

Exhibit 568

COVID-19 Data Collection, Comorbidity & Federal Law: A Historical Retrospective

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COVID-19 Data Collection, Comorbidity & Federal Law: A Historical Retrospective

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Abstract

According to the Centers for Disease Control and Prevention (CDC) on August 23, 2020, "For 6% of the deaths, **COVID-19** was the only cause mentioned. For deaths with conditions or causes in addition to **COVID-19**, on average, there were 2.6 additional conditions or causes per death."^[1] For a nation tormented by restrictive public health policies mandated for healthy individuals and small businesses, this is the most important statistical revelation of this crisis. This revelation significantly impacts the published fatalities count due to **COVID-19**. More importantly, it exposes major problems with the process by which the CDC was able to generate inaccurate data during a crisis. The CDC has advocated for social isolation, social distancing, and personal protective equipment use as primary mitigation strategies in response to the **COVID-19** crisis, while simultaneously refusing to acknowledge the promise of inexpensive pharmaceutical and natural treatments. These mitigation strategies were promoted largely in response to projection model fatality forecasts that have proven to be substantially inaccurate. Further investigation into the legality of the methods used to create these strategies raised additional concerns and questions. Why would the CDC decide against using a system of data collection & reporting they authored, and which has been in use nationwide for 17 years without incident, in favor of an untested & unproven system exclusively for **COVID-19** without discussion and peer-review? Did the CDC's decision to abandon a known and proven effective system also breach several federal laws that ensure data accuracy and integrity? Did the CDC knowingly alter rules for reporting cause of death in the presence of comorbidity exclusively for **COVID-19**? If so, why?

continued on next page

Keywords

COVID-19, SARS-COV-2, comorbidity, fatality, impact, regulation

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Abstract (Continued from page 1)

This historical retrospective will provide a timeline summary of events to help the reader orient themselves to many aspects of the crisis previously unknown and will discuss the significance of the March 24, 2020 **COVID-19 Alert No. 2** that had a dramatic impact upon cause of death reporting numbers. Supportive data comparisons suggest the existing **COVID-19** fatality data, which has been so influential upon public policy, may be substantially compromised regarding accuracy and integrity, and illegal under existing federal laws. If the fatality data being presented by the CDC is illegally inflated, then all public health policies based upon them would be immediately null and void.

1. Introduction

All federal agencies, including the Centers for Disease Control and Prevention (CDC), are lawfully required to comply with the Paperwork Reduction Act (PRA) and the Information Quality Act (IQA). Data being collected, analyzed, and published by any federal agency is required to meet the highest standards for accuracy, quality, objectivity, utility, and integrity as defined by the PRA, IQA, as well as additional guidelines issued by the Office of Management and Budget (OMB).[2][3][4][5][6]

The key to initiating legal regulatory oversight of all proposed changes to data collection, publication, and analysis is the Federal Register. Each Federal agency is required to submit a formal change proposal to the Federal Register before enacting their proposed changes. By submitting a change proposal to the Federal Register, federal agencies open the minimum 60-day public comment and peer-review process. Additionally, it is the “change proposal submission” to the Federal Register that alerts the OMB that legal oversight of the process has been initiated. Federal agencies that make changes to how they collect, publish, and analyze data without alerting the Federal Register and OMB as a result, are in violation of federal law.

The CDC published guidelines on March 24, 2020 that substantially altered how cause of death is recorded exclusively for **COVID-19**. This change was enacted apparently without public opportunity for comment or peer-review. As a result, a capricious alteration to data collection has compromised the accuracy, quality, objectivity, utility, and integrity of their published data, leading to a significant increase in **COVID-19** fatalities. This decision by the CDC may have subverted the legal oversight of the OMB as Congressionally authorized by the PRA & IQA as well.[7][8]

2. COVID-19 Data Historical Timeline

A historical timeline of events is presented relative to the PRA, IQA, cause of death reporting, and how the **COVID-19** crisis has unfolded as a result. Please note that all data, including statistical pro-

jections produced by any entity outside of federal regulatory law, must go through strict federal procedures for OMB oversight before being used by any federal agency for any purpose. These regulatory laws apply to the use of data being published at the university level, such as the **COVID-19** projection models developed by the Institute for Health Metrics Evaluation (IHME) at the University of Washington. All federal agencies must abide by the laws in place before they can use external data from any source to inform the public or develop legislation or policy.

- **December 11, 1980** – Paperwork Reduction Act (PRA) becomes law (44 U.S.C. §§ 3501–3521, Public Law 96-511, 94 Stat. 2812). PRA establishes the Office of Information and Regulatory Affairs (OIRA) under the Office of Management and Budget (OMB). PRA authorizes OIRA to establish information collection policies for all federal agencies, including the CDC.[2]
- **May 22, 1995** – PRA is amended (44 U.S.C. §§ 3501–3521, Public Law 104-13, 109 Stat. 182). PRA amendment confirms that the OIRA has authority over all data collected by and shared between federal agencies, including the CDC. PRA amendment also affirms that OIRA has authority over all data provided to the public.[3][4]
- **October 1, 2002** – Information Quality Act (IQA) takes effect (Section 515 of the Congressional Consolidated Appropriations Act, 2001 Public Law 106-554). All federal agencies, including the CDC, are required to be in full compliance with guidelines issued by the Office of Management and Budget (OMB), which has been authorized by Congress to have its OIRA branch enact executive oversight for all data collected, analyzed, and published by federal agencies.[5][6]
- **2003** – CDC publishes Medical Examiners’ and Coroners’ Handbook on Death Registration and Fetal Death Reporting and Physicians’ Handbook on Medical Certification of Death. These handbooks would immediately become the nationwide standard illustrating exactly how cause of death should be recorded in cases of comorbidity for all death certificates. These handbooks have been used successfully for 17 years without need of update. They remain in use today for all causes of death except where involvement of **COVID-19** is suspected or confirmed. When involvement of **COVID-19** is suspected or confirmed, the March 24th, 2020 **COVID-19 Alert No. 2** guidelines are used instead. [7][8]
- **August 22, 2005** – The Virology Journal publishes research demonstrating that hydroxychloroquine, “has strong antiviral effects on **SARS-COV** primate cells. These inhibitory effects are observed when the cells are treated with the drug either before or after exposure to the virus, suggesting both prophylactic and therapeutic advantage.” The research is acknowledged and lauded by Dr. Anthony Fauci.[9]
- **2014** – Dr. Anthony Fauci authorizes \$3.7 million of scientific funding to the Wuhan Institute of Virology via the National Institute for Allergy and Infectious Disease (NIAID) and National Institutes of Health (NIH) “for work on gain-of-function research on bat coronaviruses.”[10]
- **2019** – Dr. Anthony Fauci authorizes an additional \$3.7 million of scientific funding to the EcoHealth Alliance via the NIAID and NIH for “a second phase of the project” that included gain-of-function research on bat coronaviruses.[10]
- **October 18, 2019** – Johns Hopkins Center for Health Security hosts Event 201, a high-level pandemic exercise in New York, NY. [11]

Date	CDC Test Based Strategy			CDC Symptom Based Strategy		
	June 13th	July 16th	Net Change	July 17th	August 20th	Net Change
Current Hospitalizations	27,902	57,369	29,467	57,705	41,988	-15,717
Total Hospitalizations	224,420	271,758	47,338	274,436	355,276	80,840
Infection Rate	8.5%	7.8%	-0.7%	7.8%	7.6%	-0.2%
Positive Tests	2,063,542	3,499,185	1,435,643	3,576,418	5,464,854	1,888,436
Total Tests	24,262,973	44,750,039	20,487,066	45,601,827	71,942,869	26,341,042
Fatality Rate	5.3%	3.7%	-1.6%	3.7%	3.0%	-0.6%
Total Fatalities	109,249	130,572	21,323	131,523	166,139	34,616
Recovery Rate	27.0%	35.3%	8.3%	35.0%	89.8%	54.8%
Total Recoveries	556,606	1,235,326	678,720	1,251,525	4,908,347	3,656,822

