 Tammy Wilhoite
 Tanja Srebotnjak, PhD
 Tara Alpert, PhD
 Taxpayer & Mother of Black Sons
 Taylor Kelley, Health District
 Taylor Paul
 Taylor Vincent, MPH
 Tejas Venkat-Ramani, MPH
 Tenley Brownwright, PhD, Penn State University
 Teresa Johns
 Terrel Sanders
 Tessa Delaney, MD Vanderbilt University Medical Center
 Tessa Pulido
 Theresa Santos, UWSOM
 Thy Huynh
 Tiffany Kan, RSPH
 Tiffany Pomaes, MPH-Epidemiologist
 Tilton Little, Publisher, Big4Bio
 Tim Carpenter
 Tim Lahey, MD, MMSc, Professor of Medicine & Director of Ethics, University of Vermont Medical Center
 Timothy Barber
 Timothy W Menza, MD, PhD, OHSU
 Tomefa Asempa, Hartford Hospital, CT
 Ton Johnson
 Tori Cowger, MPH, Harvard School of Public Health
 Toshali Katyal BA, UC Berkeley
 Toyosi Oyelowo
 Tran Huynh, medical student
 Transgender educator from northern CA
 Trey Simril, MD, University of Colorado Internal Medicine Resident
 Tyler J Peck
 Tyler Quigley UPSTATE NEUROPHYSIOLOGY
 Tyrone
 UC Berkeley School of Public Health
 Uche BLACKSTOCK - Advancing Health Equity
 Uchechi Mitchell, PhD, MSPH, University of Illinois Chicago
 UCSF School of Medicine
 Undergraduate Student, Milken Institute School of Public Health
 University professor, North Carolina
 UNMC 2nd yr. Medical Student
 Uzma Syed, Infectious Diseases, South Shore Infectious Diseases & Travel Medicine Consultants
 V. Morrison APRN Cambridge Health Alliance
 V. Ram Krishnamoorthi, MD MPH, University of Chicago, Doctors for America
 Vaish Sridhar
 Valerie Press, physician
 Van Park
 Vanessa Aden
 Vanessa Estibeiro MD, MPH
 Vanessa K Ferrel, MD MPH
 Vanessa Lamers
 Vanessa Torrice, BUSM
 Varun Goel - UNC Chapel Hill
 Vera Schulte, University of Washington Medical Student
 Veronica Grycan
 Veronica Salvas, Epidemiologist Healing Communities Study
 Vicki Alexander, MD, MPH, Healthy Black Families, Inc
 Victor J. Schoenbach, PhD, emeritus associate professor
 Victoria Cameron, Dartmouth Board of Health
 Victoria Gontarz
 Vidya Atluri, infectious disease fellow, UW
 Vikas Saini, M.D. President, Lown Institute
 Viraj Shroff-Mehta, MD
 Virginia Tan, Medical Student, Netter School of Medicine
 Visiting Nurse Service of New York
 Wendy Armstrong MD, Emory University
 Whitney Wood, MS3, Elson S. Floyd College of Medicine
 Wilfredo Lopez
 Will Brown
 Will Flanigan, UCB/UCSF graduate student
 Will Patterson, Medical Student, CCLCM
 William Andrew Hughes
 William C. Goedel, PhD, Assistant Professor (Research), Brown University School of Public Health
 William F Parker, MD, MS, University of Chicago.
 William J Muller, MD/PhD, Northwestern University Feinberg School of Medicine
 Xavier Hill
 Xóchitl Silva
 Y. R. Usodum
 Yamile Molina, PhD MS MPH, Assistant Professor, Center for Research on Women and Gender, Community Health Sciences, University of Illinois Chicago
 Yasaman Zia, UW
 Yasmin Kamal, MD/PhD student Geisel School of Medicine
 Yefim Zaltsman, PhD, Postdoctoral Scholar, UCSF
 Yehudith Dashevsky, alumna of the University of Pennsylvania
 Yewande Dayo, Infectious Diseases Pharmacist
 Zachary West, MD
 Zara Wright, MA, Canvas Health
 Zoe McLaren, University of Maryland, Baltimore County

Peter R. Breggin, M.D.
206A Dryden Rd. PMB 112
Ithaca, New York 14850
Phone 607 272 5328

August 30, 2020

COVID-19 & Public Health Totalitarianism:

Untoward Effects on Individuals, Institutions and Society¹

By Peter R. Breggin, MD^{2, 3}

TABLE OF CONTENTS

Introduction: Basic Scientific and Political Principles Applied to COVID-19

I. The Creation and Then Control of Fearful Populations

- A. The Rise of “Fear Appeal”**
- B. How Global Threats Enable Top-Down Management**
- C. The Psychology of Moving the “Masses”**

II. Scientific Critiques of the COVID-19 Shutdown Policies and Practices

- A. Daniel T. Halperin (2020), *Coping With COVID-19: Learning from Past Pandemics to Avoid Pitfalls and Panic***
- B. Thomas V. Inglesby, Jennifer B. Nuzzo, Tara O’Toole, and D. A. Henderson (2006), *Disease Mitigation Measures in the Control of Pandemic Influenza***
- C. American Institute for Economic Research, (2020) *Urgent Report on Pandemics and Freedom***
- D. Maine Policy Institute, (2020) *COVID Catastrophe: Consequences of Societal Shutdowns***
- E. Alex Berenson, (2020) *Unreported Truths about COVID-19 and Lockdowns***

¹ This report was requested by attorney Thomas Renz to support a new legal case in Ohio seeking to restrain coercive government measures implemented in response to COVID-19. Because of its importance, we decided to work on the case *pro bono*.

² **Attachment 2** presents my credentials specifically for this report and **Attachment 3** is my complete resume, including bibliography, updated regularly from my professional website @ www.breggin.com.

³ My writing of this report draws on years of collaboration with my wife Ginger Ross Breggin who has coauthored several books and led many reform projects with me. Since the beginning of the pandemic, we have almost daily spoken about it, reviewing our thinking and research. She then helped in researching and discussing this report with me. When I use the word “we” in this report, I am referring to the two of us. If this were not a legal report requiring an identified medical expert, Ginger would be listed as coauthor of the document. However, I have done all the writing and take full responsibility for the contents.

III. Political Totalitarianism and Public Health Totalitarianism

- A. Political Totalitarianism**
- B. Public Health Totalitarianism**
- C. Combining Political and Public Health Totalitarianism to Suppress the Only Drug Effective Against COVID-19**

(1) Open letter to Dr. Anthony Fauci regarding the use of hydroxychloroquine for treating COVID-19.

(2) The Broader Context

(3) Using Lethal Doses to Discredit Hydroxychloroquine

D. “Educating” the People to Accept “Interventions”

IV. The Psychosocial Impact of Depriving People of Liberty

- A. Volition, Free Will, and Liberty**
- B. Coercion Overpowers Another’s Volition and Liberty**
- C. Understanding Coercion vs. Liberty and Love**
- D. Understanding Psychological Helplessness**
- E. Frightening and Reducing People to Objects**
- F. Censorship: YouTube, Twitter, Facebook, Google, Amazon, *The New York Times*, etc.**
- G. The “New Normal”—With Bill Gates and Anthony Fauci**
- H. The Most Vulnerable Groups under COVID-19**

V. Summary List of Government Actions to Enforce Overall Public Health Totalitarianism

VI. Hazards of Face Masks

VII. Dr. Meryl Nass on the False Narrative Created to Discredit Hydroxychloroquine

VIII. Dr. Pam Popper on Individual Personal Experiences under the COVID-19 Lockdown

IX. The Pharmaceutical Industry and Globalism

X. Anthony Fauci: Enabling the Pandemic to Occur and Then Manipulating It

- A. Fauci Supports Collaboration with China to Build More Destructive Viruses**
- B. Fauci Funds and Promotes an Expensive, Ineffective, and Proven Dangerous Drug**

XI. Collective Immunity and the Advantages of Staying Open

XII. Conclusion: Constitution and the Bill of Rights Must Supersede Political and Public Health Totalitarianism

Attachment 1: The Three Dynamics of Human Progress for Individuals, Institutions and Society from *Beyond Conflict* by Dr. Breggin

Attachment 2: Dr. Breggin's Expert Qualifications for This Case

Attachment 3: Dr. Breggin's Resume including bibliography, updated regularly from www.breggin.com

Attachment I

COVID-19 & Public Health Totalitarianism:

Untoward Effects on Individuals, Institutions and Society⁴

By Peter R. Breggin, MD

Introduction. Basic Scientific and Political Principles Applied to COVID-19

Public health experts and policymakers believe that they can estimate what is *scientifically required* to fight a pandemic and that their personally determined requirements override most or all other considerations. But as a physician, psychiatrist, and researcher who has spent more than fifty years writing and evaluating research studies, I can explain why public health experts and officials are vastly more limited in their scientific knowledge than they admit.

As other experts will confirm in this report,⁵ there is no historical precedent and no scientific basis to the ever-changing pronouncements by public health officials that have driven this nation into a state of fearful lockdown. Nearly every policy and practice—from closing of schools and the stay-at-home orders to the use of various medications and respirators—is subject to varied and conflicting scientific opinion, and to an overall lack of sound data.

The opinions being expressed with such authority come from people who have, for much of their lives, held themselves out as the last final word in their fields—but that does not make their opinions scientifically sound. In fact, the very word “authority” should never be uttered in the same breath with “scientific.” There are no “scientific authorities”—there is the body of research and opinion, always conflicted, forever evolving, with innumerable individuals searching for and comparing their versions of empirical truth. The idea of “scientific authority” is a fiction created by media analysts and politicians seeking seemingly superior experts to bolster their preconceived biases and opinions.

Given the current state of their science, all that public health scientists can do is to present us with their best guesstimates at the moment about risk/benefit ratios—for example, “If the schools are closed, it may or may not make things worse, but here’s my best guesstimate.” And of course, there will always be another expert to give a starkly opposing best guesstimate.

I have purposely used the vague term “make things worse,” because that is really what is at stake when we enforce radical, untried policies on a crisis like COVID-19. Experts who favor top-down government control will try to predict something more precise, such as “Closing the schools will temporarily decrease the spread of the pandemic.” But they never then ask the most important question, “Will closing the schools make things better or worse for our children, their families, and society?” They do not try to answer that question because they cannot do it. It is too complex a question considering what it means to children to lose months of their education, to be cut off from their friends, and to miss all the social, academic, athletic and sometimes religious projects associated with school.

The experts cannot factor in the increased social withdrawal, loneliness, conflict with parents, anxiety, depression, and suicide that we are witnessing among our children. Nor can they consider the effect on parents who have to stay home to take care of the children and maybe

⁴ This report was requested by attorney Thomas Renz to support a new legal case in Ohio seeking to restrain coercive government measures implemented in response to COVID-19. Because of its importance, we decided to work on the case *pro bono*.

⁵ See part II of this report.

their own parents as well. And, of course, they cannot estimate the impact on a society whose children are being changed forever. *Indeed, this writer cannot even begin to summarize all the vast, rippling effects of the current school closures, let alone make some “scientific prediction.” I can only say, along with many others, “It looks to me like its making things much, much worse, and especially so for our most vulnerable children who have disabilities, have disturbed or alcoholic parents, and who live in poverty. Those kids really miss school!”*

Typical of all behavioral sciences that try to deal with huge populations, predictions are at the least partially speculative, because they deal with human choice and conduct, infinite variables, unknown factors, and rapidly changing conditions. Add a mutating virus to the mix, and the difficulties of prediction become mind-boggling. Add the complexity of political interventions and unanticipated confounding events... perhaps their “scientific” guesses are no better than yours or mine, as so often seems to happen. But the fact is that there are insufficient epidemiological studies upon which to base any of the opinions offered.

What can we conclude from this analysis of the limits of current public health “science” in respect to managing COVID-19? The only sensible conclusion is to proceed with caution, to do as little harm as possible, and to respect the rights of our citizens.

Many public health scientists are physicians with MD degrees and many others have PhDs in public health; but each to some degree is acting in the role of treating physician for the individual members of our society, albeit huge numbers of people. Although many might not be licensed to prescribe actual medicines, especially the PhDs, the prescriptions for society that they are writing can cause adverse reactions and even public disaster that far exceed those of any prescription drug. Prescription drugs, for example, are tested for their adverse events in randomized, placebo-controlled clinical trials and the drugs invariably still end up inflicting unexpected harms when they go onto the market. Yet some turn out to be so harmful that, despite FDA-approval, they must be withdrawn from the market.

It is of course impossible to test public health prescriptions with any such accuracy, or even close to it, before inflicting them on society and on large numbers of individuals. As already emphasized, there are no rigorous scientific studies to bolster the Earth-shaking policies and practices being inflicted on America and the world. Indeed, withdrawing some policies, such as stay-at-home orders or school shutdowns, will still leave already-inflicted lasting scars on individuals, the economy, and society. Current public health scientists are like historians trying to predict the future from their impressions of the past—a very hazardous prospect at best, nor do they have the kind of thorough background in history or the academic self-restraint that we expect from historians.

Instead of controlled clinical trials, much of the science behind public health is, of necessity, based on epidemiology. One simple definition of epidemiology is that branch of medicine which deals with the incidence, distribution, and possible control of diseases and other factors relating to health. It is a broad field of study often involving thousands or millions of people and usually requires high-power statistical analyses to draw even tentative conclusions.

In my field of psychiatry, epidemiological studies are used to study such things as does a prescribed medication increase the suicide risk when used by doctors in routine practice. One study, sponsored by the drug company who owns the drug, will show that the drug *reduces* the suicide rate, even though the actual clinical trials showed it increases risk suicide. Then a more critically thinking or independent researcher will do another study and find that the drug does cause increased suicides much as it did in the clinical trials. And so on.

As a prescribing physician, I would never want to rely on an epidemiological study about serious drug harms without, first, knowing the source of the study. Science has an Achilles Heel—it is a process conducted by humans driven with varying motivations, nowadays often including wealth and power. Before trying to make an important judgement in medicine or any scientific field, we need a much broader array of knowledge than a few epidemiological studies. Our decision should be based on our own professional experience, observations made by other physicians and by patients and their families, clinical trials, clinical reports, patterns of adverse drug reporting to the FDA, data and opinions offered in the scientific literature, biological explanations for the origin of these bad drug effects, and so on. *Yet public health scientists and their officials leap ahead to make colossally high-risk decisions on the flimsiest kind of data, so much so that we have seen them changing their minds from day-to-day and week-to-week like children in a candy store.*

Public health scientists and policymakers who push for stringent restrictions are especially likely to ignore the insubstantial nature of their data and the looming possibility of being completely wrong. They persist in demanding obedience to their predictions, even after they have been proven ridiculously wrong in their earlier ones, as demonstrated in the vastly over-inflated death rates and total deaths predicted for COVID-19.

These public health scientists also commonly fail to factor in the negative impact of their policies on the overall quality of life or the economy, or the fear and panic they may engender. *They are even less likely to factor in the loss of basic human rights as embodied in the Declaration of Independence, the Constitution, and the Bill of Rights.* Instead, they act as if the American Dream is to live as long and safely as possible in conformity to their latest version of public health science.

But the American ideal has never been to maximize safety and security. Instead, the stated ideal since at least 1776 has been to protect each person's inalienable right to *pursue* life, liberty, and happiness, and that is an essentially risky affair. When given too much power and authority, scientists, and policymakers—undaunted by principles of liberty—will always trend toward authoritarianism and totalitarianism. Because of that human impulse, the Constitution cannot become *irrelevant* during a health crisis, it must become more critically *necessary* than ever. Because of this, a substantial section of this report will examine the impulse toward totalitarianism inherent in public health policy and planning.

Because they want to support the efforts of the pharmaceutical industry and the government to collaborate in testing and producing new medications and vaccines, experts and officials have been denigrating the safety and usefulness of hydroxychloroquine, a very old, very safe, and seemingly effective antiviral and anti-inflammatory treatment for COVID-19. This is an issue that will be examined thoroughly.

Most dismaying, public health experts and officials, although they prescribe for millions, seem entirely lacking in the skills of a good healthcare provider, such as a nurse, rehabilitation worker, or physician. They utterly lack the restraints of the Hippocratic Oath, "First, do no harm." They seem never to consider an equally important ethic, voluntary consent—to provide their patients with informed consent, including to fully advise them about the risks associated with their prescriptions that, in this case, can transform their lives forever. Instead, as we shall see, their colleagues openly teach them to use threats to get people to do what they are supposed to do. The public health experts and officials who prescribe for America are like physicians run amok, wholly lacking in the ethics and restraint of a good physician.

Unlike any decent healthcare provider, public health experts and officials seem utterly unconcerned about the freedom and autonomy of their clients. I live with my 94-year old mother in law, Jean Ross, who has balance and eyesight problems, uses a walker, and needs close help on even slightly irregular terrain. It is not safe for her go for walks outside without companionship and I try walk with her at least once a day. I had to give up asking her, “May I take you for a walk?” because it made her wince. She wanted to *share* a walk with me, not to be taken out like one of our three dogs. This and other lessons have made our walks together a blessing for both of us. Much as I am trying to relate to Jean, good healthcare providers walk in the shoes of their patients or, at the least, try to be respectful guides. I have yet to see respect or concern for individual autonomy expressed by public health scientists and officials when implementing COVID-19 policies that vastly undermine the personal freedom and self-determination of everyone in America and the world.

Then there is the practical matter of what *actually* works, succinctly voiced by a group of Johns Hopkins public health experts in 2006: “An overriding principle. Experience has shown that communities faced with epidemics or other adverse events respond best and with the least anxiety when the normal social functioning of the community is least disrupted.”⁶ *In other words, when faced with a pandemic, for best results keep the lives of individuals and communities as normal and unaffected as possible.*

Finally, what is more enduring? What is more to be relied upon? Do we base our individual lives and the survival of the nation on highly dubious and controversial predictions about the future that will always lack consensus and validity *or* do we ground ourselves in the enduring principles of liberty upon which this nation was founded?

⁶ Thomas V. Inglesby et al. Mitigation Measures in the Control of Pandemic Influenza. *Biosecurity and Bioterrorism*. Volume 4, Number 4, 2006. <https://www.liebertpub.com/doi/abs/10.1089/bsp.2006.4.366>. Also, <http://www.upmc-biosecurity.org/website/resources/publications/2006/2006-09-15-diseasemitigationcontrolpandemicflu.html>. See ahead for details of the publication.

I. The Creation and Then Control of Fearful Populations

A. The Rise of “Fear Appeal”

Fear and even terror are fundamental tools of top-down control over a population. As this report was being finished, a new wave of fear and confusion was inspired by Anthony Fauci, Director of NIH’s Institute for Allergy and Infectious Diseases.⁷ Apparently in his absence, while he was undergoing surgery, the CDC determined that it was no longer necessary to test asymptomatic people for the SARS-CoV-2—an action consistent with relieving fear and opening the nation’s life and economy. When he heard about the new guidelines, Fauci rose to the occasion, pointedly describing how he was “unconscious” when the decision was made without him and warning about dire results. *The New York Times* raised the fear level by blasting the CDC’s decision, stating “A more lax approach to testing, experts said, could delay crucial treatments, as well as obscure, or even hasten, the coronavirus’s spread in the community.”⁸ Fortunately, other sources found numerous experts to support the CDC’s decision.⁹

Fauci has continuously pushed to keep track of the death rates and the rising numbers of deaths; but as the rate of lost lives declined and then held steady at a lower level,¹⁰ he and others began to emphasize the growing number of *reported cases* rather than the death rate. At the same time, the methods of counting cases became ridiculously inflated. Under CDC guidance, a valid case of COVID-19 can now be counted if someone has, in effect, seen someone who had seen someone who may have possibly had COVID-19. We described this absurd situation earlier in this year in our blog/report, *CDC Surges Covid-19 Stats*.¹¹ For many reasons the criteria for counting deaths due to the virus have become increasingly invalid and skewed to grow in a frightening, unrealistic manner.¹²

A few days before this report was finished, it became apparent that even the current relatively low death rate is probably hugely inflated. As of August 26, 2020, the CDC reported in

⁷ For more about Anthony Fauci, see **Part III C (1)**, *Open letter to Dr. Anthony Fauci regarding the use of hydroxychloroquine for treating COVID-19*; **Part VII** which contains a summary report by Meryl Nass, MD, *How A False Hydroxychloroquine Narrative Was Created, And More*; and **Part X**. Anthony Fauci: More About His Role in Making Possible and Then in Purposely Extended the Pandemic. Much more can also be found throughout this report by searching “Fauci.”

⁸ Wu., C., 2020, August 26. C.D.C. Now Says People Without Covid-19 Symptoms Do Not Need Testing, New York Times. <https://www.nytimes.com/2020/08/06/health/coronavirus-asymptomatic-transmission.html> The quote was taken from the Google search page for the article from the NYT.

⁹ Weise, E. and Rodriguez, A., 2020, August 27, CDC clarifies surprise guidelines that people without COVID-19 symptoms don't need testing. USA Today. <https://www.usatoday.com/story/news/2020/08/27/cdc-walks-back-surprise-coronavirus-asymptomatic-testing-guidelines/5645630002/> Also, see van Bruden, I. 2020, August 27, Asymptomatic people no longer require CCP virus test: New CDC guidance. https://www.theepochtimes.com/asymptomatic-people-no-longer-require-ccp-virus-test-new-cdc-guidance_3477773.html

¹⁰ See the constantly revised chart of rates of death in several countries including the US at the top of our Coronavirus Resource Center, Chart from *Our World In Data*:

Daily confirmed COVID-19 deaths, rolling 3-day average. <https://breggin.com/coronavirus-resource-center/>

¹¹ Breggin, Peter and Breggin, Ginger Ross, 2020, CDC Surges Covid-19 Stats: Death Rates Remain Low. More Cases Needed for Herd Immunity. <https://breggin.com/cdc-surge-stats-exaggerated/>

¹² Breggin, Peter and Breggin, Ginger Ross, 2020, CDC Surges Covid-19 Stats: Death Rates Remain Low. More Cases Needed for Herd Immunity. <https://breggin.com/cdc-surge-stats-exaggerated/>

small print in an obscure place that in a mere “6% of the deaths, COVID-19 was the only cause mentioned.”¹³

Furthermore, the CDC found that “For [COVID-19] deaths with conditions or causes in addition to COVID-19, on average there were 2.6 additional conditions or causes per death.” In other words, COVID-19 was identified as the sole cause of death in a mere six of 100 deaths reported by the CDC. All the other 94% of so-called COVID-19 deaths had an average of 2.6 other *causes* listed.

Not only are COVID-19 deaths almost nonexistent in young people, we now learn in the last few days from the CDC that the coronavirus could not be specifically linked to the cause of death in 94% of the CDC’s reported cases of death.

The good news is that, since spiking in mid-April, the coronavirus death rate, as artificially and perniciously inflated as it is, has remained flattened from the end of May through the completion of this report in late August 2020.¹⁴

Fauci remains the point man for pushing for more top-down administrative government in the world—a world that we will find vastly enriches and empowers him and many others. For more details about Fauci, especially see sections **III C. (1)**, **VII** and **X**, and search his last name. He has helped to fan the threats and even terror to a level not seen since 911.

Certainly, we were afraid during World War II and under the threat of atomic war during the Cold War, during the Cuban missile crisis under President Kennedy, and then during 911 under President Bush, all of which this author lived through. But even those terrifying existential threats did not begin to lead to the kind of forced social transformations that we have now been experiencing.

As a child in World War II, I remember rationing and, living on Long Island near the ocean where German subs sank our ships seeing debris from our life rafts on the shoreline. I remember turning out all the lights at night and my father putting on his helmet to patrol our street as an air warden. But I never remember anyone telling us to isolate at home or not to go to school, and except for families with loved ones in the military, there was probably nothing like today’s pervasive invasion of fear into individual private lives.

The current fear began to spread when China, the World Health Organization (WHO), and administrative states worldwide began responding to the threat of COVID-19. What is happening today is perhaps unprecedented in democracies. Public health expert David Halperin (see ahead) observed, “a palpable climate of confusion and anxiety pervades” and “one mind-boggling indication is that the Johns Hopkins University Coronavirus Resource Center website is recording some 4 billion hits a day!”¹⁵

There is, of course, a general awareness of how governments use fear as a means of influence and control. Most people probably sift through the news with some desire to recognize news reports aimed at scaring them. However, the broad subject called “fear appeal” has become an academic discipline. Characteristic of the trend we are describing of seemingly value-free means of achieving influence and power, “fear appeal” is not a pejorative or negative descriptor but rather a field of serious and respected study.

¹³ National Center for Health Statistics. Weekly Updates by select demographic and geographic characteristics: Provisional death counts for Coronavirus Disease 2019 (COVID-19). See the small print under “Comorbidities” near bottom of the page. https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm

¹⁴ Coronavirus Resource Center, Chart from *Our World In Data*: [Daily confirmed COVID-19 deaths, rolling 3-day average.](https://breggin.com/coronavirus-resource-center/daily-confirmed-covid-19-deaths-rolling-3-day-average) [https://breggin.com/coronavirus-resource-center/daily-confirmed-covid-19-deaths-rolling-3-day-average.](https://breggin.com/coronavirus-resource-center/daily-confirmed-covid-19-deaths-rolling-3-day-average)

¹⁵ Halpern, D. (2020). Coping With COVID-19: Learning from Past Pandemics to Avoid Pitfalls and Panic. *Global Health: Science and Practice*, 8 (2), 155-165. <https://www.ghspjournal.org/content/ghsp/8/2/155.full.pdf>

A 2014 study of “Sixty years of fear appeal research: Current state of the evidence”¹⁶ examined whether arousing fear in people helps them develop or conform to standards of personal hygiene or self-care and to conform to public health laws or guidelines. The authors concluded, “presenting threatening health information aimed at increasing risk perceptions and fear arousal” (p. 63) does not lead people to take better care of themselves or to respond to public health requirements.

The infliction of fear and pain is called negative reinforcement in animal psychology experiments. It has been known for decades that negative reinforcement is ineffective in shaping animal behavior and in recent years it has been viewed as causing helplessness rather than effective behavior. Using rewards or positive reinforcement to shape animal behavior was a principle that B.F. Skinner affirmed decades ago. Frightening or inflicting pain on creatures, human or otherwise, does not produce the behavior desired by the controller, such as pressing a button to get a pellet or obeying commands to wear masks. Fear and other painful stimuli make us become “defensive” and drive us to avoid the threat rather than to adapt to it in the manner sought by the controller. In short, fear and especially terror produces negative behavior without necessarily conforming to what is sought.

So why are so many of our leaders trying to scare us? Because they know the missing ingredient. According to the study, after scaring us, our leaders must provide us “instruction on how to successfully implement the recommended actions as well as convincing people that they are personally susceptible to the threat” (p. 68). That is, after they have scared us, our leaders must make us *feel it personally* and then *they must tell us what to do!* The authors recommend this without regard for our rights as citizens of a democracy inspired by the Declaration of Independent and built on the Constitution and the Bill of Rights.

It should be added that the authors of this scientific paper on fear appeal may not have the faintest idea of the broader implications of what they are recommending. That is how much globalism¹⁷ is accepted by many, in this case at the expense of America’s freedom.

There are some in the scientific community who find fear appeal to be appalling. In their June 11, 2020 publication, Jeni A. Stolow and three public health colleagues¹⁸ wrote a heartfelt abstract to their article “How Fear Appeal Approaches in COVID-19 Health Communication May Be Harming the Global Community”:

As health professionals develop health communication for coronavirus disease 2019 (COVID-19), we implore that these communication approaches do not include fear appeals. Fear appeals, also known as scare tactics, have been widely used to promote recommended preventive behaviors. We contend that unintended negative outcomes

¹⁶ Ruiter, R., Kessels, L., Peters, G-J & Kok, G. (2014). Sixty years of fear appeal research: current state of the evidence. *Int J Psychol.* 2014 Apr;49(2):63-70. doi: 10.1002/ijop.12042. Epub 2014 Feb 24. <https://pubmed.ncbi.nlm.nih.gov/24811876/>

¹⁷ Perhaps the simplest definition of globalism is “the operation or planning of economic and foreign policy on a global basis.” There is disagreement about what whether it more closely relates capitalism or progressivism, but it incorporates elements of both. Large pharmaceutical firms that influence government policy and public opinion on an international scale are globalists who are generating great wealth and power as result of COVID-19. See part X: The pharmaceutical industry and Globalism

¹⁸ Jeni A. Stolow, Lina M. Moses, Alyssa M. Lederer and Rebecca Carter, 2020, June 11, How Fear Appeal Approaches in COVID-19 Health Communication May Be Harming the Global Community. *Health Education. Health Education & Behavior*, 47(4) 531–535 <https://journals.sagepub.com/doi/pdf/10.1177/1090198120935073>

can result from fear appeals that intensify the already complex pandemic and efforts to contain it. We encourage public health professionals to reevaluate their desire to use fear appeals in COVID-19 health communication and recommend that evidence-based health communication be utilized to address the needs of a specific community, help people understand what they are being asked to do, explain step-by-step how to complete preventative behaviors, and consider external factors needed to support the uptake of behaviors. To aid health professionals in redirecting away from the use of fear appeals, we offer a phased approach to creating health communication messages during the COVID-19 crisis. P. 531

They explained:

In this article, we discuss the use of fear appeals during the COVID-19 pandemic and the potential negative sociobehavioral outcomes fear-based messaging may have. These include distrust in public health authorities, skepticism of health messaging, a lack of uptake in recommended behaviors, and a plethora of other unintended consequences. P. 531

Citing scientific literature, they reported that “studies have documented that fear appeals or fear-inciting health communication campaigns may produce unintended consequences such as denial, backlash, avoidance, defensiveness, stigmatization, depression, anxiety, increased risk behavior, and a feeling of lack of control” (p. 532).

Perhaps to avoid conflict with their peers, Stolow et al. do not describe ongoing public health abuses that can cause such reactions, but they mention some that never made it off the drawing board:

In our work with health professionals, an example of a proposed COVID-19 campaign was to design a poster featuring an image of mass burials to persuade individuals to wash their hands. ...

Another proposed health communication campaign among health care professionals was to create television commercials portraying a fictional hospital overloaded with patients coughing up blood, fainting in hallways, and crying in pain to persuade people to physically distance. P. 532

There is a great deal of agreement among professionals and data to confirm that the COVID-19 lockdown is taking its emotional toll on the American people and others around the world. All the above untoward outcomes—“denial, backlash, avoidance, defensiveness, stigmatization, depression, anxiety, increased risk behavior, and a feeling of lack of control”—have been described as responses to COVID-19 and too restrictive and frightening health policies and practices. On August 25, 2020, Bowen Xiao wrote a report titled “Shutdowns Spur Mental Health Crisis in US, Experts say.”¹⁹ A remarkable 10% of adults reported feeling suicidal or were seriously considering it in the 30 days previous to June 2020, approximately

¹⁹ Xiao, B. Shutdowns spur mental health crisis in US, 2020, August 25. The Epoch Times.

https://www.theepochtimes.com/pandemic-spurring-mental-health-crisis-in-us-experts-say-3469596.html?ref=brief_News&utm_source=morningbrief&utm_medium=email&utm_campaign=mb

twice that reported for the same period in 2018. The CDC found that 13% of people said they had begun or had increased the use of legal and illegal substances to cope with Covid-19. There is evidence that alcohol abuse and overeating as locked-down families try to deal with each other. A psychologist warned of the “fearmongering media” as well as the anxiety and depression resulting from forced isolation caused by orders to stay at home. One observed that Covid-19 was producing a national mental health crisis.

Xiao also cited reports of children suffering from not being able to see their friends or to go to school, and from exposure to increasingly irritable and stressed parents. Social distancing is negatively affecting people and their relationships. People experience irritability, lack of sleep, restlessness, and panic attacks according to some doctors and the elderly especially are suffering from an epidemic of loneliness.

Many of these reactions are inevitable during a pandemic but many are aggravated by excessive restrictions imposed upon the population. It is worth repeating the observation made by Thomas Inglesby and his public health colleagues, “Experience has shown that communities faced with epidemics or other adverse events respond best and with the least anxiety when the normal social functioning of the community is least disrupted.”

Returning to Stolow and her colleagues, they encourage non-threatening approaches, including promoting the use of masks:

For example, if the desired outcome is for individuals to use a cloth face mask, free reusable cloth masks could be made available to people coupled with educational brochures detailing why mask use is important, where it is appropriate to use a mask, how to don, wear, and doff the mask, proper mask storage, and ways to wash the mask.

They conclude:

COVID-19 has caused the global community enough stress and fear; there is no need to exacerbate these issues by using fear appeals as a health communication strategy. We urge health professionals to consider the possible consequences when determining what health communication approaches to use, and to think systematically and innovatively about approaches. The world’s health depends on it.

Even these empathic public health professionals do not raise the issue of the individual’s right to be free of unwanted restraints on their lives and activities. There is no awareness that the Constitution and Bill of Rights can and should restrain terrorizing people and compromising their liberties. They do not imagine that the legislative and judicial process of democracy can and should be overseeing them and their more obviously threatening colleagues. The public health educators need to be educated about individual rights and the principles of liberty.

C. How Global Threats Enable Top-Down Management

What circumstances are necessary or required to achieve and maintain this kind of top-down administrative control of democracies on a worldwide scale? First, it requires globalism—a viewpoint that promotes a global perspective with global relationships and practices that transcend nations and their unique laws and customs. That has been coming together for a long

time, most notably inspired perhaps by President Woodrow Wilson's attempt to create a League of Nations after World War I and then by the creation of the United Nations after World War II, and more recently, by the development of a global economic system led by enormous corporations and super-wealthy individuals who are internationalists.

In addition to a global outlook, a global catastrophe is required to demand the need for an increase in top-down administration around the world. In this case it was a pandemic predicted to be the size of the Spanish Flu; but it could be another world war or an environment catastrophe. In the movies, we have been prepared to expect international unity and global organization to arise in response to an alien invasion, an environmental catastrophe, or a large rock in the sky hurtling toward us. And if a sufficient global catastrophe is not readily available, global opportunists must create one, preferably not out of nothing but out of the next threat that is seen emerging.

How to manage such a top-down international response was perhaps best expressed by Edward Bernays, who transformed propaganda into "influencing public opinion" from politics to selling soap. He was a man who consulted with and enlightened President Woodrow Wilson and major international industries in the first part of the last century. Bernays opens his 1928 book, *Propaganda*, with the following statement. It is worth reading carefully for its vision of how the world has begun to be governed. It is rapidly expanding on an international level at this very moment through the COVID-19 pandemic:

The conscious and intelligent manipulation of the organized habits and opinions of the masses is an important element in democratic society. Those who manipulate this unseen mechanism of society constitute an invisible government which is the true ruling power of our country. We are governed, our minds molded, our tastes formed, our ideas suggested, largely by men we have never heard of. This is a logical result of the way in which our democratic society is organized. Vast numbers of human beings must cooperate in this manner if they are to live together as a smoothly functioning society.

Our invisible governors are, in many cases, unaware of the identity of their fellow members in the inner cabinet. They govern us by their qualities of natural leadership, their ability to supply needed ideas and by their key position in the social structure. Whatever attitude one chooses toward this condition, it remains a fact that in almost every act of our daily lives, whether in the sphere of politics or business, in our social conduct or our ethical thinking, we are dominated by the relatively small number of persons—a trifling fraction of our hundred and twenty million—who understand the mental processes and social patterns of the masses. It is they who pull the wires which control the public mind, who harness old social forces and contrive new ways to bind and guide the world.

Bernays is not weaving a "conspiracy" theory. He is describing the natural evolution of individuals with great wealth and power but little other identity or ideological commitment other than becoming increasingly rich and powerful by taking advantage of infinitely expanding communications and travel and a decline of any defining values. Walter Lippmann, Twentieth Century writer, reporter, and political commentator, called this "the manufacture of consent."²⁰

²⁰ Lippman, Walter 1922 *Public Opinion* =

This globalist, top-down, administrative approach to governance is essentially undemocratic and anti-individual. It resists all barriers and will try to end the American dream of a nation that promotes individual freedom and personal opportunity. It bears repeating the theme that the Constitution and Bill of Rights should not be bypassed or sacrificed during national or international crises. Instead, they should be emphasized and zealously used to defend the freedom of individual Americans and the national commitment to being a democracy based on liberty.

C. The Psychology of Moving the “Masses”

Public Relations, and its dark-side, propaganda, consider themselves to be social sciences. In truth, as described by Bernays, they are applications of psychology to change the opinions, perspectives, and actions of groups of individuals or citizens. It is a kind of applied science, but it probably originates more from the human imagination than from empirical science. Like the more specific use of fear, propaganda (called educating the public lies at the heart of modern public health policies and practices).

One of Bernays most illustrative projects to “change minds” was his campaign to sell pianos. He did not directly tell people through advertising to buy pianos, or even that owning a piano was the thing to do. Instead Bernays launched a campaign to instill the idea that having a music room or parlor was the most desirable and most forward aspect of a home. Once a music room (or designated space) was created, homeowners thought about buying a piano “on their own,” never suspecting the manipulation and influence behind their idea.

In the same sense, our current world leaders did not sell us totalitarianism or even authoritarianism, they sold us a “very dangerous pandemic,” possibly approaching the Spanish Flu. The piano room was the pandemic. Everything else we “needed” because we bought the pandemic.

Bernays “had no equal as a propaganda *strategist*. Always thinking far ahead, his aim was not to urge the buyer to demand the product now, but to transform the buyer’s very world, so that the product must appear to be desirable as if without the prod of salesmanship. What is the prevailing *custom*, and how might that be changed to make this thing or that appear to recommend *itself* to people?”²¹

One hundred years ago Bernays was pioneering the use of science to encourage consumption of a product by inventing “sponsoring committees” of physicians to promote his product. These committees were used to successfully sell bacon and cigarettes, according to Mark Crispin Miller, in his 2004 introduction to Bernays *Propaganda*. Now we see science and physicians used ubiquitously to promote diseases (so that a company’s product can be sold) and to promote consumption choices, such as “no smoking” campaigns.

More ominously, we can see propaganda at work in the rolling out of the COVID—19 pandemic response. The result is that we are obeying the officials and preparing ourselves to accept expensive treatments and vaccines because we live in this new room called the pandemic. We feel an urgent need to respond to otherwise revolutionary policies and practices that are creating a “new normal” for most people around the world.

Here is a survey of public health methods for creating sufficient fear and anxiety to convince people of the necessity of surrendering the liberty:

²¹ Bernays, Edward, in the 2004 introduction by Miller, Mark Crispin, 1928, *Propaganda*

- *Maintain an atmosphere of fear.*
 - Begin early with predictions of millions of deaths in America.
 - Warn that the shutdowns are incomplete and will make the epidemic worse.
 - Forbid contact through handshakes or other touching.
 - Constantly message “Wash hands for 20 seconds as often as you can.”
 - Constantly message stay socially distant and wear a mask.
 - Broadcast constant information about possible infection rate of virus, its spread potential, its survival on hard and soft objects, on boxes, packages and so forth.
 - Encourage distance shopping even though grocery stores and other “essential” shops such as pharmacies and hardware stores remain open.
 - Spread news of extreme examples of COVID-19 disease, and of deaths.
 - Suppress any critical or contradictory information that might alleviate fear of the virus.
-
- *Stir up feeling of emergency.*
 - Broadcast that there is no treatment for early stages of COVID-19 disease.
 - Encourage “treatments” such as Remdesivir or plasma (which require transfusions in hospital).
 - Constantly emphasize seriousness and dangers of virus (by creating one ‘news event’ after another that does this. For example, Dr. Fauci announces everyone might need to wear goggles in addition to masks in an interview, or Dr. Fauci declares there can be no opening of professional sports, or he declares schools opening are very risky.)
-
- *Make people stay home for a few weeks, then a few months, and then for an indefinite home confinement.*
 - Order children to stay at home also.
 - Order parents to oversee ‘distance learning’ of children in the home.
 - Order working adults to telecommute.
 - Close most service or personal care establishments (including hair and nail salons, spas, gyms, therapeutic massage, daycare facilities, bars, and restaurants and so forth).
 - Create such onerous requirements for service and personal care establishments that many are forced to go out of business rather than re-open.
 - Close shopping centers, malls, and other facilities where adults might find some relief from stay at home orders.
 - Close all recreational facilities and parks and outdoor venues including beaches.
 - Cancel any “elective” medical procedures including hip and knee replacements and other operations, many of which are needed to alleviate pain and to improve the person’s health and well-being.
-
- *Make people distance themselves from each other and become isolated.*
 - Wear masks, everywhere except at home alone, scaring some people so much that they can be seen wearing the masks while driving alone in their cars or solo hiking in the distance.
 - Stay at least six feet apart.
 - Keep your dogs (when dog walking) six feet apart, too.

- Keep children six feet apart from each other and do not allow playdates or any contact outside family sheltering together.
- Forbid contact with other family members sheltering separately.
- Forbid contact with friends.
- Forbid public religious gatherings including church, synagogue, or mosque attendance.
- Forbid political gatherings except “protests” even if they devolve into destructive riots.
- Forbid mass athletic gatherings of any kind, from schoolyard games to professional sports.
- Create bizarre and isolating requirements for establishments to reopen, including plexiglass partitions around outdoor tables at restaurants, and designated circles on grass in parks. Require plexiglass or other partitioning everywhere indoors to keep people separate from one another.

III. Scientific Critiques of the COVID-19 Shutdown Policies and Practices

There is large base of scientific opinion that views current public health policies and practices as much too oppressive, unnecessary, and likely to do more harm than good. As the following analyses will indicate, the current lockdowns, shutdowns and stay-at-home orders inflicted on the public have no historical precedent, no clinical basis, and no foundation in science. *Words may have spoken by scientists in interviews and news events, but they are as the words of shamans over a ritual, aimed at influencing others without a rational or scientific basis. The following represents genuinely thoughtful and science-based opinions on the management of pandemics in general and COVID-19.*

A. Daniel T. Halperin (2020, June 15), *Coping With COVID-19: Learning from Past Pandemics to Avoid Pitfalls and Panic*²²

Halperin's article starts with a box for "Key Messages" which focuses on the issue of contagion and warns against responding with "irrational fear":

As we wrestle with how best to mitigate COVID19, it is imperative to concur on the likely main drivers of transmission (notably, infection clusters resulting from prolonged indoor respiratory exposure) in order to clearly explain risk and to determine the most effective, realistic behavioral and other means to reduce illness and mortality.

At the same time, we must avoid generating irrational fear and maintain a broader perspective, including assessing the possibility for substantial unintended consequences from the response to the pandemic. P. 155

Note that he does not see contagion from people playing or visiting together outdoors or even viewing concerts or athletic events in large venues. The concern is "infection clusters resulting from prolonged indoor respiratory exposure," which is most likely in relatively small, cramped spaces.

Under WHAT ARE THE MAIN RISK FACTORS FOR SEVERE OUTCOMES? he points out that the CDC continues to spread fear on its website by stating that asthma is associated with bad outcomes from infection with the virus, when it is not. He then summarizes (multiple citations omitted):

... severe outcomes and deaths from COVID-19 are overwhelmingly associated with preexisting (and especially multiple) serious illnesses such as diabetes and heart disease, more so in men and particularly when exacerbated by obesity and smoking. Indeed, it may be that advanced age alone, in the absence of such predisposing

²² Halpern, D. (2020). Coping With COVID-19: Learning from Past Pandemics to Avoid Pitfalls and Panic. *Global Health: Science and Practice*, 8 (2), 155-165. Halpern is an epidemiologist and adjunct professor at Gillings School of Public Health, University of North Carolina, Chapel Hill. <https://www.ghspjournal.org/content/ghsp/8/2/155.full.pdf>

conditions, is less of an independent risk factor than has been assumed. Firstly, the elderly are more likely to have chronic illnesses, which confounds the association between outcomes and age. Moreover, the fact that between 96% (in the United States) and more than 99% (in Italy) of COVID-19-related deaths, at any age, have occurred in persons with preexisting conditions could suggest that even very old but otherwise healthy people may not be at greatly elevated risk of dying from the disease. P.156

The above observations were being made early in COVID-19 and continue to be confirmed. Even the elderly may not be at high risk for severe illness and death unless they have multiple risk factors! COVID-19 is unusual in how it passes through the populations leaving nearly everyone largely unscathed except people who are already ill, usually with multiple risk factors, conditions which are usually found in the elderly.

Halperin then goes on to succinctly describe those situations most likely to cause transmission of the disease:

It is probable that, as with other respiratory illnesses such as influenza, most COVID-19 infections occur from close exposure to coughing, sneezing, shouting, singing, or other direct and relatively prolonged contact with someone who is symptomatic or presymptomatic. (There is evidence that some asymptomatic carriers are contagious, but from existing studies they appear not to represent a very substantial proportion of total COVID-19 transmission.) p. 156

Halperin then elaborates on the most dangerous circumstances for transmission:

...the large majority of transmission events occurred within indoor clusters between family members (accounting for 75%–85% of estimated infections) and coworkers, with no identified cases of child-to-adult transmission identified. In addition, some data suggest that severity of outcomes is associated with initial exposure viral-load levels. Moreover, it increasingly appears that infection risk from contaminated surfaces has been at least somewhat overstated, as the CDC recently acknowledged. Indeed, it is conceivable that future science historians may conclude that many current COVID-19 prevention strategies had little if any impact, particularly because they targeted drivers of spread accounting for no more than a small proportion of total infections. Pp. 156-157

Halperin emphasizes the fact that most transmissions (75-85%) occur with intimate, regular contact between family members and coworkers. There is little or no transmission from children to adults (so teachers need not fear opening the schools, unless they have serious risk factors). Indeed, Halperin suggests that most of what is being done for prevention is having little positive effect.

Based on these observations, Halperin suggests that the CDC and society in general “reduce time and attention spent addressing low risk concerns, such as when healthy people avoid leaving home for necessary activities even if carefully taking precautions” (p. 157).” In short, there is little or no reason to keep healthy people from going out into the world for

necessary activities if they are taking careful precautions, which seems to lead to the conclusion that most of the shutdown has been in vain.

Halperin makes clear that the political fuss over people enjoying themselves together, including in parks and on beaches, is unwarranted:

There is a crucial distinction between risk of indoor transmission—where physical distancing (whether mandated or voluntary) and perhaps other measures are critical—versus risk of outdoor transmission, which is far lower (possibly by an order of magnitude) for various reasons, including dissipation of droplets in the air and the deactivating effects of ultraviolet radiation and heat. A contact tracing study from China found that 80% of infections involved household members and 34% involved mass transit (multiple potential transmission routes were considered), whereas only a single infection event of the 7,324 cases investigated was linked to casual outdoor transmission. P. 157

The above data is stunning: In a study of more than 7,000 cases in China, only one COVID-19 infection was associated with casual outdoor transmission.

Halperin next takes on the question, “Is 6 feet distancing strictly necessary?” And like other specialists I have talked with, his answer is “no.” He concludes:

And critically, as the economy begins to reopen, it would be especially challenging for some businesses (and eventually schools) to adhere strictly to a 6-foot rule. This could be particularly excessive for outdoor activities, including construction, farming, recreation, and outdoor dining. It is certainly more practical to maintain a distance of about 3 feet than 6 feet in many situations, such as grocery shopping (where interactions are typically brief) or while strolling with a companion. P. 157

Halperin then addresses the critical issues of opening the schools. He points out:

For example, Singapore had initially achieved a notably effective response without shutting schools. (However, subsequently there was a surge in cases due to an outbreak in crowded migrant-worker dormitories.) Taiwan, which never closed its schools, has continued to report very few cases. P. 157

Halperin addresses reports of “multisystem inflammatory syndrome in children (MIS-C)” from COVID-19:

Of more than 400,000 COVID-19 deaths reported worldwide, some 20 children are known to have died, about half of them in the United States and the rest in Europe. By comparison, more than 200 children died last year from the flu in the United States alone, along with some 10,000 others from various childhood diseases. Further contextualizing the MIS-C and other childhood deaths from COVID-19, in the United States, per-capita mortality in persons aged 85 years and older is 2,000 times higher than in children aged 15 years and younger. ... Moreover, the evidence suggests that even when children do become infected, they are probably considerably less contagious than adults. ...

*...in March 2020, modelers from the Imperial College of London estimated that closing schools might prevent only 2%–4% of premature deaths in the United Kingdom (i.e., predominantly of older adults with predisposing conditions such as chronic diseases, **obesity, and smoking, who could become directly or indirectly infected from schoolchildren.**) ... Growing evidence suggests that children are less likely to become infected. Even if they become infected, they are less contagious than adults. ... analysis of different COVID-19 interventions in the United States found no evidence for the impact of school closures. P. 158*

Halperin's article addresses the unfolding situation worldwide in respect to school openings:

In Denmark, Norway, and New Zealand, where schools reopened in April 2020, the numbers of new COVID-19 cases have continued to fall, similar to trends in Finland, France, Germany, Netherlands, and Vietnam, where schools all reopened in mid-May or earlier (though cases have increased in Madagascar, but perhaps not mainly due to reopening schools). It will, of course, be vitally important to implement adequate testing and safety measures for teachers and other school employees and to closely monitor the data as schools also begin reopening in Australia, Israel, Japan, and elsewhere (even as some U.S. school districts and colleges have announced that fall 2020 instruction will be conducted strictly online). (In Switzerland, health authorities also announced permission for grandparents to hug their young grandchildren.)

Halperin's concise up-to-date scientific analysis, along with multiple citations, provides us most of the information needed to make sense out what is required from a public health viewpoint in respect to restrictive policies and practices—and it is very minimal compared to what is transpiring. Mainly, people in close proximity need to take precautions, including handwashing, not touching their own faces, and keeping when possible a distance of 3-6 feet. But there is no great risk without an intense exposure to someone who is probably ill and symptomatic.

Unlike Halperin, many public health scientists ignore or minimize the consequences to the quality of life, from socioeconomic to personal distress. Halperin writes about school closings:

Certainly, as decisions are made regarding the reopening of schools, it must be taken into account that school closures have been depriving over a billion students worldwide of essential classroom learning, vital social connections, and physical activity. In addition, socioeconomic disparities are increasingly exacerbated, as some families have the technological, parental academic assistance, and other resources to enhance online learning, while less privileged children fall further behind. Other huge consequences of school closures include documented surges in child abuse; hunger from missed subsidized meals; and greater anxiety, depression and isolation, which often are most acutely experienced by students with autism, Down syndrome, attention-deficit/hyperactivity disorder and other special needs challenges. p .159

In a section titled, *One Alternative To Lockdown: Moving Toward Herd Immunity?*, Halperin takes a position that, in my experience, has also occurred to most people who are not strongly motivated to impose controls on the population:

Although many experts continue to believe that stay-in-place measures are needed to flatten the curve, others have proposed a Phase 2 alternative—instead of attempting to prevent any new infections—of essentially allowing younger and healthier people to gradually return to work and school, based on a herd-immunity strategy. Although many of them could eventually become infected, most individuals would be expected to experience relatively mild to moderate symptoms and, ideally after self-quarantining, would effectively be “naturally vaccinated” (i.e., they would presumably no longer be contagious, for perhaps a year or more).

Halperin concludes, as many of us have, that the most basic need is to protect the most vulnerable individuals from infection, without condemning the rest of the population to a vastly limited amount of freedom and great impaired capacity to take responsibility for their own lives. He offers some hope in respect to older members of the population:

This sort of herd-immunity approach could be strongly enhanced by large-scale antibody testing to identify previous infection, as China, Germany, Spain, United Kingdom, and some U.S. locales have begun to implement. Crucially, we must determine how best to isolate or otherwise protect the most vulnerable populations from infection—certainly no easy task. If it were to be the case, as previously discussed, that elderly but otherwise healthy people are not actually at considerably greater risk of severe illness or death, then clearly this would make the challenge somewhat less daunting. However, the evidence is not yet sufficient to base policy on this still-hypothetical possibility. P. 159

Halpern does a comparison of countries that have shut down against those that have not and finds that the death rates may be in the same range; but those that have shut down have added considerable suffering to the COVID-19 epidemic (See **Section XI**, Collective Immunity and the Advantages of Staying Open).

In his last section called “Unintended Consequences of the Global Lockdown Could be Massive,” Halperin presents a thoughtful analysis of the negative consequences of the global shutdowns, but without any focus on the impact of loss of liberty or the risks associated with trampling on the principles of freedom. He finishes by correctly observing:

Furthermore, it is critical to consider the consequences of remaining inside (often cramped) living quarters for extended durations, including reported increases in domestic violence and child abuse, as well as other physical and mental health issues related to chronic diseases; obesity; social isolation; anxiety, depression, and suicide; obsessive-compulsive disorder; poisoning from overuse of toxic cleaning products; and autism, attention-deficit/hyperactivity disorder, and other developmental challenges. As has occasionally occurred with other health crises such as HIV/AIDS, we must not lose sight of the bigger picture. It is sadly possible, especially in the

lowest-income regions, that the remedy could be worse—perhaps tragically even far worse—than the disease itself. p. 161

Unfortunately, Halperin’s article, like almost all others in the field of epidemiology and pandemics, gives no consideration to the overriding importance of the Bill of Right and the Constitution, or more simply, the importance of individual liberty. The failure to factor in the restraints of a free people is the Achilles heel of almost the entire public health literature and practice.

B. Thomas V. Inglesby,²³ Jennifer B. Nuzzo, Tara O’Toole, and D. A. Henderson (2006), Disease Mitigation Measures in the Control of Pandemic influenza.²⁴

An important resource published prior to COVID-19, this report by Inglesby et al. warns about the hazards of the entire approach of top-down planning to handling influenza viruses and is almost entirely relevant to the current coronavirus pandemic. There are few if any scientific studies to justify large-scale shutdowns and other drastic measures; but warnings about draconian measures have been clearly articulated. This all-important critical paper, “Disease Mitigation Measures in the Control of Pandemic influenza” was published in 2006. The article should be read in its entirety by everyone concerned about the shutdown. Here is one continuous excerpt from Inglesby et al., broken up only by my comments:

Potential Disease Control Measures: Benefits and Consequences

Large-Scale Community Vaccination

Vaccines are the best mechanism for preventing influenza infection and spread in the community and for protecting healthcare workers caring for those who do become ill. Once an influenza strain capable of sustained human-to-human transmission emerges,

²³ **Dr. Inglesby** is a physician and a Professor with joint appointments at the Johns Hopkins Bloomberg School of Public Health and the Johns Hopkins School of Medicine. Since 2016, he is also the Director of the Johns Hopkins Center for Health Security. The mission of the Center is to protect people from epidemics and disasters through independent research, policy analysis, and program assessment. **Dr. Nuzzo** is a Senior Scholar at the Johns Hopkins Center for Health Security and an Associate Professor in the Department of Environmental Health and Engineering and the Department of Epidemiology at the Johns Hopkins Bloomberg School of Public Health. **Dr. Tara O’Toole** is Senior Fellow and Executive Vice President at In-Q-Tel (IQT), a private, non-profit strategic investment firm that links the US Intelligence Community and venture-backed start-up firms. From 2009-2013, Dr. O’Toole served as Under Secretary of Science and Technology (S&T) at the Department of Homeland Security, the principal advisor to the Secretary on matters related to science and technology. **Dr. Donald Ainslee Henderson**, MD, MPH died in 2016. He was Distinguished Scholar at the Johns Hopkins Center for Health Security and a Professor of Public Health and Medicine at the University of Pittsburgh. From November 2001 through April 2003, he served as the Director of the Office of Public Health Emergency Preparedness and, later, as a Principal Science Advisor in the Office of the Secretary of the Department of Health and Human Services.

²⁴ Thomas V. Inglesby, Jennifer B. Nuzzo, Tara O’Toole, and D. A. Henderson. Disease Mitigation Measures in the Control of Pandemic Influenza. *Biosecurity and Bioterrorism*. Volume 4, Number 4, 2006. <https://www.liebertpub.com/doi/abs/10.1089/bsp.2006.4.366>.

a vaccine specific to the pandemic strain will need to be made. It is expected that it will be at least 6 months after the emergence of the pandemic strain before the initial supplies of vaccine can be produced. Current vaccine manufacturing techniques and limitations on vaccine production constrain the total amount of vaccine that can be manufactured. Special efforts are being made to increase this capacity, but under current conditions, according to the National Strategy for Pandemic Influenza, it will be as much as 5 years (i.e., 2011) before domestic vaccine production capacity is in place to create enough vaccine for the entire U.S. population within 6 months of the start of a pandemic.

We now know that there is a good chance that no effective vaccine will be developed, in part because none has ever been found for the common everyday cold, or for more severe SARS-CoV viruses, or for one that was chimerical, that is, created in a laboratory in 2015.²⁵ Instead of holding out in anticipation of a vaccine, we need to build a response that corresponds with a healthy, thriving, open society.

From this point on, much of what Inglesby et al. criticize about radical public health interventions has now been implemented under COVID-19. This description of *what not to do* begins to look like it was used as a blueprint for *what to do*!

Home Isolation of Sick People

In light of the expected shortages of medical beds and personnel, home isolation of non-critically ill influenza patients would be necessary in a major pandemic. A policy that persuades sick individuals to voluntarily stay at home unless they are critically ill would allow hospitals to focus efforts on those most seriously threatened.

There are a number of logistical considerations that could prevent people from being able to remain isolated in their homes. Special measures would be needed to provide basic medical and food supplies, perhaps through the use of neighborhood volunteers and supplemented by communication by phone or internet. It may not be easy to persuade those without paid sick leave (some 59 million persons) to absent themselves from work, unless employers address this problem directly. A recent review of state pandemic influenza plans found that only one-third of the 49 states examined have explicit plans to encourage voluntary home isolation.

The emphasis on voluntary home isolation is especially important and does not require more authoritarian or totalitarian interventions. It has been helped by federal government's provision of unemployment insurance, initially with a \$600 per week bonus that probably delayed many people from returning to work.

²⁵Vineet D Menachery, Boyd L Yount Jr, Kari Debbink1, Sudhakar Agnihothram, Lisa E Gralinski, Jessica A Plante, Rachel L Graham, Trevor Scobey, Xing-Yi Ge, Eric F Donaldson, Scott H Randell, Antonio Lanzavecchia, Wayne A Marasco, Zhengli-Li Shi & Ralph S Baric. A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence. *Nature Medicine*, 21 (12), 1508-1514. December 2015. Follow-up letter included. <https://www.nature.com/articles/nm.3985>

Use of Antiviral Medications

*Antiviral drugs for influenza are available in limited quantities. Data on how antivirals might perform in the prevention or treatment of the H5N1 strain are scant. Prominent authorities think the likelihood of “quenching” an emergent pandemic strain through the rapid, regionwide use of antivirals is low because of technical and logistical difficulties, even if the pandemic strain proves to be sensitive to such drugs. Several countries have recommended that the top priority for antivirals is to treat the ill. If antivirals were to be used for prevention, it would imply the need for much longer administration of the drug to cover the period of a community epidemic. Specifically, using oseltamivir as the most available example, the quantity of antivirals used to prevent infection in a single healthcare worker during an 8–10-week epidemic period **would** serve to treat an estimated 5 to 7 patients (assumes prophylaxis with 75 mg, twice daily, for 8–10 weeks versus treatment with 150 mg, twice daily, for 5 days).*

Moreover, available data indicate that antiviral treatment is effective only if antivirals are given within 24–48 hours after onset of initial symptoms. Some authorities doubt the feasibility of administering the drugs soon enough to make a difference during a pandemic. Because of this concern, at least one Canadian teaching hospital is planning to use all its antiviral stocks for prophylaxis of healthcare workers. The European Union, on the other hand, decided not to stockpile any antiviral medicines, although some European countries have done so.

The effectiveness and optimal use of antivirals remain uncertain because of several factors: the propensity of the influenza virus to mutate, thus increasing the possibility that resistance could develop; the quantities of antivirals required for prophylaxis; and the logistical challenges involved in providing sufficiently rapid treatment. Contextual variables that cannot be predicted ahead of time—such as the quantity of medicines available and the development of resistance—will probably determine antiviral strategy.

Once again, we have a thoughtful almost prescient discussion that emphasizes that antiviral drugs are generally most effective for prophylaxis and with early treatment. Unfortunately, driven by drug companies hungry for profits, hydroxychloroquine has been discredited to create the illusion that there is no existing good treatment, enabling the drug companies to fast track whatever antiviral drugs they can conjure up.

Hand-Washing and Respiratory Etiquette

The influenza virus actually survives on the hands for less than 5 minutes, but regular handwashing is a commonsense action that should be widely followed. It has been shown to reduce the transmission of respiratory illness in a military trainee setting, although there are no data to demonstrate that handwashing deters the spread of influenza within a community.

General respiratory hygiene, such as covering one's mouth when coughing and using disposable paper tissues, is widely believed to be of some value in diminishing spread, even though there is no hard evidence that this is so.

Once again, we find that there is little evidence that handwashing will effectively slow down a pandemic virus; but as we all should do, the authors play it safe and encourage its use.

Large-Scale Quarantine Measures

There are no historical observations or scientific studies that support the confinement by quarantine of groups of possibly infected people for extended periods in order to slow the spread of influenza. A World Health Organization (WHO) Writing Group, after reviewing the literature and considering contemporary international experience, concluded that "forced isolation and quarantine are ineffective and impractical."² Despite this recommendation by experts, mandatory large-scale quarantine continues to be considered as an option by some authorities and government officials.

The interest in quarantine reflects the views and conditions prevalent more than 50 years ago, when much less was known about the epidemiology of infectious diseases and when there was far less international and domestic travel in a less densely populated world. It is difficult to identify circumstances in the past half-century when large-scale quarantine has been effectively used in the control of any disease. The negative consequences of large-scale quarantine are so extreme (forced confinement of sick people with the well; complete restriction of movement of large populations; difficulty in getting critical supplies, medicines, and food to people inside the quarantine zone) that this mitigation measure should be eliminated from serious consideration.

This is a critical, valid conclusion: That quarantine outside the home, even when forced, is not a valid method for slowing down the spread of epidemic viruses. Yet the US and other nations have used the power of the state to impose them on people with great cost to individual lives and society.

Home Quarantine

Voluntary home quarantine would be requested of individuals who are asymptomatic but who have had substantial contact with a person who has influenza—primarily household members. The aim of voluntary home quarantine is to keep possibly contagious, but still asymptomatic, people out of circulation. This sounds logical, but this measure raises significant practical and ethical issues.

If implemented on a communitywide scale, logistical requirements related to ensuring that quarantined households across a community had appropriate care and support would be necessary. How compliant the public might be is uncertain. Parents would

presumably be willing to stay home and care for sick children, but it is not known, for example, whether college students would agree to be interned with infected dorm-mates.

Even if home quarantine were generally acceptable to the community, individuals may not have the economic resources to stay at home. Few employers currently have provisions for paid absence unless the workers themselves are ill. For those who are hourly workers or who are self-employed, the potential loss of wages as a result of having to stay home simply because an individual had had contact with sick people might not be acceptable or feasible.

Home quarantine also raises ethical questions. Implementation of home quarantine could result in healthy, uninfected people being placed at risk of infection from sick household members. Practices to reduce the chance of transmission (hand-washing, maintaining a distance of 3 feet from infected people, etc.) could be recommended, but a policy imposing home quarantine would preclude, for example, sending healthy children to stay with relatives when a family member becomes ill. Such a policy would also be particularly hard on and dangerous to people living in close quarters, where the risk of infection would be heightened.

The authors are critical of imposing home quarantine on individuals; but they are in favor of handwashing and distancing at home when possible.

The authors warn that travel restrictions in modern times will be economically ruinous without enough compensatory value. This might not be so under the special conditions of the release of the coronavirus from the Wuhan Laboratory in China, where a shutdown of travel from China would have given the rest of the world more time to prepare, much as the shutdown of travel from China early COVID-19 probably gave an advantage to the United States in preparing for the onslaught.

Prohibition of Social Gatherings

During seasonal influenza epidemics, public events with an expected large attendance have sometimes been cancelled or postponed, the rationale being to decrease the number of contacts with those who might be contagious. There are, however, no certain indications that these actions have had any definitive effect on the severity or duration of an epidemic. Were consideration to be given to doing this on a more extensive scale and for an extended period, questions immediately arise as to how many such events would be affected. There are many social gatherings that involve close contacts among people, and this prohibition might include church services, athletic events, perhaps all meetings of more than 100 people. It might mean closing theaters, restaurants, malls, large stores, and bars. Implementing such measures would have seriously disruptive consequences for a community if extended through the 8-week period of an epidemic in a municipal area, let alone if it were to be extended through the nation's experience with a pandemic (perhaps 8 months). In the event of a pandemic, attendance at public events or social gatherings could well decrease because people were fearful of becoming

infected, and some events might be cancelled because of local concerns. But a policy calling for communitywide cancellation of public events seems inadvisable.

While seeing some value perhaps in limiting large groups during an acute 8-week period, the authors see too much hardship from extended limitations on meetings and are against a communitywide cancellation of public events.

School Closures

In previous influenza epidemics, the impact of school closings on illness rates has been mixed. A study from Israel reported a decrease in respiratory infections after a 2-week teacher strike, but the decrease was only evident for a single day. On the other hand, when schools closed for a winter holiday during the 1918 pandemic in Chicago, “more influenza cases developed among pupils . . . than when schools were in session.

Schools are often closed for 1–2 weeks early in the development of seasonal community outbreaks of influenza primarily because of high absentee rates, especially in elementary schools, and because of illness among teachers. This would seem reasonable on practical grounds. However, to close schools for longer periods is not only impracticable but carries the possibility of a serious adverse outcome. For example, for working parents, school serves as a form of day care and, in some areas, a source of nutritional meals for children from lower-income families. In 2005, some 29.5 million children were fed through the National School Lunch Program; 9.3 million children received meals as part of the School Breakfast Program. A portion of America’s workforce would be unable to go to work as long as children were out of schools. Heightened absentee rates could cripple essential service industries. Teachers might not be paid and a great many hourly workers (mall and fast-food employees; school janitorial, security, and kitchen staff; bus drivers) would face particular financial hardship.

