COVID-19: Restoring Public Trust During A Global Health Crisis

An Evidence-Based Position Paper to Ensure Ethical Conduct

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‘This Is Not Okay’ – A COVID Story

”About 10 months ago, the fear of God was put in my 80-year-old mother’s mind.

She was babysitting for my brother and had a routine doctor’s visit during which she was told that she needs to stop the babysitting immediately. ’I don’t think you understand. If you get this virus, you die,’ said her doctor. My mother called me crying and I was so disheartened and angry.

My parents immediately removed themselves from our lives, stopped regular visits, and have since done only outdoor visits from a distance over the last 10 months. My oldest brother in Brooklyn told me back in March 2020, ’I’ll see you in 2021!!’ My kids were baffled, and all of us were devastated that he told us he’d see us 9 months from now. It seemed so far away and yet he stood by his word!

My entire family has been separated for 10 months...no 80th birthday celebration for my mother, no Hanukkah family meals, dozens of missed grandkids birthdays, graduations...everything!!

I’ve sent my mom literature about protecting herself by supporting her immune system and about the stats suggesting a very high success rate for surviving COVID and thought she might be listening.

So, when my 11-year-old daughter whispered in my ear, ’Mom do you think it would be okay if I put a mask on and sanitize my hands and ask grandma if I could give her a hug at the waist?’ I told her, ’Yes, ask her.’

Worried about the reply, she asked me to do it.

So, standing in my mother’s garage in the freezing cold for our visit, and still standing 6 feet away, I asked my mom, ’Elliana wants to know whether or not she can hug you at the waist with a mask on and sanitized hands?’

My mother replied, ’Elliana, I’m so sorry maybe this thing will be done by March when it’s your birthday.’ My daughter turned away devastated, but always a pleaser, she didn’t want my mom to see how upset she truly was. She buried her head in my armpit to hide her face and leaned into me.

I think we were both so shocked, and as my mom tried to talk to her in a lighthearted manner to make it better, my daughter was quickly overwhelmed with emotion, devastated by the rejection of her request to hug her grandmother.

In that moment, it became crystal clear that what is going on is not okay.

My daughter was speechless, and while she was trying not to hurt her grandma’s feelings, she also could not bring herself to tell her grandma that, ‘it’s ok.’

Never in my life have I witnessed a child being turned away by a loving, selfless grandmother who lives for her grandchildren. This was THE moment that it became even more apparent all the pain and hurt that this ’pandemic’ has truly inflicted upon us all.”

Letter from the Authors

During our investigation into the variety of topics this manuscript covers, a theme began to stand out as a consistent concern. Safe & effective treatments are inexplicably being withheld.

As you read this position paper you will encounter many similar examples of what appear to be willful misconduct on the part of government agencies supplying inaccurate information to elected officials and the public.

While incessant arguments persist regarding the accuracy of polymerase chain reaction (PCR) testing, asymptomatic transmission, dubious projection models, and changes in the law. The issue that is still inexplicably unresolved is the withholding of safe and effective treatments from millions of people most in need.

The sad reality is that loved ones are still dying alone. Children are still being isolated from their in-person classrooms and dear friends. Experimental COVID biologics (vaccine) are being tested on millions of individuals without any long-term data to feel confident about safety. All the while, significant nutrient deficiencies that adversely impact the natural adaptive immune response (vitamins A, C, D, E and the mineral zinc) have yet to be resolved.

Imagine how many lives could have been, and still could be saved, if public health departments widely promoted the use of evidence-based nutritional therapies. Yet, these evidence-based treatments (also effective at prevention) continue to be ignored by major health organizations (CDC, WHO, NIH, et, all) in spite of their extraordinary financial feasibility.

We ask, *"Is it ethical to withhold evidence-based treatments, proven to be safe and effective, from people in need?"*

Historically, this questioned has been answered with a resounding "No."

Yet this is where we find ourselves again. Once more embroiled in an age-old struggle to an ethical question we've already repeatedly answered correctly. **A common ground we must all be able to reach is that it is unethical to withhold evidence-based treatments, proven to be safe and effective, from people in need.**

When we fail to remember our history, inevitably our history repeats itself. To ensure that life, liberty, and the pursuit of happiness are preserved for future generations, people must be presented with accurate scientific data and evidence-based options to make their own informed decisions with regard to their health.

Ethically, no one should be vaccinated with experimental biologics while those biologics are still in clinical trial, especially when safer and more effective treatments already exist.

Perhaps the question that matters most is, *"Does a government, employer, airline, or school have the right to mandate the use of an experimental product that is still in an ongoing clinical trial?"*

When living in a free and collective society, this may be the most important question to answer.

We believe that governments, employers, airlines, and schools do not have the right to mandate the use of products still in clinical trial. This position paper substantiates our point of view with respect to medical ethics, civil liberties, and individual body sovereignty. Our findings do call into question a great many of the scientific and ethical problems surrounding the COVID-19 global crisis response and raises questions of willful misconduct.

Thank you for considering our findings objectively.

Acknowledgements

People Worthy of Our Remembrance

Throughout this position paper, at the end of each topic, you will see our heartfelt attempt to honor people that have been lost during this crisis. We acknowledge the potential sensitivity of adding this to a science-driven position paper. Please allow us to share our intention for your consideration.

We are all on edge as we get bombarded with numbers, numbers, and more numbers. It is our position that the constant promotion of cases, hospitalizations, and deaths has promoted a loss of humanity. By acknowledging individuals who have passed away, we recognize that humans are not just numbers and statistics.

Throughout this unprecedented time, the fact that we all still have feelings has not changed, and many of us are hurting for a variety of completely valid reasons. Much of the suffering we have endured could have been prevented had obvious solutions not been ignored and openly attacked by the FDA and mainstream media. As human beings, we are more than an aggregate of mathematical calculations.

The inspiration for this section was a realization that weighs heavily on the hearts of all good people, *"Why are we only talking about numbers? Why are we not talking about the people that make up those numbers?"*

To the family members of the people we are honoring, we sincerely hope our position paper respectfully voices the love you have for your departed. By using your published quotes, the story of your loved ones can be heard in your words. As tears stream down my face, I say to you on behalf of my team and my family, we feel your pain…we have lost loved ones too. I very much want to give each of you a hug, so I hope my words reach your heart in the spirit they are composed. We are fighting to make this right. We hope that in doing so, we are honoring your loved ones. – Dr. Henry Lee Ealy

The Intention of Our Position Paper

The intention of our position paper is to honor our departed and everyone who has sacrificed so much that we might live free. In our opinion, discriminate censorship of genuine attempts to help is a major problem, as has been the case with the repeated suppression of effective treatments for COVID-19.

Censorship of science at any time is a direct attack upon everything we hold dear. It is a direct insult to the sacrifices made throughout this crisis by billions of well-intentioned people whose lives are forever changed. This is why we are calling for a special grand jury investigation and formal congressional hearing into the alleged willful misconduct that led to violations of federal law, medical ethics, and our Constitutional Rights.

Detailed evidence matters. This position paper is our effort to provide that detailed evidence for your consideration. Difficult conversations remain, and difficult conversations require the most accurate information available.

Executive Summary – Asymptomatic Transmission

- The theory of asymptomatic transmission as a driver of infective spread and fatalities is overstated at best and fatally flawed at worst.
- **Wuhan Participant Study** - 9,898,828 enrolled participants were tested using qualitative COVID RT-qPCR testing. Only 300 possible asymptomatic carrier candidates were identified. Of the 300 possible asymptomatic carriers, all were tested using live cell culture to determine if their PCR samples could produce replication-competent virus. All 300 live cell cultures were negative for being able to produce replication-competent virus, indicating that none of the 300 people identified as potential asymptomatic carriers from the 9,898,828 people tested were infectious. Therefore 0.00% of COVID transmissions were asymptomatic.
- **U.S. Projection Study** -Zero participants were enrolled, yet the study was still sanctioned by the CDC. This published manuscript is a mathematical projection model estimating the percentage of people that tested positive and were presumed asymptomatic based a number of dubious assumptions. It asserts that 59% of COVID transmissions in the United States were asymptomatic.

COMPARISON OF STUDIES REGARDING ASYMPTOMATIC TRANSMISSION

Category	Wuhan Study	US Study
Location	Wuhan, China	None
Publishing Journal	Nature	JAMA
Publishing Date	11/20/2020	1/7/2021
Peer-Reviewed	Yes	No
Enrolled Participants	9,898,828	0
Methods	PCR, Antibody, Viral Culture	Math Assumptions Only
Suspected Asymptomatic Carriers	300 Total	NA
Actual Asymptomatic Carriers	29 Possible	NA
Asymptomatic Contacts	1,174	None
Asymptomatic Contacts Infected	0	NA
Asymptomatics w/ Replication Competent Virus	0	NA
% Asymptomatic Carriers	0.00029%	Not Stated
% Asymptomatic Transmitters	0.00000%	59%

Wuhan Study - https://www.nature.com/articles/s41467-020-19802-w

US Study - https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774707

- The theory of asymptomatic transmission is yet to be definitively proven. There are 5 gold-standards of medical investigation: (1) Confirmed absence of clinical symptoms; (2) Confirmed serologic presence of viral antigen load; (3) Confirmed serologic absence of IgM & IgG antibodies; (4) Confirmed ability of nasal sample to produce replication-competent virus in live human cell culture; and (5) Confirmed infective spread to a susceptible host. For a person to be infectious, including persons assumed to be asymptomatic without definitive laboratory evidence, their nasal or serologic sample must be able to produce replication-competent virus in a live human cell culture.
- Until evidence exists regarding replication-competent virus in human cell cultures, the theory of asymptomatic transmission should not be used as a basis for public health policies for otherwise healthy individuals.

Executive Summary – PCR Testing

- RT-qPCR tests are quantitative tests. However, it appears PCR testing is intentionally being used qualitatively. To use a test not calibrated to be used diagnostically, as the primary diagnostic tool is a poor decision and brings forward questions of willful misconduct.
- Current Qualitative COVID RT-PCR testing is not calibrated to be used diagnostically. Yet, according to a meta-analysis by Jefferson, attempts to calibrate it to determine infectiousness are being made.

PROPOSAL FOR CALIBRATING COVID RT-qPCR TESTING BASED UPON VIRAL REPLICATION-COMPETENCE

DIAGNOSTIC INTERPRETATION	CYCLE THRESHOLD	PROPOSED ACTION
Infectious	< 25.00	Quarantine/Isolation Until No Longer Symptomatic + 2 Days. Administration Of Evidence-Based Nutritional Guidance. Retest Serologic Antibodies To Confirm (+ IgG, - IgM).
Possibly Infectious	25.00 - 33.99	Confirmatory Lab Testing. Serologic Antigen Or Live Human Cell Culture. Quanantine/Isolation Until Confirmed. Administration Of Evidenced-Based Nutritional Guidance As Precaution.
Not Infectious	≥ 34.00	Recommendation Of Evidence-Based Nutritional Guidance As Precaustion.

Oxford Academic (Jefferson) - https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1764/6018217
NEMJ Hospital Study - https://www.nejm.org/doi/full/10.1056/NEJMc2027040
Caco-2 Cell Human Cell Line Infectiveness - https://pubmed.ncbi.nlm.nih.gov/32966582/
VERO Monkey, HUH7.0 Human, 293T Human Cell Line Infectiveness - https://wwwnc.cdc.gov/eid/article/26/6/20-0516_article

- According to CDC, current testing continues to detect traces of past SARS-CoV-2 infections for as many as 12 weeks after the end of the infectious period.
- According to PhD Molecular Geneticist Dr. Pieter Borger and former Pfizer Chief Scientist Dr. Michael Yeadon, there are 10 major problems with the current version of qualitative COVID RT-PCR testing. They stated this ***"renders the SARS-CoV-2 PCR test useless"*** because of the increased likelihood of false positive results and the inability to determine infectiousness.
- Current Qualitative COVID RT-PCR testing, "***cannot discriminate between the whole virus and viral fragments. Therefore, the test cannot be used as a diagnostic for intact (infectious) viruses, making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus and make inferences about the presence of an infection."***
- Current Qualitative COVID RT-PCR testing cannot determine an infectious individual compared to a non-infectious individual. Therefore, the current testing invalidates all studies that have used it as the sole diagnostic laboratory method of evaluation. This includes the Pfizer/BioNTech Phase 2/3 experimental biologic clinical trials.
- Doctors and nurses working on the front line deserve to have the most accurate diagnostic tools to determine a definitive diagnosis and help mitigate the spread of the infection. Before consenting, people deserve to know the limitations of PCR testing.
- Clinical trials for experimental COVID biologics (vaccines) should be required to use accurate diagnostic tools ensuring that the safety and efficacy of the biologic can be assessed. The use of a single test that is not calibrated to be used diagnostically opens the door for inaccurate data collection and analysis. A formal legal petition by Dr. Sang Hi Lee on November 25, 2020 explained this issue to the FDA, but the FDA dismissed his concerns as lacking "scientific merit," despite Dr. Lee's obvious credentials as an expert in the field.

Executive Summary – Effective Treatments

- ***"Science is being suppressed for political and financial gain. Covid-19 has unleashed state corruption on a grand scale, and it is harmful to public health…When good science is suppressed by the medical-political complex, people die."*** - Kamran Abbasi, executive editor of the British Medical Journal https://www.bmj.com/content/371/bmj.m4425

- The overwhelming evidence obtained through the analysis of federally funded and published NHANES data indicates that a significant percentage of the U.S. population is clinically deficient in essential micronutrients, vitamins A, C, D, E, and zinc. NHANES data should not be ignored and excluded from clinical application during a national health crisis.

NHANES NUTRITIONAL ANALYSIS STUDIES - SUMMARY

Nutrient	RDA/EAR/ODI	Adults 2005-2016	Nutritional Deficit For Minimum Requirements	% US Population Deficient*
Vitamin A	2,333-3,000 IU	2,130 IU	870 IU	35-45%
Vitamin C	75-200 mg	83 mg	117 mg	37-46%
Vitamin D	600-800 IU	188 IU	612 IU	65-95%
Vitamin E	22-200 IU	13 IU	187 IU	60-84%
Zinc	8-30 mg	12 mg	18 mg	11-15%

Data Source - NVSS Published By CDC - https://www.cdc.gov/nchs/nhanes/index.htm

*Low End Of Range Adjusted For Supplemental Nutrient Intake Plus Dietary Intake - Reider, C. A., Chung, R. Y., Devarshi, P. P., Grant, R. W., & Hazels Mitmesser, S. (2020). Inadequacy of Immune Health Nutrients: Intakes in US Adults, the 2005-2016 NHANES. Nutrients, 12(6), 1735. doi:10.3390/nu12061735

- An overwhelming body of evidence-based studies exist to support the use of foundational nutritional guidelines that drastically reduce hospital burden and disease severity while enhancing and expediting recovery from COVID-19.

- One study used vitamin A (100,000 IU/day), vitamin C (1,000mg/hour during waking), vitamin D (50,000 IU/day), and Lugol's Iodine (25mg). **107 out of 107 patients fully recovered within 7 days of treatment.**

- A Chinese hospital treated 50 cases of moderate to severe COVID-19 infection with intravenous ascorbic acid (IVAA). The dose strategy was 100% effective at successful management of cytokine storms. There were no side effects reported from any patients in the IVAA group. Although COVID-19 patients had a 30-day hospital stay on average, COVID-19 patients who received IVAA had a hospital stay that was 3 to 5 days shorter compared to the non IVAA treated patients. **All 50 patients who received IVAA recovered, and no mortality was reported in the IVAA group.**

- Vitamin D3 has been shown to significantly reduce ICU admission rates as well as reduced the severity COVID-19 disease. Of the 50 total patients who received vitamin D3, 1 was admitted to the ICU (2%). Of the 26 patients who were not administered vitamin D3, 13 were admitted to the ICU (50%). **Of the 50 patients treated with vitamin D3, 0 deaths occurred, and all 50 patients were discharged without complications.**

- Vitamin D deficiency was associated with increased hospitalizations (OR = 1.81, 95% CI = 1.41–2.21), and increased mortality (OR = 1.82, 95% CI = 1.06–2.58). Individuals with severe cases of COVID-19 were 64% more likely to be vitamin D deficient than those with mild cases of COVID-19 (OR = 1.64; 95% CI = 1.30–2.09). Among critically ill populations, **vitamin D deficiency is associated with higher infection rates, increased incidence of sepsis, and increased mortality risk.**

- In another study, 57% of COVID-19 patients were zinc deficient. These patients had ***"higher rates of complications (p = 0.009), acute respiratory distress syndrome (18.5% vs 0%, p = 0.06), corticosteroid therapy (p = 0.02), prolonged hospital stay (p = 0.05), and increased mortality (18.5% vs 0%, p = 0.06)."***

- Ivermectin - ***"Viral clearance was treatment dose- and duration-dependent. In six randomized trials of moderate or severe infection, there was a 75% reduction in mortality (Relative Risk=0.25 [95%CI 0.12-0.52]; p=0.0002); 14/650 (2.1%) deaths on ivermectin; 57/597 (9.5%) deaths in controls) with favorable clinical recovery and reduced hospitalization."***

- **Hydroxychloroquine (HCQ)**– A meta-analysis of 192 studies concluded that HCQ is effective when used early. Early treatment is most successful, with 100% of studies reporting a positive effect and an estimated reduction of 67% in the effect measured (e.g., death, hospitalization, etc.) using a random effects meta-analysis (RR 0.33 [0.25-0.43]).

- The inclusion of evidence-based nutritional research must become an integral component of modern medical practice. **Effective natural & pharmaceutical treatments for COVID-19 exist and have been withheld from people in need throughout this crisis, which raises the question of willful misconduct.**

Our Proposal for Safe & Effective Nutritional Guidance

Seniors, Adults, & Teens

KEY NUTRIENTS	THERAPEUTIC RANGE	RDA
VITAMIN A (Beta-Carotene)	5,000 IU	1,500-2,167 IU
VITAMIN C	3000-5000 mg	65-125 mg
VITAMIN D3	10,000 IU (14-Days) 5,000 IU (After)	600-800 IU
VITAMIN E	200-600 IU	22-28 IU
ZINC	25-40 mg (min 30mg for High-Risk)	8-11 mg

Children Ages 5 to 12

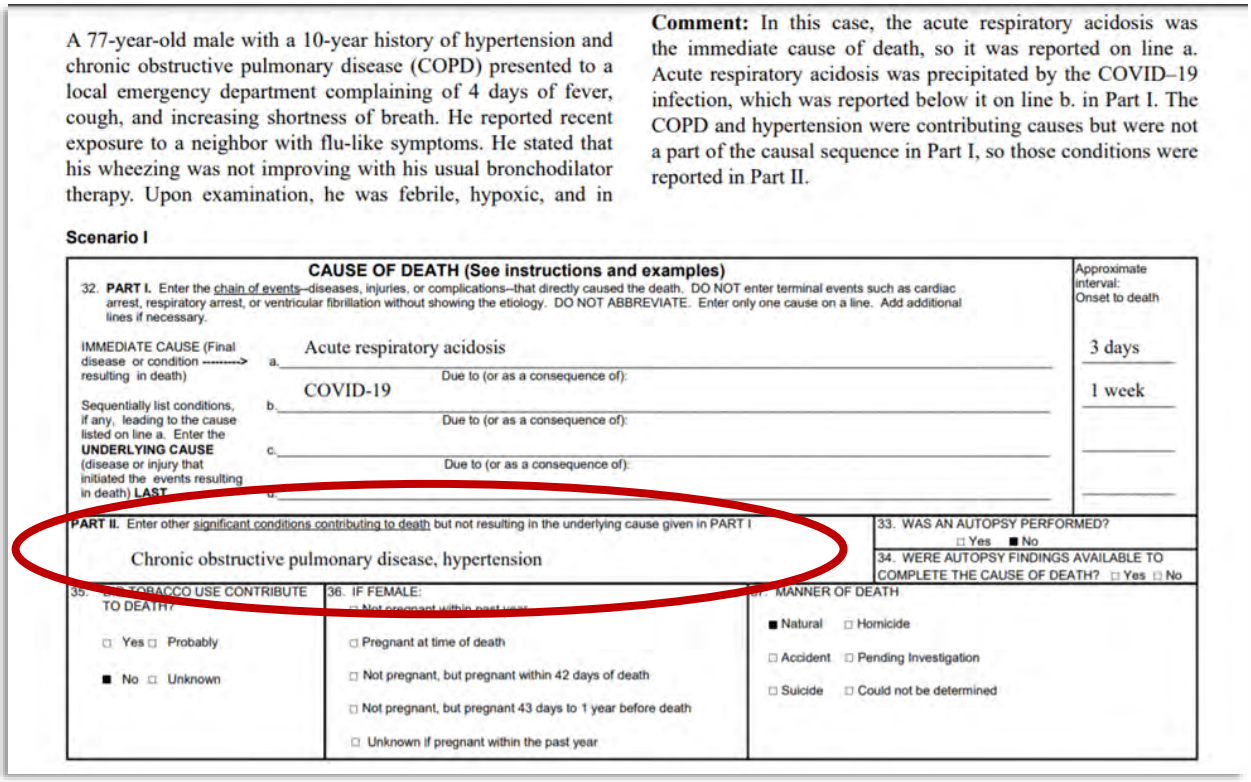
KEY NUTRIENTS	THERAPEUTIC RANGE	RDA
VITAMIN A (Beta-Carotene)	5,000 IU	1,000-2,000 IU
VITAMIN C	2,000-4,000 mg	25-45 mg
VITAMIN D3	5,000 IU (14-Days) 2,000 IU (After)	200 IU
VITAMIN E	100 IU	10-17 IU
ZINC	25 mg	8 mg

Children Aged 1 to 4

KEY NUTRIENTS	THERAPEUTIC RANGE	RDA
VITAMIN A (Beta-Carotene)	2,000 IU	1,000-1,500 IU
VITAMIN C	500-1,000 mg	15-50 mg
VITAMIN D3	1,000-2,000 IU	200 IU
VITAMIN E	50 IU	6-9 IU
ZINC	10 mg	3 mg

Executive Summary – Violations of Federal Law

- Accurate and verifiable data is essential to public health policy development.
- Data quality was irreparably compromised by the CDC's implementation of the NVSS COVID Alert No.2 document on March 24, 2020, **which significantly altered death certificate reporting**, as well as the CDC's adoption of the Council of State and Territorial Epidemiologist's position paper on April 15, 2020 **that defined the criteria for COVID cases without ensuring the same person could not be counted multiple times.** Both practices have significantly affected data aggregation and interpretation, and both adoptions were in violation of the Administrative Procedures Act, the Paperwork Reduction Act, and the Information Quality Act at minimum.
- For the previous 17 years, pre-existing/comorbid conditions were reported in Part I, not Part II, of death certificates. By reporting in Part II rather than Part I, the role of comorbidities as cause of death has been deemphasized. This change impacts statistical aggregation according to Certified Death Reporting Clerks we interviewed. The point of contention with the 2020 change is that it was made without official notification in the Federal Register to initiate federal oversight and invite mandatory public comment.
- 77-Year-Old Male Death Certificate For COVID-19 Based Upon March 24, 2020 COVID Alert No. 2.



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

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)

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.

Approximate interval: Onset to death

IMMEDIATE CAUSE (Final disease or condition ---------> resulting in death)
a. Acute respiratory acidosis — 3 days
Due to (or as a consequence of):
b. COVID-19 — 1 week
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**
c. —
Due to (or as a consequence of):
d. —

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

Chronic obstructive pulmonary disease, hypertension

33. WAS AN AUTOPSY PERFORMED? ☐ Yes ■ No

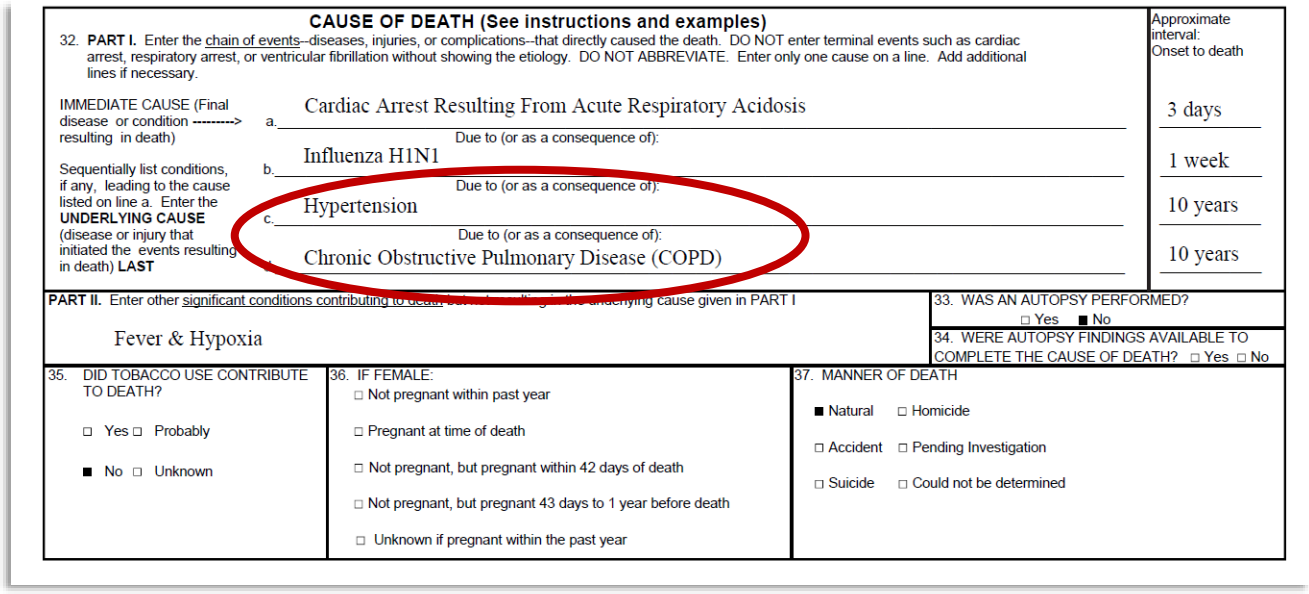
34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? ☐ Yes ☐ No

35. DID TOBACCO USE CONTRIBUTE TO DEATH?
☐ Yes ☐ Probably
■ No ☐ Unknown

36. IF FEMALE:
☐ Not pregnant within past year
☐ Pregnant at time of death
☐ Not pregnant, but pregnant within 42 days of death
☐ Not pregnant, but pregnant 43 days to 1 year before death
☐ Unknown if pregnant within the past year

37. MANNER OF DEATH
■ Natural ☐ Homicide
☐ Accident ☐ Pending Investigation
☐ Suicide ☐ Could not be determined

- Same 77-Year-Old Male Death Certificate for H1N1 Flu Based Upon CDC Handbooks Used For 17 Years.



CAUSE OF DEATH (See instructions and examples)

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.

Approximate interval: Onset to death

IMMEDIATE CAUSE (Final disease or condition ---------> resulting in death)
a. Cardiac Arrest Resulting From Acute Respiratory Acidosis — 3 days

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. Influenza H1N1 — 1 week

Due to (or as a consequence of):
c. Hypertension — 10 years

Due to (or as a consequence of):
d. Chronic Obstructive Pulmonary Disease (COPD) — 10 years

PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I
Fever & Hypoxia

33. WAS AN AUTOPSY PERFORMED? ☐ Yes ■ No

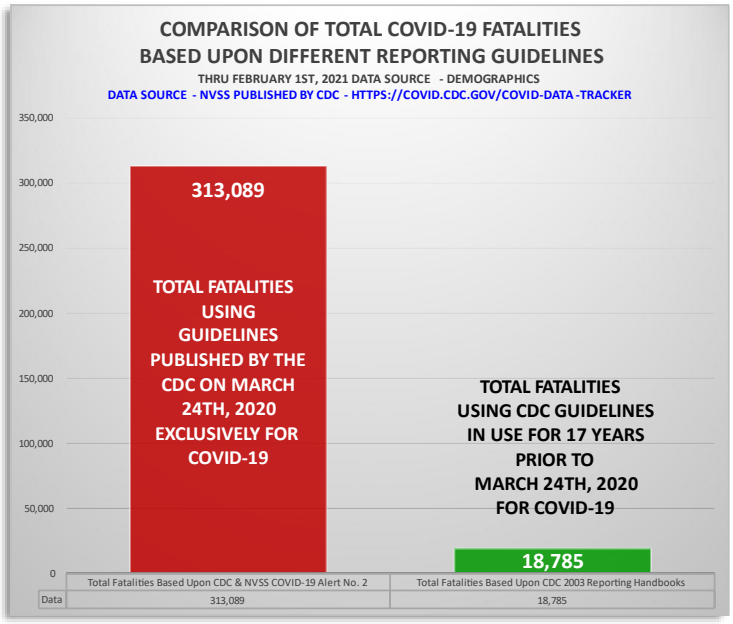
34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? ☐ Yes ☐ No

35. DID TOBACCO USE CONTRIBUTE TO DEATH?
☐ Yes ☐ Probably
■ No ☐ Unknown

36. IF FEMALE:
☐ Not pregnant within past year
☐ Pregnant at time of death
☐ Not pregnant, but pregnant within 42 days of death
☐ Not pregnant, but pregnant 43 days to 1 year before death
☐ Unknown if pregnant within the past year

37. MANNER OF DEATH
■ Natural ☐ Homicide
☐ Accident ☐ Pending Investigation
☐ Suicide ☐ Could not be determined

- It makes logical sense to openly advocate for an independent expert panel of medical examiners, coroners, and physicians with death reporting experience to audit all death certificates associated with COVID-19.
- Each fatality with a confirmed PCR test must have a record at the conducting lab of the date of the test and the cycle threshold (Ct) value that determined the positive lab result. If we were able to have the date of the death certificate, the date of the positive PCR, the Ct value at which a signal was detected on the individual's PCR, and a basic knowledge of pre-existing/comorbid conditions from medical records, the death count could be corrected for a better understanding of the number of people that died from COVID, how many died with COVID, and how many died but were miscategorized as COVID fatalities**.**
- **The correction of death counts is anticipated to be significant but may be a large as the graphic below:**



Executive Summary – Projection Models

- ***"The death rate is a fact; anything beyond this is an inference."*** – Dr. William Farr
    - Unfortunately, with respect to COVID-19 and the NVSS COVID Alert No. 2 document issued on March 24, 2020, this brilliant observation is no longer applicable.
- From the start, computer projection models were widely adopted as a mean to manage the COVID-19 health emergency. People around the world were concerned about the harm associated with COVID-19 long before it was possible to know any of the potential repercussions of the virus.
- All computer projection models make assumptions and require inputs. Understanding these aspects of the model is crucial to understanding model outputs. Unfortunately, vast uncertainty surrounds most inputs, especially at the start of a public health crisis.
- One assumption, central to all current COVID-19 models, is that the spread of germs is the main factor in disease transmission, even though susceptibility to infection is the main factor. Many models assume everyone is equally susceptible. Susceptibility depends on variables such as available nutrient status, pre-existing conditions, age, genetic predispositions, socioeconomics, individual mental outlook, stress exposure, restorative sleep, bioaccumulation of chemical pollution, environmental exposure, place of residence, and multiple other factors unique to the individual.
- Many COVID-19 projection models presume the frequency of asymptomatic transmission. The underlying assumption is that such infection *is possible.* This assumption, though widespread, is contradicted by the extensive study of nearly 10 million people carried out in Wuhan, China.
- A 2018 modeling study noted, ***"In practice, incorporating asymptomatic carriers into models is challenging due to the sparsity of direct evidence."***
- Stochastic models, such as the IHME model, must manipulate data to obtain useful inputs. This may involve using means, using medians as proxies, using moving averages, imputing values to fill in missing data, dropping numbers that seem too large, and using Gaussian regression to smooth the resulting smorgasbord of adjustments. Each input becomes its own model within a model.
- One of the early attractions of the IHME model was its "ability" to forecast hospital demand. For New York State, as of April 4, 2020, the IHME model projected a need for 65,400 hospital beds. 15,905 beds were actually used, and new hospitalizations continued to decline. For that same date, the IHME model projected a need for 12,000 ICU beds but only 4,100 were used.
- Another attraction of the early IHME model was that its projected numbers in narrower bands than rival models, suggesting its estimations were more precise. Considering data is so scarce and unreliable at the start of an epidemic, narrow estimation bands cannot be legitimate and should be assumed to misrepresent the accuracy of the projections.
- In general, there is no way for officials to evaluate how exactly a disease projection model's inputs and assumptions affect its output. Nor is there a practical way for officials to verify that a model's code and data are secure, or that the model works as advertised. Officials choose to rely on a model, *not* because of the accuracy of the model, but for reasons that are often undisclosed.

- **The Imperial College COVID Model caused international panic by using a model that predicted a vast number of deaths from COVID-19.** When the models' programming was finally made public, it was learned by an independent investigation that the Ferguson team had cleaned up their code with the assistance of Microsoft. This raises additional questions of the presence of willful misconduct.

- Insurance companies might be a better choice than academic institutions to develop projection models. ***"Insurers employ modelers and data scientists, but also employ managers whose job is to decide whether a model is accurate enough for real world usage and professional software engineers to ensure model software is properly tested, understandable and so on. Academic efforts don't have these people, and the results speak for themselves."***

- Early diagnostic models were as inaccurate as early projection models. In the beginning of April 2020, just a few months after the first cases of COVID-19 appeared in the United States, over 4900 studies analyzing diagnostic models had already been conducted and published. A meta-analysis concluded, ***"…proposed [diagnostic] models are poorly reported, at high risk of bias, and their reported performance is probably optimistic. Hence, we do not recommend any of these reported prediction models for use in current practice."***

- Regardless of how impressive the model is, or how well it fits the past, the future is always unpredictable.

Executive Summary – Violations of Medical Ethics

- For more than 2,000 years the first fundamental law governing the safe and effective practice of medicine has been exceedingly clear… 'Do No Harm'. It is a powerful statement that establishes the primary responsibility each practitioner has with respect to their patients and forms the foundation for the key concepts shaping virtually all ethics for medical conduct.

- Withholding evidence-based treatment from 399 American men during the Tuskegee Experiment was evidence of willful misconduct and the impetus for our current medical ethics laws. From 1943 to 1972, evidence-based treatment for Syphilis was willfully withheld from 399 participants enrolled into the Tuskegee Experiment. **With this understanding, would the withholding of evidence-based treatments from 332 MILLION Americans during COVID-19 be considered similar?**

- More than 12 months since the first confirmed case of COVID-19 in the U.S., the FDA and CDC have not approved any affordable evidence-based treatments currently being used in other countries with great success. **How many lives could have been saved if the FDA authorized the use of intravenous ascorbic acid (IVAA), oral nutritional therapies (vitamins D, C, A, E, and zinc), ivermectin, and hydroxychloroquine during the summer of 2020 instead of politicizing and attempting to invalidate these treatments proven to be safe and effective?**

- Informed consent laws codified as 45 CFR 46 came into existence to protect human participants in clinical trials and any medical/scientific experiments following the Nuremberg Military Tribunal & Tuskegee Experiment.

- 45 CFR 46.116(b)(8) explicitly protects a person's right to decline participation in any clinical trial. ***"A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;"***

- Since the **Moderna/NIH clinical trial does not end until Oct 27, 2022,** and the **Pfizer/BioNTech clinical trial doesn't end until Jan 31, 2023,** that continues to place the experimental COVID biologics (vaccines) as under investigation for safety and efficacy. With this in mind, every person has the right to decline the use of an experimental product still in clinical trial. On this point, we must stand resolute in protecting the individual civil rights each person has over their own body sovereignty and protected by existing informed consent laws.

Executive Summary – Clinical Trials & Adverse Events

Author's Note Regarding Use of the Words 'Vaccine' & 'Biologic'

Our investigation has raised legitimate concerns whether the current new medical technologies developed by the Pfizer/BioNTech and Moderna/National Institutes of Health (NIH) partnerships meet the legal criteria for categorization as vaccines or as gene therapies. Until a legal ruling is made, we respectfully decline to refer to the new mRNA technologies as vaccines or gene therapies. Throughout this position paper, we will refer the new technologies as '**experimental COVID biologics**', which is intended to be both scientifically neutral and legally accurate.

- According to the federal Vaccine Adverse Events Reporting System (VAERS) **929 people have died** and **15,923 people have experienced adverse events** after receiving the experimental COVID biologics for records reported from Dec 13, 2020 to Feb 12, 2021.
- As stipulated by the emergency use authorization (EUA) regarding experimental COVID biologics, all healthcare providers are REQUIRED, for the first time in U.S. history, to report all known adverse events to VAERS.
- Moderna/NIH clinical trial is ongoing until **Oct 27, 2022**.
- Pfizer/BioNtech clinical trial is ongoing until **Jan 31, 2023**.
- Pfizer/BioNtech Phase 1 clinical trial enrolled **45 participants**.
- Pfizer/BioNtech Phase 1 clinical trial lasted **6 months**.
- Pfizer/BioNtech Phase 2/3 clinical trial enrolled **43,998 participants**.
- Pfizer/BioNtech Phase 2/3 clinical trial did not prescreen for serologic IgM or IgG antibodies, qualitative COVID RT-PCR positive participants, or any other laboratory tests to ensure that enrolling participants were free from prior SARS-CoV-2 infection.
- Pfizer/BioNtech Phase 2/3 clinical trial adverse event measurement for preliminary phase of trial was extended by 6 months **for the first 360 participants only**.
- **Animal testing was not completed** on any of the experimental COVID biologics before human participants were enrolled into Phase 1 or Phase 2/3 of the clinical studies as is required by informed consent laws.
- The Pfizer/BioNTech clinical trial design measured serologic antibody production post vaccine administration in Phase 1 only and in fewer than **25 enrolled participants total**. Establishing serologic antibody production is the key to determining the efficacy of the experimental COVID biologic. Considering this was not done in Phase 2/3 constitutes a major design flaw of the clinical trial because the trials cannot demonstrate that the biologic actually provides immunity.
- In the Pfizer/BioNTech Phase 2/3 clinical trial, **43,448 of the 43,998 enrolled participants received 162BNTb2 experimental COVID biologic inoculation or placebo**. A reason for 550 participants not receiving inoculation was unable to be located within the New England Journal of Medicine (NEJM) peer-reviewed publication.

- Only 40,137 of 43,998 enrolled participants were included in final efficacy analysis. A reason for **3,861 enrolled participants not being included in final efficacy analysis** was unable to be located within the New England Journal of Medicine (NEJM) peer-reviewed publication.
- Only 37,706 of 43,998 enrolled participants were included in final safety analysis. A reason for **6,292 enrolled participants not being included in final safety analyses** was unable to be located within the New England Journal of Medicine (NEJM) peer-reviewed publication.
- Did these unaccounted participants withdraw or were they removed from the clinical trial? If removed, what was the reason?
- Qualitative COVID RT-PCR testing was used to determine efficacy without clear disclosure of the cycle threshold value utilized to delineate a positive result from a negative result. No other testing methods were used to determine efficacy despite other tests being authorized for use.
- The **95% efficacy headline** was based upon a comparative analysis between the placebo group and the experimental group measuring how many participants tested positive for SARS-CoV-2 upon follow-up Qualitative COVID RT-PCR testing. No confirmatory testing or live cell viral cultures were performed to confirm the accuracy of the PCR results or infectiousness.
- If the goal of the experimental COVID biologic clinical trial is to prove efficacy, then the question must be asked, efficacy of what? Is it the efficacy of speculative protection or the efficacy of antibody production and the subsequent ability of biologic-induced antibodies to provide protection? The clinical design and analysis checked only for efficacy and did so unreliably.
- The Pfizer/BioNTech clinical trial was flawed with respect to design and analysis making it impossible to independently verify safety or efficacy.
- In cases where causation of injury or death can be proven based upon medical records reported to VAERS, a case can be made for private right of action in civil court due. Rushing poorly tested experimental COVID biologics to market when evidence-based treatments exist but are willingly withheld from people in need, creates the appearance of willful misconduct.
- Human beings should not be treated as guinea pigs.
- There must always be freedom of medical choice, especially when risk of injury is possible.
- ***"To make decisions about the care the physician recommends and to have those decisions respected, a patient who has decision-making capacity may accept or refuse any recommended medical intervention."*** - AMA Principles of Medical Ethics: I, IV, V, VIII, IX

Switzerland Rejects Astrazeneca experimental COVID biologic

- https://www.express.co.uk/news/politics/1392962/eu-vaccine-latest-astrazeneca-switzerland-ban-oxford-vaccine-uk-latest

India Rejects Pfizer experimental COVID biologic

- https://theprint.in/health/why-indias-expert-panel-rejected-emergency-use-nod-for-pfizer-vaccine/599529/

An Argument in Favor of Personal Injury Civil Litigation

Key Questions

- Does the data support this crisis being considered an emergency?
- Does the Public Readiness and Emergency Preparedness (PREP) Act adequately protect people using an experimental COVID biologic?
- Do these experimental COVID biologics satisfy the legal definition of a vaccine?
- Does 45 CFR 46-116 & 46-117 define the sponsor of the experimental COVID biologic as the true liable party?

Argument (See 'Violations of Medical Ethics' & 'Effective Treatments for COVID-19')

As of Feb 12, 2021, according to VAERS 929, people have died after receiving the experimental COVID biologics. Additionally, 15,923 people have been injured. Emergency Use Authorization (EUA) requires reporting of all adverse events to VAERS for experimental COVID-19 biologics.

The key to the argument may be that the experimental COVID biologics are still in ongoing clinical trials. The clinical trial for the Moderna/NIH biologic ends Oct 27, 2022. The clinical trial for the Pfizer/BioNTech ends Jan 31, 2023.

The experimental COVID biologics are both still in clinical trials while evidence-based treatments exist. As such, anyone receiving either experimental biologic must be afforded the same legal protections under 45 CFR 46 as the enrolled participants. We are in unprecedented legal territory. Everyone who consents is now an unknowing participant in a global medical experiment.

Should the FDA have issued EUA for experimental COVID biologics while safe and effective evidence-based treatments exist?

The experimental COVID biologics are still in clinical trial which proves they are (1) experimental; (2) not FDA approved; and (3) should not be available to anyone outside of the clinical trial without their informed consent. Entry into the clinical trial is the lawful means for access to the experimental COVID biologics.

45 CFR 46-116(j) may make the sponsor of the trial and/or federal agencies liable for injuries resulting from the use of the experimental products. If withholding effective treatments rises to the level of willful misconduct it may create a private right of action outside or the PREP Act.

Key References

- PREP Declaration & Amendments - https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx
- Clinical Trials - https://clinicaltrials.gov/ct2/show/study/NCT04368728 & https://clinicaltrials.gov/ct2/show/NCT04470427
- Civil Immunity - https://www.law.cornell.edu/uscode/text/42/300aa-11 & https://www.law.cornell.edu/uscode/text/42/300aa-22
- Informed Consent Laws - https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116
- Informed Consent Laws - https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1117

An Argument in Opposition to Mandates

Key Questions

- Which populations were excluded from the experimental COVID clinical trials?
- Are the clinical trials completed?
- Under 45 CFR 46-116 & 46-117 does the federal government or any private business have the right to force a child or employee to use an experimental COVID biologic that remains in clinical trial status?

Argument (See 'Effective Treatments for COVID-19' & 'Violations of Medical Ethics')

The Moderna/NIH clinical trials excluded all persons under 18 years of age, pregnant & breastfeeding mothers, persons with a history of anaphylaxis and similar hypersensitivity reactions, immunodeficient populations, blood donors, and history of bleeding disorders. Everyone in these populations receiving access to this experimental COVID biologic is doing so with no clinical trial data to support its safety or efficacy. The clinical trial cannot receive FDA approval until the conclusion of the trial on Oct 27, 2022 only if the placebo group does not receive the biologic.

Despite listing the testing age for Phase 2/3 inclusion at 12 years of age and older, the Pfizer/BioNTech clinical trials in Europe excluded all persons under 18 noting that, "persons under 18 are not eligible to be enrolled in EU clinical trials." Persons with a history of suicidal ideation or other psychiatric conditions, immunodeficiency, history of severe vaccine reactions, pregnant & breastfeeding mothers are additionally excluded from the clinical trials. In Phase 1, the only phase to measure the efficacy of antibody response to the biologic, the following conditions that individuals suffered from and thus excluded from the group of 45 total participants enrolled: hypertension, diabetes mellitus, chronic pulmonary disease, asthma, current vaping or smoking, history of smoking, or a BMI > 30 k/m^2. Everyone in these populations receiving access to this experimental COVID biologic is doing so with no clinical trial data to support its safety or efficacy. The clinical trial cannot receive FDA approval until the conclusion of the trial on Jan 31, 2023 only if the placebo group does not receive the biologic.

According to Informed Consent Law (45 CFR 46) it is illegal to force, mandate, coerce, or incentivize participation into an ongoing clinical trial. Additionally, it is unethical to force children under 18 years of age to participate in a global experiment. Considering this virus, their recovery rates exceed 99.987% as of February 16, 2021.

Children need to be in school, and there are evidence-based, safe and effective treatments that enable them and teachers to be able to do so. People need to get back to work, and there are evidence-based, safe, and effective solutions for them to be able to get back to work.

A person cannot be granted access to an experimental COVID biologic for which their demographic has not been tested for, approved for, and that is still in an ongoing clinical trial.

Key References

- Clinical Trials – https://clinicaltrials.gov/ct2/show/study/NCT04368728 & https://clinicaltrials.gov/ct2/show/NCT04470427
- Informed Consent Laws - https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116
- Informed Consent Laws - https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1117

An Argument that an Emergency No Longer Exists

Key Questions

- Does current COVID data still warrant a state of emergency?
- How many Americans have recovered despite evidence-based treatments being withheld?
- What are the specific statistical criteria that define a pandemic and a public health emergency?

Argument

While challenging executive authority has proven to be increasingly difficult, it is important to note that at the time of this publication, many Americans are currently living under executive authority for the longest period in our history that did not involve a World War.

COVID-19 US Fatality Rates By Age - Thru February 16, 2021

Demographic	Cases	Fatalities	Fatality Rate	Est. Recovery Rate
Age 0 to 17	2,323,592	298	0.013%	99.987%
Age 18 to 49	11,015,803	15,547	0.141%	99.859%
Age 50 to 64	4,206,743	50,217	1.194%	98.806%
Total 0 to 64	17,546,138	66,062	0.377%	99.623%
Age 65 to 74	1,589,030	73,389	4.62%	95.38%
Age 75+	1,340,638	208,804	15.57%	84.43%
Total 65 & Over	2,929,668	282,193	9.63%	90.37%
Total	20,475,806	348,255	1.701%	98.30%

Data Source - NVSS Published By CDC - https://covid.cdc.gov/covid-data-tracker

As of February 16, 2021, more than 18 million Americans have recovered from a SARS-CoV-2 infection as defined by the CDC. The Oregon Health Authority has reported that less than 0.8% of infected persons will experience long-term effects that require more than 37 days to fully recover.

When evaluating case, fatality, and recovery data it is important to assess it based upon age demographics and pre-existing health conditions. Because data for pre-existing health conditions is sparse nationally, it forces analysis of data to be relegated to age demographics. (Note: the New York State Department of Health and several other state health departments have done an excellent job of reporting pre-existing health conditions)

When evaluating COVID case, fatality, and recovery data based upon age demographic distribution it is clear that COVID does not constitute an emergency in people under 65 years of age. With fatalities in people 65 and older constituting 81.0% of total fatalities and knowing that 36-42% of these fatalities have occurred in senior assisted living centers and similar venues, it creates the opportunity to clearly define in which populations, and at which venues, emergency situations still exist more than 12 months after this crisis began.

Key References

- CDC Data Tracker – https://covid.cdc.gov/covid-data-tracker/#demographics
- Oregon Health Authority Weekly Report page 36 of 40 - https://www.oregon.gov/oha/covid19/Documents/DataReports/COVID-19-Weekly-Report-2021-2-18-FINAL.pdf
- AARP COVID Deaths in Nursing Homes - https://www.aarp.org/caregiving/health/info-2021/nursing-homes-new-years-covid-deaths.html

Introduction

Throughout this crisis, life as we knew it changed without warning and without the input of billions of people around the world who bear the disproportionate burden of these changes every day.

What began in the United States as an ill-fated 2-week attempt to 'Flatten the Curve' morphed into a seemingly never-ending extension of executive orders and restrictive public health policies based largely upon inaccurate projections, illegally compromised data, unproven theories of asymptomatic infective spread, and severely flawed PCR viral fragment testing.

At the time of this publication, the same mitigation strategies that have proven ineffective for more than 300 consecutive days continue to be implemented and enforced under threat of law in many places.

What is done is done, but what has been done does not have to be what will be done. We have the ability and evidence to re-evaluate executive orders and public health policies by taking objective approaches guided by accurate data and legitimate research now available throughout the world.

Some well-intentioned people have nobly sacrificed their basic human rights in good faith efforts. However, they have done so based upon fraudulent data and manipulated social narratives. These people have trusted that the institutions in place to protect the public health were promoting guidelines based upon sound scientific evidence in the best interests of life, liberty, and the pursuit of happiness. Yet, many of these people have been forced to conclude that they do not know who to trust any longer. The guidelines they have followed have clearly been ineffective.

Other well-intentioned people have questioned whether this crisis qualifies as an emergency based upon the published data. These people have suffered unjustly, mourning the loss of loved ones who were forced to die alone and afraid. These people have suffered unjustly, watching their children spiral downward into depression, drug addiction, and suicide. These people have suffered unjustly, losing their jobs and businesses without any say in the matter despite being in good health and demographically at low risk for succumbing to the SARS-CoV-2 virus. These become collateral damage and have lost more than a virus could ever take away.

This position paper is a collection of seminal research, evidence-based science, legal arguments, and insights into potential solutions that can save lives. The information presented in this position paper is free from any financial or political conflicts of interest and published to provide information that can be independently verified.

It is time to objectively re-evaluate all executive orders, public health policies, and guidance previously based upon fraudulently inaccurate data and soon-to-be disproven theories of transmission. We all must maintain our right to question, verify, and reform our opinions in the presence of new information because that is exactly what living in a free society protects.

This position paper is written by volunteer professionals with more than 20,000 collective hours of investigative research regarding COVID-19.

This position paper is written by the people and for the people that we may engage in productive, collaborative, solution-oriented dialogue. Science is not what we 'believe in,' as that is the basis for faith, and faith is wonderful in its own right.