Data Sourced From All 56 US State & Territory Health Departments & CDC

Figure 1. Test Based Strategy vs. Symptom Based Strategy. The impact of using a previously untested and unproven test-based strategy (Jun 13 to Jul 17) vs the more traditional globally-accepted symptom-based strategy (Jul 17 – Aug 20). For statistical comparison, 34-day periods of time are used to equivocate the analysis. Using a symptom-based strategy, hospitalization counts dropped. As of July 17, 2020, symptoms are required along with a positive test to confirm the **COVID-19** diagnosis for hospitalization, but probable **COVID-19** cases can still be added. Using a symptom-based strategy confirmed safe by the CDC provides a more accurate count of total recoveries for Americans who did not require medical care. If accuracy in data collection and reporting was a goal, a symptom-based strategy would be best.[26][27][State & Territory Health Departments]

- **November 17, 2019** – China records 1st known case of **COVID-19**. [12]
- **November 30, 2019** – Deadline passes for any federal agency to submit 60-day notice to Federal Register for ‘Proposed Data Collection Submitted For Public Comment and Recommendations’ that would enable the use of IHME projection data to inform the public and enact federal policy. [13]
- **January 21, 2020** – CDC confirms 1st known case of **COVID-19** in US. [14]
- **January 24, 2020** – Deadline passes for CDC and/or National Vital Statistics System (NVSS) to submit 60-day notice to Federal Register for ‘Proposed Data Collection Submitted For Public Comment and Recommendations’ that would become known as the March 24th **COVID-19 Alert No. 2**. [13][15]
- **January 29, 2020** – Whitehouse Coronavirus Task Force is established and included Dr. Anthony Fauci (NIAID), Dr. Robert Redfield (CDC), and Derek Kan (OMB). Primary data being used to forecast the situation and brief the President is sourced from the IHME in potential violation of the PRA & IQA. [16]
- **February 14, 2020** – Deadline passes for CDC to submit 60-day notice to Federal Register for ‘Proposed Data Collection Submitted For Public Comment and Recommendations’ that would become known as their April 14th adoption of the Council of State and Territorial Epidemiologists (CSTE) **COVID-19** Position Paper. The CSTE is an independent, privately funded, non-governmental organization and has no legal approval to provide data for policy development without adhering to strict regulatory laws governing the use of non-governmental data. [13][16]
- **March 9, 2020** – CDC alerts American citizens over the age of 60 and with comorbidities (pre-existing conditions) that they are likely at a higher risk for fatality if **SARS-COV-2** virus is contracted. [17]
- **March 24, 2020** – In potential violation of the PRA & IQA, the CDC issues **COVID-19 Alert No. 2**, significantly altering cause of death reporting exclusively for **COVID-**

19. In doing so, the CDC bypasses federal oversight by the OIRA.[15][18]

- **March 26, 2020 (March 7, 2020 Initial Pre-Publish Date)** – Imperial College of London research team, led by Dr. Neil Ferguson, publishes **COVID-19** predictive model incorrectly asserting 2.2 million Americans will die due to **SARS-COV-2** virus in 2020 if no mitigation strategies are employed. Dr. Neil Ferguson is on record confirming that his research team had shared their wildly inaccurate projections with the White House **COVID-19** Task Force approximately 1 week prior to publication. The data projections shared were neither peer-reviewed, nor submitted to the Federal Register to initiate a 60-day public comment period as required by law. As a result, the OMB was not able to approve the use of these projections, which makes their use by any federal agency, for any reason, illegal. Dr. Neil Ferguson had previously and severely overestimated fatality data in earlier predictive models for Bird Flu, Mad Cow Disease, and Swine Flu.[19][20][21]
- **April 13, 2020** – US Surgeon General Jerome Adams confirms that the Whitehouse **COVID-19** Task Force has terminated the use of IHME Predictive Contagion Models in favor of actual data collected from each US State Health Department. [22]
- **April 14, 2020** – Dr. John Ioannidis of Stanford publishes **COVID-19** antibody seroprevalence research confirming **SARS-COV-2** virus had spread much wider than initially realized and most people infected developed natural, adaptive immunity. This study questions the necessity of continued use of IHME Predictive Contagion Models. [23]
- **April 14, 2020** – In potential violation of the PRA & IQA, the CDC adopts the CSTE **COVID-19** Position Paper, significantly altering standard established medical criteria for diagnosis, exclusively for **COVID-19**. In doing so, the CDC bypasses federal oversight by the OIRA once again.[16][18]
- **April 24, 2020** – National Institutes of Health (NIH) cancels funding on previously supported gain-of-function research for bat coronaviruses. [10]
- **June 13, 2020** – CDC initiates PCR test-based strategy requiring all patients that need hospitalization for any reason be tested at time of entry regardless of symptoms. A patient testing positive is categorized as a new **COVID-19** case and hospitalization. Patients testing positive are required to be PCR tested every 24 hours until they have 2 consecutive negative PCR tests at least 24 hours apart. There are no data collection guidelines within the CSTE Position Paper adopted by the CDC on April 14, 2020 to prevent the same patient being counted multiple times. Additionally, there are no data collection guidelines published separately by the CDC to explicitly prevent the same hospitalized patient from being inaccurately counted as a new case and hospitalization each time they are tested while hospitalized.[24]
- **June 13 thru July 16, 2020** – Over this 34-day time period using the CDC test-based strategy nationwide, current hospitalizations more than doubled while 678,720 Americans recovered, and 21,323 Americans passed away. [State & Territory Health Departments]
- **July 15, 2020** – Health and Human Services (HHS) assumes control of **COVID-19** data collection from the CDC. [25]
- **July 17, 2020** – After being unable to clinically prove the existence of one definitive case of asymptomatic transmission, one

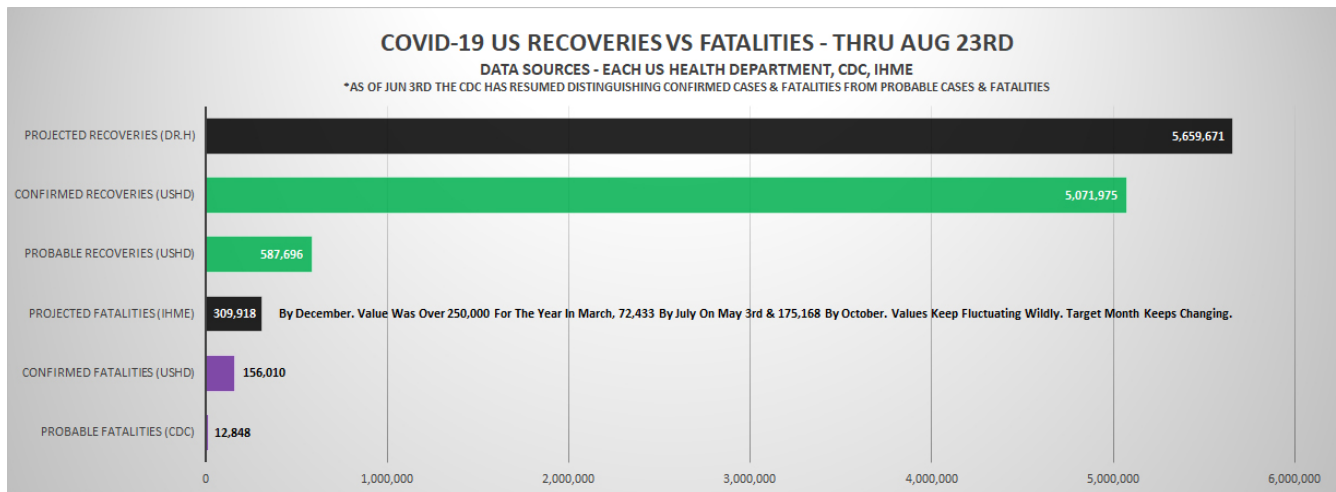


Figure 2. Confirmed Recoveries vs. Confirmed Fatalities. Based upon data collected from each US state health department, confirmed recoveries = 5,071,975 while confirmed fatalities = 156,010. Americans are now 32.5 times more likely to recover from **COVID-19** (as of 8.23.2020). [30][State & Territory Health Departments]

case of definitive reinfection, or a person being contagious with the **SARS-COV-2** virus for longer than 10 days following initial symptom presentation, the CDC no longer recommends daily testing for hospitalized patients. The CDC has also reduced the amount of quarantine time recommended for definitive or suspected exposure from 14 days to 10 days. Patients can now be released from the hospital once symptoms abate. The CDC officially moves from a PCR test-based strategy to a more traditional symptom-based strategy of differential diagnosis that incorporates corroborative PCR testing when appropriate.[24][26][27]