For all the reasons demonstrated now in the COVID-19 lockdown, the authors warn against school closures. Children lose everything from their schooling to free lunches, and parents are forced to stay at home, straining families and the economy in which they were working.

Maintaining Personal Distance

It has been recommended that individuals maintain a distance of 3 feet or more during a pandemic so as to diminish the number of contacts with people who may be infected. The efficacy of this measure is unknown. It is typically assumed that transmission of droplet-spread diseases, such as influenza, is limited to “close contacts”—that is, being within 3–6 feet of an infected person. Keeping a space of 3 feet between individuals might be possible in some work environments, but it is difficult to imagine how bus, rail, or air travelers could stay 3 feet apart from each other throughout an epidemic. And such a recommendation would greatly complicate normal daily tasks like grocery shopping, banking, and the like.

The authors find that the effectiveness of distancing is unknown, but do not see its feasibility for transportation and warn that it would greatly complicate everyday life.

Use of Masks and Personal Protective Equipment

Masks and other personal protective equipment (PPE) are essential for controlling transmission of influenza in hospitals. For people who work in hospitals, current CDC guidelines for influenza infection control recommend droplet precautions, including the use of surgical masks. But HHS planning guidelines also rightly acknowledge that the uncertainties regarding the potential of virus transmission at the start of a new pandemic would recommend that airborne precautions be used in hospitals—that is, N95 masks (already in short supply)⁷ or powered air purifying respirators (PAPRs). Patients would be advised to wear surgical masks to diminish the number of infectious respiratory particles being dispersed into the air, thereby diminishing the likelihood of further spread.

In Asia during the SARS period, many people in the affected communities wore surgical masks when in public. But studies have shown that the ordinary surgical mask does little to prevent inhalation of small droplets bearing influenza virus. The pores in the mask become blocked by moisture from breathing, and the air stream simply diverts around the mask. There are few data available to support the efficacy of N95 or surgical masks outside a healthcare setting. N95 masks need to be fit-tested to be efficacious and are uncomfortable to wear for more than an hour or two. More important, the supplies of such masks are too limited to even ensure that hospitals will have necessary reserves.

In their summary remarks, the authors warn that reserves for masks are too low and describe many of their shortcomings and difficulties, much as we have learned during COVID-19. They do not go into the enormous hazards associated with wearing masks which are mentioned in various places in this report, especially section **VI. Hazards of Face Masks.**

Following the above section, which provides an excellent review of the hazards of enforced policies and practices during a pandemic, the authors summarize the possible kinds of “Community Response to a Pandemic. It basically reflects their analyses excerpted above. They emphasize the importance of vaccinations if they can be developed. They stress the importance of planning for the isolation and treatment of active cases. They tentatively support school closing but only for 10-14 days. They support handwashing but warn against vast closures of public meetings, quarantines, and travel restrictions.

The authors conclude:

An overriding principle. Experience has shown that communities faced with epidemics or other adverse events respond best and with the least anxiety when the normal social functioning of the community is least disrupted. Strong political and public health leadership to provide reassurance and to ensure that needed medical care services are provided are critical elements. If either is seen to be less than optimal, a manageable epidemic could move toward catastrophe.

C. American Institute for Economic Research (AIER), Urgent Report on Pandemics and Freedom

The May 29, 2020 *Urgent Report on Pandemics and Freedom* by the American Institute for Economic Research (AIER)²⁶ opens:

Nearly the entire United States population was blindsided by the events of Spring 2020. We thought we lived under the rule of law with protections for commerce, freedom, and property. Suddenly we discovered otherwise. It all happened because of a virus, a subject on which most every citizen and non-medical academics know precious little. Our lives and futures were put into the hands of “public health professionals” – the appointed but untested experts – working with ignorant, ambitious, and risk averse politicians. They acted with dictatorial power to enact extreme policies over the course of just a few days. Why did this happen? We knew already in January 2020 that COVID-19 was a virus that was particularly cruel toward elderly populations in nursing homes, so why did some governors force sick patients into those homes to spread it? We knew of its potentially fatal effects on those with comorbidities, so why didn’t policy focus on the vulnerable rather than locking down everyone? Why did we force schools to close when the kids there were of exceptionally low risk, which we also knew? We knew from experience in the 20th century how to handle viruses with minimum or no disruption of the free society and the rule of law. Why did we reject the models that work? For reasons explained below, the United States took a different route: lockdown, school and business closures, shelter in place orders, travel bans, mandatory universal quarantines, checkpoints at state borders, mask mandates, and forced human separation. It felt like a socio-political experiment because it was: nothing like this has happened in U.S. history or any developed society in the modern age. P.1

It is, of course, happening now in the “modern age,” but the response has overridden almost every suggestion and conclusion made in this excellent report.

D. Maine Policy Institute, COVID Catastrophe: Consequences of Societal Shutdowns

Another excellent resource is the August 2020 report *COVID Catastrophe: Consequences of Societal Shutdowns* from the Maine Policy Institute by policy analyst Nick Murray.²⁷ The introduction observes:

Very little was known about this new virus in early 2020, as the world tried to secure accurate data from the opaque and corrupt Chinese Communist Party. Despite limits on credible information, science had determined a few crucial elements, which were informed by the surveys of passengers on quarantined cruise ships like the Diamond Princess. We began to see that a surprisingly large portion of those exposed do not

²⁶ AIER, *Urgent Report on Pandemics and Freedom*, 2020, American Institute for Economic Research. <https://www.aier.org/urgent-report-on-pandemics-and-freedom/>

²⁷ Murray, N., 2020, *COVID Catastrophe*. Maine Policy Institute. <https://mainepolicy.org/wp-content/uploads/FullCOVIDreportFinal.pdf>

contract the new virus, and a substantial number of those infected do not experience symptoms serious enough to seek medical care. We learned that the elderly and those with preexisting conditions or a compromised immune system were at the highest risk.

In Maine today, the spread of COVID-19 is largely under control. Indicators of disease spread, like infection rate, testing positivity rate, and R0 value, or “R-naught,” (the rate at which each infection leads to other successive infections) and indicators of outbreak severity, like case hospitalization rate and case fatality rate (CFR), have been on the decline since peaking in April and May. Although Governor Janet Mills has maintained the Civil State of Emergency originally declared in March, a review of current data shows that Maine is no longer in an emergency. Every public policy decision is a trade-off. Maine people should be asking themselves what aspects of their lives and livelihoods they had to trade in order to “flatten the curve.” How many businesses in remote Piscataquis or Aroostook county were forced to shut their doors, merely on the governor’s edict, despite relatively little risk to the vast majority of their rural residents? How many workers were unnecessarily pushed onto the unemployment rolls, imposing never before seen stress on the state’s unemployment insurance system? How many millions of dollars were forgone in donations to local charities because of widespread closures and event cancellations? The broader question becomes, could Maine people have avoided the immense economic hardship inflicted by government-mandated shutdowns and “stay-at-home” orders, while maintaining control of the spread of this new virus and protecting the truly vulnerable? P. 1

E. Alex Berenson, Unreported Truths about COVID-19 and Lockdowns:

Former *New York Times* reporter Alex Berenson has written two quickie pamphlets packed with information of great immediacy and importance.²⁸ In Part 1, he exposes the skewed death toll of COVID-19:

In Minnesota, the median age of the 1,000 COVID deaths is almost 84. More people over 100 have died than under 50.

The pattern is the same everywhere. Extremely elderly people are far more likely to die of SARS-coV-2 than anyone else. That is especially true for those living in nursing homes and assisted living facilities. Those people account for about 40 to 50 percent of all deaths from COVID in the United States. A figure of 43 percent has been widely used. It probably understates the real total because in some states, including New York, nursing home residents who die in hospitals are counted as hospital deaths.

The flip side of the risk to the elderly is that younger adults and especially teenagers and children are at extremely low risk from SARS-CoV-2. In Italy, a total of 17 people under 30 have died of the coronavirus. In the United Kingdom, four people under 1-5 have died. In New York, 14 under 20 and 102 under 30.

²⁸ Berenson, A. (2020, June 7). Unreported Truths about COVID-19 and Lockdowns: Part 1: Introduction and Death Count; and Berenson, A. (2020, August 8). Unreported Truths about COVID-19 and Lockdowns, Part 2: Updates and Examination of Lockdowns as a Strategy. No publisher listed; available on Amazon.com.

*Worldwide, it is almost certain that more people **over the age of 100 than under 30** have died of SARS-CoV-2. Many more children die of influenza than coronavirus; in the 2019-2020 flu season, the Centers for Disease control received about 180 reports of pediatric flu deaths. It has received 19 reports of coronavirus deaths in children under 15 so far.*

Several contemporary critiques of the shutdown for COVID-19 draw on the wisdom of 2006 study by Inglesby et al. Alex Berenson, refers to the earlier “2006” study in his conclusion to Part 2 of *Unreported Truths about COVID-19 and Lockdowns*:

The lockdowns have punished all of us (except technology and social media companies, which are reporting record profits) enormously. Which might not matter if we had compelling evidence they worked. Only we don't.

So, the calls by some members of Team Apocalypse for renewed lockdowns—even harder lockdowns, in fact, as if we didn't do enough damage in the spring—might sound like a joke.

Especially since hospitals even in the hardest-hit Sunbelt states are beginning to empty. But they're not a joke. They're serious—as the decision on Aug. 2 by the Australian province of Victoria to impose a new and draconian _lockdown on Melbourne, a city with 5 million people, shows.

Lockdowns have failed as badly as the experts warned us they would, for precisely the reasons those experts spent their careers predicting. But the hysterics have learned nothing from the last four months.

Experience has shown that communities faced with epidemics or other adverse events respond best and with the least anxiety when the normal social functioning of the community is least disrupted.

*Those words are as true now as they were in 2006 . We have forgotten them once already this year. (final page, **bold** in original)*

There is no substantial science and little reason and common sense to support the shutdowns or the overall degree of totalitarian public health impositions on American citizens. There are, instead, many good reasons to maintain the functioning of our society as its maximum for the benefit of individuals and the nation alike.

I am one of the individuals at highest risk. I am 84 years old, have mild controlled blood pressure and mild controlled asthma. I am also a bit overweight, which seems to matter in COVID-19. On the other hand, I still have more energy and engagement with life than many younger people. Regardless of my hope for many more good years of life, I do not want the rest of the nation to be suffering to contain the uncontrollable virus on my behalf. Instead, I hope that all Americans will regain the freedom they possessed before the “scientists” took over, while we oldsters take care of ourselves to the best of our ability.

What are the origins and what can we do about the enormous impulse for top-down-control of our society than has been so recently unleashed with such tragic consequences and so little gain?

III. Political Totalitarianism and Public Health Totalitarianism

A. Political Totalitarianism

There is a close relationship between totalitarianism and public health policies and their effects on the individual can be similar or the same. Before World War II broke out, Adolph Hitler was praised in Western scientific literature as The First Mental Hygiene Führer for his devotion to genetics, eugenics, and the cleansing of the population from corrupting illnesses and diseases.²⁹

Throughout this discussion, when we refer to the effect of government policies on individuals, we are referring to detrimental impacts on their psychosocial and physical well-being, including their overall quality of life.

The following definition and description of totalitarianism was written by the editors of Encyclopedia Britannica (to be referred to as Britannica). The sentence numbering has been inserted:

(1) Totalitarianism, form of government that theoretically permits no individual freedom and that seeks to subordinate all aspects of individual life to the authority of the state. ... (2) Totalitarianism is often distinguished from dictatorship, despotism, or tyranny by its supplanting of all political institutions with new ones and its sweeping away of all legal, social, and political traditions. (3) The totalitarian state pursues some special goal, such as industrialization or conquest, to the exclusion of all others. (4) All resources are directed toward its attainment, regardless of the cost. (5) Whatever might further the goal is supported; whatever might foil the goal is rejected. (6) This obsession spawns an ideology that explains everything in terms of the goal, rationalizing all obstacles that may arise and all forces that may contend with the state. (7) The resulting popular support permits the state the widest latitude of action of any form of government. (8) Any dissent is branded evil, and internal political differences are not permitted. (9) Because pursuit of the goal is the only ideological foundation for the totalitarian state, achievement of the goal can never be acknowledged. ... (10) Under totalitarian rule, traditional social institutions and organizations are discouraged and suppressed. (11) Thus, the social fabric is weakened and people become more amenable to absorption into a single, unified movement. (12) Participation in approved public organizations is at first encouraged and then required. (13) Old religious and social ties are supplanted by artificial ties to the state and its ideology. (14) As pluralism and individualism diminish, most of the people embrace the totalitarian state's ideology. (15) The infinite diversity among individuals blurs, replaced by a mass conformity (or at least acquiescence) to the beliefs and behaviour sanctioned by the state.

Many, if not all, these 15 descriptive points can be found in much of the current public health programs in response to COVID-19 that have been implemented by various U. S.

²⁹ Breggin, Peter. "Psychiatry's Role in the Holocaust." International Journal of Risk and Safety in Medicine, 4:133-148, 1993. Adapted from a paper delivered at "Medical Science Without Compassion" in Cologne, Germany and originally published in the conference proceedings. <http://breggin.com/wp-content/uploads/2008/01/psychiatrysrole.pbreggin.1993.pdf>

governors, as well as federal officials and agencies. They are key to understanding the threat inherent in the “public health” approach now being taken by a wide range of actors who are implementing policies and actions that seem erratic, often inconsistent, sometimes unnecessary, almost always unprecedented—but often *consistently* totalitarian.

B. Public Health Totalitarianism

Public health publications generally frame the totalitarianism inherent in public health as essentially an *ethical* problem or question. They do this presumably to avoid becoming mired down in “politics” or even the law. However, public health as a field focuses on and implements *government responses* to biological threats, such as COVID-19³⁰ and is therefore inherently legal and political nature, rather than simply ethical.

Faden, Shebaya and Siegel (2019)³¹ “examine the kinds of moral justification that may be marshaled in support of specific public health interventions” and do touch upon liberty:

1. *The overall benefit a public health measure produces.*
2. *The collective efficiency an intervention provides by coordinating action to ensure population-wide compliance.*
3. *Fairness in the distribution of the burdens of disease and disability.*
4. *The "harm principle." according to which the only justification for limiting a person's liberty is the prevention of harm to other persons.*
5. *Paternalism, which is the thesis that a restriction on individual liberty is acceptable if it is necessary to prevent harm or produce a benefit to the agent involved.*

The first three concern the justification of public health policies that do not directly benefit all members of the population, while the last two concern the justification of public health measures that interfere with individual liberty.

In the next chapter, Faden and Shebaya (2019)³² shorten this description of the “appropriate” “ethical justifications” for public health interventions to the following: “(1) overall benefit, (2) collective action and efficiency, (3) fairness in the distribution of burdens, and (4) prevention of harm (the harm principle), and (5) paternalism.”

In their conclusion, Faden, Shebaya and Siegel (2019)observed:

³⁰ Evans, N. and Inglesby, T. (2019). Biosecurity and public health ethics issues raised by biological threats. Chapter 66, pp. 774-785 in *The Oxford Handbook of Public Health Ethics*. Eds. Mastroianni, A, Kahn, J., & Kass. N. New York: Oxford University Press.

³¹ Faden, R., Shebaya, S., & Siegel, A. (2019). Distinctive Challenges of Public Health Ethics. Chapter 2, pp. 12-20 in *The Oxford Handbook of Public Health Ethics*. Eds. Mastroianni, A, Kahn, J., & Kass. N. New York: Oxford University Press.

³² Faden, R &, Shebaya, S. (2019). Public Health Programs and Policies: Ethical justifications. Chapter 3, pp. 12-20 in *The Oxford Handbook of Public Health Ethics*. Eds. Mastroianni, A, Kahn, J., & Kass. N. New York: Oxford University Press.

Public health is (1) a collective good, (2) focused especially on prevention, (3) reliant on government action supported by the force of law and (4) intrinsically outcome oriented. These characteristics of public health give rise to a wide range of ethical issues, such as the balancing of future health gains against current ones, the justification for the state's use of coercive powers to advance health, and the moral foundation of public health. In addition, how many of these issues are framed will depend on how we understand who it is that public health protects and the boundaries of what public health addresses. Together, these moral and conceptual questions form the distinctive challenges of public health ethics.

The observations are made from the viewpoint of advocates of public health who also want to raise “ethical” and “moral” concerns—and then to answer the questions to their own satisfaction. What is notably missing is either a legal or a political framework that would provide any control over their actions. When legal and political issues arise among advocates of public health, an odd orientation sneaks in. Such is their self-importance that public health authorities represented in the tome write as if the decision-making power simply theirs to take. For example, Faden, Shebaya and Siegel state that particularly when government programs are involved, “one task of public health ethics is determining self-imposed limitations and restrictions on what can reasonably come under the auspices of public health authorities” (p. 18). They expect to be controlled by self-restraint and not by external restraint.

There is little interest in the public’s right to impose ethical, legal, and political restraints on public health activities. I believe this self-centered, self-empowering attitude is epitomized in the attitudes and actions of Dr. Anthony Fauci, the head of NIH’s Institute for Allergy and Infectious Diseases.

The chapters thus far cited are taken from a new compendium: *The Oxford Handbook of Public Health Ethics* there are more than a dozen references beneath the term in the index.³³ The index to the tome (73 chapters, 902 pages) includes few items reflecting on liberty, the Constitution, the Bill of Rights, and other bedrock restraints built into American tradition, law and politics.

This is the perhaps the kernel of the threat of public health—it sweeps aside those kinds of concerns upon which American law and political theory have drawn so heavily and that emphasize the protection of individual rights and liberty. It also escapes from considering the harm to individuals psychosocially and physically when liberty is curtailed. Consistent with this, little or nothing is said about the psychological and social consequences of loss of liberty or the diminishment of personal responsibility, and even more obvious threats, such as impingements on freedom of speech, the right to assembly, private property or diminishment of individual well-being and quality of life, get little attention.

³³ Mastroianni, A, Kahn, J., & Kass, N. (Eds). (2019) *The Oxford Handbook of Public Health Ethics*. N. New York: Oxford University Press, p. 878-879 .

There is a long and varied literature warning about the totalitarian aspects of public health and also universal health insurance and national medical planning.³⁴ Indeed, it is at the heart of ancient discussions that weigh the public good or general welfare against the rights of the individual. But it is relatively absent from any current discourse offered by public health physicians or officials.

C. Combining Political Totalitarianism and Public Health Totalitarianism to Suppress the Only Drug Effective Against COVID-19

(1) Open letter to Dr. Anthony Fauci regarding the use of hydroxychloroquine for treating COVID-19

The cutting edge of public health totalitarianism in the US and the world today is Anthony Fauci, MD, a man who has successfully taken the reins to control what happens during COVID-19. Fauci exemplifies how totalitarianism has erupted through positions of power during the current pandemic. The open letter to Dr. Fauci characterizes and challenges the behavior of Fauci in a striking fashion but has been utterly ignored by the major media. It can only be found in smaller newspaper outlets. The entire letter should be read by anyone interested in public health policy and its implementation by Anthony Fauci. The following is the opening statement of the Open Letter to Dr. Fauci:³⁵

Open letter to Dr. Anthony Fauci Regarding the Use of Hydroxychloroquine for Treating COVID-19

By George C. Fareed, MD Brawley, California Michael M. Jacobs, MD, MPH Pensacola, Florida Donald C. Pompan, MD Salinas, California (Aug 13, 2020, Updated Aug 22, 2020):

Dear Dr. Fauci:

You were placed into the most high-profile role regarding America's response to the coronavirus pandemic. Americans have relied on your medical expertise concerning the wearing of masks, resuming employment, returning to school, and of course medical treatment.

You are largely unchallenged in terms of your medical opinions. You are the de facto "COVID-19 Czar." This is unusual in the medical profession in which doctors'

³⁴ For a specific critic of the handling of COVID-19 from a Constitutional perspective, see: Jackie McDermott and Lana Ulrich. (2020, April 15). COVID-19 and the Constitution — Key Takeaways. From the National Constitution Center. <https://constitutioncenter.org/interactive-constitution/blog/covid-19-and-the-constitution-key-takeaways>. Also, see Heath, I. (2017). The missing person: The outcome of the rule-based totalitarianism of too much contemporary healthcare. *Patient Educ Couns.* 2017 Nov;100(11):1969-1974. doi: 10.1016/j.pec.2017.03.030. Epub 2017 Apr 3; Fleming, K. (2004, December). Rapid Response: National Health Care and Totalitarianism. *BMJ* 2004;329:1424; A General Surgeon. (2018). As We Continue to Drift Into a Totalitarian Medical System: A View of a Country Boy. *Scand. J. Surg.* <https://doi.org/10.1177/1457496918757579>

³⁵ Fareed, G. et al., August 22, 2020, Open letter to Dr. Anthony Fauci regarding the use of hydroxychloroquine for treating COVID-19. *The Desert Review.* https://www.thedesertreview.com/opinion/columnists/open-letter-to-dr-anthony-fauci-regarding-the-use-of-hydroxychloroquine-for-treating-covid-19/article_31d37842-dd8f-11ea-80b5-bf80983bc072.html

opinions are challenged by other physicians in the form of exchanges between doctors at hospitals, medical conferences, as well as debate in medical journals. You render your opinions unchallenged, without formal public opposition from physicians who passionately disagree with you. It is incontestable that the public is best served when opinions and policy are based on the prevailing evidence and science, and able to withstand the scrutiny of medical professionals.

As experience accrued in treating COVID-19 infections, physicians worldwide discovered that high-risk patients can be treated successfully as an outpatient, within the first five to seven days of the onset of symptoms, with a “cocktail” consisting of hydroxychloroquine, zinc, and azithromycin (or doxycycline). Multiple scholarly contributions to the literature detail the efficacy of the hydroxychloroquine-based combination treatment.

*Dr. Harvey Risch, the renowned Yale epidemiologist, **published** an article in May 2020 in the American Journal of Epidemiology titled “Early Outpatient Treatment of Symptomatic, High-Risk COVID-19 Patients that Should be Ramped-Up Immediately as Key to Pandemic Crisis.” He further published an **article** in Newsweek in July 2020 for the general public expressing the same conclusions and opinions. Dr. Risch is an expert at evaluating research data and study designs, publishing over 300 articles. Dr. Risch’s assessment is that there is unequivocal evidence for the early and safe use of the “HCQ cocktail.” If there are Q-T interval concerns, doxycycline can be substituted for azithromycin as it has activity against RNA viruses without any cardiac effects.*

Yet, you continue to reject the use of hydroxychloroquine, except in a hospital setting in the form of clinical trials, repeatedly emphasizing the lack of evidence supporting its use. Hydroxychloroquine, despite 65 years of use for malaria, and over 40 years for lupus and rheumatoid arthritis, with a well-established safety profile, has been deemed by you and the FDA as unsafe for use in the treatment of symptomatic COVID-19 infections. Your opinions have influenced the thinking of physicians and their patients, medical boards, state and federal agencies, pharmacists, hospitals, and just about everyone involved in medical decision making.

Indeed, your opinions impacted the health of Americans, and many aspects of our day-to-day lives including employment and school. Those of us who prescribe hydroxychloroquine, zinc, and azithromycin/doxycycline believe fervently that early outpatient use would save tens of thousands of lives and enable our country to dramatically alter the response to COVID-19. We advocate for an approach that will reduce fear and allow Americans to get their lives back.

We hope that our questions compel you to reconsider your current approach to COVID-19 infection.

That this trenchant letter has been so ignored by the media and major medical organizations indicates the hold that globalism and the pharmaceutical industry, in league with government agencies, have upon the world. The letter goes on to raise a great number of questions about what Fauci is doing and should be read by anyone who wants to be further educated about the current crisis in the suppression of hydroxychloroquine by itself or in combination with azithromycin and zinc.

(2) The Broader Context

There are many reasons why the worldwide political, health and industrial establishment has ganged up to suppress hydroxychloroquine which, in combination with azithromycin and zinc, is the only demonstrated prophylaxis and the only useful drug treatment when given early in the disease process. First, Donald Trump has supported it and so they are attacking “Trump’s drug.” But this is a diversion, because the pharmaceutical industry and other interest groups all over the world are attacking the medication and for this reason the phrase “Trump’s drug” will be avoided. Second, and this is far more important, the drug combination is incredibly cheap, and the pharmaceutical industry has tooled up, with the support of Anthony Fauci and others, to support rush programs for extremely remunerative and dubious drugs, while holding out for more remunerative compulsory vaccinations. The vast powers of the pharmaceutical and chemical industry, probably the largest and most powerful lobby in the world, has determined to crush “the people’s drug,” hydroxychloroquine. This report will discuss hydroxychloroquine in many places, including in an essay by Dr. Meryl Nass contained in part **VII** and by an open letter from a group of physicians in part **III C (3)**.

There are special federal regulations for providing treatments for CBRN agents—Chemical, Biological, Radiological, and Nuclear treatments. Under federal regulations, in an emergency declared by the Health and Human Services (HHS) secretary, medicines can be used “that ‘may be effective’ to prevent, diagnose, or treat serious or life-threatening diseases that can be caused by CBRN agents...” (p. 7).³⁶ There can be no doubt that hydroxychloroquine “may be effective,” so in order for the big drug companies to stop the use of this inexpensive drug they had to declare it too dangerous to use.³⁷ Hydroxychloroquine is “an extraordinarily safe drug”³⁸ when used in the proper dose range; but it can be fatal when used in too large doses. So those who want to discredit the medication have been prescribing it in lethal or near-lethal doses to unwitting patients in clinical trials.

This report will discuss hydroxychloroquine in many places, including in an essay by Dr. Meryl Nass contained in part **VII** and by an open letter from a group of physicians in part **III C (3)**. However, because the accusation about doctors giving lethal doses is so potentially “inflammatory,” one of those studies will now be evaluated and made available by links in the following section.

(3) Using Lethal Doses to Discredit Hydroxychloroquine

³⁶ U.S. Department of Health and Human Services, et al. (2017). Emergency Use of Authorization of Medical Products and Related Authorities. Guidance for Industry and Other Stakeholders. <https://www.fda.gov/media/97321/download>

³⁷ Numerous studies have confirmed the usefulness of hydroxychloroquine as an antiviral agent and its mechanisms of action have been very well studied. E.g., [Islam, T., et al. A Perspective on Emerging Therapeutic Interventions for COVID-19. *Front Public Health*. 2020; 8: 281. Published online 2020 Jul 3. doi: 10.3389/fpubh.2020.00281. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7362761/> . Also see \[Early treatment with hydroxychloroquine: a country-based analysis. @Covid Analysis, August 5, 2020 \\(updated August 18, 2020\\) <https://hcqtrial.com/>. We have written numerous blog reports discussing the usefulness of hydroxychloroquine and the pharmaceutical industry’s attempts to discredit it. <https://breggin.com/coronavirus-resource-center/>\]\(#\)](#)

³⁸ In *Goodman & Gilman’s The Pharmacological Basis of Therapeutics* (2011, p. 1404), New York: McGraw-Hill. The word “extraordinarily” is removed in the 13th edition (2019) but otherwise remains the same.

The research community in the service of the pharmaceutical industry and its main vector, Anthony Fauci, conducted one study after another in which they gave COVID-19 patients toxic and even lethal doses of either chloroquine or hydrochloroquine. Often, they used the older drug, chloroquine, when hydroxychloroquine is “a less toxic metabolite of chloroquine.”³⁹ To further discredit these medications, they gave them to patients on death’s door, when their only proven effective is as a prophylaxis or early in the treatment of viral diseases, including COVID-19.

We became so incensed by one of the more recent studies that I titled it, “Research Study—Or Megadose Mass Murder.”⁴⁰ The authors of the study⁴¹ had to know that they were treading on dangerous territory, risking many deaths. Respected sources, such as all recent editions of the classic *Goodman & Gilman’s The Pharmacological Basis of Therapeutics* (2011, p. 1405), make the same basic observation:

***Toxicity and Side Effects.** Taken in proper doses, chloroquine is an extraordinarily safe drug; however, its safety margin is narrow, and a single dose of 30 mg/kg may be fatal.*

The study that killed so many patients used enormous repeated doses of chloroquine: *1200 mg daily for 10 days*. This dose is so large that the authors could not cite a single other clinical study that approximated this megadose range, except in a single study in which hydroxychloroquine was given in the hope of suppressing cancer.

The lethal dose of chloroquine begins at 30 mg/kg for a 40 kilo⁴² or 89-pound patient. Since the patients in this study were extremely sick, since many had comorbid illnesses, and since a number were elderly, it is likely that some were probably under 90 pounds. But we need not quibble because the 30 mg/kg death range is for a **single** dose—and these doctors gave 10 days of this toxic megadose. Furthermore, all the patients were extremely ill with COVID-19, some were elderly, and many had comorbid disease, including heart disease. The lethal dose for them would be considerably below 30 mg/kg. It is no exaggeration to observe that, given their physical condition and frailties, all the patients in this study were at risk of death from the megadoses of chloroquine administered to them for ten days.

In addition, these doses over a period of ten days are higher than they even seem because chloroquine has an extremely long half-life, measured in days and weeks rather than hours, again according to *Goodman & Gilman’s The Pharmacological Basis of Therapeutics* (2011, p. 1404). There is also evidence that the half-life increases with the dose. Altogether, this means that the high doses over ten days would accumulate in increasingly greater concentrations that would persist well beyond the termination of drug treatment—leading to increased lethality. Many of the patients were probably too ill to properly metabolize or break down the drug, increasing the

³⁹ Stokkermans, T. J., Goyal, A., Bansal, P. Trichonas, G. Chloroquine And Hydroxychloroquine Toxicity. StatPearls [Internet]. Treasure Island (FL): StatPearls. Last Update: July 4, 2020
<https://www.ncbi.nlm.nih.gov/books/NBK537086/?report=printable>

⁴⁰ Breggin, P., 2020, Scientific Study or Megadose Mass Murder. The Breggins’ Coronavirus Resource Center.
<https://breggin.com/scientific-study-or-megadose-mass-murder/>

⁴¹ Borba, M., Val, F., and Sampaio, V. et al. (2020 April 24). Effect of High vs Low Doses of Chloroquine Diphosphate as Adjunctive Therapy for Patients Hospitalized with Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) Infection: A Randomized Clinical Trial. JAMA Network Open.
<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2765499>

⁴² *Goodman & Gilman’s The Pharmacological Basis of Therapeutics* (2011, p. 1405). New York: McGraw Hill.

effect of dose through its increased concentration in the blood and hence again increasing its lethality. Worse yet, the patients were already at death's door in "intensive care units" for the "treatment of severe COVID-19 patients." They were described as "critically ill" (p. 1). Some were "unconscious," according to the prepublication version.⁴³

When the death rate reached **39%**, the megadose experiment was stopped. Sixteen of the 41 patients had died. It took the intervention of an independent monitoring group to prevent the researchers from continuing on.

The study became a big hit among the establishment working full-time to promote the interests of the pharmaceutical industry and not the people in need of treatment. I wrote in a blog/ report:

The study we call "Megadose Mass Murder" was released prepublication on-line on April 11, 2020.⁴⁴ The partisan *New York Times* was so happy to thump Trump's drug that it published a big story in support of it on April 12, 2020, one day after the prepublication report.⁴⁵ The article was then rushed to formal publication on-line on April 24, 2020 by the *Journal of the American Medical Association* on its *JAMA Network Open*.⁴⁶ The journal of the AMA even gave on-line Continuing Medication Education (CME) credits to doctors who read it.⁴⁷

Simultaneously, on April 24, 2020, the FDA ramped up its attack on hydroxychloroquine, limiting its use to hospitals, in an effort that would eventually tell doctors to stop using it at all.

The study was conducted in Brazil. Those who planned the clinical trial created a no-win study to demonstrate that the highly politicized treatment was too dangerous to treat COVID-19 patients. They administered the medications in potentially lethal doses with no other discernable goal than to discredit hydroxychloroquine and President Trump, along with their own Brazilian President, Jair Bolsonaro, a supporter of both Trump and hydroxychloroquine.⁴⁸

When the FDA joined forces against hydroxychloroquine, it used fraudulent studies like the one above to declare the drug too dangerous to use—even though chloroquine and

⁴³ Borba, S. and many other authors. Chloroquine diphosphate in two different dosages as adjunctive therapy of hospitalized patients with severe respiratory syndrome in the context of coronavirus (SARS-CoV-2) infection: Preliminary safety results of a randomized, double-blinded, phase IIb clinical trial (CloroCovid-19 Study) Unpublished at the time. See section on "Ethical Aspects."

<https://www.medrxiv.org/content/10.1101/2020.04.07.20056424v1.full.pdf>

⁴⁴ Borba, S. and many other authors. Chloroquine diphosphate in two different dosages as adjunctive therapy of hospitalized patients with severe respiratory syndrome in the context of coronavirus (SARS-CoV-2) infection: Preliminary safety results of a randomized, double-blinded, phase IIb clinical trial (CloroCovid-19 Study) Unpublished at the time. <https://www.medrxiv.org/content/10.1101/2020.04.07.20056424v1.full.pdf>

We are no longer emphasize that they are attacking "Trump's drug," because as mentioned earlier, that is a diversion. The medication has the support of many countries and untold numbers of doctors, so it is hardly "Trump's drug." In addition, the medication is being attacked around the world, not just in America as Trump's drug.

⁴⁵ Thomas, K. and Knvul, S. (Published April 12, 2020. Updated June 15, 2020). Chloroquine Study Halted Over Risk of Fatal Heart Complications: A research trial of coronavirus patients in Brazil ended after patients taking a higher dose of chloroquine, one of the drugs President Trump has promoted, developed irregular heart rates.

<https://www.nytimes.com/2020/04/12/health/chloroquine-coronavirus-trump.html>

⁴⁶ Borba, M., Val, F., and Sampaio, V. et al. (2020 April 24). Effect of High vs Low Doses of Chloroquine Diphosphate as Adjunctive Therapy for Patients Hospitalized with Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) Infection: A Randomized Clinical Trial. *JAMA Network Open*.

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2765499>

⁴⁷AMA Ed Hub. CME credits for reading Borba et al. Ibid. <https://edhub.ama-assn.org/jn-learning/module/2765499>

⁴⁸Wessel, L. (2020, June 22). Science, 'It's a nightmare.' How Brazilian scientists became ensnared in chloroquine politics. <https://www.sciencemag.org/news/2020/06/it-s-nightmare-how-brazilian-scientists-became-ensnared-chloroquine-politics>

hydroxychloroquine are among the most safe drugs in the world with experience in treating tens of millions of patients for malaria, rheumatoid arthritis, lupus and other afflictions.

D. “Educating” the People to Accept “Interventions”

Public Health advocates having a working assumption that they are right and others must learn to agree with them. Science is often invoked on their side, but their science is often corrupted by their own biases, financial interests, political ideology, or desire for power.

Redefining Events is a big part of re-educating the public. A mob becomes a protest. A single death becomes a national catastrophe to be prevented at all costs. A health official who is devoted to global top-down government, Anthony Fauci, becomes the leading political voice in the country. Dissent becomes hate speech or anti-science.

“Educational Interventions” are a favorite concept in public health. In *Public Health Ethics*, in a chapter titled “Public Health Interventions: Ethical Implications,” we find these observations which read more like a political platform than a scientific or economic study.⁴⁹

Educational and Environmental Interventions

Educational interventions are designed to change the knowledge, beliefs, and predisposing psychological and social factors that lead individuals to engage in unhealthy behaviors... p. 78

*With growing appreciation of the effects that social context has on the distribution of disease, attention has turned to developing interventions that address the social determinants of health. The “social determinants” of health and disease have been variously identified, but they generally include levels of poverty, racism, education, employment, housing quality, neighborhood environment, inequalities in wealth and status, stigmatization, access to healthy foods, access to medical care and recreational areas, and access to transportation (Wilkinson and Marmot, 2003; Marmot, 2005; Blas and Kump, 2010). Recognition of the importance of the social determinants is duly credited to the epidemiologist Michael Marmot and his pioneering Whitehall studies dating to the 1970s (Marmot and Winkelstein, 1975; Marmot et al., 1978). Marmot found a highly robust linear relationship between social class (as defined by the British employment classification system) and health status, across virtually all disease categories, despite access to health care through national health coverage. His work was highly influential in informing the British Department of Health and Social Security (DHSS) report *Inequalities in Health* (commonly referred to as the “Black Report”), released in 1980. The Black Report examined four alternative hypotheses and concluded that the cause of health inequalities was differences in material conditions and income (DHSS, 1980; Blane, 1985).*

Short of eliminating poverty, a variety of strategies have been developed under the umbrella of environmental interventions. Whether inadvertently,

⁴⁹ Buchanan, D. (2019). Public Health Programs and Policies: Ethical justifications. Chapter 8, pp. 77-80 in *The Oxford Handbook of Public Health Ethics*. Eds. Mastroianni, A, Kahn, J., & Kass. N. New York: Oxford University Press.

through technological advances such as television and automobiles, or intentionally, through advertising or product placement, physical and social environments have been transformed in ways that are far less conducive to optimal health (for example, such changes have led to people driving instead of walking to work, or children watching TV instead of playing outside). To protect and promote population health, environmental interventions seek to undo or counterbalance these untoward changes in the environment. This approach has gained popular attention in the concept of “nudges” developed by Thaler and Sunstein (2008) . One example of the use of nudges is to re-engineer cafeteria lines to feature fresh fruits more prominently, instead of the more typical conspicuous displays of candy and chips. P. 79

Some of the observations in the above commentary have undeniable reality, including that poverty and social class play a role in individual access to medical care, including around the world during the pandemic. Many observers have concluded that even in places that have universal healthcare, such as Great Britain, the level of individual healthcare is inferior for lower social classes and poor people. Here is a summary from one source:⁵⁰

Inequalities in the distribution of health

Researchers have documented inequalities in the distribution of health by social class, gender, and ethnicity. Inequalities in health have been measured using many different outcomes including infant deaths, mortality rates, morbidity, disability, and life expectancy. Page 1.

When these observations are made in the public health context, these advocates almost inevitably begin citing progressive politics and justice concepts as the approach. That is, they want to use government to “educate” and to shape the populace. Whatever their “interventions” are, they are justified by necessity as they see it. They do not raise any overarching political and economic concerns, such as “Does this rob too many citizens of their autonomy or inch us further toward an authoritarian or totalitarian state?” Instead, their conviction that they as “experts” are doing good becomes conflated with totalitarian attitudes. Even when they raise issues of “liberty,” they discuss it among themselves, with the assumption that they will decide how much liberty to seize. They fail to realize that they deserve no more decision-making power than anyone else in a democratic society where legislatures, courts, and the people are supposed to determine matters of individual and political freedom . We have witnessed this arrogance throughout COVID-19 where “experts” acting in the name of public health ignore the Bill of Rights and the Constitution in their policymaking.

⁵⁰ Rebecca Steinbach (2009). Revised by Margaret Eni-Olotu and Rachel Kwiatkowska (2016); and Robert Tolfree (2016). Inequalities in health (e.g. by region, ethnicity, socio-economic position or gender) and in access to health care, including their causes. HealthKnowledge. <https://www.healthknowledge.org.uk/public-health-textbook/medical-sociology-policy-economics/4c-equality-equity-policy>

IV. The Psychosocial Impact of Depriving People of Liberty

A. Volition, Free Will, and Liberty

Volition is the internal experience of free will, choice-making, autonomy, or self-determination. Liberty is the condition under which volition can be maximally expressed.

Liberty can be considered a need. Even the mechanistic psychologist I. Pavlov postulated a “freedom reflex” in animals to describe their distress upon being confined or restrained.⁵¹

We tried out experimentally numerous possible interpretations, but though we had had long experience with a great number of dogs in our laboratories we could not work out a satisfactory solution of this strange behaviour, until it occurred to us at last that it might be the expression of a special freedom reflex, and that the dog simply could not remain quiet when it was constrained in the stand. This reflex was overcome by setting off another against it -- the reflex for food. We began to give the dog the whole of its food in the stand. At first the animal ate but little, and lost considerably in weight, but gradually it got to eat more, until at last the whole ration was consumed. At the same time the animal grew quieter during the course of the experiments: the freedom reflex was being inhibited. It is clear that the freedom reflex is one of the most important reflexes, or, if we use a more general term, reactions, of living beings. This reflex has even yet to find its final recognition. In James's writings it is not even enumerated among the special human "instincts." But it is clear that if the animal were not provided with a reflex of protest against boundaries set to its freedom, the smallest obstacle in its path would interfere with the proper fulfilment of its natural functions. Some animals as we all know have this freedom reflex to such a degree that when placed in captivity they refuse all food, sicken and die.

Pavlov’s concept of the freedom reflex or reaction is as fresh and startling in some ways as it was when he discovered it. In the above quote, he calls it “one of the most important reflexes” of “living beings.” He describes the necessity of having this reaction, otherwise “the smallest obstacle in its path would interfere with the proper fulfilment of its natural functions.” He then directly relates the loss of freedom to extreme suffering, even in animals, that “when placed in captivity they refuse all food, sicken and die.”

Anyone who has spent time with toddlers has seen that freedom reflex expressing itself and probably has experienced the youngster’s negative reactions to being confined or restrained.

Pavlov describes the captive animal’s refusal to eat, allowing itself to die. This reflects the feeling of helplessness that overcomes animals and humans when they lose their freedom.

Pavlov does not show great empathy for the animals he experimented upon and tortured, so it is astonishing that he could recognize their impulse for freedom. I asked the person in the world whose books have most encouraged my feelings of empathy for animals if he would comment on their need or yearning for liberty. He is Jeffrey Masson, the author of *When Elephants Weep* and *Dogs Never Lie About Love*, and here is what he wrote for this report:

⁵¹ Pavlov, Ivan (2010, originally published in 1927) Conditioned reflexes: An investigation of the physiological activity of the cerebral cortex. *Ann Neurosci*. 2010 Jul; 17(3): 136–141. doi: 10.5214/ans.0972-7531.1017309. The pages for the excerpt are not paginated. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4116985/>

Commentary on Animal Freedom
By Jeffrey Masson, PhD
August 25, 2020

*In a new book *Mama's Last Hug*, Frans de Waal, director of the Living Links Center at the Yerkes National Primate Research Center, tells the story of Mama, a chimpanzee who was 59, the great matriarch of the colony in Burgers Zoo at Arnhem in the Netherlands. She was curled up in a fetal position in her straw nest, clearly in her last days.*

Nobody in their right mind would enter the cage of such an animal, but a biology professor, Jan van Hoof had known Mama many years before, and the two had become close. As soon as she saw the old professor, himself approaching 80, enter the cage (a first anywhere), barely able to move, she managed to get up from her nest and one of the staff took a video of what happened next. She came very close, and then she recognized him, and began making the sounds of joy that chimpanzees make at reunions, threw her arms open and embraced him as he cried in joy.

It's a lovely story, no doubt. But what made me sad was not that Mama was saying goodbye to her human friend, but that she had spent more than 50 years in captivity. Chimpanzees do not belong in a cage, anywhere, for any reason. Period. It is a crime against nature. But then is that not true of all zoos. I would have to say yes. No wild animal should ever live in a cage, or be fenced in, or on an island surrounded by a moat. It is not natural, that is, it goes contrary to its nature.

It has taken some time for humans to recognize the depth of suffering that animals show when they are confined in a cage or even in a corral. Remember, this is not something they EVER experience in the wild. Yes, a prey animal is killed, but swiftly. No other animal, other than man, puts a member of a different species into a cage or confinement for life. The depression that overcomes every single confined animal is well known now to animal scientists: the animals become listless, they lose their appetite (some will even starve themselves to death), they lose their interest in other animals, even their own partners, in short, they give up on life. Some will eventually recover, but their lives have been marked forever, and not for the better.

Well, you might well ask, is that not true of horses then? After all, you cannot allow a horse to simply wander. No, you cannot, and that to me is a weighty argument against the domestication of horses. How about parrots then? Absolutely not. Parrots are not even domesticated. They are not meant to live in cages. Orcas and dolphins? Perish the thought. But then what about cats and dogs?

Ah, that is a difficult topic: you cannot simply leave a dog to go in and out of your house, but the difference is that the dog wants to be there. The dog chooses to live with you. As does a cat, possibly the only animal we can allow its freedom. Cats come and go as they please, and that is how it should be.

Freedom is essential to ALL animals. They all need it, they all want it, every bit as much as we do. What is the worst thing that can happen to a human? To be locked in (prison, or a psychiatric ward) or even to be forbidden to leave a country (think of North Korea) is to be deprived of perhaps our single most cherished possession: freedom. We are animals, after all, and just like all other animals, we want to live free!

In humans this overwhelming helplessness in the face of lost freedom, as this report will describe, leads ultimately to variations on basic negative emotional reactions, including anger, emotional numbness, guilt, shame, and anxiety.⁵² In humans, loss of liberty especially brings shame and humiliation, and loss of self-respect. It can lead to despair.

An entire nation is being deprived of its pride and dignity. Yet we almost never hear about this tragic result of the shutdown and other humiliating measures. This is a large part of the dehumanization process—Robbing people of their freedom and then refusing to recognize that loss of freedom is in and of itself a demeaning process and experience.

B. Coercion Overpowers Another’s Volition and Liberty

The aim of coercion is to gain power over another, to put one's own will in place of another's. In short, coercion is used to make people do what they do not wish or choose to do. To refrain from coercing others, and to resist being victimized by it, we must be able to identify coercion and find better alternatives. This is true in both our personal and our political lives. The founders of this nation, including those who conceived of it and fought for it, often saw themselves as expressing and defending their desire for liberty and their earnest goal to see freedom spread throughout the world.⁵³

One negative psychosocial impact of suppressing freedom is relates to volition or the capacity to make choices, which can be crushed, ultimately leading to apathy, indifference, and docility. Volition is defined as:⁵⁴

1: the power of choosing or determining : WILL

2: an act of making a choice or decision.

Avolition is the lack of volition or the capacity to make choices and it has tragic results:

What avolition looks like⁵⁵

A person experiencing avolition may withdraw from social contact and normal activities. They often have no enthusiasm and get little enjoyment from life. Their emotions may become dulled and conversations may be disjointed.

Avolition is often mistaken as depression. It’s more clearly identified and understood when a person also displays positive symptoms of schizophrenia. It’s important to

⁵² Breggin, P. *Guilt, Shame and Anxiety: Understanding and Overcoming Negative Emotions*. (Prometheus Books, Amherst, NY, 2014). Also see, Breggin, P. The biological evolution of guilt, shame and anxiety: A new theory of negative legacy emotions. *Medical Hypotheses*, 85, 17-24, 2015 and Breggin, P. *Understanding and Overcoming Guilt, Shame, and Anxiety: Based on the Theory of Negative Legacy Emotions*. In Kirkcaldy, B. (Ed). *Promoting Psychological Well-Being in Children and Families*. New York, NY: Palgrave Macmillan. Chapter 5, pp. 68-80, 2015.

⁵³ Breggin, P. *Wow, I’m an American! How to Live Like Our Nation’s Heroic Founders*. (Lake Edge Press, Ithaca, NY, 2009).

⁵⁴ Merriam Webster On-line Dictionary. <https://www.merriam-webster.com/dictionary/volition>

⁵⁵ Healthline. What is avolition and how is it treated. “Medically reviewed by Timothy J. Legg, PhD, CRNP — Written by Susan York Morris — Updated on August 14, 2018.” <https://www.healthline.com/health/schizophrenia/avolition#causes>

keep in mind that a person with avolition isn't avoiding activities. They simply don't have the ability to act.

Examples of avolition

Avolition affects every aspect of daily life — personal relationships, home, and school. A person with avolition may experience the following:

- *doesn't make eye contact when speaking or spoken to*
- *limited or halted speech*
- *stops participating in events or gatherings*
- *avoids making or receiving phone calls*
- *has trouble starting or completing projects*
- *doesn't participate or show enthusiasm for special occasions or events*
- *fails to make appointments, such as for the doctor or tax preparer*

Avolition isn't the same thing as laziness

Some might assume these things are due to a person's laziness or irresponsibility. But people with avolition don't have the ability to act. In a sense, it's like being paralyzed by apathy or the inability to anticipate or experience the rewards of performing a task. In contrast, laziness may be considered a willful act of a person who doesn't have a mental health disorder.

This definition and discussion of avolition is taken from a mental health site where the term is most often used. The term is applied to symptoms of numerous psychiatric and neurological disorders. All oppressive situations from domestic violence and cult experiences to brain-washing and political oppression can result in this outcome as the person being controlled gives up trying and becomes helpless and unable to make choices, in part to avoid frustration and in part to avoid negative attention by taking unapproved actions. Guilt, shame, and anxiety are emotions which, when stirred up in the extreme, can cause people to withdraw and to experience themselves as having no free will or self-determination. Avolition is related to apathy and indifference. It involves a feeling that it is useless and dangerous to make choices.

People who are rendered avolitional by their environment tend to suffer from an overall demoralization, including depression and anxiety, and nearly every other negative emotion, including irritability and anger. Overall, they become subdued and docile. This is closely related to the emotional blunting I describe as one of the negative legacy emotions in my book, *Guilt, Shame and Anxiety: Understanding and Overcoming Your Negative Emotions*.

Studies on an individual and political level show that totalitarian environments create avolition, apathy, and difference. After the fall of the Berlin wall, older people from behind the Iron Curtain were so indoctrinated into dependence and helplessness that they could not rejoice in the changes, which was left more often to youth.⁵⁶ Individuals lacking in volition are ideal citizens for a totalitarian political system; but they vastly impair the functioning of a democratic

⁵⁶ Breggin, Peter. Chapter 9. Part I: Liberty and Love in the Former USSR, pp. 180-189. In Breggin, P. *Beyond Conflict: From Self-Help and Psychotherapy to Peacemaking*. (St. Martin's, NY, 1992).

republic. Eventually, their inability to contribute to society also impairs totalitarian societies and contributes to their demise.

The concept of avolition is closely related to the overall feeling or attitude called learned helplessness or my own concept of psychological helplessness that is more encompassing.

C. Understanding Coercion vs. Liberty and Love

The following are excerpts from my 1992 academic book: *Beyond Conflict: From Self-Help and Psychotherapy to Peacemaking*.⁵⁷

COERCION AND CONFLICT RESOLUTION

Coercion is a form of conflict resolution or, more accurately, conflict suppression. There is widespread agreement within the field of conflict resolution that genuine problem solving is incompatible with the utilization of coercive power (citation omitted).

The use of force, except in self-defense, is the most limited and hazardous approach to relationships and to conflict resolution. It leaves little room for either party—especially the victim—to fulfill any liberty or love needs. In part because coercion encourages people to manipulate each other, to lie, and to hide their vulnerabilities and needs, coercion obstructs the resolution of deep-rooted conflict.

Oppressive actions are frequently cloaked in the language of love: "I did it because I love you" or "If I didn't love you, I wouldn't care so much." Sometimes love of God, country, or other "higher values" are invoked to justify horrible atrocities against others. In reality, both perpetrator and victim become impaired in their ability to love others outside the coercive dynamic. Thus, coercion is the great impediment to conflict resolution.

DEFINING COERCION

According to the *American Heritage Dictionary of the English Language* (1979), to coerce means -"1. To force to act or to think in a given manner; to compel by pressure or threat. 2. To dominate, restrain, or control forcibly." Most dictionaries mention compulsion and restraint, both of which attempt to thwart the individual from acting on his or her own wishes or intentions.

While the broad definition of coercion raises many unanswered questions, it can be turned to practical use with very specific applications. In particular, it reminds us that all threatening and manipulative actions or communications, for any purpose whatsoever, have somewhat similar negative outcomes. P.73 ...

THE NEGATIVE EFFECTS OF COERCION

Coercion by the most well-meaning person, for the most well-intentioned purposes, still has untoward consequences. When the outcome does seem largely

⁵⁷ Breggin, P. *Beyond Conflict: From Self-Help and Psychotherapy to Peacemaking*. (St. Martin's, NY, 1992).

beneficial, coercive methods are likely to have some negative effects, including the subversion of free will and personal freedom. P. 74...

The principle that coercion always has some negative consequences is probably not subject to proof or disproof. Rather it is an assumption or viewpoint of use in organizing experience. In testing such a hypothesis, one must rely mostly upon personal experience, including one's own inner reactions to being coerced, as well as one's perceptions of the responses of others. Beyond that, there is each person's general knowledge of human affairs. One of the aims of this book is to demonstrate the usefulness of viewing all coercion—including that which seems culturally or generally accepted, routine, and innocuous—with caution and concern. This includes the emotional bullying that routinely takes place in the family and social lives of many people, the frequently oppressive control of children in the home and schools, the similar oppression of women throughout most of the society, involuntary treatment in psychiatry, and many or most government interventions.

These two fundamental assumptions—that all forms of coercion create negative effects and that these effects are somewhat similar regardless of the form of coercion—have practical importance in how conflict resolution is approached. They encourage close scrutiny of any and all attempts to use coercion, and they discourage its use as much as possible in human affairs. This has vast implications for many spheres of human activity in which coercion is frequently the sanctioned or most commonly accepted approach to resolving conflict, including family relationships, childrearing, most governmental activities, involuntary psychiatry, authoritarian religion, and war. p. 75 ...

THE COST OF COERCION: THE IMPACT ON THE VICTIM

One might wish that perpetration would cause the perpetrator to feel guilt, shame, and anxiety, but more typically their victims do. While it seems easily understandable that victims might experience anxiety, and perhaps even shame, it seems at first glance more puzzling that they also experience guilt. The key, I believe, is the psychological helplessness that is engendered in the victim, making him or her vulnerable to guilt, shame, or anxiety.

VICTIM DISHONESTY

While perpetrators lie to others and sometimes to themselves in order to cover up their abuses, victims learn to lie and to dissemble in order to avoid or minimize further oppression. p. 91 ...

No one wants to be coerced. As we have seen, humans and nonhumans alike value their liberty. In human beings, this need becomes quite elaborate. It includes the desire to think for oneself, to make choices, to exercise reason, to seek justice. As already described, the need for liberty dovetails with the need to love and to be loved. When the individual feels subject to abuse or arbitrary control, he or she tends to hide these needs in order to seem less vulnerable. P. 92 ...

In conclusion, coercion always has a cost for the victim. Most obviously, it creates psychological helplessness, including guilt, shame, and anxiety in the victim. It encourages victims to lie and to dissemble. ...

Coercion, in all its many manifestations, has little or no place in conflict resolution. At best it is a stopgap measure that temporarily suppresses conflict, ultimately increasing its ferocity. Even when coercion seems a necessity, it interferes with liberty and with love, and ultimately with the resolution of conflict.

From the psychological to the interpersonal and the global, the resort to coercion remains one of the greatest obstacles to conflict resolution. Those who seek to help others resolve conflict must stand forthrightly for the values of liberty and love. Instead of pretending or attempting to take a value-free stance, they should openly seek to educate people on the hazards and costs of coercion and on the merits and benefits of liberty and love. p. 95

The entire *Three Dynamics of Human Progress Chart* is in **Attachment 1**. It describes my concept of the three basic dynamics or methods of human interaction: Love, Liberty, and Coercion. Each has specific consequences in the personal and societal spheres. Below is an excerpt from the lower right-hand section of the chart which describes the nature and consequences of coercion.

Involuntary Relationships

Arbitrary or Unlimited Force
Prediction & Social Control
Hatred & Violence to Attain Ends
Envy & Distrust; No Cooperation
Guilt, Shame and Anxiety
Lying, Cheating, & Fraud
Alienation, Remoteness
Adjustment & Survival Values
Scientism⁵⁸
Socioeconomic Decline
Closed, Totalitarian Society

Both individuals and society are going through this devolution under government measures to shut down and control America—the downward spiral in human activity that brings out the worst in people and society.

D. Understanding Psychological Helplessness

⁵⁸ Based on my more recent work, I have added a new item to this list of results of oppression: Guilt, Shame and Anxiety. I have also removed two that were more relevant to my critique of contemporary psychiatry: Physical Theories & Therapies and Behavioral Theories & Therapies. They fall under the existing larger category of “scientism,” the reduction of science to worthless and misleading simplifications that, in my field of psychiatry, are dehumanizing. These subjects are covered in many of my books and scientific articles but go beyond the needs of this report.

When they feel oppressed, controlled, or manipulated—when they see and experience that they are losing their freedom—many or most individuals lapse into chronic apathy, persistent anger, or guilt, shame, and anxiety. This is one of the most disabling aspects of the shutdown and other oppressive measures associated with government policies and practices related to COVID-19.

In *Guilt, Shame and Anxiety*, and scientific articles,^{59, 60, 61} I have analyzed why people react in this negative manner, in effect shutting themselves down; *but in simplest terms, when subjected to oppression, many people feel overwhelmed with helplessness, and feeling helpless often leads to what I call the negative legacy emotions of emotional numbing or apathy, anger, beneath which are deeper negative feelings of guilt, shame and anxiety.* All of these emotional states are driven by a lack of volition, so that the individual feels unable to make good, effective, ethical, or happy decisions.

My latest publication,⁶² coauthored with Jeanne Stolzer, PhD, professor of childhood and family life, deals with the effects of psychological helplessness, including how it is reinforced by oppression. Here are extracts from “Psychological Helplessness and Feeling Undeserving of Love: Windows into Suffering and Healing” published in June 2020 in the *Humanistic Psychologist*:

Understanding Psychological Helplessness

Physical or objective helplessness can be distinguishable from psychological helplessness, which is subjective and emotional in origin. Physical helplessness is exemplified by being incarcerated behind bars or afflicted with a neurological paralysis. Psychological helplessness involves feeling, believing, or acting as if one were emotionally imprisoned or paralyzed, and unable to take effective or meaningful changes in one's attitudes or behaviors. Prisoners or physically paralyzed individuals may be largely unable to improve their physical status, but they do not have to become psychologically helpless. That is, they do not have to give up looking for opportunities to improve their emotional, psychological, and physical responses.

Psychological helplessness has cognitive and emotional components. Cognitively these individuals are unable or unwilling to rationally evaluate themselves and their opportunities.

⁵⁹ Breggin, P. (2015). Understanding and Overcoming Guilt, Shame, and Anxiety: Based on the Theory of Negative Legacy Emotions. In Kirkcaldy, B. (Ed). Promoting Psychological Well-Being in Children and Families. New York, NY: Palgrave Macmillan. Chapter 5, pp. 68-80, 2015. <http://breggin.com/wp-content/uploads/2015/09/Breggin%2C%20P.%20%282015%29%20Understanding%20%26%20overcoming%20GSA.pdf>;

⁶⁰ Breggin, P. and Stolzer, J. Psychological Helplessness and Feeling Undeserving of Love: Windows into Suffering and Healing. *The Humanistic Psychologist*, June 2020, 48 (2), 113-122. <https://breggin.com/psychological-helplessness-and-feeling-undeserving-of-love-windows-into-suffering-and-healing/>

⁶¹ Breggin, Peter. The biological evolution of guilt, shame and anxiety: A new theory of negative legacy emotions. *Medical Hypotheses*, 85, 17-24, 2015. <https://breggin.com/understanding-and-overcoming-guilt-shame-and-anxiety-based-on-theory-of-negative-legacy-emotions/>

⁶² Breggin, P. and Stolzer, J. Psychological Helplessness and Feeling Undeserving of Love: Windows into Suffering and Healing. *The Humanistic Psychologist*, June 2020, 48 (2), 113-122. <https://breggin.com/psychological-helplessness-and-feeling-undeserving-of-love-windows-into-suffering-and-healing/>

Emotionally, they lose control over themselves and “give up trying.” People who are feeling helpless may feel and act as if they are unable to think or make judgments.

Psychological helplessness can be defined or described from several perspectives such as giving up or surrendering the use of reason, losing autonomy and self-determination, surrendering free will and volition, or collapsing into feelings of being overwhelmed and unable to escape from emotional suffering. It limits cognitive flexibility in perceiving alternatives and making decisions and it limits resilience or the ability to "bounce back" and retake control over one's life.

The importance of overcoming psychological helplessness in order to make choices and become self-determining is found directly or indirectly in many theoretical approaches that emphasize autonomy, self-determination, self-efficacy, resilience and "authentic happiness" [citations omitted]. P. 114

Again, from my most recent scientific paper, I briefly described the result of extreme abuse upon adults. It applies directly and without modification to the effects of increasing degrees of totalitarian control:

The Effects of Extreme Abuse in Adulthood

When adults are exposed to extreme abuse, their sense of personal value and worthiness of love can be crushed. This occurs when disabled, elderly or other vulnerable persons are abused within their own families. It occurs when people are abducted and held in captivity or when they are incarcerated in total institutions such as extermination camps prisoner of war camps, mental hospitals, or prisons. In all these situations, the perpetrator [such as hardened staff] often systematically attempts to bring about psychological helplessness in the individual along with feelings of being undeserving of love and hence even life. P. 126

The observations on extreme abuse in adulthood apply directly to government and politics, as I have done in *Beyond Conflict*. The universality of these principles—that they apply in all societal settings that oppress or control people—was deeply impressed upon me when I visited East Berlin under communism in 1988, one year before the Berlin wall came down. I went with author Jeffrey Masson, who speaks German and has studied Nazi Germany. To get to East Berlin, we took an underground from West Berlin and got off at the last and only stop into a frightening labyrinth with grim faced guards beneath East Berlin. Inside the city itself, it was bleak and barren of interesting or exciting activities. The people looked fearful and depressed. We were approached by a small group of teenagers who begged us to find a way to sneak them into West Berlin—an act of despair that took considerable bravery and perhaps recklessness born of despair from living within a totalitarian system. Unlike the animals described by Pavlov as dying from loss of freedom, these youngsters were striving for freedom and it leaves me wondering how they did when the Berlin Wall came down a year later.

I was struck at the time by something that I continue to mull upon to this very day: Stepping into East Berlin was almost exactly like my experience as a Harvard college student when, as a volunteer, I first stepped into a state mental hospital.⁶³ The bleakness, the lack of normal human activity, the sadness and despair in the faces, and even the pitiable requests to

please help them go free. This is the fate of people who have gradually and inexorably been crushed by totalitarianism. They become like inmates of a giant 1950s state mental hospital.

These observations closely parallel those of sociologist Erving Goffman who described mental hospitals as “total institutions,” the institutional equivalent of totalitarianism.⁶⁴ He described how it robs people of their very identity as they adopt the necessary submissive and demoralized attributes to survive in a wholly coercive situation.

E. Frightening and Reducing People to Objects

Threats, and even terrorization, of the public is one of the single most important methods of political control, and the more so as a society moves toward totalitarianism. As I mentioned earlier, in 1964 I wrote one of my first two peer-reviewed scientific papers, “Coercion of Patients in an Open Mental Hospital,” in which I described how a supposedly “voluntary” psychiatric ward was not truly voluntary.⁶⁵ When patients resisted drug treatment or wanted to go home, the staff would often threaten them, for example, by mentioning they might have to be sent to the local state hospital, be given electroshock treatment, or committed against their will. This continues to on today in mental hospitals prison. Similar threats permeate our “free society” under COVID-19 policies and practices.

Sociologist Erving Goffman, mention in the previous section, spent much of his career studying the effects on inmates of life in total institutions which, in the Western world, include prisons and mental hospitals rather than Gulags or concentration camps. The effects on people are similar to those experienced by citizens as a state or nation becomes more totalitarian. His influential book, *Asylums: Essays on the Social Situation of Mental Patients and Other Inmates*, was published in 1961. The complex quality of Goffman’s observations are such that neither he nor the reader can easily summarize. Therefore, I will quote from a recent sociological review of Goffman’s work that captures the struggle of the individual to maintain his sense of identity or self when stripped of all the affirmation to which he or she is accustomed in the social interaction of a more free and normal life:⁶⁶

We are all familiar with Goffman’s work in *Asylums*, and especially his notion of the total institution as a “forcing house for changing persons, as a natural experiment on what can be done to the self” (p. 12). In everyday life in a civil environment—that is, in the home world—one can work at sustaining one’s identity with one’s cohabitants of social establishments because, by and large, they collaborate in the enterprise and honor one’s efforts to do so. But in the total institution the inmate is separated from ordinary collaborators and interacts with a staff that requires different terms for collaboration. Inmates are subjected to a series of abasements, degradations, humiliations, and profanations of their selves and a withdrawal of all the physical and social supports that once sustained them. ...

⁶⁴ Goffman, G. (1961). *Asylums: Essays on the Social Situation of Mental Patients and Other Inmates*, New York, Anchor Books.

⁶⁵ Breggin, P. (1964). Coercion of Voluntary Patients in an Open Hospital. *AMA Archives of General Psychiatry*. <http://breggin.com/wp-content/uploads/2005/05/coercionof.pbreggin.1982.pdf>

⁶⁶ Friedon, E., 2019, Celebrating Erving Goffman. *Contemporary Sociology*, 48, 631-635. https://journals.sagepub.com/doi/full/10.1177/0094306119880197b?casa_token=3kgXfrJjQOAAAAAA:TX-ZzgpjFARKAPLMWUgaRCNxG182Oji3Ri9lz2SgrOdRxcf5snd6gXLogLACTGIqkrgB70tj-pMR

What he documents, however, is the self's resistance to its stripping. The self struggles against its transformation, it perversely insists on preserving some portion of its familiar substance. He points out that inmates practice secondary adjustments that do not directly challenge the staff of the total institution but that, by seeking forbidden satisfactions, assert that they are still their own persons, still with some control over their environment, control apart from God, Country, Party, or whatever. In characterizing the self's struggle, Goffman employs a number of phrases—"expressed distance," "holding off from fully embracing all the self-implications of its affiliation, allowing some . . . disaffection to be seen, even while fulfilling . . . major obligations," and perhaps most precisely, "***a defaulting not from prescribed activity, but from prescribed being.***" p. 188. (bold added, italicized in original)

Goffman argues that *it is*:

. . . against something that the self can emerge . . . Without something to belong to, we have no stable self, and yet total commitment and attachment to any social unit implies a kind of selflessness. Our sense of being a person can come from being drawn into a wider social unit; our sense of selfhood can arise through the little ways in which we resist the pull. Our status is backed by the solid buildings of the world, while our sense of personal identity often resides in the cracks. P. 320 (bold added, italicized in original)

And so, it is that "whenever worlds are laid on, underlives develop" (p. 305). Those underlives are to be found everywhere in ordinary life, but they are most apparent "when existence is cut to the bone" (ibid.), as in total institutions. In such institutions the self does not triumph because its survival is hidden, in the cracks, but it does survive, and in surviving constitutes however modestly a "movement of liberty" (ibid.).