Science is asking intelligent questions, seeking answers that can be proven, and independently verifying these answers to prove their substance. Science seeks fact and never relies upon faith.

Thankfully, science is never settled because there is no such thing as 'the' science.

Science is the embodiment of diversity…diversity of intellects, curiosities, cultures, genders, perspectives, and thoughts. Science seeks to clarify and collaborate.

Our mission is to collaborate with decision makers to usher in new public health policies based upon verifiable science and accurate data to protect those of us most at risk without creating collateral damage in those least at risk.

This position paper provides key research that calls into question the many public health policy failures and proposes reasonable and logical solutions to the following topics:

- An Unproven Theory of Asymptomatic Transmission
- Fixing PCR Testing Problems
- Withholding of Effective Treatments
- Violations of Federal Law with Respect to Data Quality
- Inaccuracy of Projection Models for Public Health Policy Development
- Growing Violations of Medical Ethics

An egregious number of failures, that appears to constitute willful misconduct, have been made throughout this crisis that emphasize the essential need for accurate information, collaboration, oversight, and public participation in our own governance. Accurate data for a multitude of reasons, collaboration to ensure all points of view factor into decision making, oversight to ensure opportunistic corruption is greatly minimized, if not outright eliminated, and public participation in our own governance because too often people who bear the disproportionate burden of all legislative decisions have the least say.

A formal petition for a special grand jury investigation into events surrounding this crisis exists for your consideration at the end of this position paper.

Let's create the world we all want to live in by working together with accurate information.

Topic 1 - Asymptomatic Transmission Never Proven

Topic Introduction – Executive orders and most public health policies related to COVID-19 mitigation strategies are primarily based upon the theory of asymptomatic transmission first proposed in March and April of 2020 but still unproven when held to medical gold-standards of investigation. The theory asserts that a person could be positive for SARS-Cov-2, completely absent of any symptoms, and therefore unknowingly transmit the virus to another susceptible host. Theories are educated guesses. However, has a person ever been definitively proven to be an asymptomatic carrier or is the scientific community making too many assumptions relative to this topic?

Quarantining all healthy individuals was based heavily upon the theory of asymptomatic transmission. Many projection models for how deadly the SARS-CoV-2 infection might be were based heavily upon the theory of asymptomatic transmission. Pre-emptive closure of schools, small businesses, and places of worship for more than 300 consecutive days around the world was based upon the theory of asymptomatic transmission. Social distancing and mask guidance were based upon the theory of asymptomatic transmission. Yet, a new, large-scale study published by the highly respected journal, Nature, raises legitimate concerns that the theory of asymptomatic transmission is proving to be more science fiction than scientific fact.

For a patient to be definitively identified as an asymptomatic carrier, at a minimum the following gold-standards of medical investigation would need to be satisfied:

(1) Complete absence of any clinical signs or symptoms associated with COVID-19

(2) Confirmed serologic presence of a viral antigen load

(3) Confirmed serologic *absence* of IgM & IgG antibodies

References

- Clinical Infectious Diseases vol 31, Oxford Academic for Diagnostic Virology, Storch
- https://microbiologynote.com/laboratory-diagnosis-of-viral-infections/
- https://microbeonline.com/laboratory-diagnosis-of-viral-diseases-five-common-approaches/

The complete absence of clinical signs or symptoms associated with COVID-19 ensures that persons with mild symptoms are excluded from a controlled study, so as not to compromise the investigative goal of confirming that asymptomatic carriers exist.

The confirmed serologic presence of a viral antigen load ensures that the virus is present in the blood stream, and therefore a person is potentially contagious if the sample can produce replication-competent virus in a human cell culture.

The confirmed serologic absence of IgM and IgG antibodies ensures that there is no immunological response in the study subject. Presence of an immunological response confirms that a subject could not be a carrier of the virus.

If all 3 standards are satisfied, a subject could be confirmed to be an asymptomatic carrier.

It is important to note, as we will discuss in the PCR topic section, that Qualitative COVID RT-PCR testing is not among the gold-standards of medical investigation because Qualitative COVID RT-PCR testing is not calibrated to be used diagnostically. While there are other COVID studies that have used Qualitative COVID RT-PCR testing exclusively as the sole diagnostic criteria to assert asymptomatic transmission, the fact that the current Qualitative COIVD RT-PCR test is not calibrated to be used diagnostically immediately disqualifies those studies from scientific consideration.

Once it is established that a person could be an asymptomatic carrier, the next objective is to confirm that the same person can transmit the virus to another susceptible person using these additional gold-standards of medical investigation:

(4) Ability to culture replication-competent virus in any human cell line

(5) Ability to infect any close contact or household contact

If a suspected asymptomatic carrier, based upon the 3 gold-standard criteria, can produce replication-competent virus in a human cell culture (not a VERO monkey kidney or other animal cell culture) then they are confirmed contagious.

If there is additional evidence that a close contact or household contact contracted the virus from the asymptomatic carrier, then this could be used as anecdotal evidence to substantiate that the theory of asymptomatic transmission is a scientifically verified fact.

However, without these 5 gold-standards being satisfied, particularly (1) thru (4), the theory of asymptomatic transmission, upon which COVID specific executive orders and most public health policies are based, cannot be definitively proven.

Should unproven scientific theories dictate the lives of billions of people globally? The investigation of this question begins by comparing two key studies published in highly respected peer-reviewed journals.

Comparison of the Wuhan Participant Study to the U.S. Projection Study

Wuhan Study with Almost 10 Million Participants

https://www.nature.com/articles/s41467-020-19802-w

Key Quote – *"Virus cultures were negative for all asymptomatic positive and re-positive cases, indicating no 'viable virus' in positive cases detected in this study.*

All asymptomatic positive cases, re-positive cases, and their close contacts were isolated for at least 2 weeks until the results of nucleic acid testing were negative. Zero positive cases or their close contacts became symptomatic or newly confirmed with COVID-19 during the isolation period."

Summary – 9,898,828 enrolled participants were tested using PCR viral fragment testing set to a cycle threshold of 37 and 40 in special circumstances. 300 possible asymptomatic carrier candidates were identified. Of the 300 candidates, 110 were considered false positives because of the absence of IgM and IgG antibodies and the inability to culture replication-competent virus via nasal sample. Of the remaining 190 candidates, 161 were deemed recovered due to the presence of IgG antibodies without IgM antibodies. Their positive PCR test was likely because patients can test positive for SARS-CoV-2 up to 12 weeks following the end of their contagious phase according to a CDC cited study from South Korea. Of the remaining 29 candidates, all had IgM and IgG antibodies indicating their natural adaptive immunity development was in progress due to a recent infection. These 29 possible asymptomatic carriers make up 0.00029% of all people tested to assess how prevalent asymptomatic carriers might be in large populations.

Under strict scientific standards, these 29 possible asymptomatic participants would not be considered carriers because they are clearly demonstrating an immunological response to the infection (IgM and/or IgG antibody production). This violates gold-standard (3), and therefore they cannot be a carrier because their body is in process of destroying the SARS-CoV-2 antigen. This is *exactly* how the process of natural adaptive immunity responds to all viral infections for successful recovery from infection. For the purposes of this discussion, we will include these 29 as possible asymptomatic carriers to investigate whether or not they were contagious.

Of the 300 possible asymptomatic carriers, all were additionally tested using live cell culture to determine if their PCR samples could produce replication-competent virus. All 300 live cell cultures were negative for being able to produce replication-competent virus, indicating that none of the 300 people identified as potential asymptomatic carriers were infectious.

Additionally, the 300 possible asymptomatic carriers encountered 1,174 people who were forced to quarantine for 14 days. These 1,174 people were frequently tested using PCR and monitored for symptom development during their quarantine. All 1,174 contact traces tested negative during each PCR test and none developed symptoms of COVID-19.

This study, the largest infectious disease study ever conducted in a single year, confirms that if asymptomatic carriers exist, they make up an insignificant percentage of any population (0.00029%). This study confirms that asymptomatic carriers are unable to produce replication-competent virus or infect susceptible hosts.

As a result, this study satisfies medical gold-standards (1), (3), (4) and (5) for definitive evaluation of the existence of asymptomatic carriers and asymptomatic transmission.

Position – The results of the study suggest the theory of asymptomatic transmissions as a driver of infective spread and fatalities is severely overstated at best and fatally flawed at worst.

Asymptomatic transmission should no longer be a foundational theory for any emergency executive orders or public health policies until definitively proven in the United States in accordance with the 5 criteria for gold-standard medical investigation to ascertain infectiousness in asymptomatic individuals.

It is essential that the scientific and medical communities be able to definitively confirm the existence of asymptomatic carriers and, if they exist, confirm that they can transmit replication-competent virus. It is crucial that medical teams have the ability to easily distinguish asymptomatic carriers from non-symptomatic recoveries, who are therefore incapable of producing replication-competent virus. A person who has recovered is non-symptomatic because they have established natural adaptive immunity against the SARS-CoV-2 virus. This is exactly the outcome all medical professionals are seeking to create.

U.S. Projection Study Endorsed & Authorized By the CDC

https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774707

Key Quote – *"The Centers for Disease Control and Prevention determined that this decision analytical study, which involved no enrollment of human subjects, did not require institutional review board approval."*

Summary – Zero participants were enrolled. This published manuscript is a mathematical model for estimating what percentage of people testing positive were asymptomatic based upon several assumptions. It asserts that 59% of SARS-CoV-2 transmissions in the United States were asymptomatic.

COMPARISON OF STUDIES REGARDING ASYMPTOMATIC TRANSMISSION

Category	Wuhan Study	US Study
Location	Wuhan, China	None
Publishing Journal	Nature	JAMA
Publishing Date	11/20/2020	1/7/2021
Peer-Reviewed	Yes	No
Enrolled Participants	9,898,828	0
Methods	PCR, Antibody, Viral Culture	Math Assumptions Only
Suspected Asymptomatic Carriers	300 Total	NA
Actual Asymptomatic Carriers	29 Possible	NA
Asymptomatic Contacts	1,174	None
Asymptomatic Contacts Infected	0	NA
Asymptomatics w/ Replication Competent Virus	0	NA
% Asymptomatic Carriers	0.00029%	Not Stated
% Asymptomatic Transmitters	0.00000%	59%

Wuhan Study - https://www.nature.com/articles/s41467-020-19802-w

US Study - https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774707

Position – The U.S. published manuscript asserts, without clinical evidence, that 59% of all people testing positive contracted the virus from an asymptomatic carrier. This mathematical model significantly contrasts the findings of the Wuhan Participant Study, which provides substantial evidence that asymptomatic carriers are an insignificant percentage of the infected total and are not contagious.

Dr. Fauci is quoted in 2020 as saying, "The one thing historically that people need to realize is that even if there is some asymptomatic transmission, in all the history of respiratory-borne viruses of any type, asymptomatic transmission has never been the driver of outbreaks. The driver of outbreaks is always a symptomatic person. Even if there's a rare asymptomatic person that might transmit, **an epidemic is not driven by asymptomatic carriers**."

So, which study more closely satisfies the 5 gold-standards for medical investigation? A study with almost 10 million enrolled participants or a study with zero enrolled participants?

The Wuhan Participant Study satisfied 4 out of the 5 gold-standards for medical investigation.

The U.S. Projection Study satisfied zero out of the 5 gold-standards for medical investigation.

It is important to note that the U.S. Projection Study makes multiple assumptions to be used as baselines in the mathematical modeling, but the assumptions were not presented for independent evaluation. Obviously, this presents impediments to reproducibility. Additionally, the population used to model the projections is not evident. The following statement "*SARS-CoV-2 spread faster than SARS-CoV, and accumulating evidence showed that SARS-CoV-2, unlike SARS-CoV, is transmitted from persons without symptoms*" is irresponsible given the gravity of the situation, presented with neither reference nor evidence, and therefore lacks scientific credibility.

Further, the U.S. Projection Study did not reference the use of serology testing on human subjects in their modeling. It is not clear if PCR testing was the only testing used to develop the assumptions. The manuscript stated that "*No statistical testing was conducted, so no prespecified level of significance was set.*" To state that "these results lack quantitative precision" and then make direct claims stating that "59% of all transmission came from an asymptomatic carrier" is intellectually dishonest. Quantitative analysis cannot be made from qualitative assumptions. As a result, there is no reasonable means to evaluate the error rate for this study. Using studies such as these to develop public health policy for COVID-19 invites inaccurate assumptions that lead to further collateral damage.

Considering this study was published in response to the Wuhan Participant Study and sanctioned by the CDC is potential evidence of willful misconduct and an attempt to mislead the American public regarding the theory of asymptomatic transmission.

Mathematical models potentially have their place in forecasting provided they are based upon accurate data rather than assumptions. Projections are not data; they are only numerical assumptions. It is important for all public health agencies to re-evaluate their public health policies regarding COVID-19 to ensure they are based upon accurate data as opposed to theories and projections. At this time, it would be prudent to explore replicating the Wuhan Participant Study on a smaller scale, but in a major metropolitan area to confirm the accuracy of their findings. Until definitive proof that asymptomatic carriers exist, and until they are proven to be capable of producing replication-competent virus in human cell cultures, the theory of asymptomatic transmission should not be used as a basis for public health policies for otherwise healthy individuals.

As such, and as will be further demonstrated throughout this position paper, the data suggests that all children & teens must return to in-person education without restriction. All small businesses must be

encouraged to reopen without restriction. All families must be empowered to legally join their loved ones in hospital settings as health advocates, just as has always been done throughout the world before this crisis.

All masking and social distancing for people not exhibiting symptoms should be immediately discontinued due to the lack of scientific justification for asymptomatic transmission.

If a person is exhibiting symptoms, they should stay home unless medical care is required. If they must leave their home during quarantine, they should do so wearing a N95 mask and maintain appropriate social distance.

Continued practice of excellent hygiene, clinical nutrition for optimized immune performance, and caution when in contact with high-risk individuals (people over 65 years of age with pre-existing conditions) can remain in place for all non-symptomatic people but should not prohibit them from interacting with anyone in the high-risk demographic.

All non-symptomatic persons should return to life as previously enjoyed before this crisis began, without social restriction, and without any requirements for proof of vaccination or recovery from prior SARS-CoV-2 infection.

Additional Subtopic Reference

- "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." (Korea CDC, 2020; Li et al., 2020; Xiao et al, 2020).

  https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html

Comparison of Symptomatic vs Asymptomatic Household Transmission

JAMA Meta-Analysis

https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774102

Key Quote – *"Estimated mean household secondary attack rate from symptomatic index cases (18.0%; 95% CI, 14.2%-22.1%) was significantly higher than from asymptomatic or presymptomatic index cases (0.7%; 95% CI, 0%-4.9%; P < .001), although there were few studies in the latter group. These findings are consistent with other household studies reporting asymptomatic index cases as having limited role in household transmission."*

Summary – A meta-analysis of 54 studies that included 77,758 participants confirms a common sense understanding of transmissibility for infective spread. The most likely location of transmission is in extended close contact settings such as households. Symptomatic persons in these households drive infective spread and are 25 times more likely to infect a susceptible person in the same household as compared to asymptomatic and pre-symptomatic persons.

Position – This study suggests that household transmission from symptomatic persons is the most likely driver of SARS-CoV-2 infective spread, as is common in most infectious respiratory diseases.

This study lends credence to several commonsense ideas regarding COVID. First, the most likely location for transmission is in the household due to prolonged contact. Second, the person most likely to be infectious is the person exhibiting symptoms. Third, asymptomatic persons, if they exist based upon gold-standards for medical investigation, are not able to transmit SARS-CoV-2 with any level of significant concern relative to symptomatic persons in the locations of highest transmissibility. This study confirms that the driver of infectious spread are symptomatic persons in household settings.

Study Basing Asymptomatic Transmission Heavily Upon PCR Testing

Annals of Internal Medicine

https://www.acpjournals.org/doi/10.7326/M20-6976#t2-M206976

Key Quotes – *"Primary Funding Source: National Institutes of Health.*

Limitation: For PCR-based studies, data are limited to distinguish presymptomatic from asymptomatic infection. Heterogeneity precluded formal quantitative syntheses.

Sixty-one eligible studies and reports were identified, of which 43 used polymerase chain reaction (PCR) testing of nasopharyngeal swabs to detect current SARS-CoV-2 infection and 18 used antibody testing to detect current or prior infection. In the 14 studies with longitudinal data that reported information on the evolution of symptomatic status, nearly three quarters of persons who tested positive but had no symptoms at the time of testing remained asymptomatic. The highest-quality evidence comes from nationwide, representative serosurveys of England (n = 365,104) and Spain (n = 61,075), which suggest that at least one third of SARS-CoV-2 infections are asymptomatic.

We know for certain who is asymptomatic only in retrospect.

Infection without symptoms, whether presymptomatic or asymptomatic, is important because infected persons can transmit the virus to others even if they have no symptoms (8, 9).

Current data suggest that infected persons without symptoms—including both presymptomatic and asymptomatic persons—account for more than 40% of all SARS-CoV-2 transmission (75–77)."

Summary – This is a meta-analysis of 61 studies (43 using PCR exclusively, 18 using antibody testing exclusively). Not all studies collected in this group of 61 studies were assessing the potential role of asymptomatic transmission. For instance, reference 55, 'Declining prevalence of antibody positivity to SARS-CoV-2: a community study of 365,000 adults' was conducted in England and makes no mention of symptomatic vs asymptomatic spread of infection. The authors cite this reference as their most definitive proof of asymptomatic transmission.

Additionally, reference 8, which is the evidence for the author's baseless definitive statement, "*Infection without symptoms, whether presymptomatic or asymptomatic, is important because infected persons can transmit the virus to others even if they have no symptoms."* is a research study by Furukawa that uses anecdotal, unconfirmed reports from China of exactly 3 possible asymptomatic transmissions based upon PCR testing alone published in March and April of 2020.

Position – There are many flaws with this meta-analysis. Immediately, the use of references that make no mention of asymptomatic vs symptomatic or pre-symptomatic subjects is disingenuous and provides a reason why references should always be verified when assessing the credibility of a research study. The English study that included 365,000 participants was measuring IgG antibodies only to determine how many people likely had immunity to the SARS-CoV-2 virus. From a medical perspective, people with IgG antibodies do not qualify as asymptomatic carriers or transmitters. Instead, they are correctly classified as non-symptomatic recoveries.

Additionally, any medical assertion that the only way to know if someone was truly asymptomatic is retrospectively to pretend that the 5 gold-standards for medical investigation of viral infection do not exist. The assertion is either ill-informed or completely disingenuous.

As previously mentioned, any studies relying exclusively upon uncalibrated Qualitative COVID PCR testing to be used diagnostically immediately disqualifies such studies from consideration. This is clearly demonstrated by the Korean CDC study that confirmed subjects can test positive for SARS-CoV-2 viral fragments using PCR testing for up to 12 weeks following the end of their infectious period. As a result, 43 of the 61 studies used in this meta-analysis are disqualified.

For the remaining 18 that used antibody testing, all prove that an immunological response was present and therefore call into question the ability of the subject to (1) produce replication-competent virus in a human cell culture and (2) be able to transmit the virus to a susceptible host.

None of the 61 studies cited or the references provided as substantive evidence provided proof that even one subject was simultaneously (1) asymptomatic, (2) had a viral antigen load, (3) did not produce antibodies, and (4) produced a sample that could be cultured for replication-competent virus.

The author's decision to group asymptomatic and pre-symptomatic cases into one group negates the reported purpose of proving asymptomatic transmission. That the authors attempt to quantify transmission in this joint group by assigning a speculative percentage of 40% without mathematical proof or clinical evidence is disingenuous. Manuscripts such as these should not survive peer-review.

Of interesting note is this comment left by a reader, Ali Bangash, Shifa College of Medicine, "With great interest, the manuscript of the research article 'The Proportion of SARS-CoV-2 Infections That Are Asymptomatic: A Systematic Review' was critically evaluated. After expressing commendation for the serious effort by authors to explore the prevalence of asymptomatic SARS-CoV-2 infections, the commenter wishes to direct the attention of the Editor towards the fact that data from preprints which have not yet been peer-reviewed have been included in the synthesis of conclusions."

Obviously, Mr. Bangash checks the references as well.

This study was funded by the National Institutes of Health which has a vested financial interest in the experimental Moderna biologic. Publishing a study such as this is a potential conflict of interest and therefore potential evidence of misleading the scientific community and willful misconduct.

Uncalibrated PCR Tests Alone Cannot Determine if a Person is Infectious

Oxford Academic Clinical Infectious Disease Meta-Analysis

https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1764/6018217

Key Quotes – *"Complete live viruses are necessary for transmission, not the fragments identified by PCR. Prospective routine testing of reference and culture specimens and their relationship to symptoms, signs and patient co-factors should be used to define the reliability of PCR for assessing infectious potential.* ***Those with high cycle threshold are unlikely to have infectious potential.***

The estimated probability of recovery of virus from specimens with Ct > 35 was 8.3% (95% CI: 2.8% to 18.4%). All donors above the Ct threshold of 35 (n=5) producing live culture were symptomatic.

There is evidence of a positive relationship between lower cycle count threshold, likelihood of positive viral culture and date of symptom onset.

In one COVID-19 (former) case, viral RNA was detectable until day 78 from symptoms onset with a very high Ct 18 but no culture growth, implying a lack of infectious potential.

The results of our review agree with the scoping review by Byrne and colleagues on infectious potential periods 26 and those of the living review by Cevick and colleagues. The authors reviewed 79 studies on the dynamics, load and RNA detection for SARS CoV-1, MERS and SARS CoV-2 from symptoms onset. They concluded that although SARS-CoV-2 RNA identification in respiratory (up to 83 days) and stool (35 days) can be prolonged, duration of viable virus is relatively short-lived (up to a maximum of 8 days from symptoms onset).

The importance of symptom onset and reported PCR threshold is shown in a study that collected test data during a prospective household transmission study. The authors found that Ct values were lowest soon after symptom onset and correlated with time elapsed since symptom onset (within 7 days after symptom onset, the median Ct value was 26.5 compared with a median of 35.0 21 days after onset). Ct values were significantly higher among those participants reporting no symptoms, and lower in those reporting upper respiratory symptoms at the time of specimen collection.

The evidence is increasingly pointing to the probability of culturing live virus being related to the amount of viral RNA in the specimen and, therefore, inversely related to the cycle threshold. ***Thus, detection of viral RNA per se cannot be used to infer infectiousness.****"*

Summary – This is a meta-analysis of 29 studies attempting to correlate Qualitative COVID RT-PCR cycle thresholds (Ct) with proof of infectiousness via live cell culture of available samples. Qualitative COVID RT-PCR viral fragment tests are experimental for COVID-19 and have never been officially calibrated to establish at which Ct value replication-competent virus is no longer viable for live cell culture. Doing so is instrumental if Qualitative COVID RT-PCR viral fragment testing is to be used in a diagnostic capacity with any level of confidence for accuracy.

Position – This meta-analysis confirms that Qualitative COIVD RT-PCR viral fragment testing, as currently used around the world, cannot be used diagnostically without additional confirmatory lab tests. This meta-analysis suggests that symptom presentation is key to properly calibrating PCR viral fragment tests to be used diagnostically, because persons designated as asymptomatic typically have Ct values well above the 25 to 28 range where live culture of replication-competent virus has not proven to be possible for patients deemed asymptomatic.

There are significant flaws in both the design and implementation of current Qualitative COVID RT-PCR testing for COVID-19, as will be addressed in detail following the conclusion of this topic on asymptomatic transmission.

One of the most pressing concerns is the lack of Qualitative COVID RT-PCR calibration against live virus cultures within human cell lines (Caco-2, HUH7.0, or 293T). This would be instrumental in scientifically calibrating cycle threshold values for existing PCR tests with the ability to culture replication-competent virus in viable human cell lines, such as Caco-2 human cardiomyocytes where cytopathic effects have been observed. Currently, most researchers are using VERO monkey cell lines (E6, CCL-81), which have proven to have a much higher susceptibility for infectiousness than human cell lines and therefore could be statistically misleading for such a Qualitative COVID RT-PCR calibration.

For a person to be infectious, including persons assumed to be asymptomatic without definitive laboratory evidence, their nasal or serologic sample must be able to produce replication-competent virus in a live human cell culture. Without this calibration between cycle threshold and live virus human cell culture, there is no definitive way to extrapolate that a person is indeed infectious based upon existing Qualitative COVID RT-PCR viral fragment testing alone, even though that is exactly what is being done all throughout the world.

This realization proves very troubling for all studies utilizing existing Qualitative COVID RT-PCR viral fragment testing diagnostically, including both the Pfizer/BioNTech and Moderna/NIH clinical trials for their respective experimental COVID biologics. Our concern is that both clinical trials are significantly compromised due to the clinical trial reliance upon uncalibrated PCR viral fragment testing in Phases 2 & 3 and provide potential evidence of willful misconduct.

Additional Subtopic References

- “In another study, the Nevada Department of Public Health found an average Ct value of 23.4 in people who died from Covid-19, compared with 27.5 in those who survived their illnesses. People who were

asymptomatic had an average value of 29.6, suggesting they carried much less virus than the other two groups." (New York Times, Dec 2020, Mandavilli)

https://www.nytimes.com/2020/12/29/health/coronavirus-viral-load.html

- "Two strains of SARS-CoV-2 infected human induced pluripotent stem cell-derived cardiomyocytes as demonstrated by detection of intracellular double-stranded viral RNA and viral spike glycoprotein expression. Increasing concentrations of viral RNA are detected in supernatants of infected cardiomyocytes, which induced infections in Caco-2 cell lines, documenting productive infections. SARS-CoV-2 infection and induced cytotoxic and proapoptotic effects associated with it abolished cardiomyocyte beating." (Cardiovascular Research, Dec 2020; Bojkova et all).

  https://pubmed.ncbi.nlm.nih.gov/32966582/

- "We passaged virus isolate 2 more times in Vero CCL-81 cells and titrated by determining the 50% tissue culture infectious dose (TCID50). Titers were 8.65 × 106 TCID50/mL for the third passage and 7.65 × 106 TCID50/mL for the fourth passage…In contrast, HUH7.0 and 293T cells showed only modest viral replication, and A549 cells were incompatible with SARS-CoV-2 infection. These results are consistent with previous susceptibility findings for SARS-CoV and suggest other common culture systems, including MDCK, HeLa, HEP-2, MRC-5 cells, and embryonated eggs, are unlikely to support SARS-CoV-2 replication… In brief, we infected Vero CCL-81 and HUH7.0 cells with SARS-CoV-2 at a low multiplicity of infection (0.1) and evaluated viral replication every 6 h for 72 h postinoculation, with separate harvests in the cell-associated and supernatant compartments (Figure 4). Similar to SARS-CoV, SARS-CoV-2 replicated rapidly in Vero cells after an initial eclipse phase, achieving 10^5 $TCID_{50}$/mL by 24 h postinfection and peaking at >10^6 $TCID_{50}$/mL… Replication in HUH7.0 cells also increased quickly after an initial eclipse phase but plateaued by 24 h postinoculation in the intracellular compartment at 2 × 10^3 $TCID_{50}$/mL and decreased after 66 h postinoculation." (U.S. CDC, Jun 2020; Harcourt et all).

  https://wwwnc.cdc.gov/eid/article/26/6/20-0516_article

Symptom-Based Testing Strategies Adopted

Centers for Disease Control & Prevention

https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html

Key Quote – *"**As of July 20, 2020 a test-based strategy is no longer recommended** to determine when to discontinue home isolation, except in certain circumstances. Symptom-based criteria were modified as follows:*

- *Changed from "at least 72 hours" to "at least 24 hours" have passed since last fever without the use of fever-reducing medications.*
- *Changed from "improvement in respiratory symptoms" to "improvement in symptoms" to address expanding list of symptoms associated with COVID-19.*

https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html

Key Quote – *"**As of October 19, 2020 accumulating evidence supports ending isolation and precautions for persons with COVID-19 using a symptom-based strategy**.*

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 (Korea CDC, 2020; Li et al., 2020; Xiao et al, 2020). Investigation of 285 "persistently positive" persons, which included 126 persons who had developed recurrent symptoms, found no secondary infections among 790 contacts attributable to contact with these case patients. Efforts to isolate replication-competent virus from 108 of these case patients were unsuccessful (Korea CDC, 2020).

***Available data indicate that persons with mild to moderate COVID-19 remain infectious no longer than 10 days after symptom onset**.*

Role of viral diagnostic testing (PCR or antigen) to discontinue isolation or precautions

- *For persons who are severely immunocompromised, a test-based strategy could be considered in consultation with infectious diseases experts.*
- ***For all others, a test-based strategy is no longer recommended except to discontinue isolation or precautions earlier** than would occur under the strategy outlined in Part 1, above."*

https://www.cdc.gov/coronavirus/2019-ncov/hcp/pediatric-hcp.html

Key Quote – *"**December 30, 2020 Testing, Isolation, and Quarantine for School-Aged Children***

Pediatric healthcare providers should be prepared to answer questions from families about testing and when it is safe for children who have had, or were exposed to, COVID-19 to return to school or be with people outside the household. Review CDC's information for school administrators on symptom screening and testing for children in school as well as CDC's Community Mitigation Framework.

*School-aged children should be prioritized for viral testing **if they have**:*

*Signs or symptoms of COVID-19 **and***

- *close contact (within 6 feet of someone for a total of 15 minutes or more) with a person with laboratory-confirmed or probable SARS-CoV-2 infection **or***
- *increased likelihood for exposure (which includes living in or traveling to a community with substantial transmission as defined by the local public health department and described in CDC's Community Mitigation Framework)*

Summary – As of July 2020 and repeatedly confirmed throughout the remainder of the year, asymptomatic testing is no longer recommended by the CDC based on scientific evidence supporting that it is a useless endeavor. Non-symptomatic persons should not be tested because a positive result

is FAR more likely a false positive (or proof of recovery from a previous infection up to 12 week prior) than it is of an asymptomatic carrier capable of transmitting the virus to a susceptible host.

Additional Subtopic References

- "A molecular test (test code 39448) is available **to test symptomatic patients** for COVID-19. Through qualitative multi-target molecular diagnostics, this testing option helps to detect the presence of SARS-CoV-2.
- Quest processes four different molecular tests—the FDA Emergency Use Authorized Quest Diagnostics lab-developed test (LDT), the FDA Emergency Use Authorized Roche Diagnostics test, the FDA Emergency Use Authorized Hologic Panther Fusion test, and the FDA Emergency Use Authorized Hologic Panther Covid-19 molecular assay."

  http://www.questdiagnostics.com/home/Covid-19/HCP/NAAT/

Asymptomatic Transmission Position

One of the foundations for public health policy development has been the presumption that not only is asymptomatic transmission occurring in mass scale, but without social distancing and masking of non-symptomatic persons, asymptomatic transmission is the major driver of infective spread.

While the Wuhan study challenges the credibility of the theory of asymptomatic transmission, it stands to reason that common ground still exists on the topic of global responses and mitigation strategies for COVID-19. At the risk of being presumptuous, the following ideals are presented as important common ground after removing asymptomatic transmission as a variable:

- **No loved one should be forced to die alone.** Family members play an instrumental role as advocates between patients and medical professionals. It is unrealistic to expect incapacitated patients to make important medical decisions without the assistance of loved ones nearby. Family members must be able to sign any waivers of liability and agree to a self-imposed quarantine or testing to confirm they are not infectious so they can be present with their loved ones in hospital, congregate care, and hospice settings.

  In 2020, hundreds of thousands of people died alone, forcefully separated from their loved ones because of the excessively restrictive public health policies regarding COVID-19. This is not normal and never should be.

- **In-person education must resume in earnest.** In January 2021, due to a surge in teenage suicides, depression, anxiety, and substance abuse throughout Clark County, the Nevada Department of Education was compelled to accelerate plans for reopening in-person education. It is unconscionable that in an age demographic with a 99.987% estimated recovery rate from SARS-CoV-2, school age children and teens have been forced into isolation for more than 300 consecutive days in most school districts throughout the country. Evidence-based nutritional guidelines for the safe return to school exist and will be presented in detail later in this position paper as a separate topic. Parents should not have to fight to have their children in school.

COVID-19 US Fatality Rates By Age - Thru February 16, 2021

Demographic	Cases	Fatalities	Fatality Rate	Est. Recovery Rate
Age 0 to 17	2,323,592	298	0.013%	99.987%
Age 18 to 49	11,015,803	15,547	0.141%	99.859%
Age 50 to 64	4,206,743	50,217	1.194%	98.806%
Total 0 to 64	17,546,138	66,062	0.377%	99.623%
Age 65 to 74	1,589,030	73,389	4.62%	95.38%
Age 75+	1,340,638	208,804	15.57%	84.43%
Total 65 & Over	2,929,668	282,193	9.63%	90.37%
Total	20,475,806	348,255	1.701%	98.30%

Data Source - NVSS Published By CDC - https://covid.cdc.gov/covid-data-tracker

- **Small businesses must reopen in earnest.** Healthy citizens should never lose their job or be forced to close their businesses without definitive proof that their job or places of business are sources of infective spread. When nationwide chains are permitted to be open for business, but 'mom & pop' shops are told they must close or risk being fined, there is obvious inequity that challenges reason and credibility. What has been sorely lacking throughout the public health and executive response to COVID-19 has been opportunity for public comment, logic, compassion, and definitive proof to justify the decisions being made.

- **Quarantining the symptomatic during unprecedented times with little known in the beginning makes logical sense.** However, with so much known now, quarantining otherwise healthy people has the potential to create more collateral damage than the SARS-CoV-2 infection does. At least as early as March 9, 2020 the CDC knew that persons 65 and older with pre-existing health conditions were most at risk for severe reactions to the virus based upon verifiable data from South Korea and Italy. To invoke extended one-size-fits-all public health policies is to invite disaster into society.

- **Using an unproven theory to dictate public health policy raises the question of willful misconduct during a crisis.** Social distancing of healthy, non-symptomatic persons is based upon the unproven theory of asymptomatic transmission. Masking of healthy, non-symptomatic persons is based upon the unproven theory of asymptomatic transmission. Closures of small businesses, schools, places of worship, etc. were all based upon the unproven theory of asymptomatic transmission. Promoting an unproven theory as medical fact is an attempt at obfuscation. Funding and sanctioning projection model-based studies filled with assumptions and without any enrolled participants has biased the scientific conversation. Simultaneously, disregarding a study with almost 10 million enrolled participants, which disproves the theory of asymptomatic transmission, rather than attempting to replicate the study on a smaller scale, is scientifically irresponsible. If studies were funded to support the unproven theory of asymptomatic transmission and intentionally or unintentionally prolonged this crisis, while effective treatments are censored and suppressed, then it stands to reason that willful misconduct must be investigated.

Mental Health & Collateral Damage

- Surge of Student Suicides Pushes Las Vegas Schools to Reopen

  https://www.nytimes.com/2021/01/24/us/politics/student-suicides-nevada-coronavirus.html

- 25% of Young Adults in the U.S. Have Contemplated Suicide During the Pandemic, CDC Says

  https://foreverymom.com/health-fitness/suicide/cdc-reports-one-quarter-of-young-adults-contemplated-suicide-pandemic/

- Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic

  https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm

- The loneliness experience of the dying and of those who care for them.

  https://pubmed.ncbi.nlm.nih.gov/17578066/

- "Who would want to die like that?" Perspectives on dying alone in a long-term care setting.

  https://www.researchgate.net/publication/327607601_Who_would_want_to_die_like_that_Perspectives_on_dying_alone_in_a_long-term_care_setting

- Dear Therapist: I Can't Accept My Father's Death From COVID-19, "I was not there for his last breaths. I was not there for his last words. I'm trying to combat my guilt."

  https://www.theatlantic.com/family/archive/2020/12/dear-therapist-covid-19-took-my-father-i-am-so-angry/617516/

- Coronavirus: How to grieve a loved one when you can't say goodbye

  https://www.bbc.com/news/uk-52142660

- "How could I mourn my mom's cancer death when coronavirus robbed us of closure?"

  https://www.latimes.com/lifestyle/story/2020-08-07/how-could-i-mourn-my-moms-cancer-death-when-coronavirus-robbed-us-of-closure

People Worthy of Our Remembrance

Jo'Vianni Smith, 15 Died by Suicide

Jo'Vianni was described as an outgoing teenager who excelled at softball, basketball, and music while attending Bear Creek High School in Stockton. Her mother said she seemed happy and was active on social media.

Danielle Hunt, who lives in Stockton, told local station KTXL that her 15-year-old daughter Jo'Vianni Smith showed no signs that she would take her own life last week by hanging herself but may have had difficulty dealing with the state's stay-at-home order, which has been in place for several weeks.

https://www.bet.com/news/national/2020/04/13/karl-anthony-mother-dies-coronavirus.html

TOPIC 2 – PCR Testing Problems

Topic Introduction – Throughout the COVID-19 global crisis there has been a rush to get products to market by repeatedly skipping essential developmental steps for verifying the accuracy of the products. In each case, a 'rush to market' has led to significant inaccuracies in data collection, proof of infectiousness, objective situational assessment, and safety. One of the topics where this has been very injurious to the lives of billions of people has undoubtedly been PCR testing.

Polymerase Chain Reaction (PCR) testing has several synonyms such as (1) Molecular testing and (2) Nucleic-acid Amplification Testing (NAAT) However, what is most confusing about PCR testing regarding SARS-CoV-2 is that it is quantitative, yet it is being used qualitatively.

Quantitative laboratory testing for any type of test yields an objective numerical result that can assist doctors in the important process of reaching definitive diagnoses. Comparatively, qualitative laboratory testing is subjective and does not provide the same level of clinical detail or accuracy.

Reverse Transcriptase-Quantitative Polymerase Chain Reaction (RT-qPCR) for COVID-19 was hurriedly developed with the promise of providing clinicians and public health officials the fastest way to diagnose infectious persons during the outset of this crisis. Curiously, however, a decision was made globally to use the quantitative PCR tests qualitatively.

Essentially, the RT-qPCR is capable of providing crucial numerical data regarding the amplification cycle at which a positive signal is detected. This numerical data is available with every test performed and has been available since the beginning, but it was never published. However, rather than publishing this data, the RT-qPCR test has been reduced from a quantitative test to a qualitative either-or test.

Either a sample is deemed positive or a sample is deemed negative.

The delineation between the subjective assessment of a positive test result from a negative test result is an arbitrary value known as cycle threshold (Ct). Ct values have been set by the FDA and CDC to be 40.00 amplifications despite global scientific agreement that a Ct of 40.00 is far too high, invites an exponential increase of false positive results, and does not correlate to infectiousness.

The RT-qPCR COVID test could be calibrated to be used diagnostically. However, it is not calibrated to be used diagnostically, has not been calibrated to be used diagnostically in over 12 months of use, but continues to be used as if it is diagnostic test when in fact it is not. This is yet another example of potential willful misconduct.

Why public health officials would fast-track the approval of a quantitative test, purposely reduce it to a qualitative test, and then make the qualitative test the primary testing method for a global infectious crisis does not make scientific sense if the goal is to mitigate the infective spread.

As has been confirmed by the Korean CDC, patients are proven to test positive using the RT-qPCR test for up to 12 weeks after they are no longer infectious. Additionally, RT-qPCR test kits explicitly state that the test cannot diagnose whether a person is currently infectious. Therefore, this proves that the RT-qPCR cannot be used diagnostically, even though that is what it has been used for.

As it stands, RT-qPCR testing is intended to be a fast way to tell the clinician whether a patient has ever been infected with the SARS-CoV-2 virus. However, the test cannot tell the clinician if the patient is currently infectious. As Dr. Lee's reply to FDA notes, RT-qPCR testing cannot identify past infections reliably at high cycle thresholds because primers get mixed in with cellular sample material not specifically associated with SARS-COV-2 virus.

This is a major problem and explains why RT-qPCR, as it is currently being used, cannot determine who should be in quarantine and who is safe to go to school, work, or recreational activities (e.g., concert, sporting event).

Alone, RT-qPCR is essentially medically useless in helping to mitigate the spread of the virus through a community as has been observed over the previous year.

For the purposes of this topic, we will refer to qualitative interpretation of the RT-qPCR test as 'Qualitative COVID RT-PCR' for SARS-CoV-2 testing and 'RT-qPCR' in reference to the general medical technology.

Corman-Drosten Review Report

https://cormandrostenreview.com/report/

The International Consortium of Scientists in Life Sciences (ICSLS) was one of the first research teams to thoroughly investigate the major flaws associated with the Qualitative COVID RT-PCR test. Led by PhD Molecular Geneticist Dr. Pieter Borger and former Pfizer Chief Scientist Dr. Michael Yeadon, the ICSLS team, comprised of 22 experts in their field, uncovered 10 major problems with the Qualitative COVID RT-PCR test including the 2-day peer-review process that led to Christian Drosten's Qualitative COVID RT-PCR test's approval before any reasonable scientific review and comment could be registered.

In the ICSLS's exceptionally thorough seminal research published on November 27, 2020 and titled 'External peer review of the RT-PCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results', the ICSLS's research team uncovered 10 significant problems with Christian Drosten's Qualitative COVID RT-PCR test.

Key Quote

"***SUMMARY CATALOGUE OF ERRORS FOUND IN THE PAPER***

The Corman-Drosten paper contains the following specific errors:

1. There exists no specified reason to use these extremely high concentrations of primers in this protocol. The described concentrations lead to increased nonspecific bindings and PCR product amplifications, making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

2. Six unspecified wobbly positions will introduce an enormous variability in the real world laboratory implementations of this test; the confusing nonspecific description in the Corman-Drosten paper is not suitable as a Standard Operational Protocol making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

3. ***The test cannot discriminate between the whole virus and viral fragments. Therefore, the test cannot be used as a diagnostic for intact (infectious) viruses, making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus*** *and make inferences about the presence of an infection.*

4. A difference of 10° C with respect to the annealing temperature Tm for primer pair1 (RdRp_SARSr_F and RdRp_SARSr_R) also makes the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

5. ***A severe error is the omission of a Ct value at which a sample is considered positive and negative.*** *This Ct value is also not found in follow-up submissions making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.*

6. ***The PCR products have not been validated at the molecular level.*** *This fact makes the protocol useless as a specific diagnostic tool to identify the SARS-CoV-2 virus.*

7. The PCR test contains neither a unique positive control to evaluate its specificity for SARS-CoV-2 nor a negative control to exclude the presence of other coronaviruses, making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

8. The test design in the Corman-Drosten paper is so vague and flawed that one can go in dozens of different directions; nothing is standardized and there is no SOP. This highly questions the scientific validity of the test and makes it unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

9. Most likely, ***the Corman-Drosten paper was not peer-reviewed making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.***

10. We find ***severe conflicts of interest for at least four authors****, in addition to the fact that two of the authors of the Corman-Drosten paper (Christian Drosten and Chantal Reusken) are members of the editorial board of Eurosurveillance. A conflict of interest was added on July 29 2020 (Olfert Landt is CEO of TIB-Molbiol; Marco Kaiser is senior researcher at GenExpress and serves as scientific advisor for TIB-Molbiol), that was not declared in the original version (and still is missing in the PubMed version); TIB-Molbiol is the company which was "the first" to produce PCR kits (Light Mix) based on the protocol published in the Corman-Drosten manuscript, and according to their own words, they distributed these PCR-test kits before the publication was even submitted [20]; further, Victor Corman & Christian Drosten failed to mention their second affiliation: the commercial test laboratory "Labor Berlin". Both are responsible for the virus diagnostics there [21] and the company operates in the realm of real time PCR-testing.*

In light of our re-examination of the test protocol to identify SARS-CoV-2 described in the Corman-Drosten paper we have identified concerning errors and inherent fallacies which render the SARS-CoV-2 PCR test useless."

Summary – One of the key published manuscripts used for the development of the Qualitative COVID RT-PCR test was the Corman-Drosten paper.

Upon the paper receiving a thorough peer-review by the ICSLS team, which did not happen before the paper was published and subsequently adopted, the following key findings were revealed:

1. Qualitative COVID RT-PCR tests are incapable of distinguishing between the virus and remnant viral fragments discarded by the immune system after successfully dispatching the virus.
2. Qualitative COVID RT-PCR tests cannot be used diagnostically to determine who is infectious and who is not.
3. Recommended Cycle Threshold (Ct) Values to determine a reasonable cut off point for who is likely infectious versus who is likely not infectious were curiously omitted.
4. The products for the Qualitative COVID RT-PCR Test were never validated at the molecular level.
5. The peer-review process for the Corman-Drosten paper lasted only 2 days. For reference, it is common practice for most published manuscripts to go through an extensive 2-month (or longer) peer-review process.
6. The Corman-Drosten authors had significant financial conflicts of interest that they did not disclose during the warp speed peer-review process.

Position – This reveals that the test the entire world relies on to be accurate and calibrated to be used diagnostically to determine who is and who is not infectious, is severely inaccurate and not calibrated to be used diagnostically.

This revelation calls into question the accuracy of the data for every case, hospitalization, fatality, and recovery where Qualitative COVID RT-PCR was used as the exclusive diagnostic tool.

This also calls into question the necessity of global public health policies that have been based upon the accuracy and diagnostic prowess of the Qualitative COVID RT-PCR test.

A revelation such as this begs the question, *"With so much at stake, how was this able to happen?"*

With this in mind, several other researchers have been doing excellent work in bringing the scope of this problem to the public's awareness.

Qualitative COVID RT-PCR Significantly Inaccurate

International Journal of Geriatrics and Rehabilitation

http://www.int-soc-clin-geriat.com/info/wp-content/uploads/2020/03/Dr.-Lees-paper-on-testing-for-SARS-CoV-2.pdf

Key Quote – *"In summary, the results of re-testing the cellular components of 20 reference samples of nasopharyngeal and oropharyngeal swab rinses by heminested RT-PCR amplification followed by nucleotide sequencing showed that SARS-CoV-2 was not found in 3 of the 10 (3/10) reference samples classified as positive by RT-qPCR, and that 2 of the 10 (2/10) reference samples classified as negative by RT-qPCR in fact contained SARS-CoV-2."*

Summary – Dr. Sin Hang Lee is the internationally acclaimed Director of Milford Molecular Diagnostics Laboratory, which specializes in developing DNA sequencing-based diagnostic tests implementable in community hospital laboratories. Dr. Lee has over 40 years of clinical diagnostic experience and is a world-renowned expert with respect to RT-qPCR testing.

In a study published on July 17, 2020, Dr. Lee concluded that 30% of the positive Qualitative COVID RT-PCR samples he retested were indeed false positive when tested under more stringent protocols, and 20% of the negative Qualitative COVID RT-PCR samples he retested were indeed false negatives as well. This raised significant concerns regarding the accuracy of the Qualitative COVID RT-PCR Tests and their ability to accurately detect not only who was infectious but also who had really been infected at all.

The implications for this reached far beyond the public health crisis when Dr. Lee ultimately realized that the Qualitative COVID RT-PCR test was the sole diagnostic test being used during Phase 2/3 of the Pfizer/BioNTech clinical trials approved by the NIH. This raised concerns not only for accuracy of the clinical trial data but for safety concerns for the enrolled participants.

On November 25, 2020, Dr. Lee filed a formal petition with the FDA (Docket No. FDA-2020-P-2225) titled 'PETITION FOR ADMINISTRATIVE ACTION REGARDING CONFIRMATION OF EFFICACY END POINTS OF THE PHASE III CLINICAL TRIALS OF COVID-19 VACCINES'. Dr. Lee filed a stay of action requesting that the FDA halt the Pfizer/BioNTech clinical trials until more accurate laboratory diagnostics could be used to determine clinical efficacy of the experimental COVID biologic. Dr. Lee also outlined potential replacements and solutions to ensure the accuracy of the diagnostic tests used in the clinical trial were accurate.

On December 11, 2020, the FDA responded to Dr. Lee's formal petition, stating *"We have determined there is not scientific merit in requiring the Phase 3 trial for BNT162 or other COVID-19 vaccine candidates to qualify a PCR diagnosis of COVID-19 with Sanger sequencing. Testing used to support the detection of SARS-CoV-2 infection should be sensitive and accurate, and PCR assays can be sufficiently sensitive and accurate without the need for Sanger sequencing."*

The FDA also concluded, "*It would not be sound public policy to require testing protocols that lack scientific merit. Requiring scientifically-unjustified protocols would add unnecessary costs to the clinical trial process, which could disincentivize important medical research.*"

Dr. Peter Marks, Director of the Center for Biologics Evaluation and Research, denied the petition in its entirety.

Two days later, on December 13, 2020, the Pfizer/BioNTech experimental COVID biologic was approved under emergency use authorization (EUA) for public distribution even though the clinical trial is ongoing through January 31, 2023.

On February 10, 2021, Dr. Lee filed a replied to Dr. Marks' response.

Position – Clinical trials for experimental COVID biologics should be required to use diagnostic tools that are accurate for definitively assessing for efficacy and safety of the biologic. That there is a decided lack of redundancy with respect to diagnostic tools opens the door for inaccurate data collection, inaccurate analysis, and is a potential indication of willful misconduct.

Discussed in the 'Violations of Medical Ethics' topic later in this position statement, there were significant flaws in the design of the trials, the analysis of the trials, and the clear conflict of financial interest in the clinical trials.

No vaccine has made it to market for public distribution in less than 4 years, and most require 8 to 10 years of development. For new experimental technology that progressed without preliminary animal trials being completed until September 9, 2020 from conception to production in only 7 months, safety must be at the forefront of all considerations.

Dr. Lee's concerns are legally reasonable, scientifically valid, and demonstrate the type of compassion essential for the safety of clinical trials involving enrolled human participants. Interestingly, the Pfizer/BioNTech clinical trials report 3,861 participants who either withdrew or were withdrawn prior to completion of their preliminary phase. As a result, published analysis excludes these participants, and no published data on their outcomes is currently available.

Additional Subtopic References

- Dr. Lee is widely regarded as an international expert in Sanger sequencing, which is considered the gold-standard for accuracy in nucleic acid amplification testing. The National Cancer Institute has stated, **"Sanger sequencing is the gold standard for sequencing technology in that it provides a high degree of accuracy, long-read capabilities, and the flexibility to support a diverse range of applications."**

  https://genomics.ccr.cancer.gov/technologies/sanger-sequencing/

- Dr. Lee's full petition to the FDA can be found in the Appendix.
- Dr. Marks' response to Dr. Lee's petition can be found in the Appendix.