- **July 17, 2020** – Dr. Sin Hang Lee publishes *Testing for SARS-COV-2 in cellular components by routine nested RT-PCR followed by DNA sequencing* confirming concerns that demonstrate **SARS-COV-2** PCR testing is 50% reliable at best. CDC confirms that, ‘Although replication-competent virus was not isolated 3 weeks after symptom onset, recovered patients can continue to have **SARS-COV-2** RNA detected in their upper respiratory specimens for up to 12 weeks.’[26][28]
- **July 17 thru August 20, 2020** – Over this

34-day time period using the CDC symptom-based strategy nationwide, current hospitalizations declined by 15,717 Americans. While more Americans passed away during this time period than during the previous 34-day time period, many of these fatalities can be attributed to Americans being hospitalized from June 13th to July 16th and miscategorized as a **COVID-19** case without having **COVID-19** symptoms. Between July 17 and August 20, 3,656,822 Americans recovered, and 34,616 Americans passed away. Infection rate, fatality rate, and recovery rate improved significantly during both time periods.[State & Territory Health Departments]

- **August 23, 2020** – The CDC reports 32,582 total fatalities for New York state. The New York State Department of Health reports 25,282 for the same day. This is an inflated discrepancy by the CDC of 7,300 fatalities that they cannot justify, and another example of how the data they are publishing is compromised.[30][81]

3. Did the CDC Violate Federal Law?

3.1 Basis for Allegations That the CDC Violated the Law

The CDC's rules for data collection, published data, and statistical analyses are legally required to comply with the laws established by the Information Quality Act (IQA), enacted by Congress in December 2000 as Section 515 of Public Law 106-554, which required the Office of Management and Budget (OMB) to “**provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminates by Federal agencies,**” and the Paperwork Reduction Act (PRA) which is codified at 44 USC 3501 et seq.[33][34]

The Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) is responsible for ensuring each federal agency is in compliance with the IQA & PRA. [35][36][37][38]

The process by which any federal agency can propose changes in data collection, data publishing, and data analysis to ensure compliance is governed by 44 USC 3506 (c)(2)(A) which states,

”except as provided under subparagraph (B) or section 3507(j), provide 60-day notice in the Federal Register, and otherwise consult with members of the public and affected agencies concerning each proposed collection of information, to solicit comment to—” and 44 USC 3506 (d)(3),

” **provide adequate notice when initiating, substantially modifying, or terminating significant information dissemination products...**”

Neither of the exceptions is applicable in this case.

We are concerned that the CDC has violated federal IQA & PRA law and, in doing so, bypassed essential oversight by the OMB/OIRA, who are legally empowered by Congress with ensuring information compliance for all federal agencies.

Following review of the Federal Register for proof of the 60-day notice for ‘Proposed Data Col-

lection Submitted For Public Comment and Recommendations’, zero evidence was found demonstrating that the CDC abided by the laws established by the IQA & PRA.[39]

All federal agencies are required to submit notification for data collection, publication, or analysis to the Federal Register BEFORE gaining approval from the OMB/OIRA to ensure they are in compliance with the IQA & PRA and therefore, approved to implement the proposed changes.

Based upon the complete absence of Federal Register records for ‘Proposed Data Collection Submitted For Public Comment,’ at no point, did the CDC inform the OMB/OIRA or allow for 60 days of public comment in the following unilateral decisions that attempted to bypass Federal oversight.

We allege that the complete absence of the appropriate Federal Register records is evidence that the CDC knowingly and willingly violated the IQA & PRA. As a direct consequence of implementing the two documents below without OMB approval, there was significant inflation of **COVID-19** case and fatality data.

1. **On March 24th, the National Vital Statistics System (NVSS),** under the direction of the CDC, issued ‘**COVID-19 Alert No. 2**’ to all physicians, medical examiners and coroners as guidelines for making significant changes as to how cause of death was to be reported on death certificates exclusively for **COVID-19**.[15]

This decision was made despite pre-existing rules, approved by the OMB, issued by the CDC, and in use nationwide for at least 17 years without incident. These rules are published as, *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*.

Considering these handbooks have been approved by the OMB and in use without incident for 17 years, there was no justifiable reason for the CDC to implement these changes, bypass the oversight of the OMB, and fail to provide 60-days for public comment, as they are legally obligated to do.

COVID-19 Recovery Rates By Age - Thru August 23rd

Date	August 23rd	August 16th	August 9th	August 2nd
Age 0 to 19	99.982%	99.981%	99.980%	99.978%
Age 20 to 49	99.72%	99.72%	99.72%	99.71%
Age 50 to 69	97.31%	97.31%	97.28%	97.29%
Age 70+	82.43%	82.43%	82.15%	80.95%

Data Source - All US State & Territory Health Departments

Figure 3. Recovery Rates By Age Compared To Preceding Weeks. Recovery rates and fatality rates are reciprocal ways of looking at the data available. If a fatality rate is 0.018%, as is the case for the age 0 to 19 demographic on Aug 23, then the reciprocal recovery rate is 99.982%. Based upon this information, Americans in the age 0 to 19, 20 to 49, and 50 to 69 demographics are at extremely low risk of fatality due to **COVID-19**. Recovery rates rise even higher if the methods for recording cause of death reporting based upon the March 24, 2020 **COVID-19 Alert No. 2** guidelines are proven to have violated the PRA & IQA.[33][34][State & Territory Health Departments]

By failing to act in accordance with Congress’ clear intent as to how an agency may propose changes to data collection as codified in 44 USC 3506 (c)(2)(A), there is no record of information the CDC relied upon to make its decision to change how deaths are reported.

Previous reports detailed the substantial changes on how causes of death were forcibly modified by the CDC through the NVSS, and how together, both federal agencies inflated the actual number of **COVID-19** fatalities by approximately 90.2% through July 12th, 2020.[18]

We believe this deliberate decision by the CDC and NVSS to deemphasize pre-existing comorbidities, in favor of emphasizing **COVID-19** as a cause of death, is in violation of 44 U.S. Code 3504 (e)(1)(b), which states the activities of the Federal statistical system shall ensure **“the integrity, objectivity, impartiality, utility, and confidentiality of information collected for statistical purposes.”** In doing so, the CDC and NVSS have compromised the quality, objectivity, utility, and integrity of data, and concomitantly usurped the oversight of the “Authority and Functions of the Director of the OMB/OIRA”.[40]

2. On April 14th, the CDC adopted a position paper authored by the Council of State and Territorial Epidemiologists (CSTE), a 501c (6) non-profit organiza-

tion, with the assistance of 4 CDC-employed subject matter experts (Dr. Susan Gerber, Dr. Aron J. Hall, Sandra Roush, & Dr. Tom Shimabukuro). This document was sanctioned by Dr. Robert R. Redfield, Director of the CDC.[16]

Not only does this appear to be a potential conflict of interest, it also bypasses the OMB oversight for the IQA & PRA, as directed by Congress and is rife with *ex parte* communications. *Ex parte* communications in general violate ethical standards.

By employing a non-governmental organization (CSTE), free from the oversight of the OMB and the laws detailed by Congress via the IQA & PRA, the CDC bypassed the oversight of the OMB Director’s Information Resources Management policies, plans, rules, regulations, procedures, and guidelines for public comment. We allege this is a violation of 44 U.S. Code 3517(a), which requires an agency to provide interested persons an **“early and meaningful opportunity to comment.”**[41]

This violation has inevitably resulted in **COVID-19** data for cases, hospitalizations, and fatalities being artificially elevated, and definitively compromises prudent decision making at federal and state executive levels. This includes policy enforcement for a public health crisis that may not have existed had the CDC abided by the laws that ensure the accuracy of data collection.