Goffman documents, even celebrates that modest movement of liberty, that tenacity of the self to be what it is and resist prescribed being. He also takes its side and grants deep respect to its need to express distance. He becomes its defender as well as its observer.

Many people today, living beneath the heel of public health policies and practices, are experiencing what Goffman poignantly calls "the self's resistance to its stripping" while they do their best to express "that tenacity of the self to be what it is and resist prescribed being."

David L. Altheide concluded his paper on "Terrorism and the Politics of Fear" with the following observations that apply to much of the politics of fear used to implement the COVID-19 shutdown:⁶⁷

The rituals of control are easier to accept as they become more pervasive and institutionalized. The politics of fear with a national or international justification is more symbolically compelling than "mere crime in the streets." Accompanying heightened terror alerts are routine frisks, intrusive surveillance, and the pervasive voyeuristic camera, scanning the environment for all suspicious activity. Fear is perceived as crime and terrorism, whereas police and military forces are symbolically joined as protectors. The key point about physical security, surveillance (Staples,

⁶⁷ Altheide, D. T(2006, November) Terrorism and the Politics of Fear. Cultural Studies ↔ Critical Methodologies. November, 2006. 415-439. <https://journals.sagepub.com/doi/pdf/10.1177/1532708605285733>

2000), and body checking is to communicate the format of control to people as objects rather than subjects; they are objects to authorities, mere bodies that can be electronically [wanded], asked to disrobe, patted down, felt up, and unveiled like produce:

They seek to reduce individuals to objects rather than involving them as subjects. The element of direct, physical coercion is either open or poorly concealed and there is no further goal than that of either neutralising the threat or making it manageable.

In a paper I delivered in Germany at the only conference ever on Medicine in the Third Reich, I addressed the role of psychiatry and psychiatrists in paving the way for the Holocaust with the highly organized bureaucratic murder of the mental patients and disabled in their care. Very consistent with the final remarks of Altheide's paper (above), I concluded in my published version of the paper that in order to dominate and destroy people, the German psychiatrists had to think of them and treat them as if they were objects:

One fundamental flaw is the reduction of the human being to an object devoid of inherent worth or inviolability. In Muller-Hill's words, "It seems to be that to reduce other people to the status of depersonalized objects is of no help whatsoever to them" (p. 101).⁶⁸ Trying to view people "objectively" can be demeaning in itself. It also tends to lead toward further degradation of the individual into subhuman status. In the Nazi ideology, the Jews became "pests" or "vermin,"]n psychiatric ideology, patients become "diseases" or biochemical and genetic aberrations. Devoid of inherent value, they become suitable for various inhumane solutions, including involuntary treatment and, ultimately, sterilization and extermination. pp. 146-147

Similar objectifications accompanied by fear or terror take place in public health in the service of political totalitarianism. Individuals become "disease carriers" or merely "contacts" and all the protections given to human beings in the Constitution and Bill of rights become null and void.

Some recent threats employed by shutdown advocates are reminiscent of totalitarian governments. One such example is the mayor of New York City, Bill de Blasio telling citizens to use a special hotline to photograph and report their neighbors and other people who were not following all the shutdown rules.⁶⁹ Another example is the mayor of Los Angeles announcing that the city will turn off electrical power and water if private homes or businesses have large groups.⁷⁰

All totalitarian movements including public health around the world try to intimidate the citizenry. This is required to close the lid on freedom and to enforce docility and conformity.

⁶⁸ Muller-Hill B. Murderous science: Elimination by scientific selection of Jews, gypsies, and others, Germany, 1933- 1945. New York: Oxford University Press, 1988.

⁶⁹ Leonardi, A. (2020). Bill de Blasio asks New Yorkers to take photos of people violating social distancing rules. <https://www.washingtonexaminer.com/news/bill-de-blasio-asks-new-yorkers-to-take-photos-of-people-violating-social-distancing-rules> Also, see FoxNews.Com (2020). <https://www.foxnews.com/us/de-blasio-new-yorkers-report-social-distancing-violations-text>

⁷⁰Garcetti, E. (2020). LA mayor, threatens to cut power to noncomplying businesses: 'We will shut you down.' - Washington Times <https://www.washingtontimes.com/news/2020/mar/25/eric-garcetti-la-mayor-threatens-to-cut-power-to-n/>

We have multiple examples. Other threats include the originally horrific predictions of the menace of COVID-19, such as predictions that millions of Americans might die.

On March 6, the Australian National University reportedly declared that the “In the most disastrous scenario, the [global] death toll could reach a staggering 68 million...”⁷¹ Their best scenario was 15 million. The first author, Warwick McKibbin, was also associated with the Brookings Institute.⁷²

On March 10, 2020, Tom Frieden, the former head of CDC, wrote we could have a million deaths.⁷³ On March 16, 2020, *The New York Times* reported, “White House Takes New Line After Dire Report on Death Toll.”⁷⁴ A new twist on threats was made by a recent “scientific” publication on August 13, 2020, titled “Comparison of Estimated Excess Deaths in New York City During the COVID-19 and 1918 Influenza Pandemics.”⁷⁵ On August 15, the fantastic manipulations to make this comparison were correctly debunked by Richard Epstein in a report, “COVID-19 Confusion.”⁷⁶

After his detailed critical analysis of the report, Epstein went on to describe an array of threatening, intimidating and destructive policies and practices perpetrated by the federal and state governments and the collusion of the press in cowing the population:

The current of exaggeration gets even worse when we look beyond the study. A recent New York Times story touts that the full cost of COVID-19 not only includes the inflated death count of 169,000, but also about 35,000 additional deaths attributable to indirect effects. Unfortunately, the story gets the causal connection backwards—one of the many major blunders in New York City and elsewhere was to shut down all forms of elective medical treatments in order to make way for the wave of COVID-19 cases that never occurred. How many deaths did that decision yield? Surely a significant portion of these extra deaths are attributable to misguided public policies. This means that the net deaths attributable to the virus itself should be reduced, not increased, to properly account for the consequences of eliminating elective treatments and other hardships under New York’s lockdown.

Serious social consequences flow from the misattribution of deaths to COVID-19. In New York and other states, a common response to the artificially high death tolls has been to reimpose heavy sanctions to stem a second wave. But recently it appears

⁷¹ Stickings, T. (2020). Best-case scenario, new study predicts. Daily Mail, London.

<https://www.dailymail.co.uk/news/article-8082327/15-MILLION-people-die-best-case-coronavirus-scenario.html>

⁷² McKibbin, W. and Roshen, F. (2010). The Global Macroeconomic Impacts of COVID-19: Seven Scenarios. University of Australia.

McKibbin, W. and Roshen, F. (2010). https://anu.prezly.com/coronavirus-is-highly-uncertain-and-the-costs-could-be-high?utm_source=email&utm_medium=campaign&utm_id=campaign_Ejmb_lbzJ.contact_RBhn_IDAN&asset_type=attachment&asset_id=171409#attachment-171409

⁷³ Frieden, T. (2020). Could corona virus kill a million Americans. Think Global Health.

<https://www.thinkglobalhealth.org/article/could-coronavirus-kill-million-americans>

⁷⁴ Fink, S. (2020) White House Takes New Line After Dire Report on Death Toll.

<https://outlook.live.com/mail/0/deeplink?version=2020081002.06&popoutv2=1>

⁷⁵ Faust, J. Lin, Z., & del Rio, C. (2020, August 13, 2020). Comparison of Estimated Excess Deaths in New York City During the COVID-19 and 1918 Influenza Pandemics. *JAMA Network Open*. 2020;3(8):e2017527. doi:10.1001/jamanetworkopen.2020.17527

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769236>

⁷⁶ Epstein, R. (2020, August 17). COVID-19 Confusion. Hoover Institute. <https://www.hoover.org/research/covid-19-confusion>

that new cases are in decline. Nor has any second wave occurred in the northeast states that early experienced what remains the highest incidence of deaths. In places like New York, the trend has been sharply downward, which should ideally lead to a general relaxation of heavy sanctions. Everyone should of course wear masks in indoor public spaces, wash hands, avoid placing their hands on their face when out, stay out of high-density places, get lots of fresh air, and, if ill, take the tripartite treatment of hydroxychloroquine, zinc, and azithromycin or doxycycline, as recommended by Dr. Harvey Risch, to the evident consternation of his colleagues in the Yale School of Public Health.

These various precautions significantly reduce COVID-19 costs, freeing up resources for other uses. Unfortunately, the same panicked responses that led to so much unnecessary suffering in the early stages of the pandemic continue to wreak havoc today. One prescription that seems to have gained favor is the demand for the wearing of masks in outdoor public places to slow down the spread of the virus. Democratic Presidential nominee Joe Biden insists that “[e]very single American should be wearing a mask when they’re outside for the next three months at a minimum,” claiming that this “will save 40,000 lives during that period.” In the same vein, the IHME claims that “if mask wearing in public increases to 95%, more than 66,000 lives could be saved,” which would cut fatalities in half.

Right now, masks are already worn in the places where they are likely to do most good, where there is close and continuous contact between individuals, as in hair and nail salons. But is there any reason to think that wearing masks in public parks, where the contacts between individuals are fragmentary and fleeting at best, could produce dramatic results? It is worth asking about the trade-offs that come from the more widespread use of masks, as the Dutch government has recently done by citing the risks of wearing masks: First, masks offer people a false assurance of safety; even the best masks cannot filter out most viruses, especially when improperly worn; second, the reuse of dirty masks increases the likelihood of contamination; third, the inability to cleanly expel wastes may well reinfect persons with COVID-19 through the nose, throat, and eyes; and finally, the lack of fresh air can cause headaches and compromise the immune systems, especially for the elderly and ill who are most subject to the virus. The law of diminishing marginal returns applies to masks as it does to everything else.

Next there is the touchy subject of quarantines. Many states, including both New York and Illinois, have imposed travel restrictions on individuals that come from states with high numbers of daily coronavirus cases. The usual sanction is an order to self-quarantine for a two-week period. In New York, both Columbia and Barnard College have, as a result of the order, abandoned on-campus instruction, given that many of their students come from out-of-state. In Chicago, the order applies to any state that registers 15 new COVID cases per day per 100,000 people. The Chicago order, like all these orders, is flawed: It does not apply to people who come to Chicago from other hotspots within Illinois, but it does apply to people who come from specific areas within states that have low COVID counts. Moreover, the order fails to exempt individuals who have tested COVID-negative just before entering Chicago because these people “can develop symptoms and become contagious up to 14 days from their last exposure.” At the same time, it fails to acknowledge that sick

people are less likely to travel, and the rate of transmission for asymptomatic individuals seems to be lower than that for symptomatic people.

Compliance with such orders effectively kills tourism, as well as a significant amount of business activity. Yet city officials in cities like New York and Chicago do not offer estimates of the potential harms that result from allowing free movement across state lines of people who test COVID-negative, nor do they give any sense of the expected losses, possibly in the millions of dollars, from their policies.

The Big Lie is another aspect of controlling the public. The first big lie was there was nothing to fear. The second big lie was millions will die in America. Then came, “We will have a vaccine within months.” Creating uncertainty is another aspect of inducing fear by keeping people off balance. Anthony Fauci’s well-documented flipflopping on issues represents this kind of unnerving practice.⁷⁷

F. Censorship: YouTube, Twitter, Facebook, Google, Amazon, *The New York Times*, etc.

The control of the media and Internet is in the hands of multi-billion dollar industries who favor top-down government, who pay off or collaborate with government administrators and legislators, and who almost universally favor the extremes of the COVID-19 shutdown. The stifling of free speech on a mass scale in the name of public health is a characteristic of this shutdown.

As a most astonishing example, Alex Berenson, the highly respected former *New York Times* science reporter was censored in advance by Amazon when he tried to sell his insightful, documented booklet, on their enormous website. From all the truly bizarre and even evil publications Amazon has for sale, they decided that his book, *Unreported Truths about COVID-19 and Lockdowns: Part 1: Introduction and Death Counts and Estimates*, did not meet their standards. They gave him no reason except to say it would help if he edited out references to COVID-19, which happened to be the subject of his book. As he describes in the *Part II*, he was saved by the intervention of no less a powerful figure than Elon Musk. If Amazon had not accepted the book, Berenson writes that there was no other comparable alternative for him to get his views to the public.

The justification for censorship is typically that the publication or commentary is too “extreme” or comes from an “extremist.” This is true whether a gigantic monopolistic corporation or the government is making the negative judgement. On this subject, Timothy Snyder⁷⁸ has been eloquent and precise:

***Extremism** certainly sounds bad, and governments often try to make it sound worse by using the word **terrorism** in the same sentence. But the word has little meaning. There is no doctrine called **extremism**. When tyrants speak of **extremists**, they just mean people who are not in the mainstream—as the tyrants themselves are defining that mainstream at that particular moment. Dissidents of the twentieth century, whether*

⁷⁷ Papazian (2020, June 1). Fauci’s Flip Flops. Great America. <https://amgreatness.com/2020/06/01/faucis-flip-flops/>

⁷⁸ Snyder, T. (2017). *On Tyranny: Twenty Lessons from the Twentieth Century*. New York: Tim Duggan Books. He is the Levin Professor of History at Yale.

they were resisting fascism or communism, were called extremists. Modern authoritarian regimes, such as Russia, use laws on extremism to punish those who criticize their policies. In this way the notion of extremism comes to mean virtually everything except what is, in fact, extreme: tyranny. Pp. 101-102 (bold was italicized in original)

G. The “New Normal”—With Bill Gates and Anthony Fauci

In part I (1) of this report, the description of totalitarianism included the following:

(9) Because pursuit of the goal is the only ideological foundation for the totalitarian state, achievement of the goal can never be acknowledged.

On March 9, 2020, the *New York Times* released a report, “*Suddenly, the New Normal.*”⁷⁹ In the “New Normal,” we will all become more comfortable with big government interventions in our lives. A Goggle of “New Normal” reveals multiple additional stories in the *New York Times*, and every other significant news outlet, untold numbers of videos, and even a new TV comedy.

Those who promote top-down government are making clear that the current shutdown is not a blip in the history of America but a massive change that will dominate the future. Globalists have a great deal to gain from this. Bill Gates is one of the wealthiest men in the world with gigantic new financial investments in drug companies⁸⁰ and vaccines,⁸¹ including vaccines to treat COVID-19.⁸² In addition to supporting the world’s largest industries with billions of dollars in tax deductible donations from the Bill and Melinda Gates Foundation,⁸³ Gates is also an advocate for big government interventions and partnerships with industry,⁸⁴ making him the archetype of the globalist. Gates himself has been interviewed multiple times on the new

⁷⁹ Lerer, Lisa (March 19, 2020). “Suddenly, a New Normal.” <https://www.nytimes.com/2020/03/19/us/politics/mitt-romney-coronavirus-checks.html>

⁸⁰ Schwab, T. (2020, March 17). Bill Gates’s Charity Paradox. *A Nation* investigation illustrates the moral hazards surrounding the Gates Foundation’s \$50 billion charitable enterprise. *The Nation*. Retrieved June 16, 2020 at <https://www.thenation.com/article/society/bill-gates-foundation-philanthropy/>

⁸¹ Gates Foundation (2020, June 4). Bill & Melinda Gates Foundation pledges \$1.6 billion to Gavi, the Vaccine Alliance, to protect the next generation with lifesaving vaccines. Retrieved on June 16, 2020 from <https://www.gatesfoundation.org/Media-Center/Press-Releases/2020/06/Bill-and-Melinda-Gates-Foundation-pledges-to-Gavi-the-Vaccine-Alliance>

⁸² Calfas, J. (2020, April 5) Bill Gates to help fund coronavirus-vaccine development. *The Wall Street Journal*. Retrieved June 19, 2020 at <https://www.wsj.com/articles/bill-gates-to-spend-billions-on-coronavirus-vaccine-development-11586124716>

⁸³ Schwab, T. (2020, March 17). Bill Gates’s Charity Paradox. *A Nation* investigation illustrates the moral hazards surrounding the Gates Foundation’s \$50 billion charitable enterprise. *The Nation*. Retrieved June 16, 2020 at <https://www.thenation.com/article/society/bill-gates-foundation-philanthropy/>

⁸⁴ Bill Gates: Testimony before the Committee on Science and Technology, U.S. House Representatives, 2008. Microsoft.com. <https://news.microsoft.com/2008/03/12/bill-gates-testimony-before-the-committee-on-science-and-technology-u-s-house-of-representatives/>

normal.⁸⁵ For globalists, COVID-19, with its government and industry partnerships, is a source of great wealth and power. Their activities place great pressure on America to move toward top-down management with increased authoritarianism and ultimately totalitarianism.

Anthony Fauci, who works closely with Bill Gates on his vaccine development and marketing,⁸⁶ has similarly spoken and testified about the “new normal” which he sees in part dependent on a successful vaccine. The former director of the CDC, Richard Besser,⁸⁷ is also talking about the new normal.

H. The Most Vulnerable Groups under COVID-19

The most obviously injured victims of the public health policies are those people who have varied vulnerabilities and lack of resources, although anyone, and highly likely everyone, is or will be suffering. Here is a listing with brief descriptions of some of the more vulnerable segments or groups in our population. Making the list has broadened my own appreciation for the widespread suffering:

1. Nursing home residents both with and without severe cognitive disorders who are or will become isolated from their families as well as from other residents and their daily activities. Many are restricted to their rooms, even for meals, which is a form of solitary confinement, considered the worst, last-resort punishment in prisons. They suffer from lack of attention, loneliness, inactivity, and critical separation from family. Even the healthiest can deteriorate into a pseudodementia with avolition and apathy, while those with cognitive disorders will rapidly decline. Nursing home patients can die of self-neglect from dehydration and starvation.

2. Incarcerated prisoners, one the least cared about people in the population but very numerous and vulnerable. The shutdowns have profoundly injured prisoners who have lost access to direct family visits, been deprived of multiple services by outside providers, lost group programs from AA to group therapy, and have been subjected to isolating lockdowns in single or double cells. In one NYS facility where a forensic client of mine resides, the result was episodes

⁸⁵ Bill Gates on the new normal. (A collection of his videos on the subject.)

<https://www.google.com/search?q=fauci+on+the+new+normal&oq=fauci+on+the+new+normal&aqs=chrome..69j57.7284j0j4&sourceid=chrome&ie=UTF-8>

⁸⁶ See part X of this report.

⁸⁷ Richard Besser, MD, is president and CEO of the Robert Wood Johnson Foundation (RWJF), a position he assumed in April 2017. Besser is the former acting director for the Centers for Disease Control and Prevention (CDC), and *ABC News'* former chief health and medical editor.

<https://www.bing.com/videos/search?q=former+director+of+CDC+on+new+normal&&view=detail&mid=25F0C53F226C77D60F8525F0C53F226C77D60F85&&FORM=VRD GAR&ru=%2Fvideos%2Fsearch%3Fq%3Dformer%2520director%2520of%2520CDC%2520on%2520new%2520normal%26qs%3Dn%26form%3DQBVR%26sp%3D-1%26pq%3Dformer%2520director%2520of%2520cdc%2520on%2520new%2520normal%26sc%3D0-36%26sk%3D%26cvid%3DF32CF3CB11344CE2B9AFD6B5E2A1B40A> For the range of his public commentaries on the “new normal,” mostly on television, see:

<https://www.bing.com/videos/search?q=former%20director%20of%20CDC%20on%20new%20normal&qs=n&form=QBVR&sp=-1&pq=former%20director%20of%20cdc%20on%20new%20normal&sc=0-36&sk=&cvid=F32CF3CB11344CE2B9AFD6B5E2A1B40A>

of chaotic protest and emotional breakdowns of individual inmates, as well as acting out by guards.

3. Partially disabled ambulatory people who rely on outside programs. The shutdowns have severely affected individuals diagnosed with autistic spectrum disorders or with chronic mental disorders, and the elderly who have lost their all-important visitations to day programs, to supervised work programs, and to social, recreational, or educational programs.

4. Partially disabled homebound people who rely on in-home care. Elderly frail people, individuals with dementia, and people suffering from myriad disabilities that limit their ability to entertain themselves or to fully care for themselves commonly rely upon visits from friends and family, untrained and trained companions, as well as more specialized rehabilitation or social work professionals. These visits are typically impossible during lockdowns and other restrictions on travel or contact.

5. The acutely and dangerously physically ill who are afraid to go to medical facilities. Fear mongering to the population keeps many people who need emergency department or inpatient hospital care from going to facilities where they will be in contact with other people in waiting rooms, examination offices or hospital rooms. Most people are naturally reluctant to seek medical care and often delay too long when having chest pain, when asthma is getting out of control, when a fever is getting too high, or when they experience mental glitches, odd sensations, or minor paralyses that warn of an impending stroke. Now they simply stay home out of fear or because “non-essential” medical care is shut down.

6. People who need follow up medical care for an infinite number of disorders from cancer and myocardial infarction to diabetes and obesity. Public health policies and regulations closed down many of these facilities so that these people cannot get the necessary services, adding to their pain and suffering, and to the decline of their health.

7. People who routinely rely upon alternative physical and mental health services that require close proximity, such as chiropractic, massage, acupuncture, therapeutic dance, physical training, and the like. This group is too often dismissed as a fringe medicine, but people often rely very heavily upon these services for the quality of their lives. Even if much of the benefit is from the relationships with the providers, rather than the technical aspects of the experience, people rely on these services for their emotional and physical well-being. One of our family members was recently deprived of one of these services because the practitioner was shut down after exposure to a person who may have COVID-19.

8. People who live alone, whether by choice or not, including the young and the old. People who live alone are not, as some would suspect, especially able to handle the isolation imposed by the lockdowns. Instead, many of them rely even more heavily than other people on going out into the world to restaurants, movies, parks, group activities such as sports and dance classes, and other sources of engagement with life that people who live alone especially require. Their “isolation” becomes solitary confinement during lockdowns and solitary confinement is one of the worst punishments to inflict upon a human being.

9. Young children who cannot go to school. Schools remaining closed are a huge concern with multiple ramifications from the loss of learning and social life, delayed psychosocial development, loss of direct contact with teachers and peers, and stress of staying at home with often frazzled and frustrated siblings, parents, and other adults. This is a hugely important problem that is almost certainly leading to educational and development delays; increased physical, sexual and emotional abuse; emotional and social problems; neglect, and other unanticipated problems.

10. High school students who cannot go to school. In addition to the obvious losses that have been partially summarized in regard to “Young children who cannot go to school,” children in the later high school years are facing dramatic, despair-inducing losses, for example, enrolling in their preferred colleges and educational programs, starting work at a job or getting a scholarship (need, academic, athletic, musical, etc). Some students will experience setbacks regarding post-high school plans from which they will feel unable to recover.

11. College students with disrupted lives. The disruptions in the lives of college students vary greatly but include those we have mentioned for young children and high school students. Plans for graduate education and/or jobs following graduation have often been disrupted and will cause severe setbacks, especially for any who already lacked confidence about the future, as so many young adults do. Some professional careers that require intensive group practice such as sports, music, or theater may be aborted.

12. Those who are unemployed not by choice. This is one of the more obvious and recognized tragedies. Most Americans have little savings and must work to “survive.” Many also rely on work as the most important aspect of their identity and others as the keystone to their quality of life. The emotional toll of unemployment or underemployment can be devastating. Over generations, this has been discernable in increased suicide rates in the population of working age people and increased calls to suicide and mental health “hot lines.”

13. People who miss meaningful work. Emphasis has been appropriately placed upon trying to replace income, especially among working class people, caused by government shutdowns. It is also important to recognize that people at every income level often find great meaning and affirmation of their identity and worth from their work. This can be as true for laborers as for professionals. Doing “a good job” is a source of great pride and satisfaction to many people. The loss of work can be devastating to one’s identity and lead to a wide range of emotional or psychological difficulties.

14. People trying to enter the workforce. As a therapist, I am working with several students who have or will graduate college and whose plans have been largely disrupted by the shutdown and related unavailability of jobs. But graduating students (of all ages) are not the only ones trying to enter the workforce. Others include women whose children have started school and retirees who have found the financial or psychological need to seek work are among others.

15. Minorities who had their first or best jobs ever. Minority employees—blacks, Hispanics, and women included—were experiencing their highest employment ever in the time

leading up to the shutdowns. For many, this was rewarding both financially and psychologically, and the financial cost and disappointment associated with job loss can strike them more painfully than other groups.

16. Caregivers, loved ones and families who carry burdens. Every one of the injuries, harms or losses described in this broader analysis lays a burden on other people who must take over or fill in the gaps for injured and vulnerable people. Parents must stay home to take care of their homebound children. Older siblings must help take care of younger ones at home. Parents, partners, siblings, relatives often must find ways to live in unaccustomed constant proximity with each other, which can cause serious enough strains to break up marriages and to cause mental breakdowns. Adult children must take in their parents, and if their parents are already living with them, they have enormously increased duties to take care of their homebound parents. Disabled children and adults make demands and have needs that their new family caregivers cannot manage physically or emotionally.

17. Overburdened Frontline healthcare providers for COVID-19 patients. These individuals inevitably have new levels of emotional stress and hard work when dealing with a pandemic, and during COVID-19, public health policies have often made their tasks much harder. Governors and public health experts have developed policies and practices that have vastly hampered their work through poor planning, poor preparation, and bad policies. Some examples include, allowing and/or forcing nursing homes to take COVID-19 patients, failing to provide adequate Personal Protective Equipment (PPE), promoting deadly technology such as ventilators, forbidding or making it difficult for prescribers to give hydroxychloroquine for prophylaxis and treatment early in the disease, promoting inadequate and dangerous medications such as remdesivir that enrich drug companies, and exaggerating the value of costly masks while minimizing their health hazards.

18. Religious practitioners. Probably all individuals need goals and beliefs greater than themselves to thrive and people who have a strong spiritual orientation do not want to be kept from participating in their religious activities. They are also more likely to feel skeptical of scientific pretensions and likely to resent interference with freedom of worship. Exercising their faith can help them to manage or overcome the anxiety, depression and other negative emotions stimulated by COVID-19. Often their churches are communities that bring uplifting or consoling relationships and services. Prohibitions from participating in church services and activities can wear heavily on them and cause worry and frustration over their inability to be with other parishioners who need their help. Secular government officials who plan for other people's lives can be extremely insensitive, dismissive, or unaware of how much it matters to many individuals and families to be involved in their churches. From the policies promoted by many public health experts and officials, it seems likely that they cannot imagine that most Americans take seriously their relationship to God and find great strength through it. Meanwhile, freedom of religion is guaranteed under the Constitution and being stopped from going to church is a huge infringement on that right. What good is a right that can so easily be taken away?

19. People who love to be in groups. Many people avoid groups of any size but most people love being in groups. Throughout the evolution of humanity, we lived in extended families and prospered as highly social group-oriented creatures. Then roughly 10,000 years ago

we began to live in villages with even greater numbers of people. For many people, group experiences are central to the enjoyment of life and their mental well-being. With little or no concern for their true importance, group activities have been stifled by public health scientists and government officials. From their polices, it is easy to imagine that many government planners cannot imagine how much people love their sports teams, identify with players, make the games a family affair at the stadium or in front of TV, and look forward to each new season.

20. Families who are separated. We have children and grandchildren whom we have not been able to physically visit for many months. Separation from family or people who “feel like family” can be a source of enormous distress and even grief. One of our grandchildren wants very much to visit us for his birthday but it is looking impossible. We now have a family member hospitalized in another state with no opportunity to bring his mother to see him or to see him for ourselves. The shutdowns make us wonder if there is something about power-hungry bureaucrats and elected officials that make them insensitive to what truly matters in life, especially the opportunity to share love and companionship with family and friends.

21. People with serious emotional problems. Every human being on Earth has emotional or psychological problems but some of us are especially vulnerable to life-disrupting events from job and educational disruptions to family separations. Many are very sensitive to the widespread fear engendered by those who are inflating the risks associated with COVID-19 and the need for drastic countermeasures. In my psychiatric and psychotherapy practice, it is apparent how the most vulnerable of us are suffering the most under the government crackdown on so many of life’s important and fulfilling activities. For those already feeling anxious and insecure, the fear created and spread by government pronouncements, policies, and practices can cause intolerable anxiety and feelings of helplessness.

22. Small business owners and employees. Small businesses as a group are notoriously fragile, often requiring a constant source of revenue to keep afloat. Many are sinking and how many will revive remains uncertain. Often called the most important economic activity in America, and the greatest source of employment, harm done to them not only devastates individuals but the overall economy. Many are family owned and their dissolution can also negatively impact family life as well.

23. The elderly and the chronically ill. I have put older and physically ill into one group because it includes the most vulnerable of all people. Their compromised immune systems and less robust bodies are especially subject to COVID-19’s worst effects. The term “comorbidities” often describes their increased susceptibility to the virus. In terms of managing the pandemic, this is the group that needs the most attention, while almost everyone else should be expeditiously returned to normal living conditions.

24. Victims of abuse. Abuse victims constitute a large and varied group but among the most vulnerable during the stay-at-home orders are victims of domestic or child abuse. Not only do tensions build up when families are confined together, it is more difficult for abuse victims to reach out for help during the shutdown. Being shut-in together is, of course, an extremely abnormal situation for almost everyone and, for most people, it is an enormous stress.

25. People seeking new relationships. As most other practicing psychiatrists or psychotherapists, I work with many people who are very lonely and trying to make new relationships that will be more satisfying than earlier ones that have failed. The shutdowns have taken away most of their opportunities to meet new people. They cannot escape their loneliness or grow in their ability to create more loving and successful partnerships. Some are taking risks with people met on-line that they would otherwise have avoided.

26. People living in poverty. For many reasons, people living in poverty are among the greatest victims of COVID-19. Often, they are the least able to take care of their own needs and often outside help such as social services and medical care is much less welcoming or available to them. People in poverty are on average more poorly nourished and more overweight. They have more physical illness and greater emotional problems. They often have more poorly functioning families and single-parent families as well as fewer active relationships in the community. These are broad generalizations, but in general being poor is disadvantageous from almost every perspective. The biggest exception is where one or more family members, usually parents and grandparents, but sometimes an older sibling, manage to provide the family with the love and care that characterizes successful family life. These people, unfortunately, are under greater stress than ever when they become the only resource for their families under stay-at-home orders.

27. First responders, including police, fire fighters, and emergency medical technicians (EMTs). It seems fitting to conclude this list with People living in poverty followed by the First responders on whom they disproportionately rely for their safety and well-being. Imagine being a first responder, whose main job is often giving reassurance, and your kind smile cannot be seen through your mask, and even your soft words may be too muffled to be understood. Imagine being injured and frightened and, instead of being surrounded by caring people, you are surrounded by masked people, raising their voices to be heard. Then imagine that you cannot exchange the touches that do so much for us when hurt and terrified. Imagine being a first responder whose job exposes you, beyond its always excessive stresses, to the fear of becoming contaminated with SARS-CoV-2 from a sick person. Then add that those same officials and politicians who are imposing a rigid lockdown on society, stirring up misery and rage among disturbed young people, will not defend you from those menacing or deadly crowds who target police but also any other uniformed person.

No list like this can be exhaustive. I am sure I have left out some obvious categories of vulnerable people. In truth, everyone in the world is vulnerable to the authoritarian and totalitarian policies and practices being inflicted on Americans and on people all over the world. We must resist the experts, officials, and politicians that are imposing them on us. Their actions are doing more harm than good, while offending human dignity and freedom.

V. Summary List of Government Actions to Enforce Overall Public Health Totalitarianism

The following is a list and brief description of some of the major COVID-19 government policies and programs that are totalitarian in nature. Some overlap with Dr. Nass's analysis of methods for discrediting hydroxychloroquine and also with other sections; but it may be useful to place these more than 30 observations in a single list. It also provides an opportunity to provide footnotes and links to some of the more problematic developments during COVID-19:

1. Stimulating fear, anxiety, terror, and paralysis (avolition) by the exaggeration of threats from the epidemic and especially from citizen resistance to topdown policies.^{88, 89, 90}
2. Changing the stated practical goal of preventing the collapse of the healthcare system to the impossible goal of preventing the spread of the virus, which greatly empowers the forces aiming at a more complete and very prolonged lockdown.^{91,92,93}
3. Focusing on the increasing numbers of cases (inevitable as the lockdown is eased and more testing is done) rather than on the diminishing rate of severe illness and death. Having failed to establish baseline population rates during the most intense lockdown, increased testing tells us little other than increasing exposures to each other will of course raise the counted number of infections of an epidemic disorder.^{94,95}

⁸⁸ Pew Research Center, 2020, U.S. Public Sees Multiple Threats From the Coronavirus – and Concerns are Growing, Pew Research Center. <https://www.pewresearch.org/politics/2020/03/18/u-s-public-sees-multiple-threats-from-the-coronavirus-and-concerns-are-growing/>

⁸⁹ Bernstein, L., 2020, Covid – 19 Death Toll Rivals Fatality Rate during 1918 flu epidemic, researchers say Washington Post. https://www.washingtonpost.com/health/covid-19-death-toll-rivals-fatality-rate-during-1918-flu-epidemic-researchers-say/2020/08/13/48e1dbf2-dd01-11ea-b205-ff838e15a9a6_story.html?utm_campaign=wp_post_most&utm_medium=email&utm_source=newsletter&wpisrc=nl_most

⁹⁰ Lederman, M., et al, 2020, Defeat Covid-19 by requiring vaccination for all. It's not un-American, it's Patriotic. USA Today. <https://www.usatoday.com/story/opinion/2020/08/06/stop-coronavirus-compulsory-universal-vaccination-column/3289948001/>

⁹¹ Andreano, C., 2020, Dr. Fauci: Wear goggles or eye shields to prevent spread of COVID- 19; flu vaccine a must. <https://abcnews.go.com/US/dr-fauci-wear-goggles-eye-shields-prevent-spread/story?id=72059055>

⁹² Bendix, A., 2020, Trump's 15-day Plan to slow the coronavirus' spread is too short, experts say. Flattening the curve could take at least several more weeks. Business Insider. <https://www.businessinsider.com/coronavirus-white-house-15-day-plan-too-short-2020-3>

⁹³ Atalan, A., 2020, Is the lockdown important to prevent the COVID-9 Pandemic? Effects on psychology, environment and economy-perspective, Elsevier. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7293850/pdf/main.pdf>

⁹⁴ Atalan, A., 2020, Is the lockdown important to prevent the COVID-9 Pandemic? Effects on psychology, environment and economy-perspective, Elsevier. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7293850/pdf/main.pdf>

⁹⁵ Fischer, K., 2020, Without Lockdowns, Another 60 Million People in U.S. Could Have Developed COVID-19, Healthline. <https://www.healthline.com/health-news/without-lockdowns-another-60-million-people-in-us-could-have-developed-covid-19>

4. Loosening the criteria for a COVID-19 exposure, leading to the quarantine of healthy people.⁹⁶
5. Loosening the criteria for identifying a COVID-19 related deaths to inflate the numbers.⁹⁷
6. Stimulating avolition and passivity by warning about grave dangers when citizens resist or even complain about increasing limitations on their volitional (freely chosen) activities and liberty.^{98,99}
7. Censoring and suppressing opinions contrary to the prevailing government policies and media opinions. Making people fearful of expressing themselves on social media such as Twitter, Facebook, and YouTube by orchestrated attacks and by censorship and shutting down dissident opinions.^{100,101,102}
8. Creating uncertainty and hence anxiety with changing pronouncements and practices.^{103,104,105}
9. Undermining basic institutions necessary for a competent volitional citizenry such as schools, churches, political gatherings, sports, group activities, and family life.¹⁰⁶
10. Generating conflict between age groups, races, and diverse groups, including distinctions between essential and non-essential workers (e.g., psychiatrists and therapists are essential but ministers and other religious practitioners are not).

⁹⁶ Breggin, P., et al, 2020, CDC Surges Covid-19 Stats, 2020, Psychiatric Drug Facts. <https://breggin.com/cdc-surge-stats-exaggerated/>

⁹⁷ Breggin, P., et al, 2020 CDC Surges Covid-19 Stats, 2020, Psychiatric Drug Facts. <https://breggin.com/cdc-surge-stats-exaggerated/>

⁹⁸ Fischer, K., 2020, Without Lockdowns, Another 60 Million People in U.S. Could Have Developed COVID-19, Healthline. <https://www.healthline.com/health-news/without-lockdowns-another-60-million-people-in-us-could-have-developed-covid-19>

⁹⁹ Dhillon, R., 2020 The U.S. Needs Smarter Lockdowns. Now. Harvard Business Review. <https://hbr.org/2020/08/the-u-s-needs-smarter-lockdowns-now>

¹⁰⁰ Carrie, J., 2020, Facebook bans some anti-lockdown protest pages.

<https://www.theguardian.com/technology/2020/apr/20/facebook-anti-lockdown-protests-bans>

¹⁰¹ Berenson, A., Coronavirus crisis—How Facebook and YouTube are trying to control information about COVID. <https://www.foxnews.com/opinion/coronavirus-facebook-youtube-control-information-alex-berenson>

¹⁰² The White House, 2020, Executive Order on Preventing Online Censorship, White House.

<https://www.whitehouse.gov/presidential-actions/executive-order-preventing-online-censorship/>

¹⁰³ Matei, A., 2020, ‘Focus on right now’: how to mentally prepare for more Covid-19 uncertainty.

<https://www.theguardian.com/world/2020/may/05/coronavirus-uncertainty-how-to-prepare>

¹⁰⁴ Spitzer, M., Traveling during coronavirus causes stress, anxiety, Florida Today. <https://www.msn.com/en-us/travel/news/traveling-during-coronavirus-causes-stress-anxiety/ar-BB170edI>

¹⁰⁵ Burnett, J., 2020, Green says ‘full shutdown’ might be necessary if Covid-19 cases don’t decline.

<https://www.hawaiitribune-herald.com/2020/08/13/hawaii-news/green-says-full-shutdown-might-be-necessary-if-covid-19-cases-dont-decline/>

¹⁰⁶ Bauer, F., 2020 How the Great Awakening Undermines E Pluribus Unum, National Review.

<https://www.nationalreview.com/2020/07/pandemic-protests-undermine-public-narratives/>

11. Discouraging or suppressing immediately available treatments, such as hydroxychloroquine in combination with azithromycin and zinc for prophylaxis and early treatment, that could dampen the effects of COVID-19, offer reassurance, and save many lives.^{107,108,109} See the work of Dr. Meryl Nast, **Part VII** of this report.

12. Enforcing measures which worsen the effects of COVID-19 such as such as wearing masks that make it harder to breathe, increasing vulnerability to respiratory infection and worsening existing infections, leading to unnecessary and potentially harmful intubation and respirators.^{110,111,112,113}

13. In the extreme, increasing the real number of deaths by introducing COVID-19 into nursing and old-age homes, where people are especially vulnerable due to illness and frailty, close quarters, and lack of needed healthcare providers and practices.^{114,115,116,117}

14. Building a fantasy cure (especially the vaccines) in the future to fan fear of the present and conformity in expectation of the elusive cure. Discouraging social connectivity (the basis of human empowerment) with masks, distancing, and isolation, some of it highly questionable and all of it unsustainable.¹¹⁸

15. Encouraging and enforcing dependency on big government in partnership with global corporations, rather than local self-determination, and individual self-sufficiency, independence, and volition.¹¹⁹

¹⁰⁷ Breggin, P., et al, 2020, Stunning News about Hydroxychloroquine to Treat Covid-19, Psychiatric Drug Facts. <https://breggin.com/stunning-news-about-hydroxychloroquine-to-treat-covid-19/>

¹⁰⁸ Breggin, P., et al 2020, America: Time to Save the World Again!, Psychiatric Drug Facts. <https://breggin.com/america-time-to-save-the-world-again/>

¹⁰⁹ Early treatment with hydroxychloroquine: a country based analysis 2020 <https://hcqtrial.com/>

¹¹⁰ Bastian, H., 2020 The Face Mask Debate Reveals a Scientific Double Standard, WIRED. <https://www.wired.com/story/the-face-mask-debate-reveals-a-scientific-double-standard/>

¹¹¹ Brosseau, L., et al, 2020 Commentary: Masks-for-all for Covid-19 not based on sound data, University of Minnesota. <https://www.cidrap.umn.edu/news-perspective/2020/04/commentary-masks-all-covid-19-not-based-sound-data>

¹¹² Williams, M., 2020 Ventilators are being overused on COVID-19 patients, world-renowned critical care specialist says, CBC. <https://www.cbc.ca/news/world/ventilators-covid-overuse-1.5534097>

¹¹³ Preidt, R., 2020, Study: Most N.Y. COVID Patients on Ventilators died, WebMD. <https://www.webmd.com/lung/news/20200422/most-covid-19-patients-placed-on-ventilators-died-new-york-study-shows#1>

¹¹⁴ Breggin, P., et al, 2020, COVID-19 SOS: Saving America from Governor Cuomo, Psychiatric Drug Facts. <https://breggin.com/covid-19-sos-saving-america-from-gov-cuomo/>

¹¹⁵ Breggin, P., et al, 2020, Seniors Implore Governors: Open Up Our World Again, Psychiatric Drug Facts. <https://breggin.com/seniors-implore-governors-open-up-our-world-again/>

¹¹⁶ Breggin, P. and Breggin, G. 2020, COVID- 19 and Political Correctness: 1,700 More NY Nursing Home Deaths, Psychiatric Drug Facts. <https://breggin.com/covid-19-and-political-correctness-1700-more-ny-nursing-home-deaths/>

¹¹⁷ Ries, J., 2020, 8 Things People Diagnosed With Coronavirus Want Know, HUFFPOST. https://www.huffpost.com/entry/living-with-coronavirus-diagnosed_1_5e77a00dc5b62f90bc4c9f3a

¹¹⁸ Haseltine, W., 2020, The Risks of Rushing a COVID-19 Vaccine, Scientific American. <https://www.scientificamerican.com/article/the-risks-of-rushing-a-covid-19-vaccine/>

¹¹⁹ Morabito, S., 2020, Pandemic Panic Has Magnified the Worst Impulses of the Power Hungry Elite, The Federalist. <https://thefederalist.com/2020/04/17/pandemic-panic-has-magnified-the-worst-impulses-of-the-power-hungry-elite/>

16. Promoting inadequate or harmful treatments, such as remdesivir.¹²⁰
17. Warning about a dark and interminable future toward which we must be accepting, “The New Normal.”^{121,122}
18. Demanding subservience to scientific expertise that lacks validity and/or consistency but is used to enforce conformity to most of the previous points.^{123,124}
19. Preparing the public for more draconian measurements that encroach on volition and freedom based on previous points, including enforced vaccination with ineffective and dangerous substances developed on a rush basis, the insertion of chips with the vaccinations to identify vaccinated individuals, cell phone and other devices equipped for identification and surveillance of individuals marked for control by the government, instituting isolation camps, and locking down large apartment complexes for containment.
20. Making people feel that they cannot defend themselves as anarchy increases by punishing people who defend themselves rather than the people who threaten them.^{125,126,127,128}
21. Undermining, demoralizing, disarming, and defunding the police, increasing

¹²⁰ Breggin, P., et al, 2020, Fauci’s Remdesivir: Inadequate to Treat COVID-19 and Potentially Lethal, Psychiatric Drug Facts. <https://breggin.com/faucis-remdesivir-inadequate-to-treat-covid-19-and-potentially-lethal/>

¹²¹ Sanchez, R., 2020, America’s ‘new normal’ will be anything but ordinary, CNN. <https://www.cnn.com/2020/04/16/us/coronavirus-pandemic-new-normal/index.html>

¹²² Rapoza, K., 2020, Three Things To Expect In The ‘New Normal’ Post Pandemic, Forbes. <https://www.forbes.com/sites/kenrapoza/2020/05/04/three-things-to-expect-in-the-new-normal-post-pandemic/#4519944c1051>

¹²³ Stevens, L., et al, 2020, Trust in Science Essential in Battle Against COVID-19, Gallup. <https://news.gallup.com/opinion/gallup/287285/trust-science-essential-battle-against-covid.aspx>

¹²⁴ New Scientist, 2020, Coronavirus: Can We Trust The Science, New Scientist <https://www.newscientist.com/science-events/new-online-series-continues-coronavirus-can-trust-science/#>

¹²⁵ Horowitz, D., 2020, Horowitz: Republicans won’t even fight for self-defense, CR. <https://www.conservativereview.com/news/horowitz-republicans-wont-even-fight-self-defense/>

¹²⁶ Morefield, S., 2020, Armed Citizens Stand Guard Against Looters In Minneapolis, Daily Caller. <https://dailycaller.com/2020/05/28/armed-citizens-looting-minneapolis-george-floyd-riots/>

¹²⁷ Zapotosky, M., 2020, Ex-Trump adviser Bannon indicted on conspiracy charges in alleged fraud, The Washington Post. <https://www.washingtonpost.com/politics/2020/04/25/wisconsin-protestors-attack-stay-at-home-orders-unnecessary-or-government-cabal/>

¹²⁸ Jackman, T., 2020, St. Louis couple who aimed guns at protesters charge with felony weapons count, The Washington Post. <https://www.google.com/amp/s/www.washingtonpost.com/nation/2020/07/20/st-louis-couple-who-aimed-guns-protesters-charged-with-felony-weapons-count/%3foutputType=amp>

anxiety and fearfulness, and all the untoward effects of the lockdown listed above.
129,130,131,132

22. Predicting disastrous outcomes—such as millions of deaths, an overwhelm of the medical system, and specific lacks of medical supplies—to frighten citizens to conform.
133,134,135,136,137

23. Artificially Inflating the infection and death rates and other data to intimidate people.^{138,139,140,141}

¹²⁹ Akinnibi, F., 2020, U.S. Mayors' Group Opposes Police Defunding Efforts While Urging Reform, MSN. <https://www.msn.com/en-us/finance/news/us-mayors-e2-80-99-group-opposes-police-defunding-efforts-while-urging-reform/ar-BB17Vtpv>

¹³⁰ Matier, P., 2020, SF police appear to be doing their own defunding as cops leave in record numbers, MSN. <https://www.msn.com/en-us/news/crime/sf-police-appear-to-be-doing-their-own-defunding-as-cops-leave-in-record-numbers/ar-BB181nrU>

¹³¹ Kaplan, T., 2020, Trey Gowdy: 'Defunding the police is the single dumbest idea I've ever heard', FOX News. <https://www.foxnews.com/media/trey-gowdy-defunding-the-police-is-the-single-dumbest-idea-i-ever-heard>

¹³² Hogan, B., et al, 2020, Majority of New Yorkers oppose defunding the police, poll shows, New York Post. <https://nypost.com/2020/06/30/poll-shows-majority-of-new-yorkers-oppose-defunding-the-police/>

¹³³ Ariza, M., 2020, Pandemic parties rage on across South Florida despite growing coronavirus crisis, Sun Sentinel. <https://www.msn.com/en-us/news/us/pandemic-parties-rage-on-across-south-florida-despite-growing-coronavirus-crisis/ar-BB16AKh>

¹³⁴ Maguire, B., et al, 2020, The Ethics of PPE and EMS in the COVID-19 Era, JEMS. <https://www.jems.com/2020/04/10/ethics-of-ppe-and-ems-in-the-covid-19-era/>

¹³⁵ Stickings, T., 2020, 15 MILLION people will die and the global economy will take a \$2.3 TRILLION hit from coronavirus in the BEST-CASE scenario, new study predicts, MailOnline. <https://www.dailymail.co.uk/news/article-8082327/15-MILLION-people-die-best-case-coronavirus-scenario.html>

¹³⁶ CNN, 2020, Dr. Fauci: 'Possible' that millions could die in US, CNN. <https://www.cnn.com/videos/politics/2020/03/15/sotu-fauci-millions.cnn>

¹³⁷ Sullum, J., 2020, As Trump imagines '2.2 Million Deaths' From Covid-19 in the U.S., a Top Federal Disease Expert Cautions Against Believer Worst-Case Scenarios, reason.com. <https://reason.com/2020/03/30/as-trump-imagines-2-2-million-deaths-from-covid-19-in-the-u-s-a-top-federal-disease-expert-cautions-against-believing-worst-case-scenarios/>

¹³⁸ Allen, T., et al, U.S. COVID-19 Death Toll Is Inflated, Real Clear Politics. https://www.realclearpolitics.com/articles/2020/05/29/us_covid-19_death_toll_is_inflated.html

¹³⁹ Arter, M., 2020, CDC Director: 'I Think You're Correct' About Inflated COVID Death Statistics, CNS News. <https://www.cnsnews.com/article/washington/melanie-arter/cdc-director-i-think-youre-correct-about-inflated-covid-death>

¹⁴⁰ Casiano, L., 2020, Birx says government is classifying all deaths of patients with coronavirus as 'COVID-19' deaths, regardless of cause, Fox News. <https://www.foxnews.com/politics/birx-says-government-is-classifying-all-deaths-of-patients-with-coronavirus-as-covid-19-deaths-regardless-of-cause> You To

¹⁴¹ CCO Public Domain. Sweden uncovers 3,700 false positives from COVID-19 test kit, (2020, August 25). Medical Press. <https://medicalxpress.com/news/2020-08-sweden-uncovers-false-positives-covid.html>

24. Threatening draconian legal punishments, such as turning out the lights and shutting off the water to punish people who have large gatherings in their homes or businesses.^{142,143,144,145,146,147}

25. Warning that the epidemic will never be over and that drastic changes in the quality of life must be accepted—reducing hope for the future to encourage docility.^{148,149,150,151,152}

26. Encouraging people to report or snitch on each other—a classic practice of totalitarian regimes that encourages paranoia and isolation.^{153,154,155}

¹⁴² Olson, T., 2020, Texas Supreme Court orders Dallas salon owner released as Abbott bans jailing citizens for lockdown violations, Fox News. <https://www.foxnews.com/politics/abbott-issues-executive-order-eliminating-jail-as-punishment-for-violating-coronavirus-restrictions>

¹⁴³ Nelson, J., 2020, NJ gym opens in defiance of governor's lockdown: 'We will not stand down', Fox News. <https://www.foxnews.com/media/new-jersey-gym-owner-ian-smith-opens-lockdown>

¹⁴⁴ Lancaster, J., 2020, 'He Will Be Cited Every Day': California Gym Owner Opens Up Shop Just Days After Being Arrested For Opening, Daily Caller. <https://dailycaller.com/2020/05/14/cited-california-gym-owner-opens-shop-arrested/>

¹⁴⁵ Harbus, R., 2020, New Jersey gym owners who reopened in violation of governor's orders receive summons, New York Post. <https://nypost.com/2020/05/18/nj-gym-owners-who-reopened-in-violation-of-governors-orders-receive-summons/>

¹⁴⁶ Barone, V., 2020, LA mayor threatens to turn off water, power after Beverly Hills bash, New York Post. <https://nypost.com/2020/08/05/la-mayor-threatens-to-turn-off-water-power-after-beverly-hills-bash/>

¹⁴⁷ Ruiz, M., 2020, Los Angeles to shut off water, power of nonessential business that refuse to close amid coronavirus, FOX News. <https://www.foxnews.com/us/los-angeles-water-power-businesses-refuse-close-coronavirus>

¹⁴⁸ Panette, G., 2020, Fauci: Getting back to normal 'might not ever happen' without vaccine, MSN. <https://www.msn.com/en-us/health/medical/fauci-getting-back-to-normal-might-not-ever-happen-without-a-vaccine/ar-BB12f5uf>

¹⁴⁹ Lichfield, G., 2020, We're not going back to normal, MIT Technology Review.

<https://www.technologyreview.com/2020/03/17/905264/coronavirus-pandemic-social-distancing-18-months/>

¹⁵⁰ Diers, J., 2020, Commentary: To fight COVID-19, the time has come for draconian measures, SW News Media.

https://www.swnewsmedia.com/prior_lake_american/news/opinion/columnists/commentary-to-fight-covid-19-the-time-has-come-for-draconian-measures/article_d059c655-2680-5105-a0fd-7cd9e7a2efb7.html

¹⁵¹ Meredith, S., 2020, Millions of people are expected to fall ill with tuberculosis due to coronavirus lockdown, CNBC. <https://www.cnn.com/2020/05/06/coronavirus-millions-of-people-expected-to-fall-ill-with-tuberculosis.html>

¹⁵² Blanchard, A., et al, 2020, Coronavirus 'shutdown' could last 18 months: Another warning from the experts who triggered Boris Johnson U-turn by telling him 250,000 could die, Daily Mail.

<https://www.dailymail.co.uk/news/article-8120501/Draconian-shutdown-measures-18-MONTHS-coronavirus-report-warns.html>

¹⁵³ Moore, T., et al, 2020, De Blasio's social distancing tip line flooded with penis photos, Hitler memes, New York Post. <https://nypost.com/2020/04/21/de-blasios-social-distancing-tip-line-flooded-with-obscenities/>

¹⁵⁴ Keane, D., 2020, TIP OFF Cops as Brits to use telephone 'hotline' and 'snoopers' form to report people breaching coronavirus lockdown, The Sun. <https://www.thesun.co.uk/news/11278436/cops-brits-telephone-snoopers-form-coronavirus-lockdown/>

¹⁵⁵ CBS Los Angeles, 'Snitches Get Rewards': Garcetti Issues New Rules For Construction Sites, Encourages Community To Report Safer At Home Violators, CBS Los Angeles.

<https://losangeles.cbslocal.com/2020/03/31/coronavirus-los-angeles-eric-garcetti-snitches-get-rewards/>

27. Spreading rumors and/or true stories about building isolation and containment centers.^{156,157,158,159}

28. Spreading rumors and/or true stories about shutting down whole apartment complexes.^{160,161,162,163,164,165}

29. Enforcing contact tracing as a threat and a way of conditioning the population to accept controls by forcing people to report on each other, even though it results in the dire consequence of quarantine and separation from family, loved ones, school, work, etc.^{166,167,168,169,170}

¹⁵⁶ News Breaker, 2020, Written order shows state falsely claiming ‘isolation camps’ are ‘voluntary’, Global News Cap. <https://globalnewscap.com/written-order-shows-state-falsely-claiming-isolation-camps-are-voluntary/>

¹⁵⁷ Reuters, 2020, Partly false claim: this map shows all states currently in a state of emergency due to the COVID-19 pandemic, as well as “COVID-19 camps”, Reuters. <https://www.reuters.com/article/uk-factcheck-coronavirus-camps-idUSKBN210363>

¹⁵⁸ KOMO News Staff, 2020, Governor tours new coronavirus isolation and quarantine site in Thurston County, KOMO News. <https://komonews.com/news/coronavirus/governor-tours-new-covid-19-isolation-and-quarantine-site-in-thurston-county>

¹⁵⁹ Rahhal, N., et al, 2020, US military approves 11 coronavirus quarantine camps next to major US airports which can treat ‘up to 1,000 people’ as the 13th American case is confirmed in California, Daily Mail. <https://www.dailymail.co.uk/news/article-7992909/Military-approves-11-COVID-19-quarantine-camps-1-000-people-major-airports.html>

¹⁶⁰ @SallyKP, 2020, A California apartment building initiates lockdown, mandatory COVID testing and quarantine, Twitter. <https://twitter.com/sallyKP/status/1285784372642226182/photo/1>

¹⁶¹ Daly, K., et al, 2020, Forced County COVID-19 Lockdown of Ventura Apt Building at 137 S. Palm St., Citizens Journal. <https://www.citizensjournal.us/forced-county-covid-19-lockdown-of-ventura-apt-building-137-s-palm-st/>

¹⁶² Paynter, J., 2020, Police pounce on car outside Flemington complex as nine Melbourne public housing buildings locked down, News.Com.Au. <https://www.news.com.au/national/victoria/news/police-pounce-on-car-outside-flemington-complex-as-nine-melbourne-public-housing-buildings-locked-down/news-story/a92f9ac0e813fd62d87bf5c1979c4641>

¹⁶³ Zaczek, Z., 2020, Pictures reveal how Victoria’s ‘hard lockdown’ of 3,000 Melburnians is eerily similar to China’s Wuhan where residents were shut off from society for two months, Daily Mail. <https://www.dailymail.co.uk/news/article-8489743/Pictures-reveal-Melbournes-lockdown-nine-public-housing-towers-eerily-similar-Wuhan.html>

¹⁶⁴ Associated Press, 2020, China locks down 50 million people and has to keep them fed, Star Advertiser. <https://www.staradvertiser.com/2020/01/30/breaking-news/china-locked-down-50-million-people-and-has-to-keep-them-fed/>

¹⁶⁵ Hayward, J., 2020, Famed Dissident: China Welding People Shut In Their Homes To Fight Coronavirus, Breitbart. <https://www.breitbart.com/national-security/2020/02/11/famed-dissident-china-welding-people-shut-in-their-homes-to-fight-coronavirus/>

¹⁶⁶ Hilario, E., 2020, Draconian lockdown yielded meager health results, ManilaStandard.net. <https://manilastandard.net/opinion/columns/about-town-by-ernesto-m-hilario/325237/draconian-lockdown-yielded-meager-health-results.html>

¹⁶⁷ truthhunter, 2020, Why Contact Tracing Should Scare You And How To Avoid It, The Truth Hunter. <https://thetruthhunter.com/why-contact-tracing-should-scare-you-and-how-to-avoid-it/>

¹⁶⁸ Rucker, J.D., 2020, HR 6666, the TRACE Act, is bad as it sounds and could actually become law, NOQ Report. <https://noqreport.com/2020/05/12/hr-6666-the-trace-act-is-as-bad-as-it-sounds-and-could-actually-become-law/>

¹⁶⁹ 21st Century Wire, 2020, Washington State: Residents Who Refuse COVID Test to Be Placed Under House Arrest, SGT Report. <https://www.sgtreport.com/2020/05/washington-state-residents-who-refuse-covid-test-to-be-placed-under-house-arrest-2/>

¹⁷⁰ The Irish Times, 2020, Contact tracing could be in place in North for two years, says Foster, The Irish Times. <https://www.irishtimes.com/news/ireland/irish-news/contact-tracing-could-be-in-place-in-north-for-two-years-says-foster-1.4266867>

30. Tracking or tracing people by means of their smartphones and other devices to locate them for contact tracing or to make sure they are quarantining. ^{171,172,173,174}

31. Planning and/or threatening compulsory vaccination, including with new and untried vaccines. ^{175,176,177,178,179,180}

¹⁷¹ Global News, 2020, CANADA: Young people are causing COVID-19 spikes. But are they solely to blame? ElliotLakeToday. <https://www.elliottlaketoday.com/coronavirus-covid-19-national-news/canada-young-people-are-causing-covid-19-spikes-but-are-they-solely-to-blame-2586290>

¹⁷² Julien, C., 2020, Contact-tracing apps for COVID-19: What you need to know (and do), MSN. <https://www.msn.com/en-us/news/technology/contact-tracing-apps-for-covid-19-what-you-need-to-know-and-do/ar-BB14iciA>

¹⁷³ Prasso, S., 2020, Everyone Has a Contact-Tracing App, and Nobody's Happy About It, Bloomberg Businessweek. <https://www.bloomberg.com/news/articles/2020-05-21/big-tech-and-government-s-contact-tracing-systems-have-flaws>

¹⁷⁴ Prasso, S., 2020, Everyone Has a Contact-Tracing App, and Nobody's Happy About It, Bloomberg Businessweek. <https://www.bloomberg.com/news/articles/2020-05-21/big-tech-and-government-s-contact-tracing-systems-have-flaws>

¹⁷⁵ Creitz, C., 2020, Dershowitz says forced coronavirus vaccination could happen: 'Police power of the state is very considerable', Fox News. <https://www.foxnews.com/media/alan-dershowitz-forced-coronavirus-vaccinations-are-constitutional>

¹⁷⁶ Smith, W.J., 2020, Will We All Be Forced to Get COVID Vaccines?, The American Spectator. <https://spectator.org/will-we-all-be-forced-to-get-covid-vaccines/>

¹⁷⁷ Cox, C., 2020, Fact check: Fed buy syringes that may have RFID chips, but no evidence COVID-19 vaccination required, USA Today. <https://www.usatoday.com/story/news/factcheck/2020/06/04/fact-check-feds-syringes-may-have-rfid-chips-but-vaccines-optional/5246222002/>

¹⁷⁸ TMZ, 2020, People Who Reject Vaccine Could Be Barred From Work, School, TMZ. <https://www.tMZ.com/2020/08/13/coronavirus-vaccine-forced-stanford-law-professor-hank-greely/>

¹⁷⁹ Chumley, C.K., 2020, Anthony Fauci set stage for mandatory – lucrative! -- vaccine, The Washington Times <https://www.washingtontimes.com/news/2020/apr/8/anthony-fauci-sets-stage-mandatory-vaccine/>

¹⁸⁰ Grant, J., 2020, State Bar Group Calls for 'Mandatory' COVID-19 Vaccinations, Regardless of Objections, New York Law Journal. <https://www.law.com/newyorklawjournal/2020/05/28/state-bar-calls-for-mandatory-covid-19-vaccinations-regardless-of-objections/?slreturn=20200718215235>

32. Planning and/or threatening Big Brother means of technological control though chips implanted with vaccines and coordinating with the other technologies described above.
181,182,183,184,185186,187,188

VI. Hazards of Face Masks

The wearing of face masks has become a political litmus test used to challenge the President and to cow the people. The internet is filled with photos of strong advocates of face masks dropping them to their chin to speak clearly and to relieve discomfort. Meanwhile, beyond all reason, we see intimidated people driving alone in the cars wearing masks and walking alone in parks with their faces covered. Although face masks may protect other people who are near enough to be coughed or sneezed on, or to catch a moist exhalation of air, in most situations face masks are probably more harmful than helpful.

At the very start of the push for wearing face masks, there was a scientific pushback that was largely ignored. On April 20, 2020, a Rapid Response was published in the *BMJ* by Antonio Lazzarino, a physician and epidemiologist, University College London, UCL Institute of Epidemiology and Health Care, and two others. Their summary follows:

The two potential side effects that have already been acknowledged are:

(1) Wearing a face mask may give a false sense of security and make people adopt a reduction in compliance with other infection control measures, including social distancing and hands washing.

(2) Inappropriate use of face mask: people must not touch their masks, must change their single-use masks frequently or wash them regularly, dispose them correctly and adopt other management measures, otherwise their risks and those of others may increase.

¹⁸¹ Perez, M., 2020, Bill Gates Calls For National Tracking System For Coronavirus During Reddit AMA, Forbes. <https://www.forbes.com/sites/mattperez/2020/03/18/bill-gates-calls-for-national-tracking-system-for-coronavirus-during-reddit-ama/#279d38d16a72>

¹⁸² Trafton, A., 2019, Storing medical information below the skin's surface, MIT News. <https://news.mit.edu/2019/storing-vaccine-history-skin-1218>

¹⁸³ Austin, J., 2015, EXCLUSIVE: 'Secret plan to inject us ALL with ID chips through vaccination programme', Express. <https://www.express.co.uk/news/science/614168/Secret-plan-inject-ALL-ID-chips-vaccination-program-Simon-Parkes-conspiracy-theory>

¹⁸⁴ Stibel, J., 2017, Hacking The Brain: The Future Computer Chips In your Head, Forbes. <https://www.forbes.com/sites/jeffstibel/2017/07/10/hacking-the-brain/#30a333102009>

¹⁸⁵ Metz, R., 2019, Elon Musk hopes to put a computer chip in your brain. Who wants one?, CNN. <https://www.cnn.com/2019/07/20/tech/elon-musk-neuralink-brain-chip-experts/index.html>

¹⁸⁶ Yale Macmillan Center, 2020, Democracy and Rise of Authoritarianism in COVID-19 World, Yale Macmillan Center. <https://macmillan.yale.edu/news/democracy-and-rise-authoritarianism-covid-19-world>

¹⁸⁷ Cohen, J., 2020, Coronavirus Under Authoritarian Rule: The Wacky, The In Denial, The Problematic, Forbes. <https://www.forbes.com/sites/joshuacohen/2020/04/03/coronavirus-under-authoritarian-rule-the-wacky-the-in-denial-the-problematic/#7b0605b3f4c1>

¹⁸⁸ Ruben, B.D., 2020, Will the COVID-19 crisis trigger us to rethink our ideas about authoritarian-style leadership? | Opinion, NJ.com. <https://www.nj.com/opinion/2020/03/will-the-covid-19-crisis-trigger-us-to-rethink-our-ideas-about-authoritarian-style-leadership-opinion.html>

Other potential side effects that we must consider are:

(3) The quality and the volume of speech between two people wearing masks is considerably compromised and they may unconsciously come closer. While one may be trained to counteract side effect , this side effect may be more difficult to tackle.

(4) Wearing a face mask makes the exhaled air go into the eyes. This generates an uncomfortable feeling and an impulse to touch your eyes. If your hands are contaminated, you are infecting yourself.