- Dr. Lee's reply to Dr. Mark's response can be found in the Appendix.
- Case Transcript Allegheny County vs The Cracked Egg 20-9808 can be found in the Appendix.
- Page 72 line 8 to Page 73 line 10 – "Q. So we have heard that this PCR test is called the gold standard and previously, you weren't here on Wednesday, but **Dr. Brink had testified that false positives in her opinion can only occur in the situation of a mishandling of the samples at a lab**. Do you agree that false positives can only occur through human error or mishandling of the samples when doing the testing?
- A. Can I address the premise of the question? You said that the gold standard is the PCR?
- Q. That was the term used by Dr. Brink based on -- I guess that the CDC calls it the gold standard.
- A. You are confusing two things with that statement. The first thing is that the CDC required--considers the presence of a virus the gold standard. If you can prove the virus is present in any way, the CDC would accept the presence of the virus. **There are other techniques that can be used other than PCR.** So, CDC actually says that the presence of the virus -- and it accepts PCR as one of the levels of evidence. **The actual gold standard for clinical diagnostic testing using nucleic acid technology such as PCR, sorry if I am speaking fast, the actual gold standard acknowledged by the FDA is Sanger sequencing, sequencing of the nucleotide itself.**"

The Importance of Cycle Threshold (Ct) Values

FDA & CDC – Real Time RT-PCR Diagnostic Panel

https://www.fda.gov/media/134922/download

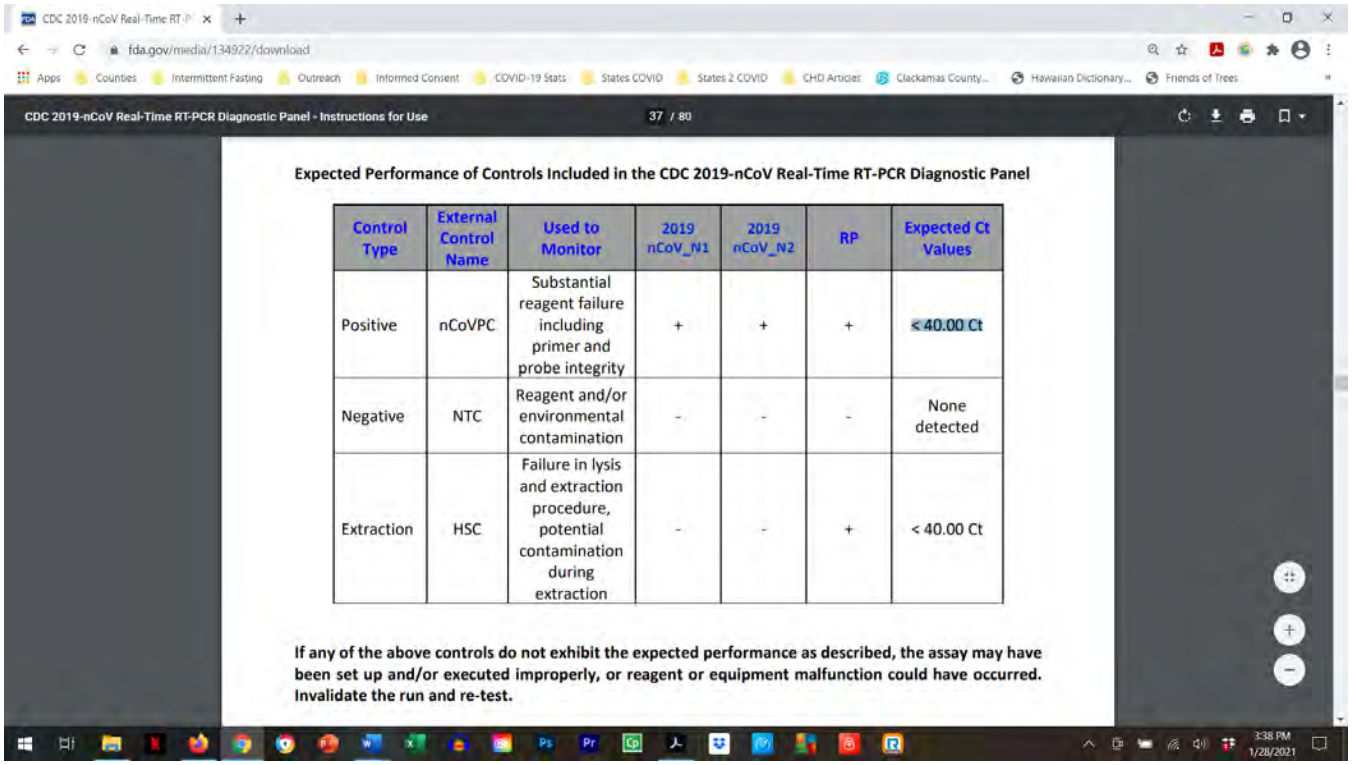
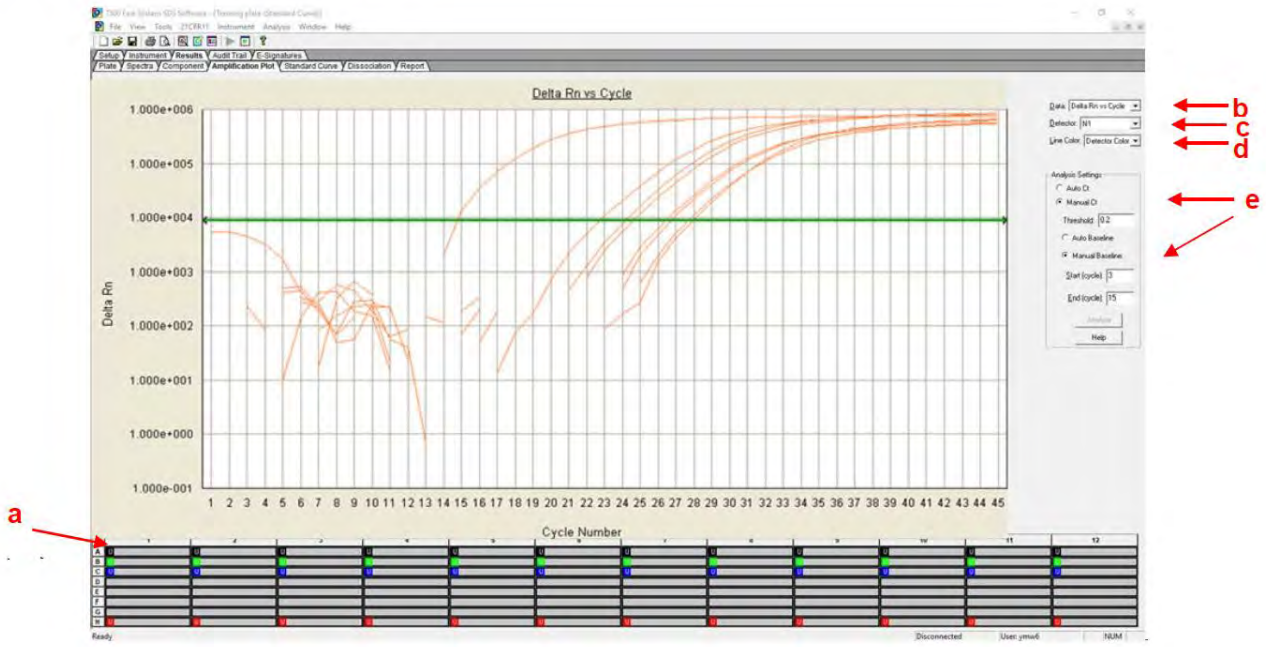
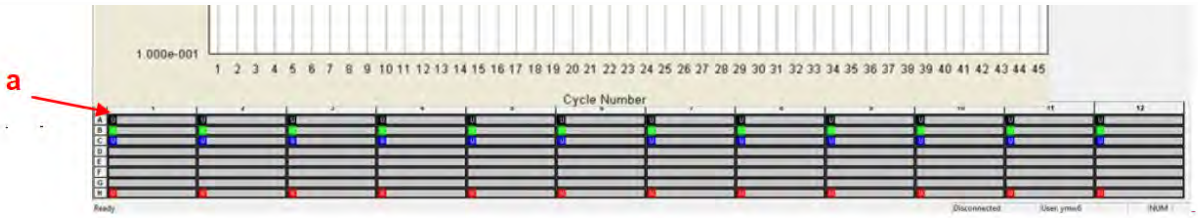


Figure 17. Amplification Plot Window





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)**.

Summary – Cycle Threshold (Ct) Values are the key to understanding Qualitative COVID RT-PCR testing. RT-qPCR is an amplification technique whereby a sample is collected, and then the genetic material

present is amplified many times to increase the genetic material available for detection of viral fragments.

It is important to note that viral fragments are not virus and therefore cannot determine whether the sample being tested is infectious without the corroboration of other testing methods.

One analogy for this process is photocopying. If you have a single document that you intend to photocopy, it will yield two copies, the original and the photocopy. If you photocopy both of those copies simultaneously, then you will have four copies. Photocopy those four copies again and you will have eight copies including the original.

Qualitative COVID RT-PCR testing is set to be amplified (photocopied) 45 times. If we applied this to the original example for photocopying documents, 45 amplification cycles would yield 17,592,186,044,416 copies (Geometric Sequences Formula $x_{45}=1*2^{(45-1)}$). It is easy to understand the allure of this style of relatively inexpensive lab test. A small sample can be amplified to detect what is present genetically.

However, at what point (or Cycle threshold) is the genetic material a mess of DNA & RNA rendering the test unreliable beyond that point?

The CDC & FDA have set the Ct Value at 40.00. What this means is that if viral fragments are detected below 40.00 cycle amplifications then the sample is deemed positive, and the patient from which the sample was collected is deemed positive for COVID-19 and treated as if they are infectious.

It is also important to note that there is an enormous difference between COVID-19 and the SARS-CoV-2 virus. COVID-19 is the diagnosis that asserts the person with the diagnosis is infectious, while SARS-CoV-2 is the virus.

Qualitative COVID RT-PCR tests are currently only calibrated to detect viral fragments, not the entire SARS-CoV-2 viral genomic sequence.

Additionally, we know from studies published by the CDC that viral fragments can be detected in amplified samples for up to 12 weeks following the end of the infectious period for people diagnosed with COVID.

Therefore, using the Qualitative COVID RT-PCR Test in its current calibration can detect whether a person has been infected by the SARS-CoV-2 virus over the previous 12 weeks, but it CANNOT detect whether a person is infectious and should be considered an active COVID case.

Qualitative COVID RT-PCR tests are being used to do exactly what they are not calibrated to do.

This is a major problem.

The key to solving this problem presented by this qualitative test is the Cycle Threshold (Ct) Value.

To determine whether or not a person is infectious, live human cell cultures (Caco-2, HUH7.0, or 293T) can be used to discover if replication-competent virus is present in the sample being tested.

If replication-competent virus can be cultured, then the person is definitively infectious.

If replication-competent virus cannot be cultured, then the person is definitively not infectious.

When researchers can determine the average Ct value at which replication-competent virus is no longer able to be cultured in human cell lines that establishes with reasonable certainty what the actual Ct Value should be.

Dr. Fauci is on record as stating, "*[I]f you get a cycle threshold of 35 or more…the chance of it being replication-competent are [sic] miniscule. And we have patients – and it's very frustrating for the patients as well as for the physicians – somebody comes in and they repeat their PCR, and it's like 37 cycle threshold, but you almost never can culture virus for a 37-cycle threshold. So, I think if someone does come in with 37-38, even 36, you got to say, 'You know, it's just dead nucleotides, period."*

Dr. Darcie Johnston of the Department of Health and Human Services, in a public email record dated January 6, 2021 stated, "*Anything over 34 cycles becomes unreliable*."

On January 13, 2021, the World Health Organization stated, "*WHO reminds IVD users that disease prevalence alters the predictive value of test results; as disease prevalence decreases, the risk of false positive increases. This means that the probability that a person who has a positive result (SARS-CoV-2 detected) is truly infected with SARS-CoV-2 decreases as prevalence decreases, irrespective of the claimed specificity."*

https://www.who.int/news/item/20-01-2021-who-information-notice-for-ivd-users-2020-05

This begs the question, if respected voices know the Ct Value is too high, why has this known error gone on for almost a year?

It is widely agreed that a Ct Value of 40.00 is far too high of a threshold and therefore opens the door to a high number of false positive COVID cases.

Many PCR experts say that the most accurate Ct value should be in the range of 24 to 34 instead of 40. Why? Because if a signal is detected at cycle amplifications less than 24, then it is a reasonable assumption that that patient is likely infectious.

In order to calibrate this flawed Qualitative COVID RT-PCR test to be used diagnostically, researchers are working to determine the Ct Value level that should be set by taking symptomatic patients with positive Qualitative COVID RT-PCR test results and attempting to culture the positive sample in a live cell culture.

The limitation of many of these studies is that researchers are using VERO monkey kidney cells, which are much more susceptible to infection with the SARS-CoV-2 virus than human cell lines. Still, it is a move in the direction of logic and reason.

Additional concerns regarding the Qualitative COVID RT-PCR test surround the threshold detection line and the possibility that lab technicians can manipulate the threshold detection line to an arbitrary value. The instruction manual states on page 33, ***"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." The threshold detection value does not appear to be numerically defined in the document titled, 'CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel' (CDC-006-00019, Revision: 06, 12/01/2020) published by the FDA.

Oxford Academic Clinical Infectious Disease Meta-Analysis

https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1764/6018217

Key Quotes – *"[From La Scola 2020 [W15] Nasopharyngeal swabs or sputum specimens.]*

183 [specimens tested positive] (4,384 specimens from 3,466 patients [collected])

183 specimens testing positive by RT-PCR (9 sputum specimens and 174 nasopharyngeal swabs) from 155 patients, were inoculated in cell cultures. SARS-CoV-2. RNA rtPCR targeted the E gene. Nasopharyngeal swab fluid or sputum specimen were filtered and then inoculated in Vero E6 Cells. All specimens were inoculated between 4 and 10 h after sampling and kept at + 4 °C before processing. After centrifugation they were incubated at 37 °C.

They were observed daily for evidence of cytopathogenic effect. Two subcultures were performed weekly and scanned by electron microscope and then confirmed by specific RT-PCR targeting E gene.

Of the 183 specimens inoculated in the studied period of time, 129 led to virus isolation. Of these 124 specimens had detectable cytopathic effect between 24 and 96 h. The letter by Jaafar et al adds that 1941 SARS-Cov-2 30 isolate cultures were positive out 3,790 inoculated specimens. These could be seen after the first inoculation or up to 2 blind subcultures. At a Ct of > 34 2.6% of specimens yielded a positive culture.

There was a significant relationship between Ct value and culture positivity rate: specimens with Ct values of 13–17 all had positive culture. Culture positivity rate decreased progressively according to Ct values to 12% at 33 Ct No culture was obtained from specimens with Ct > 34. The 5 additional isolates obtained after blind subcultures had Ct between 27 and 34, thus consistent with low viable virus load."

Summary – This is a meta-analysis of 29 studies attempting to correlate PCR cycle thresholds with proof of infectiousness via live cell culture of available samples. Focusing on the work of the La Scola, which is among the most through studies provided in the Jefferson meta-analysis, we find the following:

1. 183 specimens from 155 Qualitative COVID RT-PCR positive patients were collected.
2. Of the 183 specimens, 129 led to the isolation of the SARS-CoV-2 virus in VERO E6 monkey cells. VERO E6 monkey cells have proven to be more susceptible to infection than human cell lines to date. (See Additional Resources)
3. Additionally, in a companion study (by Jaafar) only 30 out of 3,790 samples led to VERO E6 isolates.

4. Samples with a Ct up to 17 all yielded replication-competent virus in VERO E6 cell culture.
5. Only 12% of samples with a Ct of 33 were able to produce replication-competent virus.
6. Samples with a Ct of 34 or higher were unable to produce replication-competent virus (La Scola). Only 2.6% of samples with a Ct of 34 or higher were able to produce replication-competent virus (Jaafar).
7. All participants were symptomatic for COVID.

PHD Analysis of FOIA Cycle Threshold Values Rhode Island

https://rationalground.com/covid-19-pcr-testing-cycle-threshold-values-are-the-missing-piece-of-the-pandemic-puzzle-until-now/

Key Quotes – *"We can see that nearly half of the positive tests had Ct scores of greater than 32 – meaning they were probably not infectious. Only 42% were likely infectious, and this is during a time when RI was smack in the middle of the spring pandemic, AND when they were mainly testing symptomatic people!*

We can analyze the data further by looking at what percentage of Ct scores were above 32 (likely not infectious) by month. As the Spring progresses, we see more tests with higher Ct values = more people with lower viral loads, to the point where 2/3 of tests in June were likely not infectious.

As May approaches, the average Ct score of positive tests rises linearly through the "maybe infectious" zone into the "not infectious" zone, again showing clearly that viral loads were decreasing (fewer people were actually sick).

Finally, if we overlay fatalities, we can clearly see the potential predictive effect of Ct score trends relative to pandemic severity.

Perhaps one might object that this is just one data set (sadly), so maybe this is a fluke. Well, we did manage to procure a second small data set from a lab on the U.S. west coast, also from the spring. And voila, the Ct score distributions are remarkably similar to those in RI.

It is frankly negligent that officials and "experts" on both sides of pandemic policy are ignoring or cannot access this data. Labs simply don't provide them, apparently because they are not required to do so."

Summary – In Rhode Island, based upon Freedom of Information Act (FOIA) requests for public records, 44% of all Qualitative COVID RT-PCR positive results had a Ct of 32 or higher which correlates to replication-competent virus via live cell culture being remarkably unlikely.

New England Journal of Medicine Ct, Live Cell Culture in Hospitalized Patients

https://www.nejm.org/doi/full/10.1056/NEJMc2027040

Key Quotes – *"SARS-CoV-2 was cultured in 29 of the 89 samples (33%). The median time from symptom onset to viral clearance in culture was 7 days (95% confidence interval [CI], 5 to 10), and the median time from symptom onset to viral clearance on real-time RT-PCR was 34 days (lower boundary of the 95% CI, 24 days).*

The latest positive viral culture was 12 days after symptom onset (in Patient 6).

Viable virus was identified until 3 days after the resolution in fever (in Patient 14).

Viral culture was positive only in samples with a cycle-threshold value of 28.4 or less.

The incidence of culture positivity decreased with an increasing time from symptom onset and with an increasing cycle-threshold value."

Summary – Only 33% of samples from hospitalized, symptomatic patients were able to be cultured in a live cell. The type of cell used was not identified in the peer-reviewed manuscript. Cell culture was only possible in samples with a Qualitative COVID RT-PCR Ct Value of 28.4 or less.

Position – The La Scola/Jaafar study and similar studies provided by the New England Journal of Medicine and the Jefferson meta-analysis confirm that symptom presentation is an essential factor in producing replication-competent virus during cell culture. This is also confirmed by the NEJM published study. Asymptomatic persons have yet to be proven to produce replication-competent viral cell cultures.

However, the Jefferson meta-analysis also confirms that it is possible to calibrate the existing Qualitative COVID RT-PCR for infectiousness by using live cell culture of positive samples. Once it is established at which cycle threshold value replication-competent virus is no longer able to be cultured, then the cycle threshold for all Qualitative COVID RT-PCR tests can compare against the delineation at which infectiousness is no longer likely.

While replication-competent virus is possible in symptomatic patients with Ct Values above 28, there is a point of diminishing returns regarding accuracy. For example, at a Ct Value of 33, only 12% of symptomatic patients will produce replication-competent virus meaning that 88% will not.

This affirms that cycle threshold values set above 33 open the door for false positives, meaning that people can test positive using Qualitative COVID RT-PCR and not be infectious.

Considering that many non-symptomatic people are volunteering to be tested for a variety of reasons, it is important to ensure that all people tested have clinical symptoms consistent with COVID. From there, it is possible to set a Ct value that reasonably correlates with the production of replication-competent virus (See figure below).

PROPOSAL FOR CALIBRATING COVID RT-qPCR TESTING BASED UPON VIRAL REPLICATION-COMPETENCE

DIAGNOSTIC INTERPRETATION	CYCLE THRESHOLD	PROPOSED ACTION
Infectious	< 25.00	Quarantine/Isolation Until No Longer Symptomatic + 2 Days. Administration Of Evidence-Based Nutritional Guidance. Retest Serologic Antibodies To Confirm (+ IgG, - IgM).
Possibly Infectious	25.00 - 33.99	Confirmatory Lab Testing. Serologic Antigen Or Live Human Cell Culture. Quanantine/Isolation Until Confirmed. Administration Of Evidenced-Based Nutritional Guidance As Precaution.
Not Infectious	≥ 34.00	Recommendation Of Evidence-Based Nutritional Guidance As Precaustion.

Oxford Academic (Jefferson) - https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1764/6018217

NEMJ Hospital Study - https://www.nejm.org/doi/full/10.1056/NEJMc2027040

Caco-2 Cell Human Cell Line Infectiveness - https://pubmed.ncbi.nlm.nih.gov/32966582/

VERO Monkey, HUH7.0 Human, 293T Human Cell Line Infectiveness - https://wwwnc.cdc.gov/eid/article/26/6/20-0516_article

Note from Peer-Reviewer Dr. James Lyons-Weiler – The protocols in use are not quantitative in a manner that would allow for a quantitative estimate of viremia (amount of virus in the sample). This is fundamental to the problem of using PCR in this way. The sampling procedure (nasopharyngeal swab) adds variation in the total amount of virus in the sample, so an internal control is needed. The internal control should have a spiked amount of a similar sequence with known concentration. This is why PCR testing for the SARS-CoV-2 virus needs to be based upon Sanger sequencing.

A public health testing strategy such as this would effectively calibrate the existing Qualitative COVID RT-PCR to be used diagnostically, establish a range for additional testing that is socially responsible, and prevent the collateral damage created by false positives (i.e., people who test positive but are not capable of transmitting the virus).

Additional solutions include bringing a RT-PCR test to market that uses Sanger sequencing rather than viral fragments or to serologically test for the SARS-CoV-2 antigen and accompanying antibodies. For decades, this has been the clinical methodology for the definitive diagnosis of infectious diseases.

Solutions to this major testing problem exist, and affirm an age-old medical proverb, 'Never guess when you can know."

Additional Subtopic References

- "In another study, the Nevada Department of Public Health found an average Ct value of 23.4 in people who died from Covid-19, compared with 27.5 in those who survived their illnesses. People who were asymptomatic had an average value of 29.6, suggesting they carried much less virus than the other two groups." (New York Times, Dec 2020, Mandavilli)

  https://www.nytimes.com/2020/12/29/health/coronavirus-viral-load.html

- "Two strains of SARS-CoV-2 infected human induced pluripotent stem cell-derived cardiomyocytes as demonstrated by detection of intracellular double-stranded viral RNA and viral spike glycoprotein expression. Increasing concentrations of viral RNA are detected in supernatants of infected cardiomyocytes, which induced infections in Caco-2 cell lines, documenting productive infections. SARS-CoV-2 infection and induced cytotoxic and proapoptotic effects associated with it abolished cardiomyocyte beating." (Cardiovascular Research, Dec 2020; Bojkova et all).

  https://pubmed.ncbi.nlm.nih.gov/32966582/

- "We passaged virus isolate 2 more times in Vero CCL-81 cells and titrated by determining the 50% tissue culture infectious dose (TCID50). Titers were 8.65 × 106 TCID50/mL for the third passage and 7.65 × 106 TCID50/mL for the fourth passage…In contrast, HUH7.0 and 293T cells showed only modest viral

replication, and A549 cells were incompatible with SARS-CoV-2 infection. These results are consistent with previous susceptibility findings for SARS-CoV and suggest other common culture systems, including MDCK, HeLa, HEP-2, MRC-5 cells, and embryonated eggs, are unlikely to support SARS-CoV-2 replication… In brief, we infected Vero CCL-81 and HUH7.0 cells with SARS-CoV-2 at a low multiplicity of infection (0.1) and evaluated viral replication every 6 h for 72 h postinoculation, with separate harvests in the cell-associated and supernatant compartments (Figure 4). Similar to SARS-CoV, SARS-CoV-2 replicated rapidly in Vero cells after an initial eclipse phase, achieving 10^5 $TCID_{50}$/mL by 24 h postinfection and peaking at >10^6 $TCID_{50}$/mL… Replication in HUH7.0 cells also increased quickly after an initial eclipse phase but plateaued by 24 h postinoculation in the intracellular compartment at 2×10^3 $TCID_{50}$/mL and decreased after 66 h postinoculation." (U.S. CDC, Jun 2020; Harcourt et all).

https://wwwnc.cdc.gov/eid/article/26/6/20-0516_article

- "While we're lucky to have reasonably accurate tests available so early in the course of a newly identified virus, we need better tests and easy access to them. All tests should undergo rigorous vetting by the FDA as soon as possible."

  https://www.health.harvard.edu/blog/which-test-is-best-for-covid-19-2020081020734

- FDA Emergency Use Authorizations for Medical Devices

  https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-antigen

- New York Times article discussing whether or not the PCR test should be considered positive for cycle thresholds above 30 in the absence of clinical symptoms.

  https://www.nytimes.com/2020/08/29/health/coronavirus-testing.html

PCR Testing Position

Current Qualitative COVID RT-PCR Testing is not calibrated to be used diagnostically to determine who is infectious and who is not, but it can be calibrated by using human cell lines (Caco-2, HUH7.0, or 293T) to calibrate the cycle threshold value at which replication-competent virus is no longer able to be cultured.

The safe and effective practice of medicine depends upon accurate lab testing to help clinicians arrive at definitive rather than presumptive diagnoses.

Using Qualitative COVID RT-PCR tests, incapable of determining infectiousness, renders the most widely used test in the world completely incapable of determining who is and who is not infectious. This fact severely limits medical professional's ability to mitigate the spread of the infection.

Therefore, actions taken to impede the effectiveness of clinical diagnosis essential to slowing the spread of infection is possibly another example of willful misconduct.

To further complicate matters, Pfizer/BioNTech clinical trials for their experimental COVID biologic depended upon Qualitative COVID RT-PCR tests. If the test used in the clinical trial is incapable of

determining infectiousness, then by extension, the data collected and analyzed for safety and efficacy is similarly compromised. This compromises the scientific integrity of the clinical trial.

Is this evidence of willful misconduct? There are severe flaws in how PCR testing is being used and nothing has been done to rectify these issues in more than 300 days and continued use of the flawed tests as a gold-standard is a willful act of misconduct. Knowing that the flaws are leading to numerous misdiagnoses and severe collateral damage is professional misconduct.

Doctors and nurses working on the front line deserve to have the most accurate diagnostic tools for reaching definitive diagnoses to help mitigate the spread of the virus.

All people being adversely impacted by public health policies deserve to have the most accurate data to prove the existence of an emergency beyond any reasonable doubt.

People consenting to the use of experimental COVID biologics based upon compromised clinical trials still ongoing deserve to know this information about PCR testing before consenting.

Without a test or group of tests that can definitively determine who is and who is not infectious, it is impossible to state with certainty that an emergency exists or that any infective spread can be responsibly mitigated.

Approving a test to be used diagnostically that is not calibrated to be used diagnostically when other testing options exist suggests the possibility of willful misconduct.

People Worthy of Our Remembrance

Ana Martinez Died Alone

"I was dismissed, given the run-around, and my valid concerns were downplayed. Health-care workers fed me half-truths, assuring me my mother was healthy and safe when all the while she was suffering with COVID-19, gasping for air. My family was not notified until weeks after my mother's passing that her nursing home had been admitting COVID-19 patients in accordance with a statewide mandate Cuomo had issued on March 25. Cuomo closed the doors on loved ones and opened them instead for the deadly coronavirus."

http://thegoodnewstoday.org/my-mother-died-alone-after-andrew-cuomo-trapped-her-in-a-nursing-home-with-covid/

https://www.voicesforseniors.com/

Topic 3 – Effective Treatments For COVID

Topic Introduction – The FDA and CDC could have prevented thousands of fatalities from COVID-19 if these agencies had deployed a series of dietary, nutritional, and lifestyle guidelines; bulletins; and action alerts to our nation's medical professionals, hospitals, and senior care facilities for high-risk demographic individuals. Since March 2020, the high-risk demographic has been clearly identified as persons over 65 years of age with at least 1 major pre-existing (comorbid) condition. Moreover, a compendium of published literature has emerged which clearly demonstrates that inexpensive, safe, and effective pharmaceutical treatments exist for the treatment of COVID-19.

The emergence of COVID-19 occurred amidst a chronic disease crisis in the United States, where more than 73% of all people living in the United States are overweight or obese despite the CDC's insistence that this number hovers around 20%.[109] According to the CDC, statistics state that more than 10% of the United States population is diabetic, and more than 88 million adults are pre-diabetic. 45% of adults live with hypertension, and 500 million deaths directly or indirectly involve hypertension.

Diabetes, hypertension, and obesity are significant risk factors for adverse events and mortality risk from COVID-19, and these 3 comorbidities comprise significant percentages of "contributing factors" listed on death certificates, as reported by the CDC.

The overwhelming evidence obtained through the analysis of federally funded and published NHANES data indicates that large percentages of the U.S. population are clinically deficient in essential micronutrients, vitamins A, C, D, E, and zinc.

An overwhelming body of evidence, extracted from several decades of published literature, demonstrates the necessity of these nutrients for basic physiology as well as for innate and adaptive immunity, particularly among high-risk demographics living with comorbidities. Additional evidence exists to support the use of basic nutritional guidelines to drastically reduce hospital overwhelm and disease severity while enhancing and expediting recovery from COVID-19.

NHANES data analysis enables a deeper understanding of the nutritional and micronutrient needs for a nation in crisis. This topic provides an extensive review of research from the COVID frontlines, ranging from small cohorts to large pooled meta-analyses.

On March 23rd, 2020 in Shanghai, China, a panel of medical experts convened to expand the clinical uses of vitamin C, prophylactically as well as in clinical treatment for COVID-19.[103] The panel reviewed medical literature, as well as publications from the National Cancer Institute, which identified the use of IV vitamin C in randomized controlled trials for the treatment of sepsis in the prevention of viral diseases as well as an adjunctive treatment for numerous types of cancer. The panel of medical experts also reviewed the pharmacokinetics of vitamin C as well as many of the well understood immunological mechanisms of ascorbate. This included their understanding that vitamin C inhibits viral proliferation via enhanced macrophage phagocytosis as well as the ability for ascorbate to modulate T-cell and natural killer (NK) cell activities.[101, 102] The Shanghai panel of medical experts went forward with their recommendations for the use of ascorbate for COVID-19 in hospital settings:

“For therapeutic applications for COVID-19, the Shanghai protocol recommends that dosing regime should allow sustained high plasma levels to be achieved through twice daily doses of 12 to 15 g administered at 12 ml/h. The dosage recommendation will vary with the severity of the illness ranging from 50 to 200 mg/kg/day to as much as 16,000 mg/kg/day administered IV.”

The panel of Shanghai medical experts quoted a recently published study from January 2020, which consisted of infectious disease clinicians, discussing the limited utility of developing new vaccines for rapidly changing viruses. These clinicians spoke to the importance of basic nutrition to optimize human immune function:

“…supplementing above the RDA for certain immune supporting vitamins, promotes optimal immune function, helps to control the impact of infections, and could help limit the emergence of novel, more virulent strains of pathogenic viruses. We, therefore, strongly encourage public health officials to also include nutritional strategies in their arsenal to improve public health and to limit the impact of seasonal and emerging viral infections.”[104]

Despite these recommendations by the Shanghai panel and other peer-reviewed publications, U.S. health agencies did not employ evidence-based nutritional guidance to protect the public from COVID-19. To this date, not a single treatment for COVID-19 has been approved by the FDA. Not a single nutritive recommendation has been endorsed by the FDA. To the contrary, the FDA instead decided to police the nutritional supplement industry by issuing warning letters to any business or medical practitioner attempting to make claims as to the efficacy of nutrition to prevent or treat COVID-19.[18]

Such is the shortsightedness of U.S. health agencies. Despite the enormous financial budgets of the CDC and FDA, the rate of chronic disease growth in the United States is substantial, alarming, and unprecedented. It is our position that these federal agencies have failed the public for decades, have ignored the essentiality of basic health measures, are mired in conflicts of interests with the pharmaceutical industry, and show no willingness to improve the health of the U.S. population by including nutrition as a foundational mitigation and preventative strategy. As a direct result of their failed public health policies, incompetence, conflicts of interest, and willful ignorance, millions of Americans have unnecessarily died, and many more will die until severe nutritional deficiencies are scientifically addressed.

“Optimum nutrition is the medicine of tomorrow.”

- Linus Pauling, 2-time Nobel Laureate

"An important scientific innovation rarely makes its way by gradually winning over and converting its opponents. What does happen is that its opponents gradually die out and that the growing generation is familiar with the idea from the beginning."

- Max Planck, Nobel Laureate

The CDC & FDA Knew, Yet Did Nothing

As of the date of this initial publication, 16% of all COVID-19 fatalities in the U.S. feature “Diabetes” as a comorbidity on death certificates and 20% of total fatalities feature “Hypertension”. As early as March 9, 2020, the CDC, the FDA, the U.S. Federal Government, and leading research institutions were all aware of the demographics at high risk of developing COVID-19.

On March 9, 2020, the CDC alerted Americans over the age of 60 and with comorbidities such as obesity, diabetes, and hypertension that they were likely at a higher risk for fatality if they contracted the SARS COV-2 virus.[6] This knowledge emerged from published comorbidity data obtained from: The Italian Health Ministry, South Korea, China, and eventually confirmed by the New York State Department of Health via their COVID-19 Tracker.

At the onset of COVID-19 emergence in the U.S., early reports of high-risk comorbidities associated with COVID-19 fatalities were hypertension, diabetes, cardiovascular disease, and obesity. As of January 18, 2021, the CDC attributes, 322,441 total fatalities to COVID-19.[13] “Contributing Conditions” as listed on death certificates are provided, which yield comorbidity data for this demographic: Influenza & Pneumonia: 141,763; Respiratory Failure: 117,102; Hypertensive Diseases: 65,600; Diabetes: 51,222; Adult Respiratory Distress Syndrome: 36,915; Sepsis: 29,517.

Nowhere since the arrival of COVID-19 has the FDA or CDC initiated public health strategies involving exercise, dietary modification, or nutrition for reducing the risk of disease severity or mortality for any population. If the CDC and FDA worked to create a series of public health strategies focused on the inclusion of evidence-based nutritional guidance, hospital and healthcare overwhelm could have been reduced, rates of survival could have been improved, and recovery could have been accelerated.

Hyperglycemia and pre-existing diabetes is positively associated with disease severity from COVID-19, increased ICU and hospital admissions, and increased mortality.[41-49] Hemoglobin A1C values of 6.5% and higher are associated with greater COVID-19 disease progression and higher mortality risk.[59-61] Elevated body mass index (BMI) is positively associated with tracheal intubation and/or death within 7 days.[51] Obesity triples the risk of hospitalization due to SARS-CoV-2 infection, reduces immunocompetence, and increases the risk of severe illness.[71] For hypertensive COVID-19 patients there is an increased risk for mortality, disease severity, disease progression, ARDS (acute respiratory distress syndrome), and need for ICU care.[64,65]

A compendium of meta-analyses from all over the world reveals diabetes mellitus and obesity can be adequately controlled and, in some instances, reversed, by dietary, nutritional, and lifestyle management.[52-58] The CDC and FDA could have initiated federally funded exercise and diet programs, with the objective of helping obese patients reduce BMI, reducing A1C scores, and improving the chances of survival from COVID-19 by reducing known risk factors.

These actionable items should have been implemented once the CDC was made aware of the high-risk demographics associated with COVID-19. Doing so would have reduced hospital and ICU overwhelm, empowered patients towards better health and immunocompetence, and shifted patients in the high-risk demographics towards an increased likelihood of accelerated recovery if infected.

The CDC Knew Millions Had Low Nutrient Intakes & Deficiencies

National Health and Nutritional Evaluation Survey (NHANES) is a bi-yearly, federally funded, national data collection program, that began in 1971, implemented and published by the CDC. Widespread nutritional deficiencies and their association to disease have been reported upon for several decades using NHANES data sets.[33,34]

The CDC was well aware of its own data findings of widespread nutrient deficiency when their 2003-2004 NHANES dataset revealed alarming metrics, such as an estimated 21 million Americans suffering from severe vitamin C deficiency and 66 million citizens being at a high risk of deficiency due to lifestyle and pharmacological interactions.[29,30]

A recent, published analysis of NHANES datasets ranging between 2005-2016 examined micronutrient intake from food and supplementation. The population size for the 11 years of NHANES data included a total of 26,282 adults between 19 and 99 years of age.[16] The NHANES methodologies included survey data on the population, represented as a percentage below the estimated average requirement (EAR) and above the upper limit (UL). The EAR is an estimate of the minimal amount of nutrition that is required to prevent disease based upon the RDA, RDI, ODA, and similar concepts of minimal nutrient requirements. The NHANES survey data also accounts for the effect of nutritional supplementation on the EAR/UL. The following information demonstrates the results:

Vitamin A

- From Diet: 45% did not meet EAR
- From Diet with Supplementation: 35% still did not meet EAR
- Average Vitamin A Intake from Diet: 639ug (2,130 IU). EAR=700-900ug (2,333- 3,000 IU/day)

Vitamin C

- From Diet Alone: 46% did not meet EAR
- From Diet with Supplementation: 37% still did not meet EAR
- Average Vitamin C Intake from Diet: 83mg/day. Optimal Daily Intake = 200mg/day

Vitamin D

- From Diet: 95% did not meet EAR
- From Diet with Supplementation: 65% still did not meet EAR

- Average Vitamin D Intake from Diet: 188 IU/day. RDA = 600-800 IU/day
- **Note1:** Endocrine Society recommends 1,500-2,000 IU/day
- **Note2:** Since Vitamin D levels can also be greatly influenced by sun exposure, it's necessary to review NHANES data on deficiency status, based on serum 25-OHD levels. NHANES data 2011-2014 (n=2,283) revealed that 17.4% of the population is deficient in 25-OHD, as defined by 25-OHD levels less than 20 ng/ml (50 nmol/l) by the National Academy of Medicine. Severe deficiency of 25-OHD levels defined as less than 12 ng/ml (30 nmol/l) was found in 3.4% of the NHANES population.[15]
- **Note3:** In U.S. clinical settings, serum 25-OHD levels below 50 ng/ml (125 nmol/l) is considered deficient in Vitamin D status and serum 25-OHD levels below 30 ng/ml (75 nmol/l) is considered severely deficient in Vitamin D status. In the context of COVID-19, strong associations exist between low values of 25-OHD and disease severity, increased hospitalizations, and mortality.

Vitamin E

- From Diet: 84% did not meet EAR
- From Diet with Supplementation: 60% still did not meet EAR
- Average Vitamin E Intake from Diet: 9mg (13 IU/day). RDA = 15mg/daily (22 IU/day)
- **Note 4:** Recommendation for Older Adults for Immune Health: 134mg/day (200 IU/day)

Zinc

- From Diet: 15% did not meet EAR
- From Diet with Supplementation: 11% still did not meet EAR
- Average Zinc Intake from Diet: 12mg/day. RDA = 8-11mg/day
- **Note 5:** Recommended Optimal Intake for Higher Risk Populations: 30mg/day

NHANES NUTRITIONAL ANALYSIS STUDIES - SUMMARY

Nutrient	RDA/EAR/ODI	Adults 2005-2016	Nutritional Deficit For Minimum Requirements	% US Population Deficient*
Vitamin A	2,333-3,000 IU	2,130 IU	870 IU	35-45%
Vitamin C	75-200 mg	83 mg	117 mg	37-46%
Vitamin D	600-800 IU	188 IU	612 IU	65-95%
Vitamin E	22-200 IU	13 IU	187 IU	60-84%
Zinc	8-30 mg	12 mg	18 mg	11-15%

Data Source: NVSS Published By CDC - https://www.cdc.gov/nchs/nhanes/index.htm

*Low End Of Range Adjusted For Supplemental Nutrient Intake Plus Dietary Intake - Reider, C. A., Chung, R.-Y., Devarshi, P. P., Grant, R. W., & Hazels Mitmesser, S. (2020). Inadequacy of Immune Health Nutrients: Intakes in US Adults, the 2005–2016 NHANES. Nutrients, 12(6), 1735. doi:10.3390/nu12061735

With such alarming numbers, it would be reasonable for nationally accredited nutrition programs to receive increased federal funding for community outreach, education, and actionable distribution of nutritional supplements to support high risk COVID-19 populations. To date, this has not occurred.

Depleted levels of vitamin C have been consistently observed among patients with diabetes mellitus. While this may involve dietary inadequacy, other variables are significant contributors. This may involve competition between ascorbate and glucose transporters and rapid oxidation of ascorbate due to preexisting oxidative stress.[3,8,9,32] Based on this data, it has been proposed that the RDA for vitamin C in patients with diabetes should be increased by 35mg for both men and women.[10] From a therapeutic side, the greatest reduction in fasting blood sugar was observed in studies where subjects consumed a minimum daily dose of 1,250mg of vitamin C daily for at least 3 months.[10,11]

A meta-analysis study published in 2014 selected 38 articles (26 observational, 12 RCT), pooled from 5 RCTs for their meta-analysis, and found that single intake of ascorbic acid is significantly associated with lower fasting glucose levels compared to placebo.[10]

NHANES data taken from 2003-2006 examined the relationship between Hemoglobin A1C (A1C) levels and plasma levels of vitamin C (n=7,697) and noted a significant inverse association (p=0.0017), with strong association in the 18-44 age group.[21]

The inaction of the CDC to recognize the significance of vitamin C for high risk COVID-19 diabetic patients may represent willful misconduct, particularly as it is related to the known inverse association between plasma ascorbate (a nutrient known to be depleted among diabetics) and hemoglobin A1C levels, and the fact that the CDC is well aware that diabetics are at a higher risk for COVID-19 disease severity.

What's the Point of Having NHANES Data if It's Never Used?

Beginning in 1971, and published by the CDC, NHANES data is a bi-yearly, cross sectional evaluation of health across the U.S. population. NHANES datasets reveal vital statistics related to the following factors: (1) socioeconomics, (2) diet and nutrition, (3) dental hygiene, (4) physiologic measurements, (5) prevalence of chronic disease, and (6) laboratory tests.

To enhance the reliability of statistical analysis, NHANES over-samples data collection from elderly populations (60 and over), as well as Hispanic and African American communities. If implemented scientifically, NHANES datasets of elderly populations could have played a vital role in helping to reduce mortality risk. This is particularly relevant because 81% of all COVID-19 fatalities have occurred in the 65+ age range as of January 19, 2021.[13]

Important historical data obtained from NHANES II during 1976-1980 (n=27,801) was integral in establishing the associations between vitamin C status, stroke, and cardiovascular disease (CVD). From this historical dataset, it was observed that serum concentrations of vitamin C between 63-153 umol/l were associated with a 26% reduced relative risk of both stroke and cardiovascular disease.[34] In support of this, subsequent published research identified lower vitamin C status in association with several cardiovascular disease risk factors such as smoking, hypertension, elevated LDL, and lower HDL.[3,4,5]

Data obtained from NHANES 2001-2004 examined the association between 25-hydroxy vitamin D (25-OHD) levels and all cause cardiovascular disease mortality among adults with hypertension (n=2,609). Following the initial NHANES data collection, there were 191 deaths (7.3%) from all causes, and 68 deaths (2.6%) from cardiovascular disease with hypertension. Among the recorded fatalities attributed to cardiovascular disease with hypertension, mean levels of 25-OHD was 20.9 ng/ml, compared to 23.2 ng/ml for survivors.

After multivariate adjustments were applied for a variety of lifestyle factors, a significant inverse relationship between 25-OHD levels, mortality from all causes (p=0.012), and CVD (p=0.010) appeared. Significantly, this study's researchers identified that hypertensive adults with 25-OHD levels less than 17 ng/ml had a 221% increased risk of morbidity from cardiovascular disease compared to the same patient population who had 25-OHD values of 29 ng/ml or higher.[19]

Even though these vitamin D levels are still clinically deficient, the body only needs the smallest amount to function. The question is, "Why is vitamin D not being tested for and administered to all patients with a serologic levels below 50 ng/ml upon admission to the hospital?

The lack of utility of the CDC's own NHANES data reveals a widespread disconnection between the fundamental responsibilities of the agency and the population it is supposed to support. NHANES data should not exist for the purpose of intellectual neglect and indifference. NHANES data should be presented front and center for scientific application during a national health crisis. The people with knowledge of such data who do not act upon it are potentially guilty of willful misconduct.

Key Nutrients Associated with COVID-19 Treatment Efficacy

Linus Pauling Institute at Oregon State University

The premier nutrient research center in the United States is undoubtedly the Linus Pauling Micronutrient Information Center at Oregon State University. In addition to their in-depth analyses of clinical applications for nutrition, they have authored brilliantly researched meta-analyses on the role of nutrition and natural immunity.

Their 'Overview of the Immune System' authored by Dr. Victoria Drake and Dr. Giana Angelo is supported by 267 peer-reviewed references relating to the role that nutrition plays in effective immune function. In this meta-analysis they highlight several key micronutrients (Vitamins A, C, D, E, B6, B12, and folate; essential fatty acids; zinc; selenium; iron; copper; and probiotics) as essential co-factors for optimal immune response to all microbial infections.[105]

A meta-analysis such as this takes on added relevance when contrasted against the NHANES studies that clearly show rampant vitamins A, C, D, E as well as zinc deficiency among Americans.

Recent findings on COVID-19 Immunopathogenesis and Immunotherapeutics

A recent peer-reviewed study published in December 2020 in the journal International Immunopharmacology Volume 89 (Part B) further illustrates the critical importance of nutrient therapy as a primary clinical therapeutic strategy.[106]

"Vitamin D (1,25(OH)2VD3) exerts its immunomodulatory effects by inhibiting T cell proliferation, expression of IL-2, and IFN-γ. 1,25(OH)2VD3 directs differentiation of Th cells toward the Th2 responses by inducing of IL-4 production and blocking differentiation to Th1 responses by suppressing the IL-12 production. Given the downregulatory effects on IL-6 and IL-23, 1,25(OH)2VD3 inhibits the differentiation of naïve T cells to Th17 cells. Vitamin D also raises the production of IL-10 along with downregulation of IL-12 synthesis, leading to deviation of Th1 response to IL-10-producing Treg cells. In addition to its modulatory effects on T cells, 1,25(OH)2VD3 also downregulates B cell proliferation and consequently IgG production by indirect affecting on the immunologic synapse in the antigen presenting cells (APCs)-Th cells interface. Although vitamin D exhibits inhibitory function on adaptive immunity, it has stimulatory effects on the innate immune responses.

In contrast to vitamin D, vitamin A (Retinoic acid) promotes cytotoxic capability of the immune system and also T cells expansion that may be beneficial responses in case of COVID-19. It assists signal transduction in T cells and enhances the secretions of IL-2. The definite effect of retinoic acid on B cells is not clear, however, it presumably inhibits B cells apoptosis. Similar to vitamin D, retinoic acid also aids differentiation of T cells towards Th2 response. In addition, vitamin A stimulates the production of type I interferon, thereby, exerting antiviral activities. In addition, vitamin A confers a therapeutic potential in autoimmunity by modulating the Th17/Treg balance. Taking together, vitamin A might be beneficial in COVID-19 patients by modulating immune system toward an anti-inflammatory setting during remission phase of the disease and by stimulation of anti-viral state.

Other vitamins including C, E, and B complex have also been reported to be involved in some nonspecific reactions. For instance, vitamin C exhibits antioxidant activity and vitamin E acts as a scavenger or key cellular regulator. There are scattered studies reporting that vitamin C and E perform anti-inflammatory activities. Furthermore, vitamin E has been reported to stimulate the production of type I IFN in the cells."

Vitamin C Deficiency in Hospital Settings

A Colorado-based hospital study evaluated the status of serum levels of vitamins C and D, among a critically ill COVID-19 cohort. Of 21 patients, only 11 survived (48% mortality). Mean vitamin C values for non-survivors was 15.4 umol/l (hospital range: 17-154 umol/l), compared to survivors, 29.1 umol/l.

The mean Hemoglobin A1C of all patients was 7.6, indicative of the known diabetes-interactive mortality risk association with COVID-19. Mean vitamin D levels were low for the entire cohort. Age was a factor, with the median age of survivors being 52 compared to non-survivors, 69. The study's authors identified that older age and vitamin C levels were co-dependent risk factors for mortality from this critically ill, diabetic, patient group.[1]

Similar findings were reported in another ICU cohort study where 17 of 18 COVID-19 patients (median age 59 ± 9), who developed ARDS (acute respiratory distress syndrome) exhibited non-detectable levels of vitamin C.[2]

Despite being small-sized cohorts, hospital-based studies such as these provide real world data from the frontlines that could be used to bolster recovery efforts in hospital settings.

Vitamin C Therapeutics

Vitamin C administration could have been used to enhance the rate of recovery from COVID-19 in hospitals, as evidenced by meta-analysis research, that identified vitamin C administration reduces ICU stays by 7.8-8.6% and time on mechanical ventilation by 14-18.2% for severe respiratory infections.[31, 35, 36] Hospital treatment costs for vitamin C administration are estimated to be $12-24 per day.[37]

A Chinese hospital treated approximately 50 cases of moderate to severe COVID-19 infection with Intravenous Ascorbic Acid (IVAA). The IVAA dosing was moderate and affordable, and the dose was determined by clinical status. The dose strategy was 100% effective at successful management of cytokine storms.

All 50 patients who received IVAA improved.

There was no mortality in the IVAA group.

There were no side effects reported from any patients in the IVAA group. COVID-19 patients had a 30-day hospital stay on average, but COVID-19 patients who received IVAA had a hospital stay that was 3 to 5 days shorter compared to the non IVAA treated patients.[66]

Special mention should be given to researcher Dr. Doris Loh, for her exhaustive and extensive publication on the potential mechanisms of ascorbic acid in COVID-19 patients, particularly as it is related to the regulation of free heme, redox mechanisms, ascorbate recycling, minimizing hypoxia, and serving as an antioxidant for cellular and mitochondrial mechanisms.[100]

Vitamin D

A meta-analysis and systematic review evaluated the relationship between vitamin D deficiency among patients diagnosed with COVID-19. The researchers identified 1,542 articles and selected 27 for analysis. While vitamin D deficiency was not associated with increased risk of COVID-19 infection (OR = 1.35; 95% CI = 0.80–1.88), vitamin D deficiency was associated with increased hospitalizations (OR = 1.81, 95% CI = 1.41–2.21), and increased mortality (OR = 1.82, 95% CI = 1.06–2.58).