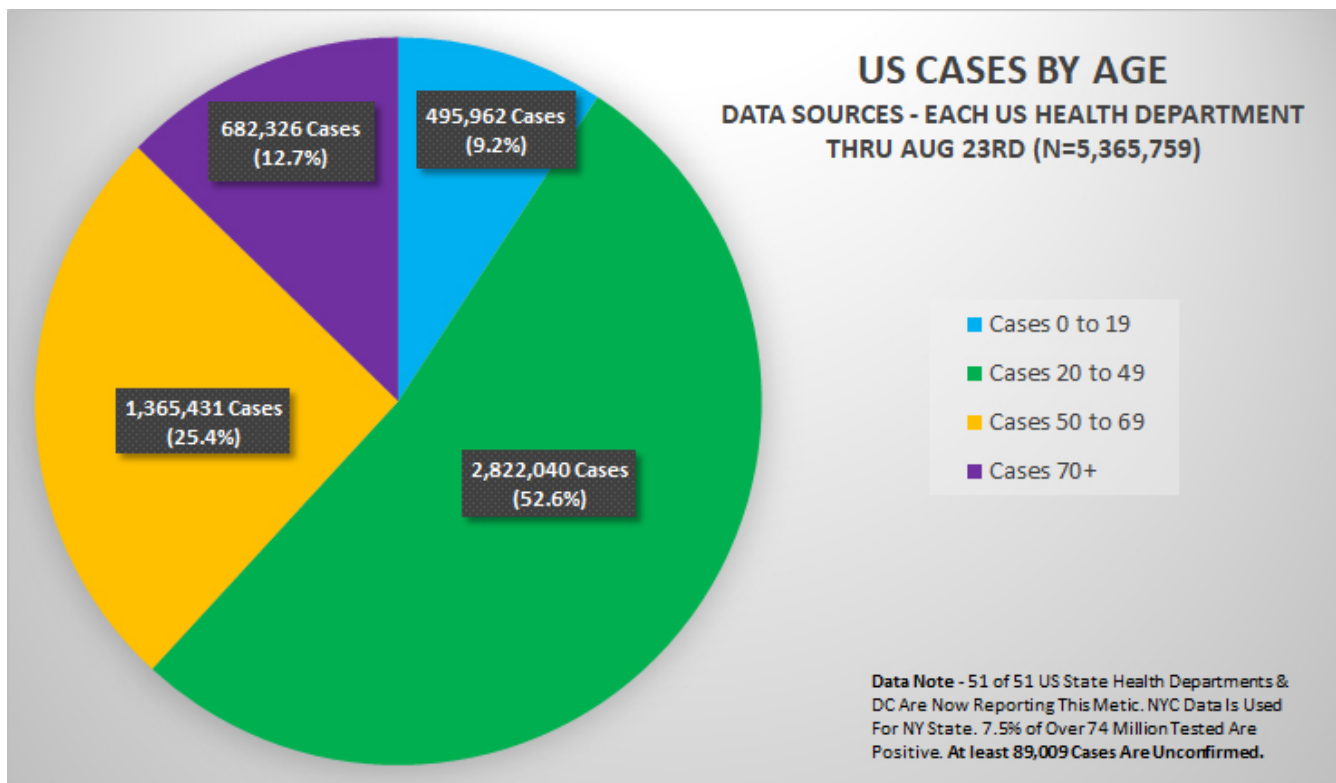


Figure 4. US Cases By Age Note: Although the age 70+ demographic makes up a small percentage of cases (12.7%), the age 70+ demographic makes up a disproportionate percentage of hospitalizations and fatalities. Additionally, roughly 92.5% of the more than 74 million Americans tested have tested negative for the SARS-COV-2 virus, and at least 89,009 reported cases are unconfirmed because of inaccuracies of contact tracing.[30][State & Territory Health Departments]

For example:

- The CSTE position paper in Section VII established rules for COVID-19 data classification and collection that allowed for probable diagnoses unconfirmed by lab testing, a test-based strategy for lab testing, and set the stage for people with no medical licensure to contact trace and illegally diagnose American citizens they have never seen.

The latter is a clear violation of nationally recognized state laws prohibiting the practice of medicine without a license.

- In Section VII.B, the CSTE position paper specifically declined to define a method for ensuring that rules for data collection prevented the same person from being counted multiple times as new COVID-19 cases.

As a result, people hospitalized with a positive PCR test could be tested every 24 hours and each time counted as new COVID-19 to the complete absence of basic rules to ensure that this could not happen.

Upon Investigation:

- The CDC did not submit a proposal to the Federal Register for public consideration and comment regarding their desire to adopt these unnecessary changes.
- The CDC did not submit a proposal to the Federal Register for public consideration and comment regarding their desire to forgo existing rules for infectious disease data collection that has been in use, without incident, for at least 17 years.

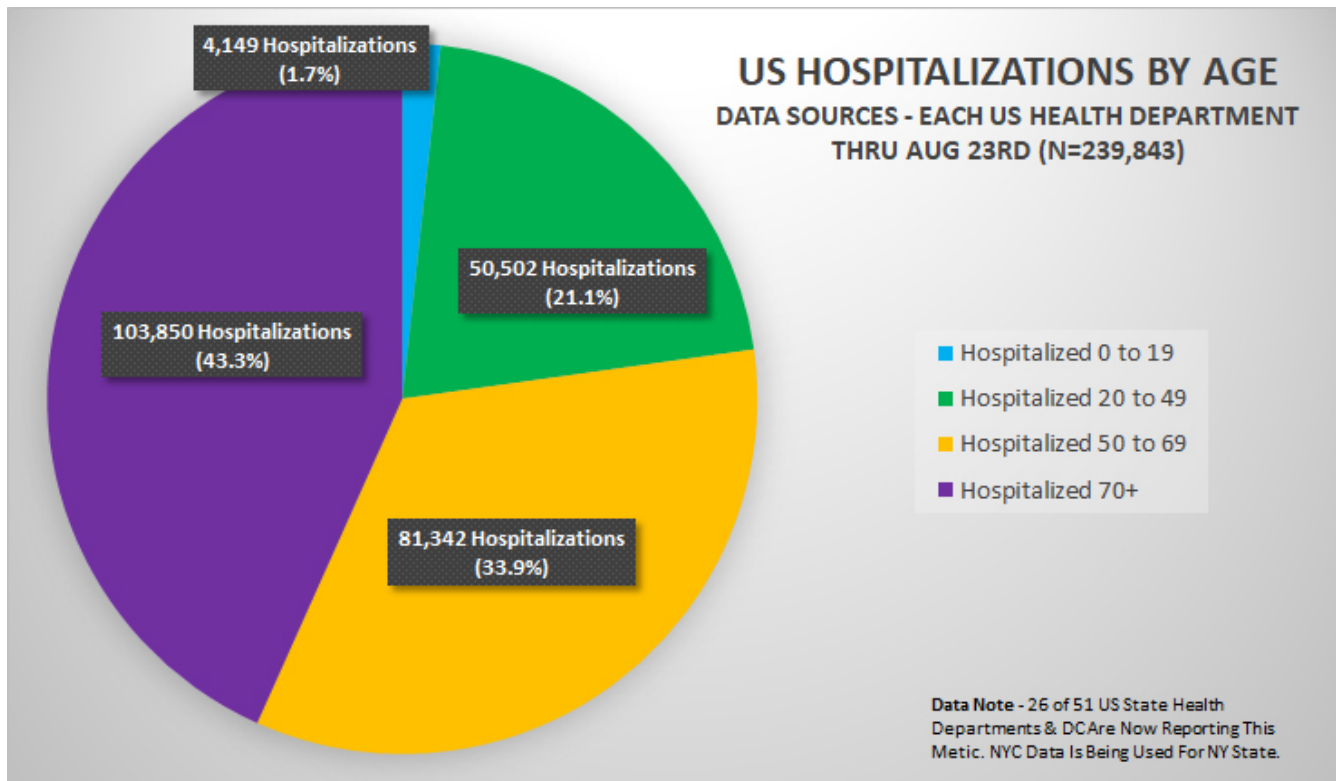


Figure 5. US Hospitalizations By Age. Note: The age 70+ demographic makes up the largest percentage of hospitalizations (43.3%) yet makes up a small percentage of cases (12.7%).[30][State & Territory Health Departments]

In adopting the CSTE position paper, the CDC violated the clear intent of Congress with respect to rule making and data collection, failed to create a record of their decision making, engaged in *ex parte* communications with CSTE personnel, and disenfranchised the public from meaningful participation in the decision making process. This compromised the accuracy and integrity of the data collected.