(5) Face masks make breathing more difficult. For people with COPD, face masks are in fact intolerable to wear as they worsen their breathlessness. Moreover, a fraction of carbon dioxide previously exhaled is inhaled at each respiratory cycle. Those two phenomena increase breathing frequency and deepness, and hence they increase the amount of inhaled and exhaled air. This may worsen the burden of covid-19 if infected people wearing masks spread more contaminated air. This may also worsen the clinical condition of infected people if the enhanced breathing pushes the viral load down into their lungs. [These breathing problems can also lead to lightheadedness, anxiety, and panic. PRB]

(5B) The effects described at point 5 are amplified if face masks are heavily contaminated (see point 2)

(6) While impeding person-to-person transmission is key to limiting the outbreak, so far little importance has been given to the events taking place after a transmission has happened, when innate immunity plays a crucial role. The main purpose of the innate immune response is to immediately prevent the spread and movement of foreign pathogens throughout the body. The innate immunity's efficacy is highly dependent on the viral load. If face masks determine a humid habitat where the SARS-CoV-2 can remain active due to the water vapour continuously provided by breathing and captured by the mask fabric, they determine an increase in viral load and therefore they can cause a defeat of the innate immunity and an increase in infections. This phenomenon may also interact with and enhance previous points.

In conclusion, ... It is necessary to quantify the complex interactions that may well be operating between positive and negative effects of wearing surgical masks at population level. It is not time to act without evidence. (citations omitted)

Wearing face masks has not be left to individual discretion. People have not been educated to face mask hazards and many mistakenly believe that wearing them will protect themselves as well as others from COVID-19. They fear that the failure to use them will be taken as irrational defiance of authority or lack of concern for others. Some people view the wearing of masks as a sign of their virtue; but others feel they it is a sign of conformity to over-zealous government control.

Wearing face masks cuts people off from each other's other facial expressions and cues. It reduces verbal communications. Today, when people go outdoors or into buildings wearing a mask, they often make no attempt to make a friendly gesture and indeed they commonly avert eyes. More than anything, masks create discomfort and alienation between people, which is a hallmark of the totalitarian society.

Decades ago, *In Crowds and Power*, Nobel Prize Winner in Literature, Elias Canetti, wrote some astonishing passages about the negative effects of wearing masks in general:

People's attitude to this play of the features varies. In some civilizations the freedom of the face is largely restricted; it is thought improper to show pain and pleasure openly; a man shuts them away inside himself and his face remains calm. The real reason for this attitude is the desire for personal autonomy: no intrusion on oneself is permitted, nor does one intrude on anyone else. A man is supposed to have the strength to stand alone and also the strength to remain himself. The two things go hand in hand, for it is the influence of one man upon another which stimulates the unending succession of transformations. They are expressed in gestures and the movements of the face and, where these are suppressed, all transformation becomes difficult and, in the end, impossible.

A little experience of the inflexibility of such unnatural "stoics" soon leads one to understand the general significance of the mask : it is a conclusion; into it flows all the ferment of the as yet unclear and uncompleted metamorphoses which the natural human face so miraculously expresses, and there it ends. Once the mask is in position there can be no more beginnings, no groping towards something new. The mask is clear-cut; it expresses something which is quite definite, and neither more nor less than this. It is fixed; the thing it expresses cannot change. P. 374...

A mask expresses much, but hides even more. Above all it separates. P. 374

In our culture in ordinary times, the wearing of a mask or kerchief in public presents several threats, most notably, the person is sick and infectious, or the person is a criminal about to threaten us. In a time of great turmoil, with riots occurring nightly in cities around the country, and acts of vandalism in the name of political retribution or righteousness, the perpetrators happily wear masks, giving them anonymity during their perpetrations.

Do masks have any use outside of an infection disease treatment setting or when in close proximity to vulnerable and elderly people? Probably not much and they do have hazards. Government enforced public health policies concerning the wearing of masks may do much more harm than letting health facilities set their own standards and letting the people under most circumstances rely upon voluntary social distancing when necessary.

VII. Dr. Meryl Nass on the False Narrative Created to Discredit Hydroxychloroquine

We recently learned about the amazing work of Meryl Nass, MD. Dr. Nass has a BS in biology from MIT and a medical degree from the New Jersey Medical School, Newark, NJ. Beginning in 1976, she has published 39 scientific papers, many of them pertaining to epidemics and other issues in this case. On August 26, 2020 she appeared on my weekly radio/TV talk show and was a stunning and informative guest.¹⁸⁹ Along with Dr. Pam Popper's section VIII, this is one of two reports by other professionals entered into this report as official parts of my testimony and opinions. In my decades of forensic work, it is unprecedented for me to include whole presentations by other experts into my reports; but the breadth and complexity of the subject, and the need for more varied and personal communications about this enormous tragedy, makes it appropriate and necessary.

On June 27, 2020, Dr. Nass published her extraordinary summary of the efforts made to successfully suppress the use of hydroxychloroquine in the US and in many other countries around the world.¹⁹⁰ I found that nearly all her points corresponded with similar points we had made in our blog reports on Dr. Breggin's Coronavirus Resource Center, but her work adds new information. Her detailed summary closely relates to authoritarian and totalitarian methods under the guise of public health. With Dr. Nass's permission, I am reprinting her authoritative summary with its multiple footnotes, which can be very useful:

How a False Hydroxychloroquine Narrative Was Created, And More By Meryl Nass, MD Saturday, June 27, 2020

It is remarkable that a series of events taking place over the past 3 months produced a unified message about hydroxychloroquine and produced similar policies about the drug in the US, Canada, Australia, NZ, and western Europe. The message is that generic, inexpensive hydroxychloroquine is dangerous and should not be used to treat a potentially fatal disease, COVID-19, for which there are no (other) reliable treatments.¹⁹¹

Hydroxychloroquine has been used safely for 65 years in many millions of patients. **And so, the message was crafted that** the drug is safe for its other uses, but dangerous when used for COVID-19.¹⁹² It does not make sense, but it seems to have worked.

In the US, "Never Trump" morphed into "Never Hydroxychloroquine," and the result for the pandemic is "Never Over." But while anti-Trump spin is what

¹⁸⁹ Dr. Meryl Nass on the Dr. Peter Breggin Hour, August 26, 2020, talking about COVID-19 and the politics surrounding it. <https://www.youtube.com/watch?v=p616Lb3fRGQ>

¹⁹⁰ Dr. Nass's report was originally published on her website: <https://anthraxvaccine.blogspot.com/> It has been republished by numerous other websites, including on August 11, 2020, *Principia Scientific International*, where I first found it. <https://principia-scientific.com/how-the-fake-hydroxychloroquine-narrative-was-created/> Here is a brief bio of Dr. Nass on WebMD: <https://www.webmd.com/meryl-nass> Dr. Nass has generously given us permission for the republication of her entire report.

¹⁹¹ Service, R., 2020, Would-be coronavirus drugs are cheap to make, American Association for the Advancement of Science. <https://www.sciencemag.org/news/2020/04/would-be-coronavirus-drugs-are-cheap-make#>

¹⁹² Li, D.K., 2020, WHO temporarily halts trial of hydroxychloroquine over safety concerns, NBC News. <https://www.nbcnews.com/news/world/who-temporarily-halts-trial-hydroxychloroquine-over-safety-concerns-n1214341>

characterized suppression strategies in the US, the frauds perpetrated about hydroxychloroquine and the pandemic include most western countries.

Were these acts carefully orchestrated? You decide.

Might these events have been planned to keep the pandemic going? To sell expensive drugs and vaccines to a captive population? Could these acts result in prolonged economic and social hardship, eventually transferring wealth from the middle class to the extraordinarily rich? Are these events evidence of a conspiracy?

Here is a list of what happened, in no special order. Please help add to this list if you know of other actions I should include. This will be a living document, added to as new information becomes available.

I have penned this as if it is the "**To Do**" list of items to be accomplished by those who pull the strings. The items on the list have already been carried out. One wonders what else might be on their list, yet to be carried out, for this pandemic.

1. You stop doctors from using the drug in ways it is most likely to be effective (in outpatients at onset of illness). You prohibit use outside of situations you can control.

Situations that were controlled to show no benefit included three large, randomized, multicenter clinical trials (Recovery, Solidarity and REMAP-COVID), the kind of trials that are generally believed to yield the most reliable evidence. However, each of them used excessive hydroxychloroquine doses that were known to be toxic and may have been fatal in some cases; see my previous articles [here](#) and [here](#).^{193, 194, 195}

2. You prevent or limit use in outpatients by controlling the supply of the drug, using different methods in different countries and states.¹⁹⁶ In NY state, by order of the governor, hydroxychloroquine could only be prescribed for hospitalized patients.¹⁹⁷ France has issued a series of different regulations to limit prescribers from using it. France also changed the drugs' status from over the counter to a drug requiring a prescription.

¹⁹³ Recovery, 2020, Randomized Evaluation of COVID-19 Therapy (RECOVERY), Recovery.

<https://www.recoverytrial.net/files/protocol-archive/recovery-protocol-v6-0-2020-05-14.pdf/@@download>

¹⁹⁴ World Health Organization, 2020, "Solidarity" clinical trial for COVID-19 treatments, World Health Organization. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments>

¹⁹⁵ Remap-Cap, 2020, Domain-Specific Appendix: COVID-19 Antiviral Therapy.

https://static1.squarespace.com/static/5cde3c7d9a69340001d79ffe/t/5ea3fd83f222897b8d528195/1587805583231/REMAP-CAP+-+COVID-19+Antiviral+Domain-Specific+Appendix+V2.0+-+01+April+2020_WM.pdf

¹⁹⁶ AMA, 2020, Boards of pharmacy and other actions relating to COVID-19 prescribing, AMA. <https://www.ama-assn.org/system/files/2020-04/board-of-pharmacy-covid-19-prescribing.pdf>

¹⁹⁷ Cuomo, A., 2020, No. 202.10: Continuing Temporary Suspension and Modification of Laws Relating to the Disaster Emergency, New York State. <https://www.governor.ny.gov/news/no-20210-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency>

3. You play up the dangers of the drug, without emphasizing that side effects are exceedingly rare when the drug is used correctly. You make sure everyone has heard about the man who died after consuming hydroxychloroquine in the form of fish tank cleaner.¹⁹⁸ Yet its toxicity at approved doses is minimal. Chloroquine was *added to table salt* in some regions in the 1950s as a malaria preventive, according to Professor Nicholas White in his study for the Recovery trial.¹⁹⁹

4. You limit clinical trials to hospitalized patients, instead of testing the drug in outpatients, early in the illness, when it is predicted to be most effective.²⁰⁰

Finally, but not until May, you have Fauci's NIAID conduct a trial in outpatients, using hydroxychloroquine plus azithromycin, but you only enroll 20 patients, after earlier planning for 2,000.^{201, 202} Only half get the drugs. You reduce the duration of followup from 24 weeks to 13 days post treatment. This ridiculously small number of subjects assures meaningless results. Who pulled the plug on this trial?¹³

5. You design clinical trials to give much too high a dose, ensuring the drug will cause harm in some subjects, sufficient to mask any possible beneficial effect.²⁰³ You make sure that trials in 400 hospitals in 35 countries (Solidarity) plus most hospitals in the UK (Recovery) use these dangerous doses, as well as additional sites in 13 countries (REMAP-COVID trial).⁵

6. You design clinical trials to collect almost no safety data, so any cause of death due to drug toxicity will be attributed to the disease instead of the drug.¹⁴

7. You issue rules for use of the drug based on the results of the UK Recovery study, which overdosed patients.^{4,204} Of course, the Recovery results showed more deaths in the hydroxychloroquine arm, since they gave patients 2.4 g in the first 24 hrs., 800 mg/day thereafter. Furthermore, the UK has the 2nd highest death rate in the world for COVID-19 (Belgium is 1st), so simply conducting the trial in the UK may have contributed to the poor results.

¹⁹⁸ BBC News, 2020, Coronavirus: Man dies taking fish tank cleaner as virus drug, BBC News.

<https://www.bbc.com/news/52012242>

¹⁹⁹ FranceSoir, 2020, Oxford Recovery Trial – An erroneous pharmacokinetic model leading to overdose, FranceSoir. <http://www.francesoir.fr/societe-sante/oxford-recovery-clinical-trial-le-modele-pharmacocinetique-utilise-pour-calculer-le>

²⁰⁰ Nass, M., 2020, It is medically illogical to wait until someone is very sick before treating them, Anthrax Vaccine. <https://anthraxvaccine.blogspot.com/2020/05/it-is-medically-illogical-to-wait-until.html>

²⁰¹ ClinicalTrials.gov, 2020, Evaluating the Efficacy of Hydroxychloroquine and Azithromycin to Prevent Hospitalization of Death in Persons with COVID-19, ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT04358068>

²⁰² ClinicalTrials.gov, 2020, History of Changes, ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/history/NCT04358068?A=7&B=11&C=merged#StudyPageTop>

²⁰³ Nass, M., 2020, WHO and UK trials use potentially lethal hydroxychloroquine dose—according to WHO consultant, Anthrax Vaccine. <https://anthraxvaccine.blogspot.com/2020/06/who-trial-using-potentially-fatal.html>

²⁰⁴ Broseley, S., 2020, Hydroxychloroquine does not cure Covid-19, say drug trial chiefs, The Guardian. <https://www.theguardian.com/world/2020/jun/05/hydroxychloroquine-does-not-cure-covid-19-say-drug-trial-chiefs>

8. You publish, in the world's most-read medical journal, the *Lancet*, an observational study from a huge worldwide database (96,000 COVID cases) that says use of chloroquine drugs caused significantly increased mortality.²⁰⁵ You make sure that all major media report on this result. This was said to be the nail in the coffin for hydroxychloroquine. Then you have 3 European countries announce they will not allow doctors to prescribe the drug.²⁰⁶

9. You do your best to ride out any controversy, never admitting culpability. Even after hundreds of people renounced the *Lancet's* observational study due to easily identified fabrications--the database used in the study did not exist, and the claimed numbers did not agree with known numbers of cases--the *Lancet* held firm for two weeks, serving to muddy the waters about the trial, until finally 3 of its 4 coauthors (but not the journal) retracted the study.²⁰⁷ But neither the authors nor the journal admitted responsibility. You make sure very few media report that the data were fabricated and the "study" was fraudulent.²⁰⁸ Even though the story was full of scandalous details, it went largely unnoticed.²⁰⁹ You make sure people believe the original story: that hydroxychloroquine routinely kills.

10. You ensure federal agencies like FDA and CDC hew to your desired policies. For example, FDA advised use only in hospitalized patients (too late) or in clinical trials (which are limited, are difficult to enroll in, or may use excessive doses).²¹⁰ As of mid-June, FDA advises patients and doctors to **only** give the drug to patients if they are in a clinical trial where, presumably, the results can be controlled.

Another example: you have FDA make unsubstantiated and false claims, such as: "*Hospitalized patients were likely to have greater prospect of benefit (compared to ambulatory patients with mild illness)*" and claim the chloroquine drugs have a slow onset of action.²¹¹ If that were true, they would not be used for acute attacks of malaria or in critically ill patients with COVID. (Disclosure: I once dosed myself with chloroquine for an acute attack of *P. vivax* malaria and it worked very fast.) Providing

²⁰⁵ Mehra, M., et al, 2020, RETRACTED: Hydroxychloroquine or chloroquine with or without macrolide for treatment of COVID-19: a multinational registry analysis, *The Lancet*.

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31180-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31180-6/fulltext)

²⁰⁶ Reuters Staff, 2020, UPDATE 1-France, Italy, Belgium act to stop use of hydroxychloroquine for COVID-19 on safety fears, Reuters. <https://www.reuters.com/article/health-coronavirus-hydroxychloroquine-fr/update-1-france-italy-belgium-act-to-stop-use-of-hydroxychloroquine-for-covid-19-on-safety-fears-idUKL1N2D911J>

²⁰⁷ Mehra, M., 2020, Retraction—Hydroxychloroquine or chloroquine with or without macrolide for treatment of COVID-19: a multinational registry analysis, *The Lancet*.

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31324-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31324-6/fulltext)

²⁰⁸ Rabin, R.C., 2020, The Pandemic Claims New Victims: Prestigious Medical Journals, *The New York Times*. <https://www.nytimes.com/2020/06/14/health/virus-journals.html>

²⁰⁹ Davey, M., et al, Surgisphere: Governments and WHO changed Covid-19 policy based on suspect data from tiny US company, *The Guardian*. <https://www.theguardian.com/world/2020/jun/03/covid-19-surgisphere-who-world-health-organization-hydroxychloroquine>

²¹⁰ FDA, 2020, FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems, FDA. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or>

²¹¹ FDA, 2020, Letter revoking EUA for chloroquine phosphate and hydroxychloroquine sulfate, 6/15/2020, FDA. <https://www.fda.gov/media/138945/download>

no other treatment advice, even though providing such information is a large part of its mission, CDC instead refers clinicians to the NIH guidelines, discussed below.^{212, 213}

Despite the fact that Belgium's COVID treatment guidelines repeatedly mention that the doses of HCQ in the Recovery and Solidarity trials were four times the cumulative dose used in Belgium, you make sure the Belgian guidelines, paradoxically, only recommend use of HCQ within clinical trials.²¹⁴

11. You make sure to avoid funding/encouraging clinical trials that test drug combinations like hydroxychloroquine with zinc, with azithromycin, or with both, although there is ample clinical evidence that such combinations provide a cumulative benefit to patients. For example, one study to look at this combination had no funding.²¹⁵

12. You have federal and UN agencies make false, illogical claims based on models (or invention) rather than human data. For example, you have the FDA state on June 15 that the dose **required** to treat COVID is so high it is toxic, after the Recovery and Solidarity trials have been exposed for toxic dosing.^{4, 5} This scientific double-speak gives some legal cover to the clinical trials that overdosed their patients. According to Denise Hinton, RN, the FDA's Chief Scientist (yes, a registered nurse without scientific qualifications is the Chief Scientist at FDA), or some clumsy FDA wordsmith:

"Under the assumption that in vivo cellular accumulation is similar to that from the in vitro cell-based assays, the calculated free lung concentrations that would result from the EUA suggested dosing regimens are well below the in vitro EC50/EC90 values, making the antiviral effect against SARS-CoV-2 not likely achievable with the dosing regimens recommended in the EUA. The substantial increase in dosing that would be needed to increase the likelihood of an antiviral effect would not be acceptable due to toxicity concerns."^{22, 216}

You have a WHO report claim toxic doses are needed. This is nonsense since:

²¹² CDC, 2019, Mission, Role and Pledge, CDC.

<https://www.cdc.gov/about/organization/mission.htm#:~:text=As%20the%20nation's%20health%20protection,and%20responds%20when%20these%20arise>.

²¹³ CDC, Information for Clinicians on Investigational Therapeutics for Patients with COVID-19, CDC.

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html>

²¹⁴ Institute of Tropical Medicine, Antwerp, 2020, Interim Clinical Guidance for Adults with Suspected of Confirmed COVID-19 in Belgium. https://covid-19.sciensano.be/sites/default/files/Covid19/COVID-19_InterimGuidelines_Treatment_ENG.pdf

²¹⁵ Carlucci, P., et al, 2020, Hydroxychloroquine and azithromycin plus zinc vs hydroxychloroquine and azithromycin alone: outcomes in hospitalized COVID-19 patients, medrxiv.

<https://www.medrxiv.org/content/10.1101/2020.05.02.20080036v1>

²¹⁶ FDA, 2018, RADM Denise Hinton, FDA. <https://www.fda.gov/node/374121>

- CDC researchers showed strong effects against SARS-1 at safely achievable concentrations,^{217, 218}
- the drug at normal doses is being tested in over 30 different medical conditions (see clinicaltrials.gov), and ²¹⁹
- reports from many different countries say that the drug is effective for COVID-19 at normal doses, while
- a high dose chloroquine treatment trial was halted in Brazil and a preprint of the study was posted April 11, or perhaps April 7, after finding that drug effects were causing ventricular arrhythmias and deaths.^{220, 221}

Toxicity was noted after only 3 days of treatment, during which 3.6 grams of chloroquine were administered. But the Solidarity (3.2 grams of hydroxychloroquine in 3 days), Recovery (3.6 grams of hydroxychloroquine in 3 days) and REMAP-COVID trials (3.6 grams of hydroxychloroquine in 3 days) continued overdosing patients until June, despite Brazil's evidence of deaths by overdose.

Tellingly, JAMA editor Gordon Rubinfeld wrote in April, after the Brazilian study came out in JAMA, *"if you are prescribing HCQ after these JAMA results, do yourself and your defense lawyer a favor. Document in your medical record that you informed the patient of the potential risks of HCQ including sudden death and its benefits (???)"* ²²²

13. You create an NIH Guidelines committee for COVID treatment recommendations, in which 16 members have or had financial entanglements with Gilead, maker of Remdesivir.²²³ The members were appointed by the Co-Chairs.²²⁴ Two of the three Co-Chairs are themselves financially entangled with Gilead. Are you surprised that their guidelines recommend specifically against the use

²¹⁷ WHO, Informal consultation on the dose of chloroquine and hydroxychloroquine for the SOLIDARITY Clinical Trial – 8 April 2020, WHO. <https://www.who.int/publications/m/item/informal-consultation-on-the-dose-of-chloroquine-and-hydroxychloroquine-for-the-solidarity-clinical-trial---8-april-2020>

²¹⁸ Vincent, M., et al, Chloroquine is a potent inhibitor of SARS coronavirus infection and spread, NCBI. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1232869/>

²¹⁹ Nass, M., 2020, Covid-19 clinical trials and Hydroxychloroquine clinical trials, Anthrax Vaccine. <https://anthraxvaccine.blogspot.com/2020/04/covid-19-clinical-trials-databases-that.html>

²²⁰ Thomas, K., et al, 2020, Small Chloroquine Study Halted Over Risk of Fatal Heart Complications, The New York Times. <https://www.nytimes.com/2020/04/12/health/chloroquine-coronavirus-trump.html>

²²¹ FranceSoir, 2020, Oxford, Recovery et Solidarity: Overdosage in two clinical trials with acts considered criminal, FranceSoir. <http://www.francesoir.fr/politique-monde/oxford-recovery-et-solidarity-overdosage-two-clinical-trials-acts-considered>

²²² Borba, M.G.S., et al, 2020, Effect of High vs Low Doses of Chloroquine Diphosphate as Adjunctive Therapy for Patients Hospitalized With Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection, JAMA. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2765499>

²²³ Full Measure with Sharyl Attkisson, 2020, Hydroxychloroquine | Full Measure, YouTube. <https://www.youtube.com/watch?v=zB-SV-y11Y>

²²⁴ NIH, 2020, COVID-19 Treatment Guidelines Introduction, NIH. <https://www.covid19treatmentguidelines.nih.gov/introduction/>

of hydroxychloroquine and in favor of Remdesivir, and that they deem this the new "standard of care"?²²⁵

14. You frighten doctors so they don't prescribe hydroxychloroquine, if prescribing it is even allowed in their jurisdiction, because prescribing outside the new NIH "standard of care" leaves them open to malpractice lawsuits.³⁶ You further tell them (through the FDA) they need to monitor a variety of lab parameters and patient EKGs when using the drug, although this was never advised before, which makes it very difficult to use the drug in outpatients.²¹ You have the European Medicines Agency issue similar warnings.²²⁶

15. You manage to control the conduct of most trials around the world by specially designing the WHO-managed Solidarity trials, currently conducted in 35 countries.⁵ WHO halted hydroxychloroquine clinical trials around the world, twice. The first time, May 25, WHO claimed it was in response to the (fraudulent) Lancet study.²²⁷ The second time, June 17, WHO claimed the stop was in response to the Recovery trial results.^{4, 5} Recovery used highly toxic doses of hydroxychloroquine in over 1500 patients, of whom 396 died. You stop the trial before the data safety monitoring board has looked at your data, a move that is unlikely to be consistent with trial protocol.²²⁸ WHO's trial in over 400 hospitals overdosed patients with 2.0 g hydroxychloroquine in the first 24 hours.¹⁴ The trial was halted 3 days after the toxic doses were exposed (by me). The trial involved doctors around the world typing minimal patient information into an online WHO platform, which assigned the patient a treatment.

The only "safety" information collected during the trial was whether patients required oxygen, required a ventilator, or died.²²⁹ This effectively masked the adverse effects of the drugs tested.

I should mention that WHO's initial plan for its Solidarity trial entirely omitted the chloroquine drugs, but they were added at the urging of participating nations.⁴⁰ WHO's fallback position appears to have been to use toxic doses.

²²⁵ NIH, 2020, COVID-19 Treatment Guidelines What's New in the Guidelines, NIH. <https://www.covid19treatmentguidelines.nih.gov/whats-new/>

²²⁶ EMA, 2020, COVID-19: reminder of the risks of chloroquine and hydroxychloroquine, EMA. <https://www.ema.europa.eu/en/news/covid-19-reminder-risks-chloroquine-hydroxychloroquine>

²²⁷ WHO, 2020, Q&A: Hydroxychloroquine and COVID-19, WHO. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/q-a-hydroxychloroquine-and-covid-19>

²²⁸ Davey, M., 2020, Australian hydroxychloroquine trial to treat Covid-19 under review after WHO safety concern, The Guardian. <https://www.theguardian.com/world/2020/may/26/australian-hydroxychloroquine-trial-under-review-world-health-organization-concern-over-safety>

²²⁹ Kupferschmidt, K., et al, 2020, WHO launches global megatrial of the four most promising coronavirus treatments, American Association for the Advancement of Science. <https://www.sciencemag.org/news/2020/03/who-launches-global-megatrial-four-most-promising-coronavirus-treatments>

16. You have the WHO pressure governments to stop doctors prescribing hydroxychloroquine.²³⁰
17. You have the WHO pressure professional societies to stop doctors prescribing hydroxychloroquine.²³¹
18. You make sure that the most-consulted US medical encyclopedia, UpToDate, advises physicians to restrict hydroxychloroquine to only clinical trials, citing the FDA.²³²
19. You have the head of the Coronavirus Task Force, Dr. Tony Fauci, insist the drug cannot be used in the absence of strong evidence...while he insisted exactly the opposite in the case of the MERS coronavirus outbreak several years ago, when he recommended an untested drug combination for use...which had been developed for that purpose by his agency^{233, 234} And while he was bemoaning the lack of evidence, he was refusing to pay for clinical trials to study hydroxychloroquine.²³⁵ And he was changing the goalposts on the Remdesivir trial, not once but twice, to make Remdesivir show a tiny bit of benefit, but no mortality benefit.²³⁶ And do not forget, Fauci was thrilled to sponsor a trial of a COVID vaccine in humans before there were any data from animal trials.²³⁷ So much for requiring high quality evidence before risking use of drugs and vaccines in humans. In addition, as we warned that, despite decades of need to find a coronavirus, for example, for the common cold, none has ever been found. Pouring money into research and corrupted clinical trials will not necessarily produce one. A report in *Business Insider* did a good review of the doubts that many other scientists also harbor.²³⁸ This is not a threat to intimidate, but

²³⁰ Lamb, K., et al, 2020, Exclusive: Indonesia, major advocate of hydroxychloroquine, told by WHO to stop using it, Reuters. <https://www.reuters.com/article/us-health-coronavirus-indonesia-chloroqu/exclusive-indonesia-major-advocate-of-hydroxychloroquine-told-by-who-to-stop-using-it-idUSKBN23227L>

²³¹ Lamb, K., et al, 2020 Indonesia, major advocate of hydroxychloroquine, told by WHO to stop using it, The Jakarta Post. <https://www.thejakartapost.com/news/2020/05/27/indonesia-major-advocate-of-hydroxychloroquine-told-by-who-to-stop-using-it.html>

²³² Kim, A. Y., et al., 2020, Coronavirus disease 2019 (COVID-19): Management in hospitalized adults, UpToDate. <https://www.uptodate.com/contents/coronavirus-disease-2019-covid-19-management-in-hospitalized-adults>

²³³ Nass, M., 2020, The Avuncular Dr. Fauci, Fluent yet Facile. Is he also a Fraud?, Anthrax Vaccine. <https://anthraxvaccine.blogspot.com/2020/04/the-avuncular-dr-fauci-fluent-yet.html>

²³⁴ Nass, M., 2020, Fauci the Hypocrite. Do NIAID royalties cloud his thinking?, Anthrax Vaccine. <https://anthraxvaccine.blogspot.com/2020/04/fauci-hypocrite-do-niaid-royalties.html>

²³⁵ Cohen, E., et al, 2020, Trump says this drug has “tremendous promise,” but Fauci’s not spending money on it, CNN. <https://www.cnn.com/2020/03/28/health/coronavirus-hydroxychloroquine-trial/index.html>

²³⁶ Nass, M., 2020, Faking results: Fauci’s NIAID-paid Remdesivir Study changed its Outcome Measures Twice, in order to show even a whiff of benefit, Anthrax Vaccine. <https://anthraxvaccine.blogspot.com/2020/05/faking-results-faucis-niaid-paid.html>

²³⁷ NIH, 2020, NIH Clinical Trials of Investigational Vaccine for COVID-19 Begins, NIH. <https://www.niaid.nih.gov/news-events/nih-clinical-trial-investigational-vaccine-covid-19-begins>

²³⁸ [Bienkov, A. \(2020\). Scientists fear the hunt for a coronavirus vaccine will fail and we will all have to live with the 'constant threat' of COVID-19. Business Insider. https://www.businessinsider.com/coronavirus-vaccine-may-be-impossible-to-produce-scientists-covid-2020-4?op=1](#)

a warning not to place all bets on a vaccine. That is already making vaccine manufacturers overreach by promoting products too hastily.²³⁹

20. You convince the population that the crisis will be long-lasting. You have the 2nd richest man in the world, and biggest funder of the WHO, Bill Gates, keep repeating to the media megaphone that we cannot go back to normal until everyone has been vaccinated or there is a perfect drug.²⁴⁰ (The Gates Foundation helped design the WHO clinical trials, helped fund the Recovery trial, and Gates is heavily invested in COVID pharmaceuticals and vaccines.)

21. You have CDC (with help from FDA) prevent the purchase of coronavirus test kits from Germany, China, WHO, etc, and fail to produce a valid test kit themselves.²⁴¹ The result was that during January and February, US cases could not be tested, and for several months thereafter insufficient and unreliable test kits made it impossible to track the epidemic and stop the spread.

22. You have trusted medical spokesmen lie to the public about the pandemic's severity, so precautions were not taken when they might have been more effective and less long-lasting. Congress was repeatedly briefed about the pandemic in January and February, which scared several Congress members enough that they sold off large amounts of stock, risking insider trading charges.^{52, 242} Senator Burr is one of them, currently under investigation for major stock sales on February 13.²⁴³

Yet Dr. Fauci told *USA Today* on February 17 that Americans should worry more about the flu than about coronavirus, the danger of which was "just miniscule."²⁴⁴ Then on February 28, Drs. Fauci and Robert Redfield (CDC Director) wrote in the *New England Journal*:

²³⁹ Owusu, T. (2020). Vaccine Study by Moderna Criticized for Lacking Key Data. The Street.

<https://www.thestreet.com/investing/moderna-vaccine-study-criticized-lack-of-data>;

<https://www.forbes.com/sites/alexandrasternlicht/2020/05/19/scientists-raise-questions-about-moderna-vaccine-in-market-shaking-report/#3896fe292136>; Scientists Raise Questions About Moderna Vaccine In Market-Shaking Report. Forbes.

<https://www.forbes.com/sites/alexandrasternlicht/2020/05/19/scientists-raise-questions-about-moderna-vaccine-in-market-shaking-report/#3896fe292136>

WUSU <https://www.thestreet.com/investing/moderna-vaccine-study-criticized-lack-of-data>

²⁴⁰ Gates, B., 2020, What you need to know about the COVID-19 vaccine, GatesNotes.

<https://www.gatesnotes.com/Health/What-you-need-to-know-about-the-COVID-19-vaccine>

²⁴¹ Whoriskey, P., et al, 2020, How U.S. coronavirus testing stalled: Flawed tests, red tape and resistance to using the millions of tests produced by the WHO, The Washington Post.

<https://www.washingtonpost.com/business/2020/03/16/cdc-who-coronavirus-tests/>

²⁴² Bertrand, N., et al, 2020, From distraction to disaster: How coronavirus crept up on Washington, Politico.

<https://www.politico.com/news/2020/03/30/how-coronavirus-shook-congress-complacency-155058>

²⁴³ Mak, T., 2020, Sen. Richard Burr's Pre-Pandemic Stock Sell-Offs Highly Unusual, Analysis Shows, NPR.

<https://www.npr.org/2020/04/16/836126532/senator-burrs-pre-pandemic-stock-sell-offs-highly-unusual-analysis-shows>

²⁴⁴ O'Donnell, J., 2020, Top disease official: Risk of coronavirus in USA is 'minuscule'; skip mask and wash hands, USA Today. <https://www.usatoday.com/story/news/health/2020/02/17/nih-disease-official-anthony-fauci-risk-of-coronavirus-in-u-s-is-minuscule-skip-mask-and-wash-hands/4787209002/>

"...the overall clinical consequences of COVID-19 may ultimately be more akin to those of a severe seasonal influenza (which has a case fatality rate of approximately 0.1%) or a pandemic influenza (similar to those in 1957 and 1968) rather than a disease similar to SARS or MERS, which have had case fatality rates of 9 to 10% and 36%, respectively."²⁴⁵

23. You destroy the reputations of respected physicians who stand in your way. Professor Didier Raoult and his team in Marseille have used hydroxychloroquine on over 4,000 patients, reporting a mortality rate of about 0.8%. (The mortality rate of patients given hydroxychloroquine in the Recovery trial was 25.7%.) Raoult is famous for discovering over 100 different microorganisms and finding the long-sought cause of Whipple's Disease. With this reputation, Raoult apparently thought he could treat patients as he saw fit, which he has done, under great duress. Raoult was featured in a *New York Times Magazine* article, with his face on the magazine cover, on May 12, 2020.²⁴⁶ After describing his accomplishments, the **Times** very unfavorably discussed his personality, implied he conducted unethical trials without approval, and using anonymous sourcing produced a detailed hit piece. Raoult is now considered an unreliable crank in the US.

You gather a group of Yale professors to dispute their Yale colleague Harvey Risch, MD, PhD epidemiologist on his publications and vocal support of the benefits of HCQ for COVID. Their first argument is that he is not an infectious disease doctor. Notably, the first signer of the statement opposing Dr. Risch is an economist.²⁴⁷

Physician and state senator Scott Jensen of Minnesota is being investigated by his state medical board due to anonymous complaints about 'spreading misinformation' and giving 'reckless advice' about COVID in interviews.²⁴⁸ Jensen was previously selected as "Family Physician of the Year" in his state. Now his medical license is at risk, not because of how he treated a patient, but for what he said outside of the office. Unprecedented.

UPDATE: Jensen was exonerated.²⁴⁹

²⁴⁵ Fauci, A., et al, Covid-19 – Navigating the Uncharted, The New England Journal of Medicine. <https://www.nejm.org/doi/full/10.1056/NEJMe2002387>

²⁴⁶ Sayare, S., 2020, He Was a Science Star. Then He Promoted a Questionable Cure for Covid-19, The New York Times. <https://www.nytimes.com/2020/05/12/magazine/didier-raoult-hydroxychloroquine.html>

²⁴⁷ Gonsalves, G., 2020, Statement from Yale Faculty on Hydroxychloroquine and its Use in COVID-19, Medium. <https://medium.com/@gregggonalves/statement-from-yale-faculty-on-hydroxychloroquine-and-its-use-in-covid-19-47d0dee7b2b0>

²⁴⁸ Van Berkel, J., 2020, Sen. Scott Jensen says he has 'no regrets' about his COVID-19 comments, Star Tribune. <https://www.startribune.com/sen-scott-jensen-says-complaints-about-covid-19-comments-may-be-political/571650782/?refresh=true>

²⁴⁹ Peterson, S., 2020, Sen Jensen "gratified" allegations of spreading misinformation dismissed (AUDIO), Minnesota News Network. <https://minnesotaneWSnetwork.com/sen-jensen-gratified-allegations-of-spreading-misinformation-dismissed-audio/>

24. You have social media platforms ban content that does not agree with the desired narrative. As YouTube CEO and ex-wife of Google founder Sergey Brin, Susan Wojcicki said:

“YouTube will ban any content containing medical advice that contradicts World Health Organisation (WHO) coronavirus recommendations. Anything that would go against World Health Organisation recommendations would be a violation of our policy.”

25. When your clinical trials are criticized for overdosing patients, you have Oxford-affiliated, Wellcome Trust-supported scientists at Mahidol University publish papers (a literature review with modeling and a modeling study) purporting to show that the doses used were not toxic.^{250, 251} You develop a new method to measure hydroxychloroquine in a handful of Recovery patients who were not poisoned.²⁵² However, there are 2 problems you forgot with this approach:

- The Brazilian data, including 16 deaths, extensive clinical information and documented ventricular arrhythmias, are much more persuasive than a theoretical model of hydroxychloroquine pharmacokinetics.
- **Either** the drug is too toxic to use, even at normal doses, for a life-threatening disease, **or** even extremely high doses are safe. **You can't have it both ways.**

Oxford is the institution running the Wellcome Trust-funded Recovery trial and invented a COVID vaccine that already has 400 million doses on order.²⁵³

26. You change your trial's primary outcome measures after the trials have started, in order to prevent detection of drug-induced deaths (Recovery)²⁵⁴ or to make your drug appear to have efficacy (NIAID remdesivir trial).²⁵⁵

²⁵⁰ Moru Tropical Health Network, 2020, COVID-19 prevention and treatment: a critical analysis of chloroquine and hydroxychloroquine clinical pharmacology, Moru Tropical Health Network. <https://www.tropmedres.ac/news/covid-19-prevention-and-treatment-a-critical-analysis-of-chloroquine-and-hydroxychloroquine-clinical-pharmacology>

²⁵¹ Watson, J., et al, 2020, Concentration-dependent morality of chloroquine in overdose, MedRxiv. <https://www.medrxiv.org/content/10.1101/2020.04.24.20078303v2>

²⁵² MacGowan, A., et al, MedRxiv preprint doi : <https://doi.org/10.1101/2020.06.23.20137992>. MedRxiv. <https://www.medrxiv.org/content/10.1101/2020.06.23.20137992v1.full.pdf>

²⁵³ AstraZeneca, 2020, AstraZeneca to supply Europe with up to 400 million doses of Oxford University's vaccine at no profit, AstraZeneca. <https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-to-supply-europe-with-up-to-400-million-doses-of-oxford-universitys-vaccine-at-no-profit.html>

²⁵⁴ Le Collectif Citoyen pour FranceSoir. 2020, June 25, Oxford, Recovery et Solidarity : Overdosage in two clinical trials with acts considered criminal? FranceSoir. <http://www.francesoir.fr/politique-monde/oxford-recovery-et-solidarity-overdosage-two-clinical-trials-acts-considered>

²⁵⁵ Nass, M. 2020, May 2, Faking results: Fauci's NIAID-paid remdesivir study changed its outcome measures twice, in order to show even a whiff of benefit. Blogspot. <https://anthraxvaccine.blogspot.com/2020/05/faking-results-faucis-niaid-paid.html>

27. You stop manufacturers from supplying the drug. Shortly after the fraudulent *Lancet* paper came out, Sanofi announced it would no longer supply the drug for use with COVID, and would halt its two hydroxychloroquine clinical trials.²⁵⁶ One of the cancelled Sanofi trials was expected to test 210 outpatients early in the course of disease. The trial remains suspended at the time of writing, while the *Lancet* paper was retracted 13 days after publication.²⁵⁷ You surely don't want a trial of hydroxychloroquine treatment early in the disease, since it might show an excellent effect.

Sanofi (a pharma company) begins acting like a regulator. From the Australian DOH's Therapeutic Goods Administration website:

*Sanofi, the supplier of one of the hydroxychloroquine products marketed in Australia (Plaquenil), has also written to health professionals reinforcing that hydroxychloroquine is not approved for use in Australia for treatment of COVID-19 outside the confines of a clinical trial. Sanofi also reinforced some of the known risks of prescribing hydroxychloroquine, in particular potentially serious cardiac issues. Globally, Sanofi has received an increased number of reports of serious cardiac issues, including deaths, in patients treated with hydroxychloroquine, this appears to be more common in patients also treated with other medicines that can affect the heart.*²⁵⁸

Then Sanofi started collecting information on all off-label use of hydroxychloroquine in New Zealand and Australia.^{259, 260} Why is Sanofi, a drug manufacturing company, becoming a surveillance/enforcement mechanism intended to frighten medical providers from using the drug for COVID, which use is by definition "off label." Sanofi alternatively suggests one may report (anonymously or not) others' off-label use to New Zealand's Pharmacovigilance Center or the Australian equivalent.²⁶¹

And see this: Novartis will supply HCQ only under certain conditions and halted its HCQ trial due to lack of enrollments, although enrollment was not an issue for its other COVID trials.²⁶²

²⁵⁶ Blamont, M., 2020, Exclusive: Sanofi stops enrolling COVID-19 patients in hydroxychloroquine trials, Reuters. <https://www.reuters.com/article/us-healthcare-coronavirus-hydroxychloroq/exclusive-sanofi-stops-enrolling-covid-19-patients-in-hydroxychloroquine-trials-idUSKBN2352IH>

²⁵⁷ Sanofi, Hydroxychloroquine in Outpatient Adults With COVID-19, ClinicalTrials.gov.

<https://clinicaltrials.gov/ct2/show/NCT04333654?term=sanofi&cond=Covid-19&entry=US&draw=2>

²⁵⁸ Australian Government Department of Health, 2020, Amendments to the new restrictions on prescribing hydroxychloroquine for COVID-19, Australian Government Department of Health.

<https://www.tga.gov.au/alert/amendments-new-restrictions-prescribing-hydroxychloroquine-covid-19>

²⁵⁹ Sanofi, 2020, Important Information on Plaquenil (hydroxychloroquine) and COVID-19, Sanofi.

<https://www.sanofi.com.au/en/our-products/Plaquenil-Update-New-Zealand>

²⁶⁰ Sanofi, 2020, Important Information on Plaquenil (hydroxychloroquine) and COVID-19, Sanofi.

<https://www.sanofi.com.au/en/our-products/Plaquenil-Update-Australia>

²⁶¹ New Zealand Pharmacovigilance Centre, Confidentiality Information for Reporters, New Zealand Pharmacovigilance Centre. <https://nzphvc.otago.ac.nz/confidentiality-information-for-reporters/>

²⁶² Novartis, 2020, Novartis discontinues hydroxychloroquine clinical trial based on slow enrollment, remains committed to pandemic research efforts, Novartis. <https://www.novartis.com/news/media-releases/novartis->

28. You attempt to retract published papers that provide evidence to support use of hydroxychloroquine for COVID.²⁶³

29. You have your 'bought' scientists conceal their financial conflicts of interest in their HCQ clinical trials and publications as well as in the guidelines they produce.⁷²

30. You can get your experimental, unlicensed drugs tested, much more expeditiously and cheaply than under ordinary circumstances, on COVID patients in large clinical trials, but only as long as no drug is designated effective for the condition. This opportunity only lasts while the "standard of care" is nothing more than supportive measures.²⁶⁴

31. You have a research organization with big Pharma members (A.O.K.I.) pressure the Russian Ministry of Health to remove hydroxychloroquine from its treatment guidelines.²⁶⁵

32. You stopped use of hydroxychloroquine, allegedly in response to the fabricated Lancet study, in France, Italy and Belgium (countries with very high COVID mortality rates) then Portugal then Switzerland. But Switzerland restarted using HCQ 15 days later. This created a natural experiment in Switzerland. About 2 weeks after hydroxychloroquine use was halted, death rates approximately tripled, for about 15 days. Then, after its use was allowed again, two weeks later death rates from COVID fell back to their baseline. (Thanks to *FranceSoir*).²⁶⁶

33. You reverse an old trick of clinical trials, to mask benefit of hydroxychloroquine. The trick was to replace the saline placebo with a substance that is being used by many clinicians and in many trials against COVID, thus by comparison likely to reduce the positive effect of your tested medication.^{267, 268} This

[discontinues-hydroxychloroquine-clinical-trial-based-slow-enrollment-remains-committed-pandemic-research-efforts](#)

²⁶³ Raoult, D., et al, Response to David Spencer, 2020, *Mediterranean Infection*. <https://www.mediterranean-infection.com/hydroxychloroquine-and-azithromycin-as-a-treatment-of-covid-19-results-of-an-open-label-non-randomized-clinical-trial-response-to-david-spencer-elsevier/>

²⁶⁴ Clinical Trials Arena, 2020, Eisai to investigate eritoran in REMAP-COVID study, Clinical Trials Arena. <https://www.clinicaltrialsarena.com/news/eisai-remap-covid-study/>

²⁶⁵ BBC News, 2020, Pharmaceutical companies ask the Russian Ministry of Health not to treat patients with Covid-19 with drugs for malaria and HIV, BBC. <https://www.bbc.com/russian/news-53310502>

²⁶⁶ Jullian, M., et al, 2020, Covid-19: does hydroxychloroquine work, solid proof?, *FranceSoir*. [French] <http://www.francesoir.fr/societe-sante/covid-19-lhydroxychloroquine-marche-une-preuve-irrefutable>

²⁶⁷ EVMS, 2020, Critical Care COVID19 Management Protocol, EVMS. https://www.evms.edu/media/evms_public/departments/internal_medicine/Marik-Covid-Protocol-Summary.pdf

²⁶⁸ ASHP, 2020, Assessment of Evidence for COVID-19-Related Treatments, ASHP. <https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/Coronavirus/docs/ASHP-COVID-19-Evidence-Table.ashx>

was done in trials both at NYU and at University of Washington, using vitamin C or vitamin C and folate respectively as placebos.^{269, 270}

34. You have the chief medical officers of Wales, England, Scotland and Northern Ireland, and the director of the UK's National Health Service, write to UK doctors, a) urging them to enroll their COVID patients in one of 3 national clinical trials, two of which greatly overdosed patients with hydroxychloroquine, and b) stopping their use of "off license treatments" outside of a trial. Yet again, we encounter a veiled threat against clinicians attempting to treat the primary SARS-Cov-2 infection. The chief doctors wrote:

*While it is for every individual clinician to make prescribing decisions, we strongly discourage the use of off-label treatments outside of a trial, where participation in a trial is possible... Any treatment given for coronavirus other than general supportive care, treatment for underlying conditions, and antibiotics for secondary bacterial complications, should currently be as part of a trial, where that is possible.*²⁷¹

35. You have a state Pharmacy Board **refuse to dispense hydroxychloroquine outside of clinical trials** on June 15, citing the FDA recommendation for use only in trials.²⁷² You issue this new regulation on the same day that FDA publishes its recommendation, indicating prior coordination. But when your regulation is exposed on July 14, you immediately rescind it.²⁷³

36. You have the IMF offer rapid financing to Belarus, but only if it follows the recommended model of COVID response and imposes quarantines, isolation, and curfews.²⁷⁴

37. A group of doctors went to Washington DC July 27-28. They called themselves "America's Frontline Doctors" and gave a press conference and livestream talks about the COVID-19 pandemic as well as about the need for physicians to be able to prescribe HCQ freely. While the media sparsely attended the press conference, the livestream got millions of views. And within hours, their livestream was banned by

²⁶⁹ Bershteyn, A., 2020, Clinical Trial Tests Efficacy of Common Antimalarial Drug to Prevent COVID-19 Infection, NYU Langone Health NewsHub. <https://nyulangone.org/news/clinical-trial-tests-efficacy-common-antimalarial-drug-prevent-covid-19-infection>

²⁷⁰ Johnston, C., 2020, Treatment for COVID-19 in High-Risk Adult Outpatients, Clinical Trials. <https://clinicaltrials.gov/ct2/show/NCT04354428>

²⁷¹ Atherton, F., et al, Novel Coronavirus: Clinical Trials, NHS. https://static1.squarespace.com/static/5cde3c7d9a69340001d79ffe/t/5e8d413e713b2d6cd799e143/1586315583723/CEM_CMO_2020_012.pdf

²⁷² Oregon Secretary of State, Board of Pharmacy, Oregon Secretary of State. <https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=271619>

²⁷³ Schlafly, J & A., 2020, Hydroxychloroquine Should Be Available Over the Counter, Townhall. <https://townhall.com/columnists/johnandandyschlafly/2020/07/15/hydroxychloroquine-should-be-available-over-the-counter-n2572496>

²⁷⁴ Belta, 2020, Belarus president unwilling to accept additional terms to get foreign loans, Belta. <https://eng.belta.by/president/view/belarus-president-unwilling-to-accept-additional-terms-to-get-foreign-loans-131164-2020/>

Google, YouTube, Facebook, and Twitter.²⁷⁵ Twitter was said to additionally ban comments about its ban. Then Squarespace took down the Frontline Doctors' website.²⁷⁶

38. After the HCQ issue got so much attention on social media, you impose another ban on July 29 on the prescribing of HCQ for COVID, starting July 30 in Ohio, using its Pharmacy Board to dictate to physicians what they may not prescribe.²⁷⁷ (A repeat of no. 35 in a different state.) This ban got so much attention that the Ohio Governor (who must have initially supported it) rescinded it the next morning.²⁷⁸ July 30, saying he agrees with FDA Commissioner Stephen Hahn, who said in a July 30 interview that the prescribing of HCQ is between a doctor and patient.²⁷⁹

39. After having Google take down physician James Todaro's article on hydroxychloroquine for 4 months, you allow it to resurface right before Google's (and Facebook's and Amazon's and Apple's) CEOs testify before Congress on July 29 on censorship and abuse of power.^{280, 281, 282} You have Twitter warn that Todaro's article is at an unsafe link.²⁸³

40. After massive attention to the banning of the videos posted by the physician group 'America's Frontline Physicians' and its website, you make intense efforts to discredit the physicians involved.

MedPageToday claimed it "*could find no evidence that any of the speakers worked in hospitals with significant numbers of COVID-19 patients.*"²⁸⁴ But the doctors claimed they used the drug early and prevented hospitalizations and deaths. With over 4.4

²⁷⁵ Passantino, J., et al, 2020, Social media giants remove viral video with false coronavirus claims that Trump retweeted, CNN. <https://www.cnn.com/2020/07/28/tech/facebook-youtube-coronavirus/index.html>

²⁷⁶ @JamesTodaroMD, 2020, We are reaching new levels of censorship., Twitter.

<https://twitter.com/JamesTodaroMD/status/1288169004985724929>

²⁷⁷ Benson, G., 2020, Ohio Dept of Health BANS hydroxychloroquine in treating COVID19, Breaking 911.

<https://breaking911.com/breaking-ohio-dept-of-health-bans-hydroxychloroquine-in-treating-covid19/>

²⁷⁸ @drsimonegold, 2020, We cannot allow the continued politicization of medicine, Twitter.

<https://twitter.com/drsimonegold/status/1288851070920187905>

²⁷⁹ Axelrod, T., 2020, FDA chief: Hydroxychloroquine use and a decision between doctor and patient, The Hill.

<https://thehill.com/policy/healthcare/509733-fda-chief-hydroxychloroquine-use-a-decision-between-doctor-and-patient>

²⁸⁰ Todaro, J., et al, An Effective Treatment for Coronavirus (COVID-19), Google Docs.

<https://docs.google.com/document/d/e/2PACX-1vTi-g18ftNZUMRAj2SwRPodtscFio7bJ7GdNgbJAGbdfF67WuRJB3ZsidgpidB2eocFHAVjIL-7deJ7/pub>

²⁸¹ @JamesTodaroMD, 2020, After 4 mos of appeals... , Twitter.

<https://twitter.com/JamesTodaroMD/status/1288694517848211457>

²⁸² Ben-Achour, S., 2020, Are the Big Tech companies breaking antitrust rules? Their CEOs testify before Congress, MarketPlace. <https://www.marketplace.org/2020/07/29/big-tech-ceos-congress-house-judiciary-testimony-facebook-google-apple-amazon/>

²⁸³ Twitter, Warning: this link may be unsafe, Twitter.

https://twitter.com/safety/unsafe_link_warning?unsafe_link=https://docs.google.com/document/d/e/2PACX-1vTi-g18ftNZUMRAj2SwRPodtscFio7bJ7GdNgbJAGbdfF67WuRJB3ZsidgpidB2eocFHAVjIL-7deJ7/pub

²⁸⁴ Basen, R., et al, 2020, No Evidence That Doctor Group in Viral Video Got Near COVID 'Front Lines', MedPageToday. <https://www.medpagetoday.com/infectiousdisease/covid19/87797>

million Americans diagnosed with COVID, what doctor *has not* seen a COVID patient?²⁸⁵

***USA Today* headlined: 'America's Frontline Doctors' may be real doctors, but experts say they don't know what they're talking about.**

You have *USA Today* review and publish detailed information on the licenses, practice locations and malpractice histories of the doctors who spoke out.²⁸⁶ *USA Today* reporters claim these doctors are not experts and lack knowledge about the use of HCQ in COVID-19, despite the fact that most work in primary care, urgent care or emergency medicine and report using the drug for COVID. Yet no one asks how many years ago 'expert' Fauci last treated a patient? Expert Brix's medical license expired in 2014, so she hasn't treated a COVID patient either.²⁸⁷

41. Hydroxychloroquine use is truly the wedge issue for understanding and turning around the pandemic. If hydroxychloroquine works reasonably well as a prophylactic and treatment for COVID-19, it could potentially end the seriousness of the pandemic and return us to life as we knew it. You must make use of the levers of government, mainstream media, and social media to stop that from happening.

So, just in case doctors thought the Frontline Doctors' video, or a new study from Spain showing the drug's usefulness meant they should use hydroxychloroquine to treat COVID, you must act fast.²⁸⁸ You use Representatives at a Congressional health subcommittee hearing on July 29 to threaten doctors about the use of the drug last April in veterans who were nursing home patients.²⁸⁹ Per the *Washington Post*:

*"doctors at the 238-bed nursing home dosed [30] patients with what came to be called a "COVID cocktail" for more than two weeks in April, often over the objections of nurses and without the full knowledge of residents' families. At least 11 residents received the drug even though they had not been tested for COVID-19, The Post found."*²⁹⁰

²⁸⁵ The New York Times, 2020, Coronavirus in the U.S.: Latest Map and Case Count, The New York Times.

<https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html>

²⁸⁶ Miller, R. W., et al, 2020, 'America's Frontline Doctors' may be real doctors, but experts say they don't know what they're talking about, USA Today. <https://www.usatoday.com/story/news/nation/2020/07/30/americas-frontline-doctors-tout-hydroxychloroquine-covid-who-they/5535096002/>

²⁸⁷ Sheffield, C., 2020, White House coronavirus official Birx under attack for no active doctors license, doesn't need one, Just The News. <https://justthenews.com/politics-policy/health/white-house-coronavirus-official-birx-under-attack-no-active-doctors-license>

²⁸⁸ Bernaola, N., et al, 2020, Observational Study of the Efficiency of Treatments in Patients Hospitalized with Covid-19 in Madrid, MedRxiv. <https://www.medrxiv.org/content/10.1101/2020.07.17.20155960v1.full>

²⁸⁹ Veterans House, 2020, Who's in Charge? Examining Oversight of State Veterans Homes During the COVID-19 Pandemic, Veterans House. <https://veterans.house.gov/events/hearings/whos-in-charge-examining-oversight-of-state-veterans-homes-during-the-covid-19-pandemic>

²⁹⁰ Mikhail, A., et al, 2020, House lawmakers probe patient care, hydroxychloroquine use, in state homes for veterans, Washington Post. <https://www.washingtonpost.com/business/2020/07/30/house-lawmakers-probe-patient-care-hydroxychloroquine-use-state-homes-veterans/>

I have treated patients in nursing homes, and one rarely discusses medication changes with family, unless the patient is seriously ill. When nursing home residents were dying like flies last April, when tests were hard to come by and confirmed diagnoses few and far between, doctors used this medicine to try to prevent nursing home deaths during a pandemic. And now they are being scapegoated for doing so.

The *Washington Post* article does not even tell us whether the patients survived, thrived, or were harmed. The article hardly makes sense. Its only purpose is to blacken the drug and the physicians who use it.

42. You use state Medical Licensing Boards to threaten doctors who claim there is a cure for COVID-19.²⁹¹

43. You have Dr. Fauci discredit published observational studies that show benefit during a Congressional hearing, demanding randomized controlled trials. Fauci never tells the Committee he has cancelled the one randomized controlled trial of HCQ that his agency, NIAID, was supposed to conduct on HCQ. NIAID claimed that it could not enroll enough subjects and the trial was cancelled after only 20 were enrolled. However, Fauci told the Committee that 250,000 Americans have shown interest in participating in trials of a COVID vaccine. It is difficult to believe there was extreme lack of interest in a treatment trial, and such massive interest in a vaccine trial.²⁹²

Doctors who wrote studies showing benefit (50% mortality reduction) defended their work from Fauci's criticism.²⁹³

44. You erode the doctor's primary responsibility to the patient, replacing it with the need to perform clinical research. This is the first time I have ever heard such a thing: research physicians are pressuring frontline doctors not to veer from protocol-determined treatment, even when patients enrolled in treatment trials are at risk of death.²⁹⁴

45. You mention the "stellar" Recovery trial in the August 5 *New York Times* but avoid any hint that its hydroxychloroquine arm gave patients a toxic dose.¹⁰³

²⁹¹ Chron, 2020, Texas medical board warns physicians who claim COVID-19 cure, Chron.

<https://www.chron.com/news/article/Texas-medical-board-warns-physicians-who-claim-15458287.php>

²⁹² Schwartz, M., 2020, Fauci Says He's 'Optimistic' Americans Will Get Coronavirus Vaccine Next Year, NPR.

<https://www.npr.org/sections/coronavirus-live-updates/2020/07/31/897728431/fauci-optimistic-americans-will-get-coronavirus-vaccine-next-year>

²⁹³ Trejo, S., 2020, Authors of Pro- Hydroxychloroquine Study Defend Their Work After Being Attacked by Dr. Fauci, Big League Politics. <https://bigleaguepolitics.com/authors-of-pro-hydroxychloroquine-study-defend-their-work-after-being-attacked-by-dr-fauci/>

²⁹⁴ Dominus, S., 2020, The Covid Drug Wars That Pitted Doctor vs. Doctor, The New York Times.

<https://www.nytimes.com/2020/08/05/magazine/covid-drug-wars-doctors.html>

This is the conclusion of Dr. Nass's report, which I include as a part of my report and testimony. Next, I will introduce the second and only other separate essay that I am including in my report.

VIII. Dr. Pam Popper on Individual Personal Experiences under the COVID-19 Lockdown

Dr. Pam Popper has her Ph.D. in naturopathy and nutrition. She is a leader in the field informed medical decisionmaking and a professional with whom I have worked closely with for many years.²⁹⁵ She is the paragon of a true healer, a woman of brilliant insights, solid science, and deep compassion in the service of humanity. Without intending it for this report, but instead for a future book,²⁹⁶ she recently wrote the following analysis that describes the personal suffering created by the lockdowns and other totalitarian measures. In her work as director of the Wellness Forum Health in Ohio, Dr. Popper talks personally with 50-100 people a week from around the world, and almost 300,000 people each week through her newsletter and videos.

What follows is her broad analysis of the untoward consequences of totalitarian policies and practices, along with personal descriptions of individual suffering, including her personal responses. Her viewpoint is consistent with my own and, in addition to her insights, it adds the humanity that this report that would otherwise be lacking.

Dr. Popper is usually a reserved person, but she wrote this previously unpublished essay early in COVID-19, and the anguish caused by the shutdowns and stay-at-home orders, deeply touched her. In this essay, she shows her emotions as I have never seen her write or express herself in public, bringing the reality of how most of us have felt at one time or another, or many times, during COVID-19:

Consequences: The Cure is Really Worse Than the Disease By Pam Popper, PhD

Almost from the beginning of the COVID-19 response, many experts were warning that the cure was likely to be worse than the disease, particularly if it continued for an extended time. And it did. A couple of weeks to “flatten the curve” turned into a few more weeks and then months of restrictions with absolutely no end in sight. The emperors and empresses running the states and health officials even stopped putting forth a goal that if reached would put an end to their unconstitutional power grab.

There seemed to be no balancing of the harm from the virus vs the potential harm from policies inflicted on the public. Both governors and mayors continued to issue one crushing decree after another with complete disregard for the consequences of their decisions.

By the end of March 2020, people were stressed, with many begging for relief. And by the end of the summer the carnage was almost unbearable. The economy had crashed, the unemployment rate was at an unprecedented high, homelessness was increasing, and the suicide and overdose rates had skyrocketed. The most vulnerable children had gone backwards academically, and nursing home patients were dying of neglect. Society as we knew it had evaporated and a growing number of people were

²⁹⁵ Pam Popper is a frequent guest on the Dr. Peter Breggin Hour, my weekly one-hour radio/TV talk show with pioneers in the field of health. Her latest appearance on August 19, 2020 was about the coronavirus and the lockdown. <https://www.youtube.com/watch?v=pYuowk-ONmk>

²⁹⁶ Popper, P. and Prier, S. COVID Operation: What happened, why it happened, and what’s next. In press for the fall of 2020.

realizing that not only the U.S. government, but the governments of other countries had been overthrown by criminals who had declared themselves unaccountable to the public and demonstrated daily that they did not care about the impact of their decisions on their “subjects.”

An honest evaluation of the consequences of the COVID debacle must start with an examination of data showing which groups of people were actually at risk, and whether the measures taken were justified.

Impact Based on Age

The data are clear – the most vulnerable people during flu season every year are seriously ill or immunocompromised people of any age, and the elderly – especially those who are sick enough or frail enough to be confined to nursing homes. This certainly turned out to be true for COVID-19.

On August 5, 2020, CDC Provisional COVID-19 Death Counts showed the following:

Total deaths from COVID-19 for all ages	142,164	
Total deaths age 85 years and older	45,845	32.2%
Total deaths age 75-84 years of age	37,495	26.4%
Total deaths age 65-74 years of age	29,870	21.0%
Total deaths age 55-64 years of age	17,583	12.4% ²⁹⁷

The above data show clearly that risk of death increases with age, and also that most deaths—79%—were people age 65 and older. On the other hand, there were only 270 deaths in the U.S. from COVID in people age 24 and younger.²⁹⁸ Total deaths for people 54 and younger in the US were 11,317.²⁹⁹

While every life lost is important, these numbers show that the heavy-handed and draconian measures implemented by government and health officials were egregiously off base and could not be justified.

Even the lockdowns of nursing homes seem outrageous when looking back at the impact of residents. Almost everywhere, visitors, including family members, were prohibited at nursing homes and extended care facilities. Employees were tested every day to reduce the risk of infection. But the strategy was miserably ineffective. On August 5, 2020, the Ohio Department of Health reported that 2060 patients had died from COVID in long-term care facilities.³⁰⁰ Total deaths from COVID-19 on that date were 3668.³⁰¹ In other words, Ohio nursing home patients were prohibited from

²⁹⁷ CDC, 2020, Provisional COVID-19 Death Counts by Sex, Age, CDC. <https://data.cdc.gov/NCHS/Provisional-COVID-19-Death-Counts-by-Sex-Age-and-S/9bhg-hcku/data> accessed 8.8.2020

²⁹⁸ IBID

²⁹⁹ IBID

³⁰⁰ Ohio Department of Health, 2020, Mortality, Ohio Department of Health. <https://coronavirus.ohio.gov/wps/portal/gov/covid-19/dashboards/long-term-care-facilities/mortality> accessed 8.8.2020

³⁰¹ Ohio Department of Health, 2020, COVID-19 Dashboard, Ohio Department of Health. <https://coronavirus.ohio.gov/wps/portal/gov/covid-19/dashboards/key-metrics/mortality> accessed 8.8.2020

having interaction with anyone other than staff and still 56% of all deaths from COVID took place in these facilities. Even now, long-term care residents can only see visitors outdoors, residents and visitors must wear masks, and social distancing is required. Visitations must be scheduled in advance and if it rains, most visits are postponed.

It is hot in the summertime in Ohio, which makes outdoor visits challenging for some older people, and the mask requirement can make these visits almost unbearable. Stroke victims have difficulty communicating under the best of circumstances and masks make it impossible. Those who do not hear well do not get much out of visits which require 6 feet between residents and their guests. Many frustrated people have stated that the Emperor DeWine thinks it is ok for long-term care residents to get COVID from strangers but not from family members.

The consequences of the isolation and restrictions? Unbearable. Most of the staff in long-term care facilities are caring people who want to offer the best care to their patients. But anyone who has had a family member in one of these facilities reports that the constant presence of family members and friends helps to keep the staff accountable. Both family and staff agree that regular visits are extremely important for the mental, cognitive, and physical health of patients. These facilities were not designed with the intention of staff providing companionship, interaction, or extras like baked goods, flower, books, and DVDs.

When visits were cut off, it did not take long for care to degenerate, and for patients to start suffering from loneliness, boredom, and mental and physical decline.

Here are just a few heart-breaking stories (italicized):

I'm in Florida and the rest of the family lives in Quebec, Canada. Last Monday my sister called me crying and very distraught. She'd been called by the retirement home where my father lived. They told her they had found my father non-responsive and rushed him to the hospital. She wasn't allowed to go to the hospital to be with him yet, but they asked her if she could come clean his room while he wasn't there. We pay extra for that cleaning service, mind you.

When she arrived, she found food and beverages all over his room, much of it with mold on it, stinking and rotting. She found his dirty Depends diapers everywhere. Under the bed, the couch and bathroom. She spent half the day cleaning this mess while balling her eyes out.

The following day, the doctor called her to the say there was nothing they could do and since he was terminal, now she could come visit. She was never able to have a coherent conversation with him the whole week and he passed a week later.