Severe cases of COVID-19 were 64% more likely to be vitamin D deficient than mild cases of COVID-19 (OR = 1.64; 95% CI = 1.30–2.09).[14]

Vitamin D Therapeutic Studies

A cohort observational study of 43 consecutive hospitalized COVID-19 patients aged 50 and above, in a tertiary academic hospital, evaluated those that received nutrient combination therapy (vitamin D, magnesium, and vitamin B-12 (DMB)) compared to a recent cohort who did not. DMB combination was associated with a significant reduction of clinical deterioration and fewer individuals requiring oxygen support and/or intensive care support compared to the non-intervention group.[67]

A randomized, placebo-controlled study involving 40 SARS-CoV-2, RNA positive individuals, aimed to study the proportion of RNA negative subjects following a 21-day trial period of either vitamin D3 (60,000 I.U.) or placebo. For the intervention group, vitamin D was given at a dosage of 60,000 I.U. daily for 7 consecutive days. 25-OHD serum values were collected at day 7. Supplementation was continued for individuals whose 25-OHD value was <50ng/ml. SARS Co-V-2 RNA was measured periodically, along with inflammatory markers: (1) fibrinogen, (2) D-dimer, (3) procalcitonin, (4) CRP and (5) ferritin. Compared to the placebo group, the intervention group turned a greater proportion of individuals SARS-CoV-2 negative after 21 days, as well as having reduction in fibrinogen measures.[68]

At the time of this writing, the literature reports that several clinical trials are in process involving high dose vitamin D3 or Calcifediol for COVID-19 patients. Initial clinical trials have been published, which suggest that the use of high dose vitamin D3 (Calcifediol) could have prevented ICU overwhelm, increased recovery rates, and reduced mortality. This important research is not receiving the media coverage that it deserves.

A pilot study conducted in a hospital in Spain involved 76 consecutive COVID-19 patients, who exhibited acute respiratory infection, which was confirmed by radiographic imaging, a SARS-CoV-2 PCR positive test, and recommended hospital admission (based on CURB65 >1). All patients received the best available therapy per hospital protocol, which included a combination of hydroxychloroquine, and azithromycin. Eligible patients for the clinical trial were randomized to receive either vitamin D3 21,280 IU (0.532mg) or no vitamin D3. On days 3 and 7, vitamin D3 patients were continued with a lower dose 10,640 IU (0.266mg) and then a weekly dosage until hospital discharge or admission to the ICU. The outcomes of this study are listed as: (1) rate of ICU admission and (2) deaths. Of the 50 total patients who received vitamin D3, 1 was admitted to the ICU (2%). Of the 26 patients who were not administered vitamin D3, 13 were admitted to the ICU (50%).

Of the 50 patients treated with vitamin D3, zero deaths occurred, and all 50 patients were eventually discharged without complications. Of the 13 untreated Calcifediol patients admitted to the ICU, 2 died, and 11 were eventually discharged. The non-vitamin D3 treated patients who were not admitted to the ICU recovered and were discharged. This randomized clinical trial demonstrates that vitamin D3 significantly reduced ICU admission rates, as well as reduces the severity of COVID-19.[94]

The study authors concluded:

> ***"Our pilot study demonstrated that administration of a high dose of Calcifediol or 25-hydroxyvitamin D, a main metabolite of vitamin D endocrine system, significantly reduced the need for ICU treatment of patients requiring hospitalization due to proven COVID-19.***

Calcifediol seems to be able to reduce severity of the disease, but larger trials with groups properly matched will be required to show a definitive answer."

A study in the United States used a retrospective, observational analysis between mid-March and mid-June 2020 with respect to serologic vitamin D levels (25(OH)D) with matching results from the preceding 12 months.[111]

The study authors concluded:

> ***"A total of 191,779 patients were included (median age, 54 years [interquartile range 40.4–64.7]; 68% female. The SARS-CoV-2 positivity rate was 9.3% (95% C.I. 9.2–9.5%) and the mean seasonally adjusted 25(OH)D was 31.7 (SD 11.7). The SARS-CoV-2 positivity rate was higher in the 39,190 patients with "deficient" 25(OH)D values (<20 ng/mL) (12.5%, 95% C.I. 12.2–12.8%) than in the 27,870 patients with "adequate" values (30–34 ng/mL) (8.1%, 95% C.I. 7.8–8.4%) and the 12,321 patients with values ≥55 ng/mL (5.9%, 95% C.I. 5.5–6.4%). The association between 25(OH)D levels and SARS-CoV-2 positivity was best fitted by the weighted second-order polynomial regression, which indicated strong correlation in the total population (R2 = 0.96) and in analyses stratified by all studied demographic factors. The association between lower SARS-CoV-2 positivity rates and higher circulating 25(OH)D levels remained significant in a multivariable logistic model adjusting for all included demographic factors (adjusted odds ratio 0.984 per ng/mL increment, 95% C.I. 0.983–0.986; p<0.001). SARS-CoV-2 positivity is strongly and inversely associated with circulating 25(OH)D levels, a relationship that persists across latitudes, races/ethnicities, both sexes, and age ranges. Our findings provide impetus to explore the role of vitamin D supplementation in reducing the risk for SARS-CoV-2 infection and COVID-19 disease."***

Zinc

A hospital-based study evaluated the fasting zinc status of COVID-19 patients upon admission (n=47), compared to healthy controls (n=45). COVID-19 patients displayed significantly lower zinc levels (median=74.5ug/dl), compared to the healthy control group (105.8ug/dl). 57% of COVID-19 patients were zinc deficient. Zinc-deficient COVID-19 patients had "higher rates of complications (p = 0.009), acute respiratory distress syndrome (18.5% vs 0%, p = 0.06), corticosteroid therapy (p = 0.02), prolonged hospital stay (p = 0.05), and increased mortality (18.5% vs 0%, p = 0.06). The odds ratio (OR) of developing complications was 5.54 for zinc deficient COVID-19 patients."

Zinc Therapeutics

An observational retrospective study was performed to evaluate the effect of zinc sulphate as an adjunct when used with hydroxychloroquine and azithromycin versus hydroxychloroquine and azithromycin alone. The study recruited 411 patients for the zinc sulphate / hydroxychloroquine / azithromycin group, and 521 for the group using hydroxychloroquine and azithromycin without zinc

sulphate. While zinc addition did not impact the length of hospitalization, ICU duration, or need for ventilation, the addition of zinc sulphate reportedly reduced the need for mechanical ventilation and increased the frequency of patients being discharged. Significantly, after the researchers adjusted for the time in which zinc sulphate was added to protocols, the zinc sulphate group had a significant reduction in mortality or transfer to hospice among patients who did not require ICU care (OR 0.449, 95 % CI 0.271–0.744).[69]

Combination Nutritional & Oxidative Therapies for COVID-19: Vitamins A, C, D, Iodine, Hydrogen peroxide (H2O2), and Ozone (O3)

A study published in the journal *Science, Public Policy & The Law* (July 2020), involved a combination of nutrient and oxidative therapies for 107 COVID-19 patients (median age=56.5). Patients were given dosing instructions for oral supplementation for 4 days at symptom onset: vitamin A (100,000 IU/day), vitamin C (1,000mg/hour during waking), vitamin D (50,000 IU/day), and Lugol's iodine (25mg). Most patients in the study were instructed to nebulize a solution of 0.04% hydrogen peroxide in saline solution with magnesium sulfate. If symptoms worsened, patients were treated with intravenous, or intramuscular nutrition of vitamin C (35%), hydrogen peroxide (30%) and intramuscular ozone (35%).

107 out of 107 patients fully recovered within 7 days of treatment initiation.[38]

Vitamin D & Potential Immunological Mechanisms of Action

Pathophysiologic, Pleiotropic, Immunologic & Anti-Viral Actions

Vitamin D in its myriad forms exerts a multitude of pleiotropic effects on neuroendocrine, immunological, and anti-viral actions in humans. While the active form of vitamin D is known as Calcitriol (1,25 dihydroxy vitamin D), a myriad number of vitamin D isoforms exert their pleiotropic effects on human physiological functions. This includes 25-OH vitamin D3 (Calcifediol). This section is predominantly focused on the known research of vitamin D in its many forms on COVID-19 related mechanisms and its therapeutic potential as a powerful clinical nutritive agent.

Vitamin D sits at the center of the SARS-CoV-2 pathophysiology. The first revealing sign is the strong association between vitamin D deficiency and increased COVID-19 related hospitalizations, increased pathogenic severity, and increased mortality. Indeed, previous meta-analysis studies have reported that vitamin D deficiency is associated with higher infection rates, increased incidence of sepsis, and increased mortality risk among critically ill populations.[82]

In terms of the pathophysiology related to COVID-19, one of the central focuses of research literature with respect to the SARS-CoV-2 viral etiology is related to the angiotensin coveting enzyme-2 (ACE-2) receptor. Notably, the SARS-CoV-2 spike protein has been shown to bind to ACE-2 in upper and lower lung epithelium as well as in neuronal tissues, with unexpectedly exceptional efficiency.

The binding of SARS-CoV-2 to the ACE-2 receptor can lead to a suppressive effect on the expression and function of ACE-2.[92] This effect has been proposed to lead to the induction of pulmonary edema in COVID-19 patients and severe lung failure.[90,91] Importantly, vitamin D has a net effect of promoting the function of ACE-2 expression via regulation of the ACE-2/Ang-(1-7)/MasR axis.

ACE-2 is an integral component of the renin angiotensin system (RAS) and the regulation of blood pressure. Notably, vitamin D is known to negatively regulate the RAS system via the induction and promotion of the ACE-2/Ang-(1-7)/MasR axis, which serves as a key feedback axis of cardiometabolic function.[78]

It is speculated that the association between hypertension and low vitamin D status may be causally related to vitamin D's regulatory effects on the ACE-2/Ang-(1-7)/MasR axis and the RAS.[81]

Research studies have identified that chronic vitamin D deficiency can: (1) induce excessive cytokine storms, (2) directly activate the RAS, (3) dysregulate the expression of ACE-2 in lungs, (4) increase renin secretion, (5) disrupt blood pressure and blood volume, (6) diminish lung function, and (7) increase the risk of fibrosis.[83,84,85,93] This pathologic profile constitutes a significant percentage of critically ill COVID-19 patients.

Vitamin D exerts wide-reaching influences on human immunological mechanisms. Of notable interest, the active form of vitamin D (Calcitriol) stimulates immune cell biosynthesis of the powerful anti-bacterial and anti-viral cationic host defense peptide (CHDP), cathelicidin, known as LL-37.[73]

As a cationic peptide, vitamin D-derived LL-37 has been shown efficacious in reducing cytokine storms that result in lung inflammation and damage, while also reducing rates of viral replication.[74]

LL-37 has been studied for its antiviral actions in numerous types of viruses, including HSV-1, HIV, rhinovirus, and dengue virus.[75,76,77]

Vitamin D also is a direct and indirect regulator of T-cell functions. As a pro hormone, vitamin D exerts both paracrine and autocrine actions. Vitamin D can increase memory T-cells, as well as induce signaling of immunosuppressive TREG's cells.[88,89]

Vitamin D can reduce the expression of inflammatory TH1 cells and thus reduce expression of type 1 inflammatory cytokines, as well as the auto inflammatory TH17 pathway.[79,80,98]

Importantly, high dose vitamin D has been shown to reduce the neutrophil to lymphocyte ratio (NLR), and CRP pro-inflammatory levels.[95]

NLR has been shown in several COVID-19 studies, including a meta-analysis, to be an independent risk factor for COVID-19 disease severity and mortality.[96,97]

A strong association exists between vitamin D deficiency among COVID-19 patients with ARDS with some studies reporting vitamin D deficiency in 81% of patients.[99]

Position – The evidence for therapeutic application of vitamins A, C, D, E and the mineral zinc as primary clinical strategic responses to COVID-19 diagnosis is overwhelming. At minimum, determining the vitamin D status for every hospital admission should be standard procedure, and all admissions with a serologic vitamin D status below 50 ng/ml should be administered an oral loading dose of vitamin D3 as follows: (1) Days 1 to 4 – 20,000 to 50,000 IU/day, (2) Days 5 to 14 – 5,000 to 10,000 IU, (3) Days 15 to discharge – 5,000 IUs.

For admissions with a serologic vitamin D status above 50 ng/ml, patients can be safely administered 5,000 IU/day of vitamin D3 orally to accelerate recovery and reduce hospital stays and medical expense.

In the position summary to conclude this topic, we will share a proposal for safe and effective nutritional guidance based upon the evidence presented for vitamins A, C, D, E and the mineral zinc by age.

Ivermectin – Evidence as An Effective Therapeutic Intervention

Peer-Reviewed Studies:

"Addition of Ivermectin to standard care is very effective drug for treatment of COVID-19 patients with significant reduction in mortality compared to Hydroxychloroquine plus standard treatment only. Early use of Ivermectin is very useful for controlling COVID 19 infections; prophylaxis and improving cytokines storm."

- https://www.researchsquare.com/article/rs-100956/v2

"One aspect that the NIH expert panel may debate is on the grade of recommendation that should be assigned to ivermectin. Based on the NIH rating scheme, the strongest recommendation possible would be an A-I in support of ivermectin which requires "one or more randomized trials with clinical outcomes and/or laboratory endpoints." Given that data from 16 randomized controlled trials (RCTs) demonstrate consistent and large improvements in "clinical outcomes" such as transmission rates, hospitalization rates, and death rates, it appears that the criteria for an A-I level recommendation has been exceeded."

- https://covid19criticalcare.com/wp-content/uploads/2020/11/FLCCC-Ivermectin-in-the-prophylaxis-and-treatment-of-COVID-19.pdf

"We report here that Ivermectin, an FDA-approved anti-parasitic previously shown to have broad-spectrum anti-viral activity in vitro, is an inhibitor of the causative virus (SARS-CoV-2), with a single addition to Vero-hSLAM cells 2 h post infection with SARS-CoV-2 able to effect ~5000-fold reduction in viral RNA at 48 h."

- https://www.sciencedirect.com/science/article/pii/S0166354220302011
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7129059/

"Viral clearance was treatment dose- and duration-dependent. In six randomized trials of moderate or severe infection, there was a 75% reduction in mortality (Relative Risk=0.25 [95%CI 0.12-0.52]; p=0.0002); 14/650 (2.1%) deaths on ivermectin; 57/597 (9.5%) deaths in controls) with favorable clinical recovery and reduced hospitalization."

- https://europepmc.org/article/PPR/PPR268166
- Full text: https://assets.researchsquare.com/files/rs-148845/v1_stamped.pdf

Publication Note: many of the studies used in the meta-analysis were not peer-reviewed.

"Raw data for asymptomatic family close contacts of confirmed COVID patients show that 2 doses of ivermectin 72 h apart resulted in only 7.4% of 203 subjects reporting symptoms of SARS-CoV-2 infection, in contrast to 101 control untreated subjects, of whom 58.4% reported symptoms; evidence of prophylaxis by ivermectin."

- https://clinicaltrials.gov/ct2/show/NCT04422561

"Recovery rate of the 28 patients that received ivermectin/AZM/cholecalciferol was 100%, with mean symptomatic recovery 3.6 days (negative PCR confirmed day 10). Imaging on day 10 showed improvement in all patients with pneumonia. Authors conclude the combination therapy might mitigate disease progression without significant adverse effects, but further studies required (preferably controlled)."

- https://www.alliedacademies.org/articles/effects-of-ivermectinazithromycincholecalciferol-combined-therapy-on-covid19-infected-patients-a-proof-of-concept-study-14435.html

"Raw data shows a significant reduction in the number of 183 patients with late clinical recovery (requiring >12 days to show clinical improvement) in the ivermectin/DOC group compared to placebo (23 versus 37.2%), as well as a significant reduction (8.7 versus 17.8%) in patients showing clinical deterioration (from mild/moderate to moderate or severe), and a significant reduction (7.7 versus 20%) in persistent Covid-19 positive patients at 14 days compared to 180 control patients; evidence of efficacy for ivermectin/DOC."

- https://clinicaltrials.gov/ct2/show/results/NCT04523831

"Professor Borody says his research has led him to a triple therapy of Ivermectin, zinc and an antibiotic – which are all TGA and FDA approved – which could be the fastest and safest way to stop the Victorian outbreak within 6-8 weeks…The therapy comprises:

1. Ivermectin – TGA and FDA approved as an anti-parasitic therapy with an established safety profile since the 1970s. Known as the "Wonder Drug" from Japan.

2. Zinc

3. Doxycycline – TGA and FDA approved tetracycline antibiotic that fights infections, such as acne, urinary tract infections, intestinal infections, respiratory infections, eye infections, gonorrhea, chlamydia, syphilis, periodontitis (gum disease), and others."

- https://www.miragenews.com/wonder-drug-ivermectin-in-a-triple-therapy-should-be-used-for-covid-19-cure-and-prevention/

“The effect of ivermectin on viral clearance was most pronounced in the randomized trials evaluating doses of up to five days of ivermectin treatment, using doses of 0.4mg/kg (Figure 1). At these doses, there were statistically significant effects on viral clearance in all four randomized trials.”

Figure 1: Effects of ivermectin on time to viral clearance

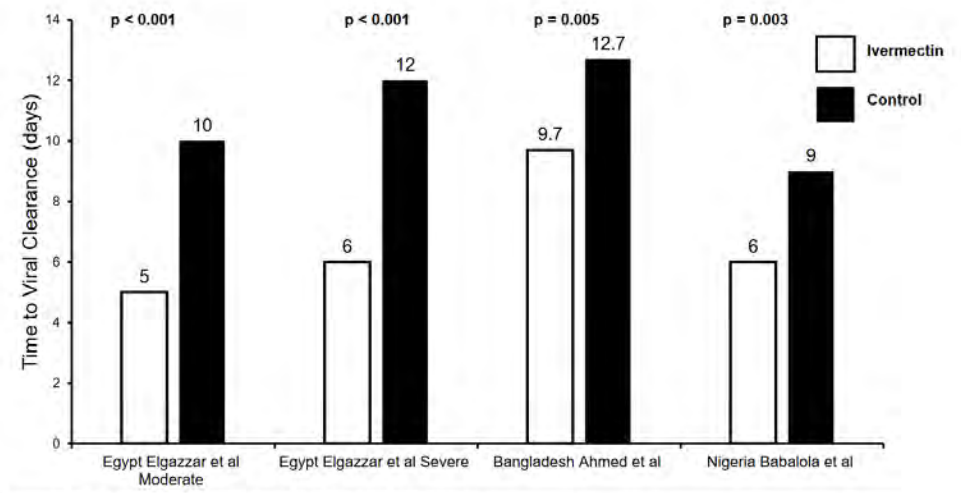


Figure 1: Effects of ivermectin on time to viral clearance

- https://assets.researchsquare.com/files/rs-148845/v1_stamped.pdf

“Several studies reported antiviral effects of ivermectin on RNA viruses such as Zika, dengue, yellow fever, West Nile, Hendra, Newcastle, Venezuelan equine encephalitis, chikungunya, Semliki Forest, Sindbis, Avian influenza A, Porcine Reproductive and Respiratory Syndrome, Human immunodeficiency virus type 1, and severe acute respiratory syndrome coronavirus 2.”

- https://www.nature.com/articles/s41429-020-0336-z

“...Among the many mechanisms by which it performs its function, the most consolidated one sees ivermectin as an inhibitor of nuclear transport mediated by the importin α/β1 heterodimer, responsible for the translocation of various viral species proteins (HIV-1, SV40), indispensable for their replication. This inhibition appears to affect a considerable number of RNA viruses...Ivermectin could prove to be a powerful antiviral, therefore also useful for a possible treatment of the new corona- virus associated syndrome, even from a new perspective. This could happen assuming its role as an ionophore agent...”

- https://link.springer.com/content/pdf/10.1007/s00210-020-01902-5.pdf

"A scoping review revealed that ivermectin has demonstrated inhibitory effects against RNA and DNA viruses, thereby opening the doors for further research and development particularly in treating the respiratory viral infections."

- https://journaljammr.com/index.php/JAMMR/article/download/30512/57209

Anecdotal Evidence/Case Reports:

"In Bangladesh, a team of medical doctors reportedly had "astounding" success in treating patients suffering from COVID-19 with two commonly used drugs, doxycycline and ivermectin. Dr Tarek Alam from the Bangladesh Medical College Hospital, and one of the senior members of the team, reportedly stated that a combination of the two drugs were administered to 60 patients, all of whom experienced full recoveries within four days."

- https://zeenews.india.com/india/covid-19-cure-in-sight-bangladeshi-doctors-claim-ivermectin-with-doxycycline-can-treat-coronavirus-patients-2285317.html

"Doctors have administered the drug ivermectin in several simultaneous trials in several countries sometimes in combination with other common medications.

Physicians who participated in the study report that patients' viral loads began declining almost immediately after they began administering ivermectin, a widely available prescription drug approved to combat parasites, scabies, and head lice.

It has not been approved for COVID-19 patients, but doctors familiar with clinical trials described patients' results as dramatic."

- https://www.newsmax.com/t/newsmax/article/968688?section=us&keywords=ivermectin-drug-virus&year=2020&month=05&date=22&id=968688&oref=m.facebook.com

HCQ – Evidence as An Effective Therapeutic Intervention

Lancet Retraction of Hydroxychloroquine Study

On June 4, 2020, the Lancet, billed as 'the world's leading independent medical journal', issued a public apology after being forced to retract a study that said the anti-malarial drug hydroxychloroquine did not help to curb COVID-19 and might cause death in patients.

The study was withdrawn because the company that provided data for the retracted study refused to provide full access to a request for data from independent investigators so they could perform a more extensive peer-review. The company that balked at fulfilling the data request said to do so would violate client agreements and confidentiality requirements.

The Lancet statement reads:

> ***"Based on this development, we can no longer vouch for the veracity of the primary data sources. Due to this unfortunate development, the authors request that the paper be retracted."***
>
> https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(20)31180-6.pdf
>
> https://www.webmd.com/lung/news/20200605/lancet-retracts-hydroxychloroquine-study

Hydroxychloroquine Meta-Analysis (192 studies)

- HCQ is effective when used early in the course of SARS-CoV-2 infection. Early treatment is most successful, with 100% of studies reporting a positive effect and an estimated reduction of 67% in the effect measured (death, hospitalization, etc.) using a random effects meta-analysis (RR 0.33 [0.25-0.43]).
- 91% of randomized controlled trials (RCTs) for early, PrEP, or PEP treatment report positive effects, the probability of this happening for an ineffective treatment is 0.0059%.
- There is evidence of bias towards publishing negative results. 88% of prospective studies report positive effects and only 75% of retrospective studies do.
- Studies from North America are 3.8 times more likely to report negative results than studies from the rest of the world combined (p = 0.00000017). "The probability that an ineffective treatment generated results as positive as the 192 studies to date is estimated to be 1 in 1 quadrillion (p = 0.00000000000000097)."

  https://hcqmeta.com

Hydroxychloroquine Meta-Analysis (43 studies)

"HCQ is consistently effective against COVID-19 when provided early in the outpatient setting, it is overall effective against COVID-19, it has not produced worsening of disease and it is safe."

- https://www.sciencedirect.com/science/article/pii/S2052297520301281

"This study demonstrated that voluntary HCQ consumption as pre-exposure prophylaxis by HCWs is associated with a statistically significant reduction in risk of SARS- CoV-2."

- https://www.medrxiv.org/content/10.1101/2020.06.09.20116806v1

4+ doses of HCQ is associated with a significant decline in the odds of getting infected, and a dose-response relationship exists.

- https://www.ijmr.org.in/article.asp?issn=0971-5916;year=2020;volume=151;issue=5;spage=459;epage=467;aulast=Chatterjee

"…the risk analysis showed that HCQ is also useful as a prophylactic agent for people over 50 years of age. This study, therefore, provides evidence of the necessity for higher-order analytics (such as MCA) in the presence of large data sets that include unknown confounders."

- https://www.researchgate.net/publication/344369617_Hydroxychloroquine_as_Post-Exposure_Prophylaxis_for_Covid-19_Why_simple_data_analysis_can_lead_to_the_wrong_conclusions_from_well-designed_studies

90% reduction in cases with HCQ pre-exposure prophylaxis. Retrospective 604 healthcare workers. "The use of HCQ as preexposure prophylaxis in HCWs was associated with reduced risk of COVID-19, suggesting its role as an effective chemoprophylactic agent."

- https://www.marinemedicalsociety.in/article.asp?issn=0975-3605;year=2020;volume=22;issue=3;spage=98;epage=104;aulast=Mathai

Study of SARS-CoV-2-IgG antibodies in 1122 health care workers finds 87% lower positives with HCQ prophylaxis, 1.3% HCQ versus 12.3% for no HCQ prophylaxis. Adequate prophylaxis is defined as 400mg 1/wk for >6 weeks.

- https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3689618

Retrospective study, 616 patients. "The use of hydroxychloroquine at an early stage is a potential therapeutic strategy for treating patients before irreversible severe respiratory complications occur. The early use of hydroxychloroquine decreased the improvement time and the duration of COVID-19 detection in throat and stool swabs."

- https://www.jstage.jst.go.jp/article/bst/advpub/0/advpub_2020.03340/_article/-char/ja/

"…both HCQ and azithromycin can be helpful to promote the recovery of most patients and reduced their signs and symptoms significantly. It also shows some manageable side effects mostly those related to heart rhythm. In the absence of FDA-approved medications to treat COVID-19, the repurposing of HCQ and azithromycin to control the disease signs and symptoms can be useful."

- https://onlinelibrary.wiley.com/doi/10.1111/ijcp.13856

"The authors' analysis suggested that hydroxychloroquine, with or without azithromycin, was associated with a reduced hazard ratio for death when compared with receipt of neither medication."

- https://www.sciencedirect.com/science/article/pii/S1201971220305300

"... patients treated with HCQ at the time of early hospital recovered faster than those who treated later..."

- https://onlinelibrary.wiley.com/doi/abs/10.1002/jmv.26193

100% reduction in hospitalization and cases with early treatment using HCQ+AZ+zinc. "HCQ could possibly provide protection against infection with SARS-CoV-2 (prophylaxis), and could, if used early, help to control the COVID-19 infection (treatment)."

- https://www.sciencedirect.com/science/article/pii/S2052297520301657

"…treatment of COVID-19 outpatients as early as possible after symptom onset using triple therapy, including the combination of zinc with low-dose hydroxychloroquine, was associated with significantly fewer hospitalisations." 79% lower mortality and 82% lower hospitalization with early HCQ+AZ+Z treatment.

- https://www.sciencedirect.com/science/article/pii/S0924857920304258

Retrospective study of 2,882 patients in China, showing that HCQ treatment can reduce systemic inflammation and inhibit the cytokine storm, thus protecting multiple organs from inflammatory injuries.

Note: The significantly lower dose used here is potentially related to the different observations from the RECOVERY trial results.

- https://link.springer.com/article/10.1007/s11427-020-1782-1

"Our findings suggest that patients confirmed of COVID-19 infection should be administrated HCQ as soon as possible."

- https://icjournal.org/DOIx.php?id=10.3947/ic.2020.52.3.396

"... for [time to clinical recovery] TTCR, the body temperature recovery time and the cough remission time were significantly shortened in the HCQ treatment group. Besides, a larger proportion of patients with improved pneumonia in the HCQ treatment group (80.6%, 25 of 31) compared with the control group (54.8%, 17 of 31)."

- https://www.medrxiv.org/content/10.1101/2020.03.22.20040758v3

"By administering hydroxychloroquine combined with azithromycin, we were able to observe an improvement in all cases, except in one patient who arrived with an advanced form, who was over the age of 86, and in whom the evolution was irreversible. For all other patients in this cohort of 80 people, the combination of hydroxychloroquine and azithromycin resulted in a clinical improvement that appeared superior when compared to outcomes of other hospitalised patients, as described in the literature."

- https://www.sciencedirect.com/science/article/pii/S1477893920301319#bib18

"In the present study, multivariate analysis performed using Cox regression modeling and propensity score matching to control for potential confounders affirmed that treatment with hydroxychloroquine alone and hydroxychloroquine in combination with azithromycin was associated with higher survival among patients with COVID-19. Patients that received neither medication or azithromycin alone had the highest cumulative hazard."

- https://www.sciencedirect.com/science/article/pii/S1201971220305348

"A total of 3,119 patients received HCQ-AZ for at least three days. QTc prolongation (>60 ms) was observed in 25 patients (0.67%), resulting in discontinuation of treatment in 12 cases, including three cases with QTc> 500 ms. No cases of torsade de pointe or sudden death were observed, including in the 9.5% of patients over 65 years of age…

Our current observations and practices illustrate the efficacy of this risk management procedures associated with the prescription of HCQ-AZ, which presents an excellent safety profile in COVID-19 patients, including elderly patients."

- https://www.sciencedirect.com/science/article/pii/S0924857920304556

"Our findings show that hydroxychloroquine is safe for COVID-19 and not associated with a risk of ventricular arrhythmia due to drug-induced QTc interval prolongation. Additionally, hydroxychloroquine was well tolerated, and there were no drug-related non-serious adverse events leading to treatment discontinuation in the majority of patients who were stable and did not require hospitalization."

- https://www.sciencedirect.com/science/article/pii/S0735675720311335

"HCQ administration is safe for a short-term treatment for patients with COVID-19 infection regardless of the clinical setting of delivery, causing only modest QTc prolongation and no directly attributable arrhythmic deaths."

- https://academic.oup.com/europace/article/22/12/1855/5910968

"Data from 3 outpatient COVID-19 trials demonstrated that gastrointestinal side effects were common but mild with the use of hydroxychloroquine, while serious side effects were rare. No deaths occurred related to hydroxychloroquine."

- https://academic.oup.com/ofid/article/7/11/ofaa500/5930834

"This comparative analysis of coronavirus infection and death among 2.4 billion persons around the world demonstrates a wide (two orders of magnitude or one hundred-fold) disparity in coronavirus fatality rates between well-developed and less-developed countries….The current data demonstrates the surprising fact that those in more affluent countries are about one hundred times more likely to become infected with coronavirus infection and die. This effect is most apparent when these countries are compared to countries with the highest rates of endemic malaria…..the mortality data presented here is highly probative for the hypothesis that prophylactic antimalarial use by its incoming visitors markedly attenuates a country's coronavirus fatality rate."

- https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3586954

Global Survey of Front-Line Physicians

- 85% said that hydroxychloroquine is at least somewhat effective for COVID-19.
- Hydroxychloroquine was the most utilized treatment for COVID-19 patients.
- 35%-40% of the doctors using the drug called it very effective or extremely effective against COVID-19.
- 65% of doctors said they would prescribe hydroxychloroquine for COVID-19 to their family members.

  https://wattsupwiththat.com/2020/07/07/hydroxychloroquine-based-covid-19-treatment-a-systematic-review-of-clinical-evidence-and-expert-opinion-from-physicians-surveys/

Remdesivir

"By way of comparison, the 13% mortality observed in this remdesivir compassionate-use cohort is noteworthy, considering the severity of disease in this patient population; however, the patients enrolled in this compassionate-treatment program are not directly comparable to those studied in these other reports. For example, 64% of remdesivir-treated patients were receiving invasive ventilation at baseline, including 8% who were receiving ECMO, and mortality in this subgroup was 18% (as compared with 5.3% in patients receiving noninvasive oxygen support), and the majority (75%) of patients were male, were over 60 years of age, and had coexisting conditions...Specifically, improvement in oxygen-support status was observed in 68% of patients, and overall mortality was 13% over a median follow-up of 18 days."

- https://www.nejm.org/doi/10.1056/NEJMoa2007016

"There was a strict correlation (Spearman test, p 0.017) between the position of doctors towards hydroxychloroquine and the average amount paid to them by the company Gilead Sciences between 2013 and 2019. In all, only 13 doctors out of 98 CMIT members did not receive any benefit, remuneration or agreement from the Gilead Sciences company between 2013 and 2019. Among these 13 doctors, seven were very favourable to the use of hydroxychloroquine, one was favourable, one was neutral and four have not taken a position. In contrast, among the 13 doctors that received the most important funding from Gilead Sciences, six were very unfavourable to the use of hydroxychloroquine, one was unfavourable, three were neutral and three had not taken a position."

"None of the studies involving remdesivir or lopinavir/ritonavir could show any effectiveness of these drugs in the prevention of mortality or the reduction of the viral load of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), whereas four studies have now shown significant differences in clinical course, radiological course, mortality and viral load for hydroxychloroquine."

- https://www.sciencedirect.com/science/article/pii/S2052297520300627?via%3Dihub

Effective Treatments for COVID Position

Modern medical practice is at a pivotal crossroads. The inclusion of evidence-based nutritional research and biochemistry must become an integral component of modern medical practice.

Despite 73% of medical schools not meeting the National Academy of Sciences minimal recommendation of 25 contact hours for nutritional education, nutritional medicine plays an essential role in the health of a nation.[110]

This includes nutritional medicine's role in disease prevention and treatment. What is currently ordained as accepted medical treatment has historically been reserved for patentable, and therefore profitable, pharmaceuticals and technologies.

The inherent bias of patent/profit-centric medicine is not synonymous with therapeutic efficacy. To the contrary, the exclusion of evidence-based nutritional science, as well as off label inexpensive drugs, severely restricts the practice of medicine. The exclusion of evidence-based nutritional science does not allow healthcare providers to practice patient-centric, personalized medicine.

If modern conventional medicine no longer envisions itself as personalized and patient-centric, then it has abdicated its primary duty to humanity to be of ethical and moral service to the people of the world.

During a global health crisis, once the most vulnerable populations are established, it is the essential duty and responsibility of federal, state, and county health agencies to disseminate evidence-based guidance to ensure the most vulnerable are as well protected as possible. However, this was not the case with COVID-19.

Guidance for evidence-based hygiene was initially disseminated. Guidance for masking of healthy people was disseminated without evidence. Guidance for social distancing of healthy people was disseminated without evidence.

Yet, guidance for clinical nutrition was inexplicably never shared with the American public or medical professionals despite the overwhelming abundance of evidence of its efficacy. Nutrition is proven to not only prevent the spread of the SARS-CoV-2 virus, but it is also uniquely positioned to accelerate recovery times and reduce severe adverse events. In a series of public health policy failures, history may view the failure to inform the public and medical professionals regarding nutrition as the most egregious failure.

Evidence-based information must be disseminated to promote health within the population. Failure to inform the public of efficacious treatment/prevention options such as vitamin D, vitamin C, vitamin A, vitamin E, zinc, ivermectin, and hydroxychloroquine during a crisis goes beyond unethical and enters the territory of potentially criminal behavior.

This failure to inform is aggravated when it is buttressed by letters to medical practitioners from the FDA threatening to suspend licenses for using evidence-based therapeutics, and national media campaigns actively censor any professional discussion of the efficacy of the aforementioned evidence-based treatments for COVID-19.

How many lives could have been saved? How much faster could this crisis have been concluded had nutrition been the primary strategy for nationwide mitigation and treatment?

These concerns are made even more troubling when one realizes that the CDC knew for more than 20 years that Americans were significantly nutrient deficient in key immune nutrients and did nothing to resolve it.

Under the pretext of a chronic disease epidemic, where 10% of the nation’s population is diabetic, at least 73% of our citizens are overweight or obese, and healthcare costs for chronic disease exceed 2.8 trillion dollars annually (which comprises 86% of all healthcare costs in the United States), it is unconscionable that the CDC and FDA failed Americans regarding nutritional guidance.

How difficult is it to issue basic nutritional guidance for vitamins and minerals in addition to guidance, hygiene, masking of the symptomatic, and social distancing for the symptomatic?

The collaborative efforts between federal agencies should have additionally resulted in the initiation of a series of basic nutrition, exercise, and supplement guidelines for the underprivileged, malnourished, and chronically ill Americans, whom these agencies knew were at a high-risk of dying.

At minimum, the issuance of nutritional guidance and recommendation of vitamin D prophylactically, especially upon admission for hospital care, would have helped flatten the curve.[14]

Vitamin C administration could have been used to enhance the rate of recovery in hospitals, as evidenced by meta-analysis research, which identified that vitamin C administration reduces ICU stays by 7.8-8.6% and time on mechanical ventilation by 14-18.2% for severe respiratory infections.[31,35,36]

Given that the projected cost of vitamin C administration in hospitals is $12-24 per day, there is no ethical or economic reason why the evidence surrounding vitamin C is being willfully ignored by federal, state, and county health agencies.[37]

Well over 12 months into the COVID-19 crisis, a large body of peer-reviewed evidence has been amassed that causally links vitamin D deficiency to the risk of disease severity, mortality, and ICU overwhelm.

A considerable body of literature directly places vitamin D deficiency at the front-row-center position in terms of the pathophysiology of SARS-CoV-2 infectivity, subsequent cytokine storms, ARDS, pulmonary edema, and severe respiratory complications, particularly among those in the high-risk demographics (60 years of age with major comorbidities).

Furthermore, ongoing clinical trials have demonstrated significant promise for vitamin D analogues, such as Calcifediol to reduce ICU overwhelm, reduce mortality, and enhance recovery from COVID-19.

The CDC had a duty and responsibility to utilize NHANES data to protect Americans. At the very least, by May/June 2020, the CDC had the duty and responsibility to ensure that every hospital admission was serologically tested for vitamin D deficiencies and provide guidance to medical professionals to ensure this easily correctible correlation to outcome was not overlooked.

Is the CDC so entrenched in the profitability of disease that they have lost their basic humanity?

Why were safe and effective treatments withheld from Americans who needed them the most? Why were so many opportunities to resolve this crisis missed? Incompetence? Willful neglect? Over reliance on a single experimental strategy?

We hope the reasons behind this epic failure of public health policy and strategy is ultimately proven to be gross, well-intentioned incompetence, and over reliance on a single experimental strategy. We are unable to objectively rule out willful neglect, corruption, and greed at this time.

Even after the former director of the CDC, Dr. Tom Frieden, announced in the media that vitamin D supplementation can likely help COVID-19 patients, and may improve resistance to infection, neither the CDC nor the FDA made any official statements to the public to correct course.[17]

In fact, the CDC has exhibited a pattern of willful neglect in their dealings with elected officials attempting to correct gross misstatements they have made to the American people.[107]

Perhaps it is time that the public finally acknowledges the fact that the CDC is a multinational corporation with locations in 61 countries around the world.[108]

Withholding evidence-based treatments is not only unethical, but also it is tantamount to being criminal.

We find that withholding evidence-based treatment from people in dire need constitutes a clear dereliction of duty to the American public the CDC and FDA are sworn to serve.

The CDC's fiscal year budget for 2018 was $11.9 billion dollars. The CDC received an additional $500 million in funding through the CARES Act in 2020. The amount allocated to states for nutritional guidance and education is minuscule by comparison compared to what has been allocated for PCR testing, the promotion of the Asymptomatic Transmission theory, and experimental COVID biologic development.

If serologic vitamin D testing had been performed for every hospital admission, it could have led to the immediate collection of a large and statistically significant body of data that in turn, could have been utilized to guide healthcare professionals on what was working rather than holding out hope for a warp speed experimental COVID biologic to swoop in and save the day.

Yet, it is nutritional guidance that is desperately needed for a nation trapped in a year-long crisis.

Proposal for Safe & Effective Nutritional Guidance

Note: Therapeutic range is a compilation of the following resources:

- Suggested Optimal Nutrient Allowance (SONAs)
- Linus Pauling Institute Micronutrient Research Center
- Summary of well-known Naturopathic clinical texts (Murray, Pizzorno, Marz, Mateljan, Etc.)
- Pubmed & Google Scholar research updates, Thorne research, Pure Encapsulations research, research of trusted nutraceutical companies
- Observations in clinical practice shared and confirmed by colleagues & student practitioners since 2007 (n>3500).
- Recommending use of supplementation from reputable companies with at least one of the following certifications for purity and potency: cGMP, NSF, USP, UL, NonGMO Project, or ConsumerLabs.

Seniors, Adults, & Teens

KEY NUTRIENTS	THERAPEUTIC RANGE	RDA
VITAMIN A (Beta-Carotene)	5,000 IU	1,500-2,167 IU
VITAMIN C	3000-5000 mg	65-125 mg
VITAMIN D3	10,000 IU (14-Days) 5,000 IU (After)	600-800 IU
VITAMIN E	200-600 IU	22-28 IU
ZINC	25-40 mg (min 30mg for High-Risk)	8-11 mg

- Age 13 & Up
- For all genders
- Includes expecting mothers & breastfeeding mothers
- Nutrients should be taken with a small amount of food to minimize nausea
- Multivitamin & omega 3 fatty-acids recommended as well

Children Ages 5 to 12

KEY NUTRIENTS	THERAPEUTIC RANGE	RDA
VITAMIN A (Beta-Carotene)	5,000 IU	1,000-2,000 IU
VITAMIN C	2,000-4,000 mg	25-45 mg
VITAMIN D3	5,000 IU (14-Days) 2,000 IU (After)	200 IU
VITAMIN E	100 IU	10-17 IU
ZINC	25 mg	8 mg

- Age 5 to 12
- For all genders
- Nutrients should be taken with a small amount of food to minimize any nausea
- Multivitamin & omega 3 fatty-acids recommended as well

Children Ages 1 to 4

KEY NUTRIENTS	THERAPEUTIC RANGE	RDA
VITAMIN A (Beta-Carotene)	2,000 IU	1,000-1,500 IU
VITAMIN C	500-1,000 mg	15-50 mg
VITAMIN D3	1,000-2,000 IU	200 IU
VITAMIN E	50 IU	6-9 IU
ZINC	10 mg	3 mg

- Age 1 to 4
- For all genders
- For infants no longer breastfeeding
- Liquid multivitamin & omega 3 fatty-acids recommended as well

Topic References

1. Arvinte, C.; Singh, M.; Marik, P.E. Serum levels of vitamin C and vitamin D in a cohort of critically ill COVID-19 patients of a north American community hospital intensive care unit in May 2020: A pilot study. Med. Drug Discov. 2020, doi:10.1016/j.medidd.2020.100064

2. Luis Chiscano-Camón, Juan Carlos Ruiz-Rodriguez, Adolf Ruiz-Sanmartin, Oriol Roca, Ricard Ferrer; Vitamin C levels in patients with SARS-CoV-2-associated acute respiratory distress syndrome; Crit Care: 2020 Aug 26;24(1):522. doi: 10.1186/s13054-020-03249-y.

3. Robert A. Jacob, PhD, FACN, Gity Sotoudeh, MSPH; Vitamin C Function and Status in Chronic Disease; Nutrition in Clinical Care; First published: 18 June 2002: https://doi.org/10.1046/j.1523-5408.2002.00005.x

4. Panel on Dietary Antioxidants and Related Compounds, Institute of Medicine. Chapter 5: Vitamin C. In: Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids. A Report of the Institute of Medicine. Washington, DC: National Academy Press; 2000:95–185.

5. Harris JR, ed. Ascorbic acid: biochemistry and biomedical cell biology. In: Subcellular Biochemistry. New York, NY: Plenum Press; 1996:vol. 25.

6. Kopecki D, Higgins-Dunn N, and Miller H; CDC tells people over 60 or who have chronic illnesses like diabetes to stock up on goods and buckle down for a lengthy stay at home. CNBC, March 2020.

7. NY State Department of Health COVID-19 Fatalities Dashboard: May 4, 2020

8. Mooradian AD. Effect of ascorbate and dehydroascorbate on tissue uptake of glucose. Diabetes, 1987; 36:1001–1004.

9. K.D. Price, C.S.C Price, R.D. Reynolds: Hyperglycemia-induced latent scurvy and atherosclerosis: The scorbutic-metaplasia hypothesis; Medical Hypotheses, Volume 46, Issue 2, February 1996, Pages 119-129; https://www.sciencedirect.com/science/article/abs/pii/S0306987796900110

10. Ozra Tabatabaei-Malazy, Shekoufeh Nikfar, Bagher Larijani, Mohammad Abdollahi; Influence of Ascorbic Acid Supplementation on Type 2 Diabetes Mellitus in Observational and Randomized Controlled Trials; A Systematic Review with Meta-Analysis: J Pharm Pharm Sci (www.cspsCanada.org) 17(4) 554 - 582, 2014

11. Delvarianzadeh M, Abbasian M, Norouzi P. Effect of vit C supplement on fasting blood glucose and plasma lipid level in type II diabetic patients. Knowledge and Health, 2008; 3: 39- 43.

12. Mohammad Afkhami-Ardekani, Ahmad Shojaoddiny-Ardekani; Effect of vitamin C on blood glucose, serum lipids & serum insulin in type 2 diabetes patients; Indian J Med Res. 2007 Nov;126(5):471-4. https://pubmed.ncbi.nlm.nih.gov/18160753/

13. Provisional Death Counts for COVID-19, Table 3: CDC, https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm#Comorbidities

14. Marcos Pereira, Alialdo Dantas Damascena, Laylla Mirella Galvão Azevedo, Tarcio de Almeida Oliveira & Jerusa da Mota Santana (2020) Vitamin D deficiency aggravates COVID-19: systematic review and meta-analysis, Critical Reviews in Food Science and Nutrition, DOI: 10.1080/10408398.2020.1841090

15. Wei, J., Zhu, A. & Ji, J.S. A Comparison Study of Vitamin D Deficiency among Older Adults in China and the United States. *Sci Rep* **9,** 19713 (2019). https://doi.org/10.1038/s41598-019-56297-y

16. Reider, C. A., Chung, R.-Y., Devarshi, P. P., Grant, R. W., & Hazels Mitmesser, S. (2020). Inadequacy of Immune Health Nutrients: Intakes in US Adults, the 2005–2016 NHANES. Nutrients, 12(6), 1735. doi:10.3390/nu12061735

17. Tom Friedman, MD: Former CDC Chief Dr. Tom Frieden: Coronavirus infection risk may be reduced by Vitamin D, https://www.foxnews.com/opinion/former-cdc-chief-tom-frieden-coronavirus-risk-may-be-reduced-with-vitamin-d

18. Fraudulent Coronavirus Disease 2019 (COVID-19) Products, FDA https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products

19. Guixiang Zhaoa, Earl S. Forda, Chaoyang Lib, and Janet B. Croft; Serum 25-hydroxyvitamin D levels and all-cause and cardiovascular disease mortality among US adults with hypertension: the NHANES linked mortality study; Journal of Hypertension 2012, 30:284–289. DOI:10.1097/HJH.0b013e32834e1f0a

20. Yeo Jin Choi 1,Sang-Min Jeon, Sooyoung Shin; Impact of a Ketogenic Diet on Metabolic Parameters in Patients with Obesity or Overweight and with or without Type 2 Diabetes: A Meta-Analysis of Randomized Controlled Trials; Nutrients 2020, 12(7), 2005; https://doi.org/10.3390/nu12072005

21. Jatupol Kositsawat & Vincent L Freeman (2011) Vitamin C and A1c Relationship in the National Health and Nutrition Examination Survey (NHANES) 2003–2006, Journal of the American College of Nutrition, 30:6, 477-483, DOI: 10.1080/07315724.2011.10719993

22. Matthias Rath M.D. and Linus Pauling Ph.D; A Unified Theory of Human Cardiovascular Disease Leading the Way to the Abolition of This Disease as a Cause for Human Mortality; Journal of Orthomolecular Medicine Vol. 7, No. 1, 1992; http://orthomolecular.org/library/jom/1992/pdf/1992-v07n01-p005.pdf

23. Horgan, J (1993). "Profile: Linus C. Pauling – Stubbornly Ahead of His Time". Scientific American. **266** (3): 36 40. Bibcode:1993SciAm.266c..36H. doi:10.1038/scientificamerican0393-36

24. Carr AC, Frei B. Toward a new recommended dietary allowance for vitamin C based on antioxidant and health effects in humans. Am J Clin Nutr. 1999;69: 1086–1107

25. May JM. How does ascorbic acid prevent endothelial dysfunction? Free Radic Biol Med. 2000;28:1421–1429.

26. Grossmann M, Dobrev D, Himmel HM, Ravens U, Kirch W. Ascorbic acid-induced modulation of venous tone in humans. Hypertension. 2001;37:949–954

27. Duffy SJ, Gokce N, Holbrook M, et al. Effect of ascorbic acid treatment on conduit vessel endothelial dysfunction in patients with hypertension. Am J Physiol Heart Circ Physiol. 2001;280:H528–H534.

28. Hirashima O, Kawano H, Motoyama T, et al. Improvement of endothelial function and insulin sensitivity with vitamin C in patients with coronary spastic angina. J Am Coll Cardiol. 2000;35:1860–1866.

29. Schleicher R. L. et al. Serum vitamin C and the prevalence of vitamin C deficiency in the United States: 2003–2004 National Health and Nutrition Examination Survey (NHANES). Am J Clin Nutr, August 2009.

30. Nutri-Facts: https://www.nutri-facts.org/en_US/news/u-s---nhanes.html

31. Holford, Carr, Jovic, Ali, Whitaker, Marik, Smith: Vitamin C—An Adjunctive Therapy for Respiratory Infection, Sepsis and COVID-19; Nutrients 2020, 12(12), 3760; https://doi.org/10.3390/nu12123760

32. Jacob RA. Chapter 29: Vitamin C. In: Shils ME, Ol- son JA, Shike M, Ross AC, eds. *Modern Nutrition in Health and Disease*. 9th ed. Baltimore, MD: Williams & Wilkins; 1999:467–483.