- The CDC has yet to publish its own unique Information Quality Statement as mandated by the IQA and OMB Guidelines. The referenced CDC webpage for Information Quality is also filled with "404 – Page Error" links, which places them further out of compliance with the OMB/OIRA.[42]

4. The CDC Actions Violated Data Quality, Objectivity, Utility, and Integrity Requirements

The Information Quality Act became law through the U.S. Congress, in Section 515 of the Consolidation Appropriations Act of 2001, which empowered the OMB to ensure all federal agencies are in compliance with the IQA & PRA. [34]

Section 515 of this act reads:

(a) In General. – The Director of the Office of Management and Budget shall, by not later than September 30, 2001, and with public and Federal agency involvement, **issue guidelines under sections 3504(d)(1) and 3516 of title 44, United States Code, that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of**

information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of chapter 35 of title 44, United States Code, commonly referred to as the Paperwork Reduction Act.

(b) Content of Guidelines. – **The guidelines under subsection (a) shall**

– (1) apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies; and

(2) **require that each Federal agency** to which the guidelines apply

– (A) **issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency**, by not later than 1 year after the date of issuance of the guidelines under subsection (a)...

The IQA & PRA are intended to function as a ‘checks and balances’ system for federal agencies, including the CDC, that disseminate data and statistics. The enforcement of the IQA & PRA falls directly under the administrative regulation of the Executive Branch of Government, specifically the Office of Management and Budget (OMB), and its sub-agency Office of Information and Regulatory Affairs (OIRA).[33][34][35][36][37][38]

From the OMB Guidelines Published October 1, 2001[36]

I. Procedures for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Prior to Dissemination In Government-wide Guidelines, “quality” is defined as an encompassing term comprising utility, objectivity, and integrity.

A. Objectivity and Quality of Information

1. As defined in Section IV, below, **“objectivity” is a measure of**

whether disseminated information is accurate, reliable, and unbiased and whether that information is presented in an accurate, clear, complete, and unbiased manner.

“Utility” refers to the usefulness of the information for the intended audience’s anticipated purposes. OMB is committed to disseminating reliable and useful information. **Before disseminating information, OMB staff and officials should subject such draft information to an extensive review process including open public comment.** It is the primary responsibility of the Division or Office (hereafter collectively referred to as “Division”) drafting information intended for dissemination to pursue the most knowledgeable and reliable sources reasonably available to confirm the objectivity and utility such information.

Based upon our investigation of Federal Register Records for 2020, there was no formal, transparent, public review process initiated by the NVSS or CDC prior to or following the issuance of the March 24th NVSS **COVID-19 Alert No. 2** that dramatically altered cause of death reporting exclusively for **COVID-19**. In this regard, we allege that the CDC and NVSS’s alterations to cause of death reporting guidelines exclusively for **COVID-19**, violated the IQA & PRA by compromising data quality, objectivity, and utility.

Additionally, our investigation into Federal Register Records for 2020 revealed that there was no formal, transparent, public review process initiated by the CDC prior to or following the adoption of the April 14th CSTE position paper that dramatically altered what defines a new case exclusively for **COVID-19**. In this regard, we allege that the CDC changes to cause of death reporting exclusively for **COVID-19** violated the IQA & PRA by compromising data quality, objectivity, and utility.

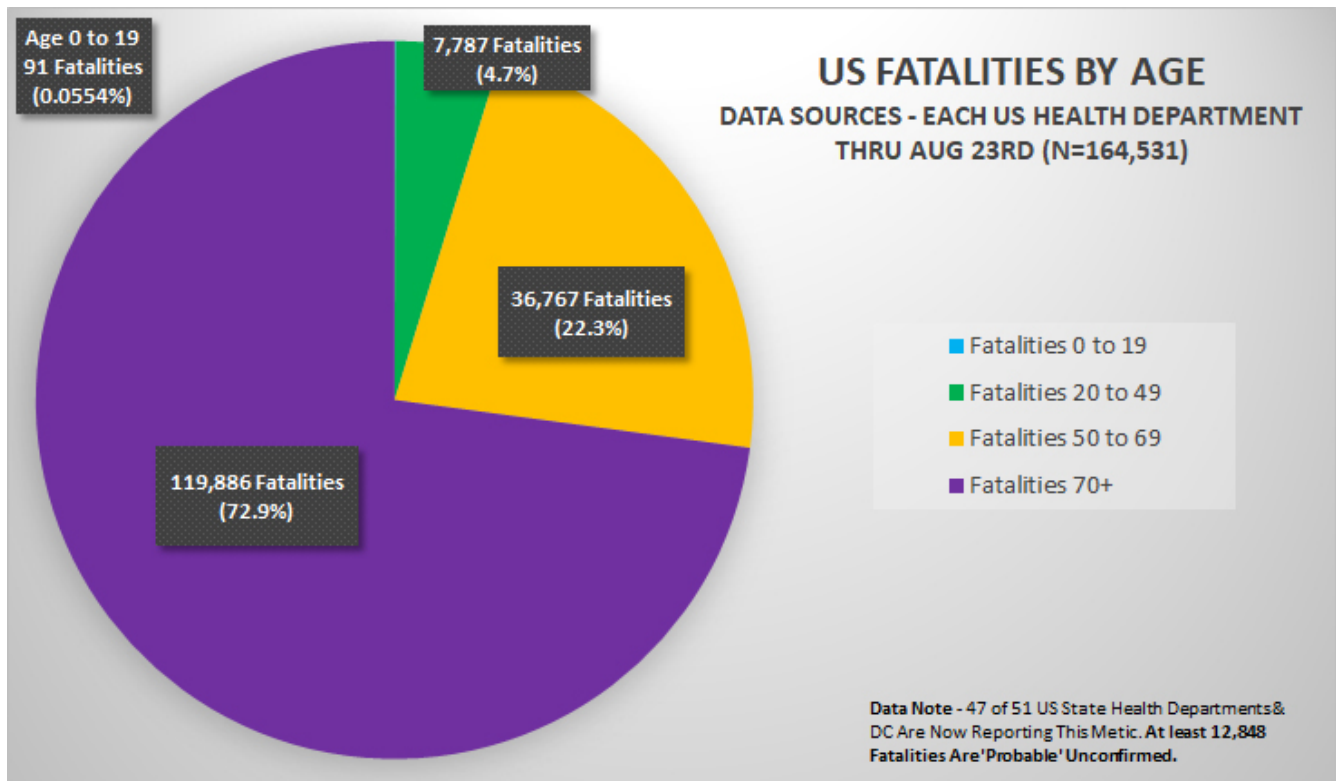


Figure 6. US Fatalities By Age. Note: The age 70+ demographic makes up the largest percentage of fatalities (72.9%). This is alarmingly disproportionate to their relatively small percentage of cases (12.7%), and thus defines them as a high-risk population. The opposite is true for the age 0 to 19 demographic which makes up a small percentage of fatalities (0.0554%).[30][State & Territory Health Departments]

By implementing new rules exclusively for COVID-19, while denying the public an opportunity for meaningful participation in the decision making process and failing to create a record in which the agency clearly set forth the reasons for its action, we allege the CDC violated the express intent of Congress and acted in an arbitrary and capricious manner.

As a result of these changes, we allege the CDC compromised the quality, objectivity and integrity of all COVID-19 data collected to date.

(OMB Guidelines for IQA & PRA Enforcement – Continued)[36]

Sections 6 & 8 are purposefully omitted.

- The Lead Division should consider the uses of the information both the perspective of and the public. **When it is determined that the transparency of information is relevant**

for assessing the information’s usefulness from the public’s perspective, the Lead Division should ensure that transparency is appropriately addressed.

- When the Lead Division determines that the information it will disseminate is influential scientific, financial, or statistical information, extra care should be taken to include a high degree of transparency about data and methods to meet the Government-wide Guidelines’ requirement for the reproducibility of such information. In determining the appropriate level of transparency, the Lead Division should consider the types of data that can practically be subjected to a reproducibility

requirement given ethical, feasibility, and confidentiality constraints. In making this determination, the Lead Division should hold analytical results to a higher standard than original data.

7. The Division responsible for the dissemination of information should generally take the following basic steps to assure the “objectivity” and “utility” of the information to be disseminated:

- a. Preparing a draft of the document after consulting the necessary parties, including government and non-government sources, as appropriate;
- b. Determining/assuring accuracy and completeness of source data;
- c. Determining the expected uses by the government and public;
- d. Determining necessary clearance points;**
- e. Determining where the final decision shall be made;
- f. Determining whether peer review would be appropriate and, if necessary, coordinating such review;
- g. Obtaining clearances, and
- h. Overcoming delays and, if necessary, presenting the matter to higher authority.