Since this whole nonsense started, all she could do was stand in the parking lot while he was peaking his head out his 3rd story window. She'd ask him "how's everything?" And he'd respond "Fine."

She couldn't see the mess in his room. He wasn't eating and was withering away. Something she would have noticed if able to visit him as usual.

The residents in this home went from a routine of going to the cafeteria 3x day, eating their favorite food. My father had no teeth, so it was usually soft eggs and a juice, soup, and mashed potatoes etc. He socialized with friends, spent time on the patio

And then one day, he was imprisoned, confined to a small room for months. My father got too lonely to cope with this and just gave up and stopped eating. AND they were bringing him coffee that he doesn't drink in the first place and fruits he couldn't chew.

I wanted to let you know that I am sick with worry that my 91-year-old mom, who is in an assisted living facility in Oakwood, Ohio, might succumb to the quarantine rather than the virus. On December 15, 2019, we lost my father. My parents were married 66 years. We moved my mom to a pricier facility with the idea of having more activities and chances to interact with others.

Then the quarantine. None of her four kids can visit her. She has been hysterical, and the facility does not like it. Consequently, they load her up on drugs. I just had a Zoom conference with her and she couldn't communicate. She arrived at this new facility with slight dementia. The loneliness and isolation are killing her. I am writing to you because I want her voice heard.

My husband's Aunt and Uncle, who are in their late 80's, reached a point where they were no longer able to care for themselves and so they checked themselves into an assisted living center about a year ago in Oregon, where they were born and raised. He had been a career minister and, besides being a Sunday school teacher, his wife volunteered selflessly in every way possible helping out the church and community. Both were very sociable, beautiful people with countless friends who loved them dearly.

When the lockdowns ensued in March, their health started going downhill rapidly. Of course, no one was allowed to visit them, but when his Aunt's health failed further, they took her away to a separate intensive care ward in the same building, and not even her husband of 65 years was allowed to visit her. There has not been a single case reported in the facility. Of course, they would argue that is because they did such a good job locking everyone up :(To date, there have only been 3 deaths in a county of 30,000, and who knows if those 3 were even legit.

Two months later, his Aunt died (NOT from COVID!), and the family wanted to have some sort of funeral for her and involve his Uncle in some way. The only solution allowed was to hold a small service of immediate family only, in the parking lot of the care center where the Uncle, who is extremely hard of hearing, could watch through a window if we all wore masks. So, the day came, and as luck would have it, the weather did not cooperate. We all gathered outside of the window, in a torrential downpour, getting absolutely drenched (including my husband's 90 year old mother) trying to hold a service, while the Uncle sat in his wheelchair behind the window where he could watch. There he sat, looking out at a bunch of masked faces, unable to hear, unable to be comforted, and we could all see him crying like a little baby and were helpless to console him in any way. He was not allowed to go with us to the burial site, so we tried saying our goodbyes by waving at him through the window and I expect

that will be the last we ever see of this kind and gentle Godly man. I'm just relieved that my 98-year-old mother died two years ago with all 8 of her kids at her bedside, as it should be. What kind of cold, heartless, cowardly, unconscionable people do this? Great moments in public health, indeed.

Perhaps saddest of all was a news story featuring 52 nursing home patients in Gatesville Texas who were photographed holding signs asking for people to become pen pals.³⁰²

The criminals and despots in charge of our lives seem unconcerned by the consequences of their decisions, which clearly did not prevent death from COVID in long-term care facilities. Data from most states and even most other countries was similar to Ohio – most deaths were in elderly people, and a significant percentage of those who died were locked down in nursing homes.

According to psychiatrist Dr. Peter Breggin, the isolation of seniors:

...was contrary to every principle of caring for the elderly. There is no controversy about the best way to help the elderly with their overall health, cognitive and emotional problems, or dementia. Keeping them in close touch with the people who love them while providing maximum autonomy and opportunity for a degree of normal functioning is critical to maintaining the mental and physical function of these fragile humans. The restrictions imposed by the lockdown on nursing homes was devastating to the morale and the health of the patients, destroying both quality of life and life itself.³⁰³

Impact on the Children and Adolescents

Lockdowns and school closures were particularly difficult for children. According to the American Institute for Economic Research, closing schools in March was, essentially, a grand, unethical social experiment designed by supposed infectious disease experts. The AIER says, “We consider the experiment to be unethical because there has been no informed consent, either from parents, children, or even our legislative representatives. The bottom line is that our children’s future and the quality of their lives have been sacrificed to conduct this experiment.”³⁰⁴

Schools had little time to convert to “schooling at home,” and the challenges in making this conversion were almost unsurmountable. According to an April 7 article in the *New York Times*, in rural communities many children did not have internet access. In these areas, educators reported that students and parents just dropped out of touch and are not available by phone or email. Absences were very common in low-income school districts. According to Michael Cassidy, Executive director of the Council of the Great City Schools “The dramatic split promises to further deepen the

³⁰² Kiss 103.3 FM, 2020, Gatesville Nursing Home Residents are Seeking Pen Pals, News Break. <https://www.newsbreak.com/texas/gatesville/news/1612656601307/gatesville-nursing-home-residents-are-seeking-pen-pals>

³⁰³ Breggin, P., et al, 2020, COVID-19 SOS: Saving America from Governor Cuomo, Psychiatric Drug Facts. <https://breggin.com/covid-19-sos-saving-america-from-gov-cuomo/>

³⁰⁴ Sauer R.M., et al, 2020, CDC Has Become Centers for the Destruction of Childhood American Institute for Economic Research. <https://www.aier.org/article/cdc-has-become-centers-for-the-destruction-of-childhood/>

typical academic achievement gaps between poor, middle-class and wealthy students and unfinished learning will be a serious issue that could have implications for years.”

Eric Gordon, CEO of the Cleveland Metropolitan School District reported that 30-40% of students did not have access to internet. A teacher in that district reported that most of her students’ parents do not speak English.

A school district in Minford Ohio distributed laptops and work packets to students. But Mari Applegate, school psychologist, reported that regardless of whether or not the students can log in or turn in assignments they will be passed on to the next grade since it is not their fault and they “cannot be held accountable.”³⁰⁵

An analysis of 800,000 students conducted by researchers at Brown and Harvard Universities determined that student progress in math decreased by about half in poor zip codes, and one third in middle income zip codes. Kids in high income zip codes were not affected. They estimate that the average student will fall behind by 7 months, 9 months for Latinos and 10 months for black children. The hardest hit may be rural areas, since only 27% of schools in these areas required any instruction at all while the schools were closed.³⁰⁶

In addition to falling behind academically, keeping kids out of school resulted in lack of social and emotional development because they were deprived of play, sports, and other activities. And autistic and special needs children were hurt most, since their routines were interrupted, and they had little to no access to the specialized help that they required.

According to Shelley Allwang, program manager at the National Center for Missing and Exploited Children (NCMEC) the COVID-19 response resulted in a significant increase in the reports of child abuse. In April 2019, NCMEC received about one million reports. During the month of April 2020, 4.1 million reports of child abuse and exploitation were reported.

The staff attributed the increased reports to bad actors who were taking advantage of the fact that children were out of school and at home, along with parents who were overwhelmed with schooling at home while trying to work. Kids suddenly stopped spending time outside and playing with their friends, and spending more time online than ever before, which created more opportunities for exploitation. Another issue was assignments from teachers that often involved internet searches which were broad and had the potential to result in visiting inappropriate sites, or alerting bad actors patrolling online that the child was online and available.³⁰⁷

Adolescents missed important rites of passage, like the school prom and graduation. Their college educations were interrupted and they were sent back home with nothing to do. For athletes, the consequences might be particularly punishing

³⁰⁵ Goldstein D., et al, 2020, As School Moves Online, Many Students Stay Logged Out, New York Times. <https://www.nytimes.com/2020/04/06/us/coronavirus-schools-attendance-absent.html>

³⁰⁶ Goldstein D., 2020, Research Shows Students Falling Months Behind During Virus Disruptions, New York Times. <https://www.nytimes.com/2020/06/05/us/coronavirus-education-lost-learning.html#:~:text=New%20research%20suggests%20that%20by%20year's%20worth%20of%20academic%20gains.>

³⁰⁷ Alfonso III, F., 2020, The pandemic is causing an exponential rise in the online exploitation of children, experts say, CNN. <https://www.cnn.com/2020/05/25/us/child-abuse-online-coronavirus-pandemic-parents-investigations-trnd/index.html>

since college sports are often the ticket to lucrative professional career, as the next stories illustrates:

I am so angry. My son was enjoying his junior year of college abroad in London. First his friends at the university were ordered back one by one to their home states, some states which had higher rates of the virus than in London. I kept telling him to stay because there was more risk (although still extremely low) of flying back than just staying put. Eventually within the span of a couple weeks, he was practically the only one left. His school was open, so I still told him to stay. Then the school eventually went online, but he was still allowed to stay. Then the school closed and he was basically kicked out. Now he's home and sits in his room all day except for taking a run or the dog for a walk (which I'm worried will eventually be banned also.)

I have another son in college forced to come home and he sits in his room all day also. I'm more worried about their mental health at this point. They are both well adjusted, happy, social kids, so I hope this doesn't affect them too negatively. I seriously worry this will trigger some sort of mental instability. These young people should be out living their lives!

Like the other stories you are sharing on your videos, this mishandled situation has significantly affected our family. We have 2 teenage sons; one is a sophomore and one is a senior. At the beginning of March our senior had a part time job and was successfully completing his senior year in high school and eagerly looking forward to the end of year senior activities. Now he and the other classes of 2020 are missing out on those milestone activities and graduation. Now he isn't working and is home doing distance learning. He has been working on his Boy Scout Eagle Project process for the last year and a half. Thankfully, his Eagle Scout service project at a county park, which had been scheduled months in advance, was a week and a half before the shelter in place orders were issued here in the middle of March.

Our younger son, a sophomore, was in the process of starting his Eagle Scout project but his project has been postponed indefinitely due to the shelter in place order and cancellation of non-essential activities and gatherings here. Future schooling (college and high school) is completely up in the air for our sons, based on whether or not schools reopen or continue with online and distance learning.

My niece is traumatized by missing all her high school senior year activities she looked forward to for four years, not to mention she still had to meet the deadline to choose a college while not being allowed to visit any of the campuses.

The same niece's teenaged boyfriend who suffers from depression had suddenly gotten so bad the past month in isolation that he said he didn't think he would make it another month and would kill himself. She grew so concerned she contacted his mother, and he cannot get an appointment with a therapist to get medication for a few more weeks.

Suicides and Overdose Deaths

The increase in overdoses and suicides started shortly after the lockdowns began. This is not difficult to understand since the effect of unemployment, business failure, isolation, financial insecurity, and other consequences of the lockdown are well-known.

Doctors at John Muir Medical Center in Walnut Creek reported on May 21 that there were more deaths by suicide during the quarantine than deaths from COVID-19. The head of trauma, Dr. Mike deBoisblanc stated it was time to end the shelter-in-place order because it was clear that the hospitals were not overwhelmed, there were adequate resources to take care of COVID patients, and the rest of the community was suffering. "We've never seen numbers like this, in such a short period of time," he said. "I mean we've seen a year's worth of suicide attempts in the last four weeks."

Kacey Hansen has worked as a trauma nurse at John Muir Medical Center for almost 33 years and expressed concern because not only was the facility dealing with more suicide attempts, they were not able to save as many patients as usual.³⁰⁸

Robert London MD, a psychiatrist, noted that the country was experiencing "a national epidemic of trauma," which he described as "a clinical picture of PTSD." He stated that isolation...is both painful and stressful," and cautioned that worry about many things, including family, finances and work is overwhelming for millions of people. In addition to social distancing, for many people there is no work, people cannot spend time with people they care about, there is no recreation, no shopping, no normalcy.

London expressed concern about people experiencing nightmares, anxiety, and insomnia, and reports that people were stocking up on guns and ammunition.³⁰⁹

The next story amplifies the anguish felt by many people:

I'm exhausted.

*I am tired of the garbage on FB and mask shaming and self-righteous sanctimony spewed by every noodle out there who thinks they are right and if you disagree, you are not only wrong but *dangerous*.*

The 15-year-old son I've never met of people we knew during our Seminary years killed. him. self. the other evening. At home. Feet away from his pastor father and mother. No warning. Their only child. He couldn't process the "new normal" and the constant drumbeat of negativity. The loss of everything a normal child needs in his life.

Shame. On. Us. That we have allowed this happen. That we have sat by complicit in the erosion of liberties and the decimation of our economy. That we have excused

³⁰⁸ Hollyfield A., 2020, COVID crisis: Suicides on the rise amid stay-at-home order, Bay Area medical professionals say, ABC7. <https://abc7.com/suicide-covid-19-coronavirus-rates-during-pandemic-death-by/6204524/> accessed 8.8.2020

³⁰⁹ London R.T., 2020, Is COVID-19 Leading to a Mental Illness Pandemic?, Medscape. <https://www.medscape.com/viewarticle/927849>

the behaviors that have left adults and CHILDREN so bereft that suicide can happen right in their home. All because of a bad flu. There. I said it. THE FLU.

*Hate me? Think I'm wrong? Crazy conspiracy theorist? Don't bother commenting. Two can play at this. You cannot justify a total lack of compassion and empathy at this point while demanding compliance. Door's over there, see yourself out. I'm done defending myself. I'm done being castigated for daring to think differently. There is no tolerance. No discussion. No agree to disagree. In a world where the EXPERTS can't agree, and have changed their stance a hundred times, *I'M WRONG* when I don't immediately buy the science du jour. And who pointed it out? My 15yo son. Who spends 8 hours a day in his room, on the internet, "doing school". Not with friends. Not at the rink. Not at school. He said, "When did it become only one thought process was acceptable?" NEVER, Lex. It should NEVER be that way.*

I thought my charge was to protect my kids from a virus. The virus doesn't scare me anywhere near as much as this insidious darkness falling over society. Where neighbors are tattling on each other. Actually, MAD that other people are not living in fear. "Defying orders". Embracing masks which make everyone look angry and hide expression, furthering the feeling that everyone is suspicious and dangerous. I can't wear a mask, and the amazing thing I've found is people are GLAD TO SEE MY FACE. The like to see my smile! They miss human contact and they know they can converse with a mask-less person because we aren't going to freak out. I haven't encountered one single cashier who wasn't delightful and pleasant (except Menards, and they need Jesus over there, for sure).

*No, my charge is to protect them from the Biblical levels of darkness falling. Their entire world has been damaged, and to believe that the love and protection of their parent is enough to save them is naive. Their world is far bigger than me, and it should be. But it has been taken from them and there is no hope being offered by ANYONE in authority that they will get it back. Nope, instead there is the constant drumbeat of "new normal". That discourages *ME* and I've got the maturity and life experience to process that better than our children.*

So...I'm not participating. I'm not excusing any of it. I'm not playing the middle. I'm not trying to be "balanced". I'm done. I refuse to sit by and just mourn, from a distance, no less, for a CHILD who despite being raised in the church, by devoted and loving parents, and showered with the love of Christ, still was so hopeless he was compelled to take his life at 15.

Shove your masks. Screw your fears. I'm done participating. I'll be in church, same row as ever, no masks, hugging all takers. I will not contribute to the darkness.

Shame. On. Us

The Inhumanity of it All

During a five-month period, we received thousands of horrible stories about horrible and inhumane treatment that reflected a general disregard for human life. Many of these people reported that they had contacted called and written letters to government officials and were either ignored or treated badly. In other words, reports of harm and pleas for mercy fell on deaf ears. Some people who answered the phone

casually mentioned that “a lot of people were complaining” but appeared to have become almost immune to hearing about suffering people and seemed not to care.

Here are two:

On Saturday, a friend and client passed away. I am so sad and angry. Not that it's ever a good time to die or go through the many difficulties of cancer but doing it during this COVID19 "pandemic" is horrific. She turned 59 on April 8th. Her mom and sister had booked plane tickets at the beginning of March to visit her for her birthday. Due to COVID, they were not able to visit her before she died. On April 13th, the pain she was experiencing from ascites was so bad her daughter took her to the ER. She stayed in the hospital ALONE for 4 days and was then released to hospice care. At the end of March, when she really started going downhill, I asked her if there was something she really wanted to do. She wanted to go to the beach. I was unable to grant her wish because the beaches were closed due to COVID. There are so many more atrocities I witnessed her go through during her cancer treatments, but I can't continue typing right now. I'm just so furious with the whole medical establishment and overcome with sadness.

My husband and I have 3 kids who still currently live at home with us. The oldest is my son from a previous marriage, he is 22 and is intellectually disabled. He has suffered the most from all of this tyrannical behavior, so my letter to you is mainly about him. He is considered high functioning autistic. He is able to do things for himself and be fairly independent, however he will never live on his own independently.

He will never drive, so therefore he takes the county transit in order to go to and from work. He has worked at his job for over 3 years, he loves it there and his fellow employees are very kind to him. Customers love him and some come in just to see him and his big smile.

He considers himself famous because he is very involved in Special Olympics and went to the 2018 USA Games and last year we went to Abu Dhabi for the World Games to watch him compete and bring home four gold medals in Powerlifting. He was on cloud nine and living up his best life.

But lately, that smile has disappeared, it has been replaced with anger and frustration, uncertainty. He is not the same person he was at the beginning of this year and I completely blame it on our state governor, whom I don't even like saying his name anymore at this point, Mr. Dictator DeWine. Along with his former sidekick, Acton, they have caused my son severe mental anguish that I fear will affect him long term. We have come so far with my son, and now all his successes are failing him.

My son went to his local gym three days every week so when the dictator of Ohio closed gyms, this was traumatizing to say the least. Fortunately, we have gym equipment here at home, so that became his only outlet. It still wasn't the same though overall. He still has not returned to the gym due to the strict guidelines that have been ordered for gyms to even be open. He wouldn't have the time to follow everything and still get his workout in before work. He is also afraid he will not follow as well as is

being demanded and therefore be kicked out of the gym. Along with the fact that they make them sign in, which I am not willing for him to do because of the whole contact tracing mumbo jumbo. He ended up almost, call it what you will, having a mental breakdown over all this.

He was off work for about a month with no income but not because his place of employment shut down or closed. He just couldn't even function at work so there was no point in him going there. He couldn't go to acupuncture because they were closed down, which is vital to him and a vital balance for his mental health, so that on top of everything else, he was like a ticking time bomb. To see your grown 22-year-old son breaking down, sobbing...it's not something I even knew how to handle, and I know him best.

Once things started opening back up again and it seemed more relaxed for him and he could go back to acupuncture, he then returned to work, and I was seeing his smile again. He was still frustrated at times because of the mandates the health departments were now enforcing and would come home and need to tell me everything they were making him do. We would talk it over and then he was fine.

Then the mask thing started intensifying. He was seeing people on social media shaming others for not masking up and implying those that don't do it, do not care for others. I told him to quit looking at it, those people are not doctors and they don't know everything. He said but I do care about people, I just can't handle having that on my face. He is a kind soul who would do anything to help others, truly unique. He is a good boy :) He kind of has a tick type thing where he tends to rub his fists on his face, not all the time, just some. He is careful and keeps his hands washed and tries to control touching his face. Honestly, I believe our whole family already had this virus back in February, but that is not important to any of our rulers.

Back to the masks...He obviously is exempt but that did not keep people from making comments to him. We had a plan and it was just that he was to respond by saying it was none of their business and smile, walk away. Thankfully, this did not happen much. Now that Licking County was moved to red level and masks were mandated last week because we had like 14 positive cases added to our faulty total of like 400 cases out of nearly 180,000 people, I was more concerned for my son and what might be said to him. People can be cruel and this whole masking has gone way out of control. No one seems to care that there are people who cannot tolerate or physically can't wear one. Our entire family are not mask wearers and we are doing all we can to avoid that entirely.

My son was encountered by his transit driver just yesterday, telling him if he didn't wear a mask that he would be kicked off and no longer permitted to ride. Not a good thing to tell my son at all, he was furious and called me at work. He was to the point of almost crying. I called the county transit service and got it straightened out and noted on his file that he is indeed exempt. The kicker was at first, they were going to require a doctor note to excuse him from wearing one. I was like what? That was not mentioned in the health departments standards at all. They hem hawed around and I told them he is exempt from wearing a mask along with exempt from having to get a doctors' note because he is on a waiver through the County DD and they have transportation provided by county transit as part of his ISP plan and the DD pays for it as part of his plan. That settled it and I was glad to have it resolved. I was just

somewhat still taken back by the fact of the doctor note request, where did this come from?? People will be required to now prove why they can't mask up??

Sadly, my son thinks our world is ending now and he is back to his state of mental breakdown mode once more. So, to all this, thank you so much dictator DeWine for ruining my happy, smiling, somewhat carefree son who had everything going for him - you basically took it all away in a matter of several months. He was set to compete in more competitions this year and obviously participate in the Summer Special Olympic games, which was canceled due to all this mess. The last time my son competed was at the Arnold Sports Festival, which thankfully that happened just in time before the tyrants took total control of that situation. My son misses so much of what has made him who he is, that he has lost himself in the midst of everything. He is even having trouble identifying with himself and can't think straight, he is confused easier. He hasn't seen his special olympic teammates since, I honestly can't remember when.

In closing, now with the episode that happened yesterday with transit and other things that have been mentioned at his work and his mental state, he is going to have to take more time off work. My son is at the breaking point and with what DeWine has done and is doing, I hold him ultimately responsible for. He has made my son with his pandering rules and regulations into someone who is not happy and can't handle the day to day. Yesterday was the first day since my son first got a job, in like 3 plus years, he has begged me to not have to go to work. This guy has loved his job, a totally dedicated employee that any employer would be happy to have. He is a hard worker and now his face is long and tired, he is mentally exhausted. I have it in my mind to speak to an attorney friend, because my son has lost income over this and mental wellbeing. I have never seen someone have a mental breakdown and I don't care to either, but it has come to that point. Everyday life is harming my son!!! Who would have ever thought that.

I just wanted to share my story with you as far as the mental toll this is taking on the intellectually disabled and how basically criminal this all is. Our state government is not taking any of this into consideration at all, it's harmful and why so many suicides have occurred. DeWine would rather have someone get on and talk about things to do for your mental health, he forgets about the ones that do not understand what that even means. I hope and pray for better days ahead, but the path this is taking is dim and I don't see it getting any brighter any time soon...at least not until the election perhaps.

The Economy in Freefall

In February 2020, the unemployment rate in the United States was 3.5%. In April of 2020, due to the government response and shutdown, and 20.5 million jobs were lost.³¹⁰ The numbers continued to rise throughout May, and as of May 8, the

³¹⁰ Davidson, P., 2020, Unemployment sours to 14.7%, job losses reach 20.5 million in April as coronavirus pandemic spreads, USA Today. <https://www.usatoday.com/story/money/2020/05/08/april-jobs-reports-20-5-m-become-unemployed-covid-19-spreads/3090664001/>

unemployment rate had risen to 14.7%, according to the Bureau of Labor Statistics.³¹¹ The United States had a thriving economy, a thriving stock market, and companies were reporting record earnings. Almost overnight, millions of people saw their businesses evaporate, their life savings depleted, and a significant percentage were thrust into poverty.

Government officials felt compelled to do something, and tens of millions of now financially insecure people were demanding assistance. The government's response? Congress passed a \$2.4 trillion dollar stimulus bill designed to help Americans to survive.

This stimulus bill pushed The United States' national debt well above \$25 trillion, with China continuing to own a large percentage of it. This move, which essentially meant the government was printing money it did not have, will most certainly result in a devaluation of U.S. currency, and will ultimately cause inflation to rise.³¹² In fact, many economists, including Martin Hutchinson, a well-known author and market analyst in the industry, believe that by early 2022, this will lead to double digit inflation rates.³¹³

Qualifications for the check were based on most recent tax returns (either 2018 or 2019) and any person whose adjusted gross income did not exceed \$99,000 received a check.³¹⁴ This included people who were still employed, many of whom while happy to receive a check from the government, did not need it. And it is doubtful that the assistance was meaningful to most households that did need the money. Other than feeling better for a short time, how helpful is a \$1200 check to the average person who has lost some or all his household income? Most likely not much.

Most middle-income Americans tend to live on what they make. A family making \$50,000 per year tends to live in a residence and have other expenses that are affordable within that range. This is also true for individuals and families with a \$100,000 income or more. And these individuals and families were excluded from the stimulus check.

For example, a restaurant owner with an AGI of \$100,000 in 2018 or 2019 was not eligible to receive a check, even though his income currently may have been reduced by 50% or even dropped to zero due to lockdown restrictions.

Another \$3 trillion dollar bill introduced by Congress on May 12, 2020 was no better. Included in "stimulus" was bailout money for the already failing and mismanaged postal service (again), and "election assistance," which included dropping the requirement for identification to vote.³¹⁵ This, of course, will have the

³¹¹ Bureau of Labor Statistics, 2020, The Unemployment Situation, BLS. <https://www.bls.gov/news.release/pdf/empst.pdf>

³¹² Sergent, J., et al, 2020, 4 coronavirus stimulus packages. \$2.4 trillion in funding. See what that means to the national debt., USA Today. <https://www.usatoday.com/in-depth/news/2020/05/08/national-debt-how-much-could-coronavirus-cost-america/3051559001/>

³¹³ Hutchinson, M., 2020, The Coronavirus Economy Will Bring Inflation, National Review. <https://www.nationalreview.com/2020/04/the-coronavirus-economy-will-bring-inflation/>

³¹⁴ Kane, L., et al, The IRS has sent over 159 million stimulus checks so far. Here's what to know if you're still waiting on yours., Business Insider. <https://www.businessinsider.com/personal-finance/coronavirus-stimulus-check-questions-answers-2020-4>

³¹⁵ Segers, G., 2020, What's in the House Democrats' \$3 Trillion coronavirus relief bill?, CBS News. <https://www.cbsnews.com/news/coronavirus-relief-package-heroes-act-3-trillion-bill-house-democrats/>

effect of making it easy for illegal immigrants to vote. And it offered little in the way of relief for the tens of millions of people who had lost their jobs or whose businesses remained closed.

Art Laffer, a former economic advisor to the Reagan administration who was opposed to this approach to resolving the economic crisis the government created said, “Whenever people make decisions, when they are either panicked or drunk, the consequences are rarely attractive and that especially goes for politicians, so I thought Trump's proposal of a tax cut on payrolls was great, but that's about all I would suggest him doing.”³¹⁶

As of the time that this book was being finished, there were no meaningful proposals from Congress, or anyone else for that matter, that had the potential for addressing the coming explosion of joblessness, financial devastation, homelessness, food insecurity and other related consequences of the draconian measures the governors of various states had caused.

Gross Domestic Product (GDP) is often the primary metric used to determine the state of the U.S. economy. A recession is typically defined as two consecutive quarters of negative GDP. Given the unemployment rate and business shutdowns, many economists have made dire predictions for the U.S. economy. Goldman Sachs predicts an annualized decrease in GDP for 2020 at 34%. Deutsche Bank predicts 33%. JPMorgan's prediction is grimmer at 40%. A Deutsche Bank report stated, “With \$2.8 trillion already announced, the U.S. fiscal response at 13 percent of GDP is the largest ever.”³¹⁷

Some economists are optimistic that the economy will bounce back toward the end of the year but given the fact that it took several years to build the economy from the last disaster in 2008, this is not likely. Many states implemented a phase-in plan for businesses to reopen, but many remain closed, or are forced to operate at limited capacity, like restaurants, or with extreme restrictions like gyms. Even for those businesses that fully open, sales are down since customers have been frightened by the ginned-up hysteria over “cases,” or remain unemployed.

A discussion of the post-lockdown economy would not be complete without returning to China and the Chinese Communist Party (CCP). We may never know if the release of the virus was deliberate or accidental, but the CCP was certainly not going to let an opportunity go to waste. The CCP withheld information, in collusion with the corrupt World Health Organization (remember that Tedros re-appointed President Xi's wife, Peng Liyuan to another 2-year term as “goodwill ambassador to the WHO) which allowed the virus to spread while most in the world were unaware of its existence.³¹⁸ While the data make it clear that COVID-19 never qualified for pandemic status, the WHO declared it as such, which is what triggered the closing down of the entire global economy, including that of the U.S.

³¹⁶ Kaplan, T., 2020, Art Laffer on market selloff amid coronavirus fears: ‘Put your hands in your pockets’ and wait it out, Fox News. <https://www.foxnews.com/media/art-laffer-on-market-volatility-advise-investors-to-keep-hands-in-pockets-do-nothing>

³¹⁷ Akan E., 2020, Economists: World Slumps Into Worst Recession in Decades, The Epoch Times. https://www.theepochtimes.com/economists-world-slumps-into-worst-recession-in-decades_3313512.html

³¹⁸ Chellaney, B., 2020, Opinion: The World Health Organization must stop covering up China's mistakes, MarketWatch. <https://www.marketwatch.com/story/the-who-has-a-big-china-problem-2020-04-22>

Knowing full well that troubling economic times have historically created difficulties for an incumbent President to get re-elected, the CCP had a powerful incentive to do play a role in these events. Joseph Bosco, former China Country Desk Officer for the Department of Defense stated “Xi might well have asked his colleagues: Who will rid me of this troublesome president? Suddenly, thanks to the export of China's virus, Trump's reelection prospects seem considerably less favorable than they did just a few months ago. And a return to a more accommodating U.S. China policy with a new president seems disturbingly more likely.”³¹⁹

In fact, right on cue some politicians in Washington began calling for the removal of the tariffs, and if they are lifted, the CCP will have free range to saturate the U.S. market with their products. Michael Wessel, a commissioner on the U.S.-China Economic and Security Review Commission stated “As our steel and other manufacturers all suffer, when the bottom hits, China is poised to come back in, China is now looking at ways of taking advantage of everyone else’s suffering.”³²⁰

The Chinese have not necessarily been quiet about their delight about recent events. Han Jian, the Chinese Academy of Sciences and director of the Ministry of Civil Affairs for the China Industrial Economics Association, and who received his doctorate at our own Johns Hopkins University, said on March 4, 2020: “It is possible to turn the crisis into an opportunity — to increase the trust and the dependence of all countries around the world of ‘Made in China’.”³²¹

The Impact on Businesses

It is almost impossible to describe the devastation and destruction the lockdowns had and continue to have on businesses. People literally watched their life’s work destroyed within only a few weeks. Both frustration and anger are palpable in this account from a business owner in Washington state:

I am mad as hell.

The intent of this statement is to share with you and all others involved, that the Regulatory Taking without compensation of my businesses in the emergency period, has been misused and abused by Governor Jay Inslee of Washington State. The original intent of the 2 week Stay at Home order was to slow the spread of the COVID-19 virus from China. Judging by the infection numbers, death rates of actual COVID patients and the counties affected, Jay Inslee has intentionally killed my livelihood in Chelan County and I demand it stops now!

We are in the 11th week of a 2-week shut down. I am mad as hell that I have had to take 2 loans against my business that I have painstakingly built 7-days a week for the last 24 years. I am mad as hell that at 50 years old, the term on the SBA loan puts the payoff on my 80th birthday. These new loans may not even save my businesses,

³¹⁹ Bosco, J., 2020, The Wuhan virus and regime change in Washington, The Hill.

<https://thehill.com/opinion/national-security/488141-the-wuhan-virus-and-regime-change-in-washington>

³²⁰ Rogin, J., 2020, How China is planning to use the coronavirus crisis to its advantage, The Washington Post.

<https://www.washingtonpost.com/opinions/2020/03/16/how-china-is-planning-use-coronavirus-crisis-its-advantage/>

³²¹ Rogin, J., 2020, How China is planning to use the coronavirus crisis to its advantage, The Washington Post.

<https://www.washingtonpost.com/opinions/2020/03/16/how-china-is-planning-use-coronavirus-crisis-its-advantage/>

because the re-opening of our County has been batted around as a toy by our Governor and King, Inslee. This is not a game; this is life and death for us and I am mad as hell.

When asked to be a good citizen and “flatten the curve” and then I hear “we are all in this together” my blood boils because I know it’s political bull-excrement at this point and I am mad as hell. We are not in this together, if we were, there would be a remedy post haste. I have laid off all 63 employees that have families, mortgages, rents, diapers, food, and the list goes on. The extended actions of Jay Inslee have put their lives in danger. How dare you, Jay?

His orders have crushed my \$3 million a year business with a payroll of more than \$1.4 million because we are deemed “non-essential”. By scaring our communities to the point of endless isolation, the future of my business is also in jeopardy.

Since we were unable to open this past weekend for Memorial Day and begin to dig out of this mess, it was a slap in the face of every soldier that laid down his life for the freedoms we celebrate. If I lose my life’s work to Jay Inslee’s ignorance and arrogance, by no damaging act of my own, there will be restitution due.

Marie Ann Longlade School of Dance has been my mother’s business since 1965. Yes, 55 years in the business of sharing the love of dance. A female entrepreneur that rode out the recessions and made sure, no matter what, that “The show must go on,”

For the first time, in all those years, the catch phrase of “The show MUST go on,” FAILED. The studio has been hosting remote Zoom classes since the end of March break. Parents paid a \$100 deposit for their child’s recital costume for each class the child was registered for. Some costumes were made already in preparation of the International Dance Educators of America and Canadian Dance Teacher’s Association Spring. These competitions were obviously cancelled. Her 55th Spring Melody Recital with a BIG surprise celebration including of decades of past students returning to the stage in honor of this tenacious woman WAS CANCELLED.

As a result of the FEAR that Trudeau has instilled, and the crushing cancellations throughout 2020.... my mother, age 77 with COPD, and my stepdad, age 66, with Parkinson’s have decided to give up one of their vehicles. They made this choice in light of the NEW NORM. They are convinced my mom will need to restrict her lifestyle forever more.

Not only has this destroyed her business, but it has crushed her drive to live. My stepdad has been observed crawling in his hands and knees to get across a room... with tools in tow as he is constantly, building repairing, and creating things. Parkinson’s and COPD never stopped them. But COVID has held them hostage in their home since Feb 27th.

My mom had pneumonia in December. They found nodules on her CT that were highly suspicious of Cancer. They repeated the CT IN Jan. Still there. They took biopsies, but the results were negative. The Specialist told us she was certain it was a false negative and reordered a biopsy. She endured 12 hours in hospital in Feb due to a collapsed lung. The results were still inconclusive. Then all hospitals shut down

except for severe COVID patients. Soooooo, nothing has been done since. My mom thinks she has cancer and is waiting to die, paralyzed to live life as she once had.

Do you think this NEW NORM of isolation for the rest of their lives is healthy? I am so sad that their fear has totally stripped them of living a full life. They are being robbed of life!

"Shelli and I did not post this to offend anyone, from our perspective this was very good news for our employees and our business. We have worked tirelessly for the past 20 years building first our ice sculpting business and then the restaurant. Then in a very short amount of time all this work has collapsed around us without our doing. It is extremely hard to see all that we have worked for, the very future of our children and ourselves disappear.

We grieve for those of you who have lost loved ones thru this illness and we continue to follow the guidelines with the exception of wearing a mask. We do greatly care about our patrons and our staff. We believe everyone has a choice. We offer both indoor outdoor dining and our staff each has a mask in his/her pocket and will wear it at your table if you ask. Our staff tried to wear them but at the rate they rush around and the summer heat they were having difficulties breathing and felt faint.

At this point though for us it is exceedingly difficult to see this as not being politically motivated. We have faced 4 months of either forced closure or lowered abilities to have our business open while so many others were not financially burdened. We are facing unrealistic minimum wage and unemployment issues that threaten the very fabric of our business and therefore our lives. With all the government has done to the hospitality industry we have not been able to catch up and make ends meet. We are not being taken care of by the government. Shelli and I did not collect unemployment. Nor have we received all the promised grants for the business. We are 500,000 in debt for this business and prior to the forced shut down we were a financially sound business. We had to make a choice to open without restrictions so we could try to rescue our livelihood and keep the 35 individuals that work for us employed as well as ourselves.

This is in no way a political stance we are just fighting for our livelihood.

What made business owners even more furious was the backlash from government officials and citizens who had been brainwashed by the media. These people accused anyone who was concerned about their livelihood as being a heartless capitalist who cared only about profits. Business owners who were justifiably panicking about their economic futures had to endure accusations from self-righteous and indignant individuals that they were selfish and had no regard for human health.

The selfish ones were those who seemed to lack any understanding about how the world works. The economy is what sustains human life. For many people, their business is their life's work. Business owners, along with their employees, often are driven by purpose – to better the lives of one another, their families, and their customers. All businesses are essential – to the people who own them and who are

employed by them. Businesses allow people to take care of and feed their families and to contribute to their communities. And communities rely on businesses for their tax base, funding of arts organizations, museums, and culture. To suggest that businesses are not important is preposterous. And further, to think that commerce could all be indefinitely suspended and then reconstituted at some later date is insane.

Worldwide Impact

According to David Beasley, director of the World Food Programme, the world is now at risk of famines “of biblical proportions” as a result of actions taken in response to COVID-19. He noted that many parts of East Africa and South Asia already had severe food shortages caused by numerous factors such as drought and insect infestation. He referred to the developing famine as the worst humanitarian catastrophe since WWII.

According to Beasley, the crisis most affected millions of people who were “already hanging by a thread,” and is particularly devastating for those “...who can only eat if they earn a wage.”³²²

According to a report by Oxfam, the COVID-19 response is likely to throw another half a billion people into poverty. This would be the first time since 1990 that poverty increased and could be severe enough to put some countries back to where they were three decades ago.³²³

There were 1.4 million additional TB deaths, 500k additional HIV deaths, 385k additional malaria deaths due to lockdown.³²⁴

No one even knows what the goal is now. We flattened the curve, the hospitals were empty, and cases are only rising because tens of thousands of people are being tested every day, most asymptomatic and many as a condition of employment or attendance at school. The conversation seems to have shifted to “safety.”

But what does safety mean? Does it mean no cases? Does it mean that there are no deaths from COVID? If this is the case, we will never regain our freedom. There is no such thing as elimination of all risk. People are injured or die every year as a result of car accidents, flying in airplanes, and diving. People are struck by lightning, they fall while mountain climbing, and they can be injured while performing household tasks like mowing the lawn and painting while standing on a ladder.

Humans understand the risks associated with all these things and choose to do them anyway. And we historically have allowed them to because we lived in a free society that allowed people to take personal responsibility while making their own choices.

³²² BBC, 2020, Coronavirus: World risks ‘biblical’ famines due to pandemic – UN, BBC News. <https://www.bbc.com/news/world-52373888>

³²³ Strohecker K., 2020, Coronavirus crisis could plunge half a billion people into poverty: Oxfam, Reuters. <https://www.reuters.com/article/us-health-coronavirus-poverty/coronavirus-crisis-could-plunge-half-a-billion-people-into-poverty-oxfam-idUSKCN21R0E7>

³²⁴ Mandavilli, A., 2020, ‘The Biggest Monster’ Is Spreading. And It’s Not The Coronavirus., The New York Times. <https://www.nytimes.com/2020/08/03/health/coronavirus-tuberculosis-aids-malaria.html>

That concludes Dr. Popper's remarkable discussion of the suffering caused by governments, especially the states, to cope with and perhaps even to worsen the suffering from the COVID-19 epidemic to increase their own political advantage and/or wealth and power.

IX. The Pharmaceutical Industry and Globalism

A great has been written about globalism or international planning at the highest level to coordinate foreign policy, economics, government, and industry. Obviously, great power and wealth are involved. Perhaps most relevant to government response to COVID-19, the chemical and pharmaceutical industries are already among the powerful globalist forces working with and influencing governments around the world. Most relevant to this report, Bill Gates is at the top of this powerful influence, and he has known and worked with Anthony Fauci for years. Fauci is one of only six other powerhouses, including the Director General of WHO and the Executive Director of UNICEF, who sit on the Leadership Council of the Bill and Melinda Gates Foundation to head “a collaboration to increase coordination across the international vaccine community and create a Global Vaccine Action Plan.”³²⁵ This is globalism near or at its summit, and both Gates and Fauci are growing in power, influence and the control of wealth as a result of COVID-19.

I have written many books and scientific articles about the unscrupulous power exerted by the pharmaceutical industry. I have also investigated drug companies as a part of many lawsuits in which I have been a medical and psychiatric expert. In a product liability case that was settled against GlaxoSmithKline for its antidepressant Paxil (paroxetine), and a later judge made my report public,³²⁶ and I was able to publish three scientific peer-reviewed papers based on it.³²⁷

The giant international pharmaceutical industry plays a major role in the coercion and authoritarianism, leading toward totalitarianism, that has been unfolding during COVID-19. These drug manufactures are seizing the opportunity to rush through medications and vaccines for COVID-19 and has required them to exert control over multiple governments around the world, as well as medical and public health establishments, WHO, leading universities, and many other institutions. It is extraordinary, for example, how they have managed to crush any movement to widely use hydroxychloroquine in many countries, including America, despite the support of President Trump. Information and opinions favorable to the medication is censored on social media and excluded from the major media, and even respected medical doctors and professors are been harassed for speaking out or daring to prescribe it in the US. In this report

³²⁵ Press Release, 2010, Global Health Leaders Launch Decade of Vaccines Collaboration. Bill and Melinda Gates Foundation. <https://www.gatesfoundation.org/Media-Center/Press-Releases/2010/12/Global-Health-Leaders-Launch-Decade-of-Vaccines-Collaboration>

³²⁶ Breggin, P. DECLARATION OF PETER R. BREGGIN, MD. SUPERIOR COURT OF THE STATE OF CALIFORNIA COUNTY OF SANTA CLARA. Case No.: CV 773623. Lacuzong v. Davidson. July 21, 2001. <http://breggin.com/wp-content/uploads/2004/01/Breggin%20Paxil%20Lacuzong%20Report%20Filed%20with%20Court.pdf>

³²⁷ Breggin, Peter. Court filing makes public my previously suppressed analysis of Paxil’s effects. Ethical Human Psychology and Psychiatry, 8, 77-84, 2006. 57-58 http://breggin.com/wp-content/uploads/2003/01/court_filing_p.breggin.2006.pdf; Breggin, Peter. Drug company suppressed data on paroxetine-induced stimulation: Implications for violence and suicide. Ethical Human Psychology and Psychiatry, 8, 255-263 <http://breggin.com/wp-content/uploads/2001/01/Peter%20Breggins%20Paxil%20Special%20Report%20III.pdf>; Breggin, Peter. How GlaxoSmithKline suppressed data on Paxil-induced akathisia: Implications for suicide and violence. Ethical Human Psychology and Psychiatry, 8, 91-100, 2006. <http://breggin.com/wp-content/uploads/2002/01/Peter%20Breggins%20Paxil%20special%20report%20II.pdf>

we have extreme cases of patients being given overdoses of hydroxychloroquine in clinical trials in order to make it look unsafe for general use.

Many good books have been written about the degree of corruption in the pharmaceutical industry, including its willingness to stifle any criticism. One of the best books is by Peter Gøtzsche, MD: *Deadly Medicines and Organised Crime: How Big Pharma Has Corrupted Medicine*, which received a surprisingly laudatory and informative review in the *Lancet*:³²⁸

Throughout Deadly Medicines and Organised Crime Gøtzsche uses many anecdotes, provides countless facts and comments based on facts, and cites more than 900 references to draw attention to the allegedly shocking crimes committed by the drug industry (including manufacturers of medical devices). Gøtzsche understands pharmaceutical companies only too well because of his long and varied career in health care, with roles that have included drug representative for big pharma, researcher in clinical trials, physician, lecturer, and author of papers and books. He cofounded the Cochrane Collaboration and is the Director of the Nordic Cochrane Centre in Copenhagen. With his expertise and uncompromising attitude, Gøtzsche is outraged and outspoken in his book about pharmaceutical companies being “just like street drug pushers”.

Some pharmaceutical companies have been caught and fined for their activities. For example, Gøtzsche details how during 2007–12, in the USA, Abbott, AstraZeneca, Eli Lilly, GlaxoSmithKline, Johnson and Johnson, Merck, Novartis, Pfizer, and Sanofi-Aventis were fined from \$95 million to \$3 billion for illegal marketing of drugs, misrepresentation of research findings, hiding data about the harms of the drugs, Medicaid fraud, or Medicare fraud. However, some companies seem not to be deterred and apparently regard fines as marketing expenses.

Another good book, this one from the center of the establishment, was written by Marcia Angell, MD, former-editor-in chief of the *New England Journal of Medicine* and now a member of Harvard Medical School’s Department of Global Health and Social Medicine. A summary of her book, *The Truth about the Drug Companies* (New York: Penguin Random House, 2014) states her view accurately and was certainly approved by her:³²⁹

During her two decades at The New England Journal of Medicine, Dr. Marcia Angell had a front-row seat on the appalling spectacle of the pharmaceutical industry. She watched drug companies stray from their original mission of discovering and manufacturing useful drugs and instead become vast marketing machines with unprecedented control over their own fortunes. She saw them gain nearly limitless influence over medical research, education, and how doctors do their jobs. She sympathized as the American public, particularly the elderly, struggled and increasingly failed to meet spiraling prescription drug prices. Now, in this bold, hard-

³²⁸ Yaqub, F. Reforming Big Pharma. *Lancet*, V. 383, Issue 9915, p. 402, February 1, 2014.

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(14\)60139-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)60139-2/fulltext)

³²⁹ This summary is taken from the Penguin Random House offering of the book.

<https://www.penguinrandomhouse.com/books/3901/the-truth-about-the-drug-companies-by-marcia-angell-md/>

hitting new book, *Dr. Angell* exposes the shocking truth of what the pharmaceutical industry has become—and argues for essential, long-overdue change.

Currently Americans spend a staggering \$200 billion each year on prescription drugs. As *Dr. Angell* powerfully demonstrates, claims that high drug prices are necessary to fund research and development are unfounded: The truth is that drug companies funnel the bulk of their resources into the marketing of products of dubious benefit. Meanwhile, as profits soar, the companies brazenly use their wealth and power to push their agenda through Congress, the FDA, and academic medical centers.

Zeroing in on hugely successful drugs like AZT (the first drug to treat HIV/AIDS), Taxol (the best-selling cancer drug in history), and the blockbuster allergy drug Claritin, *Dr. Angell* demonstrates exactly how new products are brought to market. Drug companies, she shows, routinely rely on publicly funded institutions for their basic research; they rig clinical trials to make their products look better than they are; and they use their legions of lawyers to stretch out government-granted exclusive marketing rights for years. They also flood the market with copycat drugs that cost a lot more than the drugs they mimic but are no more effective.

The American pharmaceutical industry needs to be saved, mainly from itself, and *Dr. Angell* proposes a program of vital reforms, which includes restoring impartiality to clinical research and severing the ties between drug companies and medical education. Written with fierce passion and substantiated with in-depth research, *The Truth About the Drug Companies* is a searing indictment of an industry that has spun out of control.

The views of doctors Gotzsche and Angell reflect my own experience and conclusions in many books and scientific articles, going back decades earlier, when I was perhaps the first physician and psychiatrist to study and critique psychiatric drug development and marketing in any depth.³³⁰ Especially noteworthy, *Talking Back to Prozac* (1994), with Ginger Breggin as coauthor, provides an analysis of Eli Lilly's corruption in the development and marketing of Prozac, and its secret collaborations with the FDA, medical organizations, and other sources of power and influence. The book was written after I researched the company following my appointment by a consortium of lawyers and approval by a federal judge to be the single scientific investigator for more than 150 combined product liability suits against the company.

³³⁰ My first book about psychiatric drugs and industry corruption was a medical book *Psychiatric Drugs: Hazards to the Brain* (New York: Springer Publishing Company, 1983—37 years ago).

X. Anthony Fauci: Enabling the Pandemic to Occur and then Manipulating It³³¹

Anthony Fauci MD, Director of NIH's Institute for Allergy and Infectious Diseases (NIAID), exemplifies the public health activist who plays the role of "scientist," taking over the dialogue about and the implementation of policies and programs for treating COVID-19. See **Part VII** of this report which contains a summary report by Meryl Nass, MD, *How A False Hydroxychloroquine Narrative Was Created, And More* as well as **Part III C (1)** of this report, *Open letter to Dr. Anthony Fauci regarding the use of hydroxychloroquine for treating COVID-19*. More discussion of the doctor in relation to globalism, the pharmaceutical industry, and Bill Gates can also be found in **IV G, IX, and X**, as well as throughout this report by searching "Fauci." With no intention to focus this much on Fauci, he turned out to be deeply enmeshed in some of the most coercive and threatening aspects of globalist policymaking for COVID-19.

A. Fauci Supports Collaboration with China to Build More Destructive Viruses

We were first motivated to begin researching, investigating and writing about coronavirus issues when my wife Ginger brought me an article she had happened upon that looked so bizarre she could hardly believe it was real.³³² It led to our developing the Coronavirus Resource Center.³³³ What motivated us was the discovery that Chinese and American scientists were working together to create the *precursor* to SARS-Cov-2 with federal funding from Anthony Fauci's NIH Institute for Allergy and Infectious Diseases (NIAID). We know this because they shamelessly published this catastrophic collaboration in a leading scientific journal³³⁴—Americans, without any qualms, making epidemic viruses and showing Wuhan Institute Chinese researchers how to do it. Even today, we shall document, many American scientists and intellectuals cannot understand why, after our disclosures, President Trump would have defunded our American collaboration with the Chinese in making more potent viruses that easily become bioweapons. There will be much to document about this as we proceed. Right now, we are proud to say that our blog/report and YouTube video on this scientific disaster³³⁵ may have led the President to cancel its funding³³⁶ within 48 hours or less of our releasing them.

³³¹ A great deal of information in section has been previously published in a series of blog reports on our Coronavirus Resource Center. Breggin, P., Breggin, G., 2020, Coronavirus Resource Center, Psychiatric Drug Facts. <https://breggin.com/coronavirus-resource-center/>

³³² We tell much of the story in Video and Report: US and China Collaborated to Make a Deadly Coronavirus and in Video and Report: Trump Cancels US/China Research Making Epidemic Viruses. Breggin, P., 2020, A Special Report, Psychiatric Drug Facts. <https://breggin.com/us-chinese-scientists-collaborate-on-coronavirus/>

³³³ All our blog reports relating to the pandemic can be found on the Coronavirus Resource Center by Peter and Ginger Breggin. Breggin, P., Breggin, G., 2020, Coronavirus Resource Center, Psychiatric Drug Facts. <https://breggin.com/coronavirus-resource-center/>

³³⁴ Vineet D Menachery, Boyd L Yount Jr, Kari Debbink1, Sudhakar Agnihothram, Lisa E Gralinski, Jessica A Plante, Rachel L Graham, Trevor Scobey, Xing-Yi Ge, Eric F Donaldson, Scott H Randell, Antonio Lanzavecchia, Wayne A Marasco, Zhengli-Li Shi & Ralph S Baric. A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence. *Nature Medicine*, 21 (12), 1508-1514. December 2015. With follow-up letter included: <https://www.nature.com/articles/nm.3985>

³³⁵ Breggin, Peter and Breggin, Ginger (2020, March April 15 & 16, 2020, Video and Blog: 2015 Scientific Paper Proves US & Chinese Scientists Collaborated to Create Coronavirus that Can Infect Humans. <https://breggin.com/us-chinese-scientists-collaborate-on-coronavirus/>

³³⁶ Breggin, Peter and Breggin, Ginger: Video & Blog: Trump Cancels Funding of Us/China Research Making Epidemic Viruses. <https://breggin.com/trump-cancels-funding-of-us-china-research-making-epidemic-viruses/>

Here is the story in more detail:

In 2015, American researchers and Chinese Wuhan Institute of Virology researchers collaborated to transform an animal coronavirus into one that can attack humans. Scientists from prestigious American universities and the US Food and Drug Administration (FDA) worked directly with the two coauthor researchers from Wuhan Institute of Virology, Xing-Yi Ge and Zhengli-Li Shi. Funding was provided by the Chinese and US governments. The team succeeded in modifying a bat coronavirus to make it capable of infecting humans and added to its deadliness. The research was published in December 2015 in the prestigious British journal, *Nature Medicine* by Vineet D. Menachery et al. and titled, “A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence.”³³⁷

In the same year of 2015, the Wuhan Institute became “China’s first laboratory to achieve the highest level of international bio research safety (known as BSL-4).” But by 2018, its safety measures were being seriously questioned by US officials.³³⁸ Since they were lagging far behind the US, Chinese collaboration with us was a boon to them, their new institute, and the Chinese military.

Footnotes to the scientific paper disclose that the research was funded by both the Chinese and US Governments, including grants from Fauci’s NIH Institute of Allergy & Infectious Disease. Footnotes also document that the two Chinese researchers were active in their own newly approved laboratories as part of this coronavirus project. At the bottom of the first page, the affiliation of both Chinese coauthors is listed as “Key Laboratory of Special Pathogens and Biosafety, Wuhan Institute of Virology, Chinese Academy of Sciences, Wuhan, China.” The Chinese were being aided by the American government, American universities, and American researchers in developing a potential military weapon *with the capacity to cause a pandemic intentionally or accidentally*.

Multiple prestigious American researchers and institutions were involved. The first author of the article, Vineet Menachery, is from the Department of Epidemiology, University of North Carolina at Chapel Hill. Several other authors are from the University of North Carolina and one is from Harvard Medical School. One is from the FDA’s National Center for Toxicological Research in Jefferson, Arkansas.

The researchers themselves noted in the text of the article that the risks associated with the creation of their human pathogen were significant. They openly wondered if their research compromised U.S. federal standards for research on dangerous pathogens.

The dangers inherent in creating new human coronavirus pathogens in the US/Chinese Menachery research were exposed in a commentary by Jef Akst in *The Scientist* on November 16, 2015.³³⁹ *However, the danger of the Chinese collaboration went unmentioned.* There seems to be an assumption that “science” is pure and should be shared among competing and even hostile nations for the sake of science and peace, even though we were simultaneously helping the Chinese Communist Party develop a bioweapon. This is the prevailing attitude among globalists.

³³⁷ Menachery, V., Yount, B., Debbink, K. et al., 2015, A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence. *Nature Medicine* 21, 1508-1513 <https://doi.org/10.1038/nm.3985>
Follow-up letter included. <https://www.nature.com/articles/nm.3985>

³³⁸ Kelly, M. & Cahlan, S., 2020, Was the new coronavirus accidentally released from a Wuhan lab? It’s doubtful., *Washington Post*. <https://www.washingtonpost.com/politics/2020/05/01/was-new-coronavirus-accidentally-released-wuhan-lab-its-doubtful/>

³³⁹ Akst, J., 2015, Lab-Made Coronavirus Triggers Debate, *The Scientist*. <https://www.the-scientist.com/news-opinion/lab-made-coronavirus-triggers-debate-34502>

Of all the technologies we have given to China, how to make highly infectious and lethal viruses from bat viruses may be the most dangerous. There was a nearly total lack of concern about China building biological weapons displayed by the media, science commentators, and politicians. This confirmed the pervasiveness of the globalist viewpoint that has no special interest in protecting American interests or seemingly even in America's survival.

We wrote our first blog/report related to COVID-19 on this subject and sent it to the media, and several contacts,³⁴⁰ and with 48 hours President Trump overrode Fauci and cancelled funding.³⁴¹ Both the joint US/Chinese virus and the current pandemic viruses are variants of SARS-CoV. It is now indisputable that the novel coronavirus, similar to but not the same as the one created in the joint US/Chinese research project, was made in the Wuhan facility and accidentally released, followed by the cover up by China and WHO, and then China's enabling of the virus to spread around the world by air traffic.

Why did Fauci fund the joint US/Chinese collaborative venture in making a new epidemic SARS-CoV virus and support the Wuhan Institute itself? It is likely that Fauci was especially interested in the research because it was using the virulent virus as a test case to see if they could create a vaccine for a coronavirus, but the researchers failed. Fauci's search for a vaccine can be seen as a contributing factor to the occurrence of COVID-19, because without our research support and our scientific information sharing with China—and our sharing the actual virus with Chinese researchers—the Wuhan Institute might never have developed the technology to create the SARS-Cov-2 that now afflicts the world.

Fauci was also the person in the best position to make sure that China corrected its well-known security risks in its new highest level of security research facility at the Wuhan Institute. But instead of withholding support from the Wuhan Institute and its researchers until they met the prevailing standards of safety, he continued to fund them. In this way, he is additionally responsible for the leak of the virus that caused COVID-19.

Fauci's support of the US/Chinese collaboration was in part due to his globalist orientation to disregard national interests and to collaborate with all comers. Also, the study was an important aspect of his work with Bill Gates (see part **IV G**) and with the worldwide pharmaceutical industry in developing treatments and vaccines for pandemic viruses.

Fauci has had the most influential scientist and political personality in requiring a shutdown. Because of his support for US/Chinese collaborations in building deadly viruses and his support for the Wuhan Institute, he may also be the individual most responsible for the situation American and the world are in with SARS-CoV-2 and COVID-19 and yet he seems to be seeking increased influence and power for himself, Bill Gates, and the drug companies through the prolongation of the very disaster he helped to create.

On April 15, 2020, we published an analysis, "2015 Scientific Paper Proves US & Chinese Scientists Collaborated to Create Coronavirus that Can Infect Humans," that criticized the research as extremely risky in respect the virus accidentally or purposely being allowed to escape and in giving the virus and the technology to the Chinese Communist Party; and on April 16, I followed up with a video that now has over 50,000 viewers.³⁴² Over those two days, Ginger

³⁴⁰ Breggin, P. and Breggin, G., 2020, Video & Report: US and China Collaborated to Make a Deadly Coronavirus, Psychiatric Drug Facts. <https://breggin.com/us-chinese-scientists-collaborate-on-coronavirus/>

³⁴¹ Breggin, P. and Breggin, G., 2020, Video & Report: Trump Cancels Funding of US/China Research Making Epidemic Viruses, Psychiatric Drug Facts. <https://breggin.com/trump-cancels-funding-of-us-china-research-making-epidemic-viruses/>

³⁴² Breggin, P., 2020, 2015 Scientific Paper Proves US & Chinese Scientists Collaborated to Create Coronavirus that Can Infect Humans, Psychiatric Drug Facts. <https://breggin.com/us-chinese-scientists-collaborate-on-coronavirus/>

Breggin and I began sending the blog report and video to every scientific, media, and political contact available to us.

At a news conference the next day, April 17, 2020, according to *Politico*,³⁴³ a reporter asked President Trump about the funding of the project. The President, who seemed to have been already briefed, stated, “We will end that grant very quickly. It was granted quite a while ago.” *Politico* further reported that the project had become a political liability for NIH by the time the administration wrote the institute on April 20, 2020 demanding “a list of all Chinese participants.” It was shortly after this that *Politico* announced, “Trump cuts U.S. research on bat-human virus transmission over China ties.”

Neither *Politico* nor any major media that we could locate, such as ABC News,³⁴⁴ supported the President’s decision to stop developing and sharing lethal technology with the Wuhan Institute and the government of China. The American researchers justified their efforts as leading to better methods of fighting epidemic viruses. This public health motive might have been the purpose for the naïve US researchers, but Wuhan Institute researchers are part of China’s military establishment.³⁴⁵

It is probable that Fauci’s drive to finally make a coronavirus vaccine—which once again failed in the 2015 study—knew no limits, such as commonsense, ethics, the law, or the protection of America and the world from the accidental or purposeful release of a deadly lab-made coronavirus.

A new book has reportedly confirmed that the Chinese military has command of the Wuhan Institute. The book also “explains the origins of the virus with precision and scientific resolve, starting from the Chinese attempt to study vaccines against SARS, inserting genomes from HIV into organisms (which makes them more aggressive), adding elements of coronavirus discovered in horseshoe bats, using a method called reverse genetics system 2.”³⁴⁶ This confirms what virus and vaccine scientists have shared with me and what I concluded after reading early scientific reports.³⁴⁷

³⁴³ Owerhohle, S., 2020, Trump cuts U.S. research on bat-human virus transmission over China ties, *Politico*. <https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076>

³⁴⁴ Finnegan, C., 2020, Trump admin pulls NIH grant for coronavirus research over ties to Wuhan lab at heart of conspiracy theories, ABC News. <https://abcnews.go.com/Politics/trump-admin-pulls-nih-grant-coronavirus-research-ties/story?id=70418101>

³⁴⁵ Thomson, B., 2020, China ‘appoints its top military bio-warfare expert to take over secretive virus lab in Wuhan’, sparking conspiracy theories that coronavirus outbreak is linked to Beijing’s army. *Daily Mail*.

A small-print note states: “**PUBLISHED:** 06:39 EDT, 14 February 2020 | **UPDATED:** 13:41 EDT, 14 February 2020,” which is when we first found out about it—long before the new article tries to indicate with its fresh headline. <https://www.dailymail.co.uk/news/article-8003713/China-appoints-military-bio-weapon-expert-secretive-virus-lab-Wuhan.html>

³⁴⁶ Cervellera, B., 2020, Prof Tritto: COVID-19 was created in the Wuhan laboratory and is now in the hands of the Chinese military. *AsiaNews.iT*. <http://www.asianews.it/news-en/Prof-Tritto:-COVID-19-was-created-in-the-Wuhan-laboratory-and-is-now-in-the-hands-of-the-Chinese-military-50719.html> A new book from an Italian scientist, not yet translated into English, has come out confirming the ties between the Wuhan institute and the military. The author, Professor Joseph Tritto, is described as president of the Paris-based World Academy of Biomedical Sciences and Technologies (WABT), a non-governmental institution founded in 1997 under the auspices of UNESCO. He also is said to have documented the Wuhan Institute as the source of the virus, as two virus and vaccine experts have told and as I concluded from early research.

³⁴⁷ Coutard, B., et al, 2020, The spike glycoprotein of the new coronavirus 2019-nCoV contains a furin-like cleavage site absent in CoV of the same clade, *Antiviral Research*, vol. 176, 104742. <https://doi.org/10.1016/j.antiviral.2020.104742>
<https://www.sciencedirect.com/science/article/pii/S0166354220300528>

B. Fauci Supports an Expensive, Ineffective and Proven Dangerous Drug

Fauci has called placebo-controlled randomized clinical trials the Gold Standard for testing drugs. The problem is that science is only as reliable as the scientists who plan, monitor, and later promote the clinical trials—and Fauci has showed bias from the beginning. He criticized President Trump for encouraging the use of a very safe and helpful hydroxychloroquine for COVID-19, and then proceeded to push remdesivir which had failed in two earlier trials, one because too many patients were dying and the other because it did not help.

By Fauci's gold standard of clinical trials, Remdesivir should have been trashed before its clinical trial began and other more hopeful drugs should have replaced it at the head of line. Fauci had to know from the beginning that remdesivir was a failed antiviral drug that would probably do more harm than good. An earlier, famous remdesivir trial for Ebola was stopped because remdesivir was causing a significantly higher mortality rate than other antiviral drugs in the same trial.³⁴⁸ As one recent medical source noted, the remdesivir arm of the Ebola trial had to be aborted "because of an increase in death among patients taking it, meaning it did not help those patients."³⁴⁹

Then, shortly before Fauci began his remdesivir clinical trial, a strong peer-reviewed article with a double-blind was published indicating that remdesivir is both useless and dangerous in treating COVID-19. The *Lancet* study found remdesivir devoid of any statistically significant clinical improvements:³⁵⁰

***Interpretation** In this study of adult patients admitted to hospital for severe COVID-19, remdesivir was not associated with statistically significant clinical benefits. (p. 1, bold in original).*

In addition, the study found no antiviral effect for the drug in human patients:

Remdesivir did not result in significant reductions in SARS-CoV-2 RNA loads or detectability in upper respiratory tract or sputum specimens in this study. (p. 9)

More frightening, remdesivir produced very severe adverse reactions in the form of "respiratory failure" or "acute respiratory distress syndrome" in 5% of patients. In other words, five of every 100 patients taking remdesivir developed a life-threatening decline in their condition. This echoes the findings of the disastrous remdesivir Ebola trial.³⁵¹

³⁴⁸ Mulangu, S., et al, 2019, A Randomized, Controlled Trial of Ebola Virus Disease Therapeutics, The New England Journal of Medicine. N Engl J Med 2019; 381:2293-2303. DOI: 10.1056/NEJMoa1910993 <https://www.nejm.org/doi/full/10.1056/NEJMoa1910993>

³⁴⁹ MedicineNet, 2020, Remdesivir (RDV): Experimental Antiviral for Coronavirus (COVID-19), MedicineNet. https://www.medicinenet.com/remdesivir_rdv Ebola covid-19 coronavirus trial/article.htm#what_is_remdesivir_rdv

³⁵⁰ Wang, Y., et al, 2020, Remdesivir in adults with severe COVID-19: a randomized, double-blind, placebo-controlled, multicentre trial. DOI: [https://doi.org/10.1016/S0140-6736\(20\)31022-9](https://doi.org/10.1016/S0140-6736(20)31022-9) <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2931022-9>

³⁵¹ The authors found that "More patients in the remdesivir group than the placebo group discontinued the study drug because of adverse events or serious adverse events (18 [12%] in the remdesivir group vs four [5%] in the placebo group), among whom seven (5%) were due to respiratory failure or acute respiratory distress syndrome in the remdesivir group. (p. 10)

Long before his promotion of remdesivir and his corruption of its clinical trial, Fauci already professionally invested in Gilead, the manufacturer of remdesivir. Fauci's institute already had a panel for the purpose of developing treatment guidelines for the pandemic on an ongoing basis. It is called "NIH COVID-19 Treatment Guidelines." Hundreds of drugs were coming up the pipeline seeking federal approval for treating the novel coronavirus.³⁵² On a government treatment advisory panel, would you expect to find a dominant membership block that was financially indebted to one drug company with a single drug, while almost every other drug company and their drugs were left out?