33. Catherine M Loria, Michael J Klag, Laura E Caulfield, Paul K Whelton; Vitamin C status and mortality in US adults; The American Journal of Clinical Nutrition, Volume 72, Issue 1, July 2000, Pages 139–145, https://doi.org/10.1093/ajcn/72.1.139

34. Joel A. Simon, Esther S. Hudes and Warren S. Browner; Serum Ascorbic Acid and Cardiovascular Disease Prevalence in U.S. Adults; Epidemiology; Vol. 9, No. 3 (May, 1998), pp. 316-321 (6 pages), https://www.jstor.org/stable/3703063

35. Harri Hemilä Elizabeth Chalker; Vitamin C Can Shorten the Length of Stay in the ICU: A Meta-Analysis: Nutrients 2019, 11(4), 708; https://doi.org/10.3390/nu11040708

36. Hemilä, H., Chalker, E. Vitamin C may reduce the duration of mechanical ventilation in critically ill patients: a meta-regression analysis. *j intensive care* **8,** 15 (2020). https://doi.org/10.1186/s40560-020-0432-y

37. Anderson PS (2020) Intravenous ascorbic acid for supportive treatment in hospitalized COVID-19 patients. J Orthomol Med. 35(1)

38. David Brownstein, M.D., Richard Ng, M.D., Robert Rowen, M.D., Jennie-Dare Drummond, PA, Taylor Eason, NP, Hailey Brownstein, D.O., and Jessica Brownstein; A Novel Approach to Treating COVID-19 Using Nutritional and Oxidative Therapies; Science, Public Health Policy, and The Law Volume 2:4-22 July, 2020; Clinical and Translational Research: https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864_cc5004cfa84a46d3b1a0338d4308c42c.pdf

39. Harri Hemilä Pekka Louhiala; Vitamin C for preventing and treating pneumonia; Cochrane database of systemic reviews; August 8, 2013: https://doi.org/10.1002/14651858.CD005532.pub3

40. Carr, Spencer, Dixon, Chambers: Patients with Community Acquired Pneumonia Exhibit Depleted Vitamin C Status and Elevated Oxidative Stress; Nutrients 2020, 12(5), 1318; https://doi.org/10.3390/nu12051318

41. Kumar A, Arora A, Sharma P. Is diabetes mellitus associated with mortality and severity of COVID-19? A meta-analysis. Diabetes Metab Syndr Clin Res Rev. 2020;14:535–545.

42. Li B, Yang J, Zhao F. Prevalence and impact of cardiovascular metabolic diseases on COVID-19 in China. Clin Res Cardiol. 2020;109:531–538

43. Fadini GP, Morieri ML, Longato E, Avogaro A. Prevalence and impact of diabetes among people infected with SARS-CoV-2. J Endocrinol Invest. 2020;43:867–869

44. Petrilli CM, Jones SA, Yang J. Factors associated with hospitalization and critical illness among 4,103 patients with COVID-19 disease in New York City. BMJ. 2020 https//:doi.org.10.1101/2020.04.08.32444366 published online April 11.

45. Roncon L, Zuin M, Rigatelli G, Zuliani G. Diabetic patients with COVID-19 infection are at higher risk of ICU admission and poor short-term outcome. J Clin Virol. 2020;127

46. Zhou F, Yu T, Du R. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. Lancet. 2020;395:1054–1062

47. Zhu L, She ZG, Cheng X. Association of blood glucose control and outcomes in patients with COVID-19 and pre-existing type 2 diabetes. Cell Metab. 2020;31:1068–1077

48. Yang J, Zheng Y, Gou X. Prevalence of comorbidities and its effects in coronavirus disease 2019 patients: a systematic review and meta-analysis. Int J Infect Dis. 2020;94:91–95.

49. Matteo Apicella, MD,a,† Maria Cristina Campopiano, MD,a,† Michele Mantuano, MD,a,† Laura Mazoni, MD,a,† Alberto Coppelli, MD,b and Stefano Del Prato, Prof, MDa,; COVID-19 in people with diabetes: understanding the reasons for worse outcomes; Lancet Diabetes Endocrinol. 2020 Sep; 8(9): 782–792. Published online 2020 Jul 17. doi: 10.1016/S2213-8587(20)30238-2

50. National Diabetes Statistics Report, 2020; CDC; National Diabetes Statistics Report, 2020

51. Cariou, B., Hadjadj, S., Wargny, M. *et al.* Phenotypic characteristics and prognosis of inpatients with COVID-19 and diabetes: the CORONADO study. *Diabetologia* **63,** 1500–1515 (2020). https://doi.org/10.1007/s00125-020-05180-x

52. Yan Mengac,Hao Bai et al: Efficacy of low carbohydrate diet for type 2 diabetes mellitus management: A systematic review and meta-analysis of randomized controlled trials; Diabetes Research and Clinical Practice Volume 131, September 2017, Pages 124-131; https://doi.org/10.1016/j.diabres.2017.07.006

53. Joshua Z Goldenberg, research, Andrew Day, Grant D Brinkworth, professor, Junko Sato, professor, Satoru Yamada, Tommy Jönsson, professor, Jennifer Beardsley, Jeffrey A Johnson, professor, Lehana Thabane, professor, , Bradley C

Johnston, associate professor; Efficacy and safety of low and very low carbohydrate diets for type 2 diabetes remission: systematic review and meta-analysis of published and unpublished randomized trial data; BMJ 2021;372:m4743; https://doi.org/10.1136/bmj.m4743

54. Snorgaard O, Poulsen GM, Andersen HK, et alSystematic review and meta-analysis of dietary carbohydrate restriction in patients with type 2 diabetesBMJ Open Diabetes Research and Care 2017;5:e000354. doi: 10.1136/bmjdrc-2016-000354

55. Yuan, X., Wang, J., Yang, S. *et al.* Effect of the ketogenic diet on glycemic control, insulin resistance, and lipid metabolism in patients with T2DM: a systematic review and meta-analysis. *Nutr. Diabetes* **10,** 38 (2020). https://doi.org/10.1038/s41387-020-00142-z

56. Pan, B., Ge, L., Xun, Yq. *et al.* Exercise training modalities in patients with type 2 diabetes mellitus: a systematic review and network meta-analysis. *Int J Behav Nutr Phys Act* **15,** 72 (2018). https://doi.org/10.1186/s12966-018-0703-3

57. Grace, A., Chan, E., Giallauria, F. *et al.* Clinical outcomes and glycaemic responses to different aerobic exercise training intensities in type II diabetes: a systematic review and meta-analysis. *Cardiovasc Diabetol* **16,** 37 (2017). https://doi.org/10.1186/s12933-017-0518-6

58. Lee, JH., Lee, R., Hwang, MH. *et al.* The effects of exercise on vascular endothelial function in type 2 diabetes: a systematic review and meta-analysis. *Diabetol Metab Syndr* **10,** 15 (2018). https://doi.org/10.1186/s13098-018-0316-7

59. Liu L, Wei W, Yang K, et al. Glycemic control before admission is an important determinant of prognosis in patients with coronavirus disease 2019. J Diabetes Investig. 2020. 10.1111/jdi.13431.

60. Liu Z, Bai X, Han X, et al. The association of diabetes and the prognosis of COVID-19 patients: a retrospective study. Diabetes Res Clin Pract. 2020;169:108386.

61. Wang Z, Du Z, Zhu F. Glycosylated hemoglobin is associated with systemic inflammation, hypercoagulability, and prognosis of COVID-19 patients. Diabetes Res Clin Pract. 2020;164:108214 10.1016/j.diabres.2020.108214.

62. De Faria Coelho-Ravagnani, C., Corgosinho, F. C., Sanches, F. L. F. Z., Prado, C. M. M., Laviano, A., & Mota, J. F. (2020). Dietary recommendations during the COVID-19 pandemic. Nutrition Reviews. doi:10.1093/nutrit/nuaa067

63. Adult Obesity Prevalence Maps; CDC: https://www.cdc.gov/obesity/data/prevalence-maps.html

64. Yingyu Chen, Xiao Gong, Lexun Wang, Jiao Guo; Effects of hypertension, diabetes and coronary heart disease on COVID-19 diseases severity: a systematic review and meta-analysis; medRxiv 2020.03.25.20043133; doi: https://doi.org/10.1101/2020.03.25.20043133

65. Raymond Pranata, Michael Anthonius Lim,1 Ian Huang,Sunu Budhi Raharjo, and Antonia Anna Lukito; Hypertension is associated with increased mortality and severity of disease in COVID-19 pneumonia: A systematic review, meta-analysis and meta-regression; J Renin Angiotensin Aldosterone Syst. 2020 Apr-Jun; 21(2): 1470320320926899. Published online 2020 May 14. doi: 10.1177/1470320320926899

66. Holford, P., Carr, A. C., Jovic, et al. Vitamin C—An Adjunctive Therapy for Respiratory Infection, Sepsis and COVID-19. Nutrients, 12(12), 2020 3760. doi:10.3390/nu12123760

67. Chuen Wen Tan, Liam Pock Ho, Shirin Kalimuddin, Benjamin Pei Zhi Cherng, Yii Ean Teh, Siew Yee Thien, Hei Man Wong, Paul Jie Wen Tern, Manju Chandran, Jason Wai Mun Chay, Chandramouli Nagarajan, Rehena Sultana, Jenny Guek Hong Low, Heng Joo Ng; A cohort study to evaluate the effect of combination Vitamin D, Magnesium and Vitamin B12 (DMB) on progression to severe outcome in older COVID-19 patients; medRxiv 2020.06.01.20112334; doi: https://doi.org/10.1101/2020.06.01.20112334

68. Rastogi A, Bhansali A, Khare N*, et al*Short term, high-dose vitamin D supplementation for COVID-19 disease: a randomised, placebo-controlled, study (SHADE study)*Postgraduate Medical Journal* Published Online First: 12 November 2020. doi: 10.1136/postgradmedj-2020-139065

69. Philip M. Carlucci, Tania Ahuja, Christopher Petrilli, Harish Rajagopalan, Simon Jones, and Joseph Rahimian; Zinc sulfate in combination with a zinc ionophore may improve outcomes in hospitalized COVID-19 patients; J Med Microbiol. 2020 Oct; 69(10): 1228–1234. Published online 2020 Sep 15. doi: 10.1099/jmm.0.001250

70. Nutrition advice for adults during the COVID-19 outbreak: World Health Organization, Regional office for the Eastern Mediterranean: http://www.emro.who.int/nutrition/nutrition-infocus/nutrition-advice-for-adults-during-the-covid-19-outbreak.html

71. Obesity, Race/Ethnicity, and COVID-19: CDC; https://www.cdc.gov/obesity/data/obesity-and-covid-19.html

72. Sara Åkerström, Mehrdad Mousavi-Jazi, Jonas Klingström, Mikael Leijon, Åke Lundkvist, and Ali Mirazimi; Nitric Oxide Inhibits the Replication Cycle of Severe Acute Respiratory Syndrome Coronavirus; J Virol. 2005 Feb; 79(3): 1966–1969. doi: 10.1128/JVI.79.3.1966-1969.2005

73. Peter G. Barlow,Pavel Svoboda,Annie Mackellar,Anthony A. Nash,Ian A. York,Jan Pohl,Donald J. Davidson ,Ruben O. Donis; Antiviral Activity and Increased Host Defense against Influenza Infection Elicited by the Human Cathelicidin LL-37; Published: October 21, 2011 https://doi.org/10.1371/journal.pone.0025333

74. Peter G. Barlow,Pavel Svoboda,Annie Mackellar,Anthony A. Nash,Ian A. York,Jan Pohl,Donald J. Davidson ,Ruben O. Donis; Antiviral Activity and Increased Host Defense against Influenza Infection Elicited by the Human Cathelicidin LL-37; Published: October 21, 2011 https://doi.org/10.1371/journal.pone.0025333

75. Bergman P, Walter-Jallow L, Broliden K, Agerberth B, Söderlund J. The antimicrobial peptide LL-37 inhibits HIV-1 replication. Curr HIV Res. (2007) 5:410–5. 10.2174/157016207781023947

76. Lee C-J, Buznyk O, Kuffova L, Rajendran V, Forrester VJ, Phopase J, et al. . Cathelicidin LL-37 and HSV-1 corneal infection: peptide versus gene therapy. Transl Vis Sci Technol. (2014) 3:4. 10.1167/tvst.3.3.4

77. Arboleda Alzate JF, Rodenhuis-Zybert IA, Hernández JC, Smit JM, Urcuqui-Inchima S; Human macrophages differentiated in the presence of vitamin D3 restrict dengue virus infection and innate responses by downregulating mannose receptor expression. PLoS Negl Trop Dis. 2017 Oct; 11(10):e0005904.

78. Aida Malek Mahdavi; A brief review of interplay between vitamin D and angiotensin-converting enzyme 2: Implications for a potential treatment for COVID-19; medical virology; 25 June 2020 https://doi.org/10.1002/rmv.2119

79. Sharifi, A.; Vahedi, H.; Nedjat, S.; Rafiei, H.; Hosseinzadeh-Attar, M.J. Effect of single-dose injection of vitamin D on immune cytokines in ulcerative colitis patients: A randomized placebo-controlled trial. APMIS 2019, 127, 681–687.

80. Gombart, A.F.; Pierre, A.; Maggini, S. A Review of Micronutrients and the Immune System-Working in Harmony to Reduce the Risk of Infection. Nutrients 2020, 12, 236.

81. Hadis Musavi , Omid Abazari , Zeinab Barartabar , Fatemeh Kalaki-Jouybari , Mohsen Hemmati-Dinarvand , Parisa Esmaeili & Soleiman Mahjoub (2020): The benefits of Vitamin D in the COVID-19 pandemic: biochemical and immunological mechanisms, Archives of Physiology and Biochemistry, DOI: 10.1080/13813455.2020.1826530

82. de Haan, K., Groeneveld, A.J., de Geus, H.R. et al. Vitamin D deficiency as a risk factor for infection, sepsis and mortality in the critically ill: systematic review and meta-analysis. Crit Care 18, 660 (2014). https://doi.org/10.1186/s13054-014-0660-4

83. Shi Y, Liu T, Yao LI, et al. Chronic vitamin D deficiency induces lung fibrosis through activation of the renin-angiotensin system. Sci Rep. 2017;7:3312.

84. Tomaschitz A, Pilz S, Ritz E, et al. Independent association between 1,25-dihydroxyvitamin D, 25-hydroxyvitamin D and the renin- angiotensin system: the Ludwigshafen risk and cardiovascular health (LURIC) study. Clin Chim Acta. 2010;411:1354-1360.

85. Daneshkhah, A., Agrawal, V., Eshein, A. et al. Evidence for possible association of vitamin D status with cytokine storm and unregulated inflammation in COVID-19 patients. Aging Clin Exp Res 32, 2141–2158 (2020). https://doi.org/10.1007/s40520-020-01677-y

86. Li YC, Qiao G, Uskokovic M, Xiang W, Zheng W, Kong J. Vitamin D: a negative endocrine regulator of the renin-angiotensin system and blood pressure. J Steroid Biochem Mol Biol. 2004;89-90:387-392.

87. Li YC, Kong J, Wei M, Chen ZF, Liu SQ, Cao LP. 1,25- Dihydroxyvitamin D(3) is a negative endocrine regulator of the renin- angiotensin system. J Clin Invest. 2002;110:229-238.

88. Schett G, Sticherling M, Neurath MF. COVID-19: risk for cytokine targeting in chronic inflammatory diseases? Nat Rev Immunol. 2020;20(5):271-272.

89. 94Baeke F, Takiishi T, Korf H, Gysemans C, Mathieu C. Vitamin D: modulator of the immune system. Curr Opin Pharmacol. 2010;10(4):482-496.

90. Van de Veerdonk F, Netea MG, van Deuren M, et al. Kinins and Cytokines in COVID-19: A Comprehensive Pathophysiological Approach. (2020).

91. Machado CDS, Ferro Aissa A, Ribeiro DL, Antunes LMG. Vitamin D supplementation alters the expression of genes associated with hypertension and did not induce DNA damage in rats. J Toxicol Environ Health A. 2019;82(4):299-313.

92. Xiao, L.; Sakagami, H.; Miwa, N. ACE2: The key Molecule for Understanding the Pathophysiology of Severe and Critical Conditions of COVID-19: Demon or Angel? Viruses 2020, 12, 491. https://doi.org/10.3390/v12050491

93. Yan Chun Li, Guilin Qiao, Milan Uskokovic, Wei Xiang, Wei Zheng, Juan Kong,Vitamin D: a negative endocrine regulator of the renin–angiotensin system and blood pressure, The Journal of Steroid Biochemistry and Molecular Biology, Volumes 89–90, 2004, Pages 387-392,ISSN 0960-0760,https://doi.org/10.1016/j.jsbmb.2004.03.004.\

94. Castillo, M. E., Entrenas Costa, L. M., Vaquero Barrios, J. M., Alcalá Díaz, J. F., Miranda, J. L., Bouillon, R., & Quesada Gomez, J. M. (2020). "Effect of Calcifediol Treatment and best Available Therapy versus best Available Therapy on Intensive Care Unit Admission and Mortality Among Patients Hospitalized for COVID-19: A Pilot Randomized Clinical study." The Journal of Steroid Biochemistry and Molecular Biology, 105751. doi:10.1016/j.jsbmb.2020.105751

95. Tabatabaeizadeh, S.-A., Avan, A., Bahrami, A., Khodashenas, E., Esmaeili, H., Ferns, G.A., Abdizadeh, M.F. and Ghayour-Mobarhan, M. (2017), High Dose Supplementation of Vitamin D Affects Measures of Systemic Inflammation: Reductions in High Sensitivity C-Reactive Protein Level and Neutrophil to Lymphocyte Ratio (NLR) Distribution. J. Cell. Biochem., 118: 4317-4322. https://doi.org/10.1002/jcb.26084

96. Lagunas-Rangel, F.A. (2020), Neutrophil-to-lymphocyte ratio and lymphocyte-to-C-reactive protein ratio in patients with severe coronavirus disease 2019 (COVID-19): A meta-analysis. J Med Virol, 92: 1733-1734. https://doi.org/10.1002/jmv.25819

97. Yuwei Liu, Xuebei Du, Jing Chen, Yalei Jin, Li Peng, Harry H.X. Wang, Mingqi Luo, Ling Chen, Yan Zhao,Neutrophil-to-lymphocyte ratio as an independent risk factor for mortality in hospitalized patients with COVID-19,Journal of Infection,Volume 81, Issue 1,2020,Pages e6-e12,ISSN 0163-4453,https://doi.org/10.1016/j.jinf.2020.04.002.

98. Aygun, H. Vitamin D can prevent COVID-19 infection-induced multiple organ damage. Naunyn-Schmiedeberg's Arch Pharmacol 393, 1157–1160 (2020). https://doi.org/10.1007/s00210-020-01911-4

99. Carpagnano, G.E., Di Lecce, V., Quaranta, V.N. et al. Vitamin D deficiency as a predictor of poor prognosis in patients with acute respiratory failure due to COVID-19. J Endocrinol Invest (2020). https://doi.org/10.1007/s40618-020-01370-x

100. Doris Loh: Townsend Letter; https://www.townsendletter.com/article/online-covid-19-ards-cell-free-hemoglobin-ascorbic-acid-connection/

101. Meng L, Zhao X, Zhang H. HIPK1 interference attenuates inflammation and oxidative stress of acute lung injury via autophagy. Med Sci Monitor Int Med J Exp Clin Res. 2019;25:827 835.

102. Patel V, Dial K, Wu J, et al. Dietary antioxidants significantly attenuate hyperoxia-induced acute inflammatory lung injury by enhancing macrophage function via reducing the accumulation of airway HMGB1. Int J Mol Sci 2020;21(3). doi:10.3390/ijms21030977

103. Cheng RZ, Kogan M, Davis D. Ascorbate as Prophylaxis and Therapy for COVID-19—Update From Shanghai and U.S. Medical Institutions. Global Advances in Health and Medicine. January 2020. doi:10.1177/2164956120934768

104. Calder, P.C.; Carr, A.C.; Gombart, A.F.; Eggersdorfer, M. Optimal Nutritional Status for a Well-Functioning Immune System Is an Important Factor to Protect against Viral Infections. Nutrients 2020, 12, 1181. https://doi.org/10.3390/nu1204118

105. Drake, V.; Angelo, G. Overview of the Immune System. Linus Pauling Institute 2010-2021. https://lpi.oregonstate.edu/mic/health-disease/immunity

106. Ebrahimi N, Aslani S, Babaie F, et al. Recent findings on the Coronavirus disease 2019 (COVID-19); immunopathogenesis and immunotherapeutics. Int Immunopharmacol. 2020;89(Pt B):107082. doi:10.1016/j.intimp.2020.107082

107. Full Measure CDC Investigation based upon transcripts between Congressman Thomas Massie and representatives from the CDC. http://fullmeasure.news/news/cover-story/cdc-investigation

108. Centers for Disease Control and Prevention, 'Where We Work'. https://www.cdc.gov/globalhealth/countries/default.htm

109. Monaco, K. 'Over 73% of U.S. Adults Overweight or Obese' Medpage Today, Dec 2020. https://www.medpagetoday.com/primarycare/obesity/90142

110. Adams KM, Kohlmeier M, Zeisel SH. Nutrition education in U.S. medical schools: latest update of a national survey. Acad Med. 2010;85(9):1537-1542. doi:10.1097/ACM.0b013e3181eab71b https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4042309/

111. Kaufman HW, Niles JK, Kroll MH, Bi C, Holick MF (2020) SARS-CoV-2 positivity rates associated with circulating 25-hydroxyvitamin D levels. PLoS ONE 15(9): e0239252. https://doi.org/10.1371/journal.pone.0239252

People Worthy of Our Remembrance

Hayden Hunstable, 12 Died by Suicide

"What I remember is hugging him," Brad Hunstable said. "I miss kissing him on the head and feeling his hair. I miss playing football with him. I miss joking around with him and wrestling." There's so much to miss for a dad who is missing his son.

"My son died from the coronavirus as I mentioned," Hunstable says in his online video. "But not in the way you think. The isolation... there's no doubt in my mind [it] had an affect," he said. "No doubt in my mind there was something missing."

https://www.10tv.com/article/news/local/ohio-state-alum-shares-story-childs-suicide-tells-parents-covid-19-isolation-real-2020-may/530-c62f7060-3775-448a-bfd9-d21ad5aeeca5

Topic 4 – Violations of Federal Law & Data Quality

Topic Introduction – There is nothing more important to public health policy development than accurate and verifiable data. Decisions that will impact hundreds of millions of people have to be held to the highest standards of integrity. This responsibility to be impeccable from a data perspective takes on even greater importance during a nationwide and global crisis.

To ensure that data collected, analyzed, and published is always accurate and of the highest quality, various U.S. Congresses have displayed a visionary wisdom with the implementation of the Administrative Procedures Act (APA), Paperwork Reduction Act (PRA), and Information Quality Act (IQA) enacting federal laws that apply to all federal agencies and agents whether elected or appointed.

> **The Administrative Procedures Act** (5 U.S.C. Chapter 5) was first made federal law in 1946. The APA is responsible for (1) requiring agencies, including the FDA & CDC, to keep the public informed of how the agency is organized and functions to ensure transparency, (2) ensuring the public can participate in rulemaking through public comment, (3) establishing uniform standards for the formal means of rulemaking and addressing of concerns, and (4) defining the scope of judicial review so there is appropriate oversight over all agencies.
>
> **The Paperwork Reduction Act** (44 U.S.C. §§ 3501-3521, Public Law 96-511, 94 Stat. 2812) was first made federal law in 1980. Despite its name, the PRA is far more than a simple attempt to reduce paperwork. The PRA is responsible for establishing and empowering the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB). The PRA gives the OIRA the responsibility of federal oversight over all federal agencies to ensure each agency is in full compliance. An amendment to the PRA in 1995 (44 U.S.C. §§ 3501-3521, Public Law 104-13, 109 Stat. 182) explicitly empowered the OIRA with authority over all federal agencies for the collection, analysis, and publication of data. The PRA (44 U.S.C. §§ 3506 (c)(2)(A)) specifically requires all federal agencies to report any potential changes to data collection, analysis, and/or publication to the federal register to accomplish 2 compliance objectives: (1) notification of the OIRA of intention to make modifications to data and (2) launch of a 60-day opportunity for public comment and scientific review.
>
> **The Information Quality Act** (Section 515 of the Congressional Consolidation Appropriations Act, 2001 Public Law 106-554) was first made federal law in 2002. This federal law defined four key principles for information quality including: (1) quality, (2) objectivity, (3) utility, and (4) integrity.
>
> - **Quality** is defined as an encompassing term comprising objectivity, utility, and integrity.
> - **Objectivity** is defined as 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** is defined as the usefulness of the information for the intended audience's anticipated purposes, which is the basis for opening public comment.

- **Integrity** is defined as the security of the information from unauthorized modification to ensure the information is not compromised through corruption or falsification.

The brilliance of these 3 laws is that they ensure oversight that make corruption exceedingly difficult, but not impossible. These 3 laws demand all agencies to uniformly follow the same laws, protect public opportunities for participation in their own governance, create transparency, and ensure that the data being provided for public consumption is accurate, reliable, unbiased, clear, complete, useful, and free from intentional and unintentional modification.

These 3 laws, when strictly enforced, build public trust in our government.

However, when these 3 laws are violated, as the following paper alleges and substantiates, the vision for our country that great men and women created becomes blurry and dark.

We have laws for a reason, and these laws are intended to protect and serve the people of our great nation. All just laws such as these must always be followed. A global crisis is the opportunity to reaffirm the wisdom of these laws, not ignore, bypass, and disregard them as has occurred repeatedly and without any accountability to date.

Modifying Fatality Data Without Oversight or Public Comment

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

https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864_c39029cd980642e48797cdb2ef965972.pdf

Key Quotes – *"Supportive data comparisons suggest the existing COVID-19 fatality data, which has been so influential upon public policy, maybe substantially compromised regarding accuracy and integrity, and illegal under existing federal laws.*

The key to initiating legal regulatory oversight of all proposed changes to data collection, publication, and an analysis is the Federal Register.

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.

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."

Summary – On March 24, 2020 the CDC, by way of the National Vital Statistics System (NVSS), issued COVID-19 Alert No.2 that significantly changed how death certificate reporting would be submitted for all fatalities with probable or confirmed COVID-19 involvement. This change in data reporting was exclusive for COVID-19 and in direct contrast to the previous guidelines used nationwide for the previous 17 years. The previous guidelines can be found within the *2003 CDC Medical Examiners' & Coroners' Handbook on Death Registration and Fetal Death Reporting* and the *2003 CDC Physicians' Handbook on Medical Certification of Death*.

The major changes were as follows:

- *"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****."*

  For the previous 17 years pre-existing/comorbid conditions were reported in Part I, not Part II, which can impact statistical aggregation according to certified death reporting clerks interviewed. Additionally, in the presence of pre-existing/comorbid conditions, infectious disease that directly led to the fatality could be listed on the last line item in Part I as an initiating factor.

  However, that determination was always left to the discretion of the attending medical examiner, coroner, or physician who are far more familiar with the deceased patient's medical history.

  Additionally, if significant pre-existing/comorbid conditions were present making the patient more susceptible to infections, these were more commonly entered in Part II as contributing factors rather than causative factors in Part I.

  The point of contention of this change is that it was made without official notification in the federal register to initiate federal oversight and mandatory public comment.

- *"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****."*

  This quote tells the medical professional filling out the certificate of death what the cause of death is EXPECTED to be more often than not.

Not only is this presumptuous, but it also comes with the knowledge that the NVSS can reject any death certificate registration that they feel is in conflict with this alert or they can alter the final record without the knowledge of the signatory medical professional without oversight. This leaves the family of the deceased with the responsibility of correcting the public record should a grieving family member desire to take on more burden.

Additionally, one must objectively consider how COVID diagnoses are unethically incentivized financially for hospitals and congregate care centers where most of the reported fatalities have occurred.

Position – Laws in place, since 1946, are in place for a reason and must be followed, especially during times of crisis. Modifying certificate of death registration for only one disease greatly compromises the accuracy, clarity, and unbiased nature of the data. In doing so, it compromises the objectivity and renders the utility of the date virtually useless. Additionally, because the APA and PRA were procedurally violated, it calls into question the integrity of the data that effectively shaped the reactionary response to public health policy development.

Because fatalities associated with COVID are recorded differently than non-COVID associated fatalities, comparison between them for analysis is additionally compromised. The proverbial ability to compare apples (COVID) to apples (Flu) is impossible without correcting all certificates of death.

Nonetheless, there is hope.

Each fatality with a confirmed PCR test must have a record at the conducting lab of the date of the test and the cycle threshold value that determined the positive lab result. According to the published work of Dr. Jefferson, we know that replication-competent virus is unlikely above a Ct of 25 and certainly above 34.

If we were able to have the date of the death certificate, the date of the positive PCR, the Ct value that a signal was detected on the individual's PCR, and a basic knowledge of pre-existing/comorbid conditions, we could accomplish the following:

(1) For all reported fatalities associated with COVID, we could eliminate all presumptive fatalities

(2) Eliminate all fatalities from injury that were misclassified as COVID related

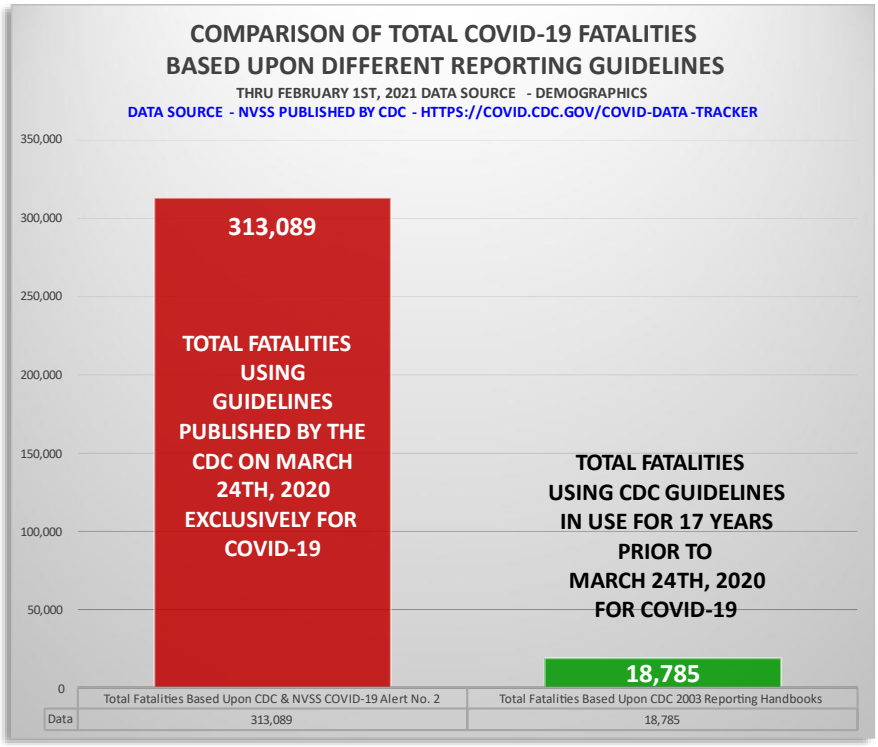
(3) Eliminate all fatalities with significant comorbid conditions as those conditions should have been listed in Part I

(4) Eliminate all certificates of death with a cycle threshold greater than 25 (conservatively, 34)

(5) Eliminate all certificates of death where the last positive PCR was more than 28 days before the day of death

This would provide a way to effectively correct death certificate reporting and clarify the number of deaths that could confidently be considered caused by COVID-19 versus the deaths attributable to pre-existing comorbidities where COVID-19 was not a significant contributor.

In August 2020, the CDC admitted that 94% of COVID fatalities had on average 2.6 major pre-existing comorbidities. Our previous statistical analysis from each individual state health department publishing comorbidity data through August ranged from an aggregate 90.8 to 95.2%, which was similar to the CDC's confirmation. Based upon this finding, and in light of our research into the appropriate 2003 medical examiner, coroner, and physician handbooks on death certificate reporting, we were able to extrapolate the following analysis in anticipation of what death counts would look like for COVID-19 had the 2003 guidelines been followed.



Modifying Case Data Without Oversight or Public Comment

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

https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864_c39029cd980642e48797cdb2ef965972.pdf

Key Quotes – *"Supportive data comparisons suggest the existing COVID-19 fatality data, which has been so influential upon public policy, maybe substantially compromised regarding accuracy and integrity, and illegal under existing federal laws.*

The key to initiating legal regulatory oversight of all proposed changes to data collection, publication, and an analysis is the Federal Register.

By employing a non-governmental organization (Council of State and Territorial Epidemiologists - 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.

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

Summary – Early into this crisis, the CDC apparently outsourced the definitions for diagnostic criteria to a little-known non-profit organization outside of federal government regulation known as the Council of State and Territorial Epidemiologists (CSTE). On April 14, 2020, the CDC adopted this position paper for which they provided subject matter experts but technically did not publish. Therefore, a question arises. Why would a federal agency like the CDC, with many respected PhDs, need to outsource the development of diagnostic criteria to a non-profit organization?

That does not immediately make sense unless in doing so, the CDC was attempting to bypass federal laws (APA & PRA) to bypass oversight and public comment. Even if other reasons arise, the CDC compromised the quality of the data collected, analyzed, and published in alleged violation of the IQA.

Below are the major flaws with the CSTE position paper that could have been unearthed with federal oversight and opportunity for public comment:

- **Failure to Prevent the Same Person from Being Counted as a New Case Multiple Times**

  "Criteria to distinguish a new case of this disease or condition from reports or notifications which should not be enumerated as a new case for surveillance. ***N/A until more virologic data are available.****"* (Section VII.B, Page 6)

  Position – In error, the presence or absence of data is not a requirement for ensuring the same person cannot be counted multiple times as new cases.

- **Asserting Asymptomatic Carriers Exist Without Scientific Proof or Citation**

  "Symptoms of COVID-19 are non-specific and the ***disease presentation can range from no symptoms (asymptomatic)*** *to severe pneumonia and death."* (Section VI.A, Page 3)

  Position – A statement such as this requires the application of the 5 gold-standards for medical intervention previously described in the Asymptomatic Transmission topic.

- **Defining 'Probable' Cases Based on Flimsy Medical 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."* (Section VII.A2, Page 5)

  Position – There are many pathologies that can lead to fever and chills, myalgia, headache, fever, and/or sore throat. These are not symptoms unique to COVID-19, and thus compromises the accuracy of the data. Additionally, there are MANY pathologies where a cough or shortness of breath or difficulty breathing are common symptoms. These are not symptoms unique to COVID-19. Radiographic evidence of pneumonia is not diagnostic for the cause of pneumonia. To assert that all of these qualify a patient to be diagnosed with COVID as a 'probable' or 'presumptive' case is not the way appropriate and accurate medical diagnoses occur. The CSTE position paper adopted by the CDC throws medical investigation out the window, and then incentivizes the COVID diagnosis above all other possibilities. This clearly compromises data accuracy and therefore quality.

  Applying these criteria greatly inflates case, hospitalization, and fatality data making it impossible to be reasonably confident that the data being collected, analyzed, and published is accurate for public health policy development.

- **Failure to Establish a Reasonable Cycle Threshold Value for Infectiousness**

  Position – Missing from this CSTE position paper is any discussion of cycle threshold (Ct) values even though molecular amplification is openly discussed to confirm a case. PCR testing, as it is currently utilized globally, cannot determine infectiousness, but it can produce an inordinate number of false positives where replication-competent virus is unable to be cultured. The CSTE would have been wise to state a recommended cycle threshold of 30 Ct based upon what is accepted as a reasonable Ct for other infectious respiratory disease.

- **Empowering Contact Tracers to Practice Medicine Without a License**

  *"In a person with clinically compatible symptoms with one or more of the following exposures in the 14 days before onset of symptoms: Travel to or residence in an area with sustained, ongoing community transmission of SARS-CoV-2; OR Close contact** with a person diagnosed with COVID-19; OR Member of a risk cohort as defined by public health authorities during an outbreak."* (Section VI.A3, Page 3)

  Position – While the HHS, FDA, and CDC are much more responsible for authorizing the creation of the contact tracing industry, the CSTE position paper laid the groundwork for its birth. Nowhere in this document is there concern for infectiousness, which is the key component required for precision curtailing of spread. Had there been legitimate concern for infectiousness, this document would have discussed the need for replication-competent virus

cell culture to calibrate PCR testing at the correct cycle threshold. Had there been legitimate concern for infectiousness, this document would have scoffed at any notion of 'probable' cases. Had there been legitimate concern for infectiousness, testing would have focused on antigen testing until the PCR is properly calibrated. Had there been legitimate concern for infectiousness, this paper would have never based diagnosis on such capricious criteria as what has been established for contact tracers. Contact tracers are empowered to diagnosis a person that they have never examined, or even spoken to, with COVID. This is a blatant violation of existing medical laws and only further compromises the accuracy, objectivity, utility, and integrity of the data being collected, analyzed, and published.

Additional Subtopic References

- CDC/NVSS COVID-19 Alert No. 2 issued March 24, 2020

  https://www.cdc.gov/nchs/data/nvss/coronavirus/Alert-2-New-ICD-code-introduced-for-COVID-19-deaths.pdf

- CSTE Position Paper adopted by CDC on April 14, 2020

  https://cdn.ymaws.com/www.cste.org/resource/resmgr/2020ps/Interim-20-ID-01_COVID-19.pdf

Federal Law & Data Quality Position

Oversight and protection of public participation in governance are hallmarks of the United States of America. They are a part of our DNA because they have worked for hundreds of years and what is not broken should not be discarded, only improved. Our country was born because the founding fathers were unable to participate effectively in their own governance and decisions were made unilaterally by an oligarch across an ocean without significant oversight for checks and balances.

Their experiences of impending tyranny gave them incredible insight on how to thwart corruption and protected public participation. While their early model was admittedly hypocritical and far from perfect, it was the beginning of a great nation, which was passed down from generation to generation. This has been demonstrated by the historical timeline from 1946 to 2002 of the three key federal laws enacted from three different generations of legislators as illustrated throughout this topic.

Yet in 2020, our elected and appointed officials have chosen to abandon what has worked so well for our country for centuries in favor of a private, 'we know what's best' mentality that has produced historical levels of collateral damage and severely injured the trust that citizens must have in their government to effectively co-exist and create a promising future for younger generations to emerge into.

In data analysis, there is a common colloquial phase, 'garbage in becomes garbage out.' What this means is that if the data that is entered is inaccurate then any calculations for analysis will also be inaccurate.

With COVID-19 Alert No.2 and the CSTE Position Paper, it is clear why oversight and the protection of public participation is essential to solving this crisis and the forward direction as a unified country. After all, how can a country be united when significant portions of the electorate do not trust the accuracy of the data or the people promoting the data as accurate?

Perhaps the best way to solve this problem is to start over and use the methods for data collection that have been used for all other infectious disease and then turn all efforts towards correcting death certificate reporting and case counts.

It is our duty to thoroughly investigate how this happened, who was responsible, and hold those responsible accountable to the strictest letter of the law so that this level of incompetence and malfeasance, if proven, will never happen again in a country where everyone's birthright is life, liberty, and the pursuit of happiness.

People Worthy of Our Remembrance

Irene Wright Died Alone

“I just felt helpless. Couldn't do nothing. Couldn't see her, couldn't go over there. Nothing I could do," Irene Wright’s daughter Geraldine Wiggins said. "The nurse was in the room and she answered the phone," Wiggins recalled. "I asked her if she could put the phone up against my mother's ear -- she did -- I said 'Mom, I want you to get well, and I love you.' She said, 'I love you too.' But Wright never recovered. Three days later she needed CPR, but Wiggins said it was too late. Wright died alone.”

https://abc11.com/coronavirus-covid-19-death-vance-county-dies-alone/6173081/

Topic 5 – Projection Models Lead Us Astray

Topic Introduction – Computer projection models have been used for decades to provide planners and decision-makers with important estimates of key statistics and to study how changes in assumptions may affect financial, health, ecological, and even social outcomes. As early as 1967, Klaus Dietz's paper "Epidemic and Rumours: A Survey" discussed the use of epidemic models for tracking ***"the propagation of ideas, rumours and consumers' goods."***

Because epidemic models can be used to track the spread of ideas as well as diseases, it is especially important for democratic nations to understand the nature of such models and how they can be used and abused.

Improvements in computing speed have made it possible to build more complex computer models and to use them to model increasingly complex phenomena. Today, it is possible to simulate individual behavior and to perform complex multivariate regression modeling of disease parameters that earlier model builders never imagined.

Improvements in computer languages and modeling tools have increased the availability of potential model builders and lowered the cost of model building.

As a result, computer projection models are ubiquitous today.

As with all computer programs, the phrase "garbage in, garbage out" applies to computer projection models. Model output quality depends entirely on how well the inputs and the internal algorithms fit the reality they are supposed to model. Unfortunately for modelers, reality is extremely complex.

Modelers are forced to make many assumptions that have a direct impact on the chosen modeling algorithm and the ultimate outcome. Due to the complex nature of these models, the assumptions made are simplified, and in a complex environment, these simplifications ultimately result in measurement error and face external validity threats. Assumptions allow the modeler to reduce the many uncertain factors that *influence* reality to a few easily measured quantities that can be used as inputs to the model. In addition, every computer program requires tradeoffs among speed, accuracy, ease of use, development time, development cost, program organization, and readability. Assumptions enable the modeler to make practical choices when programming the model's internal algorithms.

These decisions are made for ease of modeling and do not necessarily match reality.

At the start of an epidemic like COVID-19, it can be difficult to determine what assumptions are reasonable and more difficult to reliably measure key inputs. Unreasonable assumptions and inaccurate inputs lead to poor projections. For this reason, projection models are not reliable guides for policy decisions. In general, computer models are better used as part of a framework to design actual clinical trials and to refine measurement instruments.

Despite the impossibility of accurate modeling at the start of an epidemic, policymakers face intense pressure to take informed action. People want to know how the epidemic will unfold before it is

possible to predict. In earlier times kings facing an epidemic consulted specialists to interpret dreams, read tealeaves, toss bones, or roll dice to explain the future. Today policymakers hire specialists to develop computer projection models that incorporate mathematics, statistics, and computers.

The human desire to know the future has not changed, and neither has the blind faith in the modern approach to predicting the future works. Yet, even with new technologies that make people feel increasingly secure in the predictions being made; the future remains uncertain.

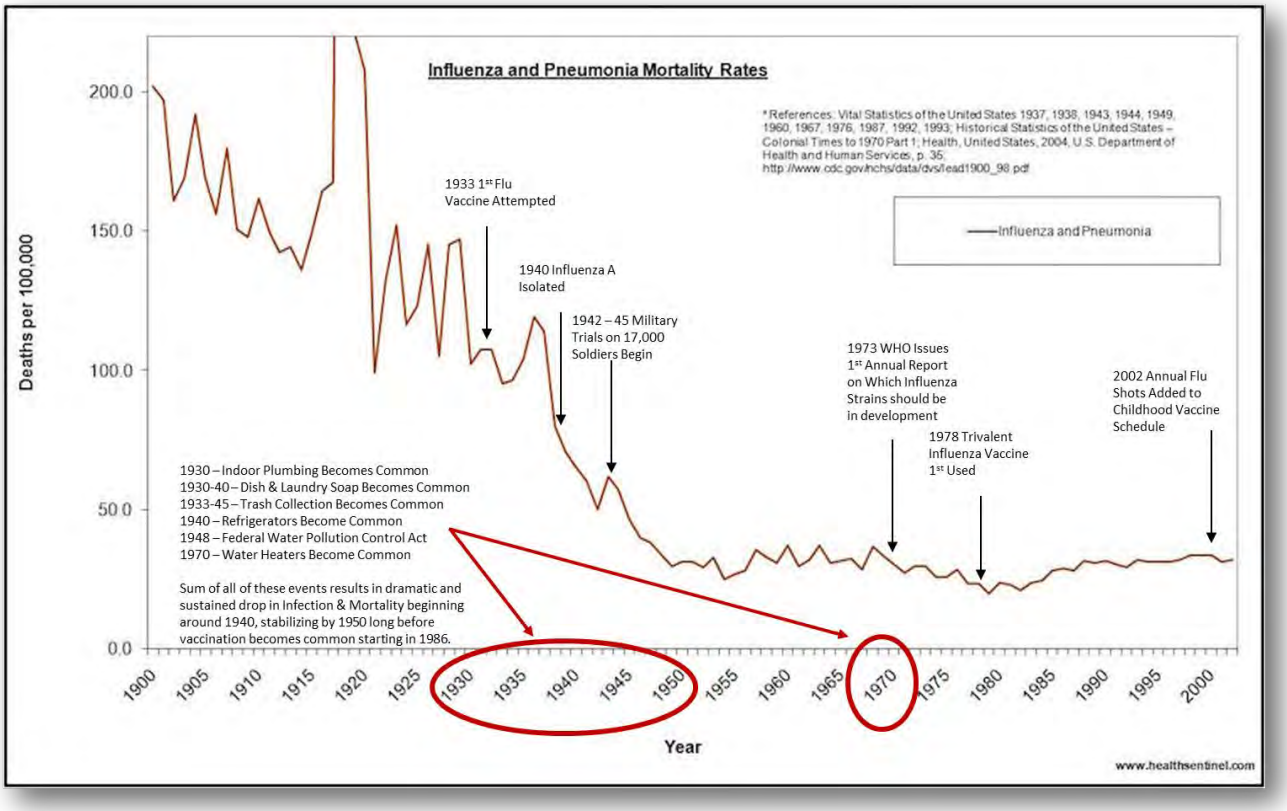
This strong human desire to predict the future, combined with technological advances, created a huge market for computer projection models. That market strongly believes that such models will provide useful projections if they can just get the assumptions and inputs correct.

One assumption, central to all current COVID-19 models, is that the spread of germs is the main factor in disease transmission, even though susceptibility to infection is the main factor. A related assumption is that people are equally susceptible to infection. In fact, susceptibility depends on variables such as available nutrient status, pre-existing conditions, age, genetic predispositions, socioeconomics, individual mental outlook, stress exposure, amount of sleep, bioaccumulation of chemical pollution, environmental exposure, place of residence, and a host of other factors unique to the individual. These aspects of reality are much harder to model than the germ 'reproduction rate.'

As a result, all disease projection models focus entirely on modeling the spread of germs, far from an exact science, and ignore the state of the bodies that the germs identify as susceptible hosts for infection. For example, age clearly influences the activity of many diseases, but often plays a limited role in most epidemiological models.

Other basic assumptions built into current projection models are that interventions like lockdowns, social distancing, and masks work to reduce transmission of germs. Such interventions have not been independently proven to do so. By building the assumption of expected success of these interventions into the model, it becomes impossible to use the model to test whether such interventions work as assumed.

Other assumptions are missing. It is well known that improved sanitation during the nineteenth century led to a significant reduction in deaths from infectious diseases. In fact, all major diseases were already in major decline before vaccines were introduced. Yet none of the current models can project the impact of environmental factors such as nutritional intervention, HVAC air purification, or reductions in chemical, air, or noise pollution on disease transmission or outcomes.



Current disease projection models are self-limiting and self-referential. If their fundamental assumptions are wrong, they cannot discover this fact. Instead, they discover that their projections do not fit the data.

The usual response to a mismatch between projections and actual data is to adjust the model to fit the data as new facts become known. Model designers confidently assert they have applied the scientific method to improve their model, and *now* the model gives better results. **They ignore the fact that their original model was simply wrong and so were its projections.**

Retrofitting a model to incorporate past data does not mean the model has become any better at forecasting. If that were so, the world would be filled with millionaires who invested based on financial models that fit the past performance of stocks; such models are plentiful, but millionaires are not. Disease modelers, like many investors, never question their fundamental assumptions.

Due to the demand for computer models as well as the supply of potential model builders, it is inevitable that model quality will be highly variable. It is also inevitable that models will sometimes be developed for situations where they are irrelevant and inaccurate. With many people involved, there will also be large variations in skill and knowledge. As a result, some people will misuse their models, and some will misinterpret the outputs. New features and new approaches have made epidemiological modeling much more complex, and the added complexity makes it more difficult for individuals to properly understand and assess model performance.

Computer projection models were widely adopted to deal with the COVID-19 health emergency from the onset of the pandemic. Everyone wanted to know the health impacts of COVID-19 would be long before it was possible to know. Those COVID-19 models led to policy decisions that have dramatically infringed upon people's lives and that have distanced people from their traditional constitutional rights around the world.

As stated earlier, mathematical modeling has great potential to support the design of strong clinical trials and measurement instruments, but projection models should not be used to make policy decisions. Projection models suffer from both internal and external validity threats, and the variable rates of measurement error built into the models are extremely hard to quantify.

It is reasonable to expect that policy decisions that have weighed so heavily on so many people's lives would rely on actual data rather than assumption-based computer models. If not, the policy makers certainly owe their citizens an explanation.

What Kinds of Disease Projection Models Are in Use?

Disease projection models can be described along several dimensions. Models can be macroscale or microscale, deterministic or stochastic, compartmental or phenomenological. In addition, models may eschew traditional biological approaches in favor of a purely data driven curve-fitting approach.

Macroscale vs. Microscale

Macroscale models deal with the entire population at once and use differential or algebraic equations to determine how fractions of the population change status from susceptible, to exposed, to infected, and hopefully to recovered. Traditional epidemiological models have been macroscale models.

In contrast, *microscale* models attempt to simulate interaction among either individuals or small groups of individuals in a population. Such models require much more computing power than macroscale models. They also require detailed assumptions about individuals that may affect disease transmission, and it can be difficult to estimate values for such assumptions.

Microscale models may use differential equations like a macroscale model, but more commonly use random numbers and probability distributions to model individual decisions and their consequences. Projections are usually average values of outputs obtained after running the microscale model many times. Unfortunately, microscale models, intended to better fit reality, are more complex and harder to validate than macroscale models.

Reference - Saltelli, Andrea; Funtowicz, Silvio (2014). "When all models are wrong". Issues in Science and Technology. 30 (2): 79–85.

Deterministic vs. Stochastic

In a *deterministic* model, the output of the model is fully determined by parameter values and initial conditions. Traditional epidemiological models solved three or more differential equations after estimating certain parameter values and making assumptions about starting values. Once such features are set, the model will always predict the same results.

Of course, at the outset of an epidemic, correct values for parameters cannot be known precisely. Hence, to be useful, a deterministic model must adjust its parameters as additional data becomes available. The adjusted parameters will produce a fixed result, but it will be different from a previously reported result using other parameters.

In contrast, *stochastic* models include randomness. The same set of parameter values and initial conditions can lead to different results. Reality includes a great deal of variation and seemingly random events that are best modeled using probabilities. A typical stochastic model uses probabilities to decide such things as whether someone becomes infected, how long they remain sick before recovery, or when they die.