9. The quality control procedures followed by OMB should be determined by the nature of the information and the manner of its distribution. **Any information collected by OMB and subject to the Paperwork Reduction Act should be collected, maintained, and used in a manner consistent with Paperwork Reduction Act and the OMB information quality standards. The OMB clearance package should demonstrate that the proposed collection of information will result in infor-**

mation that will be collected, maintained, and used in a way consistent with the Government-wide Guidelines and OMB guidelines.

COVID-19 was declared a pandemic on March 11, 2020 by the World Health Organization. As such, any data gathering related to this illness must be done with the utmost transparency to ensure the public and public officials have sound data upon which to make vitally important decisions.

Yet, the CDC failed to follow the OMB Guidelines as required by Congress and, in doing so, violated the law and also violated the public trust.

(OMB Guidelines for IQA & PRA Enforcement – Continued)[36]

B. Integrity of Information

1. **”Integrity” refers to the security of information -protection of the information from unauthorized unanticipated, or unintentional modification -to prevent information from being compromised through corruption or falsification.**

The CDC compromised data integrity by altering how cause of death records are reported, and did so exclusively for **COVID-19**, in the March 24, 2020 NVSS **COVID-19 Alert No. 2**.

On April 14, 2020, the CDC again compromised data integrity when it adopted the CSTE position paper and created categories for ‘probable’ cases that eliminated the medical standards of proof of infection through positive lab testing. From April 14th to July 16th, the CDC actively promoted a test-based strategy for diagnosis, meaning everyone should be tested regardless of the presence or absence of symptoms. Additionally, the CSTE position paper paved the way for unlicensed and medically untrained contact tracers to illegally diagnose patients without any medical examination or confirmatory lab testing. In fact, they could do so without even seeing or talking to the patient in question.

Comorbidities

Table 3 shows the types of health conditions and contributing causes mentioned in conjunction with deaths involving coronavirus disease 2019 (COVID-19). For 6% of the deaths, COVID-19 was the only cause mentioned. For deaths with conditions or causes in addition to COVID-19, on average, there were 2.6 additional conditions or causes per death. The number of deaths with each condition or cause is shown for all deaths and by age groups. For data on comorbidities,

[Click here to download](#)

▼ Table 3. Conditions contributing to deaths involving coronavirus disease 2019 (COVID-19), by age group, United States. Week ending 2/1/2020 to 8/22/2020.*

Updated August 26, 2020

Conditions Contributing to Deaths where COVID-19 was listed on the death certificate ¹	ICD-10 codes	Number of Conditions								
		Age Group								
		All ages	0-24 years	25-34 years	35-44 years	45-54 years	55-64 years	65-74 years	75-84 years	85 years and over
Total COVID-19 deaths ² , as of 8/22/2020	U071	161,392	330	1,241	3,228	8,501	20,295	34,334	42,587	50,867
Respiratory diseases		-	-	-	-	-	-	-	-	-
Influenza and pneumonia	J09-J18	68,004	111	564	1,428	3,967	9,438	15,389	18,116	18,989

Figure 7. CDC Conditions Contributing to Deaths involving Coronavirus Disease (COVID-19) Data from the CDC shows that only 6% of 161,392 COVID fatalities had no mention of any comorbidity. This calculates to approximately 9,684 total fatalities in the US directly due to COVID-19 .[1]

While the rationale for doing so is speculative at this point, the reality is that **COVID-19** became emphasized as a cause of death as frequently as possible, while comorbidity was simultaneously deemphasized as causes of death. We reported this in a previous research article.[18]

By adopting both the March 24, 2020 NVSS **COVID-19 Alert No. 2** and the April 14, 2020 CSTE position paper, the CDC knowingly and willfully compromised the integrity of data they collected, published, and analyzed. We allege the CDC intentionally violated federal law with respect to integrity of information.

5. How Aware Was the CDC of Their Responsibility to Be In Full Compliance With IQA & PRA?

As of August 16, 2020, the Federal Register returns the following results from their database of federal documents dating back to 1994, for the following search terms:

NVSS – Eighteen documents resulted from the Federal Register. (Most Recent Dated 2.18.2020) The Federal Register shows zero federal filings from the NVSS for ‘Proposed Data Collection Submitted For Public Comment and Recommendations’ in 2020.

COVID – A total of 2,006 documents resulted from the Federal Register. The Federal Register shows 31 federal filings from the CDC for COVID and **8 filings from the CDC for ‘Proposed Data Collection Submitted For Public Comment and Recommendations’ in 2020. Of these 8 federal filings, zero reference the March 24th, 2020 NVSS COVID-19 Alert No. 2 or the April 14th, 2020 CDC adoption of the CSTE position paper.**

CDC – A total of 13,124 documents resulted from the Federal Register. (Most Recent Dated 8.21.2020) The Federal Register shows that 1,429 of these filings were for ‘Notices of Closed Meetings’. 3,904 of the federal filings were for ‘Proposed Data Collection Submitted For Public Comment and Recommendations’. **Of the 3,904 fil-**

ings, 120 were made this year. Of the 120 that were made this year, zero reference the March 24, 2020 NVSS COVID-19 Alert No. 2 or the April 14, 2020 CDC adoption of the CSTE position paper.

CSTE – 1 document resulted from the Federal Register unrelated to the CSTE position paper adopted by the CDC on April 14, 2020. (Most Recent Dated 2/10/2020) **The document was filed by the CDC in acknowledgement of their organization being in review by the Office of Management and Budget for compliance with the Paperwork Reduction Act.[42]**

IHME – Zero documents resulted from the Federal Register. **This demonstrates that the wildly inaccurate Institute for Health Metrics and Evaluation (IHME) projection data, used by the COVID Task Force to influence and justify executive responses to this crisis, was done so in violation of the IQA & PRA.**

As evidenced by the 120 filings in 2020 alone, our investigation of the Federal Register confirms that the CDC was well aware of their legal obligations to file all intended changes for data collection, publishing, and analysis with the Federal Register for oversight by the OMB.

Further, our investigation of the Federal Register confirms that, while the CDC has routinely filed to be in compliance with the IQA & PRA for the vast majority of their activities, they violated the law in failing to do so for the March 24th NVSS **COVID-19 Alert No. 2** and the April 14th adoption of the CSTE Position Paper.

Additionally, according to an April 24, 2019 memorandum issued by acting director of the Office of Management and Budget, Russell T. Vought, the agency reminded all federal agencies that the OMB bears the responsibility for the enforcement of the IQA & PRA which ensure the accuracy of data by protecting the quality, objectivity, utility, and integrity of all data collected, published and analyzed by all federal agencies.[44]

Prudent decision making depends on reliable, high-quality information. Congress has long recognized

that federal agencies should make decisions using the best data reasonably available, and Congress has entrusted OMB with the statutory role of ensuring that federal agencies collect, use, and disseminate information that is fit for its intended purpose. Within OMB, the Office of Information and Regulatory Affairs (OIRA) works with agencies to maintain information quality standards.

Implementing statutory requirements in the IQA, the Guidelines provide a framework for oversight of the quality of information disseminated by the federal government throughout its lifecycle, which includes creation, collection, pre-dissemination review, transparent and reproducible use, and ultimately correction and disposition.

All federal agencies, including the CDC, are required to comply with the IQA & PRA and are required by law (IQA: Section 515 2(a) of the Consolidated Appropriations Act of 2001) to issue their own unique guidelines in order to transparently demonstrate how their agency is in compliance with the IQA and the OMB published guidelines for IQA enforcement. In order to facilitate this, the OMB Guidelines require each agency to have at least one webpage dedicated to their own unique Information Quality Statement (IQS).[36]

Despite the April 24, 2019 OMB Memorandum issued by Director Vought that gave all federal agencies 90 days to get into full compliance, the CDC has failed to publish its IQS.[41] The CDC webpage for this is filled with "404 – Page Error" links and redirects to the Health & Human Services (HHS) Information Quality Guidelines rather than their own unique guidelines, further placing them out of compliance with the express intent of Congress and the OMB/OIRA.[42]

Moreover, our research team has found that the CDC may be in violation of several additional IQA & PRA laws and the OMB guidelines established to ensure compliance.