Of the 50 members on Fauci's committee to set treatment guidelines, only 11 had financial ties to drug companies.³⁵³ *But nine of the eleven had financial ties to Gilead, remdesivir's manufacturer.* The ties consisted of "Research Support," "Consultant," and "Advisory Board." Put simply, from the beginning, Fauci was stacking his treatment guidelines committee with Gilead, remdesivir's manufacturer.

The stacked panel, *before any clinical trials*, came out strongly in favor of the highly experimental remdesivir and wholly against the commonly used hydroxychloroquine: "On the basis of preliminary clinical trial data, the Panel recommends the investigational antiviral agent remdesivir for the treatment of COVID-19 in hospitalized patients with severe disease" and "The Panel **does not recommend remdesivir** for the treatment of mild or moderate COVID-19 outside the setting of a clinical trial" (bold in original). Fauci's outcome was predetermined from the start.³⁵⁴

What did Gilead get from Fauci? The remdesivir clinical trial was "sponsored by the National Institute of Allergy and Infectious Diseases (NIAID)" and was "the first clinical trial launched in the United States to evaluate an experimental treatment for COVID-19."³⁵⁵

NIH organized and funded their trial, saving Gilead in the range of \$100,000,000 dollars and, more importantly, years of time, while Fauci did his best to clean up any messy results.

Fauci and his institute collaborated with his favorite corporation, Gilead, to get expedited approval for Remdesivir.³⁵⁶ Gilead is estimated to have spent one billion dollars on developing and promoting Remdesivir on its own and Fauci's institute is estimated to have contributed 70 million more dollars to implementing the NIH clinical trial of the drug.³⁵⁷

Once Fauci got the remdesivir study going, he had to start manipulating it. One example was highlighted by a May 1, 2020 headline in *The Washington Post*: "Government researchers

³⁵² Dunn, A., 2020, There are already 72 drugs in human trials for coronavirus in the US. With hundreds more on the way, a top drug regulator warns we could run out of researches to test them all, Business Insider.

<https://www.businessinsider.com/fda-woodcock-overwhelming-amount-of-coronavirus-drugs-in-the-works-2020-4>

³⁵³ NIH, 2019-2020, Appendix A, Table 2. COVID-19 Treatment Guidelines Panel Financial Disclosure for Companies Related to COVID-19 Treatment or Diagnostics, NIH.

<https://www.covid19treatmentguidelines.nih.gov/panel-financial-disclosure/>

³⁵⁴ NIH, 2020, What's New in the Guidelines, NIH. <https://www.covid19treatmentguidelines.nih.gov/whats-new/>

³⁵⁵ NIH, 2020, NIH clinical trial of remdesivir to treat COVID-19 begins, NIH. <https://www.nih.gov/news-events/news-releases/nih-clinical-trial-remdesivir-treat-covid-19-begins>

³⁵⁶ Strauss, D., 2020, FULL INTERVIEW: Houston-area doctor in viral video touting hydroxychloroquine as virus cure doubles down on claims, Click2Houston. <https://www.click2houston.com/news/local/2020/07/31/full-interview-houston-doctor-in-viral-video-touting-hydroxychloroquine-as-virus-cure-doubles-down-on-claims/>

³⁵⁷ Brennan, Z., 2020, Remdesivir helps coronavirus patient – but at what cost?, Politico.

<https://www.politico.com/news/2020/05/06/remdesivir-helps-coronavirus-patients-but-at-what-cost-240230>

changed metric to measure coronavirus drug remdesivir during clinical trial.”³⁵⁸ The trial had changed the primary metric for measuring success, a mere two weeks before Fauci’s announcement that the drug would be the new “standard of care.”

When clinical trials are begun, the researchers are required to establish the “endpoints,” including a “primary endpoint,” which is the major measure of outcome and the main criterion for success. That is what the *Washington Post* was referring to as the metrics. The endpoints for remdesivir are listed in the original plan for the trials called the protocols. These initial endpoints included truly meaningful criteria, such as the all-important lowered fatality rate and complete recovery.³⁵⁹

As the trial continued, it must have become apparent to Fauci that his drug was not going to reduce mortality or even lead a meaningful definition of recovery. The one primary marker for success became “time to recovery”—two out of three possibilities for being recovered *included patients who remained hospitalized or who were at home requiring limitations on their activities and/or requiring oxygen*.³⁶⁰ Here are the three categories for “success”:

*1) Hospitalized, not requiring supplemental oxygen – no longer requires ongoing medical care; 2) Not hospitalized, limitation on activities and/or requiring home oxygen; 3) Not hospitalized, no limitations on activities.*³⁶¹

Not only did recovery time become the single primary criterion for improvement, “recovery” was achieved even when the patient remained in the hospital or returned home with limited activities and/or requiring oxygen.

Fauci’s NIH press release estimated that remdesivir shortened the recovery time for the COVID-19 illness by a mere four days (from 15 to 11).³⁶² But as inadequate as that sounds for a wonder drug’s only achievement, it looks ridiculous when realizing that Fauci still had to reinvent the concept of recovery in order to get those limited results.

Also, Fauci or the media told few people that remdesivir *must be given intravenously over a ten-day period*. This procedure itself has risks. It also limits its use to patients sick enough to be hospitalized. As a result, it cannot be used as hydroxychloroquine is used around the world, as a prophylaxis and as a treatment to be given at the earliest signs of the disease before any need for hospitalization.

Finally, the remdesivir trials must have been a complete bust because Fauci terminated them ahead of time by breaking the double-blind. In an interview, Fauci said that the results of the remdesivir trial were so promising, there was “an ethical obligation to immediately let the placebo group know so they can have access” to the drug.³⁶³ But that was a lie. As noted, the

³⁵⁸ Rowland, C., 2020, Government researchers changed metric to measure coronavirus drug remdesivir during clinical trial, The Washington Post. <https://www.washingtonpost.com/business/2020/05/01/government-researchers-changed-metric-measure-coronavirus-drug-remdesivir-during-clinical-trial/>

³⁵⁹ Schwitzer, G., 2020, What the public didn’t hear about the NIH remdesivir trial, Health News Review. <https://www.healthnewsreview.org/2020/04/what-the-public-didnt-hear-about-the-nih-remdesivir-trial/>

³⁶⁰ Clinical Trials, 2020, History of Changes for Study, Clinical Trials. <https://clinicaltrials.gov/ct2/history/NCT04280705?A=10&B=16&C=Side-by-Side#StudyPageTop>

³⁶¹ Clinical Trials, 2020, Adaptive COVID-19 Treatment Trial, Clinical Trials. <https://clinicaltrials.gov/ct2/show/NCT04280705>

³⁶² NIH, 2020, NIH Clinical Trial Shows Remdesivir Accelerates Recovery from Advanced COVID-19, NIH. <http://breggin.com/coronavirus/remdesivir/NIH-release-Remdesivir-Accelerates-Recovery-4-29-20.pdf>

³⁶³ Edwards, E., 2020, Remdesivir shows promising results for coronavirus, Fauci says, NBC News. <https://www.nbcnews.com/health/health-news/coronavirus-drug-remdesivir-shows-promise-large-trial-n1195171>

study at best was going poorly. Furthermore, as described earlier in the section of the report, two earlier clinical trials showed that remdesivir was potentially lethal. *By encouraging placebo patients to switch to remdesivir in the NIH clinical trials, Fauci exposed them to potentially lethal adverse effects.*

Fauci's remdesivir was never allowed to meet Fauci's own gold standard—a finished placebo-controlled clinical trial. This turned Fauci's "gold standard" into one of the weakest kinds of study, an open observational study—one in which highly biased researchers and analysts, such as Fauci, manipulate the unblinded data and offer their subjective opinions. Meanwhile, we will never know just how ineffective and damaging the drug had become to bring about this radical, unethical destruction of the clinical trial. What a bizarre ending to the miracle drug that Fauci so highly touted two weeks earlier, declaring "This will be the standard of care."³⁶⁴

The point has not been to discredit Dr. Anthony Fauci, but to exemplify the dangers when a scientist becomes the framer and monitor of public health policies and practices. Fauci not only encouraged drastic shutdowns, he even manipulated the Remdesivir clinical trials to satisfy the needs of the larger system in which they are enmeshed, including the global pharmaceutical empire.

Fortunately, there are other physicians and scientists both in the news and on Twitter, who have spotted that Fauci is untrustworthy in his handling of the trials.³⁶⁵ However, unless the political tide turns against top-down coercive public health policies and measures, the nation will continue to move toward increasingly totalitarian rule.

³⁶⁴ Clancy, C.J., 2020, Fauci on remdesivir for COVID-19: 'This will be the standard of care', Healio. <http://breggin.com/coronavirus/remdesivir/Fauci-on-remdesivir-for-COVID-19-This-will-be-the-standard-of-care.pdf>

³⁶⁵ Schwitzer, G., 2020, What the public didn't hear about the NIH remdesivir trial, Health News Review. <https://www.healthnewsreview.org/2020/04/what-the-public-didnt-hear-about-the-nih-remdesivir-trial/>

XI. Collective Immunity and COVID-19

Many physicians like myself have been deeply puzzled by the switch in goals by public health scientists and government officials. The nation went from temporarily shutting down to prevent overloading of the health system to long-term shutdowns to prevent the spread of the disease. Commonsense observers warned of the futility of trying to prevent the spread of a virus that in most or many cases shows little or no signs of its presence. Only when a viral disease is virulent, making most people deathly sick, can it be slowed down or stopped by identifying and isolating those people, as has been done with Ebola and other earlier outbreaks. When the effects of a virus are as subtle and varied as the common cold, there is no way to eradicate it by isolating everyone.

So why are some many states reconsidering or employing draconian measures as COVID-19 spreads? Some of these drastic steps are driven by misinformation which is widespread in the media. But some of it is driven by this worldwide impulse toward using the pandemic as an excuse for exerting authoritarian and totalitarian measures.

One of the most virulent outbreaks of COVID-19 occurred in the Brazilian city of Manaus, in the heart of the Amazon rain forest and at the frontier of the Amazon river. *The Washington Post* reported that the skyrocketing hospitalizations of COVID-19 patients in Manaus has receded since May 2020 to less than 300 in August 2020.³⁶⁶ And deaths from COVID-19 have fallen to “practically zero.” This is especially surprising because “Manaus never imposed a lockdown or other strict containment measures...And what policies did exist, many people ignored,” according to *The Washington Post*. Scientists speculate in the article that the mass exposure during the outbreak in April and May 2020 led to a collective or community immunity, commonly called herd immunity.

Sweden, once reviled for its failure to enforce strict “public health” rules, is proving the potential value of leaving most restrictions to the voluntary choice of individuals. Sweden’s strategy of largely relying upon voluntary social distances is resulting in a remarkable economic recovery and a tailing off of the both new cases and deaths.³⁶⁷ It may be too early to determine if Sweden has been as successful as it now seems, but the signs are very good. Certainly, the Swedish experience is making an argument for remaining a democracy rather than a totalitarian state during COVID-19.

Sweden refused to lockdown and did not enforce most social distancing measures including masks and closing schools and is now experiencing a falling rate of infections after having a much higher number of deaths during the spring outbreak of COVID-19. It becomes a complex equation weighing the increased initial death rate and perhaps the longer-term success compared to countries that rigorously shut down.³⁶⁸

³⁶⁶ Washington Post. https://www.washingtonpost.com/world/the_americas/brazil-coronavirus-manaus-herd-immunity/2020/08/23/0eccda40-d80e-11ea-930e-d88518c57dcc_story.html?utm_campaign=wp_post_most&utm_medium=email&utm_source=newsletter&wpisrc=nl_most

³⁶⁷ Savage, M. (2020, July 24). Did Sweden's coronavirus strategy succeed or fail? BBC News. <https://www.bbc.com/news/world-europe-53498133>

³⁶⁸ Steiner, Rupert. Market Watch. <https://www.marketwatch.com/story/sweden-has-developed-herd-immunity-after-refusing-to-lock-down-experts-claim-its-coronavirus-infection-rate-is-falling-2020-08-24>

In the United States, an August 24, 2020 analysis indicates that states that did not do hard lockdowns seem to have lowest death rates and, naturally, higher employment rates.³⁶⁹

*To assess Fauci's claims that stay at home orders, in particular, are a model policy that every state should have adopted, we can look to **Utah, South Dakota, North Dakota, Nebraska, Iowa, Wyoming, and Arkansas**. These are the only seven states to never issue stay at home orders and the results are telling, but not necessarily in Dr. Fauci's favor.*

All seven states outperformed the majority of the country in both minimizing death as well as protecting their economies. Some of these states even experienced spikes in cases and still managed the disease far better than states with similar caseloads that issued a stay at home order. ...

There is no definitive evidence to suggest that stay at home orders are effective at addressing COVID-19. Furthermore, the United States experiment with the policy has yielded results that are not favorable to Dr. Fauci's suggestion regarding the nationwide implementation of stay at home orders. (bold in original)

Similarly, some states with the most draconian measures, such as New York, have the highest death rates.

Evaluating the variables that go into comparing states for the success of their public health policies and practices is complicated and difficult, and studies do not even try to evaluate the emotional harms of loss of liberty itself, including its impact on dignity and pride. Nonetheless, the weight of evidence seems to be that the lockdown was too draconian and has done considerably much more harm than good.

³⁶⁹ Yang, E. (2020, August 24). A Closer Look at the States that Stayed Open. American Institute for Economic Research. <https://www.aier.org/article/a-closer-look-at-the-states-that-stayed-open/>

XII. Conclusion: The Constitution and the Bill of Rights Must Supersede Public Health Totalitarianism

There is little or no scientific or genuine public health justification for the enormous crackdowns on human life taking place in America and around the world in response to COVID-19. This report examines the validity of all elements of government activity and public health policies and practices, not one of which justifies the oppressive demands being made on the citizenry.

Some experienced and well-informed experts and scientists do not even believe that distancing is required except in small, cramped quarters crowded with people and that even then three feet is a safe separation. Some believe that the masks are too dangerous to the wearer to be used outside of treatment settings. As for massive government shutdowns and stay-at-home orders, there is no historical precedent or scientific evidence to justify them. The radical idea has been recently generated by the minds of public health scientists and politicians with a strong bent to enforcing top-down government for the duration.

As the daily updated chart on our Coronavirus Resource Center shows, the number of deaths in the US declined abruptly after its April peak and remains low.³⁷⁰ This is key: the number of *cases* go up as the virus inevitably spreads through the country, but the death rate remains fairly stable and relatively low. Few medical facilities are being overwhelmed. This is good news.

Almost every informed expert agrees that children are remarkably safe from COVID-19 and much less at risk than from the annual flu. They also agree that children are not likely to infect each other and adults, and that they should be allowed to resume school with minimal precautions. Only older or chronically ill teachers need to offer distance learning to protect their own health.

There is also agreement that any serious risk of lethality from the coronavirus is limited to older people and those with multiple comorbid disorders. The death rate escalates around age 75, in part because older people have a much higher proportion of multiple physical infirmities.

People 65 and older account for 70%-94% of all deaths, depending on the state.³⁷¹ This means that overall death-rate estimates are mostly accounted for by deaths of people 65 and older. This indicates that most preventive efforts can and should be focused on the relatively small population of older people, especially those with preexisting illnesses.

It is difficult to get accurate, reliable statistics on the actual annual rate of death from the coronavirus, probably because it is much lower than the experts and advocates of top-down government control predicted and they do not want the public knowing how low it is. Former *New York Times* science reporter, Alex Berenson, whose work seems both independent and reliable, made an annual rate estimate of 0.26% in June, which is far below estimates from public health pundits who were predicting up to 5.0% or more.³⁷² Berenson's relatively low estimate

³⁷⁰ The Breggin's Coronavirus Resource Center, from Our World in Data, <https://breggin.com/coronavirus-resource-center/>

³⁷¹ Freed, M. et al., 2020, July 24. KFF Coronavirus Stats (based on CDC data up to July 22, 2020). <https://www.kff.org/coronavirus-covid-19/issue-brief/what-share-of-people-who-have-died-of-covid-19-are-65-and-older-and-how-does-it-vary-by-state/> CDC data at <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html>

³⁷² Berenson, A., 2020, June 27, Getting realistic about the coronavirus death rate. New York Post. <https://nypost.com/2020/06/25/getting-realistic-about-the-coronavirus-death-rate/>

of a 0.26% annual death rate was identical to the CDC's own best estimate made in June 2020, a figure which disappointed and frustrated the mainstream pundits.³⁷³

On June 27, 2020, Berenson summarized:

The actual figure could be as low as 0.1 percent or as high as 0.4 to 0.5 percent, though treatment advances should mean it will trend lower over time. Even at 0.26 percent, the rate is still significantly higher than influenza most years, more comparable to a bad flu strain like the 1968 Hong Kong flu.

To this, it can be added the virus may be losing its lethality as time goes on, which is consistent with the virus's inability to maintain a stable form.

Meanwhile, all these figures, even those from the reliable Berenson, are based largely or entirely on CDC reporting and these CDC estimates are turning out to be wildly inflated. In the last few days, the CDC reported that the coronavirus was the sole or only cause of death in a mere 6% of coronavirus deaths reported to the CDC and that 94% had an average of 2.5 other listed causes.³⁷⁴

It is beginning to look like a great proportion of deaths were actually caused by other diseases and that much of the threat from COVID-19 has been manufactured by experts, public health scientists, and government agencies. These special interest groups want to frighten Americans into conforming to drastically suppressive measures while the government subsidizes the pharmaceutical industry in its massive efforts to find a better drug than hydroxychloroquine and an elusive and perhaps unmakeable vaccine.

Although COVID-19 is a serious pandemic, it is not nearly the scourge it was made out to be and it is probably less dangerous to children and young adults than the flu, while it becomes a considerable threat to older people, especially those with comorbid disorders.

At the bidding of the pharmaceutical companies and its allies, leaders of the shutdown are using censorship, threats, and outright coercion to exclude the most safe and effective treatment, hydroxychloroquine. Researchers have literally given lethal doses of hydroxychloroquine to patients in clinical trials, in some cases killing them, to make this extremely safe drug look deadly. Meanwhile, as described in the report, the CDC has become irrational in its attempts to make COVID-19 seem much more deadly than it is, including counting obvious deaths from other causes as long as the presence of SARS-Cov-2 is suspected.

Innumerable independent scientists and physicians, those not under the thrall of the government and pharmaceutical industry, believe we are losing lives in America and elsewhere by prohibiting the use of hydroxychloroquine, especially in combination with azithromycin and zinc. President Trump recently chose a new advisor and member of the White House Coronavirus Task Force, physician Scott Atlas, who yesterday declared that "the drug hydroxychloroquine has gotten a bad rap thanks to politics, media hype, and some 'garbage'

³⁷³ Richardson, I. 2020, June 5, Fact check: CDC's estimates COVID-19 death rate around 0.26%, doesn't confirm it, USA Today. <https://www.usatoday.com/story/news/factcheck/2020/06/05/fact-check-cdc-estimates-covid-19-death-rate-0-26/5269331002/>

³⁷⁴ National Center for Health Statistics. Weekly Updates by select demographic and geographic characteristics: Provisional death counts for Coronavirus Disease 2019 (COVID-19). See the small print under "Comorbidities" near bottom of the page. https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm

medical research.”³⁷⁵ He elaborated, “I sort of make the analogy that we all know objective journalism is basically dead in this country, I’m very cynical about that, and now what we’re seeing is that objective science is nearly dead. ... Hydroxychloroquine is super safe. It’s a complete myth, it’s a total distortion, to say that, oh, my God, this drug is very dangerous for people. It’s been used for 65 or 70 years, not just prophylactically for malaria, which I used it myself for that many years ago, but also used for people with things like rheumatic arthritis, autoimmune-type diseases. Very safe drug.” Dr. Atlas’ thoughts are consistent with the conclusions of this report.

Our observations in this report on the probably massive overcounting of coronavirus deaths in the US has received further confirmation in the last week from Sweden’s recent experience:³⁷⁶

Sweden's Public Health Agency said Tuesday a faulty test kit had returned some 3,700 false positive results, an error discovered by two laboratories during routine quality controls.

The agency said the PCR kits, which test for an ongoing COVID-19 infection, were made in China by the company BGI Genomics and had been distributed worldwide.

Some the most corrupt practices in the name of public health are to satisfy the ravenous appetite of the pharmaceutical industry for wealth and power. But something much more threatening is going on than pandering to big industries. COVID-19 is being used to give energy to an ancient but relentless movement in the world that is pushing harder than ever toward greater top-down government, authoritarianism, and even totalitarianism. The plan is to threaten us so horrifically with falsehoods about COVID-19 that we will continue to forsake the principles of the Declaration of Independence and especially the Constitution and the Bill of Rights.

The US Constitution and the Bill of Rights are *intended for* emergencies, not *expendable during* emergencies. We must cleave to them and enforce them with even more vigor when the population feels under assault and frightened by an enemy like COVID-19. If human societies were not plagued by perceived or real emergencies and if seemingly good people were not easily corrupted by the lust for power, there would be no need for a Bill of Rights. Individual rights are the heart of the American Experiment. By becoming lulled into bypassing the Constitution and the Bill of Rights, we risk the rapid unraveling of the American Dream and its foundation in individual liberty.

The global movement to promote topdown government can only achieve its end by trampling on individual rights. It is authoritarian and it is bordering on outright totalitarianism. In countries around the world, from democracies to dictatorships, public health policies and practices, allegedly to control COVID-19, are being used to ratchet up measures of top-down control. In the US, with compliance or outright support from the left and the right, politicians are

³⁷⁵ Richardson, V. (2020, August 29). Hydroxychloroquine 'very safe,' says Dr. Scott Atlas; blasts 'garbage' medical studies. Washington Times. <https://www.washingtontimes.com/news/2020/aug/29/hydroxychloroquine-uproar-shows-objective-science/>

³⁷⁶ CCO Public Domain. Sweden uncovers 3,700 false positives from COVID-19 test kit, (2020, August 25). Medical Press. <https://medicalxpress.com/news/2020-08-sweden-uncovers-false-positives-covid.html>

throwing their weight behind persistently locking down America, and with it, our Republic and democracy. They are working in collaboration with giant international corporations who want to own the governments of the world and with the support of news media, network TV, universities, the Deep State bureaucracy, organized sports, and entertainment—all calling for more top-down government and less individual liberty.

The Founders created the United States of America as the first nation on Earth based on the principle of individual liberty—a principle so powerful that it would eventually help to justify a Civil War in which many volunteers personally chose to risk and to give their lives to liberate the slaves. This principle of liberty would eventually eradicate Jim Crow laws and vastly increase the opportunities for women and minorities in America. The American ideal of liberty continues to promote freedom around the world by protecting and supporting democracies. This is not to say America is perfect, but it is to confirm that our ideals are the best ever conceived and built into a nation's founding and laws.

Because human beings are so imperfect, and because larger institutions amplify those imperfections, there can be no end to the work of defending and expanding liberty. As events around the world constantly remind us, liberty is a mighty spearhead of progress, yet a fragile construct like a thin crystal held together and polished only by the devotion and determination of brave people. Liberty can be set back and shattered in the blink of an eye.

Fighting for liberty is a process requiring endless toil because it must overcome the fears and prejudices of people and the lust for power of more tyrannical ones. For the first time ever perhaps, Americans have dramatically forfeited their liberty almost overnight without a fight because it has been cloaked as a necessity of public health. This must be reversed; liberty must be recovered by reimplementing the Constitution and the Bill of rights, along with our great traditions of freedom, individuality, and independence.

There is no other nation in the world that can or will even try reverse this worldwide catastrophe—not COVID-19 but opportunistic authoritarianism and totalitarianism. With its grounding in the Constitution and Bill of Rights, and a people who love liberty, America must lead.

Peter R. Breggin, MD

Three attachments follow:

Attachment 1. Table of *The Three Dynamics of Human Progress for Individuals, Institutions, and Societies* excerpted from *Beyond Conflict: From Self-Help and Psychotherapy to Peacemaking*, by Peter R. Breggin MD

THE THREE DYNAMICS OF HUMAN PROGRESS FOR INDIVIDUALS, INSTITUTIONS, AND SOCIETIES



INDIVIDUAL SPIRITUAL STATE MODE OF INTERACTION

DYNAMIC I: LOVE—THE HIGHEST PRINCIPLE OF LIFE

<i>Beingness</i>	<i>Loving Affiliation or Gifting</i>
The Human as a Being or Soul	Abhorrence of Force
Self as Source of Love	Mutual Unconditional Love
Reverence for Self	Treasuring of All People
Acceptance of Self & Life	Peace & Harmony with Life
Spiritual Self-fulfillment	Kindness, Empathy, & Generosity
Equal Worth of All Selves	Concern for Human Destiny
Communality of All Selves	Humanity as One Family
Integrity, Wholeness of Self	Oneness with Nature, God, Life
Devotion to Higher Values	Promotion of Liberty & Love
Love of Truth & Knowledge	Enlightenment

DYNAMIC II: LIBERTY— THE NECESSARY PRINCIPLE FOR PROGRESS

<i>Doingness</i>	<i>Voluntary Exchange</i>
The Human as Agent or Doer	Force Limited to Self-defense
Self as Creator of Effects	Control over Physical Universe
Uniqueness of Self	Concern with Personal Satisfaction
Responsibility; Honesty	Contracts & Agreements
Egoism & Self-interest	Competition; Limited Cooperation
Respect for Self	Personal and Business Ethics
Self-direction; Autonomy	Bargaining and Free Enterprise
Reliance on Reason	Scientific & Technical Progress
Individualism	Respect for Rights & Freedoms
Personal Success	Personal & Socioeconomic Progress
Antiauthoritarianism	Open, Pluralistic Society

DYNAMIC III: COERCION—THE MOST DESTRUCTIVE PRINCIPLE OF LIFE

<i>Thingness</i>	<i>Involuntary Relationships</i>
The Human as Object or Thing	Arbitrary or Unlimited Force
Self as a Reaction or Effect	Prediction & Social Control
Self-hate & Self-oppression	Hatred & Violence to Attain Ends
Selfishness & Egoomania	Envy & Distrust; No Cooperation
Dishonesty toward Self	Lying, Cheating, & Fraud
Out of Touch with Self	Alienation, Remoteness
Anti-individualistic	Adjustment & Survival Values
Biological View of Self	Physical Theories & Therapies
Behavioral View of Self	Behavioral Theories & Therapies
Mechanistic View of Self	Scientism
Personal Failure; Psychosis	Socioeconomic Decline
Authoritarianism	Closed, Totalitarian Society

Attachment 2. Dr. Breggin's Expert Qualifications for this Case

This legal case is unusual in its breadth of issues, spanning multiple areas of expertise. My opinions will include the effects of government policies and practices on the psychosocial well-being of individual persons and on society itself. It will examine specialized topics such as the approval of medications by the FDA and the evaluation of adverse drug effects, including death as an adverse effect of antiviral medications.

My resume including extensive forensic experience and a complete bibliography is attached. I have published 73 peer reviewed articles and letters spanning from 1964 to June 2020, and 24 professional books spanning 1962 to 2014. I have also written many non-medical articles and book chapters on related subjects that can be found in my Resume, **Part V: Chapters in Professional Books, Letters to The Editor in Public Media, And Other Selected Publications.**

As a physician and psychiatrist, I am best known for my expertise in the field of psychiatric drugs, the FDA drug approval process, and the politics of the pharmaceutical industry, so I will begin with my additional expertise and publications on broader political, ethical, and societal issues, including the effects of liberty and its deprivation.

A. Publications Regarding Broader Issues of Liberty, Society and Ethics

I have published on a broad array concerns about liberty vs. authoritarianism and totalitarianism. From my Resume bibliography (**Attachment**), here are a selection of peer-reviewed articles related to the subject of liberty, social control, and the results of coercion and oppression:

Breggin, Peter. "Coercion of Voluntary Patients in an Open Hospital." *Archives of General Psychiatry*, 10:173-181, 1964. Reprinted with a new introduction in Edwards, R.B. (ed): *Psychiatry and Ethics*. Buffalo, Prometheus Books, 1982, and in Edwards, R.B. (ed): *Ethics of Psychiatry*. Amherst, New York, Prometheus Books, 1997.

Breggin, Peter. "Psychotherapy as Applied Ethics." *Psychiatry*, 34:59-75, 1971.

Breggin, Peter. "Therapy as Applied Utopian Politics." *Mental Health and Society*, 1:129-146, 1974.

Lundy PJ and Breggin, Peter. "Psychiatric oppression of prisoners." *Psychiatric Opinion*. 11(3):30-7, 1974.

Breggin, Peter. "Psychosurgery for Political Purposes." *Duquesne Law Review*, 13:841-862, 1975.

Breggin, Peter. "Psychiatry and Psychotherapy as Political Processes." *American Journal of Psychotherapy*, 29:369-382, 1975.

Breggin, Peter. "Madness is a Failure of Free Will; Therapy Too Often Encourages It." *Psychiatric Quarterly*, 53:61-68, 1981. Originally published (in French) in Verdiglione A (ed): *La Folie Dans La Psychoanalyse*. Paris, Payot, 1977.

Breggin, Peter. "The Three Dynamics of Human Progress: A Unified Theory Applicable to Individuals, Institutions and Society." *Review of Existential Psychology and Psychiatry*, 21(1-3):97-123, 1988-89.

Weinberg MH and Breggin, Peter. "The homeless mentally ill." *American Journal of Psychiatry*, 148(5):690-1, 1991.

Breggin, Peter. "Psychosurgery for Political Purposes." *Duquesne Law Review*, 13:841-862, 1975.

Breggin, Peter. "Psychiatry and Psychotherapy as Political Processes." *American Journal of Psychotherapy*, 29:369-382, 1975.

Breggin, Peter and Breggin, Ginger Ross. "A Biomedical Programme for Urban Violence Control in the US: The Dangers of Psychiatric Social Control." *Changes: An International Journal of Psychology and Psychotherapy*, 11(1) (March):59-71, 1993.

Breggin, Peter. "Campaigns Against Racist Federal Programs by the Center for the Study of Psychiatry and Psychology." *Journal of African American Men*, 1(3), 3-22, Winter 1995/96.

Breggin, Peter. "Empowering social work in the era of biological psychiatry." [The annual Ephraim Lisansky lecture of the University of Maryland School of Social Work.] *Ethical Human Sciences and Services*, 3:197-206, 2001.

Breggin, Peter. "Psychopharmacology and human values." *Journal of Humanistic Psychology*, 43: 34-49, 2003.

Breggin, Peter. "The Rights of Children and Parents in Regard to Children Receiving Psychiatric Drugs." *Children & Society*, 28, 231-241, 2014.

One of my book chapters that seems especially appropriate to issues in this case is:

Breggin, Peter. A hierarchy of values for evaluating human progress on an individual, institutional and societal basis," in Kollenda K (ed): *Ethical Individualism and Organizations*. New York: Praeger, 1988.

I have also published several books, some coauthored with my wife, Ginger Ross Breggin, relating to these larger issues of liberty, the effects of losing liberty, and related human values:

Breggin, Peter. *Beyond Conflict: From Self-Help and Psychotherapy to Peacemaking*. (St. Martin's, NY, 1992).

Breggin, Peter & Breggin, Ginger. *The War Against Children of Color: Psychiatry Targets Inner City Children*. (Common Courage Press, ME, 1998) (with Ginger Breggin) Revision and update of *The War Against Children*. (St. Martin's, NY, 1994).

Breggin, Peter. *Reclaiming Our Children: A Healing Solution to a Nation in Crisis*. (Perseus Books, Cambridge, MA, 2000).

Breggin, Peter; Breggin, Ginger; and Bemak, Fred. Eds.). *Dimensions of Empathic Therapy*. Springer Publishing, NY, 2002)

Breggin, Peter. *Wow, I'm an American! How to Live Like Our Nation's Heroic Founders*. (Lake Edge Press, Ithaca, NY, 2009).

B. Peer-Reviewed Publications Related to the Pandemic of Lethargic Encephalitis and its Extraordinary Neurological and Neuropsychiatric Sequelae

Breggin, Peter. "Parallels Between Neuroleptic Effects and Lethargic Encephalitis: The Production of Dyskinesias and Cognitive disorders." *Brain and Cognition*, 23:8-27, 1993.

Breggin, Peter. "Brain Damage, Dementia and Persistent Cognitive Dysfunction Associated with Neuroleptic Drugs: Evidence, Etiology, Implications." *Journal of Mind Behavior*, 11:425-464, 1990.

Breggin, Peter. "Encephalitis lethargica." *Journal of Neuropsychiatry and Clinical Neurosciences*, 7(3), 387, 1995.

I also discuss the epidemic of lethargic encephalitis (occurred nearly simultaneous with the Spanish Flu Pandemic during and after WW I) in some of my medical books, especially the first and second editions of *Brain-Disabling Treatments in Psychiatry* (see below).

C. Publications Related to Adverse Drug Reactions, Drug Development and Marketing, and Problems within the FDA

Setting aside my many popular or mass market books on these subjects, some coauthored by Ginger Ross Breggin, here are my medical textbooks that deal with these larger issues of the politics of drug approval the pharmaceutical empire, and the FDA including both electroshock (ECT) and medications:

Breggin, Peter. *Electroshock: Its Brain-Disabling Effects* (Springer, NY, 1979).

Breggin, Peter. *Psychiatric Drugs: Hazards to the Brain* (Springer, NY, 1983).

Breggin, Peter. *Brain-Disabling Treatments in Psychiatry: Drugs, Electroshock, and the Role of the FDA* (Springer, NY, 1997).

Breggin Peter. *Brain-Disabling Treatments in Psychiatry: Drugs, Electroshock and the Psychopharmaceutical Complex, Second Edition* (Springer Publishing Company, NY, 2008).

Breggin, Peter. *Psychiatric Drug Withdrawal: A Guide for Prescribers, Therapists, Patients, and their Families.* (Springer Publishing Company, NY, (2013).

I have also written numerous books chapters and non-medical articles on these subjects, but I will limit myself to mentioning a few peer-reviewed articles:

Breggin, Peter. "Psychotherapy in the Shadow of the Psycho-Pharmaceutical Complex," *Voices* (journal of the American Academy of Psychotherapists), 27:15-21, 1991

Breggin, Peter. "Recent U.S., Canadian and British regulatory agency actions concerning antidepressant-induced harm to self and others: A review and analysis." *Ethical Human Psychology and Psychiatry*, 7, 7-22, 2005. Simultaneously published in the *International Journal of Risk and Safety in Medicine*, 16, 247-259, 2005.

Breggin, Peter. "Recent regulatory changes in antidepressant labels: Implications for activation (stimulation) in clinical practice." *Primary Psychiatry*, 13, 57-60, 2006.

Breggin, Peter. "Court filing makes public my previously suppressed analysis of Paxil's effects." *Ethical Human Psychology and Psychiatry*, 8, 77-84, 2006.

Breggin, Peter. "How GlaxoSmithKline suppressed data on Paxil-induced akathisia: Implications for suicide and violence." *Ethical Human Psychology and Psychiatry*, 8, 91-100, 2006.

Breggin, Peter. "Drug company suppressed data on paroxetine-induced stimulation: Implications for violence and suicide." *Ethical Human Psychology and Psychiatry*, 8, 255-263, 2006.

D. Editorial Board Activities.

I am on several journal editorial boards, two of which are most relevant to this report:

Editorial Board, *The International Journal of Risk and Safety in Medicine*
Consulting Editor, *The Humanistic Psychologist*

I am also the cofounder of the journal, *Ethical Human Sciences and Services*, which has been renamed *Ethical Human Psychology and Psychiatry*. I am frequently asked to peer-review articles for journals.

E. Miscellaneous Relevant Activities

I have testified before the U.S. House of Representatives and Senate on several occasions, spoken or consulted to federal agencies, and given innumerable professional presentations on subjects related to this report and relevant to this case. I have been a scientific consultant to the Federal Aviation Administration (FAA) on the adverse effects of medications on pilots; consulted with a panel of federal attorneys surrounding drug approval and adverse drug effects; and lectured audiences of attorneys on adverse drug effects as applied to forensics. I have testified in more than 100 trials, many of which touch on issues in the case and consulted to many more that did not go to trial, sometimes surrounding high profile cases such as the mass murders at Columbia High School and the Aurora Theater.

My work has caused or influenced revisions of the FDA-Approved Full Prescribing Information (the label or package insert) for dozens of antidepressants and antipsychotic medications.

Attachment 3: Link to Dr. Breggin's Resume on his website (continuously updated):
<https://breggin.com/resume/>

END OF DOCUMENT

Attachment J

Plaintiff Affidavits and Declarations

Affidavit of Renee D. Hedges

State of Ohio / Summit County:

I, Renee D Hedges, being first duly sworn according to law, state that I am legally competent to testify in this matter, and I have personal knowledge of all the facts contained within this affidavit. I am competent to testify as to all matters stated herein:

1. All documents attached to this affidavit are genuine copies of the original and are fully incorporated by reference herein as if fully rewritten herein. All Exhibits referenced and/or attached thereto and fully incorporated by reference herein are all true and genuine copies of the originals and each is incorporated herein as evidence in support of the plaintiff's motion. All documents as was filed in this matter attached to the complaint are also incorporated herein fully by reference by this affidavit as if fully and completely rewritten herein. This includes all documents contained in the Exhibits attached to the complaint as filed for record. All Exhibits referenced and/or attached thereto and fully incorporated by reference herein are in support my individual claims that my Constitutional Liberties, Freedoms and God-given, absolute, fundamental, and inalienable Rights have been unconstitutionally infringed upon and denied and/or jeopardized to me as I detail herein.
2. The DeWine, Acton, Himes Orders as have been issued since March 2020 have adversely impacted my Constitutional Liberties, Freedoms and God-given, absolute, fundamental, and inalienable Rights.
3. As a direct and proximate result of these unconstitutional orders and their mandated implementation, my family and I have been made to endure the following harms in this affidavit.
4. The declared "State of Emergency" made by DeWine and the ODH, and it's continuous, unnecessary and unfounded extension of said orders have wreaked havoc, turmoil, angst, and undue stress upon me, as well as my entire family. These baseless orders have affected us in numerous adverse ways in a multitude of situations. I believe our constitutionally guaranteed freedoms, including religious and medical, have clearly and repeatedly been violated as a result of the governor's mask mandates and inducement of panic, and the very essence of the Emergency Order itself.

Renee

5. HEALTH DIAGNOSISES

Active Medical Conditions via Cleveland Clinic Mychart:

- Vitamin D deficiency 3/14/2014
- Optic neuritis 3/16/2014
- GIST (gastrointestinal stromal tumor) of small bowel malignant (HCC) 5/20/2014
- Convulsive syncope 4/12/2016
- Pulmonary nodules 4/12/2016
- Dysautonomia (HCC) 6/27/2016
- POTS (postural orthostatic tachycardia syndrome) 7/8/2016
- Labile blood pressure 7/8/2016
- Inflammatory and toxic neuropathy (HCC) 1/8/2017

- Neuropathy due to Sjogrens syndrome 1/8/2017
- Sjogrens syndrome 1/9/2017
- Orthostatic hypotension 3/16/2017
- Demyelinating neuropathy 5/7/2017,
- Paraneoplastic neuropathy 5/7/2017
- Long-term use of high-risk medication(Plaquenil) 1/22/2018
- Keratoconjunctivitis sicca in Sjogrens syndrome (HCC) 1/22/2018
- Autonomic nervous system disease or syndrome 2/27/2018
- H/O aortic valve insufficiency 4/24/2018
- Hypertension Positive GAD antibody 9/20/2018
- Heavy metal exposure 1/28/2019
- Compound heterozygous MTHFR mutation
- C677T/A1298C (HCC) 1/29/2019
- Cervical dystonia 6/11/2019
- Stiffness in joint 6/11/2019, Stiff person syndrome 2/3/2020.

All medical records are saved via zip drive since July, 2016. Cleveland Clinic

Specialist include: PCP, Oncologist, Neurologist, Rheumatologist, Cardiologist, Pain Management, Physical Therapy, Neuro Ophthalmologist and In-Home Nursing. * My neurologist has deemed me as total and permanently disabled as of July, 2016. My conditioned are progressive and degenerative.

6. SYMPTOMS THAT MAKE IT DIFFICULT TO WEAR A MASK BASED ON DIAGNOSISES

- 24/7 dizziness and lightheadedness
- Cerebral hyproprofusion
- Low BP and high BP fluctuations throughout the day (sometimes dangerous upon standing)
- Low and High HR upon sitting and standing
- Tachycardia
- Stiffness that causes severe pain
- Slow gut motility
- Dry mouth
- Syncope and pre-syncope
- All day major fatigue
- Visual disturbances
- Sensory intensity due to autonomic problems
- Headache
- Difficulty with word finding due to low blood volume and oxygen to the brain
- Chest pain and need to breathe deeply
- Shortness of breathe
- Nausea
- Muscle Spasms/locking that cause me to need to breathe deeply
- Severe neck and jaw pain

7. MEDICAL DECLINE AND PROBLEMS WITH MEDICAL APPOINTMENTS

3/12/2020 My neurologist called me to cancel my appointment with him due to COVID19 that was to take place the next day. It can take 6-9 months to get an appointment with him. I had been waiting a long time to see him for my neurological evaluation, but he did a phone consult instead and did not charge me. He also suggested I stop Cardiac Rehab at my local gym due to COVID19 risk. Gyms were closing anyway. I can't do these at home. I can choose what program to do between PT program and Cardiac program depending on daily symptoms, and I need equipment. I had a major decline in my baseline symptoms due to not having access to the machines I rely upon from March thru June. I have not recovered to my baseline to date. Appointment rescheduled for October, 2020 (6 more months).

4/27/2020 Was supposed to see Cardiologist, but I had to reschedule for a later date in July. Cleveland Clinic wasn't seeing patients in person at this time and offering telehealth. Seeing a cardiologist in person is only optimal for current condition. Cleveland Clinic started doing telehealth for many doctor visits at the start of the lockdown.

4/29/20 I went for blood work at a local Cleveland Clinic in Cuyahoga Falls for an upcoming cancer test (CT). I was able to enter without a mask due to medical conditions, but was sternly told by the receptionist to stay 6ft from her due to not having a mask on, and I had to loudly share personal information in front of the entire waiting room. I also called Cleveland Clinic Twinsburg to get clearance to not wear a mask for my upcoming scan. At that time, it was highly recommended. However, radiology wrote a note that I was coming without a mask for my regular oncology scan.

5/4/2020 Went to Cleveland Clinic Twinsburg for scan. Was asked the typical COVID questions at the door, and was asked to wear a mask. I had to explain that I called and got clearance to enter due to cerebral hypoperfusion and other symptoms. I was able to enter, but was hassled once again at radiology where I told her the same thing and was able to proceed.

5/12/2020 Distance health follow up with Oncologist as Cleveland Clinic wasn't seeing too many in person visits due to COVID19.

5/26/2020 I was supposed to see my neurology nurse for a neurological appointment. This appointment was rescheduled by Cleveland Clinic at least five times before this date because the neurology nurse was assigned to different duties due to COVID19. Tele-health was the only option as they were not seeing in person yet. This was supposed to be a follow up to my cancelled 3/13/2020 appointment that was cancelled with my neuromuscular neurologist due to COVID 19 lockdown. I had a major increase in symptoms as stated in mychart notes: "Renee has noted an increase in her symptoms. She states she has increased issue of dizziness. She is noting fluctuation of heart rate and blood pressure from low to high. States her symptoms of dizziness are increasing her fatigue. The dizziness is constant unless she lays down. Dizziness begins with any postural change or being upright. She states she has to take a break and lay down every hour or so. She is seeing postural increase in heart rate >30 beats per minute. Blood pressures have fluctuated--has seen blood pressures 90/40 and even high with systolic >140 and diastolic >100. She states that her left arm will hurt with high blood pressure. She has not been able to exercise over the last 2 months due to lack of gym access. She tried to exercise at home with walking exercise, but this was difficult. She has some muscle weakness that began in her right arm over a month

ago. She states when she begins to reach out with her right arm it will hurt. When she goes to lift her arm above her head, her arm will shake. Mild numbness is noted and it intermittent. The weakness is in the shoulder/deltoid area and is constant and pain is associated with it. Monthly IVIG every 4 weeks." Rescheduled follow-up for July in person.

7/1/2020 I once again called a couple days prior to this date, because I had my cardiology appointment. Cleveland Clinic was strongly recommending masks, but cardiology said I was ok to come in. Once in the room, the nurse indicated that my doctor, Dr. Pace might not agree to see me since I can't wear a mask. I told her I had called ahead. He did come into the room, barely looked at me and told me to sit 6ft from him. He never examined me, nor listened to my heart for the regurgitation. He just asked me questions and ordered testing. I filed a grievance because of this, and he had put in my notes that he encouraged aerobic exercise, which he never did. I can't even do those types of exercises. He also indicated he discussed weight, which was never mentioned. He did write: "Additional exam deferred as patient unable to wear a mask and to maintain social distance of 6 feet."

7/15/2020 Mask Ordinance passed in Cleveland. Called Cleveland Clinic main (which my husband has to drive me to since it's an hour away) about me coming in for my upcoming neurological nurse appointment. They said to call back a few days before since they were unclear of the mask policy. I had explained that my medical conditions make it extremely difficult to wear a mask due to reduced oxygen flow to the brain. At this time, caregivers were also not able to attend, so in case I felt syncope, I was very concerned about walking with a mask on even for a short time by myself into Cleveland Clinic main.

7/17/2020 Called Cleveland Clinic Neurology about mask policy. They indicated masks were required due to COVID19 and medical exemptions weren't being written as much, so they could accommodate me through tele-health again. I reluctantly did agree to that but was concerned about insurance covering it. I did have my tele-health with the neurology nurse again. He told me that if I were to come to main for an in-person visit, I would need to do my best with a mask. He indicated the argument would be that I'm not on oxygen and most exemptions are for those on oxygen. I reminded him that I do not get oxygen to the brain automatically and wearing one increases dizziness and syncope. He didn't disagree, but it seemed his hands were tied. Appointment focused on increase in symptoms due to response to COVID19 (stress and lack of cardiac rehab). Stiff Person can progress due to stress. I had just started cardiac rehab back up as this can take months to notice any improvement once stopped: "She has not had any improvement in her symptoms since our last visit. She has been doing cardiac rehab the last 3 weeks. Has not noticed the benefit yet. Without the beta blocker, the heart rate will spike quite high (>160 beats per minute). If symptoms do not improve in next 4-6 weeks, will obtain a ziopatch and consider the possibility of utilizing Ivabradine for heart rate control as it will not cause hypotension."

7/22/2020 Governor Dewine issued a mask mandate, so my rheumatologist office called concerning an upcoming appointment to remind me to bring my mask. I explained the difficulty I have with wearing one and a current increase in autonomic issues which include lack of oxygen to the brain. My appointment was scheduled for the next day. They offered Tele-health as an accommodation. I wanted to be seen in person, and I was afraid my insurance might not cover it, so they rescheduled me with a nurse for August 24th since my rheumatologist had no other openings. I also called Cleveland Clinic Twinsburg as I had an upcoming cardio echogram. I was afraid that I'd be turned away without a mask. A

manager had to call me back a few times stating she was trying to work this out. I didn't hear anything back, so I called again on 7/24/20.

7/24/20 Called Cardiac department about the mask issue at 10:38 regarding upcoming echo. I have them audiotaped. The receptionist accidentally hung up on me. I called back at 10:40 AM. The receptionist talked to the nurse (Monica) who indicated I would be fine, and she'd mark it in mychart. They got an email that she read to me, and with my conditions I should be exempted with no issues. Then at 11:50, I got a call from a nurse manager named Jared Leal. He said they updated their mask policy as of Wednesday and everyone has to wear one starting Wednesday. He stated that he would probably have to "reschedule me for a much later date." I have the message. I did call him back at 11:55, which is audiotaped. He had no idea what stiff person was, nor the autonomic issues I have, so any face covering would not be acceptable. He ended the conversation by saying he'd call me back. The tech doing my exam "was scared," so he'd talk to her about using a plastic drape between the two of us. I did get a phone call back from him who said he'd email me the plan. I'd have to show the email he had written upon entrance: "Hi Renee, Thank you for speaking with me about your upcoming appointment on Monday, July 27th at 3:30pm. I appreciate you sharing with your challenges with wearing a mask or face shield. **You may present this email to the screeners to be admitted without a mask or face shield.** I secured the drape and it will be ready in cardiology so it won't touch your face during the exam but still offer protecting to the technician."

7/27/20: Was able to do exam and test but not without hassle at the front door where I had to show an email for the nurse excusing me from a mask and shield.

8/13/2020: Requested a mask exemption from my PCP for upcoming appointments at the Cleveland Clinic. Here is the response from my PCP: "Renee, I am not writing mask exemptions for anyone who does not have severe COPD at this time." From there she told me to ask my cardiologist or neurologist.

8/14/2020 I wrote the following to my neurologist: "I sent a message to my PCP, requesting a mask exemption. I can't wear these. It triggers more symptoms. She indicated to contact you. She is only writing letters for those with severe COPD. As you know, I have the same symptoms as those with severe COPD and that's not all. I'm having to reschedule appointments because of this, and I have a documented timeline of the harm this is causing not only from the stress but increase in symptoms. I'm getting the feeling that CC is not able to write these for some reason. I'm frustrated, and I'm clearly venting to you. What do you suppose I do?" I did receive a response back from the office indicating mask exemptions were not being written: "Unfortunately we cannot go against CDC guidelines and we must follow them. Please refer to the CDC website for more information. X doctor has said that you can have your visits with a virtual platform using zoom if needed."

As a result, an upcoming appointment with my rheumatologist was rescheduled for a virtual. Even my 6 month follow-up for 2/2021 was scheduled via zoom. I had a physical scheduled with my PCP. She changed my appointment from a physical to a virtual follow-up. I won't be getting a physical. I have an appointment in October with my neurologist that is subject to change to virtual.

8. MASK MANDATE IN THE COMMUNITY AND INCREASE IN STRESS

Even prior to the mandate, I was often approached by store employees about wearing a mask. I was actually followed by a manager in Pet Supplies Plus who had a box of masks. When I told him politely that I have medical issues, he told me to hurry up or order online next time. I don't go out much as it is, but even when I do, I have to constantly explain why I'm not able to wear a mask. I have invisible disabilities. As you can see, I have also had a difficult time getting adequate health care without hassle in the previous section. This stress has increased my symptoms. It is well known that Stiff Person can progress to the next stage with induced stress and autonomic dysfunction symptoms become severe due to stress. Between the medical merry go round, and other issues related to COVID19 response that is impacting my family, I know this is negatively impeding my health.

9. VOTING ISSUES

Beginning of April: Due to in person voting being cancelled, I requested a mail in ballot.

4/26/2020 Received wrong mail in ballot two days before due. Had to call to figure out what to do to get correct ballot. I was told to show up to the polls on 4/28/2020, in person to vote using correct ballot. The only issue is that the closest place is twenty minutes away in Akron, and I can't drive that far.

4/28/2020 I was highly symptomatic this day. My husband took me to Akron anyway, so I could vote in person and with the correct ballot. He was not able to accompany me into the building due to COVID-19. I was asked to wear a mask, but explained I had medical conditions. It took about 45 minutes, which increased my symptoms, and I was sick through the next several days. I could not get back to my baseline which is brain fog, stiffness and dizziness. Standing this long and being in a car causes my heart rate and blood pressure to fluctuate causing worsening symptoms as well as headache, muscle locking, difficulty with vision, word finding issues, and jerking movements.

CHILD/SON

10. EDUCATION

- a) Our 14-year-old was attending a college preparatory Christian middle and high school where he received honors, band and athletic achievements. When the schools closed it progressively and severely negatively impacted his emotional and social well-being. Because he is at a rigorous school, they quickly went to an online platform from 8:00-3:00 daily with 4 more hours of homework online daily and on weekends. He was in his room working hard to keep his honor roll status or at the kitchen table where he became very frustrated for hours daily. Our son was also a first chair saxophone player. Online Wind Ensemble turned into workbook work, and he wasn't given the opportunity to learn or play the rest of year.
- b) Due to the mandated masks, our son will no longer be attending his school, because masking goes against our religious beliefs. His school also would not accept a medical exemption from his chiropractor he has seen since birth.
- c) He is instead enrolled in Liberty Christian Online for the 2000-2001 school year. Our son learns better with in person instruction and deserves to continue with his in person college prep school, but due to mask mandates, daily temperature checks at school, and contact tracing which is against our Christian beliefs and constitutional rights, we had no other choice other than homeschool.

11. SPORTS

- a) Our son was not able to play any fall/summer sports even with our recreation league due to too many confusing changes in the orders. Our park and recreation league cancelled baseball. Our son has been playing baseball since he was four. This put our son in a deeper state of sadness.

12. MEDICAL

a) Our son was scheduled for his yearly sports physical in July, 2020 with his primary doctor at Summa. We were told through phone conversations and email that my husband and son would need to wear masks for his physical, and would not be allowed admission without one. As a result, his doctor told us to find other means of getting his physical done and cancelled his appointment. He was refused service over the mask mandate which goes against our Christian faith. At the time, we were also going to inquire about a medical exemption for school, but was never able to do this. So, we went through Austin's Chiropractor for his physical. His school allows chiropractors to do physicals, but would later tell us we couldn't turn in an exemption from his chiropractor. They would only accept letters from an MD.

FAMILY RELIGIOUS CONVICTION

13. CHRISTIAN FAITH

- a) Our bodily autonomy and our right to choose what medical procedures best suit our family are hallmarks of our Christian faith.
- b) Mask Mandates, forced temperature checks and contact tracing questions goes against our beliefs that God is sovereign and has made us in his image. It goes against our right to choose for our child. God gave us our child to make medical decisions. It's our belief that it's up to the parents to ensure the health and well-being of our child is monitored. It's not up to the government or any school to do this. Any interference with forced medical compliance goes against God and our fundamental right to choose what is best for us based on Biblical truth.

14. MASKING

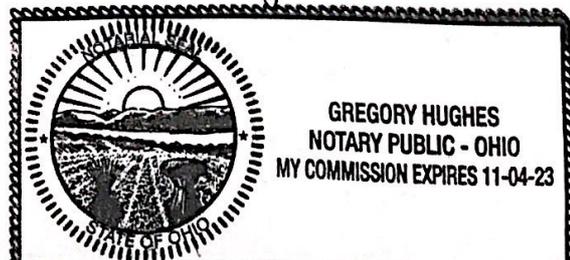
- a) Masking, to our family, is cultic and goes against Christ. Government masking orders during a virus with a 99% recovery rate, and without proper safety and efficacy studies should never infringe on our religious and constitutional freedoms. My husband has been forced to go against his religious beliefs due to this mandate. He has to wear a mask to keep employment. This has increased anxiety, stress, and depression.
- b) God gives sole authority to Christian parents to shepherd, discipline and protect our families. Examples of scripture references which apply include, but are not limited to, Deuteronomy 6:6-9, 2 Samuel 12:16, Proverbs 22:6, 29:15-17, John 4:46-54, Ephesians 6:4, 1 Timothy 5:8. Additionally, 2 Corinthians 3:16-18 says, "But when anyone turns to the Lord, the veil is taken away. Now the Lord is the Holy Spirit. And where the Spirit of the Lord is, freedom is also there. Our faces are not covered with a veil. We all display the Lord's glory." As a Christian, my husband and I simply cannot relinquish to governmental authorities decision-making authority to care for the well-being of our family. The wearing of any sort of facial covering is against our core religious beliefs. This is infringed on daily as we can't go into public as a family anymore without being ridiculed, hassled, or turned away.

15. Further, Affiant sayeth naught.

Bene D. Hedges

Sworn to before me and subscribed in my presence this 28th day of August, 2020.

Gregory Hughes
Notary Public



I, Michael Renz, on my own behalf and also acting with Power of Attorney for Scott and Kathleen Renz, being first duly sworn according to the law, state that I am legally competent to testify in this matter, and I have personal knowledge of all the facts contained within this affidavit. I am competent to testify as to all matters stated herein:

1. All documents attached to this affidavit are genuine copies of the original and are fully incorporated by reference herein as if fully rewritten herein. All Exhibits or Attachments referenced and/or attached thereto and fully incorporated by reference herein are all true and genuine copies of the originals and each is incorporated herein as evidence in support of the plaintiff's motion and/or case. All documents as were filed in this matter attached to the complaint are also incorporated herein fully by reference by this affidavit as if fully and completely rewritten herein. This includes all referenced and/or attached thereto and fully incorporated by reference herein are in support of my individual claims that my Constitutional Liberties, Freedoms, and God given, absolute fundamental and inalienable Rights have been unconstitutionally infringed upon and denied and/or jeopardized to me as I detail herein.
2. The Dewine, Acton, Himes and other Orders as have been issued since March 2020 have adversely impacted my Constitutional Liberties, Freedoms, and God-given, absolute, fundamental and inalienable Rights.
3. As a direct and proximate result of these unconstitutional orders and their mandated implementation, I have been made to endure:

Summary of Impact – MICHAEL RENZ

1. 20th Century Lanes, a bowling alley/bar/grill ("BA") located in Oak Harbor, Ohio was forced to close down because of the mandates. The BA had been damaged prior to the shutdown by a car hitting one of the walls. We had planned to complete repairs over the summer and perform other renovations but were unable to complete any of this because of the shutdown. First we lost money from having to close and then we could not do the work to get the place ready for this season because of the lockdown and the impacts. Now we are going to lose more money because of the fact that we could not get the place fixed.
2. My father and mother and I were all locked in our house during the statewide house arrest. We should not have been imprisoned.
3. The stress and fear created by the never-ending lies the Governor and Health Director told as well as the fact that our rights were trampled on really upset my parents. Mom finally seemed to get hit hard enough by it that she had a stroke. Since then she has had limited or no visitors because of the orders. Her greatest fear has always been to be locked in a nursing home without family and friends. That is exactly where she is now

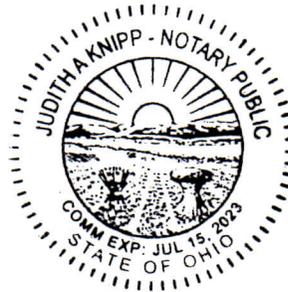
until she can recover enough that we can take care of her at home. It should be our decision whether or not to visit my Mom. She has been married to my dad for 50 plus years and he cannot go see his wife. He is devastated by this and I can only pray it does not cause further health problems for him.

4. I enjoy traveling and have been unable to go to many of the other states I had been planning to go to. It is not uncommon for me to take a week or two in the summer and drive to different places around the country. That has not been an option this summer.
5. I cannot breathe when I wear a mask. I have had health problems in the past and do not think it is safe for me to wear one. If I do not wear a mask I am looked at as a monster.
6. I am a large person and have always struggled to manage my weight. Being cut off from the gym has resulted in substantial additional weight gain and my doctor wants me to lose weight.



Sworn to before me and subscribed in my presence this 31 day of August, 2020.

 Notary Public



Summary of Impact – JESSICA FRANZ

1. My journey into the “new normal” began on March 9th, when Governor DeWine declared a “state of emergency” in Ohio after 3 people tested positive for Covid-19. I was alarmed, but like most Ohioans at that time, I gave him the benefit of the doubt due to the supposed “novel” nature of the virus and the unsettling news coming out of countries like Italy and China. In hindsight, however, I find it interesting that Democratic presidential candidates Joe Biden and Bernie Sanders had separate rallies planned for March 10th in Cleveland. DeWine said he would not order them to cancel because candidates are allowed under the First Amendment to gather if they wish. [1]
2. On March 12th, after health officials confirmed the 5th case of Covid-19, DeWine and Acton ordered schools be closed for three weeks, and Acton banned gatherings of 100 or more. [2]. It was at this point in time that I really began to become concerned. This was my oldest son’s senior year of high school at Miami Valley Career Technology Center. He had been preparing for months to compete in several automotive skills competitions, spanning from March-May, that would more than likely have resulted in scholarship monies for him. He had also been one of two students selected to give a graduation speech at the Nutter Center located at Wright State University in front of hundreds of his classmates, teachers, administrative staff, and parents. Due to the shutdown, he was also prevented from attending events like prom, field trips, and other school functions.
3. On March 15th, DeWine and Acton said that 37 people had tested positive for Covid-19. They announced that bars and restaurants would close. I thought it was very rash and premature when DeWine said "If we don't take these actions now, it'll be too late. This is a matter of life and death. We have to do this to save lives." He also began hinting that schools might be closed for much longer than three weeks only three days after announcing they would be on an extended spring break for three weeks. [3] At this point, I began to question how he could speak with such certainty about a virus that he himself claimed to know so little about. Additionally, no solid evidence was being presented to support these measures other than that Ohioans were told that Covid-19 cases were climbing daily. By March 16th, I was convinced that my feelings of unease had been correct when DeWine backed a lawsuit attempting to move Ohio’s primary election to June 2. When the judge denied the measure, Acton ordered the polls be closed as a health emergency. DeWine failed to call a special legislative session as required by law to cancel a primary election. [4] At this point, only 50 people had tested positive and 14 people were purportedly hospitalized. [5]
4. DeWine began to continue to issue unconstitutional orders through his ODH Director, Amy Acton. On March 17th, he issued an order that elective surgeries and procedures be postponed [6]. The next day, he ordered barbershops, beauty salons, tattoo parlors, hair and nail salons closed. He also closed 181 BMV’s. He took these extreme measures when there were only 88 positive cases in the state. [7]
5. On March 19th, Chief Justice Maureen O’Conner released inmates from jail, who were deemed at risk for contracting Covid-19. [8] Given the statewide mask orders that are

now in place, I'd like to ask her why they didn't just have the prisoners wear masks if masking is so effective. As March progressed, DeWine continued to issue orders, including closing adult day services for those with developmental disabilities. On March 22, the ODH issued a stay-at-home order, which was supposed to expire on April 6. On March 23rd, it started to become clear to me that DeWine was purposefully misrepresenting data. [9] It was at this time that it also began to dawn on me that this couldn't just be about a virus -the facts were simply not there to support the kind of rapid-paced and oppressive measures being daily imposed upon Ohio citizens.

6. The Governor admitted in an interview with the Xenia Daily Gazette that “[His] experience has been when you have all the facts, and the facts are right, you generally make the right decisions. I’ve been really focused on getting the facts. This is not any area of my expertise at all.” He admitted to not being an expert, but when an expert – Dr. Andy Pekosz, a virologist at John Hopkins University appeared on a webinar at about the same time as DeWine’s interview, he emphatically stated FOUR times that Covid-19 was a “mild disease” with “mild symptoms” for the vast majority of people. However, DeWine insisted on comparing Covid-19 to the Spanish Flu of 1918 for weeks even when the evidence clearly showed that COVID-19 was not the Spanish Flu. For example, “Young people were devastated by the flu virus of 1918. The symptoms were horrible, and the death toll was 625,000 out of a total U.S. population of about 100 million.” [10] According to Dr. Atlas, Governors and Mayors are NOT adjusting to what is being learned about Coronavirus and are continuing to hold destructive policies. The WHO said recently that “It’s very rare” to have asymptomatic people transmit. We know there’s virtually NO risk to young people, which means the schools and universities should be open! In fact, 99.9% of Covid deaths were from people age twenty-four and older. Even DeWine admitted in an April 17th radio interview that the majority of people who get the virus, will NEVER show any symptoms [11]
7. DeWine promised to be transparent about the number of Covid-19 cases, as he was using these numbers as a justification to take away the rights of Ohioans. [12] He has failed to provide information concerning the number of deaths in long-term health facilities, even when he was repeatedly asked by the administration to do so. ODH has refused to provide data, citing “privacy concerns” but offered no real legal justification. On April 2nd, The Ohio Roundtable, a division of the American Policy Roundtable, filed a Freedom of Information request with Dr. Amy Acton of the Ohio Department of Health. They requested that all Ohioans be allowed to “see the math” behind the construction of Dr. Acton’s latest model which was controlling public policy decisions in Ohio. The ODH refused, claiming immunity.
8. DeWine wrote a letter to President Trump on March 28th requesting federal funding. Within the letter, he hints that businesses will be closed indefinitely. He stated, “The indefinite closure of businesses proves difficult for owners and employees to gauge the true impacts.” I’d like to know how he knew that the closures would be indefinite, unless he had already planned that they would be. [13] This letter was sent only 19 days after he declared a “state of emergency.” At this time, only 25 deaths had been attributed to Covid-19. On the same day (March 28th) that DeWine requested funding, Acton told

Ohioans they could expect to see 10,000 new cases per day. She also claimed that "The effectiveness of what we're doing now [staying at home] will show up in our data two weeks from now." However, staying home didn't seem to make any difference because DeWine and Acton continued to extend the emergency orders time and time again, and usually in the midnight hour.

9. As history has shown, Ohio citizens were deceived. You were deceived, and I was deceived. The model Acton used, Ferguson's Model, (and which she would never share the math behind because it still remains locked up at OSU) was off by 96%! And yet, Acton revised her projections only twice – once to 10,000 cases per day and the second time to 2000 per day. In reality, the number of cases never exceeded 100 per day, with the exception of one prison in which all prisoners were tested. "Acton's continued [flawed] projections remained 20 times higher than the actual infection rate, and these inflated numbers were used to continue the state's draconian measures which included a ban on visiting nursing home residents, religious services and gatherings, and even small groups in private homes." [14] This proves that DeWine lied about his transparency with the data and about his supposed commitment to facts.

10. DeWine and Acton have repeatedly refused to provide statistics on just who was dying from Covid-19. Acton claimed that nursing home deaths comprised only 20% of the total, but that proved to be a lie as well. By May 21, it was revealed that 79% of the state's deaths had been nursing home residents. [15]. Despite the evidence that 99.8% of all Ohioans have survived Covid-19, 79% of Covid-19 deaths occurred in nursing homes, and despite the fact that the CDC has said that Covid-19 is no longer a pandemic and has been declining for eleven straight weeks [16] - Ohioans are still living under severe restrictions imposed on us with absolutely no evidence to back up these kinds of measures.