Unfortunately, building probability estimates into a model adds complexity and requires either additional assumptions or separate statistical validation based on actual data. Typically, a stochastic model will be run many times and the outputs will be analyzed statistically to determine ranges of value for such numbers as expected new deaths or new cases.

Mechanistic vs. Phenomenological

Usually, the term *mechanistic* is used to describe a model in which biological processes are assumed to occur that explain disease data such as deaths or cases. Parameters are built into the model to describe the effect of those biological processes. Because the parameters have biological meanings, they can be independently derived from other aspects of the epidemic than the data the model is trying to describe. For example, a mechanistic model would not attempt to estimate its key parameters from counts of deaths, because dead people cannot infect anyone and so are no longer part of the model from a biological standpoint.

A *phenomenological* model is a *statistical* model, and the terms are interchangeable. A statistical model incorporates assumptions that certain factors influence observed outcomes like deaths, but the model does not require or specify a biological reason for the connection. The model uses statistical multivariate regression to find equations that best model the observed data given assumptions about and estimates of factors that influence the observed data. It assumes that past relationships among the factors of influence and the data will continue. The IHME model includes both mechanistic and statistical components and has been heavily criticized by traditional epidemiologists for its heavy reliance on statistical regression rather than the standard disease transmission concepts of biology.

Compartmental Models

Many models use compartments to organize either fractions of a population or individuals, and the compartmental approach has the longest history, dating back a century. Models that ground themselves in biological assumptions tend to use compartments to analyze disease transmission.

The usual compartments are S= susceptible to a disease; E= exposed but not yet contagious; I= infected and contagious; and R= formerly infectious, removed by death, recovery with immunity, or isolation. This set of compartments describes an SEIR model. Some modelers have added categories to account for temporary immunity of infants after birth, or temporary immunity after recovery. Traditionally the "(E) exposed" compartment reflected the time lapse between infection and the appearance of symptoms because traditional SEIR models associated the appearance of symptoms with the start of contagiousness.

SEIR models typically assume everyone starts out as equally susceptible to a virus. Modelers estimate a rate at which people become infected based on the available data. Infected people are initially considered exposed but not infectious, and the modeler must estimate how long it takes on average for someone to become infectious after exposure. The modeler also needs to estimate a recovery rate and a mortality rate among infected people, as well as how long it takes on average for people to recover or die. These various estimates are used as parameters in equations that allow the model to predict transitions across the population from the susceptible class to the exposed class to the infected class to the recovered class.

Any effort to model COVID-19 using an SEIR-type model runs into certain immediate difficulties because "cases" do not always indicate infectiousness, individuals are often isolated without proof of infectiousness, and if truly asymptomatic carriers exist, there is no clear way to determine a time from infection to infectiousness in such people. Each of these issues makes it hard to determine proper parameters for an SEIR model. These issues are discussed further below.

Curve-Fitting Approaches

A new curve-fitting approach to modeling has appeared with COVID-19.

CASE STUDY – The IHME and University of Texas Models

The popular IHME model is a product of the Institute for Health Metrics and Evaluation at the University of Washington. It is one of many ongoing disease management projects at IHME that have been made possible by large grants from the Bill and Melinda Gates Foundation.

According to the Foundation press release announcing a 2017 grant:

> *"The $279 million grant is the largest private donation in the university's history and continues a long tradition of critical investments in the University of Washington by the Gates Foundation, which include grant awards across its academic disciplines including library science, global*

health, education, law and others. As of January 25, 2017, the foundation has awarded the University of Washington over 250 grants totaling nearly $1.25 billion."

Reference Jan 25, 2017 - https://www.gatesfoundation.org/Media-Center/Press-Releases/2017/01/IHME-Announcement

According to Tim Schwab writing in The Nation in December 2020:

"Fueled by … funding from the Bill & Melinda Gates Foundation… the IHME has outgrown and overwhelmed its peers, most notably the World Health Organization (WHO), which previously acted as the global authority for health estimates."

"'In a relatively short period of time, the IHME has exerted a certain kind of hegemony or dominance on global health metrics production,' says Manjari Mahajan, a professor of international studies at the New School. 'It's a kind of monopoly of knowledge production, of how to know global health trends in the world. And that produces a concentration of…power that should make anybody uncomfortable.'"

"'It's quite impossible to criticize or indeed comment on their methods, since they are completely opaque,' says Max Parkin, from the International Network for Cancer Treatment and Research."

Reference - https://www.thenation.com/article/society/gates-covid-data-ihme/ "Are Bill Gates's Billions Distorting Public Health Data?"

This "completely opaque" IHME organization produced a highly popular COVID-19 projection model. The IHME model describes itself as a hybrid modeling approach ***"which incorporates elements of statistical and disease transmission models,"*** and states it is ***"grounded primarily in real-time data instead of assumptions about how the disease will spread."*** According to current documentation, ***"The primary model for estimating future infections and deaths is a mechanistic compartmental model….an SEIR model."***

Instead of estimating the biological parameters used in the equations of an SEIR model, the IHME model calculates values for parameters that the modelers claim are associated with COVID-19 transmission. These 'covariate' parameters include such things as social distancing mandates, population mobility, testing per capita, mask effectiveness and use, pneumonia seasonality, lower respiratory infection mortality, altitude, smoking, ambient particulate matter pollution, population density, and demography.

The model's documentation explains why such factors may be associated with the rate of transmission, and details how each is calculated. The calculation of each parameter estimate requires its own statistical mini model inside the overall IHME model.

Once these time-based parameter values are calculated, the IHME model uses multivariate regression to develop an equation connecting these parameters to the transmission rate. It then projects these

parameters into the future using several scenario-based assumptions and uses the projected parameter values to forecast future transmission intensity and future infections. The IHME model then uses these forecast infections to forecast deaths.

The documentation explains that the ***"final component of the modelling approach uses past, current, and future infections and deaths to estimate hospitalisations[sic], including estimates of ICU usage and invasive ventilation need."***

Reference - (https://static-content.springer.com/esm/art%3A10.1038%2Fs41591-020-1132-9/MediaObjects/41591_2020_1132_MOESM1_ESM.pdf - page 6)

IHME's current approach is significantly more complex than the approach used in early 2020. The model changed to better reflect the effect of government interventions on the curve of death rates.

In essence, the March/April 2020 version of the IHME model for COVID-19 used mortality data from Wuhan China, Italy, and Spain to develop a standardized COVID-19 mortality pattern. That pattern can be visualized as a type of bell curve showing newly reported deaths by time period. The model then used a short time sequence of local death data to estimate where on that graph a given city, state, or country fit at a given moment. It attempted to use the nearby shape of the standardized graph of deaths to project the future deaths for that jurisdiction. The early IHME model assumed that the pattern of deaths would be fairly similar across locations and was roughly shaped like a bell curve.

The original IHME model deviated significantly from conventional practice and was heavily criticized for doing so.

One sharply critical article from April 2020, for example, focused mostly on issues connected with the mortality data that drove the model—assumptions, sources, and reliability.

The authors also criticized the wide prediction bands offered by the model, suggesting that:

> "*Unaccounted sources of uncertainty arise from inaccurate temporal data on mortality and hospitalization counts; model misspecification, including parametrization[sic] choices; and inaccuracies in assumptions regarding the timing and effect of social distancing policies across regions.*"

The critics also took issue with the volatility of the IHME model projections, apparently failing to consider that a curve-fitting model would necessarily be more sensitive to changes in data than a model dependent on biological parameters.

The final criticism concerned misleading publicity surrounding the model's projections. Misleading publicity about epidemic projection models should concern everyone. The pressure to be the first to deliver a disease projection model is much like the pressure to deliver any new type of software in a competitive landscape.

The first researchers to deliver a model, even a bad one, get the most prestige, and their model becomes standard among public officials who watch each other's choices. At the beginning of an

epidemic, public officials are simultaneously desperate for "science" to justify their decisions, and incompetent to judge model quality. It is a prescription for hype and poor choices.

The authors concluded that:

> "*Ultimately, IHME's model may be reliable only for short-term projections… It is also unlikely that a "one-size" model will fit all regions at all times. Policymakers will be best served when they consider projections from multiple models, thus increasing the understanding of factors that influence disparate projections and enhancing comprehension of unaccounted uncertainty in any one model. Major policy decisions need model input, but models are valuable only to the extent that outputs are transparent, are valid, are based on accurate documented sources, are rigorously evaluated, and yield robust and reliable projections.*"

Reference - "Caution Warranted: Using the Institute for Health Metrics and Evaluation Model for Predicting the Course of the COVID-19", https://doi.org/10.7326/M20-1565

A single example of the model's mistaken projections should suffice to explain the widespread concern.

One of the early attractions of the IHME model was its ability to forecast hospital demand. For New York State as of April 4, the IHME model projected a need for 65,400 hospital beds; 15,905 were used and new hospitalizations continued to fall. For that same date, the IHME model projected a need for 12,000 ICU beds but only 4,100 were used.

Reference - https://www.thegatewaypundit.com/2020/04/bill-gates-funded-ihme-coronavirus-model-wrong-12000-icu-beds-projected-new-york-today-4100-used/

Researchers at the University of Texas developed a competing curve-fitting model, and in April 2020 published a paper comparing their model to the IHME model.

Reference - "Projections for first-wave COVID-19 deaths across the U.S. using social-distancing measures derived from mobile phones", https://COVID-19.tacc.utexas.edu/media/filer_public/d8/c1/d8c133e3-8814-4b30-9d3f-f0992ca66886/ut_COVID-19_mortality_forecasting_model.pdf

The Univ. of Texas paper states that:

> *"[a]t a high level, our model shares some key properties of the IHME model.*" Those properties are "*a statistical curve-fitting approach*" that uses "*time-evolving Gaussian curves*" whose parameters are calculated using "*regression on social-distancing covariates.*"

The Texas researchers explained that the IHME:

> "*model postulates that COVID-19 deaths will rise exponentially and then decline in a pattern that roughly resembles a bell curve (i.e., normal distribution). The model assumes that the shape of the curve will be curtailed by social distancing measures. Key inputs driving this component of the IHME model include the reported dates of state-wide shelter-in-place orders and shapes of*

COVID-19 epidemiological curves observed in Chinese and European cities following the implementation of similar measures."

They further explain that:

"*our model is purely statistical: we are fitting a curve and a probabilistic error model to observed death rates in a state, and we are extrapolating from that curve. The advantage of this approach is that it does not require estimates of critical epidemiological parameters, some of which remain elusive. The disadvantage is that it cannot project longer-term epidemiological dynamics beyond the initial wave of mitigated transmission. For this reason, we do not use the model to make projections beyond a moderate (2-3 week) horizon."*

The Texas model uses the same family of curves as IHME to approximate expected daily death rates over time. The Texas curve relies on three parameters that evolve over time as a function of state-level factors assumed to be associated with the death rates. The resulting curves, when plotted over time, differ markedly from traditional bell curves. The modelers claim that ***"[c]hanges in each state's social-distancing covariates can 'flatten the curve' by changing the peak death rate, the timing of that peak, and the deceleration in death rate near the peak."***

It is crucial to remember what has happened. A computer model has flattened a hypothetical curve by adding certain parameters. This does not mean that the real world factors these parameters are assumed to model cause any 'flattening' observed in actual data. This conclusion is a leap of faith, not science.

Farr's Law -- A Lesson from History

Critics have complained about IHME's use of curve fitting and the assumption that all death curves would be about the same, regardless of jurisdiction. IHME's approach breaks with tradition and seems disconnected from biology. Nevertheless, the model fits comfortably within Farr's Law.

Farr's Law relates to an observation made in 1840 by the eminent English physician, William Farr. He noted that epidemic events rise and fall in a roughly symmetrical pattern—what is now referred to as a bell curve. The pattern is determined by the ratio of changes in rates of death.

In 2018, the developers of a simplified two-parameter model known as Incidence Decay with Exponential Adjustment (IDEA), stated a specific mathematical formula for Farr's Law and showed that Farr's model was mathematically equivalent to their own IDEA model.

Reference - https://doi.org/10.1016/j.idm.2018.03.001, "Relatedness of the incidence decay with exponential adjustment (IDEA) model, "Farr's law" and SIR compartmental difference equation models", Mauricio Santillana, Ashleigh Tuite, Tahmina Nasserie, Paul Fine, David Champredon, Leonid Chindelevitch, Jonathan Dushoff, David Fisman

Other authors have considered COVID-19 modeling in terms of Farr's Law. For example, in an April 2020 paper, the authors suggested that "Farr's law is a simple arithmetical model that provides useful

and important insights on epidemic dynamics, concluding that ***"Farr's Law seems to be a useful model to give an overview of COVID-19 pandemic dynamics."***

Reference - Pacheco-Barrios K, Cardenas-Rojas A, Giannoni-Luza S, Fregni F (2020) COVID-19 pandemic and Farr's law: A global comparison and prediction of outbreak acceleration and deceleration rates. https://doi.org/10.1371/journal.pone.0239175

Given its simplicity, and the fact that many consider it relevant to this day, it seems worth mentioning how Dr. Farr described his law and what his peers thought of it.

Dr. Farr has been often quoted:

> *"The death rate is a fact; anything beyond this is an inference."*

As Dr. Farr observed, the only fact we can observe in an epidemic is death. Everything else involves assumptions. Symptoms and 'cases' may be observable, but symptoms may not be unique to a disease and are never as obvious as death. In the case of respiratory diseases, even deaths may not be obviously connected to the disease being investigated; pneumonia often afflicts people suffering from such diseases.

Dr. Farr did not speculate about how diseases spread. Rather, he analyzed the incidence of deaths. The first disease he considered was smallpox.

In 1840, in a short note included in an annual report to the Registrar-General in England, Dr. Farr observed that the 30,000 smallpox deaths in a recent epidemic appeared to fit a roughly bell-shaped curve that we now refer to as a Normal or Gaussian curve.

He apparently made no further study of the matter until 1866 when England was facing a cattle epidemic. A member of the House of Commons warned that ***"by the middle of April"*** England would face ***"a calamity beyond all calculation."*** The lord predicted that deaths ***"which have been thousands, [will] grow to tens of thousands" assuming that "the same terrible law of increase which has prevailed"*** would continue.

We see in this prediction the same fear of an exponential rise in deaths that accompanied early COVID-19 warnings everywhere.

Dr. Farr wrote a letter to his daily newspaper calmly observing that ***"the law of increase which has hitherto prevailed, instead of implying 'that the averages which have been thousands will grow to tens of thousands' implies the reverse; and leads us to expect that the subsidence will begin in the month of March."*** Dr. Farr correctly projected the turning point of the epidemic and forecast that the rate of deaths would decline about as rapidly as it had risen.

Dr. Farr made two observations in support of his general claim that deaths follow an approximate bell curve in any epidemic. They are worth considering in the context of COVID-19.

First he noted, with reference to studies of cattle disease in Russia, that ***"All the epidemic poisons are reproduced in every individual that they attack; and if they lose part of the force of infection in every body through which they pass, the epidemic has a tendency to subside from this cause, which is***

strengthened in its operation by the fact that the individuals left are less susceptible of attack, either by constitution or by hygienic conditions, than those destroyed."

It has been observed many times during the COVID-19 pandemic that the disease seems to have lost its virulence as it passed through a population. The sudden rise of deaths in Italy and Spain quite probably involved the 'weakest' individuals in those countries. The regions most affected have a long history of serious symptoms from respiratory illness. Once the most vulnerable have succumbed, any disease can be expected to produce fewer deaths among those who remain. This natural rising and falling of deaths from disease has been known for over 150 years.

Second, Dr. Farr noted that traditionally in England ***"precautions as regards all common zymotic [infectious] diseases are never pushed so as to interfere with nursing, medical attendance, traveling, or social intercourse in England; yet all these epidemics subside within limited terms as certainly as they spring up."***

In other words, in the absence of any significant 'social distancing' interventions, past epidemics have always died out. COVID-19 should naturally subside within a reasonable time frame. If history is any indication, the massive efforts to 'flatten the curve' that have taken such a toll on economic and social life may have merely prolonged the world's encounter with this disease.

The reaction to Dr. Farr's prediction is also currently relevant.

According to Dr. Brownlee's 1915 "Historical Note on Farr's Theory," ***"no member of Parliament-- though the cattle plague was being discussed nightly-- seems to have thought it [Dr. Farr's prediction] worthy of mention. The Lancet ignored the communication entirely."***

Reference - The British medical journal. Aug 14, 1915 p250, "Historical Note on Farr's Theory of the Epidemic" by John Brownlee, M.D., D.Sc.

Dr. Brownlee quotes the British Medical Journal's reaction to Dr. Farr:

> "Dr. Farr will not find a single historical fact to back his conclusion that in nine or ten months the disease may quietly die out-- may run through its natural curve. Dr. Farr says again that the returns show that the weekly relative increase in the number of cattle which now fall with the disease is less than it was at first, and he attributes this to the view that the disease is running the usual course of epidemics. He quite forgets to take into account the fact that at the present time everyone is satisfied as to the virulently contagious nature of the disease, and consequently takes measures to prevent it."

Dr. Farr was right. The prestigious British Medical Journal, The Lancet, and the politicians were wrong. The claims made by a broad consensus of experts about a cattle epidemic were wrong in 1855. Perhaps similar consensus claims about COVID-19 are wrong today.

Based on Farr's Law, it seems possible that COVID-19 interventions will eventually be shown to have been irrelevant to the final death toll, simply spreading deaths out over a longer time period. 'Flattening the curve' might have value in conserving medical resources at the initial 2-week outset,

but no current projection models factor in the economic and social costs of 'social distancing' mandates.

Existing computer models do not tell us whether government interventions work as advertised.

Models Projecting Individual Outcomes

In addition to models designed to project mortality, cases, and hospital requirements, models have been designed to help doctors predict the course of COVID-19 in individual patients. Such models also suggest factors that may predispose people to suffer more serious outcomes.

An ongoing systematic review of such models reported that as of April 7, 2020 the authors had "retrieved 4903 titles through our systematic search (fig 1; 1916 on 13 March 2020 and 774 on 24 March 2020… and 2213 on 7 April 2020…)."

Reference - https://pubmed.ncbi.nlm.nih.gov/32265220/ "Prediction models for diagnosis and prognosis of COVID-19 infection: systematic review and critical appraisal" (original to which this is an update-- BMJ, 2020 Apr 7;369)

This study shows that by early April 2020, just a few months after the first cases of COVID-19 appeared in the United States, over 4900 studies analyzing diagnostic models had already been conducted and published. Serious medical research studies are usually time-consuming to organize and carry out. It also takes time to design a reasonable computer diagnostic model for any disease. It is no surprise that the authors of this review concluded that ***"proposed models are poorly reported, at high risk of bias, and their reported performance is probably optimistic. Hence, we do not recommend any of these reported prediction models for use in current practice."***

The early diagnostic modeling effort did not serve patients, doctors, or hospitals. Who then did these models serve, and why was there such a rush to design them? Why was so much energy spent designing and writing about models, when the models had no real medical value?

Many of the diagnostic models the reviewers studied focused on analyzing easily observable factors such as body chemistry details obtained from lab reports, blood pressure, reported symptoms, and age. Easily observable criteria are appealing when researchers are in a hurry, but the obvious are not necessarily useful. Everyone would have benefited by broadening the search for relevant diagnostic criteria *before* proposing models.

For example, research suggests that low levels of vitamin D are associated with severe COVID-19 outcomes. Vitamin D levels are known to be low in the elderly. Checking vitamin D and supplementing where necessary might have avoided the COVID-19 nursing home disaster.

Reference -
http://orthomolecular.activehosted.com/index.php?action=social&chash=b73ce398c39f506af761d2277d853a92.164&s=a3b8ba524fa5d84e9ad7899052087eb7, "HOW WE CAN FIX THIS PANDEMIC IN A MONTH", Orthomolecular Medicine News Service, June 22, 2020

Doctors had limited time to fully evaluate patients when modelers were pressing inadequate diagnostic tools. In the case of COVID-19, rushed diagnostic modeling seems likely to have *cost* lives.

Fundamental Challenges in Disease Modeling

Disease modeling faces major challenges, especially when attempted at the start of an epidemic involving a disease that is not well understood. It is crucial for policy makers to be familiar with such challenges and how those modeling challenges affect projections.

Inadequate Experimental Foundation

Disease projection models involve a complicated form of experimentation on human subjects. An epidemic model represents a hypothesis about how both the disease and certain types of government intervention affect a population's health. As such, each version of a computer projection model can be considered an experiment.

Appropriate and adequate experimental practice includes randomization in choosing participants and the treatments they receive, a control comparison group, blinding to prevent bias, and replication of results by third parties.

Randomization is essential to balance the presence of unknown factors that might influence the outcome of the experiment. Control groups are needed to verify what would happen if a treatment was not applied. Blinding makes sure treatments do not produce psychological effects unrelated to the factors being analyzed. Replication helps to make sure the experimental results are not a mere coincidence.

These standard practices cannot realistically be applied to a computer model during an epidemic.

Populations analyzed by a model are not random and are often studied as an entirety rather than as individuals. Traditional disease projection models assume that all members of a population are equally susceptible to a disease. By assuming the population is homogenous, models can study subgroups without obvious sample bias. The models hide sample bias within the assumption of homogeneity.

There is no way to separate a random part of the population to serve as a control group to evaluate the effectiveness of a governmental intervention. Instead, modelers are forced to compare effects of different interventions on different populations with different contact networks. In some cases, a rural state is compared to an urban state. The variables involved become significant enough to render the models invalid.

Modelers, citizens, and policy makers know that computer simulations are being performed, and that governmental interventions are happening. No "blinding" is possible under such circumstances.

The lack of blinding negatively affects disease models in at least two ways. First, the model itself influences behavior which is amplified through media accounts of its projections. Predicting high death

rates creates unnecessary fear which ultimately leads to changes in behavior, even if such predictions are inaccurate. If high death rates never materialize, there is no way to know whether the original prediction was simply wrong or whether it was correct and personal choices changed the outcome. If a model predicts case counts will rise, concerned people may decide to visit their doctor to report even trivial symptoms. If reported cases do indeed rise, because the question becomes whether disease transmission increased or because more people decided to visit their doctors and report symptoms.

Second, government interventions affect modelers, citizens, and policy makers themselves. Modelers build assumptions into their models to reflect the effect they imagine interventions will have. People, thinking they are safe from disease at home, may choose to skip a visit to the doctor when they have mild symptoms. When cases drop, it is important to determine if that drop was a result of a lockdown that kept people from transmitting the disease or because confidence in the government's approach kept people from getting tested. Quarantine measures might lead to a drop in cases because they work, or because sick people avoid doctors for fear of being quarantined. If a model predicts a flattening of the curve because of social isolation policies, and such a flattening occurs, is it because the policy worked as expected, or is it possible that the flattening would have occurred naturally?

All the questions offered above arise because control groups and blinds are not available to test disease projection models.

Finally, most models have become so complex that third parties cannot evaluate them and verify their results before the model gets changed to reflect new data. The models themselves never face the same fact situation twice in their modeling history. Typically, a modeler will use old data in a new model to make sure the new model's projections match what is already known. Such action is not experimental "replication" but rather a form of computer regression testing to make sure the new program can do the same things the old one could do.

Modelers generally report their success at reproducing the past as if it ensures their model will correctly predict the future. Since the main reason for changing models is because actual data did not agree with the initial model predictions, the past models were wrong. In the absence of independent validation, it is a leap of faith to believe the new models are any better.

Assumptions and Uncertain Inputs

All computer projection models make assumptions and require inputs. Understanding these aspects of projection models is crucial to understanding model outputs. Unfortunately, uncertainty surrounds most inputs, especially at the start of an epidemic.

A SEIR model requires an estimate of how many people are susceptible to a disease. Regarding COVID-19, some models assume everyone is susceptible. Other models assume a fraction such as 60% of the population is susceptible. How do we determine which models are right? Some research suggests that prior exposure to other coronaviruses, including the common cold, provides some level of T-cell immunity to COVID-19 and is an important reason why so many people show few or no symptoms. If so, the number of people susceptible may be much lower than models anticipate. Modelers should test

the sensitivity of their models to assumptions about susceptibility and report that sensitivity analysis to users of the model.

When estimating numbers of exposed and infected people, an SEIR model makes the underlying assumption that it is possible to reliably count the number of infectious individuals at any given time. Variations in assumptions about how many infected people are circulating will lead to large variations in predictions.

A SEIR model must also make assumptions about how frequently infected individuals come in contact with susceptible people and consider the chance that such people will become infected themselves. These numbers are unknown. The modelers guess or estimate values.

The IHME modelers chose to use complicated statistical regression analysis to sidestep the issue of not knowing these numbers. They claim their approach has made their model independent of assumptions about infection rates. In fact, their model incorporates an implied infection rate because past case counts and mortality data feed into the model's multivariate regression analysis.

Most models assume that the frequency of contact among the infected and the susceptible population will decrease with government interventions such as lockdowns or masks. This assumption is often built into the model. A parameter may decrease over time after a given date when a government intervention took place or is contemplated. The models reverse the effect when modeling re-opening plans.

It has not been independently proven that lockdowns, masks, or social distancing reduce transmission of a disease. The experience of the countries and states that did not apply stringent social distancing measures raises doubt that such measures work as claimed. Unfortunately, the structure of current models makes it impossible to use the model outputs to study the matter because all models assume that such interventions affect transmission in a predetermined way.

Hidden Feedback Loops and Unstable Inputs

As epidemiological models change to reflect real world data, they take on characteristics of a machine-learning system. Google engineers have analyzed such systems extensively. Referenced are two issues with such systems that may affect the accuracy of disease projections.

Reference - "Machine Learning: The High-Interest Credit Card of Technical Debt"
https://storage.googleapis.com/pub-tools-public-publication-data/pdf/43146.pdf

> *"Another worry for real-world systems lies in hidden feedback loops. Systems that learn from world behavior are clearly intended to be part of a feedback loop... In such a setting, the system will slowly change behavior… Gradual changes not visible in quick experiments make analyzing the effect of proposed changes extremely difficult…."*

When a disease model takes its outputs for inputs in any form, it sets up a feedback loop as described above. Feedback loops of any kind (e.g., the high-pitched squeal of a microphone to speaker link) can

have unanticipated and difficult consequences to detect. For example, do predictions of high transmission rates *cause* the exceedingly high rates predicted? Disease modelers rarely consider the impact of feedback loops on their models. How can modelers guard against such a result if the impact of feedback loops is often not considered?

In addition, unstable inputs are known to lead to unreliable outputs. The engineers observe ***"changes and improvements to the input signal may be regularly rolled out… [and] may have arbitrary, sometimes deleterious, effects that are costly to diagnose and address."*** *(p4)*

The inputs to all disease projection models are regularly out of the control of the modelers. Governments make changes to data reporting practices on a whim during an emergency. One example is a decision to stop reporting mortality data on weekends, as happened for a month in one state in 2020. Modelers and the users of models may not discover such changes until long after the changes have distorted projections.

To see a potential feedback loop in an actual disease projection model, we need only examine the IHME documentation.

> *"3.5.2 Deaths as a function of reported cases and hospitalisations*
>
> *In the first stage we model the cumulative death rate with either the cumulative case rate or the cumulative hospital admission rate as independent variable. Where data for both of these variables are available, a separate model is run for each."*
>
> *"3.6 Estimating infections from deaths*
>
> *Conditioning on the death draws produced in SI Section 2.5 and the Infection Fatality Rate (IFR) and age-specific mortality rate (MR) calculated in SI Sections 4.2 and 4.1, daily infections are inferred by stratifying all-age deaths into age-specific deaths, using the age-specific IFR to determine the number of infections that would have led to this quantity of age-deaths, and then backshifting the infections in time to account for the lag between infection and deaths."*
>
> **Reference** - https://doi.org/10.1038/s41591-020-1132-9

According to the documentation, cases are used to estimate deaths. After undergoing extensive statistical manipulation, deaths are used as an input to project infections. Are infections the same as cases? Perhaps this question is answered somewhere in the 92-page "supplement" to the main documentation. How many users of the model know or care about the answer?

Models Within Models Within Models

What do modelers do when certain input data is not available or is unreliable? They search for other seemingly relevant data that *is* available or *is* reliable and use statistical methods to use that data instead.

Consider for example what happens when a model, such as the IHME model, needs daily death data. Some jurisdictions delay their death report, some report data on different schedules, and some occasionally skip reporting entirely. Without modifying the death data, models will treat missing data as "no deaths" for the day in question, and projections will be distorted.

> *"States report at different rates. Currently, 63% of all U.S. deaths are reported within 10 days of the date of death, but there is significant variation between states.*
>
> *It takes extra time to code COVID-19 deaths. While 80% of deaths are electronically processed and coded by NCHS within minutes, most deaths from COVID-19 must be coded by a person, which takes an average of 7 days."*
>
> **Reference** - https://www.cdc.gov/nchs/nvss/covid-19.htm

As a result of these variations, all projection models that use daily death data "smooth" the data. They usually do so by calculating rolling averages of reported death data. Such rolling averages conceal spikes that may be important and do not correctly handle unusual delays.

Delays happen and can be significant:

> *"The South Carolina Department of Health and Environmental Control said a system upgrade to their Vital Statistics system led to the slow down of deaths being reported in a timely manner by coroners and other medical officials who confirm and record death in the state.*
>
> *Due to the upgrade issue, DHEC announced on Thursday [January 28, 2021] 254 confirmed and probable COVID-19 deaths for individuals who died over the last several weeks."*
>
> **Reference Jan 28, 2021** - https://www.live5news.com/2021/01/28/dhec-database-issue-leads-delay-covid-deaths-reported/

Unfortunately, the parameters needed by a traditional SEIR disease projection model are simply not known and can only be estimated by manipulating source data. To avoid the uncertainty surrounding the biological parameters of a tradition SEIR mode, the IHME model resorts to a great deal of statistical complexity. It uses multivariate regressions involving many factors the modelers assume affect disease transmission. Each factor requires its own data sources and often its own smoothing operations because of variations among sources.

Here is one example involving the "mobility" covariate as described in the IHME Supplemental Documentation (**Reference** - https://doi.org/10.1038/s41591-020-1132-9, p15-16):

> *"These data come from mobile phone users. We used four primary resources to gauge the changes in relative mobility of populations within each state:*
>
> Google Community Mobility Reports (https://www.google.com/covid19/mobility/),
>
> Facebook Data for Good (https://dataforgood.fb.com/docs/covid19/),
>
> Safegraph (https://www.safegraph.com/dashboard/covid19-shelter-in-place), and

Descartes Laboratories (https://www.descarteslabs.com/mobility/).

Each of these sources have different definitions of mobility."

For Google data, ***"No further processing is undertaken prior to modelling."***

For Descartes Laboratories, ***"the top 10% of their data is removed due to possible inclusion of outlier data due to poor GPS recording. The index is reported from 01 March, 2020 through to three days prior to-date. The index is transformed by subtracting 100 from the m50_index value."***

For Safegraph, IHME, ***"determine[s] an index representing the percent difference between the number of devices that flagged as having not stayed within their home range as compared to the mean number of devices that stayed within their home range over a baseline reference period (08 February and 14 February, 2020). … Using the associated FIPS codes, we can aggregate to the various analysis locations (whether counties, or states, or territories) by taking the device-weighted mean of the census block group ratios."***

Facebook Data for Good seems to require the most manipulation, as it requires 24 lines of details to describe its use. Here are a few of the manipulations needed:

> *"For each [location-specific administrative region], a baseline period for future comparison is developed by considering the prior 45 days of Facebook user activity. Subsequent to the date of initiation, all future days of reporting cross-reference their own baseline activity period...Where latitudes and longitudes were missing or did not accurately represent a location, we manually assigned a model geography by name. Using the start location from out[sic] modelled geographies, we find the mean percent change in mobility… We weight this mean by the number of users who normally take this trip (n_baseline). Given the variable baseline periods, we must transform Facebook data so that it is comparable to other sources…"*

The mobile phone data section concludes:

> *"There are several steps to smooth and standardise the data. We observe strong patterns in mobility by the day of the week. The data from Google is already corrected for these day-of-week patterns. For all other sources we calculate a 7-day rolling mean to account for weekly trends."*

To estimate mobility *data*, IHME removes some data, shifts data, calculates a special index value, aggregates device data using a weighed mean of calculated ratios, fills in missing data, calculates mean percent changes in mobility and weights them by an estimated number of people, only to then smooth and standardize the results using a 7-day rolling mean.

But specifying the data is just the beginning:

> *"To account for differences in time coverage between sources we calculate the median ratio between each available pair of sources for each location across the time series. In locations where we are missing the time series for a given source, we impute based on all other sources and the median ratio in that location over time… Because the sources tend to provide*

systematically different estimates, and when a given location is missing data from a component source, we impute values for the missing source based on the available source(s) and the global median ratio(s) with the missing source."

"After all missing dates and sources have been imputed, we average across sources and take a 5-day rolling mean using Gaussian process regression to smooth over time. For locations where we are missing data early in the time series, we use Holt smoothing back in time, linear damped with phi = 0.9 to create a full time series…"

Mobility is just one of twelve covariates described in the documentation. It takes four pages of densely detailed documentation to explain how just this covariate is used in the model.

How many officials who relied on this model understand the significance of the mobility covariate? How many can judge how accurate the estimated values are, what accuracy may be needed, and how significant is the covariate is to the model's projections? Has anyone ensured IHME does all the work described?

Each time a model uses another model to estimate an input, it compounds the uncertainty in its projections and moves further from reality. Worse, models within models compound the difficulty in testing the model and in understanding whether inputs serve the purpose claimed. They also make it almost impossible for a third-party investigator or a public official to understand and evaluate the accuracy of the model's projections.

Statistic estimates and statistical regressions can be calculated for any data. It is always up to people to decide if such calculations make sense. Because modelers provide detailed explanations of the way they manipulate data to obtain parameters, it is easy for everyone to lose sight of the fact that most inputs are just speculations. Every time we speculate, it may be wrong. As speculations increase, the chance of being wrong also increases. Like ancient peoples, our strong desire to predict the future leads us to believe our methods work.

But as programmers say, 'garbage in, garbage out.'

Practical Challenges in COVID-19 Modeling

In addition to the weaknesses faced by any epidemiological model, the COVID-19 models face certain practical difficulties related to how deaths and cases are counted. In addition, although asymptomatic transmission of viruses has historically been extremely difficult to establish, COVID-19 modelers chose to include parameters to model this unproven theory. Modelers also have decided to make various assumptions about how government interventions affect COVID-19 transmission and have decided to build those factors directly into their models.

Mortality

All COVID-19 models rely on COVID-19 mortality data in some way. SEIR models need estimated mortality and recovery rates. Curve-fitting models like IHME use actual death counts.

Unfortunately, when the CDC changed death certificate reporting for COVID-19 in March 2020, they created a situation where many reported COVID-19 deaths involve pre-existing conditions such as cancer, heart attacks, strokes, and pneumonia that would have traditionally been reported as the cause of death. COVID-19 is merely one of many opportunistic infections that might otherwise cause death in the elderly suffering from co-morbidities.

What this change means is that there is no real connection between reported "cases" of COVID-19 and reported deaths because the deaths are from other causes. It should be no surprise when models built on assumption of a correlation between COVID-19 cases and deaths project deaths incorrectly.

The May 2020 Vox article ***"This coronavirus model keeps being wrong. Why are we still listening to it?"*** criticized the IHME model because ***"as the weeks have passed, it has become clear that the IHME's projections have been too optimistic, and slow to adjust to reflect the fact that deaths have plateaued rather than rapidly decreasing to zero."***

The reported 'plateau' may well have been a consequence of the fact that COVID-19 mortality data after March 2020 included mostly deaths from common diseases, which occur at a fairly constant rate. It seems entirely possible that the IMHE model projections would have been quite accurate if adjusted to reflect the CDC change.

Unfortunately, no one can know exactly how many deaths would have been reported using the earlier death reporting rules.

Asymptomatic Transmission Rate

All SEIR models make some assumptions about how frequently asymptomatic people infect others. The underlying assumption is that it *is* possible for asymptomatic people to infect others. This assumption is widespread but is contradicted by the extensive study of nearly 10 million people carried out in Wuhan China.

Assuming a model could estimate an asymptomatic rate of infection, the model would also have to estimate how many asymptomatic people exist and how the disease progresses in each individual. Since asymptomatic individuals appear like everyone else, it is impossible to estimate how many asymptomatic individuals exist. Nevertheless, some studies suggest that from 20% to 40% of all COVID-19 cases are entirely asymptomatic.

A 2018 study investigated the impact of asymptomatic transmission assumptions on model projections about the impact of potential health interventions.

Reference - https://royalsocietypublishing.org/doi/pdf/10.1098/rsos.172341, "Implications of asymptomatic carriers for infectious disease transmission and control"

In their introduction the authors observed that:

> *"In practice, incorporating asymptomatic carriers into models is challenging due to the sparsity of direct evidence. This absence of data leads to uncertainty in estimates of model parameters and, more fundamentally, in the selection of an appropriate model structure.… selecting an inappropriate model structure, even when parameters are correctly estimated, may lead to over- or under-estimates of intervention effectiveness."*

The authors' analysis ***"reveals that interventions that alter the relative incidence of symptomatic infections compared to asymptomatic carriers are particularly vulnerable to being incorrectly assessed by models with inappropriate structure."***

Recall that no actual data mentions how government interventions such as lockdowns, social distancing, and masks actually affect disease transmission. This study should generate questions about the reliability of model projections about such interventions as well as asymptomatic transmission of COVID-19.

Case Counts do not Measure Infectious Individuals

All SEIR models must estimate the infected population and how that population will spread infection. Case counts are the go-to answer for COVID-19 models. Unfortunately, case count data based on PCR testing, as currently used, cannot identify people who are contagious when tested. According to the CDC, people who have recovered from COVID-19 can test positive for up to 12 weeks after recovery. Such people belong in the "Recovered" category, but if they happen to test positive within twelve weeks of their recovery, they add to the case counts and inflate the size of the "Infected" class.

If a rate of infection cannot be reliably estimated, an SEIR model fails to produce reliable outputs.

Private Models Raise Special Concerns

When government relies on private computer models, the government gives up control over fundamental aspects of the information supply required to make policy decisions, and the public no longer has legal access to essential details that affect their lives.

Where Does the Buck Stop?

The Los Alamos National Laboratory COVID-19 projection model LANL includes this disclaimer with its reports:

> *"Unless otherwise indicated, this information has been authored by an employee or employees of the Triad National Security, LLC., operator of the Los Alamos National Laboratory with the U.S. Department of Energy. The U.S. Government has rights to use, reproduce, and distribute this information. The public may copy and use this information without charge, provided that this Notice and any statement of authorship are reproduced on all copies. While every effort has*

been made to produce valid data, by using this data, User acknowledges that neither the Government nor Triad makes any warranty, express or implied, of either the accuracy or completeness of this information or assumes any liability or responsibility for the use of this information. Additionally, this information is provided solely for research purposes and is not provided for purposes of offering medical advice. Accordingly, the U.S. Government and Triad are not to be liable to any user for any loss or damage, whether in contract, tort (including negligence), breach of statutory duty, or otherwise, even if foreseeable, arising under or in connection with use of or reliance on the content displayed on this site."

Surely no one wants people suing the government or the companies working with it for publishing data they hope will be of use during an emergency. However, there is a dark side to this kind of disclaimer.

First, who owns the reports? It seems that Triad National Security owns the reports rather than the United States Government. Did Triad pay for the preparation of these reports, the development of the model, or the collection of the data? Only the government and Triad know. If Triad owns the reports, they are not subject to Freedom of Information Requests.

Computer models and the deliberations that produce them are also free from public records requests if they are in private hands. Public access to discussions among model developers might go far to reduce concerns about model assumptions and functionality.

How Secure are Models and Data?

Private projection models share many of the risks of commercial software. Computer operating systems such as Microsoft Windows have been attacked for years by hackers. The open-source software movement arose partly as a response to security questions raised about privately developed software that no one could analyze outside of the company developing the software. Recently, several private networking devices have been found to have hidden 'backdoors' that allow foreign agents to take over those devices to hack into government and business networks. Phone apps are regularly found to contain hidden functions that transmit private data to third parties. Even security firms are finding their software and networks hacked.

Any disease projection model, especially ones developed and controlled by private parties, should raise questions about who created the model, and how robust and secure the model is. Currently, very few are asking such questions.

Accurate data is crucial to all data modeling. When models affect lives, like COVID-19 models have, the public has reason to expect everyone involved with modeling pay close attention to data quality and security. The medical research community seems to be approaching data sharing about COVID-19 in an idealistic way that may have been appropriate before international actors with conflicting agendas joined the community.

.

One example is Data.World (https://data.world/datasets/covid-19), which explains that ***"When you create a free account, you don't just gain access to a rich bank of open data and a powerful platform for analytics and insights: you become a member of the world's largest collaborative open data community. Together, our community members uncover new insights, helping the world get answers and formulate response strategies."*** The website seems to mention nothing about data quality or security.

Another example is the COVID-19 open database managed by the National Institutes of Health Office of Science Strategy (https://datascience.nih.gov/covid-19-open-access-resources). The entry page contains the disclaimer: ***"The Office of Data Science Strategy seeks to provide the research community with links to open-access data, computational, and supporting resources. These resources are being aggregated and posted for scientific and public health interests. Inclusion of a resource on this list does not mean it has been evaluated or endorsed by NIH."***

One dataset listed is the COVID Digital Pathology Resource (COVID-DPR). It states that, "Although hosted at the NIH, the COVID19 DPR seeks international and U.S. submissions, and is designed to support both clinical need and foster research for all investigators."

The contribution form for its COVID-19 Digital Pathology Repository (https://covid19pathology.nih.gov/request) states **"A rigorous QA policy will be enforced to ensure patient privacy, diagnostic accuracy and image quality."**

The form is reassuring because it refers to a rigorous quality assurance policy. Yet, a search on 'quality assurance' on the website lists nothing but general documents describing international standards for data quality.

Does the NIH check data quality as the form suggests? Or does it not, as the entry page to the database suggests? Only the NIH knows for sure.

A quick internet search reveals dozens of stories about university researchers who have been charged with espionage or with accepting secret funding and concealing contacts with the Chinese government. This fact should make policy makers ask difficult questions about the models developed by universities or other private organizations and the data sources they rely on.

The entire field of epidemiology and genetics has become so important and so potentially threatening that perhaps it is time to require a security clearance for all researchers, disease modelers, and data suppliers.

Are Private Models Transparent?

Most private computer projection models publish extensive information about their assumptions, algorithms, and limitations. Some use open-source programming and allow the public to examine their source code. Some reveal to the public the data they use for inputs.

All of this creates an illusion that these models are transparent.

Ask yourself how often you read the 'User Agreements' required by social media sites and internet providers. How often do you read credit card and other contract terms before signing up?

It seems reasonable to wonder how many public health officials, at the start of the COVID-19 pandemic, read and understood the complex documentation that accompanies COVID-19 projection models. How many health departments studied a model's code before its adoption?

In 2014, two European researchers noted a ***"background of declining trust and increasing problems with the reliability of scientific knowledge in the public sphere"*** and observed that ***"the dangers for science become most evident when models—abstracts of more complex real-world problems, generally rendered in mathematical terms—are used as policy tools. Evidence of poor modeling practice and of negative consequences for society abounds."***

They suggested a need ***"to revisit statistician George E. P. Box's 1987 observation that 'all models are wrong, but some are useful,'"*** and proposed that ***"a key implication of Box's aphorism for science policy [is] that stringent criteria of transparency must be adopted when models are used as a basis for policy assessments. Failure to open up the black box of modeling is likely to lead only to greater erosion of the credibility and legitimacy of science as a tool for improved policymaking."***

Reference - Saltelli, Andrea; Funtowicz, Silvio (2014). "When all models are wrong". Issues in Science and Technology. 30 (2): p80

Can We Trust the Programming and the Modelers?

Using models created by academics or private institutions raises other questions. Can government leaders trust the actual computer programming in the models, and have the modeler's demonstrated their ability by successfully modeling in past epidemics?

If referring to The Imperial College Model used to forecast deaths at the start of the COVID-19 pandemic, the answer is a resounding no.

CASE STUDY: The Imperial College Model

The Imperial College Model predicted that by October 2020 more than 500,000 people in Great Britain and 2 million people in the United States would die because of COVID-19 in 2020. The prediction caused so much panic around the world that almost every government chose to resort to wide lockdowns, irrespective of risk to various age groups.

After the source code for the model was released, on May 16, 2020, two experienced software developers published an editorial in the Telegraph criticizing the code. The critics were David Richards, founder, and chief executive of WANdisco, and Dr Konstantin Boudnik, vice-president of architecture at WANdisco, author of 17 U.S. patents, and a veteran developer of a software framework that allows computers to solve problems using vast amounts of data.

Reference - "Neil Ferguson's Imperial model could be the most devastating software mistake of all time" https://www.telegraph.co.uk/technology/2020/05/16/neil-fergusons-imperial-model-could-devastating-software-mistake/

These critics observed:

> *"One file alone in the Imperial model contained 15,000 lines of code…Industry best practice would have 500 separate files instead. In our commercial reality, we would fire anyone for developing code like this and any business that relied on it to produce software for sale would likely go bust."*

They noted further that:

> *"…[t]he approach ignores widely accepted computer science principles known as "separation of concerns", which date back to the early 70s and are essential to the design and architecture of successful software systems… Without this separation, it is impossible to carry out rigorous testing of individual parts to ensure full working order of the whole."*

Their conclusion was:

> *"Ultimately, this [epidemiological modeling] is a computer science problem and where are the computer scientists in the room? Our leaders [in the UK] did not have the grounding in computer science to challenge the ideas and so were susceptible to the academics. I suspect the Government saw what was happening in Italy with its overwhelmed hospitals and panicked."*

Earlier in May a person using the pseudonym Sue Denim and claiming to be an experienced Google software engineer, published an even harsher critique of Imperial Model.

Reference - "Code Review of Ferguson's Model" https://lockdownsceptics.org/code-review-of-fergusons-model/

She noted that the source code released to the public:

> *"…isn't the code Ferguson ran to produce his famous Report 9. What's been released on GitHub is a heavily modified derivative of it, after having been upgraded for over a month by a team from Microsoft and others. This revised codebase is split into multiple files for legibility and written in C++, whereas the original program was 'a single 15,000 line file that had been worked on for a decade'"*

The team had cleaned up the code before releasing it to the public, and what was released was not what mislead the world. It is interesting to note that the Bill and Melinda Gates Foundation has provided substantial disease research support to the Imperial College of London for at least a decade. With that connection, it should be no surprise that Microsoft helped the Imperial College improve a data model whose original programming was an embarrassment.

Ms. Denim further criticized the indeterminate nature of the algorithms the model uses. She noted ***"the code produces critically different results, even for identical starting seeds and parameters."*** The term 'seed' refers to an input that is placed into a random number generator to ensure the generator

always produces the same string of digits. Such reproducibility is essential to testing any probabilistic computer model.

Ms. Denim goes on to cite tests demonstrating that the model produced different results when run on single-CPU and multi-CPU computers and also produced different results when code was changed to make the program run faster or more efficiently.

For example, a team at Edinburgh University tried storing data tables in a more efficient format for faster loading. The team discovered that the ***"resulting predictions varied by around 80,000 deaths after 80 days."***

Unpredictable results from a computer program should always be a cause for concern.

Since programming epidemiological models often goes wrong, who *should* create them?

According to Ms. Denim, insurance businesses would be a better choice than academic institutions.

> *"Insurers employ modelers and data scientists, but also employ managers whose job is to decide whether a model is accurate enough for real world usage and professional software engineers to ensure model software is properly tested, understandable and so on. Academic efforts don't have these people, and the results speak for themselves."*

Apparently, the Imperial College Model that drove the entire world's early COVID-19 decision-making was poorly programmed, generated unpredictable results, and was designed in a way that made it impossible to reliably test and adjust.

We might charitably chalk up government reliance on such a poor model to a sense of urgency and plain bad luck.

However, Neil Ferguson, the driver behind the model, has been poorly forecasting for a long time. His models for swine flu and mad cow disease also produced wildly inflated mortality projections. In an interview in 2005, Ferguson likened bird flu to the deadly 1918 Spanish flu and predicted that up to 200 million people might die. Approximately 100 people died. In 2009, his models led the British Government to forecast a worst-case scenario of 65,000 dead from swine flu. In fact, only 457 died.

The British Government could surely have demanded access to the source code before accepting the Imperial College model projections. However, they did not. Even a cursory review of that source code by an experienced software engineer would have revealed the flaws.

Can Anyone Reproduce the Results?

A fundamental problem in epidemiology is that people cannot be willingly infected to test the results of various approaches to manage an epidemic. It is difficult to provide a treatment to one group while withholding it from another if the treatment is believed to be effective. This problem is magnified when it comes to larger social measures such as quarantines.

Unfortunately, this means there are limited scientific ways to test disease interventions. Disease projection models suffer from the same problem.

Modelers uniformly imply their models are scientific. A key characteristic of scientific claims is that they should be replicable. Assuming an official reads the documentation associated with a model (IHME provides a 92 page 'Supplement' with detailed formulas) does not imply that the official understands the suggested outcomes.

The only way to know a model works as proposed is to try to reproduce the model's outputs.

In the case of private models, there are two reasons that attempts to replicate output are not performed. First, neither the source code nor inputs are necessarily available when a model has been privately developed. Travel data, for example, is often purchased from private trade associations such as the International Air Transport Association (IATA). Anyone wishing to verify a model using IATA data must purchase their own license to use that data. Second, all COVID-19 models are being actively changed to 'better reflect' new data. Which version of a rapidly changing model should be tested for accuracy?

If they older versions were accurate, they would not have to be changed. The time needed to verify a model exceeds the time before it gets changed, which makes it nearly impossible to confirm any scientific claims about COVID-19 models.

The Only Way to Choose

Because it is difficult to independently confirm models, public officials commonly compare the results of different privately created models and select the one they prefer. Some officials choose a model because it presents numbers they favor; others choose a model because a well-known institution developed it.

The inability to verify a disease projection model suggests such models are not chosen for their quality but for some other reason. Since model quality is not a factor in choosing a model, inaccurate and sometimes unnecessary policy decisions result.