According to the April 24, 2019 memorandum issued by the OMB Director these may include:[44][45]

- **Incompetent pre-dissemination review of information:** Fitness for Purpose and Pre-Dissemination Review the IQA requires agencies conduct pre-dissemination review of their information products. During this review, each agency should consider the appropriate level of quality for each of the products that it disseminates based on the likely use of that information.
- **Incompetent attention to standards of quality:** OMB guidelines recognize that "information quality comes at a cost," and "that some government information may need to meet higher or more specific quality standards than those that would apply to other types of government information, depending on the information's expected use."
- **Under Executive Order 12866, federal agencies that peer review complex models underlying economically significant regulations are required to obtain inter alia peer review.** The March 24th NVSS COVID-19 Alert No. 2 and the April 14th adoption of the CSTE Position Paper that shaped all data collection for COVID-19 were **not independently peer reviewed as required by this Executive Order.** [46]
- **Lack of reproducibility of influential information** - The guidelines include a "reproducibility standard" for influential information. The purpose of the reproducibility standard is to increase the credibility of federal decisions. The standard requires that influential analyses must be disseminated with sufficient descriptions of data and methods to allow them to be reproduced by qualified third parties who may want to test the sensitivity of agency analyses. This is a higher standard than simply documenting the char-

acteristics of the underlying data, which is required for all information.

We allege the CDC violated the IQA, PRA, OMB compliance guidelines, and Executive Order 12866. In doing so, the CDC has fatally compromised all **COVID-19** data and adversely impacted federal, state, and local public health policies regarding **COVID-19**. **As a result of these far-reaching and adverse impacts, the CDC as a federal agency MUST be held to the highest of standards for the assurance of flawless data quality.**

6. The Impact of Potential PRA & IQA Violations Upon the Current COVID-19 Data

Data provided for all figures is collected directly from each US Health Department through August 23, 2020. The data collected is based upon the CDC's March 24, 2020 **COVID-19 Alert No. 2** guidelines and the CDC's adoption of the CSTE's **Position Paper** on April 14, 2020.

7. COVID-19 Fatality Data Using 2003 CDC Published Guidelines

Of all the data collected at state health department levels, comorbidity data are the most statistically significant in light of the March 24, 2020 **COVID-19 Alert No. 2** guidelines published by the CDC and the revelation presented at the beginning of this historical retrospective, "For 6% of the deaths, **COVID-19** was the only cause mentioned. For deaths with conditions or causes in addition to **COVID-19**, on average, there were 2.6 additional conditions or causes per death." [1][15]

To understand the significant implications of these guidelines and how they substantially emphasized **COVID-19** as a cause of death, while simultaneously deemphasizing comorbidity (pre-existing conditions) in cause of death records, we encourage readers to review our previously published reference [18]; *If COVID Fatalities Were 90.2% Lower, How Would You Feel About Schools Reopening?*.

Despite the CDC's March 9, 2020 admission that the highest risk group of Americans would be over 60 years of age and have pre-existing conditions, only 7 state health departments are reporting comorbidity in a manner that can be statistically analyzed (New York Pennsylvania, Massachusetts, Georgia, Utah, Oklahoma, Iowa).[17]

Would the 94% of fatalities with at least 1 comorbidity have been counted as COVID-19 fatalities if the CDC had used the guidelines for reporting that the nation has been using for 17 years instead of the COVID-19 guidelines issued on March 24, 2020?

To properly answer this question, it is necessary to compare the unproven March 24 **COVID-19 Alert No. 2** cause of death reporting guidelines against the *2003 CDC Medical Examiner's and Coroner's Handbook on Death Registration* that has been the proven national standard for 17 years without incident.

March 24th, 2020 – NVSS COVID-19 Alert No. 2 [15]

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** 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. 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)

Recall from the historical timeline presented earlier that the CDC understood the high-risk demographic would be over 60 years of age with comorbidities.[18] Emphasizing that **COVID-19** be specifically placed in part 1 of the death certificate while any comorbidities be listed in part 2 is genuinely concerning.

Changing reporting rules exclusively for **COVID-19** cause of death reporting without notifying the Federal Register, OMB, OIRA, or the public, and therefore potentially breaching the PRA & IQA, is even more concerning.

It's worth noting that Part I of a death certificate is the immediate cause of death listed in sequential order from the official cause on line item (a) to the underlying causes that contributed to death in descending order of importance on line item (d), while Part II is/are the significant conditions NOT relating to the underlying cause(s) in Part I.

Comorbid conditions have been listed on Part I of death certificates as causes of death per the CDC Handbook since 2003 to ensure accurate reporting can be developed. Comorbidities are seldom placed in Part II. Part II is typically the section where coroners and medical examiners can list recent infections as underlying, initiating factors.

Prior to the CDC's March 24th decision, any comorbidities would have been listed in Part I rather than Part II and initiating factors such as infections including the **SARS-COV-2** virus, would have been listed on the last line in Part I or more commonly in Part II.

The 2003 CDC Medical Examiner's and Coroner's Handbook on Death Registration [7][8]:

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."

The principal responsibility of the medical examiner or coroner in death registration is to complete the medical part of the death certificate. 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 [**SARS-COV-2** in this case] 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.

Under these 2003 guidelines, the highest **COVID-19** could be listed in the presence of an established comorbidity would be on the lowest used line at the bottom of Part I as an initiating factor or, more correctly, in Part II as an infection that contributed to death.

However, on March 24, 2020 the CDC elected to forgo this trusted method of cause of death recording in favor of recording comorbidities in Part 2, so **COVID-19** could be listed exclusively in Part 1.

This has had a significant impact on data collection accuracy and integrity. It has resulted in the potential false inflation of **COVID-19** fatality data and is a potential breach of federal laws governing information quality.

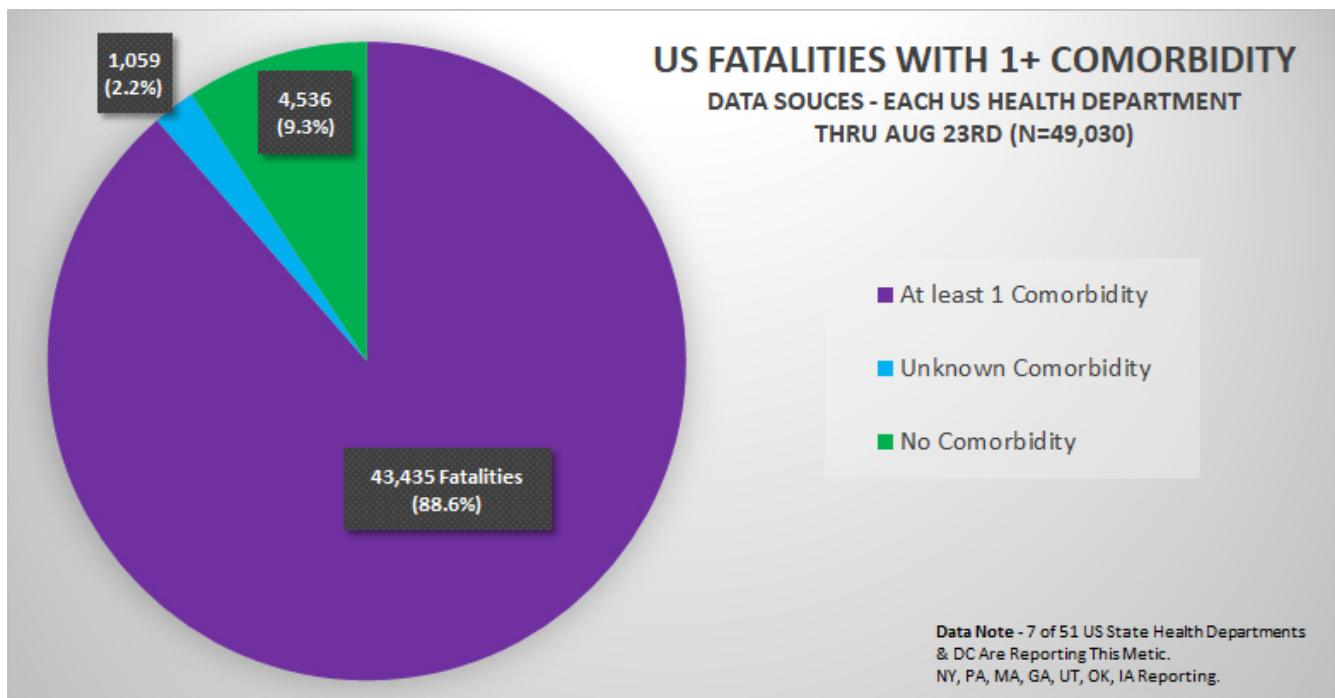


Figure 8. US Fatalities With At Least 1 Comorbidity. Note: 88.6% of fatalities had at least 1 comorbidity, which is below the more official 94% reported by the CDC on Aug 22, 2020.[30][State & Territory Health Departments]

8. Implications for Public Health Policy

As a result of state policies based on potentially compromised data published and promoted by the CDC, Americans have lost jobs and businesses in historically unprecedented numbers.