11. There are many ways in which the actions taken by DeWine and the ODH have personally affected me and my family. Below is a brief synopsis:
 - a) As an Ohio citizen, I have been lied to by my governor and by the ODH Director about the Science, data, and facts surrounding Covid-19. I was denied access to the model being used to justify keeping me and my family in lockdown and isolation. They have acted fraudulently either because they are mentally ill (suffering from Munchausen syndrome by proxy, which means they are unfit to serve in positions of leadership), or because they have a politically motivated agenda, in which they are submitting Ohio citizens to unconstitutional mandates to achieve their goals. There is a deliberate denial of the science and the data that is going on with these closures. DeWine and ODH have made up their own rules, and they didn't listen to guidelines provided by WHO. For example, the ODH says 6ft, but WHO says 3 ft. ODH is mandating mask wearing for employers and employees (and now there is a statewide mask mandate – affecting even our schools and places of worship!), and yet WHO says they "Do not recommend masks

for the general public,” and to only wear masks if you are in a high-risk group in an area of widespread transmission of the disease. I am sick of being lied to.

- b) My son lost a part of his senior year; this includes field trips, prom, competition experiences, scholarship opportunities, virtual graduation ceremony instead of the ceremony that was to take place at Nutter Center. My son had opportunities and experiences stolen from him, he will never get this time back.
- c) My family (my husband, myself, and our 6 children) do not wear masks for both medical and religious purposes. My 16-yr. old daughter was denied care by her pediatrician (Dr. Denen with Internal Medicine/Centerville Pediatrics), who wouldn't see her without a mask, even when we explained we were there to see about her getting a medical exemption for school. When I asked him to provide a copy of Premier Health's policy requiring masks be worn during visits and that they weren't accepting exemptions- he failed to provide me with one. Additionally, we were treated like lepers by the office staff and the pediatrician violated HIPAA by sharing my daughter's private medical information with the office manager. They made absolutely no attempt to work with us by offering alternative solutions. Initially, Dr. Denen refused to speak with me on the phone, but eventually he agreed to a phone conversation. During our conversation, I was actually challenged on my religious beliefs when I told him I had religious reasons for not wearing a mask. He asked me, "Where does it say in the Bible that you can't wear a mask?" Not only was this question intrusive, it was obnoxious. The fact that he thought he had the right to question my personal religious convictions and experiences was unprofessional and inappropriate.
- d) During the shutdown, my family was kept from exercising the core tenets of our faith; such as assembling with other Christian believers, visiting the sick in hospitals, and we were unable to visit my husband's grandmother in her retirement community. I was also prevented from hosting social events for teenagers at my local rec center. My husband and I rent out the rec center twice a month, so homeschool teens will have the opportunity to socialize with other teens. My husband, myself, and many other parents, students, and local leaders consider this a ministry to our local community.
- e) Per my conversation with staff in April/May, my OBGYN (Dr. Guy with Premier Health Women's Health Specialists and Midwives of Dayton) will not see me without a mask and cannot (will not?) provide me with a company policy stating they are not recognizing 13 exemptions set forth by ODH. I have a lump in my breast that needs addressed. Due to religious reasons associated with my understanding of occult initiation practices and masking, I will not wear a mask. I called again the week of August 24th and tried to make an appointment. I explained to the receptionist that I really needed to be seen due to the issue aforementioned. She acted as the go-between for me and another lady in the office (presumably the office manager). I could hear them talking back and forth and the office manager told her that I would only need to wear it for just a short time to pass through the

public areas. I explained that as a Christian, this was against my deeply held religious convictions, and that it would be like asking me to wear an occult symbol or a hijab. After much discussion back and forth, they finally agreed to allow me to make an appointment. They told me I would need to call upon arrival and come in through the back door, so that no one in the reception area would see me. I cannot begin to describe the emotional and mental toll this has taken. Having to fight for my civil and religious freedoms to see my doctor about something that could potentially be life threatening is something I have never before encountered in my life. Additionally, being segregated from others because I was told they might feel uncomfortable by my unmasked face has been an incredibly humiliating and dehumanizing experience.

- f) My son may not be able to take a class at Sinclair that is meeting at the campus once a week due to his religious conviction not to wear a mask and because he doesn't want to give his school permission to practice medicine on him by impeding his oxygen levels, lowering his immunity, and making him more vulnerable to contracting a virus. In addition to religious reasons, he also has medical reasons, which would preclude him from wearing a mask. A Sinclair College Representative, who was slated to be handling issues with Covid-19 (Andrew) told my son that Sinclair would accept a medical exemption. My son obtained an exemption from his doctor and sent it to the accessibility office. The accessibility office responded that they were in receipt of his exemption, but it "wasn't enough." They asked to know his medical condition that made him exempt. He replied that per HIPAA, he didn't have to discuss the details with them. They then sent an email that in order to receive an accommodation at Sinclair College, students were required to submit documentation of proof of disability and limitations. They told him that a "mask exemption" falls under the policy of an accommodation, and therefore, their accommodation policy must be met. They also contacted his instructor and told him not to allow my son in class until it was worked out. My son then requested an accommodation form, which his doctor filled out and sent in for him. Sinclair is now requesting an intake appointment with him. As of Friday, August 28, he is still not certain if he will be granted access to attend his class. He is on track to graduate with an associate degree in Engineering at the end of the year. However, if Sinclair prevents him from attending class over not wearing a surgical/cloth mask, they will delay his academic pathway and he will not graduate on time.
- g) My daughter's school (Miami Valley Career Technology Center) informed us a week before classes started that they are moving to ALL online classes. They did have a hybrid (2 day a week in the classroom) model in place, but due to "Governor's guidance," they are moving everything online. We have been provided with no credible science, data, or facts that would support this measure, only that the Governor said so.
- h) My daughter attended one day at school (MVCTC) before they moved everything to online until September 8th, when they are going to try to go back to a hybrid model. She was the only one NOT wearing a mask out of hundreds of students. All day long, she heard students complaining about not being able to breathe and how hot it was. She said

her classroom was so hot that she was having difficulty breathing even without a mask. She experienced high levels of anxiety at seeing everyone else wearing masks.

- i) My husband and I were denied service at a Little Caesar's in Troy, Ohio by the acting manager. He told us he could refuse to do business with us because we weren't wearing a mask. We cited medical and religious reasons, but it didn't matter to him. He also demanded to know what our medical reasons were. He failed to provide a company policy backing up what he was saying when we asked for one. He called the police on us and the health department. I filed a complaint with Little Caesar's Customer Care. They said they would have a representative call me back. I called a total of four times. After each of the first three calls, I was informed that they would pass on my information to supervisors and area managers and I would receive a call back. However, I never heard back from anyone. On the fourth time I called, a supervisor finally agreed to speak with me. They told me their lawyers had worked with ADA and ADA told them that people who wore masks were considered a "direct threat" to the health of others. I asked if they could share ADA's documentation with me, and they could not.
- j) My two daughters and I were refused entry into the Walmart Vision Care Center (even though we had been there the week before to get eye exams). They told us that the doctors were separate from the eye glass store (we were there to pick out glasses), and that it was Walmart's policy to not allow entry if we didn't wear masks. We again cited religious and medical reasons. They called their marketing manager, who wanted to know what our exemptions were. I told her we didn't have to share that per HIPAA. They strung us along for close to two hours, we dealt with countless vision care staff, two Walmart managers, and the marketing manager over the phone. In the end, we were STILL denied entry, even after we said we'd wear face shields at the Walmart manager's suggestion. The vision care staff said they couldn't make the call (apparently, no one could or wanted to take the responsibility) and we were denied entrance into the store. I filed a complaint with Walmart's Ethic's department. Eventually, I was given the Human Resource manager's phone number, which was a non-working phone number. When I called the Ethic's department to tell them the number was not in service, they had no one else available for me to contact.
- k) On Thursday, August 13th, my daughter and I were denied entry into the health food store by the manager. I asked to see the store policy, and she had nothing she could provide me with. She refused to give me the owner's contact information when I requested to speak to someone in a higher position. As we left the store, my daughter saw her spraying some kind of spray (most likely disinfectant) in the area where we were standing. This deeply troubled my sixteen-year-old daughter, and I worry about the psychological ramifications of being treated as if we are infected lepers, simply for not wearing a cloth/surgical mask which has been scientifically proven through countless studies to not be an effective tool against Covid-19. Even Anthony Fauci admitted that masking was largely symbolic. Other psychological and medical experts have cited that the mask does nothing to prevent the virus and is largely used to quell anxiety.

- l) My son and his friends wanted to go to King's Island recently. My son called and asked about the Covid-19 policies. He was told that everyone 2 and over had to wear a mask in the park. He was also told he could wear a plastic shield while walking in the park, but he had to wear a fitted mask when he was on the rides. My son asked about exemptions, and the Supervisor tried to evade the question, stating they were following CDC guidelines. Then she said they had worked directly with the State to create their guidelines. My son pointed out that CDC guidelines and State guidelines provide for exemptions and don't require anyone to wear a mask unless they are ten years of age and older. The supervisor backpedaled and finally admitted it was their company policy. My son asked to see the policy, and specifically, where it said they weren't honoring any exemptions, which of course, the supervisor couldn't provide. I had thought about calling again this week and pointing out that if it truly was their company policy, why couldn't they change their policy to allow people in without masks? Additionally, if someone decided to sue businesses refusing to allow customers to enter without masks, and those businesses couldn't provide a copy of their policies, aren't they using their employees/supervisors/managers as human shields to take the hits for them for potential lawsuits?
- m) I am very concerned about my son and my daughter and forced Covid testing and vaccinations. My son is a University of Dayton-Sinclair Academy student. This means that he will finish his associate degree at Sinclair and then transfer to UD. Unfortunately, UD is already mandating testing and masking with all of their students. This impacts my son because as a UD-Sinclair Academy student, he is considered a UD student as well, and he has access to all of the campus amenities and clubs. However, due to the forced masking and testing policies, he can't participate in any of it.
- n) My kids and I have been harassed, even at places that have publicly stated they are accepting exemptions. We have been asked to produce our "medical exemption," we have been chased through the store by employees/ managers demanding, "where is your mask?!" and we have been made to feel like we are terrible people by managers, employees, and other customers for not wearing masks. We have endured eye-rolling, snide remarks, lectures, sighs, and glares from employees and managers who think we should be wearing a mask. Additionally, I was stared down and followed by a gentleman at Hobby Lobby until I confronted him. I have been called names such as "selfish" and "Karen" by customers, and another customer at a Walmart acted like she was going to run me down with her cart- ALL because I was not wearing a mask. Daily, I deal with anxiety over whether this will be the day I'm accosted by another employee/manager who won't let me in their store. I wonder if there will come a day when I'm prevented from going to the grocery to get food for my family. I worry about my children being harassed and discriminated against at school and at stores by militant mask wearing individuals. I am concerned that they will miss out on scholastic and extracurricular opportunities and experiences (my son already has). In addition, it feels incredibly invasive and threatening to be questioned by security personnel at stores about my lack of a mask.

- o) My youngest son (7 years old) and I were denied entry into Kettering Health Network Urgent Care in Huber Hts. He had injured his toe, which had developed a bad infection. They refused to see us without masks, and they failed to provide a copy of their policy when I requested it. Most common responses I receive from businesses when I request a policy are: “We’re in a Pandemic,” or “It’s posted on the door.” However, this isn’t true. The policy is not posted on the door, they are referring to a poster with something to the effect of: “Per Governor’s orders, masks are required.”
 - p) My husband and I have run into employees at restaurants and at our vet’s office who have suffered from hives/bumps/rashes and respiratory issues, such as asthma, who are being forced by their employers to wear masks against their will and against their better judgment. I spoke with a nurse and a food distributor at during a shopping trip to Kroger. The nurse said that none of the Covid-19 regulations made sense from her perspective, and masking is harmful; neither she, nor her son were wearing masks in the store. The food distributor (also not wearing a mask) told me that Kroger had requested that he remove his badge, which listed his place of employment if he was going to not wear a mask in their store. This gentleman was not wearing a mask, and he was “off the clock” when we spoke.
 - q) I had to find a new vet, hairdresser, eye doctor, family doctor, health food store- ALL because I don’t wear a mask! In summary, pandemic panic has unleashed unchecked governmental power, and it must be stopped. [17]
12. DeWine has stated that his job is to make sure that [Ohioans] don’t get sick. That is false, it is absolutely NOT his job to make sure I don’t get sick. He is not my Emperor and he is certainly not my God. His job is to make sure that he is preserving and protecting the freedoms of Ohio citizens, and he has grossly failed in his duties to the people.

- 1) <https://abc6onyourside.com/news/local/timeline-of-coronavirus-in-ohio>
- 2) <https://abc6onyourside.com/news/local/gov-dewine-says-ohio-schools-will-have-extended-spring-bring-due-to-covid-19-concerns>
- 3) <https://abc6onyourside.com/news/local/ohio-governor-considering-closing-bars-and-restaurants>
- 4) <https://www.nga.org/consulting-2/powers-and-authority/#role>
- 5) <https://abc6onyourside.com/news/local/march-16-coronavirus-in-ohio-update>
- 6) <https://abc6onyourside.com/news/local/ohio-department-of-health-issues-order-postponing-elective-surgeries-in-ohio-hospitals>
- 7) <https://abc6onyourside.com/news/local/hair-and-nail-salons-barbershops-and-tattoo-parlors-ordered-to-close-by-gov-dewine>
- 8) <https://abc6onyourside.com/news/local/ohio-chief-justice-recommends-safe-release-of-vulnerable-inmates-and-keeping-courts-open>
- 9) <https://ohiostatehousenews.com/2020/05/governor-dewine-suppresses-data-disproving-covid-19-policies/>
- 10) <https://aproundtable.org/news-show-text/where-ohios-covid-19-strategy-went-wrong/>
- 11) https://wethepeopleconvention.org/articles/Covid-data-update?fbclid=IwAR1fjFljrsFyw-X5BxnG2Bdwq8qm705TBN5V8pac1W2CV_vDukQjmD20AZk
- 12) <https://www.dispatch.com/news/20200420/dewine-pledges-to-release-number-of-coronavirus-deaths-in-long-term-care-facilities>
- 13) https://www.scribd.com/document/454239257/President-Trump-Letter-Regarding-FEMA-Region#download&from_embed
- 14) <https://mariettaoh9-12project.com/the-rise-and-fall-of-emperor-dewine/>
- 15) <https://www.statenews.org/post/huge-percentage-ohio-covid-19-deaths-come-nursing-homes>
- 16) <https://www.thegatewaypundit.com/2020/07/cdc-reports-china-coronavirus-mortality-currently-pandemic-threshold/>
- 17) <http://www.ronpaulinstitute.org/archives/featured-articles/2020/march/23/i-am-an-american-constitutional-lawyer-and-i-see-our-government-using-covid-19-to-take-away->

[our-fundamental-rights/?fbclid=IwAR0yjoCeaYVa5vs-ZwFDX6qxRgg3xIPJSfeJAoCcoWZs5tQGdgDrbMnrX0](#)

Affidavit of Jessica Franz

State of Ohio / *Montgomery* County ss:

I, Jessica Franz, being first duly sworn according to law, state that I am legally competent to testify in this matter, and I have personal knowledge of all the facts contained within this affidavit. I am competent to testify as to all matters stated herein:

1. All documents attached to this affidavit are genuine copies of the original and are fully incorporated by reference herein as if fully rewritten herein. All Exhibits referenced and/or attached thereto and fully incorporated by reference herein are all true and genuine copies of the originals and each is incorporated herein as evidence in support of the plaintiff's motion. All documents as was filed in this matter attached to the complaint are also incorporated herein fully by reference by this affidavit as if fully and completely rewritten herein. This includes all documents contained in the Exhibits attached to the complaint as filed for record. All Exhibits referenced and/or attached thereto and fully incorporated by reference herein are in support my individual claims that my Constitutional Liberties, Freedoms and God given, absolute, fundamental, and inalienable Rights have been unconstitutionally infringed upon and denied and/or jeopardized to me as I detail herein.

2. The DeWine, Acton, Himes Orders as have been issued since March 2020 have adversely impacted my Constitutional Liberties, Freedoms and God given, absolute, fundamental, and inalienable Rights.

3. As a direct and proximate result of these unconstitutional orders and their mandated implementation, I have been made to endure: See Attached document.

Describe here every serious incident attributed to the orders and how the orders have impacted your life and your family. See Attached document.

Insert your data here See Attached document.

49. Further, Affiant sayeth naught.

Jessica M. Franz

Sworn to before me and subscribed in my presence this 28 day of August, 2020.
Public

Jennifer Miller Notary



Jennifer Miller
Notary Public, State of Ohio
My Commission Expires 05-26-2021

Affidavit of Kristen Beckman

State of Ohio /

County ss:

I, **Kristen Beckman**, being first duly sworn according to law, state that I am legally competent to testify in this matter, and I have personal knowledge of all the facts contained within this affidavit. I am competent to testify as to all matters stated herein:

1. All documents attached to this affidavit are genuine copies of the original and are fully incorporated by reference herein as if fully rewritten herein. All Exhibits referenced and/or attached thereto and fully incorporated by reference herein are all true and genuine copies of the originals and each is incorporated herein as evidence in support of the plaintiff's motion. All documents as was filed in this matter attached to the complaint are also incorporated herein fully by reference by this affidavit as if fully and completely rewritten herein. This includes all documents contained in the Exhibits attached to the complaint as filed for record. All Exhibits referenced and/or attached thereto and fully incorporated by reference herein are in support my individual claims that my Constitutional Liberties, Freedoms and God given, absolute, fundamental, and inalienable Rights have been unconstitutionally infringed upon and denied and/or jeopardized to me as I detail herein below.
2. The DeWine, Acton, Himes Orders as have been issued since March 2020 have adversely impacted my Constitutional Liberties, Freedoms and God given, absolute, fundamental, and inalienable Rights.
3. As a direct and proximate result of these unconstitutional orders and their mandated implementation, I have been made to endure the following serious incidents attributed to the orders and how the orders have impacted my life and my family.
4. A little bit further about me, my name is Kristen Beckman. I was born and raised in Metro Detroit, but moved to Ohio in 2014. I have been in Oregon (Lucas County) since 2017. I am 35 years old, married, with two small children, and a dog.
5. I work as a corporate auditor for a fortune five hundred company. In September, I will celebrate my 15th anniversary with the company. I have moved up through several positions, and worked at 2 previous locations. I have held my current title, Specialist-Operations Risk & Compliance, for almost two years.
6. I am a busy body. I like to experience life first hand. I enjoy traveling, hockey, concerts, holidays, date nights, and all of the things we are being robbed of this year. I am also an advocate for medical freedom, which is how I came across the group, Ohioans Against Mandatory Masks, which evolved into Ohio Stands up.

7. I have suffered the following injuries and damages all proximately caused by the illegal behaviors and unconstitutional orders of these state actors Acton, DeWine and Himes.

8. I have arranged chronologically, a timeline as set forth below that is for me the best way to list everything, along with some other points. These are all-encompassing, so they don't really fit into a specific time frame yet emanate from the unconstitutional State orders of Acton, DeWine and Himes. Due to these unconstitutional Orders, I Have Suffered as follows:

- Uncertainty at work. Will I be forced to work remotely? Can I work remotely instead of wearing a mask? How long will I have to continue doing tasks, other than my own workload?
- Anxiety over having to stock up on food and supplies for my family and stay home for weeks at a time.
- Anxiety over DeWine's impending doom each time he pushes off a press conference or foreshadows what's to come next.
- Anxiety over my son being able to start kindergarten in the fall. We don't do computers at his age and want no part of distance learning.
- Anger over the forcing of healthy people to be quarantined.
- Anger over forcing masks on people. What about informed consent? What about a standard to follow? What about proper disposal? What about the satanic symbolism? What about the increased ease of human trafficking when both victims and criminals have their faces covered?
- Anger over psychological warfare being used on society, especially children, to wear masks.

9. Due to these unconstitutional Orders, I Have Suffered as follows in March:

I had called Oregon Schools to see about enrolling my son for the fall, but the person who handled that was on vacation for two weeks. When that time was up, Covid was in full swing.

12th - Work cancelled all travel and I had to begin assisting the local operation at my domicile center.

13th - lockdown and shelter in place began, along with travel bans to other states, or having to quarantine for 14 days upon return.

15th - churches started to cancel. Both our home churches were cancelled. Restaurants and bars were ordered to shut down at 9 pm.

18th - my husband's day job as a correctional officer at the county was shut down due to Covid.

23rd - 24 hour lockdown and non-essential businesses were shut down until April 6th.

10. Due to these unconstitutional Orders, I Have Suffered as follows in April:

3rd - We missed being able to celebrate my grandmother's 86th birthday, because she lives in Michigan and we couldn't afford to quarantine for 2 weeks off work.

12th - We weren't able to celebrate the resurrection of Jesus Christ in church, or with our families because of the restrictions set in place by the government.

14th - We went to a Sonic Drive-In to get ice cream and they wouldn't accept cash. They told us they couldn't get a truck to take the money to the bank due to Covid.

My son was supposed to begin his first session of learn-to-play hockey, but it was cancelled due to Covid.

Menards started imposing restrictions that no children under the age of 16 could enter their store. So while we are locked in our homes, wanting to complete home improvement projects, we have to get a sitter to go shop?

11. Due to these unconstitutional Orders, I Have Suffered as follows in May:
The governor mandated masks for all, but flip-flopped quickly on that. Instead, he made businesses require their employees to wear masks. My employer mandated masks for all service centers in Ohio on May 1st, due to the government mandate.
Costco was the next big store to mandate masks for entry. We have a membership, but stopped going because of the requirement.
I advised my employer that I would not be wearing a mask due to the exemptions listed in the executive orders, for health reasons. I was told I would have to get paperwork from my doctor, which I did. I worked on the 1st, the 4th, and the 5th with no mask, but was made to sit in the conference room so that no one would see me without a mask. (I normally sit in a cubicle in the main office area). Mind you, I had work without a mask, since this began, taking on the workload of 1-2 employees that stayed home after there was 1 positive case at our work (out of 270 employees). On Tuesday the 5th, I was sent home midday and had to wait through the reasonable accommodation review of my medical paperwork, citing claustrophobia and anxiety. It was 13 days before I was able to return to work on the 18th. They paid me for the first week (I'm salaried), but I had to use up vacation time to get paid for the second week. Upon return to work, I was treated like a leper. The same people I had been around every day, now wouldn't let me come up to their tape lines on the ground and talk to them (with their masks on), but wanted me to call them on the phone.
12. Due to these unconstitutional Orders, I Have Suffered as follows in June:
Hockey finally was able to start for my son, but they require temperature checks and contact tracing. If we didn't walk up to the counter but just sat down to put his gear on, they would chase us down to take temperatures. One week, they take all of ours. The next, they say they don't have to take our 1 year old daughter's, because she's under 10. But wait! You just took our 4 year old's temperature. Then there's no authentication to the contact tracing. The couple of times I actually was cornered in to doing it, I put partial information or completely made up information. They know who is enrolled in the clinic. This stuff makes no sense.
About two weeks after President Trump declared churches should reopen, I posted to the fellowship page of our main church, the one that has baptized both our children, and that has just married us last October. They were reopening, but sadly were requiring masks for all to attend. Several members attacked me,

claiming things like I was an insensitive, asymptomatic carrier, who was going to kill grandma. Needless to say, we severed ties with them.

13. Due to these unconstitutional Orders, I Have Suffered as follows in July:
- 1st - my husband was finally back to work at his day job, but only getting 12 hours a week, as opposed to the 20 he was getting. And unemployment said they couldn't help that he's losing approximately \$600 a month, because he makes too much at his other job. We were under the impression that if he was losing hours due to Covid, he was eligible.
- 20th - I was refused service at Buckeye Cable, even after informing them of my medical exemption. Their solution was to have me place my old modem down and walk outside to wait, in over 90 degree heat. The next day, my husband went in with a mask around his neck and was helped without anything being said.
- 31st - I was refused service at Chilly Treats, a walk-up ice cream place, that we have frequented this summer, mask free. All of a sudden, we can't order without a mask, even when I disclosed that I had a medical exemption, AND what the exemption was for.
- This month we also severed ties with the other church we attended over forcing masks. My husband has volunteered at this church for over 5 years, and this particular location for the 2 years since they've been open.
- This month we decided we will homeschool our son, even while we are both working 40+ hours a week.
14. Due to these unconstitutional Orders, I Have Suffered as follows in August:
- 2nd - I hadn't gone to Menard's since they quit allowing kids in, but desperate to resolve some contractor issues without driving clear across town again, I went in the morning for paint swatches. My sister and I went in mask free, looked for a while to find the right shade and do some comparing. Since they have one way in and one way out, we walked the long way to go out and I found something that caught my eye, so I took it to the register and checked out without any issues. I was in the store, easily, 15 minutes. When I chose the paint color, I went back to the store. I walked in and all the way back to the paint counter, waited my turn and had the employee mix me up a 5 gallon bucket of paint. As he was working, he told me I had to have a mask. I explained how I was just in there earlier AND I claimed my medical exemption. He told me he wasn't aware of the several exemptions, like that was my problem. Another employee came over, seemingly a manager of sorts, and told me I had to leave. I again explained being in the store earlier and about my exemption, adding that the other employee already had mixed my paint. He just said that I could not be in there without a mask, but that I could buy one of theirs or come in with a face shield, or that I could do curbside pick-up. I just gave it up and walked out.
- 3rd - my grandma's brother, the only boy out of 10 siblings, died in New York City. The funeral home only allowed 25 people, and 14 were immediate family. There was no way we could make the 9 hour drive and not even know if we could get in to the funeral home. The only other option was to drive all that way

to go to just the church service, as they allowed 100 people. Going that far, and only being allowed to attend a 1 hour church service, caused us to make the unfortunate decision to stay home.

10th - My son and I both woke up with sore throats, more than allergies and headed straight to the doctor, so we could be there when they would open. Our doctor is an hour away, so I called on the way for the earliest available appointment. The receptionist told me that they can't have anyone in the office with symptoms (mind you we've gone many times because they are naturopathic and chiropractic). I had to have a virtual appointment, which still, by the way, cost me the same amount of money.

16th - The pediatrician's office had an automated call reminder for my children's well check-ups on the 19th. The recording stated that all patients must wear a mask. I called on Monday, the 17th questioning this at a peds office. Both my kids are under 10, and not required by the state mandate. I was advised they could be seen without masks. I then asked about myself being in the office without a mask due to my medical exemption. They first said I could not because I was over 10. After me telling them I was going to cancel and they would not get the money from my insurance company, someone in the background told the receptionist that I was allowed in with my exemption.

20th - I went to the mall for a few things and stopped at Kay Jewelers to have my ring inspected and serviced. It is required every 6 months to keep up the insurance through them. It's already been over that, but I believe they are extending the time due to having been closed and now having limited hours. I was told I needed a mask, to which I replied that I have an exemption. They still wouldn't allow me in. (they have ropes up at each entrance.) I asked what I'm supposed to do then because I have insurance and I'm trying to keep it up and get my ring serviced. The employee ended up helping me from outside the store front. This same day, the dentist office called for a reminder for mine and my son's appointments the following week. I asked about the masks. They stated we have to call upon arrival, stay in our car until they tell us to come in, and wear a mask for the 1 minute walk from the door to the chair. I told them we would not be coming and to cancel our appointments. They asked if I just wanted to postpone. I stated we would not be coming back if they keep up their policy.

15. Further, Affiant sayeth naught.

Kristen Beckman 8/27/2020
Kristen Beckman

Sworn to before me and subscribed in my presence this 27 day of August, 2020.

Deborah Jao Lucas
Notary Public



Deborah Jao Lucas
Notary Public, State of Ohio
My Commission Expires June 18, 2022

Affidavit of Kirsten P. Hill

State of Ohio / Lorain County ss:

I, Kirsten P. Hill, being first duly sworn according to law, state that I am legally competent to testify in this matter, and I have personal knowledge of all the facts contained within this affidavit. I am competent to testify as to all matters stated herein:

1. All documents attached to this affidavit are genuine copies of the original and are fully incorporated by reference herein as if fully rewritten herein. All Exhibits referenced and/or attached thereto and fully incorporated by reference herein are all true and genuine copies of the originals and each is incorporated herein as evidence in support of the plaintiff's motion. All documents as was filed in this matter attached to the complaint are also incorporated herein fully by reference by this affidavit as if fully and completely rewritten herein. This includes all documents contained in the Exhibits attached to the complaint as filed for record. All Exhibits referenced and/or attached thereto and fully incorporated by reference herein are in support my individual claims that my Constitutional Liberties, Freedoms and God given, absolute, fundamental, and inalienable Rights have been unconstitutionally infringed upon and denied and/or jeopardized to me as I detail herein.

2. The DeWine, Acton, Himes Orders as have been issued since March 2020 have adversely impacted my Constitutional Liberties, Freedoms and God given, absolute, fundamental, and inalienable Rights.

3. As a direct and proximate result of these unconstitutional orders and their mandated implementation, I have been made to endure:

- a. I was denied the right to breath fresh air. Further explanation in e.2. below.
- b. I was denied the ability to fulfill my duties as an appointed member and current vice chairman of the Board of Zoning Appeals in Amherst Township, Ohio. The responsibility of this board is to act and render a decision on Amherst Township property owners' appeal applications. These appeal applications request variances to the regulations of building and land use in Amherst Township as written in the Amherst Township Zoning Resolution. I was appointed to this board in 2007 by the Amherst Township Trustees and have served continuously to the current date, also serving as the board chairman from 2009 to 2018. Further explanation in e.3. and e.5. below.
- c. I was denied the right to earn compensation for performing the prescribed duties of members of the Amherst Township Board of Zoning Appeals. Further explanation in e.3. and e.5. below.
- d. I was unwarrantably shamed in a public meeting in the Amherst Township Hall, 7530 Oberlin Rd., Elyria, Ohio. Further explanation in e.2. below.

KH

- e. Below is a description of the incident at the Amherst Township Hall on the evening of August 19, 2020. Paragraphs are numbered for ease of reference.
1. Kirsten Hill, as a member of the Amherst Township Board of Zoning Appeals, entered the Amherst Township Hall before 7 p.m. when a hearing was to take place on August 19, 2020, to consider, act upon and render a decision about a variance application from John Eavenson/Hampshire Farms LLC for a variance to regulations written in the Amherst Township Zoning Resolution.
 2. The hearing was called to order a few minutes after 7 p.m. by the Amherst Township Board of Zoning Appeals (BZA) Chairman, Bill Latrany. Latrany asked Hill to wear a mask, which would restrict her right to breath fresh air. A few minutes later Latrany recused board Vice Chairman Kirsten Hill from participating in the hearing because she was not wearing a facial covering. Just before Latrany recused Hill, he unwarrantably shamed her for not wearing a mask by describing that everyone else in the hall was wearing a mask and that another member of the board who was present in the hall had an inoperable health condition, insinuating that Hill was jeopardizing that other person's health because Hill was not wearing a mask.
 3. Hill told Chairman Latrany and those assembled that she was healthy and that the mask-wearing requirement was unconstitutional. Hill also stated to Chairman Latrany and those assembled for the hearing they could assume she has a medical condition. Chairman Latrany asked Hill to recuse herself from participation in the hearing. Hill said 'no' she would not recuse herself from the hearing. Chairman Latrany then stated he recused Hill from participation in the hearing. Thus Hill was denied her ability to perform her appointed duties and to earn related compensation as a member of the Amherst Township Board of Zoning Appeals.
 4. Just after Chairman Latrany said he recused Hill from the hearing Daniel Samms stood up and expressed that he could not believe [that Hill was being dismissed from performing her duties on the Board that evening], that this [recusal by Chairman Latrany of Hill] was happening in the United States for Hill not wearing a mask [in the Amherst Township Hall]. Samms owns property adjacent to the Hampshire Farms property thus he had received notice and an invitation to attend the hearing at the Amherst Township Hall on August 19, 2020.
 5. After Daniel Samms spoke, and as Chairman Latrany, Amherst Township Trustees, other Board of Zoning Appeals members, John Eavenson, adjacent property owners and other township officials observed, Hill gathered the variance application papers, the Amherst Township Zoning Resolution binder (issued), left her seat on the podium and exited the Amherst Township Hall several minutes after 7 p.m. on August 19, 2020. Thus Hill was denied her ability to perform her appointed duties and to earn related compensation as a member of the Amherst Township Board of Zoning Appeals.

6. The hearing proceedings on John Eavenson/Hampshire Farms LLC zoning variance application took place on August 19, 2020, without Hill being present.
 7. A video of the hearing on August 19, 2020 was being recorded by Georgianne Lynch, assistant to the Secretary of the Amherst Township Board of Zoning Appeals.
4. Further, Affiant sayeth naught.

Kirsten P. Hill

Kirsten P. Hill

Sworn to before me and subscribed in my presence this 29th day of AUGUST, 2020.

Robert J. Gargasz

, Notary Public

~~ROBERT JOHN GARGASZ, Attorney at Law~~
Notary Public, State of Ohio
My commission has no expiration date
Section 147.03 R.C.

Affidavit of Eric J. Calderaro

State of Ohio / Clermont County:

I, Eric Calderaro, being first duly sworn according to law, state that I am legally competent to testify in this matter, and I have personal knowledge of all the facts contained within this affidavit. I am competent to testify as to all matters stated herein:

1. All documents attached to this affidavit are genuine copies of the original and are fully incorporated by reference herein as if fully rewritten herein. All Exhibits referenced and/or attached thereto and fully incorporated by reference herein are all true and genuine copies of the originals and each is incorporated herein as evidence in support of the plaintiff's motion. All documents as was filed in this matter attached to the complaint are also incorporated herein fully by reference by this affidavit as if fully and completely rewritten herein. This includes all documents contained in the Exhibits attached to the complaint as filed for record. All Exhibits referenced and/or attached thereto and fully incorporated by reference herein are in support my individual claims that my Constitutional Liberties, Freedoms and God-given, absolute, fundamental, and inalienable Rights have been unconstitutionally infringed upon and denied and/or jeopardized to me as I detail herein.
2. The DeWine, Acton, Himes Orders as have been issued since March 2020 have adversely impacted my Constitutional Liberties, Freedoms and God-given, absolute, fundamental, and inalienable Rights.
3. As a direct and proximate result of these unconstitutional orders and their mandated implementation, I have been made to endure the following:
4. We The People of Ohio, including myself and my family, have been more than patient, understanding, flexible and cooperative with the deprivation of our inalienable rights and freedoms under the guise of safety and security from COVID-19, and we have embodied the American goodwill of sacrificing for our fellow Americans; and we did so even to the detriment of our own health, welfare and being able to provide basic necessities for our own families. Come to find out, Governor DeWine, Lieutenant Governor Husted, former Director of Health, Amy Acton, and current Interim Director of Health Lance Himes, all breached public trust with an abundance of serious constitutional violations and criminal acts, not the least of which was and continues to be, their illegal suppression, manipulation and presentation of incomplete, misleading and false COVID-19 data and models which they use as justification to deprive us 11.7 million Ohioans of what were supposed to be our inalienable rights and freedoms under the Ohio and U.S. Constitutions; rights and freedoms for which millions of Americans died defending.
5. The State of Ohio's actions have wreaked havoc, turmoil, angst, anxiety and undue stress upon me, my entire family, and all 11.7 million Ohioans. These baseless orders have affected my family and me in numerous adverse ways in a multitude of situations. For five months and with no end in sight, the State of Ohio has acted with impunity by depriving my family and me of our once guaranteed constitutional rights and freedoms. "Somewhere a perversion has taken place. Our natural, unalienable rights are now considered to be a dispensation of government, and freedom has never been so fragile, so close to slipping from our grasp as it is at this moment." While Ronald Reagan said this in 1964, his words are sadly, befitting of today. I often have conversations with my children asking the same questions Reagan asked in 1964, "Whether we believe in our capacity for self-government or whether we abandon the

American revolution and confess that a little intellectual elite in a far-distant capitol can plan our lives for us better than we can plan them ourselves.”

6. As Samuel Adams wisely stated, “It does not require a majority to prevail, but rather an irate, tireless minority keen to set brush fires in people’s minds,” because “security without liberty is called prison.” (Thomas Jefferson).

7. This is my story, my stand for the truth and justice against the State of Ohio.

8. My primary goal in life, the one thing that brings me the most fulfillment in life, my overall sense of purpose in life, is to provide for my family and ensure their happiness, safety, security and overall wellbeing. There is nothing more important in my life than my family. Seeing my family suffer mentally, emotionally, physically and financially for five straight months due to the State’s unnecessary, egregious, deceptive, callous, irrational, hypocritical, unconstitutional and criminal actions has negatively impacted my overall health, my once positive outlook for the future of my family, and caused me to be disillusioned about the state and country that I have loved ever so dearly my entire life. The State has shredded the once high esteem I held it in, and the State has caused me to see what I can now never unsee – how un-American it has become. The State is killing my patriotic American spirit – which for me, is worse than death. My last beacon of faith is our Judicial Branch.

9. My wife, Tara L. Calderaro and I have two children. I am my children’s step-father and have dedicated my life to loving and raising them for the past 14 years. Our 24 year-old daughter, CHILD 1 and 17 year-old son, CHILD 2 are both on the Autism Spectrum (high functioning).

10. I realized early on during the COVID-19 crisis that the cure was indeed far worse than the disease. And as a result, I witnessed my family suffer never-before-experienced levels of anxiety, sadness, depression, disillusionment and deep raw emotional pain that I would not wish on my worst enemy. Since that time, I have fought tirelessly on every level possible, to bring attention to these facts and to return my family, our community, our state and our country back to the old normal. I have repeatedly reached out to my elected officials and law enforcement at the local, county, state and federal levels via phone, email, social media and in person; all of which has been to no avail. I became so desperate that on April 18, 2020 I humiliated myself out of the love for my family, state and country, by literally begging Governor DeWine and Lieutenant Governor Husted in an email as follows:

11. Dear Governor DeWine & Lieutenant Governor Husted,

12. Did you know the 2017-2018 annual flu in just the U.S. infected 45 Million with 61,000 deaths, and that was the worst flu season since the 2009 H1N1 pandemic which infected 61 Million? And that was with a readily available flu vaccine, which is only 40%-60% effective according to the CDC. If a vaccine wasn’t available, we would have had 51 MILLION cases and 66,700 deaths in 2017-2018 according to the CDC.

13. I wonder how different our country would have been during 2017- 2018 if every day, we were fed stats on infection and death rates as we are fed now with COVID-19. Now thinking about it, the infection rate in 2017-2018 was more than 67 times higher and death rate twice as high as COVID-19 is today, so why the disproportionate response now vs. then? It’s sad that the flu victims in 2017-2018 received virtually no additional government assistance, no media coverage of their stories of suffering or stories of medical heroes, no public outcry, no freedoms were taken away.

14. Don't all lives matter? And if so, why does it now seem that the lives and freedom of the 11.6 MILLION Ohioans matter less, including the nearly 1 MILLION whose livelihoods have been destroyed with unemployment, which will undoubtedly have grave consequences, the 46 MILLION suffering from mental illness and the 19 MILLION with a substance abuse problem?

15. My family is suffering greatly, just like all Ohioan families. My 2 children have autism, anxiety and depression. Their entire lives have been turned upside down. Do you have any idea what happens when you significantly change the routines of autistic children? I hope you are blessed to never have to witness, parent and feel helpless watching your children repeatedly cry, scream, panic, have outbursts that last for literally 4 hours non-stop, have sleepless nights, have an empty look in their eyes all day with all hope lost because their routines have not only changed, but they are in a limbo state awaiting your next decisions as to when they can return to their beloved schools and friends – the only things that allowed them to feel normal.

16. We, like all Ohioans, have been more than patient, understanding and cooperative with the lockdown in every way; even to the detriment of being able to provide basic necessities for our own families. And yet you continue to plod forward as if your grossly flawed prediction models weren't flawed at all, as if the reality of what is actually happening to ALL 11.6 MILLION Ohioans, should play no role at all in the decisions we make going forward.

17. The negative impact this unnecessary continued lockdown is having on my children, like all children, especially those with special needs like mine, will never be able to be undone and will last a lifetime; and the effects progressively worsen each day you keep us waiting with baited breath to have our freedoms completely restored and life returned to normal.

18. And now you push masks. Do you have any idea how some children, like mine, respond when having anything forced over their face like a mask? Watch children with autism and learn about how they need to “stim” to deal with anxiety; some go so far as having to bang their heads against walls when anxiety is so great. Now you want me to put my autistic children in that position by forcing them wear masks? Whether or not you mandate it makes no difference because you clearly know by strongly urging (i.e. forcing) businesses to implement masks, they will soon require it of their customers. My children cannot wear masks; therefore they will be discriminated against because their access to the normal freedoms all other Ohioans enjoy (shopping, movies, etc.) will become extremely limited to only those businesses brave enough to act with common sense and let us Ohioans determine what to place on our faces and when.

19. I beg you, for the mental, physical and emotional wellbeing of my children, of all Ohio families, to end this lockdown and return us to normal life immediately and allow us the freedom to live with voluntary common sense measures. Forcing us to live in fear with some slow phased in approach for the next 18 months until a vaccine comes, as if a vaccine is a miracle cure, is completely un-American, as is the thought of any government attempt to mandate vaccines for adults. I know other State Representatives, including Nino Vitale agree, and his letter to you is attached herein for reference.

20. Our American courage to live free has often reminded us that freedom comes with inherent risks, including fear and death. My compromised immune system (I have emphysema) should not take precedence over your freedom, just as my freedom should not end where your fear begins.”

21. And sadly, to no surprise, I received no response of any type.

22. My family and I all qualify for medical exemptions from masks. I have emphysema, asthma and anemia. Placing a mask over my face for any length of time makes it difficult for me to breathe, causes

me to feel like I'm gasping for air, I become lightheaded and dizzy causing me to have to be seated or lie down and I have to use my inhaler. The State's COVID response has caused me to experience unending stress from the moment I awaken until I go to bed. My sleep is not restful, I often awaken in night terrors. My Irritable Bowel Syndrome (IBS) and Gastroesophageal Reflux Disease (GERD) have worsened greatly.

23. Were it not for the governor's mask mandate and continued inducement of panic to all Ohioans over a virus with a 99% survivability rate that primarily impacts select members of our population, my family and I would not be deprived of our constitutionally guaranteed freedoms as outlined under Article 1 Section 1 Bill of Rights of the Ohio Constitution which guarantees that "All men are, by nature, free and independent, and have certain inalienable rights, among which are those of enjoying and defending life and liberty, acquiring, possessing, and protecting property, and seeking and obtaining happiness and safety."

24. Prior to the mask mandate, enjoying the simple basic freedoms to go retail shopping, leisurely walks, hikes in the parks, the zoo, museums, which we enjoyed as a family, husband/wife and/or individually at least once or twice per week. Those activities provided us an opportunity to bond as a family, enjoy new experiences, meet new fellow members of our community, were critical to the psychosocial development of my children, it brought me and my family a tremendous sense of happiness, and we could do so in relative safety. However, since the governor's mask mandate and the State's continued inducement of panic to most Ohioans, including retailers, we have been deprived of these freedoms because all retailers now require masks, many retailers will discriminate against us by not honoring our medical exemptions from masks, and even when they do honor our medical exemptions, it's often at the expense of having to endure public ridicule and shaming as well as demeaning and/or aggressive behavior towards us by store employees and customers and we feel our safety is now at grave risk.

25. This causes my family and I to needlessly suffer extreme anxiety at the mere prospect of having to leave our home for any reason. Because of the amount of anxiety my family and I have due to the State pitting mask-wearers against non-mask wearers, and the fact that everyone in my family is medically exempt from the mask mandate, my family and I are deprived of the same constitutionally guaranteed rights and freedoms as other mask-wearing Ohioans enjoy. To avoid the extreme negative experiences and risks to our personal safety mentioned previously, my family or I no longer go out for any leisure activities. We only go out for essential items/services.

26. So, while the State's mandated house arrest has ended, its psychological arrest on the mental and emotional health of myself and my family continues unimpeded. The State's intentional divisive and panic inducing rhetoric has real life impacts to the average Ohioan like me and my family. Examples of such language include:

- [05/04/20 DeWine Tweeted](#) "There are legitimate reasons why some may not be able to wear one [mask] in a store, but the fact remains that when you do – you're saying that you care about other people. We're going to do everything we can to get that message across."
- [05/07/20 DeWine Tweeted](#) "You have it within your power not only to impact your family but other families as well. You might not be concerned with what happens to you, but you should be careful for others. Wear a mask for others."

27. It's what DeWine did not say that is just as big of a concern which is - what are Ohioans with ADA protected medical conditions, conditions which prevent them from wearing a mask, saying by not wearing a mask in a store? The State is clearly and blatantly creating an unhealthy and unsafe divide between Ohioans who wear masks versus those that can't, and by default they are demonizing and ostracizing Ohioans with ADA protected medical conditions like my family and I. Additionally, DeWine made it clear that if you don't wear a mask that means you don't care about yourself, nor care about others.

COMMUNITY CONFRONTATIONS

28. Due to our medical exemptions from masks, we have endured several shopping trips where we have been verbally harassed, shamed, physically assaulted, been the subject of eye rolls, disapproving head shakes, glares, refused service and dehumanized. We have been told to stand outside and offered ridiculous alternatives to masks, furthering our point of view that masks are for compliance only and not for safety.

COSTCO – Mason, Ohio

29. In addition to the medical exemptions outlined in DeWine's mask orders, Costco specifically provides a medical exemption on their website which reads as follows: "To protect our members and employees, all Costco members and guests must wear a face covering that covers their mouth and nose at all times while at Costco. This requirement does not apply to children under the age of 2 or to individuals who are unable to wear a face covering due to a medical condition."

<https://www.costco.com/covid-updates.html>. Tara and I have been Costco members together since about 2006, and my Costco membership started back in 1995. In fact, I worked for Costco for a winter season while in college back in about 1996. For most of the shopping trips documented below for all retailers, I have them video recorded on my device. The current atmosphere of government-sponsored COVID fear, panic, misinformation and government-sponsored societal division pitting mask wearers versus non-mask wearers, has resulted in increasing reports across the country of harassment, shaming and in some cases violence by masks wearers onto non-mask wearers. So, I feel compelled to secretly record my shopping trips just in case, God forbid, something was to happen. After all it's my unmasked word versus the word of those in the majority who are masked, and I don't ever intend on being a victim of any false allegations that I said or did something wrong. So, I want video evidence on my side.

COSTCO - July 6, 2020 – Recounted by Tara

30. We entered into Costco, with our medical exemption to allow us to shop maskless. We decided to stop by the optical department first, because Eric, our daughter and I are all in desperate need for updated eye glass prescriptions and glasses. The woman behind the counter in the optometrist's office said very rudely "Where's your mask?" Eric said, "We have medical exemptions." She said rudely "Both of you?" Eric and I said "Yes". She stated, "You need to wear masks." Again, we stated we have medical exemptions. I then asked, "I take it that means we would need to wear masks during the eye exam as well?" Both she and the optometrist, who was sitting literally 3 feet from me both said in unison "Yes". I said, "Okay then, well, that isn't going to work because I can't breathe in a mask. Thanks anyway." Eric and I proceeded to walk away. That event was so belittling, that we were both angry and I was distraught. That woman made us feel like we were walking disease. As I was pushing the grocery cart, I accidentally crashed into the signage advertising a TV. When I glanced up to see if anyone had witnessed my less than graceful cart maneuvering, I saw a woman standing in an aisle, watching us, approximately 20 feet away. Eric noticed her as well. So, we made an off-handed joke about my bad cart steering and driving. The woman looked at us and said, "I am not concerned about that. I am more concerned that

you both don't have masks on." Eric said to her, "Maybe you shouldn't be so quick to judge. Did you think that maybe there is a reason we can't wear masks? We have medical exemptions." As we proceeded to walk away, which entailed walking past her, she started to back up. I looked at her and said "Relax lady. You're safe." Eric and I had to go to another aisle and take a minute to regroup. Two back to back negative encounters is taxing. At that point, I was teary-eyed from the sheer frustration and exhaustion of the situations. Basic shopping should not evoke a fight or flight response.

COSTCO - July 13, 2020 and July 21, 2020 – Recounted by Tara

31. On two separate occasions, we were rudely questioned when entering Costco. As per usual, Eric shows the membership card and walks on the side closest to the door attendant. I walk on Eric's other side and push the cart. As Eric shows the membership card, we are asked "Do you have masks?" Eric clearly and very audibly states, "We have medical exemptions." At which point, the door attendant asks in a condescending tone, "Both of you?". Eric replies "Yes, BOTH of us." To be questioned rudely, in front of other customer's is unnecessary and demeaning. Eric's voice is loud and clear. There is no reason that the door attendant needs to clarify both of us, unless they lack command of the English language and are unfamiliar with the word "we". Which, given the fact that these same door attendants on other occasions, have not had to clarify the word we, I find that unlikely.

COSTCO - July 30, 2020 – Recounted by Eric

32. My son, who has autism, and I entered Costco without masks. I said very politely, "How you doin'?" as I showed my membership card to the two Costco employees (male and female) screening at the door. The male employee said, "You've gotta have masks." I politely said, "We have medical exemptions, thank you." The male employee said, "What?" His tone was clearly one of not believing me, rather than a way to indicate he didn't hear what I had to say. And there was at least one other customer standing near me observing the encounter, which certainly only heightened the level of anxiety my son already felt. So, I politely repeated again by saying, "medical exemptions." He said "Okay" in a sarcastic condescending tone and clearly rolled his eyes at us. It was impossible to not see his eye roll, as his eyes were about the only thing we could see on his face given he was wearing a mask. Being that I was with my son who has autism, and he feels abnormal and ostracized as it is for just being himself, the last thing he needs is further reinforcement of his differences by some employee mistreating him with a sarcastic condescending tone and eye roll for not being able to wear a mask. So, I said to the male employee that "the little eye roll is not appreciated, thanks" and as I did that the male employee waived his hand to shoo us away. I then said to him, "You should not assume. That's the problem in our society people assume the wrong thing. Look at the law it's got 13 exemptions. You should know them if you're going to try and enforce it." The employee muttered something I could not understand, and we then walked away and began shopping. My son said he saw the employee's eye roll and said his (my son's) heart was still a mess inside with anxiety as a result. I did the best I could to reassure him and let him know it's ok to respond back to someone who is being rude to him.

COSTCO - August 6, 2020 – Recounted by Eric

33. When Tara and I shop anywhere we wear our patriotic freedom themed t-shirts which we design, have printed and we sell as part of our small business. As we approached the Costco entrance, Tara and I recognized the employee, John from an encounter we had about one month prior. During that prior encounter when we entered and John said we needed masks, I politely advised him we both have medical exemptions. He challenged us and did so in a rude, condescending and loud manner by stating, "both of you!" I said yes as we continued entering Costco unobstructed and without delay.

34. As Tara and I tried to enter Costco August 6, 2020, in an effort to do all we could to avoid any issue with John and just shop in peace, when I showed my membership card, I was certain to be extra friendly to John by stating, "How you doin' my friend. We have medical exemptions." Normally that's all that is ever required, and we are allowed in without delay or having to stop for any reason. However, as we attempted to enter like every other customer, John lifted his right arm in front of me while simultaneously placing his right hand pushing into my stomach to stop me from entering. I immediately stopped, shocked and appalled at his actions. I immediately told him that he didn't need to touch me, nor did he need to try and stop me. He said I was blocking him in some way (which made no sense). I told him he didn't need to touch me, and he could simply say "excuse me" if he needed something from me. I asked him why he was trying to stop me. I reiterated how I didn't understand why he was physically touching me. John said I was blocking him from seeing Tara's cart as we entered. This made no sense, as there was no reason to screen an incoming cart – no one steals anything *entering* the establishment. I asked him why he didn't just simply say "excuse me sir" and I would have known to stop, and why did he have to touch me? He then said, "I'm sorry my hand touched you." As we were standing there, there was at least one other customer observing our encounter. John still did not permit us to enter as evidenced by the fact he was still standing in front of us blocking our entrance. However, during that time John did find the time to screen and allow entry to other incoming customers who walked right by us. This was humiliating to us. Because we were not wearing masks due to medical exemptions which I clearly announced to John, John discriminated against us by not allowing us entry and then proceeded to assault me by placing his hand into my stomach.

35. I then asked John what he was looking for in our cart. He said he was looking to see if there was something underneath Tara's purse which was inside the cart, or empty boxes, empty bags and "stuff like that." I told John that next time I would appreciate that if he needs something to say, "Hey sir excuse me." I advised him that I didn't know he was trying to stop me. I explained that I've never had an employee actually stop me and put his hand out to physically touch me, and I said, "I don't understand." John said, "sorry I touched you." I said, "thank you." Despite my wife and I being humiliated, discriminated against and me being assaulted, and despite being extremely angry and anxious inside as a result, I remained calm, composed and overly polite over the 1.5 minute encounter. And Tara didn't speak a word.

36. I then went to report it to an on duty manager named Reggie and continued to video record. Reggie said John should not have touched me or made any contact with me whatsoever, and John should have stopped when I said we had medical conditions. I told the manager if employees are worried about a virus, that last thing they should be doing is touching me. I explained how we have been hassled at the entrance several times in the past, and how I didn't come complain prior because I don't want a hassle. I just want to shop in peace. Reggie apologized numerous times and thanked us for bringing it to his attention.

37. After we completed our shopping, I wanted to find out what was found out and done about our incident. We went to find Reggie, however he had left so we spoke to another manager, Justin. Justin said he saw the video tape and hadn't talked to John yet. Justin said from what he heard second-hand from Reggie, John was trying to see our membership card which is why he stopped us. Tara and I both told Justin that is incorrect, and makes no sense as I was standing closest to John and showing my membership card which covers for the both of us entering, and when I asked John why he stopped us he said it was to look for boxes in our cart not, to double check our membership card. I explained to Justin that our medical conditions may be invisible but that doesn't mean we don't have them. I also brought up the example of my son who has autism and was hassled in our prior visit and how it is very

judgmental for employees to behave this way. I explained that if Costco is going to try and enforce the mask mandate, they need to be aware and honor the 13 exemptions in that mandate. I told Justin that I would appreciate if he talks to his staff. Justin went on to vent and say that he is having the conversation “more and more” with his employees to not touch people. Justin said he cannot believe he has to tell grown employees to stop touching people and explain that some people would give a “butt whooping” for touching them. Justin also said he’s coached his staff that they are not the “mask police.”

38. There was no rational reason for John to do what he did. It’s clear he simply wanted to harass us and physically assault me because he didn’t like us exercising our rights in accordance with the state mask mandate and in accordance with his employer’s corporate policy to honor medical exemptions.

COSTCO - August 17, 2020 – Recounted by Eric

39. While walking in Costco keeping to myself, an elderly woman wearing a mask only half on (only covering her mouth but not nose) confronted me and said, “Where’s your mask?” I replied, “Ma’am, where is your ability to not make assumptions about the fact I have a medical condition?” She interrupted me and said, “to come in here you need a mask.” I said, “not when you have a medical condition. Did you take a look at the governor’s orders because they have 13 exemptions?” She said that she did. I said, “apparently you didn’t read them.” She said, “you just wanted to be a smart ass.” I explained to her that the problem in our society is people like to assume. And then a male customer who was not a part of the conversation nor did he appear to be with the woman, yelled at me, “Oh shut the fuck up!” The woman then said, “You want us to get it [COVID] from you!?”

AUTO ZONE – Mason, Ohio - August 4, 2020 – Recounted by Eric

40. Our daughter’s car broke down at the home of one of her pet-sitting clients. Her battery had leaked and was smoking. I removed the battery and Tara and I went to Auto Zone to get a new car battery to repair her car. Upon entering Auto Zone, the woman at the counter motioned that we needed masks. I said, “we have medical exemptions, thank you.” Her facial expression was one of disgust. She said we needed to talk to the male employee who was just entering from outside. To mitigate the chances of any issue, I was extra friendly to the man by saying, “Hi my friend, how are you?” He asked us if we had masks. We said, “we have medical exemptions, thanks.” He said “because it’s private property, we still don’t...we have to have something of some kind..” I politely explained the ADA and the mask order has 13 exemptions. He said, “I understand, I also know it’s called peddler’s privilege. I’ve done all my research.” I again tried to explain how he was going to enforce the mask mandate but ignore the 13 exemptions within that mandate. He then stated, “I can’t wait on you cuz I have...unfortunately I’m one of the ones that can die from this, so I won’t wait [serve] on you.” That was the end of the interaction. We were left standing there momentarily, embarrassed, humiliated, dehumanized and discriminated against while holding our daughter’s leaking car battery and offered no options to resolve it. Another male employee (Billy) spoke up and said he can offer curbside pickup and he could help us outside. We took care of the battery using curbside pickup, and had Auto Zone informed us of this option from the outset, we could have avoided the entire situation. While outside Billy said we could return to have our daughter’s charging system checked given her battery leaked and smoked. I thanked him and advised we would return shortly.

41. After replacing the old battery with the new one, about one hour later we returned to Auto Zone. We went inside to ask for Billy. As soon as we walked in a male employee rudely motioned to me to put a mask on. I told him we have medical exemptions and he should ask me first before assuming anything. The female employee at the counter said Billy was in the restroom. She then offered us what I can only

described as a failed attempt at a “mask” and explained it as follows, “we just have like little paper things to hold in front of your face.” She then reached her visibly dirty greasy hands underneath the cash register and pulled out an 8.5”x 11” piece of floppy paper taped to a popsicle stick and offered it to us saying, “just so you can be in here.” We were expected to walk around the store while holding this in front of our face. She offered this as some sort of mask substitute, as if a piece of paper on a popsicle stick would do anything except further humiliate, degrade and discriminate against us. Despite this abhorrent treatment, we remained polite and said we will wait outside for Billy.

42. The female employee who offered us the popsicle stick “mask” came outside to check the car’s charging system. She did not seem worried about any virus considering she rubbed her eyes with her fingers, repeatedly adjusted her mask, pulled her mask down at one point to wipe her face with her hands. The mask is clearly not about a virus – it’s about compliance.

DSW (Designer Shoe Warehouse) - Mason, Ohio – August 17, 2020 – Recounted by Eric

43. As Tara and I entered, Chris, the same employee that mistreated Tara a couple of weeks prior, said “get you a couple masks.” I replied, “we have medical exemptions, thank you.” He replied, “Oh well, the building said masks are required.” I said, “Sir don’t give us a problem, unless you want to violate ADA. The law [mask mandate] has 13 exemptions. Do you not know them?” He replied, “if you don’t want to wear a mask then you can shop at home” and he motioned for us to leave while saying this. I replied, “no, that’s not a reasonable accommodation, so we’re going to continue to shop.” Chris then said to his staff, “call the police.” This was humiliating and degrading, especially given the fact that 2 other DSW employees (Jason and a female) along with at least one other female customer were observing our encounter. It’s as if Tara and I are dangerous animals on display at some circus for all spectators to gawk at. Despite this feeling, Tara and I remained polite and simply proceeded to shop.

44. While at the register to pay for the shoes, we spoke to Jason; the same Jason that helped Tara during the last visit. Tara asked Jason if Chris was a manager and explained how we felt Chris accosted us when we walked in. Despite the fact Jason was standing and watching us interact with Chris as we entered, Jason said he didn’t know what had happened exactly. Tara explained this was the second time she had been given a hard time by Chris and she explained the incident on July 29th. Tara and I then both explained how we have medical reasons why we cannot wear a mask. Tara explained as she began to cry, “I don’t think I should be coming in here and having to have a panic attack because I’m going to be accosted” by an employee for just buying a pair of shoes. Jason said the mask requirement is a company policy. Tara asked, “is it a written company policy that I can see?” Jason said it is a written policy but he “does not have the policy available.” I then asked, “what about people who have ADA protected medical conditions?” Jason hesitated and said, “I don’t have the answers that to be honest with you.” We explained we should be treated like normal fellow citizens and like regular humans, rather than treated as lepers and being rude and confrontational, and refusing to serve us. We also explained how we feel discriminated against for being denied the same freedoms everyone else gets to enjoy, which are constitutionally guaranteed, simply because we have medical conditions that exempt us from wearing masks. I then asked Jason about the fact Chris said we should shop online or at home. Jason said, “that’s not what he should have said. I apologize.” I then asked, “what should he have said.” Jason replied, “he shouldn’t have said you can shop online.” He said, “that’s an idea that’s a suggestion.” In that moment “we could have worked through that conversation a little better.”

HOT TOPIC – Cincinnati, Ohio July 13, 2020 – Recounted by Eric

45. We have shopped at Hot Topic for over 12 years for our children. It's their favorite store. Hot Topic denied Tara and me entry for not wearing a mask, despite the fact we told them we have medical exemptions. The employee manning the door even recognized us for having shopped in there so often. That didn't matter, we were still treated rudely as if we were subhuman. We advised them by refusing to allow us entry after having informed them we have medical exemptions, it's clear discrimination. The employee didn't care, and just cited it's corporate policy. Hot Topic did not offer any options or accommodations for us to shop. It was only after I insisted Hot Topic provide some type of reasonable accommodation, did the employee say he can shop for us and bring things to the door. The employee began to ask us questions as to what we were looking for – what theme or genre. We explained that we don't have anything specific we are looking for since our children like almost everything in the store, and we don't know what is available in the store to purchase. The employee asked, if we wanted him to bring up a mug or a t-shirt or a blanket, etc. And again, we said we didn't know we had to shop around to determine what we wanted. We explained that typically we spend one hour or so shopping in Hot Topic trying to find the perfect gifts for our children. He then responded in a rude, sarcastic, snarky fashion, "do you want me to just bring everything up, because I can for you, if that's what you guys want?" Realizing that was not reasonable either, and nor would he do it even if we asked, we then spent several minutes providing constructive ideas for reasonable accommodations to the Hot Topic employee.

TARGET/CVS Pharmacy, Milford, Ohio – Recounted by Tara

46. I, my husband, and our daughter have each had issues with our pharmacist regarding our lack of masks. Each time we go in to pick up prescriptions, we are given the third-degree as to why we don't have masks on and why we should have masks on. It has gotten so bad, that our 24-year-old daughter will not go to pick up her medications because she simply can't tolerate the barrage of questions and condemnation from the pharmacist. I have had numerous encounters with the pharmacist myself. The pharmacist had the audacity to bring up my daughter's asthma and say that that is a reason why our daughter should wear a mask. My daughter has asthma that causes her blood oxygen saturation to be around 85% on a good day. The last thing she needs is to be masked and deprive her body of even less oxygen. It is ridiculous to have to be subjected to discrimination, lectures, and propaganda when all we simply are there to do is pick up medicine.

TARGET – Mason, Ohio - July 30, 2020 – Recounted by Eric

47. Target or Lowe's are no longer pleasant experiences, as they induce unnecessary panic for my son with Autism. Due to DeWine's continual panic inducement and his constant mask up commercials that are even on the kids shows on YouTube that my son watches, my son has become an even bigger germaphobe. Sometimes it's so bad that my son is too afraid to even go outside in our yard worried he will get COVID from breathing fresh air. When he does have the courage to go out shopping, he gets bombarded with this Orwellian psychological manipulation that is so intrusive and so loud. Because we're in a relatively small indoor enclosed environment in Target and Lowe's, the loudspeakers are of a volume similar to how loud it sounds at a sporting event. And for kids with Autism their hearing is often over-sensitized, and they can't handle extreme noises. This just further induces panic and overall anxiety for everyone especially kids like my son.

48. Here's what the 15-second announcement over loudspeaker says, "Thank you for shopping with us today. Our first priority is the health of you, your families and our team members. So, we'd like to remind you that due to local ordinance, wearing a face mask is required while shopping. And remember, please keep a distance of 6 feet from those around you while you shop and at checkout. We appreciate your understanding."

LOWES – Mason, Ohio - July 30, 2020 – Recounted by Eric

49. Shopping with my son, we endured the same psychological manipulation as we experienced at Target a little while earlier. Lowe's manipulation began with 3 loud beeps then a 35-second announcement over loudspeaker saying, "At Lowe's safety is a priority for our associates and customers. Please remember to maintain social distancing of at least 6 feet, wash your hands frequently and cough into your elbow. We are committed to your safety while visiting our store. We continue to resupply our store daily with product inventory to ensure you have the items you need, though some items may be limited. We appreciate you visiting Lowe's and look forward to seeing you again soon. Have a Lowe's safe day."

50. During these past five months, I have watched my family's mental state go from happy and optimistic to pensive, tired, anxious, depressed and angry. I have seen the light and excitement for life fade from my children's eyes. For what? For a virus that most of us need a test to know if we even have it. For a virus that has a 99% survival rate. For a virus that has been egregiously mismanaged and misrepresented by the State. I have provided some additional background information on my family to help the Court understand further how the State's actions have harmed my family, which in turn harms me. Nothing is worse than being a parent and being helpless as your children fall victim to unjustified, illegal and unconstitutional government orders that negatively impact your children's overall health, their entire way of life and their futures.

CHILD 1 - DAUGHTER

51. EDUCATION

- Our 24 year old daughter was attending Sinclair Community College in Dayton. When the colleges closed it progressively and severely negatively impacted her educationally, personally, emotionally, and socially.
- Due to the mandated masks, our daughter will no longer be attending college because she cannot wear a mask all day long. Our daughter has been pursuing her lifelong dream of becoming a veterinarian/animal behavioralist, and she needs in-person classroom instruction. Her career goals have been ripped away from her.
- Additionally, she was considering transferring to The Ohio State University and she has since changed her mind based on the fact the school requires mandatory COVID-19 testing, which is a clear invasion of a right to privacy and bodily autonomy.