Some officials avoid relying on a single model. Instead, after comparing several models, they accept the "consensus" predictions. Unfortunately, good science is not a matter of consensus. If it were, we would still believe the sun revolves around the earth or that Newtonian physics describes the universe. Agreement among models may demonstrate that modelers share implicit assumptions and rely on similar data sources. Everyone may just be making similar mistakes.

In the 1983 movie Wargames, an AI computer programmed to play games is about to "play" nuclear war and destroy the world. After it plays tic-tac-toe it finally learns that some games cannot be won, and the world is saved.

There seems to be no 'tic-tac-toe' to teach the world's policymakers the facts about disease modeling. Nevertheless, the only way for policy makers to win the disease modeling game is not to play.

Position Regarding Projection Models

When an epidemic occurs, government officials are often charged with the need to make potentially life-changing decisions for their citizens. When such decisions are based on preliminary disease projection models that exaggerate harms, policy choices reflect projected worst-case scenarios.

Although the possibility of an early exponential increase in deaths and hospitalizations exists, it often decreases as people adjust their behavior with respect to their interpretation of perceived danger.

This suggests there is more of a time cushion than some policy makers may realize. It also suggests that modelers should strive not to exaggerate and inflate data.

Disease projection models are inherently complex and unscientific because they attempt to model a rapidly changing real world phenomenon without experimental verification. Before relying on a model, it is crucial for policy makers to understand what key assumptions that model makes and how the model gets its inputs. Elaborate statistical methods used to manipulate data to obtain model inputs can be expected to increase error and raise the overall uncertainty in the model's outputs.

Private projection models, even when sponsored by a university, are associated with risks including poor programming practices, lack of transparency in the documentation, an inability to verify that the model works as described, and possible security issues with personnel and data.

Governments have public health emergency laws on the books and these laws usually require emergency planning. As part of that planning every government could create general rubrics to help in selecting a disease projection model. Legislators could pass laws requiring full public transparency in any disease projection model the government adopts.

Models exist and will continue to be used before they are ready. Modelers should ensure their models do not exaggerate threats, and policy makers should hesitate before imposing drastic restrictions based on doubtful projections.

Rushed decisions are frequently bad decisions.

Regardless of how impressive the model is, or how well it fits the past, the future will always be unpredictable.

And garbage in, will always lead to garbage out when it comes to data analysis.

People Worthy of Our Remembrance

Dylan Buckner, 18 Died by Suicide

Buckner's father, Chris Buckner, said the teen had been battling depression the last few years but "his depression worsened significantly after COVID hit."
"The family believes that had COVID not happened, or the country's response to COVID had been more effective, Dylan would still be alive today," In a statement, Chris Buckner wrote, i "we are really, really going to miss him."

Buckner, who played quarterback and was captain of the school's football team, was expected to graduate with honors and hoped to play football at MIT in the fall, his family said. He had received 14 offers to play football at Division III schools, according to his father.

https://www.nbcchicago.com/news/local/suburban-football-star-dies-in-apparent-suicide-family-says-covid-worsened-depression/2411545/

Topic 6 – History of Medical Ethics

Topic Introduction – For more than 2,000 years, the first fundamental law governing the safe and effective practice of medicine has been exceedingly clear in its simplicity, 'To Do No Harm'.

It is a powerful statement that establishes the primary responsibility each practitioner has with respect to their patients and forms the foundation for the key concepts shaping virtually all ethics for medical conduct.

Throughout history this altruistic ethos has been repeatedly challenged by people that seek to operate outside of this basic philosophy and most often for their own selfish pursuits of fame, fortune, and control.

Each time this has happened, innocent people have suffered, sometimes individually and sometimes in mass. Each time this has happened, the perpetrators have falsely claimed that their intentions were in the best interests of 'scientific' breakthrough or the more nebulous 'greater good.' In these instances, their claims have always been to shroud the true nature of their true motives. They argue disingenuously that the small number of people harmed is a necessary part of scientific advancement for society. But did the injured parties share that same perspective?

People who do not know history are doomed to repeat it, and this sad reality confronts us yet again regarding COVID-19.

Central to any productive discussion regarding medical ethics, duty, and conduct is the basic concept of helping people in need with every possible avenue of assistance. This is why the earlier topic explorations into the problems associated with projection modeling, data manipulation, PCR testing, asymptomatic transmission, and especially the withholding of evidence-based treatments is so alarming.

Additionally, important to this discussion is how the concept of informed consent came into existence. Interestingly, while the development of the legal concept of informed consent has taken centuries to become codified, it affirms each person's right to decide what is in their own best interest.

Where there is medical risk, there must always be freedom of medical choice.

The very notion of consent is the philosophical affirmation that each patient (or research subject) has basic human rights that supersede all medical opinions, experiments, and ideological concepts of serving the greater good at the expense of the individual's sovereignty. Each patient and research subject has full autonomy and control over their own body. This autonomy must be legally protected.

The very notion of being properly informed is an acknowledgement that historically, patients (and research subjects) have been purposely misled, coerced, lied to, and even forced to do as the doctor (or scientist) says without question or ability to protest and terminate the interaction.

Failing to provide known options to choose from and to properly inform a patient as to the risk of experimental therapies is the gateway for harm to be done, a direct violation of the first fundamental law in the practice of medicine 'To Do No Harm,' and therefore evidence of willful misconduct.

Before illustrating violations of medical ethics relative to COVID-19, it is important to revisit 2 key historical events, The Nuremberg Military Tribunal and The Tuskegee Experiment. We will then take a tour through the widely adopted Patient Bill of Rights and 45 C.F.R. 46, the code of federal regulations that establishes specific and extensive protections for all human research subjects.

As this subject begins, it is important to establish that the horrors of war are never one-sided, and that history is often biased towards the victors who get to write it.

Additionally, it is important to acknowledge the polarizing effect any discussion of race potentially conjures within the subconscious. So often, the very thing we need to discuss in order to dispel its destructive influence upon objectivity, is the thing that is avoided to preserve the feelings of people. This conversation will not shy away from this topic in our conversation here as the stakes are simply too great.

The Nuremberg Code, Eugenics & Slavery

Overview – In 1946, during the time for the Nuremberg Military Tribunal to deliberate over the allegations of war crimes perpetuated by members of the Nazi party, twenty-three high ranking Nazi physician-scientists were charged with conducting human experimentation on unconsenting prisoners. The 'medical' experimentation these persons were accused of consisted of injecting prisoners with infectious diseases, mutilation, starvation, chemical poisoning, and various forms of torture.

Artifacts recovered from the concentration camps by the Allied Forces were damning examples of human experimentation that forced people around the world to reconsider what is right and openly question how something like this could take place. With the advent of video and newsreels, images that can never be unseen were sent around the world.

In the final analysis of the 23 defendants, 7 were sentenced to death, 7 were acquitted, and 9 were sentenced to prison terms. The 9 sentenced to prison terms were ultimately released before serving their full terms.

The commonality among the guilty was their belief in eugenics. Eugenics is the morally corrupt philosophy that asserts its mission is to improve the overall genomic profile of a population by eliminating people deemed 'unfit' genetically to procreate and contribute to that genomic profile.

The philosophy of eugenics asserts that one group of people, always wealthy, have the right to decide the fate of those deemed to be beneath their socioeconomic status. This is the basic philosophy that forms the foundation of racism that justified the existence of slavery in the United States from 1619 to 1865. History has proven time and again that when a group of people of excessive wealth pool their resources they create the ability to turn any lie into a believable truth backed by the force of the laws they purchase.

The methods used to accomplish the implementation of eugenic philosophies has historically varied from society to society. The methods include such practices as forced euthanasia of the elderly, poor, mental disabled, physically disabled, homosexual, and people deemed unintelligent or unproductive.

Historically, eugenic methods have also included forced sterilization, forced abortion, legal limitations to family size, and even government issued passports and licenses authorizing select people to be 'free' to procreate.

Eugenics in practice removes individual sovereignty and empowers the government to control the lives of people deemed 'unfit'. Eugenics was a hallmark of Hitler's vision for the world's future, but interestingly many of his adopted philosophies were born from U.S. slavery laws and practices as well as U.S. forced sterilization laws from 1907 to 1981.

In fact, the state of California has the dubious distinction, during what was known as the 'Progressive-era,' of forcefully sterilizing approximately 80% of all people who were legally forced to be sterilized in the U.S. Overall, an estimated 65,000 people were forcefully sterilized in 33 states under various sterilization laws in the U.S., most of whom were Black, Latina, or Native American women.

Forced sterilization was not a new concept to the United States. For more than 200 years, castration of male slaves deemed uncontrollable, and therefore threatening, was routine.

How can a society that openly legalizes the philosophies of eugenics be considered free?

The United States has extended historical periods of being a free society in name only for a substantial percentage of her residents. Nazi Germany was not a free society. Freedom is the right to life, liberty, and the pursuit of happiness. Intrinsic to these rights are the right to decide what goes into and upon one's body.

The lessons of history underscore the essential nature of preserving an individual's right to decide what is in their best interest. When exploring how informed consent laws have come into existence, it's important to begin by examining the Nuremberg Military Tribunal and the Code that set the stage for the evolution of informed consent.

The Nuremberg Code is as follows:

1. The voluntary consent of the human subject is essential.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed, based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. **No experiment should be conducted where there is a prior reason to believe that death or disabling injury will occur**; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made, and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Key Quote – *"The defendants in this case are charged with murders, tortures, and other atrocities committed in the name of medical science. . . All of them have in common a callous lack of consideration and human regard for, and an unprincipled willingness to abuse their power over the poor, unfortunate, defenseless creatures who had been deprived of their rights by a ruthless and criminal government. All of them violated the Hippocratic commandments which they had solemnly sworn to uphold and abide by, including the fundamental principles never to do harm—"primum non nocere."*

https://www.ushmm.org/information/exhibitions/online-exhibitions/special-focus/doctors-trial/nuremberg-code

Position – Where medical experimentation of human subjects or the use of experimental medical therapy is concerned, the individual sovereignty of the person must always be affirmed and protected.

The Nuremberg Code was established during the trial of the 23 Nazi physician-scientists after they argued on their behalf that they could not break laws that did not exist. To thwart this defense strategy, prosecutors met during breaks in the trial to develop a 'legal' code based upon the principle of doing no harm in an effort to convict the 23 Nazi physician-scientists of known atrocities.

While the ethics of creating a 'legal' code during an ongoing trial is highly questionable, it does stand as the first framework for ensuring that individual sovereignty is a fundamental human right. A fundamental human right that we must all agree is worthy of eternal preservation.

To be clear, laws can be unethical as clearly evidenced by the legal practice of slavery and WWII internment camps. The absence of compassion is also unethical. How can it be that it took the horrors

of a 20th century World War to realize the sovereignty of the individual against medical experimentation is wrong? The presence or absence of law does not dictate or determine what is right. The tolerance of the public often dictates righteousness.

The more people tolerate injustice, the greater injustice will spread.

The legal codification of eugenic philosophies is akin to allowing a government 'to play God' over a life it did not create and does not own. Throughout World War II, over 60 million people died before the legalized eugenic philosophy of Nazi Germany could be defeated. During slavery, at least 60 million people died before legalized eugenics could be defeated.

Born from these horrific experiences of human suffering was a wisdom that affirms the medical ethics of doing no harm and a wisdom that protects the individual sovereignty of each life.

Idealized objectives for recycled eugenic initiatives masquerading as goodwill cannot supersede the wisdom born of horrific experience that affirms fundamental human rights.

As a historical reminder, masking and social distancing is not new. While the rationale and implementation may be different, the psychological impact is similar. It matters not that the masks of today are cloth, and the enforcement of distancing was done using iron chains in years long past. The psychological impact eugenic practices create dehumanize and injure the psyche to the point where the only choices for those deemed 'unfit' are to surrender their will to their oppressor, flee or take their own life. The ultimate right to decide what is in the best interest of the individual must remain with the individual.

So, what happens when the ability to flee is no longer an option? What happens when the surrender of will is also giving up life, liberty, and the individual pursuit of happiness?

Eugenics is an ethically reprehensible philosophy that the Nuremberg Code makes the first modern attempt to preempt. The ultimate right to decide what is in the best interest of the individual must eternally remain with the individual. If we are not the owners of our own body, then we will set the stage for the repetition of many of the worst chapters in human history.

Those that don't know history are doomed to repeat it.

Additional Subtopic References

- Masterful Legal History of Informed Consent beginning in 1905 by Ms. Michelle Wandler via Harvard University composed on April 12, 2001 during her 3rd year in study. Beautifully referenced and incredibly insightful.

  https://dash.harvard.edu/bitstream/handle/1/8852197/Wandler.pdf?sequence=1

- Nazi Eugenic Practices & Philosophy Overview

  https://en.wikipedia.org/wiki/Nazi_eugenics

- California's Dark History of Forced Sterilizations

  https://www.smithsonianmag.com/history/california-targeted-latinas-forced-sterilization-180968567/

- The National Museum of African American History & Culture – Where to Learn More

  https://nmaahc.si.edu/explore/exhibitions/slavery-and-freedom

- The 8 Most Common & Horrific Punishments for Slaves (Warning Graphic)

  https://answersafrica.com/8-most-horrific-and-inhuman-black-slaves-punishment-in-the-history-of-slavery.html

- Slavery by The Numbers

  https://www.theroot.com/slavery-by-the-numbers-1790874492

The Tuskegee Experiment

Overview – The story of the United States of America cannot be written with any level of authenticity without responsibly acknowledging centuries upon centuries of vicious human rights violations thrust upon black men, women, and children (and all peoples of non-European descent) in the name of progress, financial gain, and medical advancement. This is an indisputable fact, not open to public debate or individual rationalization.

As authors, we do not support any concept that suggests anyone should feel guilty due to the atrocities of their ancestors. Similarly, we do not support anyone attempting to rewrite the historical record in order to minimize the atrocities of their ancestors.

Tell people the truth, do it in a non-judgmental way, and let people decide for themselves what they feel. History is meant to be learned so that the wise may learn from the mistakes of the past and be freed from repeating them.

That slavery has existed since the first Egyptian dynasties does not in some way ameliorate the horrific realities of its existence in American history. In many ways, the end of the Civil War in 1865 was just the beginning of the long walk to freedom for Black Americans.

At the beginning of this long walk, acclaimed scholar (and former slave turned freedman) Dr. Booker T. Washington founded the Tuskegee Institute on July 4, 1881. His vision and self-determined approach to cultural upliftment for all Black people led the charge for economic empowerment following the end of the slavery. Dr. Washington worked tirelessly writing, speaking, organizing and advising Presidents on behalf of all Black Americans until his passing in 1915.

Seventeen years after his passing, in 1932, a medical experiment one can assume he would have rejected, was instead approved by the leadership that followed his tenure as President of the school. The “Tuskegee Study of Untreated Syphilis in the Negro Male” would become known as the Tuskegee Experiment and would ultimately form the basis for current informed consent laws because of egregious violations of medical ethics and willful misconduct.

While this experiment began prior to the establishment of the Nuremberg Code (1946-47), it extended long after despite many opportunities to terminate the experiment that exploited hundreds of Black men and their families.

In 1932 the Tuskegee Experiment began with a lie.

The medical experiment began by offering 600 Black men in Macon County, Alabama free medical care in exchange for samples of their blood, so what was termed 'Bad Blood' could be studied. In reality, what was being studied were the long-term negative health consequences if an infectious disease was purposely left untreated throughout their lifetimes.

These 600 Black men did not receive free medical care they were promised as their actual diagnosis of Syphilis was intentionally withheld from their knowledge. All were well educated in agricultural practices, but none were informed of their true disease state even following the discovery of a treatment.

Of the many willful failures that directly harmed these Americans and their families, the most reprehensible was the misconduct of withholding evidence-based treatments from them for over 29 years.

In 1943, doctors at the U.S. Marine Hospital on Staten Island discovered that penicillin could effectively treat syphilis. By 1947, the United States Public Health Service (USPHS) established 'Rapid Treatment Centers' for syphilis, but none of the 399 Tuskegee men with confirmed syphilitic infections were notified of their conditions or offered the opportunity for treatment.

It wasn't until 1968, thirty-six years after the inception of the medical experiment and twenty-five years after the discovery of penicillin for the treatment of Syphilis, that a USPHS investigator, Peter Buxton, stumbled upon the existence of the Tuskegee Experiment and raised his objections within the USPHS, to the clinical trial still ongoing. His objections were based upon valid concerns of medical ethics violations following the development of the Nuremberg Code just twenty-two years earlier.

The collective response of officials at the USPHS was as shocking as it was deplorable.

In 1969 the CDC, a part of the USPHS, willfully ignored the violations of medical ethics and the criminal withholding of an efficacious treatment from these Americans. To further exemplify their willful disregard of the clinical trial participants, the CDC employed the support of the American Medical Association and National Medical Association to ensure the study continued as designed without notifying the enrolled participants.

By 1972 and all internal efforts exhausted, Peter Buxton was left with no alternative except to whistle blow the medical experiment to Jean Heller of the Associated Press.

In July 1972, Jean Heller published the information Peter Buxton provided her and national outrage over the story resulted in the immediate termination of the medical experiment, but not before significant damage to real people had been done.

By the time the truth finally came to light, 28 of the enrolled participants had died from Syphilis, 100 more had died due to syphilitic-related complications, 40 of the men's spouses had contracted Syphilis, and at least 19 of their children had been born with Syphilis.

In 1973, Congressional hearings were held to investigate the violations, the familial heirs were compensated for the pain and suffering of their patriarchs, yet none of the people responsible for withholding treatment and violating medical ethics were even brought to trial to be held accountable for their crimes.

In 1974, the National Research Act (NRA) was created to establish criteria for responsible and safe involvement of human participants in medical experiments. The National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research (NACPSBB) was commissioned by the NRA.

In 1979, the NACPSBB published the Belmont Report that identified 3 clear ethical principles for the protection of human research subjects: (1) Respect for Persons which reaffirmed the basic human rights for autonomous decision making of all persons and the essential nature of informed consent, (2) Beneficence which reaffirmed the foundational philosophy of doing no harm and maximizing benefits while minimizing risks, and (3) Justice which spoke directly to the exploitation of disadvantaged people by the Nazi party in Germany and the Tuskegee Experiment here in the U.S.

The Belmont Report would begin the process of formally defining informed consent based on three principles: (1) Information which discusses the complete disclosure of clear & detailed information, (2) Comprehension which addresses the ability for a test subject to comprehend the information provided, and (3) Voluntariness which reaffirms that medical research can never be mandated and must always be voluntary and free from coercion.

The intention of the Belmont Report was to have it codified as law in its entirety, but this never took place despite the public outrage surrounding the Tuskegee Experiment.

However, many of these principles elucidated by the Belmont Report were included and expanded upon in what would become 45 C.F.R. 46, the code of federal regulations that establishes specific and extensive protections for all human research subjects under informed consent laws.

Key Quotes – *"In 1932, the Public Health Service, working with the Tuskegee Institute, began a study to record the natural history of syphilis in hopes of justifying treatment programs for blacks. It was called the "Tuskegee Study of Untreated Syphilis in the Negro Male."*

The study initially involved 600 black men – 399 with syphilis, 201 who did not have the disease. ***The study was conducted without the benefit of patients' informed consent.*** *Researchers told the men they were being treated for "bad blood," a local term used to describe several ailments, including syphilis, anemia, and fatigue. In truth, they did not receive the proper treatment needed to cure their illness. In exchange for taking part in the study, the men received free medical exams, free meals, and burial insurance. Although originally projected to last 6 months, the study actually went on for 40 years.*

1947 - USPHS establishes "Rapid Treatment Centers" to treat syphilis; men in study are not treated, but syphilis declines.

1968 - Concern raised about ethics of study by Peter Buxton and others.

*1969 - **CDC reaffirms need for study and gains local medical societies' support (AMA and NMA chapters officially support continuation of study).**"*

https://www.cdc.gov/tuskegee/timeline.htm

Position – Enrolling participants into a clinical trial under false pretense using coercion and deceit is clearly deplorable. However, even transgressions such as these pale in comparison to the willful act of intentionally withholding evidence-based treatments. As it pertains to COVID-19, the question before us is, 'Has the CDC once again withheld evidence-based treatments from people in need?'

Maya Angelou is quoted as saying, "When someone shows you who they are, believe them the first time." When we apply the wisdom of this quote to the Tuskegee Experiment, is it any wonder why Black Americans routinely distrust the CDC and public health officials?

As presented during the previous topic on Effective Treatments for COVID-19, there is overwhelming evidence for the safe and efficacious use of Intravenous Ascorbic Acid (IVAA) and additional oral nutrient therapies (e.g., ivermectin, hydroxychloroquine, and remdesivir). Yet, more than 12 months since the first confirmed case of COVID-19 in the U.S., the FDA and CDC have not approved any of the evidence-based treatments presented in this position paper as therapeutic options for Americans most in need.

To make matters even worse, the FDA has openly threatened licensed medical practitioners that attempt to provide potentially life-saving therapeutics to their patients with fines and revocation of their license.

Is it murder to willfully withhold evidence-based treatments from people in need?

Is it murder to not only withhold evidence-based treatments, but to aggressively prevent licensed medical professionals from providing potentially life-saving treatments to people in need?

How many lives could have been saved had the FDA authorized the use of IVAA, oral nutritional therapies (Vitamins D, C, A, E and the mineral zinc), ivermectin and hydroxychloroquine?

Sadly, we will never know, but some epidemiologists like Dr. Harvey Risch of Yale University and Dr. Dolores Cahill of the World Freedom Alliance estimate hundreds of thousands of American lives could have been saved.

When the CDC showed us who they are during the Tuskegee Experiment, perhaps we should have believed them the first time.

Additional Subtopic References

- Brief History of the Tuskegee Experiment

  https://www.history.com/news/the-infamous-40-year-tuskegee-study

- National Research Act

  https://www.congress.gov/bill/93rd-congress/house-bill/7724

- Detailed History of the Tuskegee Experiment

  http://tuskegeestudy.weebly.com/informed-consent.html

- The Full Belmont Report

  https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report

Current Federal Informed Consent Laws

https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116

https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1117

Summary – For the purposes of this section, the entirety of 45 C.F.R §46.116 (General requirements for informed consent) and 45 C.F.R §46.117 (Documentation of informed consent) will be quoted, which make up the backbone for informed consent laws in the United States. Comments and positions will not be offered, and all topics and key revisions will be bolded for reference only.

§46.116 General requirements for informed consent.

(a) **General.** General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials is described in paragraph (e) of this section. General waiver or alteration of informed consent is described in paragraph (f) of this section. Except as provided elsewhere in this policy:

(1) **Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.**

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative **sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.**

(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

(5) Except for broad consent obtained in accordance with paragraph (d) of this section:

(i) **Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.** This part of the informed consent must be organized and presented in a way that facilitates comprehension.

(ii) **Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates** the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(6) **No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence**.

(b) **Basic elements of informed consent**. Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

(1) **A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental**;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(4) **A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject**;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) **For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained**;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(8) **A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled**; and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(c) **Additional elements of informed consent**. Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

(1) **A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable**;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

(3) **Any additional costs to the subject that may result from participation in the research**;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

(6) The approximate number of subjects involved in the study;

(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) **A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions**; and

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

(d) **Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens**. Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of this section. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

(1) The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9) of this section;

(2) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information

such that a reasonable person would expect that the broad consent would permit the types of research conducted;

(3) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

(4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

(5) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

(6) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

(7) **An explanation of whom to contact for answers to questions about the subject's rights** and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

(e) **Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials.**

(1) Waiver. An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (e)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) Alteration. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (e)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) Requirements for waiver and alteration. In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

(i) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

(A) Public benefit or service programs;

(B) Procedures for obtaining benefits or services under those programs;

(C) Possible changes in or alternatives to those programs or procedures; or

(D) Possible changes in methods or levels of payment for benefits or services under those programs; and

(ii) The research could not practicably be carried out without the waiver or alteration.

(f) **General waiver or alteration of consent**

(1) Waiver. An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (f)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) Alteration. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (f)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) **Requirements for waiver and alteration**. In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

(i) **The research involves no more than minimal risk to the subjects**;

(ii) The research could not practicably be carried out without the requested waiver or alteration;

(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

(iv) **The waiver or alteration will not adversely affect the rights and welfare of the subjects**; and

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

(g) **Screening, recruiting, or determining eligibility.** An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

(1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

(h) **Posting of clinical trial consent form.**

(1) For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

(2) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

(3) The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

(i) **Preemption.** The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

(j) **Emergency medical care**. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable

Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

(Approved by the Office of Management and Budget under Control Number 0990-0260)

§46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, **informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative**. A written copy shall be given to the person signing the informed consent form.

(b) Except as provided in paragraph (c) of this section, **the informed consent form may be either of the following**:

(1) A written informed consent form that meets the requirements of §46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.

(2) A short form written informed consent form stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

(c) **[Untitled Section]**

(1) **An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following**:

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

(ii) **That the research presents no more than minimal risk of harm to subjects** and involves no procedures for which written consent is normally required outside of the research context; or

(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

(2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

(Approved by the Office of Management and Budget under Control Number 0990-0260)

The Patient Bill of Rights

https://www.ama-assn.org/delivering-care/ethics/patient-rights

Key Quotes – *"The health and well-being of patients **depends on a collaborative effort between patient and physician in a mutually respectful alliance**. Patients contribute to this alliance when they fulfill responsibilities they have, to seek care and to be candid with their physicians, for example.*

*Physicians can best contribute to a mutually respectful alliance with patients by serving as their patients' advocates and by respecting patients' rights. **These include the right**:*

a) *To courtesy, respect, dignity, and timely, responsive attention to his or her needs.*

b) *To receive information from their physicians and to have opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives, including the risks, benefits and costs of forgoing treatment. Patients should be able to expect that their physicians will provide guidance about what they consider the optimal course of action for the patient based on the physician's objective professional judgment.*

c) *To ask questions about their health status or recommended treatment when they do not fully understand what has been described and to have their questions answered.*

d) ***To make decisions about the care the physician recommends and to have those decisions respected. A patient who has decision-making capacity may accept or refuse any recommended medical intervention.***

e) *To have the physician and other staff respect the patient's privacy and confidentiality.*

f) *To obtain copies or summaries of their medical records.*

g) *To obtain a second opinion.*

h) *To be advised of any conflicts of interest their physician may have in respect to their care.*

i) To continuity of care. Patients should be able to expect that their physician will cooperate in coordinating medically indicated care with other health care professionals, and that the physician will not discontinue treating them when further treatment is medically indicated without giving them sufficient notice and reasonable assistance in making alternative arrangements for care.

AMA Principles of Medical Ethics: I, IV, V, VIII, IX:"

Summary – In 1973, the American Hospital Association's House of Delegates adopted a Patient's Bill of Rights following the revelations of the Tuskegee Experiment. While these rights have yet to be officially adopted into federal law, they have been adopted in various forms by such reputable organizations as the American Medical Association and are widely taught around the world in most courses on medical ethics.

The key statutes acknowledge that a doctor's responsibility is to work in collaboration with their patients to offer recommendations for treatment and clearly places their patients at the head of all decisions. The key statutes assert to protect all patient's rights to refuse any treatment and to protect the patient's rights to privacy as is also required under HIPAA laws.

Position – The Patient Bill of Rights is well reasoned and has historical ties to seminal events we universally agree should never be repeated. The Patient Bill of Rights is a clear affirmation of individual sovereignty that no medical treatment should ever be mandated upon a person in need and no evidence-based option ever withheld.

While there are 27 Constitutional Amendments, the 26th Constitutional Amendment was first proposed and ratified in 1971. Since that time, the only Constitutional Amendment to be ratified is the 27th amendment which was first proposed in 1789 but not officially ratified until 1992.

A patient's bill of rights that reaffirms the Constitutional right to refuse medical treatments and protects both informed consent and medical privacy, while also affirming that no evidence-based treatment can ever be withheld is long overdue.

Additional Subtopic References

- Health Insurance Portability and Accountability Act of 1996 (HIPAA)

  https://www.cdc.gov/phlp/publications/topic/hipaa.html

History of Medical Ethics Position

'Those that don't know history are doomed to repeat it.'

'Fools rush in.'

‘Quick to judge, quick to be wrong.’

‘When someone shows you who they are, believe them the first time.’

There is an incredible wisdom in quotes such as these, a wisdom born often from horrific experiences that we must do all we can to ensure never happen again.

A mistake with good intention may occur but withholding evidence-based treatments is not a mistake. It is a demonstration of willful intent to harm or at least ensure that nothing can be done to prevent harm.

The public depends upon individuals of high moral character to protect them from attempts at wrongdoing.

When we are discussing human rights, ethics, and COVID there is no such thing as acceptable casualties. This is the mentality of war.

Living is not war.

Living is a sacred event, a fortunate blessing that didn’t have to happen, but how amazing that it did?

Health isn’t a war against disease, health is the promotion of life.

How can medical professionals promote life when evidence-based treatments are withheld?

If withholding evidence-based treatment from 399 American men during the Tuskegee Experiment was wrong, then why is the withholding of evidence-based treatments from 332 MILLION Americans during COVID-19not considered the same?

People Worthy of Our Remembrance

Rosanna Un Died Alone

“In the early hours of Dec. 13, as her mother’s breathing became shallow and laboured, Natalia Munnion was told to leave her long-term care facility. Her one-hour compassionate visit with her mother, Roseanna Un, was over. The nurse said her mother would be better by morning, and that she would call Munnion with any news then.

Two hours later, the nurse called Munnion to say the serious chest infection had slowed her mother’s breathing more and that she should get there as soon as she could. Munnion rushed back to Hawthorne Seniors Care Community in Port Coquitlam with her sister, but their mother had already died. Un was 88. “My mom didn’t have to go that way. My mom did not have to die alone,” said Munnion, who lives in nearby Coquitlam.

https://ca.news.yahoo.com/mom-did-not-die-alone-165144824.html

Topic 7 – Violations of Medical Ethics During COVID

Topic Introduction – Considering the medical ethics presented, a deeper dive can dig into a thorough examination of the multitude of violations of medical ethics throughout the global reaction to the SARS-CoV-2 virus led by the World Health Organization and the Centers for Disease Control and Prevention.

Incentivizing Disease & Death

Summary – In April 2020, highly respected senator and physician Dr. Scott Jensen was wrongfully vilified for a statement he made regarding incentivizing medical insurance reimbursements for COVID-19.

Dr. Jensen was quoted as saying, "*Hospital administrators might well want to see COVID-19 attached to a discharge summary or a death certificate. Why? Because if it's a straightforward, garden-variety pneumonia that a person is admitted to the hospital for – if they're Medicare – typically, the diagnosis-related group lump sum payment would be $5,000. But if it's COVID-19 pneumonia, then it's $13,000, and if that COVID-19 pneumonia patient ends up on a ventilator, it goes up to $39,000.*"

Ultimately, Dr. Jensen's brave statement of fact was substantiated by at least seven independent fact-checking services and the USA Today, but that did not stop the attacks he had to endure for speaking truth.

As this crisis has unfolded, Dr. Jensen's statement regarding the potential for corruption and egregious violations of medical ethics became reality. An investigative report by the New York Times followed the sad story of RC Kendrick, an 88-year-old senior with dementia.

"*On a chilly afternoon in April, Los Angeles police found an old, disoriented man crumpled on a Koreatown sidewalk.*

Several days earlier, RC Kendrick, an 88-year-old with dementia, was living at Lakeview Terrace, a nursing home with a history of regulatory problems. His family had placed him there to make sure he got round-the-clock care after his condition deteriorated and he began disappearing for days at a time.

But on April 6, the nursing home deposited Mr. Kendrick at an unregulated boardinghouse — without bothering to inform his family. Less than 24 hours later, Mr. Kendrick was wandering the city alone.

According to three Lakeview employees, Mr. Kendrick's ouster came as the nursing home was telling staff members to try to clear out less-profitable residents to make room for a new class of customers who would generate more revenue: patients with Covid-19."

The New York Times investigation confirmed that according to 22 watchdogs and dozens of elder-care attorneys that this deplorable situation was occurring across the nation.

Key Quote – *"CMS this week will begin sending a 20% increase in Inpatient Prospective Payment System (IPPS) payments for patients previously treated for COVID-19 — far in advance of the latest quarterly update. The payments, as required by the CARES Act, will be automatically sent to previously paid providers that used the COVID-19 code (diagnosis code B97.29).*

CMS on April 21 will start to increase inpatient hospital payments by 20% for Medicare claims related to the care of COVID-19 patients on April 1 or later (diagnosis code U07.1)."

https://www.hfma.org/topics/news/2020/04/increased-medicare-payments-for-covid-19-care-to-stretch-back-to.html

Position – The example of RC Kendrick is exactly why financially incentivizing one infectious disease during a crisis is unethical. It opens the door for corruption. because enforcement of corruption and criminal activity cannot keep pace with opportunistic human parasites willing to do wrong in hopes they can get away with it.

Incentivizing death and disease are medically unethical because it assumes all persons associated with the care of people in need are working from the highest ideals of professional integrity. While many people in the healthcare industry do, many do not. Hospitals have become profitable organizations. If a hospital administrator is concerned about profitability in a time when they are forced to dramatically reduce services, but incentives offer an opportunity to mitigate financial losses, they may be forced into ethical decisions. Should they refuse the economic opportunity and risk the long-term viability of their facility or should they accept the economic opportunity even though they know it is morally corrupt?

Incentivizing death and disease inject unnecessary chaos into a situation already filled with chaos. This creates ethical dilemmas that compromise the integrity of medical practice, which invites the corruption and harm that Dr. Jensen brought to the public's attention yet was vilified for doing.

Additional Subtopic References

- Center for Medicare and Medicaid Services Coverage and Payment Bulletin for COVID

  https://www.cms.gov/files/document/03052020-medicare-covid-19-fact-sheet.pdf

- USA Today Exonerates Dr. Jensen

  https://www.usatoday.com/story/news/factcheck/2020/04/24/fact-check-medicare-hospitals-paid-more-covid-19-patients-coronavirus/3000638001/

- New York Times Investigative Article

  https://www.nytimes.com/2020/06/21/business/nursing-homes-evictions-discharges-coronavirus.html?referringSource=articleShare

- LA Times Investigative Article

  https://www.latimes.com/california/story/2020-05-03/coronavirus-nursing-homes-financial-profits

Problems with Clinical Trials for Experimental Biologics

Summary of Pfizer Experimental COVID Biologic Clinical Trial Design – An experimental COVID biologic has no previously known and FDA authorized use in human subjects and therefore must be categorized as experimental until such time as significant longitudinal data is collected and analyzed for safety and efficacy over a significant sample size of participants. As this mRNA biologic therapy is experimental, its only legal administration is supposed to be in an ongoing clinical trial with volunteer participants and signed informed consent authorizations.

Key Quotes – *"Estimated Study Completion Date – January 31, 2023. Recruitment - Active, not recruiting.*

In Phase 1 participants, SARS-CoV-2 serum neutralizing antibody levels, expressed as GMTs [Time Frame: Through 2 years after the final dose] As measured at the central laboratory

In the first 360 participants randomized into Phase 2/3, percentage of participants reporting serious adverse events *[Time Frame: From dose 1 through 6 months after the last dose] As elicited by investigational site staff*

Confirmed COVID-19 in Phase 2/3 participants without evidence of infection before vaccination [Time Frame: From 14 days after the second dose of study intervention to the end of the study, up to 2 years] Per 1000 person-years of follow-up

Previous clinical (based on COVID-19 symptoms/signs alone, if a SARS-CoV-2 NAAT result was not available) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID 19

Phase 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit.

Phase 1 only: Any screening hematology and/or blood chemistry laboratory value that meets the definition of a ≥ Grade 1 abnormality.

Phase 1 only: Positive test for HIV, hepatitis B surface antigen (HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at the screening visit.

Phase 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention.

Responsible Party: BioNTech SE

Study Sponsor: BioNTech SE

Collaborators: Pfizer

Investigators: Pfizer CT.gov Call Center"

https://clinicaltrials.gov/ct2/show/record/NCT04368728

Clinical Trial Design Phase 1

Enrolled Participants: **45**

Measurement Length: **2 Years**

Placebo: **Saline**

Prescreening for Serologic IgM & IgG Antibodies: **Yes**

Prescreening Nasal PCR for Viral Fragments: **Yes**

Other Prescreening Laboratories: **No**

Post Inoculation Evaluation of Antibody Production: **Yes**

Measurement of adverse events: **1 month, all participants**

Measurement of serious adverse events extends: **6 months, all participants**

Sample size reduction may occur due to placebo participant's right to decline offer of experimental COVID biologics at later date, participants exercising legal right to withdraw from study at any time for any reason, or death.

Second 100 microgram inoculation was withheld from administration "*because of the increased reactogenicity and a lack of meaningfully increased immunogenicity after a single dose compared with the 30-µg dose.*"

It appears a second 30 microgram dose was administered in place of the previously intended 100 microgram dose.

Additional Subtopic References

- https://pubmed.ncbi.nlm.nih.gov/32785213/

Clinical Trial Analysis Phase 2/3

Enrolled Participants: **43,998**

Measurement Length: **2 Years**

Placebo: **Saline**

Prescreening for Serologic IgM & IgG Antibodies: **No**

Prescreening Nasal PCR for Viral Fragments: **No**

Other Prescreening Laboratories: **No**

Post Inoculation Evaluation of Antibody Production: **No**

Measurement of adverse events: **1 month, first 360 participants**

Measurement of serious adverse events extends: **6 months, first 360 participants**

No measurement of adverse events or serious adverse events in the remaining participant population is mentioned.

Sample size reduction may occur due to placebo participant's right to decline offer of experimental COVID biologics at later date, participants exercising legal right to withdraw from study at any time for any reason, or death.

Position – Without long-term data and with Phase 3 clinical trials still underway, anyone electing to, or being coerced into, receiving either of the 2 current COVID experimental COVID biologics is agreeing to the use of an experimental biologic still under investigation within an ongoing clinical trial. Therefore, each person should be protected by the same informed consent laws that enrolled participants are.

If a clinical trial is active and the medical treatment being tested is not FDA approved, which the COVID experimental COVID biologics are not (they are only EUA approved), then each person consenting to receiving the dual inoculation, or being coerced into receiving the dual inoculation, is effectively entering a clinical trial.

As such, the authors of the clinical trial and the entities that authorized the clinical study should become immediately liable for any injuries incurred by the public who are being coerced by public health officials as well as news and media outlets to consent to an experimental COVID biologic. The coercion tactics make no mention of risks and reports of adverse events including a growing number of fatalities resulting from the administration of the experimental COVID biologics.

It bears repeating that evidence-based treatments for COVID-19 exist and have existed since February 2020. Each existing treatment is exceedingly inexpensive and saves lives via prevention, accelerated recovery, and reduced hospital stay.

Despite warnings during the Phase 1 clinical trial of increasing reactogenicity in a significant percentage of enrolled participants, the clinical trial was approved to move into Phase 2/3 by the IRB. This explains why government oversight is put into place to ensure bad decisions such as this never make it to the public as well as to protect human participants enrolled in clinical trials.

Federal health agencies and corporate researchers have no reasonable idea about the long-term effects of the COVID biologic. Will persons subjecting their body to the experimental COVID biologic develop autoimmune conditions? Will they become infertile? Will pregnant women auto-abort their babies in womb, as has happened according to reports in VAERS?

Federal health agencies and corporate researchers do know that experimental COVID biologics will do harm.

In Phase 1 of the clinical trial, modifications were made to the design of the clinical trial in progress, which is one of many red flags. During Phase 1, in a sample size of only 45 participants further subdivided into 2 experimental groups of 11 to 12 participants, the BNT162b1 experimental biologic was shown to generate greater adverse events and thus discontinued, while the BNT162b2 scheduled second dose of 100 micrograms was discontinued after concerns were raised. The result for the BNT162b2 Phase 1 clinical trials was that only half of the enrolled participants in that experimental group received the single 30 microgram dose.

Additionally, Phase 2/3 did not prescreen participants for the presence of IgM or IgG antibodies and did not prescreen for previous infection using PCR nasal swab or serologic viral antigen, compromising the purity of the entire participant population, and rendering the results of the study null and void due to the likelihood of sample population contamination with pre-existing exposure to the SARS-CoV-2 virus.

Further, Phase 2/3 did not include measurement of antibody production post-inoculation, which is the very point of the entire study. Efficacy for these experimental COVID biologics is based upon the verification that they could indeed co-opt cellular ribosomal complexes to produce viral antigen fragments and ultimately inspire an immunological response that cultivated long-term antibody immunity.

What was done in the Pfizer clinical trial is not science, it's the appearance of science. The Pfizer study is severely flawed and compromises the integrity of all test results.

Human should not be treated as guinea pigs, and they are protected by law. Yet, human beings are being treated like guinea pigs and coerced through a variety of deeply troubling tactics to consent to the use of experimental COVID biologics still being investigated in an ongoing clinical trial.

Is the public being informed that these biologics are neither as safe nor as effective as people with vested financial interests would lead the world to believe?

How a clinical trial of this importance reaches approval for the enrollment of human subjects, without data from preceding animal experiments is a scientific travesty that sets the stage for this experimental COVID biologic to not only be ineffective, but also injurious to the people consenting to its use.

This clinical trial isn't science…it's the appearance of science.

It is reasonable to expect independent and transparent oversight of the experimental COVID biologic clinical trials. Why was the public not given the opportunity to comment on the design of these clinical trials before they began enrolling participants?

Why were the corporations, with clear financial conflicts of interest, essentially allowed to police themselves?

Why were the experimental COVID biologics able to get to market in only 8 months when it normally takes 8 years?

Evidence of safe and effective treatments has been in existence from the beginning of this crisis, which creates time for experimental COVID biologics to undergo rigorous safety and efficacy testing. There was never a need to rush development of a new technology.

Rushing a warp speed new technology to the public without long-term proof of safety and immediate proof of efficacy is ethically capricious and scientifically irresponsible.

This should not happen in a free society.

This simply cannot happen with so much at stake.

Human beings are not guinea pigs, but humans are being treated as such with each administration of these experimental COVID biologics.

Problems with Clinical Trials for Experimental Biologics – Analysis

Summary Pfizer Experimental COVID Biologic Clinical Trial Analysis – Experimental COVID biologic has no known, nor FDA authorized, use in human subjects and therefore must be categorized as experimental until such time as significant longitudinal data is collected and analyzed for safety and efficacy over a significant sample size of participants. As this mRNA biologic therapy is experimental, its only legal administration can be in a clinical trial with willing participants and signed informed consent authorizations.

https://www.nejm.org/doi/10.1056/NEJMoa2034577

Key Quotes – *"In an ongoing multinational, placebo-controlled, observer-blinded, pivotal efficacy trial, we randomly assigned persons 16 years of age or older in a 1:1 ratio to receive two doses, 21 days apart, of either placebo or the BNT162b2 vaccine candidate (30 µg per dose).*

A total of 43,548 participants underwent randomization, of whom 43,448 received injections: 21,720 with BNT162b2 and 21,728 with placebo.

There were 8 cases of Covid-19 with onset at least 7 days after the second dose among participants assigned to receive BNT162b2 and 162 cases among those assigned to placebo;

BNT162b2 was 95% effective in preventing Covid-19 (95% credible interval, 90.3 to 97.6).

The first primary end point was the efficacy of BNT162b2 against confirmed Covid-19 with onset at least 7 days after the second dose in participants who had been without serologic or virologic evidence of SARS-CoV-2 infection up to 7 days after the second dose; the second primary end point was efficacy in participants with and participants without evidence of prior infection. Confirmed Covid-19 was defined according to the Food and Drug Administration (FDA) criteria as the presence of at least one of the following symptoms: fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhea, or vomiting, combined with a respiratory specimen obtained during the symptomatic period or within 4 days before or after it

that was positive for SARS-CoV-2 by nucleic acid amplification–based testing, either at the central laboratory or at a local testing facility (using a protocol-defined acceptable test).

An explanation of the various denominator values for use in assessing the results of the trial is provided in Table S1 in the Supplementary Appendix, available at NEJM.org. In brief, the safety population includes persons 16 years of age or older; a total of 43,448 participants constituted the population of enrolled persons injected with the vaccine or placebo. The main safety subset as defined by the FDA, with a median of 2 months of follow-up as of October 9, 2020, consisted of 37,706 persons, and the reactogenicity subset consisted of 8183 persons. The modified intention-to-treat (mITT) efficacy population includes all age groups 12 years of age or older (43,355 persons; 100 participants who were 12 to 15 years of age contributed to person-time years but included no cases). The number of persons who could be evaluated for efficacy 7 days after the second dose and who had no evidence of prior infection was 36,523, and the number of persons who could be evaluated 7 days after the second dose with or without evidence of prior infection was 40,137.

The 95.0% credible interval for vaccine efficacy and the probability of vaccine efficacy greater than 30% were calculated with the use of a Bayesian beta-binomial model. The final analysis uses a success boundary of 98.6% for probability of vaccine efficacy greater than 30% to compensate for the interim analysis and to control the overall type 1 error rate at 2.5%. Moreover, primary and secondary efficacy end points are evaluated sequentially to control the familywise type 1 error rate at 2.5%. Descriptive analyses (estimates of vaccine efficacy and 95% confidence intervals) are provided for key subgroups.

These data do not address whether vaccination prevents asymptomatic infection; a serologic end point that can detect a history of infection regardless of whether symptoms were present (SARS-CoV-2 N-binding antibody) will be reported later. Furthermore, given the high vaccine efficacy and the low number of vaccine breakthrough cases, potential establishment of a correlate of protection has not been feasible at the time of this report.

This report does not address the prevention of Covid-19 in other populations, such as younger adolescents, children, and pregnant women.

The development of BNT162b2 was initiated on January 10, 2020, when the SARS-CoV-2 genetic sequence was released by the Chinese Center for Disease Control and Prevention and disseminated globally by the GISAID (Global Initiative on Sharing All Influenza Data) initiative.

Pfizer was responsible for the design and conduct of the trial, data collection, data analysis, data interpretation, and the writing of the manuscript. BioNTech was the sponsor of the trial, manufactured the BNT162b2 clinical trial material, and contributed to the interpretation of the data and the writing of the manuscript.

(Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728.)"

Investigative Note – Links to all PDF Supplementary Materials are broken or not responding at the time of investigation January 24, 2021. See end of subtopic to confirm visually attempts were made on multiple browsers without success.

Clinical Trial Analysis Phase 2/3

Enrolled Participants: **43,998**

Number of Participants Receiving Inoculations: **43,448**

Number of Participants Receiving BNT162b2 Experimental Biologic: **21,720**

Number of Participants Receiving Saline Placebo: **21,728**

Main Safety Subset Participants: **37,706**

Participants Exhibiting Reactogenicity: **8,183**

Final Number of Participants: **40,137**

Number of Enrolled Participants Who Withdrew or Were Removed from Trial: **3,861**

Trial Status: **Ongoing For 2 Year from Date of 2nd Inoculation**

Post Inoculation Laboratory Methods for Assessment of Safety & Efficacy: **Unknown**

Exact methods for verifying presence or absence of post-inoculation infection are not clearly identified via the NIH Clinical Trial Study Detail or New England Journal of Medicine Published Manuscript.

If PCR tests were used, there is no mention of the company or NIH approved entity processing the results or the cycle threshold value used to determine a positive vs negative result.

Safety percentages were calculated based upon the first 360 participant reports rather than the full subset of participants according to the published NIH clinical trial study details.

Serologic and PCR Prescreening for participants before entry into the clinical trial was not performed during Phase 2/3.

Reprint of Clinical Trial Analysis Phase 2/3 from Previous Subtopic Section

https://clinicaltrials.gov/ct2/show/record/NCT04368728?view=record

Prescreening for Serologic IgM & IgG Antibodies: **No**

Prescreening Nasal PCR for Viral Fragments: **No**

Other Prescreening Laboratories: **No**

Post Inoculation Evaluation of Antibody Production: **No**

Measurement of adverse events: **1 month, first 360 participants**

Measurement of serious adverse events extends: **6 months, first 360 participants**

No measurement of adverse events or serious adverse events in the remaining participant population is mentioned.

Position – Concerns include that Pfizer and BioNTech had a demonstrative role in the analysis of the safety and efficacy of the clinical trials. It is unethical and a definitive conflict of interest for the corporations that have vested financial interests in the approval of their experimental biologics to have authorship regarding the analysis of their products during a crisis.

This confirms that no independent analysis was done to verify the accuracy, objectivity, and integrity of their analysis. No legal penalties for data manipulation were acknowledged by Pfizer/BioNTech, which is concerning. What is the deterrent for data manipulation or exclusion of enrolled participants that might adversely impact the final analysis?

Another flaw in the study design and analysis is the reckless absence of thorough prescreening. To validate that the participant population is definitively free from prior exposure to the SARS-CoV-2 virus, serologic IgM and IgG antibody tests and molecular tests with stated cycle threshold values must be provided prior to entry into the study.

Due to this failure, it is impossible to state with scientific integrity or confidence that the participants in the study demonstrated a pure sample population to properly assess both efficacy and especially safety.

An additional flaw in the analysis is the omission of data of at least 3,861 enrolled participants who either voluntarily withdrew or were withdrawn from the study. What happened in each of these cases? Where is the data for independent evaluation?

The declarative statement of safety and efficacy of an experimental biologic that is still in an ongoing clinical trial is also a flaw in the analysis. With 2 years of data still to be collected how can an objective scientist make such a presumptive statement regarding safety and efficacy?

These are scientifically irresponsible conclusions while data is still being collected and the clinical trial is still in progress.

The final major flaw in analysis is the headline suggesting 95% clinical efficacy of the vaccine in prevention of infective spread following dual dose administration.

First, this information is not based on equal environmental controls for the experimental and control groups as there is no means to establish a definitive equivocal number of actual confirmed exposures to infectious persons following administration without placing all participants in highly controlled environments that would violate ethical standards of clinical trial design.

Second, the methods used for testing are not clearly stated. Are these subjective determinations or laboratory objective determinations?

If the methods included laboratory testing, which testing was used? If PCR was used, which PCR tests were used and what was the cycle threshold used as the cut off for positive signal detection?

If PCR testing was used, is the cycle threshold calibrated for infectiousness or merely prior existence of possible infection?

If the goal of the experimental COVID biologic clinical trial is to prove efficacy, then the question must be asked, efficacy of what, inducing an immunological IgM and IgG antibody response?