At the peak of the crisis, an estimated 20.5 to 42 million Americans had lost their jobs without having any voice in the decision-making process due to shelter in place mandates issued by every state with the exceptions of Arkansas, Iowa, Nebraska, South Dakota, Utah & Wyoming.[30][31]

Anxiety, depression, suicide rates, domestic violence, and alcoholism have all reportedly risen significantly due to the economic hardships brought on by how state governors decided to exercise their authority in response to the potentially compromised data published by the CDC.[32]

Tens of thousands of Americans have died without access to potentially life-saving medications like hydroxychloroquine or nutrient therapies like intravenous Vitamin C. Couple this with the tragic reality that so many Americans

passed away alone, without the comfort of their family members, and the collateral damage of our one-size fits all policies becomes even more unpalatable.[47]

All non-COVID related healthcare priorities have also suffered including elective surgeries, proper monitoring of medications, and checkups for the elderly and our children. De-prioritizing all non-COVID cases created collateral damage that far outweighs the infective damage of the **SARS-COV-2** virus. Public health policies that create more collateral damage while attempting to avoid an infection with a 99.05% rate of recovery in the vast majority of citizens must be objectively investigated and critically questioned if the goal of living in a healthy society is to be realized.

9. Conclusions

Arguing over what the most accurate COVID fatality count may be is an exercise in futility without intimate knowledge of case history and accompanying certificates of death, and it is the exact reason we entrust these determinations to the skill of our

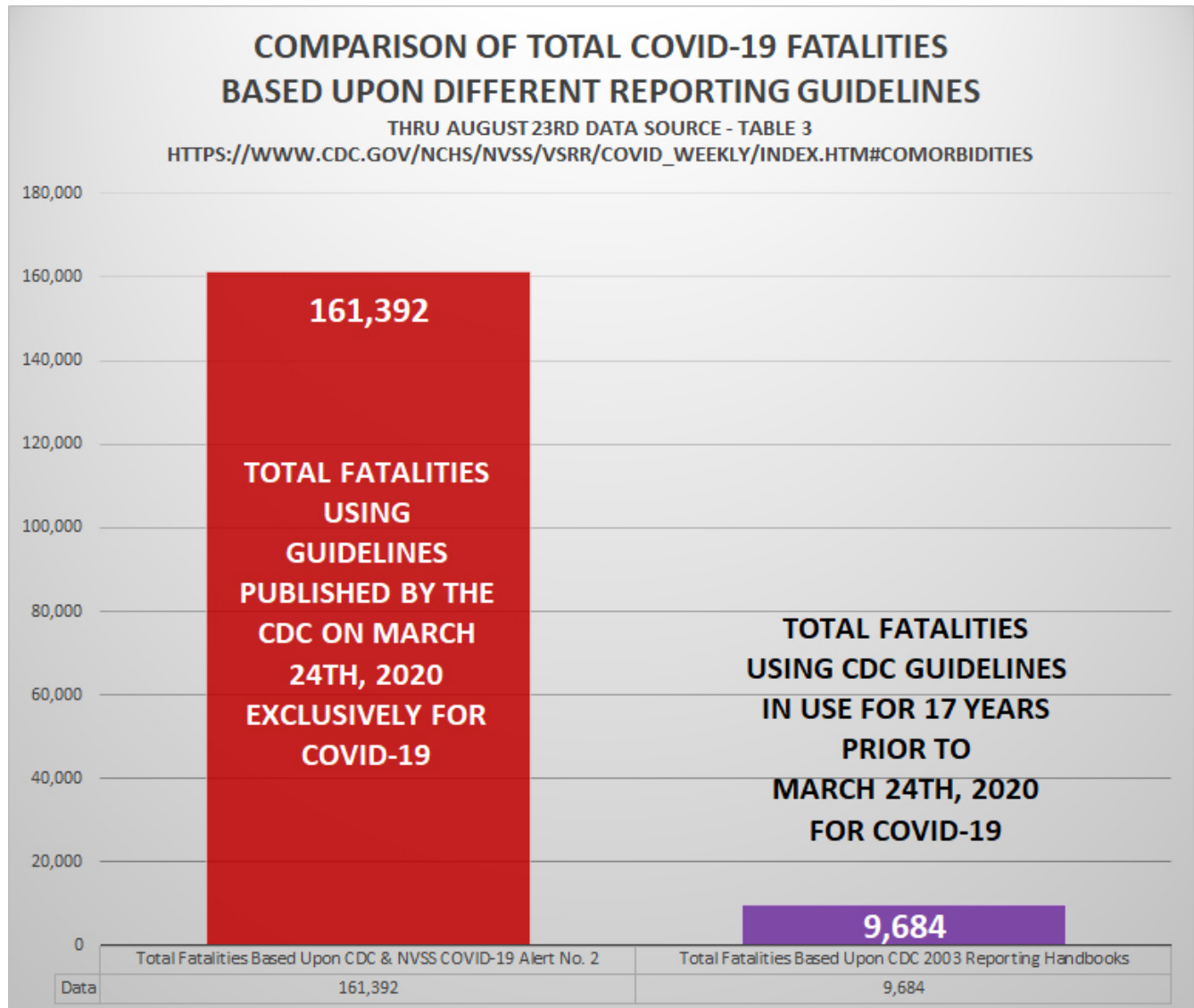


Figure 9. COVID-19 Using the March 24 Exclusive Guidelines vs Using the 2003 Guidelines. Had the CDC used the 2003 guidelines, the total **COVID-19** be approximately 16.7 times lower than is currently being reported. [1][30][State & Territory Health Departments]

licensed professionals. With the inclusion of probable fatalities and significant changes made to how certificates of death are recorded exclusively for COVID-19, scientific objectivity demands that we acknowledge the data presented is inaccurate.

Federal agencies have a legal obligation to provide the most accurate data to the public, fellow agencies, and policy makers they are advising, and they have a responsibility to abide by every federal law. This responsibility to collect, analyze, and publish data accurately, transparently, and with unquestionable integrity increases exponentially during a national crisis.

It is concerning that the CDC may have willfully failed to collect, analyze, and publish accurate data used by elected officials to develop public health policy for a nation in crisis.

Further federal investigation is justified by the magnitude of the crisis and the collateral damage generated by policies based upon projection data that was unproven and never peer reviewed. If the data being reported was indeed compromised by the CDC's perplexing decision to abandon proven data collection and reporting practices in favor of untested methods, then all public health policies based upon these inaccurate data must be reexamined.

10. Author Statements

All authors have contributed and are in full agreement with the facts and positions presented in this publication. None have declared any conflicts of interest.

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- ∅. [Arkansas **COVID-19** Data and Surveillance Dashboard: [HERE](#)
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[66] Louisiana Department of Health: [HERE](#)

[67] Massachusetts Department of Public Health COVID-19 Dashboard -Dashboard of Public Health Indicators: [HERE](#)

[68] Maryland Department of Health: [HERE](#)

[69] Maine Center for Disease Control & Prevention: [HERE](#)

[70] Michigan Coronavirus Data: [HERE](#)

[71] Minnesota Department of Health: [HERE](#)

[72] Missouri COVID-19 Dashboard: [HERE](#)

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[74] Montana Response: COVID-19 - Coronavirus - Global, National, and State Information Resources: [HERE](#)

[75] North Carolina NCDHHS COVID-19 Re-sponse: [HERE](#)

[76] Coronavirus COVID-19 Nebraska Cases [HERE](#)

[77] New Hampshire Department of Health & Human Services: [HERE](#)

[78] New Jersey COVID-19 information Hub: [HERE](#)

[79] New Mexico Department of Health: [HERE](#)

[80] State of Nevada Department of Health & Human Services, Office of Analytics: [HERE](#)

[81] New York Department of Health, NYSDOH COVID-19 Tracker: [HERE](#)

[82] New York City Coronavirus Data [HERE](#)

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