52. HEALTH/MASK

- Our daughter cannot wear a mask due to the following medical issues:
 - high-functioning Autism (previously known as Asperger's Syndrome)
 - severe asthma, which limits her oxygen level to about 85% on most days

- severe allergies, which results in chronic nasal/sinus congestion prohibiting her ability to breathe in and out of her nose
- deviated septum
- anxiety
- depression
- She has had adverse physical reactions to wearing masks.
 - She had to wear a mask for longer than a few minutes during a food pick-up for Door Dash and she became nauseated, flushed, and dizzy. By the time she got back into her car (she had already taken her mask off), she became physically ill, vomiting all over her car and herself. She had to come back home to change and rest for the remainder of the day.
 - She developed a sinus infection, which we believe is a result from wearing a mask.
 - She suffers headaches if she has to wear the mask for more than a few minutes at a time.
- Our daughter cannot wear a mask while shopping, etc. She cannot wear a mask for more than a few minutes before she begins to feel ill. Therefore, she uses her right to medical exemption when shopping, except that it has become so anxiety provoking for her, that she will not go shopping alone, for fear of backlash, shaming and physical and verbal assault.

53. EMPLOYMENT/FINANCES

- Our daughter works for Door Dash and she's required by each restaurant to wear a mask when picking up food. Despite being very unhealthy and unsafe for her, she has no choice if she wants to continue to earn a living and pay for her bills. She wears the lightest and smallest mask that I could make for her, so she can simply comply.
- She was impacted financially. Her primary job is a pet sitter. While her clients were all on lockdown, she was not needed and therefore had no work. Even now, many clients have not returned to work and as a result, my daughter's earning opportunities have been crippled.
- She will not be able to work at King's Island Halloween Haunt, as she has for the past two years, due to the fact that the governor's mandates have made it next to impossible for the theme park to operate under such strict and ridiculous mandates, and therefore her beloved Halloween Haunt and Winterfest have been canceled.

54. SOCIAL/ACTIVITIES

- Both she and her brother were unable to get basic exercise by going to the park and playing their favorite, basketball. This very basic right to go to a park and play a game was stripped away because the courts actually had the basketball hoops removed. This was not only an enjoyable past time but a vital component to her mental and emotional well-being.
- Her social life has been completely paralyzed by DeWine's overreaching and irrational measures. She cannot go to concerts, restaurants, bars, clubs, amusement parks, movie theaters or any large gatherings with friends, as prohibited by the emergency order.
- Her boyfriend was scheduled to fly out from California, a visit that had been planned for over 6 months. He subsequently canceled his flight, due to the emergency order only allowed for travel into the state for essential business or operations. He would have had to self-quarantine for 14 days. Needless to say, our daughter was devastated and remains devastated 5 months later.

55. MENTAL WELL-BEING

- Our daughter had finally started to come out of her shell. She was cultivating friendships and a social life, had career and life goals. Now she isn't even sure if she will have a future. She has no idea where her career path will go. She is confused, scared, and feels hopeless. She has begun having night terrors. She is plagued with nightmares and wakes up crying and screaming. Her depression, which had been manageable prior to the governor's orders, has started to afflict her once again and her anxiety has increased ten-fold. The overreaching, unreasonable and unnecessary "emergency orders" have most definitely negatively impacted our daughter's life on every front- educationally, personally, emotionally, socially and financially. I have spent countless hours comforting my daughter, into the late hours of the night, while she cried, trying to reassure her that life will return back to normal, pre-emergency order days. I have tried to reassure her that she will have a future where she will be free to go to concerts and movies and shopping without the worry and stigma of doing so without a mask. When my children were little, I told them they could be and do whatever they could dream of. I never thought she and I would be discussing if we would ever be free again.

CHILD 2 - SON

56. EDUCATION

- Our 17 year-old son has high-functioning Autism/PDD-NOS (Pervasive Development Disorder/Not Otherwise Specified)
- He is on the Ohio Autism Scholarship Fund and attends Skyward Academy – a private school in Montgomery for children with conditions similar to his. He is in 11th grade and this fall begins his third year there.
- He is on an IEP (Individualized Education Plan) which includes receiving regular speech therapy, as well as additional reading tutoring, both of which were impacted by the shutdown.
- When the schools closed it progressively and severely negatively impacted his educational, personal, emotional and social development.
- The shutdown caused him to be deprived of his right to education and critical enrichment activities (talent show, field trips, end of year awards ceremony). Our son was not able to obtain the full and intended benefits of his IEP due to school moving to a remote online distance learning. This has stunted his development on every level.
- The shutdown disrupted his social growth. Being out of school, kept him away from his friends. Friendships that he had been working incredibly hard at making were not able to be maintained online. Some of his friends only had access to a computer for schoolwork, not for socialization. Interaction online for these types of kids is very difficult.
- The current mandates for the school are causing him a great deal of stress. The plexiglass desk dividers, limited seating arrangements, limited interaction, anxiety regarding teachers/students with masks, is all taking a toll on a usually very calm, easy-going young man.
- He had a STEM (Science Technology Engineering Math), art, animation and drama classes that were not able to be done remotely. So, he was cheated out of those classes and education.

57. HEALTH/MASKS

- Our son cannot wear a mask due to the following medical issues:
 - Autism. He cannot tolerate having his mouth and nose covered in any way.
 - Scoliosis, which compresses one of his lungs
 - Mitral valve prolapse (Improper closure of the valve between the heart's upper and lower left chambers).
 - Anxiety

58. SOCIAL/ACTIVITIES

- Both he and his sister were unable to get basic exercise by going to the park and playing their favorite, basketball. This very basic right to go to a park and play a game was stripped away because the courts actually had the basketball hoops removed. It is the one sport he is able to play, considering his scoliosis and heart issue.
- Our son finally began to make friends. Last fall, he was invited to friend's birthdays and get-togethers. Last October was the first year that he EVER had a birthday party with friends. It was a bowling alley and he had the time of his life. This type of socialization is CRUCIAL for kids on the Autism spectrum. The shutdown as well as the past and current emergency orders have and are continuing to prevent him from this critical component of his life- being around other kids who are like him, which makes him feel normal and accepted. This is vital to kids on the Autism spectrum because they often feel ostracized and are frequently left out by neurotypical peers. The governor has literally ripped that away from him.
- He was unable to participate in the school variety show, something he had been looking forward to since the previous spring. The amount of disappointment he experienced was heart wrenching. For a kid with autism to WANT to come out of his shell, do something that is as nerve-wracking as performing for parents, teachers and students is remarkable. And then to have that ruined is devastating.
- The school was unable to host their usual end-of-year awards ceremony. This is HUGE for these kids!!! It is a big production, held at a country club. Each child is individually recognized for an achievement. They are given little "Oscars". There is a banquet buffet. The entire celebration is beautiful and moving. THAT TOO was ripped away from my son, as well as those other kids.
- There have social events cancelled by friends because the kids and/or their parents have been so indoctrinated by DeWine's panic inducing rhetoric, they are too afraid to go out and be with people.

59. MENTAL WELL-BEING

- Our son, a usually mild-mannered, calm, easy going, happy young man is now anxiety ridden and sad. He has nightmares. We have watched him go from slightly germophobic (something that we have been working on and making progress with), to being too frightened to go outside. When this virus first appeared, he was very scared. We reassured him it was nothing to be afraid of. Nothing scarier than the average flu. But, despite our monitoring of all media, he was still subject to DeWine's continuous propaganda campaigns. He was so afraid; he wouldn't even want to step out into his own backyard because he thought the virus was in the very air we were breathing. When we were finally able to convince him that was not the case, not the facts, we were able to get him to go on quick outings to the store with us. However, the repeated propaganda signage and recorded droning messages over the store's loudspeakers, reminding us to remember to socially distance, wear a mask and wash our hands, simply rekindled the fears. He would walk with his head tucked down and his arms either in his pockets or crossed

tightly against his chest. He would not touch a thing. We have once again begun to make progress in getting him to relax in the stores and to remember that this is nothing more than a virus like the flu. He has meltdowns, something he has NEVER EVER had before. I have watched this young man stand before me in frustration, tears streaming down his face, head back, face red and screaming to the sky about how he just wants his life back, then have him collapse against me or his dad and just sob. I have never felt more helpless as a parent in my entire life. It was soul-crushing.

60. Further, Affiant sayeth naught.

Sworn to before me and subscribed in my presence this _____ day of _____, 2020.

Notary Public

tightly against his chest. He would not touch a thing. We have once again begun to make progress in getting him to relax in the stores and to remember that this is nothing more than a virus like the flu. He has meltdowns, something he has NEVER EVER had before. I have watched this young man stand before me in frustration, tears streaming down his face, head back, face red and screaming to the sky about how he just wants his life back, then have him collapse against me or his dad and just sob. I have never felt more helpless as a parent in my entire life. It was soul-crushing.

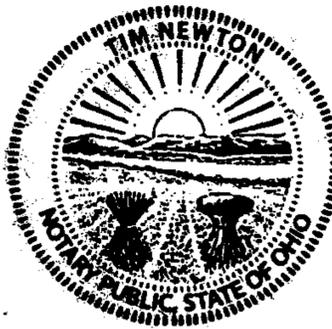
60. Further, Affiant sayeth naught.



Sworn to before me and subscribed in my presence this 27th day of August, 2020.



Notary Public



TIM NEWTON
NOTARY PUBLIC, STATE OF OHIO
HAMILTON COUNTY
My Commission Expires 11/18/2020

Affidavit of Tara L. Calderaro

State of Ohio / Clermont County:

I, Tara L. Calderaro, being first duly sworn according to law, state that I am legally competent to testify in this matter, and I have personal knowledge of all the facts contained within this affidavit. I am competent to testify as to all matters stated herein:

1. All documents attached to this affidavit are genuine copies of the original and are fully incorporated by reference herein as if fully rewritten herein. All Exhibits referenced and/or attached thereto and fully incorporated by reference herein are all true and genuine copies of the originals and each is incorporated herein as evidence in support of the plaintiff's motion. All documents as was filed in this matter attached to the complaint are also incorporated herein fully by reference by this affidavit as if fully and completely rewritten herein. This includes all documents contained in the Exhibits attached to the complaint as filed for record. All Exhibits referenced and/or attached thereto and fully incorporated by reference herein are in support my individual claims that my Constitutional Liberties, Freedoms and God-given, absolute, fundamental, and inalienable Rights have been unconstitutionally infringed upon and denied and/or jeopardized to me as I detail herein.

2. The DeWine, Acton, Himes Orders as have been issued since March 2020 have adversely impacted my Constitutional Liberties, Freedoms and God-given, absolute, fundamental, and inalienable Rights.

3. As a direct and proximate result of these unconstitutional orders and their mandated implementation, I have been made to endure the following:

4. The declared "State of Emergency" made by DeWine and the ODH, and it's continuous, unnecessary and unfounded extension of said orders have wreaked havoc, turmoil, angst, anxiety and undue stress upon me, as well as my entire family. These baseless orders have affected us in numerous adverse ways in a multitude of situations. I believe our constitutionally guaranteed freedoms have clearly and repeatedly been violated as a result of the governor's mask mandates and inducement of panic, and the very essence of the Emergency Order itself.

TARA

5. HEALTH/MASKS

- I cannot wear a mask for the following medical reasons:
 - a) History of seizures (cause unknown). I am very careful as to not become episodic again.
 - b) Asthma
 - c) Extreme claustrophobia
 - d) Inappropriate Sinus Tachycardia (rapid heartbeat without reason). I have been seen by multiple doctors for this issue. My heart rate can spike to 140+ bpm. I experience nausea and lightheadedness with these episodes. These episodes can last for hours. Echocardiogram reveled no cause.
 - e) Placing a mask over my nose and mouth is literally impossible. I immediately panic. I cannot breathe. I feel like I am suffocating. My heart rate increases and the few times I have tried, I had a tachycardia episode, each lasting for numerous hours.

6. MENTAL WELL-BEING

- a) This entire fiasco has had a huge toll on my mental well-being. The constant deception and lies and executive order extensions from the governor and the ODH has me feeling utterly despondent. It feels like there is no hope for life to ever return to normal. And I refuse to accept this dystopian alternative as my “new normal”.
- b) I have missed numerous days from work (currently building a home business) and simply put, life, because I could not get out of bed and face the day, another day without hope for normal life to resume. What began as 2 weeks to flatten the curve, which has been flattened for some time now, has turned into 5 months and counting.
- c) I now suffer from depression. As a naturally bubbly, upbeat, and optimistic person, DeWine and his draconian orders have plummeted me into a depressive state that I have to fight against everyday simply to continue to function for the good of my family. I am constantly stressed. I have cried more in the past 5 months than I have in the past 5 years. There has literally not been a day that has gone by that I haven’t cried, either out of frustration or hopelessness.
- d) I suffer EXTREME anxiety now at the mere prospect of having to go out shopping. The sea of masked faces is unnerving. I cannot tell who is friend or foe. Everyone has been stripped of their identity. Not only that, but there is the constant fear of mask shaming, and confrontations (both of which have occurred multiple times).
- e) Something as the simple, basic, and once enjoyable freedoms, such as going to the store, restaurant, zoo, museum, or any other public place is now panic inducing and anxiety provoking. Since the governor’s mask mandate and continued inducement of panic that he broadcasts regularly in his press briefings to any Ohioans that will listen, including retailers/business establishments, we have been deprived of these freedoms because all businesses now require masks. Many retailers will discriminate against us by not honoring our medical exemptions from masks, and even when they do honor our medical exemptions, it’s often at the expense of having to endure public ridicule as well as demeaning and/or aggressive behavior towards us by store employees and customers and we feel our safety is now at grave risk.
- f) Because of the amount of anxiety I have due to the governor pitting mask-wearers against non-mask wearers, and the fact that everyone in my family is medically exempt from the mask mandate, my family and I no longer have the same rights and freedoms as other Ohioans. To avoid the discrimination, hassle, stares, and confrontations, we do not go out for any leisure activities. We only go out for essential items/services.
- g) In addition to the fear of confrontation, the retail establishments constantly play on loop the mask/social distancing propaganda over their store speakers, furthering my anxiety. It is clear and blatant psychological manipulation.

7. MEDICAL

- a) Costco eye center refuses to see us, will not honor mask exemptions
- b) Cannot find a chiropractor who will honor mask exemptions
- c) Cannot have overdue mammogram performed because Tri Health will not honor mask exemptions
- d) I, my husband, and our daughter have each had issues with our pharmacist regarding our lack of masks. Each time we go in to pick up prescriptions, we are given the third-degree as to why we don’t have masks on and why we should have masks on. It has gotten so bad, that our 24-year-

old daughter will not go to pick up her medications because she simply can't tolerate the barrage of questions and condemnation from the pharmacist. I have had numerous encounters with the pharmacist myself. The pharmacist had the audacity to bring up my daughter's asthma and say that that is a reason why our daughter should wear a mask. My daughter has asthma that causes her blood oxygen saturation to be around 85% on a good day. The last thing she needs is to be masked and deprive her body of even less oxygen. It is ridiculous to have to be subjected to discrimination, lectures, and propaganda when all we simply are there to do is pick up medicine.

8. My husband and I have two children. My husband is their stepfather and has helped raise them for the past 14 years. The abnormality and unending Executive Orders have affected them adversely as well. Our daughter, age 24 and son, age 17 are both on the Autism Spectrum (high functioning). Because the governor's executive orders have adversely affected them, which in turn, affects me, I am including information as it pertains to them as well as any accounts/confrontations that have happened while I was with them. Nothing is worse than being a parent and being helpless as they fall victim to unjustified, draconian orders, that affects their entire overall being and life as they know it.

CHILD 1 - DAUGHTER

9. EDUCATION

- a) Our 24-year-old daughter was attending Sinclair Community College in Dayton. When the colleges closed it progressively and severely negatively impacted her educationally, personally, emotionally, and socially.
- b) Due to the mandated masks, our daughter will no longer be attending college because she cannot wear a mask all day long. Our daughter has been pursuing her lifelong dream of becoming a veterinarian/animal behavioralist, and she needs in-person classroom instruction. Her career goals have been ripped away from her.
- c) Additionally, she was considering transferring to The Ohio State University and she has since changed her mind based on the fact the school requires mandatory COVID-19 testing, which is a clear invasion of a right to privacy and bodily autonomy.

10. HEALTH/MASK

- a) Our daughter cannot wear a mask due to the following medical issues:
 - high-functioning Autism (previously known as Asperger's Syndrome)
 - severe asthma, which limits her oxygen level to about 85% on most days
 - severe allergies, which results in chronic nasal/sinus congestion prohibiting her ability to breathe in and out of her nose
 - deviated septum
 - anxiety
 - depression
- b) She has had adverse physical reactions to wearing masks.
 - She had to wear a mask for longer than a few minutes during a food pick-up for Door Dash and she became nauseated, flushed, and dizzy. By the time she got back into her car (she had already taken her mask off), she became physically ill, vomiting all over her

car and herself. She had to come back home to change and rest for the remainder of the day.

- She developed a sinus infection, which we believe is a result from wearing a mask.
 - She suffers headaches if she has to wear the mask for more than a few minutes at a time.
- c) Our daughter cannot wear a mask while shopping, etc. She cannot wear a mask for more than a few minutes before she begins to feel ill. Therefore, she uses her right to medical exemption when shopping, except that it has become so anxiety provoking for her, that she will not go shopping alone, for fear of backlash, shaming and physical and verbal assault.

11. EMPLOYMENT/FINANCES

- a) Our daughter works for Door Dash and she's required by each restaurant to wear a mask when picking up food. Despite being very unhealthy and unsafe for her, she has no choice if she wants to continue to earn a living and pay for her bills. She wears the lightest and smallest mask that I could make for her, so she can simply comply.
- b) She was impacted financially. Her primary job is a pet sitter. While her clients were all on lockdown, she was not needed and therefore had no work. Even now, many clients have not returned to work and as a result, my daughter's earning opportunities have been crippled.
- c) She will not be able to work at King's Island Halloween Haunt, as she has for the past two years, due to the fact that the governor's mandates have made it next to impossible for the theme park to operate under such strict and ridiculous mandates, and therefore her beloved Halloween Haunt and Winterfest have been canceled.

12. SOCIAL/ACTIVITIES

- a) Both she and her brother were unable to get basic exercise by going to the park and playing their favorite, basketball. This very basic right to go to a park and play a game was stripped away because the courts actually had the basketball hoops removed. This was not only an enjoyable past time but a vital component to her mental and emotional well-being.
- b) Her social life has been completely paralyzed by DeWine's overreaching and irrational measures. She cannot go to concerts, restaurants, bars, clubs, amusement parks, movie theaters or any large gatherings with friends, as prohibited by the emergency order.
- c) Her boyfriend was scheduled to fly out from California, a visit that had been planned for over 6 months. He subsequently canceled his flight, due to the emergency order only allowed for travel into the state for essential business or operations. He would have had to self-quarantine for 14 days. Needless to say, our daughter was devastated and remains devastated 5 months later.

13. MENTAL WELL-BEING

- a) Our daughter had finally started to come out of her shell. She was cultivating friendships and a social life, had career and life goals. Now she isn't even sure if she will have a future. She has no idea where her career path will go. She is confused, scared, and feels hopeless. She has begun having night terrors. She is plagued with nightmares and wakes up crying and screaming. Her depression, which had been manageable prior to the governor's orders, has started to afflict her once again and her anxiety has increased ten-fold. The overreaching, unreasonable and unnecessary "emergency orders" have most definitely negatively impacted our daughter's life on every front- educationally, personally, emotionally, socially and financially. I have spent

countless hours comforting my daughter, into the late hours of the night, while she cried, trying to reassure her that life will return back to normal, pre-emergency order days. I have tried to reassure her that she will have a future where she will be free to go to concerts and movies and shopping without the worry and stigma of doing so without a mask. When my children were little, I told them they could be and do whatever they could dream of. I never thought she and I would be discussing if we would ever be free again.

CHILD 2 - SON

14. EDUCATION

- a) Our 17-year-old son has high-functioning Autism/PDD-NOS (Pervasive Development Disorder/Not Otherwise Specified)
- b) He is on the Ohio Autism Scholarship Fund and attends Skyward Academy – a private school in Montgomery for children with conditions similar to his. He is in 11th grade and this fall begins his third year there.
- c) He is on an IEP (Individualized Education Plan) which includes receiving regular speech therapy, as well as additional reading tutoring, both of which were impacted by the shutdown.
- d) When the schools closed it progressively and severely negatively impacted his educational, personal, emotional and social development.
- e) The shutdown caused him to be deprived of his right to education and critical enrichment activities (talent show, field trips, end of year awards ceremony). Our son was not able to obtain the full and intended benefits of his IEP due to school moving to a remote online distance learning. This has stunted his development on every level.
- f) The shutdown disrupted his social growth. Being out of school, kept him away from his friends. Friendships that he had been working incredibly hard at making were not able to be maintained online. Some of his friends only had access to a computer for schoolwork, not for socialization. Interaction online for these type of kids is very difficult.
- g) The current mandates for the school are causing him a great deal of stress. The plexiglass desk dividers, limited seating arrangements, limited interaction, anxiety regarding teachers/students with masks, is all taking a toll on a usually very calm, easy-going young man.
- h) He had a STEM (Science Technology Engineering Math), art, animation and drama classes that were not able to be done remotely. So, he was cheated out of those classes and education.

15. HEALTH/MASKS

- a) Our son cannot wear a mask due to the following medical issues:
 - Autism. He cannot tolerate having his mouth and nose covered in any way.
 - Scoliosis, which compresses one of his lungs
 - Mitral valve prolapse (Improper closure of the valve between the heart's upper and lower left chambers).
 - Anxiety

16. SOCIAL/ACTIVITIES

- a) Both he and his sister were unable to get basic exercise by going to the park and playing their favorite, basketball. This very basic right to go to a park and play a game was stripped away because the courts actually had the basketball hoops removed. It is the one sport he is able to play, considering his scoliosis and heart issue.
- b) Our son finally began to make friends. Last fall, he was invited to friend's birthdays and get-togethers. Last October was the first year that he EVER had a birthday party with friends. It was a bowling alley and he had the time of his life. This type of socialization is CRUCIAL for kids on the Autism spectrum. The shutdown as well as the past and current emergency orders have and are continuing to prevent him from this critical component of his life- being around other kids who are like him, which makes him feel normal and accepted. This is vital to kids on the Autism spectrum because they often feel ostracized and are frequently left out by neurotypical peers. The governor has literally ripped that away from him.
- c) He was unable to participate in the school variety show, something he had been looking forward to since the previous spring. The amount of disappointment he experienced was heart wrenching. For a kid with autism to WANT to come out of his shell, do something that is as nerve-wracking as performing for parents, teachers and students is remarkable. And then to have that ruined is devastating.
- d) The school was unable to host their usual end-of-year awards ceremony. This is HUGE for these kids!!! It is a big production, held at a country club. Each child is individually recognized for an achievement. They are given little "Oscars". There is a banquet buffet. The entire celebration is beautiful and moving. THAT TOO was ripped away from my son, as well as those other kids.
- e) There have social events cancelled by friends because the kids and/or their parents have been so indoctrinated by DeWine's panic inducing rhetoric, they are too afraid to go out and be with people.

17. MENTAL WELL-BEING

- a) Our son, a usually mild-mannered, calm, easy going, happy young man is now anxiety ridden and sad. He has nightmares. We have watched him go from slightly germophobic (something that we have been working on and making progress with), to being too frightened to go outside. When this virus first appeared, he was very scared. We reassured him it was nothing to be afraid of. Nothing scarier than the average flu. But, despite our monitoring of all media, he was still subject to DeWine's continuous propaganda campaigns. He was so afraid; he wouldn't even want to step out into his own backyard because he thought the virus was in the very air we were breathing. When we were finally able to convince him that was not the case, not the facts, we were able to get him to go on quick outings to the store with us. However, the repeated propaganda signage and recorded droning messages over the store's loudspeakers, reminding us to remember to socially distance, wear a mask and wash our hands, simply rekindled the fears. He would walk with his head tucked down and his arms either in his pockets or crossed tightly against his chest. He would not touch a thing. We have once again begun to make progress in getting him to relax in the stores and to remember that this is nothing more than a virus like the flu. He has meltdowns, something he has NEVER EVER had before. I have watched this young man stand before me in frustration, tears streaming down his face, head back, face red and screaming to the sky about how he just wants his life back, then have him collapse against me or his dad and just sob. I have never felt more helpless as a parent in my entire life. It was soul-crushing.

18. During these past five months, I have watched my family's mental state go from happy and optimistic to pensive, tired, anxious and depressed. I have seen the light and excitement for life fade from my children's eyes. For what? For a virus that most of us need a test to know if we even have it. For a virus that has a 99% survival rate. For a virus that has been egregiously mismanaged and misrepresented by Governor DeWine and the ODH.

CONFRONTATIONS

19. Due to our medical exemptions from wearing masks, we have endured several shopping trips where we have been verbally harassed, shamed, physically assaulted, been the subject of eye rolls, disapproving head shakes, glares and refused service. We have been told to stand outside and offered ridiculous alternatives to masks, furthering our point of view that masks are for compliance only and not for safety.

Walmart - Mason, Ohio - June 15, 2020

20. I was shopping alone in the clothing aisle of Walmart in Mason, Ohio. I happened to cross paths with a masked woman and she and I met eyes. She looked at me and said hostilely, "Are you smiling at me?" I responded, "Yes, I am". She said, "How dare you be without a mask and smile at me during this deadly pandemic." I told her to relax and walked away. On this same shopping trip, I encountered a man that felt it necessary to flatten himself up against his car, because I had to be in the same vicinity to get into my car to leave the parking lot. He said to me, "you don't have a mask on." Again, I said "Oh, relax. I'm just getting in my car."

DSW (Designer Shoe Warehouse) - Mason, Ohio - July 29, 2020

21. My daughter and I went to DSW to buy her a new pair of athletic shoes. Given the current circumstances, she is far too anxious to go shopping alone, so she asked if I would accompany her. As we walked into the store, there was signage stating masks were required. We didn't think much about it, as we both have medical reasons for exemption. We were greeted by an employee at the door, who clearly saw our unmasked faces. She said nothing about our lack of masks but informed us of the current sales and the new shoe try-on policies the store had adopted during the COVID-19 issue. We listened, said thank you and went to find shoes. We weren't two steps into the shoe aisle when another employee (Chris) approached us. He said, "Oh here, let me get you some masks." I responded with "No thank you. We have medical exemptions." His previous somewhat friendly demeanor quickly evaporated. He became confrontational and he rudely said, "You must wear a mask. It is the law." I said firmly, "The mandate allows for medical exemptions. We are simply here for a pair of shoes." He turned on his heel and literally stomped away.

21. At that point, my daughter and I were simply shaken. My hands were shaking. Our hearts were beating out of our chests. My daughter felt like she was going to have a panic attack. I thought if my heart rate didn't slow down, I'd go into tachycardia. My daughter said, "Forget it, let's just go." I said, "No. We won't be bullied, and you need new shoes." Neither one of us could think straight at that point. We could not locate the women's athletic shoes. We had no choice but to ask someone because wandering around and looking for the shoe section seemed far too intimidating. Neither one of us wanted to be in the store any longer than we had to be. The ONLY sales associate on the floor at that moment was the employee we just had an altercation with. He was two aisles over from where my daughter and I stood. He was walking from the front to the back of the store. I called out to him, "Excuse me, can I ask you a

quick question?" He glanced over at us and said "No, no you can't. I don't have time to answer your question. I'm not talking to you." At this point, he is scurrying away. I continued to talk to him because I simply wanted to get the shoes and get out. I said, "I just need to know where the women's athletic shoes are." He said, "I am not talking to you." And he jogged to the back of the store. I stood there, flabbergasted. I turned towards my daughter and said, "Wow, I can't believe how rude that guy is." It was then that another employee (Jason) approached us and must have heard me and asked what was wrong. I recounted the entire situation. He said nothing about us not having masks on. He simply pointed us in the direction of where we could find the shoes we were looking for. My daughter and I thanked him for listening, for his help and for being kind. We went over to the athletic shoes, still rattled over the entire confrontation. She found shoes as quickly as humanly possible, tried them on in the designated location, paid and left.

DSW (Designer Shoe Warehouse) - Mason, Ohio August 17, 2020 – Recounted by Eric

22. As Tara and I entered, Chris, the same employee that mistreated Tara a couple of weeks prior, said "get you a couple masks." I replied, "we have medical exemptions, thank you." He replied, "Oh well, the building said masks are required." I said, "Sir don't give us a problem, unless you want to violate ADA. The law [mask mandate] has 13 exemptions. Do you not know them?" He replied, "if you don't want to wear a mask then you can shop at home" and he motioned for us to leave while saying this. I replied, "no, that's not a reasonable accommodation, so we're going to continue to shop." Chris then said to his staff, "call the police." This was humiliating and degrading, especially given the fact that 2 other DSW employees (Jason and a female) along with at least one other female customer were observing our encounter. It's as if Tara and I are dangerous animals on display at some circus for all spectators to gawk at. Despite this feeling, Tara and I remained polite and simply proceeded to shop.

23. While at the register to pay for the shoes, we spoke to Jason; the same Jason that helped Tara during the last visit. Tara asked Jason if Chris was a manager and explained how we felt Chris accosted us when we walked in. Despite the fact Jason was standing and watching us interact with Chris as we entered, Jason said he didn't know what had happened exactly. Tara explained this was the second time she had been given a hard time by Chris and she explained the incident on July 29th. Tara and I then both explained how we have medical reasons why we cannot wear a mask. Tara explained as she began to cry, "I don't think I should be coming in here and having to have a panic attack because I'm going to be accosted" by an employee for just buying a pair of shoes. Jason said the mask requirement is a company policy. Tara asked, "is it a written company policy that I can see?" Jason said it is a written policy but he "does not have the policy available." I then asked, "what about people who have ADA protected medical conditions?" Jason hesitated and said, "I don't have the answers that to be honest with you." We explained we should be treated like normal fellow citizens and like regular humans, rather than treated as lepers and being rude and confrontational, and refusing to serve us. We also explained how we feel discriminated against for being denied the same freedoms everyone else gets to enjoy, which are constitutionally guaranteed, simply because we have medical conditions that exempt us from wearing masks. I then asked Jason about the fact Chris said we should shop online or at home. Jason said, "that's not what he should have said. I apologize." I then asked, "what should he have said." Jason replied, "he shouldn't have said you can shop online." He said, "that's an idea that's a suggestion." In that moment "we could have worked through that conversation a little better."

Hot Topic – Cincinnati, Ohio July 13, 2020 – Recounted by Eric

24. We have shopped at Hot Topic for over 12 years for our children. It's their favorite store. Hot Topic denied Tara and me entry for not wearing a mask, despite the fact we told them we have medical exemptions. The employee manning the door even recognized us for having shopped in there so often. That didn't matter, we were still treated rudely as if we were subhuman. We advised them by refusing to allow us entry after having informed them we have medical exemptions, it's clear discrimination. The employee didn't care, and just cited it's corporate policy. Hot Topic did not offer any options or accommodations for us to shop. It was only after I insisted Hot Topic provide some type of reasonable accommodation, did the employee say he can shop for us and bring things to the door. The employee began to ask us questions as to what we were looking for – what theme or genre. We explained that we don't have anything specific we are looking for since our children like almost everything in the store, and we don't know what is available in the store to purchase. The employee asked, if we wanted him to bring up a mug or a t-shirt or a blanket, etc. And again, we said we didn't know we had to shop around to determine what we wanted. We explained that typically we spend one hour or so shopping in Hot Topic trying to find the perfect gifts for our children. He then responded in a rude, sarcastic, snarky fashion, "do you want me to just bring everything up, because I can for you, if that's what you guys want?" Realizing that was not reasonable either, and nor would he do it even if we asked, we then spent several minutes providing constructive ideas for reasonable accommodations to the Hot Topic employee.

Panera Bread - Mason Ohio – July 29, 2020 – Recounted by Tara

25. My daughter and I decided to have lunch at Panera Bread. I called ahead to see what their mask policy was. I was told that if we were maskless, we could not come into the café to order. We would have to order from home or our car and pay online. Then, when we arrived, we could walk in MASKLESS, pick up our food as a to-go order and then proceed to a table and sit down and eat. Although they were polite and kind, the whole situation was down-right ridiculous. We could walk into the establishment, we could interact with employees as we picked up our food, we could eat in the café area ALL MASKLESS. We could not order our food at the register though.

Joann Fabrics – Mason, Ohio – July 29, 2020 – Recounted by Tara

26. My daughter and I went shopping for fabric. Despite the store's signage for mask requirements, we had no issues shopping without masks. We interacted with 4 different employees while in the store, no issues... until we got to the checkout counter. We were called up to the register to pay for our items, and as I placed my items on the counter to purchase, the young lady employee behind the plexiglass shield, said muffled through her mask rudely, " You know, masks are required to shop in our store." I politely told her we have medical exemptions. She rolled her eyes. At that point, I continued and said, "Furthermore, we have been shopping in the store for over an hour and had encountered 4 other of your fellow employees without issue. I don't appreciate the hard time I am getting from you. The governor's mandate allows for medical exemptions." She said nothing more but huffed and puffed and slammed her hands down upon the counter. She was sullen and continued to be rude. We paid for our purchase and left.

Costco – Mason, Ohio

27. In addition to the medical exemptions outlined in DeWine’s mask orders, Costco specifically provides a medical exemption on their website which reads as follows: “To protect our members and employees, all Costco members and guests must wear a face covering that covers their mouth and nose at all times while at Costco. This requirement does not apply to children under the age of 2 or to individuals who are unable to wear a face covering due to a medical condition.”

<https://www.costco.com/covid-updates.html>. Eric and I have been Costco members together since about 2006.

Costco – Mason, Ohio- July 6, 2020 – Recounted by Tara

28. Eric and I were doing our bimonthly Costco shopping. We entered into Costco, with our medical exemption to allow us to shop maskless. We decided to stop by the optical department first, because Eric, our daughter and I are all in desperate need for updated eye glass prescriptions and glasses. The woman behind the counter in the optometrist’s office said very rudely “Where’s your mask?” Eric said, “We have medical exemptions.” She said rudely “Both of you?” Eric and I said “Yes”. She stated, “You need to wear masks.” Again, we stated we have medical exemptions. I then asked, “I take it that means we would need to wear masks during the eye exam as well?” Both she and the optometrist, who was sitting literally 3 feet from me both said in unison “Yes”. I said, “Okay then, well, that isn’t going to work because I can’t breathe in a mask. Thanks anyway.” Eric and I proceeded to walk away. That event was so belittling, that we were both angry and I was distraught. That woman made us feel like we were walking disease. As I was pushing the grocery cart, I accidently crashed into the signage advertising a TV. When I glanced up to see if anyone had witnessed my less than graceful cart maneuvering, I saw a woman standing in an aisle, watching us, approximately 20 feet away. Eric noticed her as well. So, we made an off-handed joke about my bad cart steering and driving. The woman looked at us and said, “I am not concerned about that. I am more concerned that you both don’t have masks on.” Eric said to her, “Maybe you shouldn’t be so quick to judge. Did you think that maybe there is a reason we can’t wear masks? We have medical exemptions.” As we proceeded to walk away, which entailed walking past her, she started to back up. I looked at her and said “Relax lady. You’re safe.” Eric and I had to go to another aisle and take a minute to regroup. Two back to back negative encounters is taxing. At that point, I was teary-eyed from the sheer frustration and exhaustion of the situations. Basic shopping should not evoke a fight or flight response.

Costco – Mason, Ohio- July 13, 2020 and July 21, 2020 – Recounted by Tara

29. On two separate occasions, we were rudely questioned when entering Costco. As per usual, Eric shows the membership card and walks on the side closest to the door attendant. I walk on Eric’s other side and push the cart. As Eric shows the membership card, we are asked “Do you have masks?” Eric clearly and very audibly states, “We have medical exemptions.” At which point, the door attendant asks in a condescending tone, “Both of you?”. Eric replies “Yes, BOTH of us.” To be questioned rudely, in front of other customer’s is unnecessary and demeaning. Eric’s voice is loud and clear. There is no reason that the door attendant needs to clarify both of us, unless they lack command of the English language and are unfamiliar with the word “we”. Which, given the fact that these same door attendants on other occasions, have not had to clarify the word we, I find that unlikely.

Costco – Mason, Ohio - August 6, 2020 – Recounted by Eric

30. When Tara and I shop anywhere we wear our patriotic freedom themed t-shirts which we design, have printed and we sell as part of our small business. As we approached the Costco entrance, Tara and I recognized the employee, John from an encounter we had about one month prior. During that prior encounter when we entered and John said we needed masks, I politely advised him we both have

medical exemptions. He challenged us and did so in a rude, condescending and loud manner by stating, "both of you!" I said yes as we continued entering Costco unobstructed and without delay.

31. As Tara and I tried to enter Costco August 6, 2020, in an effort to do all we could to avoid any issue with John and just shop in peace, when I showed my membership card, I was certain to be extra friendly to John by stating, "How you doin' my friend. We have medical exemptions." Normally that's all that is ever required, and we are allowed in without delay or having to stop for any reason. However, as we attempted to enter like every other customer, John lifted his right arm in front of me while simultaneously placing his right hand pushing into my stomach to stop me from entering. I immediately stopped, shocked and appalled at his actions. I immediately told him that he didn't need to touch me, nor did he need to try and stop me. He said I was blocking him in some way (which made no sense). I told him he didn't need to touch me, and he could simply say "excuse me" if he needed something from me. I asked him why he was trying to stop me. I reiterated how I didn't understand why he was physically touching me. John said I was blocking him from seeing Tara's cart as we entered. This made no sense, as there was no reason to screen an incoming cart – no one steals anything *entering* the establishment. I asked him why he didn't just simply say "excuse me sir" and I would have known to stop, and why did he have to touch me? He then said, "I'm sorry my hand touched you." As we were standing there, there was at least one other customer observing our encounter. John still did not permit us to enter as evidenced by the fact he was still standing in front of us blocking our entrance. However, during that time John did find the time to screen and allow entry to other incoming customers who walked right by us. This was humiliating to us. Because we were not wearing masks due to medical exemptions which I clearly announced to John, John discriminated against us by not allowing us entry and then proceeded to assault me by placing his hand into my stomach.

32. I then asked John what he was looking for in our cart. He said he was looking to see if there was something underneath Tara's purse which was inside the cart, or empty boxes, empty bags and "stuff like that." I told John that next time I would appreciate that if he needs something to say, "Hey sir excuse me." I advised him that I didn't know he was trying to stop me. I explained that I've never had an employee actually stop me and put his hand out to physically touch me, and I said, "I don't understand." John said, "sorry I touched you." I said, "thank you." Despite my wife and I being humiliated, discriminated against and me being assaulted, and despite being extremely angry and anxious inside as a result, I remained calm, composed and overly polite over the 1.5 minute encounter. And Tara didn't speak a word.

33. I then went to report it to an on-duty manager named Reggie and continued to video record. Reggie said John should not have touched me or made any contact with me whatsoever, and John should have stopped when I said we had medical conditions. I told the manager if employees are worried about a virus, that last thing they should be doing is touching me. I explained how we have been hassled at the entrance several times in the past, and how I didn't come complain prior because I don't want a hassle. I just want to shop in peace. Reggie apologized numerous times and thanked us for bringing it to his attention.

34. After we completed our shopping, I wanted to find out what was found out and done about our incident. We went to find Reggie, however he had left so we spoke to another manager, Justin. Justin said he saw the video tape and hadn't talked to John yet. Justin said from what he heard second-hand from Reggie, John was trying to see our membership card which is why he stopped us. Tara and I both told Justin that is incorrect, and makes no sense as I was standing closest to John and showing my membership card which covers for the both of us entering, and when I asked John why he stopped us he

said it was to look for boxes in our cart not, to double check our membership card. I explained to Justin that our medical conditions may be invisible but that doesn't mean we don't have them. I also brought up the example of my son who has autism and was hassled in our prior visit and how it is very judgmental for employees to behave this way. I explained that if Costco is going to try and enforce the mask mandate, they need to be aware and honor the 13 exemptions in that mandate. I told Justin that I would appreciate if he talks to his staff. Justin went on to vent and say that he is having the conversation "more and more" with his employees to not touch people. Justin said he cannot believe he has to tell grown employees to stop touching people and explain that some people would give a "butt whooping" for touching them. Justin also said he's coached his staff that they are not the "mask police."

35. There was no rational reason for John to do what he did. It's clear he simply wanted to harass us and physically assault me because he didn't like us exercising our rights in accordance with the state mask mandate and in accordance with his employer's corporate policy to honor medical exemptions.

Auto Zone – Mason, Ohio - August 4, 2020 – Recounted by Eric

36. Our daughter's car broke down at the home of one of her pet-sitting clients. Her battery had leaked and was smoking. I removed the battery and Tara and I went to Auto Zone to get a new car battery to repair her car. Upon entering Auto Zone, the woman at the counter motioned that we needed masks. I said, "we have medical exemptions, thank you." Her facial expression was one of disgust. She said we needed to talk to the male employee who was just entering from outside. To mitigate the chances of any issue, I was extra friendly to the man by saying, "Hi my friend, how are you?" He asked us if we had masks. We said, "we have medical exemptions, thanks." He said "because it's private property, we still don't...we have to have something of some kind." I politely explained the ADA and the mask order has 13 exemptions. He said, "I understand, I also know it's called peddler's privilege. I've done all my research." I again tried to explain how he was going to enforce the mask mandate but ignore the 13 exemptions within that mandate. He then stated, "I can't wait on you cuz I have...unfortunately I'm one of the ones that can die from this, so I won't wait [serve] on you." That was the end of the interaction. We were left standing there momentarily, embarrassed, humiliated, dehumanized and discriminated against while holding our daughter's leaking car battery and offered no options to resolve it. Another male employee (Billy) spoke up and said he can offer curbside pickup and he could help us outside. We took care of the battery using curbside pickup and had Auto Zone informed us of this option from the outset, we could have avoided the entire situation. While outside Billy said we could return to have our daughter's charging system checked given her battery leaked and smoked. I thanked him and advised we would return shortly.

37. After replacing the old battery with the new one, about one hour later we returned to Auto Zone. We went inside to ask for Billy. As soon as we walked in a male employee rudely motioned to me to put a mask on. I told him we have medical exemptions and he should ask me first before assuming anything. The female employee at the counter said Billy was in the restroom. She then offered us what I can only described as a failed attempt at a "mask" and explained it as follows, "we just have like little paper things to hold in front of your face." She then reached her visibly dirty greasy hands underneath the cash register and pulled out an 8.5"x 11" piece of floppy paper taped to a popsicle stick and offered it to us saying, "just so you can be in here." We were expected to walk around the store while holding this in front of our face. She offered this as some sort of mask substitute, as if a piece of paper on a popsicle stick would do anything except further humiliate, degrade, and discriminate against us. Despite this abhorrent treatment, we remained polite and said we will wait outside for Billy.

38. The female employee who offered us the popsicle stick “mask” came outside to check the car’s charging system. She did not seem worried about any virus considering she rubbed her eyes with her fingers, repeatedly adjusted her mask, pulled her mask down at one point to wipe her face with her hands. The mask is clearly not about a virus – it’s about compliance.

Target/CVS Pharmacy, Milford, Ohio – Recounted by Tara

39. I, my husband, and our daughter have each had issues with our pharmacist regarding our lack of masks. Each time we go in to pick up prescriptions, we are given the third-degree as to why we don’t have masks on and why we should have masks on. It has gotten so bad, that our 24-year-old daughter will not go to pick up her medications because she simply can’t tolerate the barrage of questions and condemnation from the pharmacist. I have had numerous encounters with the pharmacist myself. The pharmacist had the audacity to bring up my daughter’s asthma and say that that is a reason why our daughter should wear a mask. My daughter has asthma that causes her blood oxygen saturation to be around 85% on a good day. The last thing she needs is to be masked and deprive her body of even less oxygen. It is ridiculous to have to be subjected to discrimination, lectures, and propaganda when all we simply are there to do is pick up medicine.

40. Further, Affiant sayeth naught.

Sworn to before me and subscribed in my presence this ____ day of _____, 2020.

Notary Public

38. The female employee who offered us the popsicle stick "mask" came outside to check the car's charging system. She did not seem worried about any virus considering she rubbed her eyes with her fingers, repeatedly adjusted her mask, pulled her mask down at one point to wipe her face with her hands. The mask is clearly not about a virus – it's about compliance.

Target/CVS Pharmacy, Milford, Ohio – Recounted by Tara

39. I, my husband, and our daughter have each had issues with our pharmacist regarding our lack of masks. Each time we go in to pick up prescriptions, we are given the third-degree as to why we don't have masks on and why we should have masks on. It has gotten so bad, that our 24-year-old daughter will not go to pick up her medications because she simply can't tolerate the barrage of questions and condemnation from the pharmacist. I have had numerous encounters with the pharmacist myself. The pharmacist had the audacity to bring up my daughter's asthma and say that that is a reason why our daughter should wear a mask. My daughter has asthma that causes her blood oxygen saturation to be around 85% on a good day. The last thing she needs is to be masked and deprive her body of even less oxygen. It is ridiculous to have to be subjected to discrimination, lectures, and propaganda when all we simply are there to do is pick up medicine.

40. Further, Affiant sayeth naught.

Tara Caldera

Sworn to before me and subscribed in my presence this 27th day of August, 2020.

[Signature]
Notary Public



TIM NEWTON
NOTARY PUBLIC, STATE OF OHIO
HAMILTON COUNTY
My Commission Expires 11/18/2020

Attachment K

Expert Declarations

Declaration of: Dr. Sherri Tenpenny

I declare under penalty of perjury under the laws of the United States of America that the

foregoing is true and correct. Executed on (date) August 30, 2020

Signature: 

1. I have substantial past investigative research and work experience as well as first-hand knowledge of the subject matter I am attesting to which I believe will assist the trier-of-fact in this case in understanding relevant evidence and/or making a factual determination in this case. Please note my attached curriculum vitae which is also true and accurate.
2. I have read and reviewed all of the attached materials and related materials and attest, based on my knowledge or experience, to their relevance to this declaration.
3. I believe that the opinions that I am offering in this declaration are the product of reliable principles and methods as applied to the facts of this case.
4. Each of my opinions as stated herein are provided in support of establishing the claims in this case in a Court of Law and are stated to a reasonable degree of medical certainty.
5. As pertaining to this case, I believe the following to be a true and correct statement of facts and if called to testify, I will provide the following opinions:
 - a. Statements made in the Complaint for this case regarding masks, testing, death counts, cases, manipulation, the overall danger of COVID-19, and COVID-19 tests are true and correct to a reasonable degree of medical certainty.
 - b. Attachment B is true and correct statements of facts and I agree with their conclusions to a reasonable degree of medical certainty.
 - c. I agree with Dr. Fauci, the Surgeon General of the United States, and many others that the general public and healthy individuals should not wear a mask.
 - d. The use of masks will likely have no substantial impact in reducing the spread of COVID-19.
 - e. The use of masks in common daily activities can be harmful to both physical and mental health.
 - f. Prolonged mask usage is particularly dangerous in children.

- g. Use of masks outdoors in the heat and to people participating in athletic activities can be deadly.
- h. Improper use of a mask makes the spread of COVID-19 more likely.
- i. Along with oxygen deprivation and elevation of carbon dioxide levels, masks reduce cognitive abilities and have negative psychological impacts.
- j. COVID-19 testing for the SARS-CoV2 virus is inaccurate at best.
 - i. PCR testing was never intended to be used for diagnosing illness.
 - ii. Deaths from SARS-CoV2 virus has not been proven. The virus has not been show to transmit infection; it does not follow Koch's postulates. <https://www.globalresearch.ca/no-one-has-died-coronavirus/5717668>
- k. To my knowledge, no governmental agency has defined what it means to have to test "positive" for SARS-CoV2 infection.
 - i. The FDA has given fast-track approval to various manufacturers of COVID-19 tests who have set their own standards as to what it means to be "positive" or "negative" for COVID-19.
 - ii. Tests determined to be "positive" are called "cases" even when associated with healthy, asymptomatic people.
 - iii. Extreme public policies that have had devastating effects on global industries are being set in place based on "cases."
- l. Based on my knowledge of PCR testing, it is inaccurate for identifying the presence of the SARS-CoV2 virus, the virus said to be associated with the condition referred to as COVID-19.
- m. The diagnosis of COVID-19, as defined by either the CDC or the Ohio Department of Health, is based on vague symptoms and is wildly inaccurate. Many unrelated illnesses and conditions have been assigned the diagnosis of COVID-19.
- n. The number of deaths said to be COVID-19 and reported by the State of Ohio is almost certainly inaccurate.
- o. Infection and illness caused by SARS-CoV2 has been reported to be less significant and fewer numbers that annual illness caused by influenza viruses and influenza illness.

Declaration of: Dr. Aubrey Whewell

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date) Aug. 30, 2020.

Signature: _____

A Whewell

1. I have academic and work experience as well as first-hand knowledge of the subject matter I am attesting to which I believe will assist the trier-of-fact in this case in understanding relevant evidence and/or making a factual determination in this case. Please note my attached curriculum vitae which is also true and accurate.
2. I have read and reviewed all the attached materials and related materials and attest, based on my knowledge or experience, to their relevance to this declaration.
3. I believe that the opinions that I am offering in this declaration are the product of reliable principles and methods as applied to the facts of this case.
4. Each of my opinions as stated herein are provided in support of establishing the claims in this case in a Court of Law and are stated to a reasonable degree of professional certainty.
5. As pertaining to this case, I believe the following to be a true and correct statement of facts and if called to testify, I will provide the following opinions:
 - a. Statements made in the Complaint for this case regarding death counts, excess deaths, impacts of the reaction to COVID-19, and the danger of COVID-19 are true and correct to the best of my knowledge.
 - b. Attachments A and E are true and correct statements of facts and I agree with their conclusions.
 - c. The CDC's reported numbers of COVID-19 deaths represent the number of patients that have died with COVID-19 and not necessarily from COVID-19.
 - d. The number of people that have died from COVID-19 is substantially fewer than the reported number of COVID-19 deaths.
 - e. As of May 30th, it is extremely unlikely that anywhere near 100,000 people were killed by COVID-19.

- f. I believe that excess deaths have occurred in the United States throughout the year 2020 and that many or most of those deaths can be attributed to policies implemented in response to COVID-19 in across the nation.
- g. COVID-19 appears to be roughly as dangerous as a severe seasonal flu.

AUBREY T. WHEWELL

Phone: 419.344.5322
Email: aubreytt@yahoo.com

3330 Darlington Road
Ottawa Hills, Ohio 43606

EDUCATION

PhD	University of Toledo Health Education	May 2016
MPH	Northwest Ohio Consortium of Public Health Health Promotion and Education	December 2005
BA	Adrian College Sociology, Biology	May 2004

TEACHING EXPERIENCE

Eastern Michigan University; Ypsilanti, Michigan January 2017 to present
Adjunct Lecturer, School of Health Promotion and Human Performance

- **Concepts of Sexuality Education**, 3 credit hours, a classroom-based undergraduate course providing the student with information related to human sexuality and developing student skills in sexuality education program planning. The effectiveness of existing sexuality education programs and instructional strategies are explored. Analysis of one's own attitudes and values regarding human sexuality are also addressed.
- **Healthful Living**, 3 credit hours, an online-based undergraduate course focused on students developing the responsibility for guiding and evaluating their own health. The acquisition of attitudes, habits, skills, and ideas favorable to efficient and healthful living are explored.
- **Health Education in the Elementary Grades**, 2 credit hours, a classroom- and hybrid-(online/classroom) based undergraduate course preparing future and current primary and intermediate grade teachers to integrate health into their teaching. The course presents health education within the framework of the Whole School, Whole Community, Whole Child model. In this course, special emphasis is placed upon the healthy school environment and health education content and teaching strategies.
- **Health Education Methods and Materials**, 3 credit hours, a classroom-based graduate course exposing students to a wide variety of methods and materials used in the practice of health education. Curricula, videos, text, and computerized materials are discussed. Andragogical and pedagogical techniques for individuals and groups in settings such as, but not limited to schools, communities, and worksites are included
- **Healthy Sexuality**, 3 credit hours, a classroom-based undergraduate course examining various topics related to healthy sexuality emphasizing aspects in the health education and community health education.

- **Principles of Health Education**, 3 credit hours, a classroom-based undergraduate course providing students with an understanding of the professional roles and competencies of the Health Education Specialist. Course content addresses professional development, code of ethics, application of health education theory, and recommendations for practice.

University of South Carolina – Beaufort; Bluffton, SC August 2019 to present
Adjunct Lecturer, Department of Nursing and Health Professions

- **Basic Health**, 3 credit hours, an online-based undergraduate course addressing knowledge concerning attitudes and practices which promote and maintain the present and future health of the individual and the community. This course emphasizes the prevention of disease and a positive health attitude including topic such as nutrition, fitness, drugs, and sexuality.
- **Introduction to Public Health**, 3 credit hours, an online-based undergraduate course presenting a broad-based overview of those processes that enable people to assume responsibility for health and wellness as well as the role of the Public Health professional.
- **Senior Seminar**, 2 credit hours, co-taught an online-based undergraduate capstone course that summarizes the experiences of the health promotion major and prepares students for employment and/or graduate study.

University of Toledo; Toledo, Ohio January 2019 to May 2019
Adjunct Lecturer, School of Population Health

- **Community Health Organization**, 3 credit hours, a classroom-based graduate (combined Masters and Doctorate) course focused on techniques that bring about change in a community's health status through assessment, public advocacy, coalition building, decision making, planning, policy development and political influence, emphasizing application.

PROFESSIONAL EXPERIENCE

Independent Evaluation Consultant 2016 to present

- Ohio Area Health Education Centers (AHEC) – 2017-present
 - Develop, implement, assess, and modify Statewide AHEC program evaluation objectives, methods, and tools as well as provide timely reporting to project directors, stakeholders, and funders.
- Imagination Station, Tinker Thinking – 2016-2017
- United Way, Imagination Library – 2016-2017

Susan G. Komen Northwest Ohio; Toledo, Ohio 2013-2016
Mission Manager

- Developed, implemented, and maintained all grants-related policies, procedures, guidelines and materials for the grants programs.

- Coordinated the review process ensuring all applications received a fair review and that funding decisions were aligned with the funding priorities.
- Coordinated and managed the grants programs in the online Grants e-Management System.
- Served as staff liaison and assisted with the coordination of the grant's programs Peer Review Panel and Komen's Strategic Mission Committee.
- Represented Komen on breast health/cancer coalitions in the 24-county service area.
- Served as the advocacy representative responsible for interactions with state and federal elected officials regarding breast health/cancer legislation.
- Ensured the completion and implementation of the Community Profile identifying the breast health/cancer needs of target counties in the service area.
- Oversaw the breast cancer survivor initiatives including the Newly Diagnosed Breast Cancer Survivor Initiative and the Breast Cancer Survivor bi-monthly e-newsletter.
- Supervised the Mission for Minority Breast Health initiative with the Minority Breast Health Coordinator providing breast health/cancer training, education, and outreach to African American and Hispanic/Latina women in Allen, Erie and Lucas Counties.
- Implemented, maintained, and evaluated the Worship in Pink program providing breast health/cancer education and awareness to places of worship.
- Supervised and mentored public health and community health student interns.
- Prepared reports identifying the impact of outreach and education in the Komen service area.
- Managed annual operating plans and budget for mission programs

University of Toledo; Toledo, Ohio

2009-2012

Graduate Assistant

- Coordinated, managed, and advanced the Ohio Department of Alcohol and Drug Abuse Services Grant projects as well as provide timely reporting.
- Designed, planned, and implemented initiatives and education to reduce Alcohol, Tobacco and Other Drug (ATOD) use at the University of Toledo Main Campus (University).
- Assisted in the development of University policies including Medical Amnesty policy, August 1, 2010; Restricted tobacco use to designated areas, August 1, 2011.
- Conducted ATOD presentations for University students, faculty, staff, and professionals.
- Coordinated, implemented, and evaluated University ATOD Prevention Committee initiatives.
- Contributed to the development of an online alcohol education course.
- Utilized Statistical Package for Social Sciences (SPSS) to analyze experimental and survey research.
- Lecturer for Drug Awareness course; including developing and implementing syllabus, developing course materials and presentations, and assigning and submitting grades.

Toledo Lucas County Health Department; Toledo, Ohio

2007-2009

Cardiovascular Health Project Director

- Coordinated, managed, and advanced Cardiovascular Health (CVH) Grant projects to successful and timely completion.
- Developed and led the "For Your Heart" Coalition consisting of over 20 collaborators whose focus was to improve the health of citizens in Lucas County.

- Coordinated, conducted, and evaluated CVH program initiatives relating to diabetes, hypertension, tobacco, nutrition, physical activity, and cholesterol.
- Composed CVH program reporting and grant proposals.
- Created, implemented, and developed the “Worksite Wellness Network” including worksite wellness conferences and work session initiatives.
- Represented the Toledo-Lucas County Health Department on over a dozen community coalitions.

American Cancer Society; Perrysburg, Ohio

2005-2007

Regional Health Promotions Supervisor

- Supervised strategic direction and planning to remote working staff for 19 counties.
- Developed plan and work budget for Region Health Promotions.
- Recruited, hired, and trained all new Health Promotion staff to work remotely in 19 counties.
- Oversaw and ensured complete and accurate maintenance and submission of information and data for Regional and Division databases.
- Communicated effectively with Regional leadership team, staff, and Ohio leadership counterparts.
- Assisted health promotion in quality of life services, worksite wellness services, early detection in colorectal and breast cancer, and primary prevention collaborative and programming.

RESEARCH EXPERIENCE

- Recommendations for Teaching Health Education Skills in High School, 2016.
- Community Profile, Susan G. Komen Northwest Ohio, 2015.
- Administered the University of Toledo Alcohol & Drug Survey, 2012.
- Administered the Mad Challenge, University of Toledo, 2011.
- Conducted 21st Birthday Survey, University of Toledo, 2011/2012.
- Administered the University of Toledo Alcohol & Drug Survey, 2010; 2012.
- Conducted Game Day Survey, University of Toledo, 2009.

PUBLICATIONS

Whewell, A., Westphal, M. (2015). Susan G. Komen Northwest Ohio Community Profile Report.

Glassman, T., Blavos, A., Paprzycki, P., Deakins, B., Reindl, D., **Whewell, A.,** & Ingraham, A. (2013) Mad Challenge – 30 Day Alcohol Abstinence Pledge. *American Journal of Health Studies* 28(4), 190-196.

Glassman, T., **Whewell, A.,** Sheu J.J. & Reindl, D. (2012) “Implications for college students posting pictures of themselves drinking alcohol on Facebook.” *Journal of Alcohol and Drug Education*, 56, 38-58.

Glassman, T., Braun, R., **Whewell, A.**, & Reindl, D. (2011). Blood (breath) alcohol concentration rates of college football fans on game day. *Journal of Alcohol and Drug Education, 55*(2), 55-73.

Glassman, T., Reindl, D., & **Whewell, A.** (2011). "Strategies for implementing a tobacco free campus policy." *Journal of American College Health, 59*(8), 764-768.

Braun, R.E., Glassman, T., Wohlwend, J., **Whewell, A.**, & Reindl, D. (2011). "Hookah use among college students from a Midwest university." *Journal of Community Health, volume 36*, issue 5. DOI 10.1007/s10900-011-9444-9 Online First - Available from: <http://www.springerlink.com/content/p07x522728766318/>

PRESENTATIONS

Local Presentations

Whewell, A., Glassman, T., & Reindl, D. *An exploratory study: College students posting pictures of themselves drinking alcohol on Facebook.* Poster Presentation at The University of Toledo Graduate Research Presentation, Toledo, OH, 2011.

Reindl, D., Glassman, T., **Whewell, A.**, & Braun, R. *The University of Toledo Tobacco-Free Vote Results.* Poster Presentation at The University of Toledo Graduate Research Program, Toledo, OH, 2010.

Braun, R., Glassman, T., Reindl, D., & **Whewell, A.** *Blood Alcohol Consumption Levels of College Football Fans on Game Day.* Poster Presentation at The University of Toledo Graduate Research Program, Toledo, OH, 2010.

State Presentations

Whewell, A., Dake, J., Telljohann, S., Seabert, D., & Glassman, T. *Recommendations for Teaching Health Education Skills in High School.* Poster Presentation at the Ohio Association for Health, Physical Education, and Dance, Kalahari Resorts and Conventions, Sandusky, OH, 2019.

Whewell, A., Dake, J., Telljohann, S., Seabert, D., & Glassman, T. *Recommendations for Teaching Health Education Skills in High School.* Poster Presentation at the Health Educators' Institute (HEI), Dublin Integrated Education Center, Dublin, OH, 2018.

Reindl, D., Glassman, T., **Whewell, A.**, & Blavos, A. *Medical Amnesty: Considerations in Policy Development.* Oral Presentation at the Health Educators' Institute (HEI), Mohican State Park, Loudonville, OH, 2011.

Reindl, D., Glassman, T., **Whewell, A.**, & Braun, R. *Best practices: Utilizing Environmental Management for High-Risk Drinking Prevention on College Campuses. What is your University doing?* Poster Presentation at the Health Educators' Institute, Hueston Woods State Park, College Corner, OH, 2009.

National Presentations

Whewell, A., Dake, J., Telljohann, S., Seabert, D., & Glassman, T. *Recommendations for Teaching Health Education Skills in High School*. Accepted: Roundtable discussion at the American School Health Association School Health Conference, Virtual Conference, 2020.

Blavos, A., Glassman, T., Reindl, D., & **Whewell, A.** *Risk-Reduction Strategies: 21st Birthday Intervention*. Poster presentation at the Eta Sigma Gamma (ESG) Conference, San Antonio, Texas, 2012.

Whewell, A., Glassman, T., & Reindl, D. *College students posting pictures of themselves drinking alcohol on Facebook*. Poster Presentation at American Public Health Association (APHA) Conference, Washington D.C., 2011.

Glassman, T., Reindl, D., **Whewell, A.**, & Braun, R. *Voting Results for Student, Faculty, and Staff Support of a Tobacco-Free Campus Environment at a Large University in the Midwest*. Oral Presentation at the American Public Health Association (APHA) Conference, Denver, CO, 2010.

Glassman, T., Braun, R., **Whewell, A.**, & Reindl, D. *Blood (breath) Alcohol Consumption Levels of College Football Fans on Game Day*. Poster Presentation at the American Public Health Association (APHA) Conference, Denver, CO, 2010.

Thompson, A., Reindl, D., **Whewell, A.**, & Hunt, B. *Super Charging Your School Wellness Program*. Round table discussion at the American School Health Association (ASHA) Conference, Kansas City, MO, 2010.

GRANTS

Whewell, A. “Newly Diagnosed Breast Cancer Survivor Support Initiative”, **\$40,500**, Toledo Community Oncology Program. Granted January 2016.

Whewell, A., Frederick, D. “Mission for Minority Breast Health Project”, **\$64,743**, Walgreens through Susan G. Komen. Granted November 2014.

Whewell, A., Glassman, T., Blavos, A. “The Alcohol, Tobacco and Other Drug Prevention Project”, **\$4,000**, Ohio Department of Alcohol and Drug Abuse Services, Granted June 2012.

Whewell, A., Glassman, T. “Just Ask”, **\$1,000**, Ohio College Health Association, Granted April 2012.

Whewell, A., Glassman, T. “The Alcohol, Tobacco and Other Drug Prevention Project”, **\$16,795**, Ohio Department of Alcohol and Drug Abuse Services, Granted June 2011.

Whewell, A., Glassman, T. “The Alcohol, Tobacco and Other Drug Prevention Project”, **\$21,795**, Ohio Department of Alcohol and Drug Abuse Services, Granted June 2010.

Whewell, A., Gibson, A. “Creating Healthy Communities Project”, **\$140,000**, Ohio Department of Health. Granted December 2009.

Whewell, A., Gibson, A. “Cardiovascular Health Grant”, **\$98,000**, Ohio Department of Health. Granted December 2008.

Whewell, A., “Women’s Health Grant”, **\$2,000**, The University of Toledo Medical Center. Granted May 2008.

Whewell, A., “Body & Soul Program”, **\$2,000**, American Cancer Society. Granted April 2008.

Whewell, A., Gibson, A. “Cardiovascular Health Grant”, **\$98,000**, Ohio Department of Health. Granted December 2007.

PROFESSIONAL MEMBERSHIPS

- Great Lakes Society for Public Health Education
- Ohio Society for Public Health Education
- Society for Public Health Education

SERVICE

- Abstract reviewer,
 - American Evaluation Association, 2020
 - Society for Public Health Education, 2019 – present
 - American School Health Association, 2015 – 2016
- Health Educators Institute planning committee member, Ohio Society for Public Health Education, 2019 – present
- Northwest District Representative, Ohio Society for Public Health Education, 2020 - present
- Grant reviewer, Toledo Lucas County Homelessness Board, 2018 – 2019
- Health Education and Physical Education Standard Setting and Linking Activity, MTTC Standard Setting and Linking Activity Conference, accepted reviewer, 2019

REFERENCES

Courtney K. Combs, J.D., Director, Ohio Statewide Area Health Education Centers
College of Medicine and Life Sciences
Center for Creative Education 3105B, Mail Stop 1029
Phone: 419.383.4880
Email: courtney.combs@utoledo.edu

Dr. Tavis Glassman, Associate Professor
College of Health and Human Services
University of Toledo
Health & Human Services 1006
Phone: 419.530.2770
Email: tavis.glassman@utoledo.edu

Diana M. Reindl, PhD, Assistant Professor
Department of Nursing and Health Professions
University of South Carolina Beaufort
Science & Technology 218
Phone: 843.208.8316
Email: dreindl@uscb.edu