Although the pursuit of answering such questions makes sense, unfortunately the clinical trial is not designed to answer such questions in Phase 2/3. As a result, Pfizer and BioNTech are both relying exclusively on Phase 1 studies, with exceedingly small sample sizes, to have any understanding of this crucial information.

The Phase 1 clinical trial involved only 45 participants, some of whom received the saline placebo and some of whom received the BNT162b1 experimental biologic that was discontinued for Phase 2/3 evaluation, and some of whom received the BNT162b2 experimental biologic.

What this means is that the data being collected for actual efficacy of this experimental COVID biologic is based upon a very small sample size of participants.

The design of this clinical trial compromises the investigatory objectives rendering all data and subsequent analysis of the data for safety and efficacy incomplete until the conclusion of the clinical trial. At worst, the severely flawed design of the clinical trial renders the data and subsequent analysis null and void.

Phase 3 Clinical Trial – Administration & Surveillance

Vaccine Adverse Events Reporting Database (VAERS)

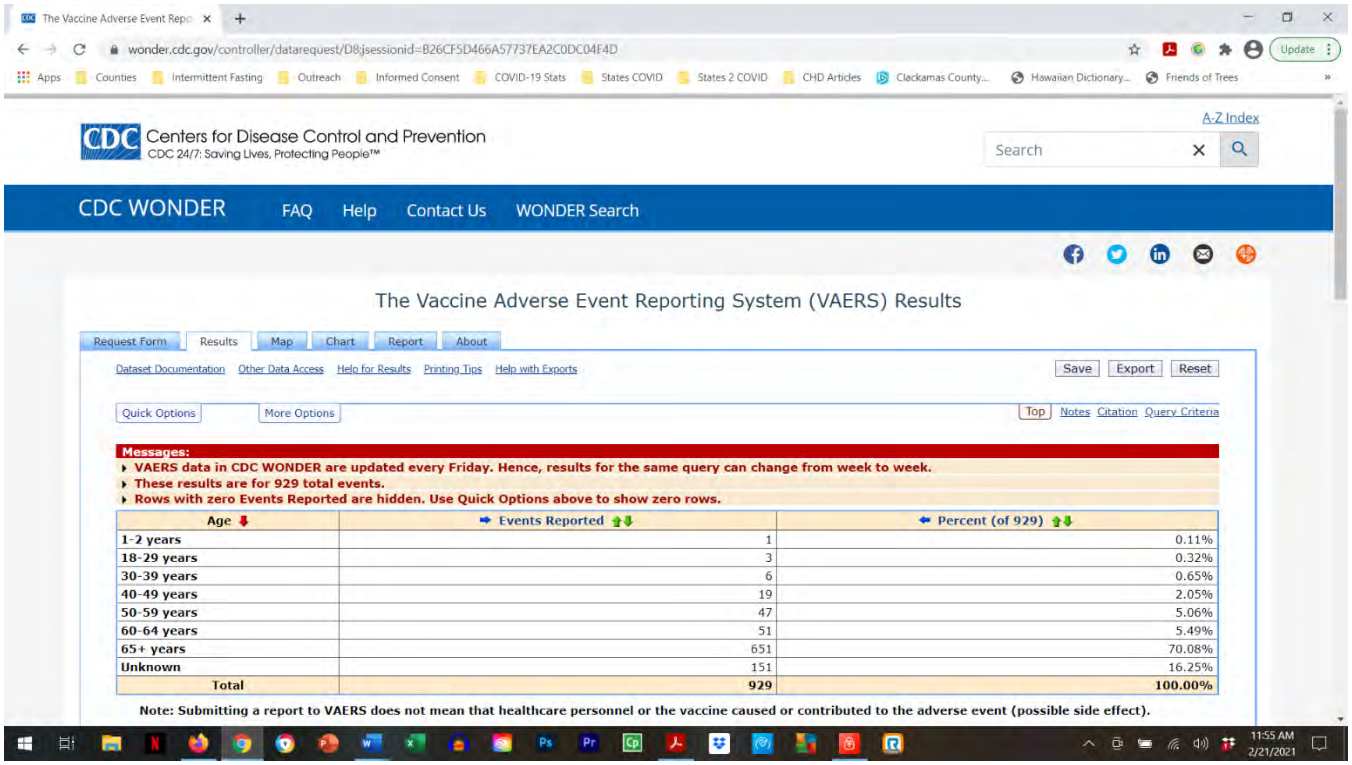
https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=D1E28EE61A7BAC75C32778FDBCF3

Reported Fatalities - Dec 13, 2020 to Jan 29, 2021

Reported Adverse Events – Dec 13, 2020 to Feb 12, 2021

929 Reported Fatalities Related to Experimental COVID Biologics

15,923 Reported Adverse Events Related to Experimental COVID Biologics



CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

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CDC WONDER | FAQ | Help | Contact Us | WONDER Search

The Vaccine Adverse Event Reporting System (VAERS) Results

Request Form | Results | Map | Chart | Report | About

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

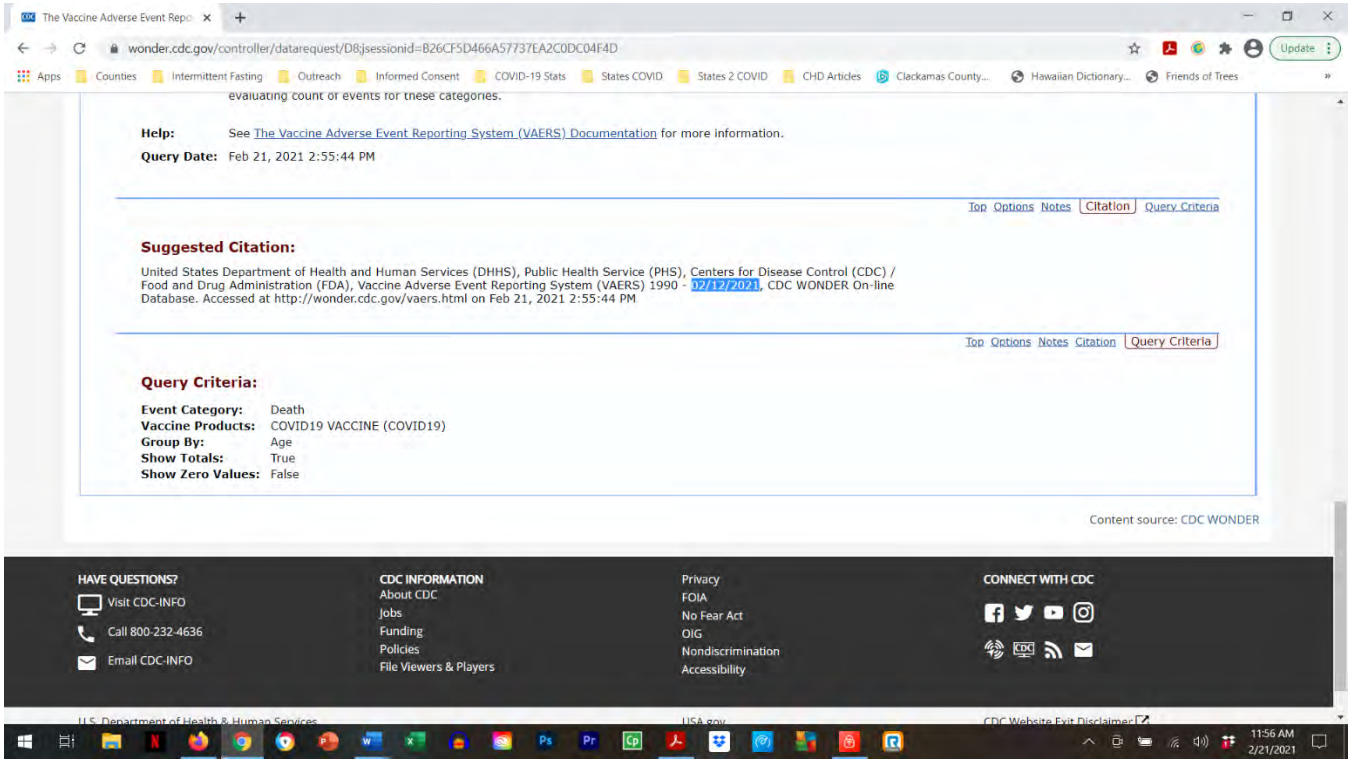
Quick Options | More Options | Top | Notes | Citation | Query Criteria

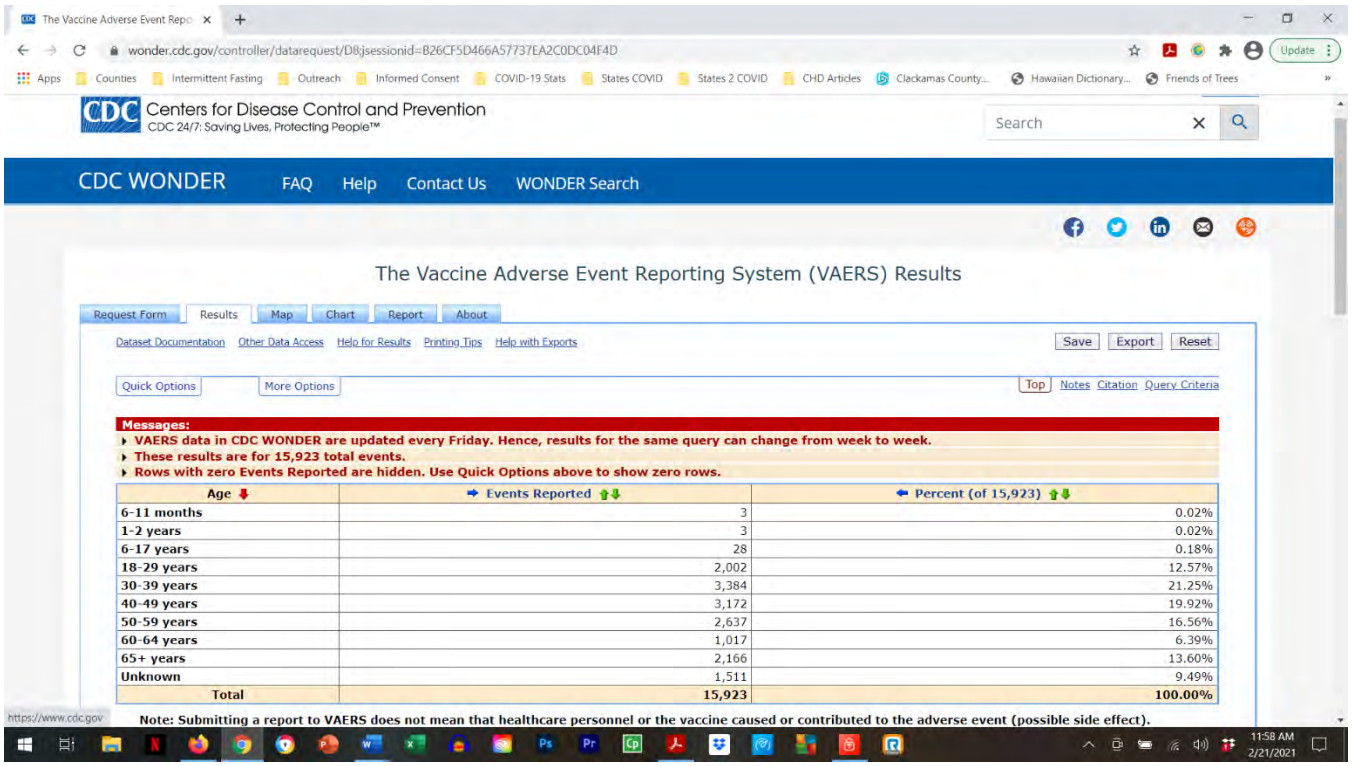
Messages:
- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 929 total events.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Age	Events Reported	Percent (of 929)
1-2 years	1	0.11%
18-29 years	3	0.32%
30-39 years	6	0.65%
40-49 years	19	2.05%
50-59 years	47	5.06%
60-64 years	51	5.49%
65+ years	651	70.08%
Unknown	151	16.25%
Total	**929**	**100.00%**

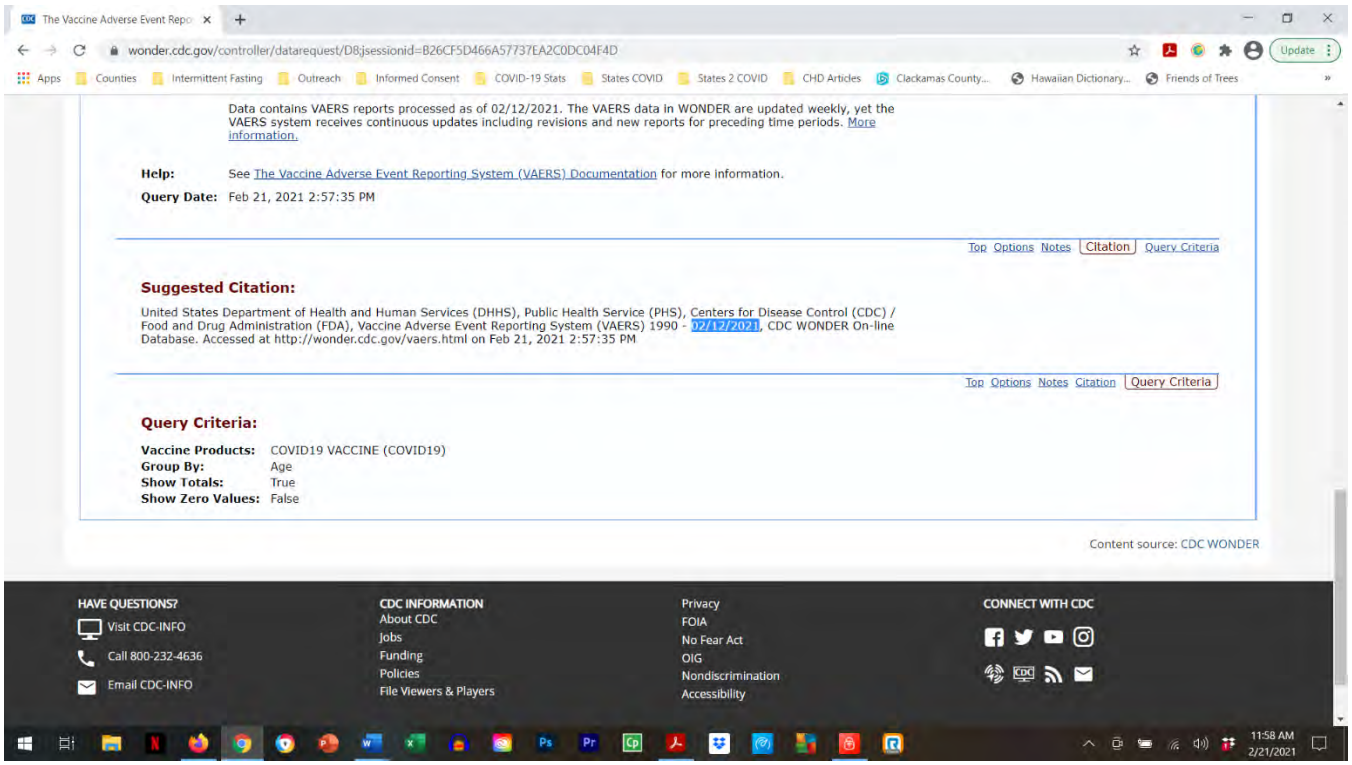
Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Reported Fatalities Search Criteria





Reported Adverse Events Search Criteria



Summary – When examining data from the federal Vaccine Adverse Events Reporting System (VAERS) it is important to note several key facts to maintain objectivity.

(1) VAERS is a federal database with criminal penalties for submitting fraudulent records. **"Knowingly filing a false VAERS report is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment."**

(2) Providers are legally required to report the following adverse events to VAERS for all experimental COVID biologics per Emergency Use Authorization:

a. Death

b. Life-threatening Adverse Event

c. Inpatient or Prolonged Hospitalization

d. Persistent or Significant Incapacity or Substantial Disruption of the Ability to Conduct Normal Life Functions

e. Congenital Anomaly/Birth Defects

f. All Important Medical Events That Based on Appropriate Medical Judgement May Jeopardize the Individual and May Require Medical or Surgical Intervention to Prevent One of the Outcomes Listed Above

g. Cases of COVID-19 That Result in Hospitalization or Death

h. Cases of Multisystem Inflammatory Syndrome

i. Vaccine Administration Errors, Whether or Not Associated with an Adverse Event

https://vaers.hhs.gov/faq.html

Position – Humans are not guinea pigs. Use of experimental COVID biologics should not be mandated based upon the reported injuries alone.

In order to fulfill informed consent, all persons considering the use of the experimental COVID biologics must: (1) be informed of the reports in VAERS, (2) be informed that the experimental COVID biologics are still being evaluated for long-term adverse events in ongoing clinical trials, (3) be informed of whether or not there is any data for their demographic, (4) be informed of the existence of evidence-based treatment options, (5) be informed of how the theoretical mechanism of action works, (6) be informed of the ingredients, (7) be confirmed to have had no prior adverse reactions to vaccine administration, (8) be informed of the potential for autoimmunity and infertility, and (9) be made aware that there is no requirement to provide consent.

As more tech companies begin to endeavor into medicine it is important that they don't view the human body as they view a computer, where viral codes and antivirus measures can be uploaded and updated without much consequence.

If we view the fact that clinical trials are ongoing ethically, then that means the global distribution of these experimental COVID biologics is an ongoing experiment because of the absence of long-term data. The ever-growing number of fatalities and adverse events is concerning because definite harm is ongoing. Further, will we be able to definitely compare the use of the biologic to the use of known evidence-based treatments for efficacy and safety to provide people with a choice? This is disappointing outcome of poorly designed clinical trials for completely new medical technologies that were rushed through evaluation at 'warp speed'.

This isn't a science fiction movie, even though science fiction terms have been used to market it. This isn't a movie humans will be able to walk out of the theater if they don't like what they're watching.

This is a global science experiment underway with no long-term data available to find confidence in.

Phase 3 Clinical Trial – Liability

https://www.lawinsider.com/dictionary/vaccine

Key Quotes for Legal Definition of Vaccine – *"(1) a specially prepared antigen which, upon administration to a person, will result in immunity and, specifically for the purposes of this rule, shall mean influenza and pneumococcal vaccines, (2) a specially prepared antigen administered to a person*

for the purpose of providing immunity, or (3) a specially prepared antigen, which upon administration to a person may result in immunity."

Summary – This legal definition is based on over 90 references. There is no mention of experimental COVID biologic technology in these definitions.

Position – By legal standards these new experimental COVID biologics do not meet the criteria for being categorized as a vaccine. As such, we have elected to use the phrase 'experimental COVID biologics' and derivatives until such time as the exact classification of the biologics are universally agreed upon following global scientific comment and subsequent legal codification.

Key Quotes Granting Vaccine Manufactures Immunity from Civil Litigation – *"42 USC 300aa-11(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death…*

42 USC 300aa-11(3) No vaccine administrator or manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988.

42 USC 300aa-22(b)(1) Unavoidable adverse side effects; warnings: No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."

https://www.law.cornell.edu/uscode/text/42/300aa-11

https://www.law.cornell.edu/uscode/text/42/300aa-22

PREP Declaration & Amendments
https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx

Summary – Vaccine manufacturers are currently exempt from civil litigation involving vaccine injuries from FDA approved vaccines only. However, the apparent law governing liability is the PREP Act, which can only be bypassed in the pursuit of compensation for injury if willful misconduct can be proven.

Position – With the evidence already amassed regarding violations of Federal Laws for data collection and with the FDA willfully withholding evidence-based treatments for COVID from the public, we believe willful misconduct can be argued successfully.

As experimental COVID biologics do not meet the legal criteria as a vaccine, and whereas the current experimental COVID biologics are not FDA approved due to the respective clinical trials ongoing, Pfizer, BioNTech, and Moderna should be liable for all death and injuries related to administration of the experimental COVID biologics.

Pfizer, BioNTech, and Moderna do not qualify for protection from civil litigation normally provided by 42 USC 300aa-11(2)(A), 42 USC 300aa-11(3), and 42 USC 300aa-22(b)(1). This is clear.

However, the PREP Act is the obstacle that must be surmounted to protect the Constitutional rights of anyone injured by the experimental COVID biologics.

If willful misconduct can be proven, then this may open the door for an eventual repeal of sections 42 USC 300aa to finally place the burden of liability upon the very industry reporting record annual profits and incessantly pushing legislation for mandating of the use of their products.

If a company/industry stands to profit in the billions of dollars annually from their product then they should assume all liability when their product injures or leads to death from the use of their product.

No other product in the world has protection from civil litigation because civil litigation is how the public can enact oversight over the company to ensure product safety and efficacy.

We call on federal legislators to protect all people consenting to the use of experimental COVID biologics and to then go one step further and repeal 42 USC 300aa-11(2)(A), 42 USC 300aa-11(3), and 42 USC 300aa-22(b)(1) immediately.

Allow Americans to hold vaccine manufacturers financially responsible for products they profit from.

Key Quote Affirming the Legal Liability of Clinical Trial Sponsors – *"45 CFR 46-116(a)(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence."*

https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116

Summary – Informed consent law affirms that sponsors of clinical trials are liable for negligence.

Position – Is it negligent to accept billions of U.S. taxpayer dollars to develop a new technology and enroll human participants into a clinical trial without first performing routine animal clinical trials to verify safety?

Is it negligent to progress the clinical trial from Phase 1 to Phase 2/3 when injuries were discovered in Phase 1?

Is it negligent to expedite Emergency Use Authorization and rush a poorly tested product to market?

Is it negligent to approve for public use a fast-tracked, poorly tested experimental COVID biologics that are still in ongoing clinical trials?

Is it negligent to produce an experimental COVID biologic for public administration without fulfilling informed consent including daily updates of reports of experimental COVID biologic induced injury and death?

These are questions that will have to be argued and decided in a court of law.

Anyone injured, while subsequently not being properly informed as to the risks and progress of the existing clinical trial, should have a right to seek appropriate compensation for their injuries through personal rights of action in civil court.

Release of an experimental medical therapy proven to injure people is unethical when evidence-based treatments exist.

In the case of these experimental COVID biologics, all recipients have rights that are being trampled upon and must be protected.

Position Regarding Violations of Medical Ethics During COVID

Are the experimental COVID biologics FDA approved? **No, they are EUA approved.**

Did the experimental COVID biologics undergo animal clinical trials before being approved under Emergency Use Authorization? **Yes & No. Animal Clinical Trials were completed on September 9, 2020 well after human participants were enrolled in the human clinical trials.**

Are there significant flaws in the design of the clinical trials? **Yes.**

Are there significant flaws in the analysis of the clinical trials? **Yes.**

Were Pfizer/BioNTech and Moderna/NIH essentially allowed to police themselves without opportunity of public comment, independent scientific peer-review, and oversight? **Yes.**

Is the Phase 2/3 human clinical trial still active? **Yes, Oct 27, 2022 Moderna & Jan 31, 2023 Pfizer.**

Is the medical experiment ongoing? **Yes.**

Are the experimental COVID biologics new technologies with no long-term data? **Yes.**

Are people being coerced into participation by company mandates that threaten their employment if they don't comply? **Yes.**

Are people being coerced into participation by government officials eager to simultaneously ignore safety concerns for the experimental COVID biologics and pretend that evidence-based, low-cost treatments for COVID-19 don't exist? **Yes.**

Is this a violation of medical ethics and informed consent? **Yes.**

Have people died following the administration of the experimental COVID biologics? **Yes.**

Has every person receiving experimental COVID biologics been properly informed that the Phase 2/3 clinical trials are ongoing, that they are not FDA approved and are therefore experimental, that they have been shown to induce serious adverse events, that people have died, that there are risks because of the lack of longitudinal data? **Unknown.**

Has every person been made aware of their rights, protected under 45 CFR 46-116 and 45 CFR 46-117, to decline participation regardless of repeated attempts to coerce entry into the clinical trial? **Unknown.**

Has every person agreeing to receive the experimental COVID biologics signed an authorization certifying the legal obligations for informed consent have been achieved? **Unknown.**

Is every person being given a copy of the paperwork they are signing before receiving the experimental COVID biologic? **Unknown.**

Has every person been notified that effective treatments both natural and pharmaceutical exist prior to consenting to use the experimental COVID biologics? **No.**

Who is ultimately liable for injuries induced by these experimental COVID biologics? **This remains to be seen, but the law suggests these biologics do not meet the legal definitions for a vaccine, which removes the protections of 42 USC 300aa-11 and 42 USC 300aa-22 for these manufactures from civil litigation. Additionally, as clinical trials are still on going 45 CFR 46-116 and 45 CFR 46-117 potentially place liability on the sponsors of these clinical trials.**

If willful misconduct can be successfully argued based upon the summary of findings throughout this position paper, then the protections of the PREP Act can be challenged. At the very least, the call for discovery can be made to further investigate.

As in the Tuskegee Experiment, where the withholding of treatment was an example of willful misconduct, with respect to COVID-19, evidence-based treatments exist and have also been withheld.

Has any vaccine ever reached market in less than 4 years before? **No.**

Is A Person's Body Their Autonomous Sovereign Territory? **Yes.**

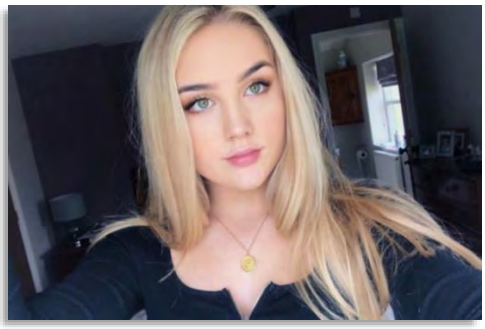
The existential right to decide what goes into and upon one's sovereign territory must always remain with the person who owns that body. Human being are not guinea pigs.

Human beings as property ended in 1865, human beings are not property of the state or corporations.

In the face of repeated violations regarding COVID-19, and with people being adversely impacted by public health policies, investigation into the potential of willful misconduct is reasonable and appropriate. If willful misconduct is proven, then all individuals and entities responsible should be held accountable for any damages.

The time has come for us to come together and say in one voice…**ENOUGH!**

People Worthy of Our Remembrance



Emily Owen, 19 Died by Suicide

"Our darling, beautiful, crazy daughter and sister tragically decided that she could no longer cope and tried to take her own life on Wednesday. She has been in critical care since then. 'The decision has been made today to turn off her life-support tomorrow afternoon, giving time for the hospital to prepare for organ donation, something she signed up for in 2012 when she was only 12-years-old. That sums her up – always caring for other people."

https://metro.co.uk/2020/03/25/teenager-19-kills-fears-will-stuck-inside-coronavirus-12453434/

Topic 8 – Formal Grand Jury Petition

Conclusions – It is undeniable that public trust in our governance and public health departments has been significantly eroded, and rightfully so. As this position paper has presented, there have been significant and consistent problems with nearly every aspect of how this crisis has been handled as death tolls and collateral damage from public health policies continue to mount.

Perhaps the best method for restoring faith in our governance and public health officials is for them to take ownership of their failures and open in-person dialogue with citizens whose voices have been muted throughout this crisis.

The first step to fixing a problem is admitting that one exists.

The second step to fixing a problem is to discontinue using strategies and tactics that have proven ineffective.

The third step to fixing a problem is to start listening to new ideas.

The fourth step to fixing a problem is acting on objective, independent, science free from financial conflicts of interest as opposed to fear-based narratives masquerading as 'the science.'

If the first step never becomes reality, citizens have other peaceful means of legal discovery, so we can understand who was responsible for what went wrong.

This legal tool is known in the United States as a Special Grand Jury Investigation.

On the following pages is a copy of the formal grand jury petition filed on October 16, 2020 to the U.S. Department of Justice, All U.S. Attorney Generals, and their administrative staff via printed and electronic filing.

Disappointingly, this formal petition was never responded to despite proof of receipt and more than 200 copies of the petition being distributed.

In this instance, we are not deterred because we have a Constitutional right to know what elected officials and corporate influencers are doing being closed doors.

We are confident that a Formal Grand Jury Petition will ultimately be heard, and the truth will be brought into the light. If willful misconduct did take place, then it will be discovered.

If willful misconduct did not occur, then citizens can rest at night knowing gross incompetence was rampant.

Something is broken and we have to figure out what it is so we can work together to fix it,

When we lift up our voices and sing so loud that we can no longer be ignored, the truth will find us.

For our ancestors, for our children, for the children yet to come, it is our duty to place the mantle of freedom upon our shoulders and carry it until the next generation is prepared to do so.

ON BEHALF OF ALL CONCERNED CITIZENS

Formal Citizen Petition Overview[1-8]

This petition is presented by a group of American citizens with professional expertise in medicine, law, statistics, and death certificate reporting that have come together to investigate irregularities in COVID-19 data. Irregularities that played a significant role in justifying executive orders. Irregularities that were used to establish excessive and ineffective health policies. Irregularities that have led to major collateral damage including: (1) historic economic collapse, (2) dramatic rises in mental illness, and (3) unnecessary loss of life.

Several exhibits are provided within this formal citizen petition for a grand jury investigation into the legalities of COVID-19 data collection for your review. This exhibit is a synopsis of the agencies involved and potential violations of law that led to irregularities in COVID-19 data collection and recording. Additionally, a peer-reviewed research paper is included that provides an in-depth, historical summary of key findings relative to COVID-19 data collection. Several documents and links are also provided to aid the research process and assist your confirmation of the key findings. On behalf of all concerned citizens, we humbly ask you to review each exhibit within this citizen petition and to exercise your power as a U.S. Attorney to formally initiate a grand jury investigation based upon the evidence provided within these exhibits. Our volunteer investigative research is in honor of every American who has sacrificed so that we may live in freedom.

Your Honor, this is our formal petition.[1-8]

Expert witness list available upon request via AllConcernedCitizens@protonmail.com

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1. The right to petition a grand jury is codified in the first amendment to the United States Constitution and in ***18 USC §3332 Powers and Duties***; "It shall be the duty of each such grand jury impaneled within any judicial district to inquire into offenses against the criminal laws of the United States alleged to have been committed within that district. Such alleged offenses may be brought to the attention of the grand jury by the court or by any attorney appearing on behalf of the United States for the presentation of evidence. Any such attorney receiving information concerning such an alleged offense from any other person shall, if requested by such other person, inform the grand jury of such alleged offense, the identity of such other person, and such attorney's action or recommendation."
2. This right is also affirmed again by ***In Re Grand Jury Application*** (No. 85 Civ. 2235 (VLB), 617 F. Supp 199 | 1985); "Since the United States Attorney has been requested to present certain information to the grand jury he must do so. I will not relieve him of a duty which Congress has seen fit to impose. 18 U.S.C. § 3332(a) imposes a "plainly defined and peremptory duty" on the part of the United States Attorney to present the plaintiffs' information concerning the alleged wrongdoing of the other defendants to the grand jury."
3. The right to petition a grand jury pre-exists codification, and we stand on this right. See ***McDonald v Smith***, (472 U. S. 479, 482–484 | 1985) and ***District of Columbia v. Heller***, (554 U.S. 570, 579, 592 | 2008).
4. Yet, when we examine English common law, we see this right pre-exists both the Constitution and the United States Code when, in 1689, the Bill of Rights exacted of William and Mary stated: "[I]t is the Right of the Subjects to petition the King."
5. The ***US Attorney Manual*** confirms the independence of the grand jury; "The prosecutor must recognize that the grand jury is an independent body." (USAM Chapter 9-11.010 – Introduction).
6. The Fifth Amendment "presupposes an investigative body acting independently of either prosecuting attorney or judge." ***United States v. Dionisio***, (410 U.S. 1, 16 | 1973)
7. In ***Frisbie v. United States*** (157 U. S. 160), it is said by Justice Brewer, "But, in this country, it…is for the grand jury to investigate any alleged crime, no matter how or by whom suggested to them, and, after determining that the evidence is sufficient to justify putting the party suspected on trial, to direct the preparation of the formal charge or indictment."
8. "They [grand juries] are not appointed for the prosecutor or for the court; they are appointed for the government and for the people…" ***Hale v. Henkel, 201 US 62***.

Summary of Primary Concerns

All federal agencies are required to comply with all federal laws. For your convenience, relevant federal agencies and excerpts of relevant laws are included later in this exhibit.

The CDC and National Vital Statistics System (NVSS), a federal agency within the CDC, are required to comply with the Administrative Procedures Act (APA), the Paperwork Reduction Act (PRA), and the Information Quality Act (IQA). As you are aware, these three laws ensure essential oversight of our federal agencies in order to ensure accuracy in data collection, analysis, and publication.

Upon investigation, the following has been revealed:

(1) The CDC and NVSS violated the APA, PRA, and IQA by issuing COVID-19 Alert No. 2 on March 24th, 2020. This alert significantly modified how death certificates were recorded and did so exclusively for COVID-19. This alert ensured COVID-19 was emphasized as the cause of death. This modification was made exclusively for COVID-19 fatalities which makes COVID-19 exclusively a cause of death and rarely a contributing factor to death. The 2003 CDC *Medical Examiner's and Coroner's Handbook on Death Registration and Fetal Death Reporting* states that in the presence of pre-existing conditions infectious disease is recorded as the contributing factor to death, not the cause. This modification was medically unnecessary, as existing rules for data collection and recording had been in successful use nationwide for the previous 17 years. Most egregiously, this material modification does not apply to any other infectious disease creating a double-standard exclusively for COVID-19 data collection. **As a result, COVID-19 fatality data used to shape public health policy is significantly inflated.**

(2) The CDC violated the APA, PRA, and IQA by adopting the Council of State and Territorial Epidemiologists (CSTE) Interim-20-ID-01 COVID-19 Standard Surveillance position paper on April 14th, 2020. This position paper significantly increased COVID-19 case counts. As seen in Section VII.B on page 6, the CSTE paper acknowledged the need to define a methodology for ensuring multiple tests on the same person were not counted multiple times as new cases, and then declined to define one.

Additionally, Section 5 of the CSTE paper creates the option of "probable" COVID-19 cases with an extraordinarily low standard of proof for diagnosis. For example, the standard of medical diagnosis in this section allows a simple cough to be sufficient to diagnose a patient as COVID-19 positive. Even without confirmatory symptoms or lab testing, this patient can now be included in data collection such as total cases, hospitalizations, and cause of death. The adoption of the CSTE position paper creates material modifications exclusively for COVID-19 data collection that does not apply to any other infectious disease. **As a result, COVID-19 case and fatality data used to shape public health policy is significantly inflated.**

(3) The Office of Management and Budget (OMB) is appointed to oversee data collection for all federal agencies. Should a federal agency, even in an emergency situation, desire to modify

any aspect of their data collection, analysis, or publication, they must first notify the Federal Register. Notification of intent to modify any aspect of data collection, analysis, or publication in the Federal Register alerts the Office of Information and Regulatory Affairs (OIRA) within the OMB. Notification in the Federal Register also opens the mandatory 60-day period for public comment on proposed modifications to data collection, analysis, or publication. The CDC and NVSS failed to notify the Federal Register and therefore failed to comply with federal law. **The CDC has made unilateral changes, with far-reaching consequences, to data collection and recording exclusively for COVID-19, without federal oversight, independent of peer-review, and without public comment.**

(4) Due to the historical levels of collateral damage created, the actions of the CDC and NVSS may have violated additional laws such as 18 USC §1035 (False Statements Related to Healthcare Matters), 18 USC §1001 (False Statements), 18 USC §1040 (Fraud in Connection with Major Disaster or Emergency Benefits), 18 USC §1038 (False Information & Hoaxes), 18 USC §371 (Conspiracy to Defraud the United States), 18 USC §242 (Deprivation of Rights Under Color of Law), 18 USC §241 (Conspiracy Against Rights), 18 USC §2331 - Chapter 113B (Domestic Terrorism), 18 USC §1031 (Major Fraud Against the United States), 18 USC §3333 (Malfeasance), 18 USC §1622 (Subornation of Perjury), 18 USC §4 (Misprison of Felony). **Considering these potential violations and referring to 18 USC §3332 (Powers and Duties), we are formally calling for a grand jury investigation into the legality of events related to COVID-19 data collection by the CDC and NVSS.**

Relevant Federal Agencies

Research conducted points to, but is not limited to, the following federal agencies being immediately worthy of grand jury investigation regarding the potential illegal composition and collection of COVID-19 data:

Office of Management and Budget (OMB)

The Office of Management and Budget (OMB) is a federal agency within the Executive Branch that serves the President of the United States by assisting the President with management and regulatory objectives, among other things, and to fulfill the agency's statutory responsibilities.

Office of Information and Regulatory Affairs (OIRA)

Within the OMB, the Office of Information and Regulatory Affairs (OIRA) is tasked with ensuring that all federal agencies are in legal compliance with the APA, PRA, and IQA.

Department of Health and Human Services (HHS)

The Department of Health and Human Services (HHS) is a cabinet level department. The HHS is a federal agency within the Executive Branch.

Centers for Disease Control (CDC)

The Centers for Disease Control and Prevention (CDC) is a federal agency within the HHS. The CDC is responsible for developing evidence-based public health strategies, monitoring disease

statistics, and providing effective guidance for citizens and public officials in times of public health crises.

National Center for Health Statistics (NCHS)

The National Center for Health Statistics (NCHS) is a federal agency within the CDC. The NCHS is the nation's principal health statistics agency, compiling statistical information to guide actions and policies to ensure the health of the population.

National Vital Statics Service (NVSS)

The National Vital Statistics System (NVSS) is a federal agency within the NCHS. The NVSS is responsible for the accurate collection of data for all births, deaths, and disease processes attributed to citizens of the United States of America.

Relevant Law

All federal agencies are required to comply with the Administrative Procedures Act, the Paperwork Reduction Act, and the Information Quality Act. Below is a brief summary of relevant law.

Administrative Procedures Act (APA)

One of the primary objectives of the Administrative Procedures Act (APA) 5 USC §551 et seq. (1946) is to govern the process by which federal agencies develop and issue regulations. This includes requirements for publishing in the Federal Register notices of both proposed and final rulemaking, and it provides opportunities for public comment on proposed rules. Most rules have a 30-day delayed effective date. The APA also addresses other agency actions including the issuance of policy statements. (See Additional Considerations Regarding the APA on Page 12)

Paperwork Reduction Act (PRA) and Creation of the Office of Information of Regulatory Affairs (OIRA)

The Paperwork Reduction Act (PRA) (44 U.S.C. §§ 3501–3521, Public Law 96-511, 94 Stat. 2812) passed on December 11, 1980 and later amended on May 22, 1995 (44 U.S.C. §§ 3501–3521, Public Law 104-13, 109 Stat. 182) gives authority over collection of certain information by Federal agencies to the Office of Management and Budget (OMB).

To facilitate this, the PRA created within the OMB a new Office of Information and Regulatory Affairs (OIRA). The OIRA is the "central authority for the review of Executive Branch regulations, approval of Government information collections, establishment of Government statistical practices, and coordination of Federal privacy policy."

https://www.whitehouse.gov/omb/information-regulatory-affairs/

Information Quality Act (IQA)

Congress passed the Information Quality Act (IQA i.e., the Data Quality Act) in 2000, which amended the PRA and added two additional requirements. (Section 515 of the Congressional Consolidated Appropriations Act, 2001 Public Law 106-554)

The first provision directs the OMB to issue information quality guidelines for Federal agencies to follow to ensure and maximize the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by federal agencies.

The second provision sets out the requirements for those guidelines, including the requirement that affected federal agencies must establish a process for people to submit correction requests when they believe that the information quality guidelines have not been followed.

18 USC §1035 – False Statements Related to Healthcare Matters

"Whoever, in any matter involving a health care benefit program, knowingly and willfully (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; or (2) makes any materially false, fictitious, or fraudulent statements or representations, or makes or uses any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 5 years, or both."

https://www.law.cornell.edu/uscode/text/18/1035

18 USC §1001 (a) – False Statements

"Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; (2) makes any materially false, fictitious, or fraudulent statement or representation; or (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry; shall be fined under this title, imprisoned not more than 5 years or, if the offense involves international or domestic terrorism (as defined in section 2331), imprisoned not more than 8 years, or both. If the matter relates to an offense under chapter 109A, 109B, 110, or 117, or section 1591, then the term of imprisonment imposed under this section shall be not more than 8 years."

https://www.law.cornell.edu/uscode/text/18/1001

18 USC §1040 – Fraud in Connection with Major Disaster or Emergency Benefits

"Whoever, in a circumstance described in subsection (b) of this section, knowingly (1) falsifies, conceals, or covers up by any trick, scheme, or device any material fact; or (2) makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or representation, in any matter involving any benefit authorized, transported, transmitted, transferred, disbursed, or paid in connection with a major disaster declaration under section 401 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5170) or an emergency declaration under section 501 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5191), or in connection with any procurement of property or services related to any emergency or major disaster declaration as a prime contractor with the United States or as a subcontractor or supplier on a contract in which there is a prime contract with the United States, shall be fined under this title, imprisoned not more than 30 years, or both."

https://www.law.cornell.edu/uscode/text/18/1040

18 USC §1038 – False Information and Hoaxes

"Whoever engages in any conduct with intent to convey false or misleading information under circumstances where such information may reasonably be believed and where such information indicates that an activity has taken, is taking, or will take place that would constitute a violation of chapter 2, 10, 11B, 39, 40, 44, 111, or 113B of this title, section 236 of the Atomic Energy Act of 1954 (42 U.S.C. 2284), or section 46502, the second sentence of section 46504, section 46505(b)(3) or (c), section 46506 if homicide or attempted homicide is involved, or section 60123(b) of title 49, shall (A) be fined under this title or imprisoned not more than 5 years, or both; (B) if serious bodily injury results, be fined under this title or imprisoned not more than 20 years, or both; and (C) if death results, be fined under this title or imprisoned for any number of years up to life, or both."

https://www.law.cornell.edu/uscode/text/18/1038

18 USC §371 – Conspiracy to Defraud the United States

"If two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both."

https://www.law.cornell.edu/uscode/text/18/371

18 USC §242 – Deprivation of Rights Under Color of Law

"Whoever, under color of any law, statute, ordinance, regulation, or custom, willfully subjects any person in any State, Territory, Commonwealth, Possession, or District to the deprivation of any rights, privileges, or immunities secured or protected by the Constitution or laws of the United States, or to different punishments, pains, or penalties, on account of such person being an alien, or by reason of his color, or race, than are prescribed for the punishment of citizens, shall be fined under this title or imprisoned not more than one year, or both; and if bodily injury results from the acts committed in violation of this section or if such acts include the use, attempted use, or threatened use of a dangerous weapon, explosives, or fire, shall be fined under this title or imprisoned not more than ten years, or both; and if death results from the acts committed in violation of this section or if such acts include kidnapping or an attempt to kidnap, aggravated sexual abuse, or an attempt to commit aggravated sexual abuse, or an attempt to kill, shall be fined under this title, or imprisoned for any term of years or for life, or both, or may be sentenced to death."

https://www.law.cornell.edu/uscode/text/18/242

18 USC §241 – Conspiracy Against Rights

"If two or more persons conspire to injure, oppress, threaten, or intimidate any person in any State, Territory, Commonwealth, Possession, or District in the free exercise or enjoyment of any right or privilege secured to him by the Constitution or laws of the United States, or because of his having so exercised the same; or If two or more persons go in disguise on the highway, or on the premises of another, with intent to prevent or hinder his free exercise or enjoyment of any right or privilege so secured. They shall be fined under this title or imprisoned not more than ten years, or both; and if death results from the acts committed in violation of this section or if such acts include kidnapping or an attempt to kidnap, aggravated sexual abuse or an attempt to commit aggravated sexual abuse, or an attempt to kill, they shall be fined under this title or imprisoned for any term of years or for life, or both, or may be sentenced to death."

https://www.law.cornell.edu/uscode/text/18/241

18 USC §2331 (Chapter 113B) – Domestic Terrorism

"Definitions: As used in this chapter (5) the term "domestic terrorism" means activities that (A) involve acts dangerous to human life that are a violation of the criminal laws of the United States or of any State; (B) appear to be intended (i) to intimidate or coerce a civilian population; (ii) to influence the policy of a government by intimidation or coercion; or (iii) to affect the conduct of a government by mass destruction, assassination, or kidnapping;…"

https://www.law.cornell.edu/uscode/text/18/2331

18 USC §1031 – Major Fraud Against the United States

"Whoever knowingly executes, or attempts to execute, any scheme or artifice with the intent (1) to defraud the United States; or (2) to obtain money or property by means of false or fraudulent pretenses, representations, or promises, in any grant, contract, subcontract, subsidy, loan, guarantee, insurance, or other form of Federal assistance, including through the Troubled Asset Relief Program, an economic stimulus, recovery or rescue plan provided by the Government, or the Government's purchase of any troubled asset as defined in the Emergency Economic Stabilization Act of 2008, or in any procurement of property or services as a prime contractor with the United States or as a subcontractor or supplier on a contract in which there is a prime contract with the United States, if the value of such grant, contract, subcontract, subsidy, loan, guarantee, insurance, or other form of Federal assistance, or any constituent part thereof, is $1,000,000 or more shall, subject to the applicability of subsection (c) of this section, be fined not more than $1,000,000, or imprisoned not more than 10 years, or both."

https://www.law.cornell.edu/uscode/text/18/1031

18 USC §3333 – Malfeasance

"A special grand jury impaneled by any district court, with the concurrence of a majority of its members, may, upon completion of its original term, or each extension thereof, submit to the court a report: (1) concerning noncriminal misconduct, malfeasance, or misfeasance in office involving organized criminal activity by an appointed public officer or employee as the basis for a recommendation of removal or disciplinary action; or (2) regarding organized crime conditions in the district. (etc.)"

https://www.law.cornell.edu/uscode/text/18/3333

18 USC §1622 – Subornation of Perjury

"Whoever procures another to commit any perjury is guilty of subornation of perjury and shall be fined under this title or imprisoned not more than five years, or both."

https://www.law.cornell.edu/uscode/text/18/1622

18 USC §4 – Misprision of Felony

"Whoever, having knowledge of the actual commission of a felony cognizable by a court of the United States, conceals and does not as soon as possible make known the same to some judge or other person in civil or military authority under the United States, shall be fined under this title or imprisoned not more than three years, or both."

https://www.law.cornell.edu/uscode/text/18/4

18 USC §3332 – Powers and Duties

"It shall be the duty of each such grand jury impaneled within any judicial district to inquire into offenses against the criminal laws of the United States alleged to have been committed within that district. Such alleged offenses may be brought to the attention of the grand jury by the court or by any attorney appearing on behalf of the United States for the presentation of evidence. Any such attorney receiving information concerning such an alleged offense from any other person shall, if requested by such other person, inform the grand jury of such alleged offense, the identity of such other person, and such attorney's action or recommendation."

https://www.law.cornell.edu/uscode/text/18/3332

Additional Exhibits

The following exhibits provide evidence corroborating what appears to be violations of relevant law.

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

This is a detailed look into the historical timeline describing how the CDC appears to have violated federal law and how these violations have adversely impacted COVID-19 data leading to public health policies that compromised the Constitutionally protected rights of all Americans. (Printed, attached, and link provided)

https://www.publichealthpolicyjournal.com/ethics-in-science-and-technololgy

March 24th, 2020 NVSS COVID-19 Alert No. 2 Published By the CDC

This document significantly modified how certificate of death was recorded exclusively for COVID-19. (Printed, attached, and link provided)

https://www.cdc.gov/nchs/data/nvss/coronavirus/Alert-2-New-ICD-code-introduced-for-COVID-19-deaths.pdf

April 5th CSTE Interim-20-ID-01 Position Paper Adopted by the CDC on April 14th, 2020

This document significantly lowered the medical standards for what constitutes a COVID-19 case and has had far-reaching consequences by inaccurately increasing case counts, hospitalizations, and fatalities. This document also neglected to define a methodology for ensuring that the same individual was not counted multiple times in data collection. The CSTE is not a federal agency. They are a non-profit organization. This paper includes authors from state health departments (page 8) and subject matter experts from the CDC (page 7). (Printed, attached, and link provided)

https://cdn.ymaws.com/www.cste.org/resource/resmgr/2020ps/Interim-20-ID-01_COVID-19.pdf

Medical Examiner's and Coroner's Handbook on Death Registration and Fetal Death Reporting

This handbook, published by the CDC, has been in use nationwide in every state since 2003 without incident. This is the proven handbook that the CDC and NVSS elected to abandon in

favor of new and untested guidelines for certificate of death recording that did not have proper legal oversight, opportunity for independent peer-review, or public comment. (Attached and link provided. Not Printed.)

https://www.cdc.gov/nchs/data/misc/hb_me.pdf

Physician's Handbook on Medical Certification of Death

This handbook was published by the CDC and has been in use nationwide in every state since 2003 without incident. Another proven handbook that the CDC and NVSS elected to abandon in favor of new and untested guidelines for certificate of death recording that did not have proper legal oversight, opportunity for independent peer-review, or public comment. (Attached and link provided. Not Printed.)

https://www.cdc.gov/nchs/data/misc/hb_me.pdf

If COVID Fatalities Were 90.2% Lower, How Would You Feel About Schools Reopening?

Data analysis compiled from every state health department concerning comorbidity, global research supporting the safety of children attending in person school, as well as participating in athletics, performance arts, and extracurricular activities. (Attached and link provided. Not Printed.)

https://childrenshealthdefense.org/news/if-covid-fatalities-were-90-2-lower-how-would-you-feel-about-schools-reopening/

COVID-19…Have You Heard? There Is Good News!

Data analysis compiled from every state health department supporting many new cases and hospitalizations were the result of the CDC's test-based diagnosis strategy from June 13, 2020 to July 17, 2020. (Attached and link provided. Not Printed.)

https://childrenshealthdefense.org/news/covid-19have-you-heard-there-is-good-news/

Are Children Really Recovering 99.9584% of the Time From COVID-19?

Data analysis compiled from every state health department supporting extremely high recovery rates without the use of FDA approved vaccine or treatments regardless of infection rates. (Attached and link provided. Not Printed.)

https://childrenshealthdefense.org/news/are-children-really-recovering-99-9584-of-the-time-from-covid-19/

U.S. District Judge William Stickman IV Ruling in Pennsylvania

"The congregate gathering limits imposed by defendants' mitigation orders violate the right of assembly enshrined in the First Amendment; (2) that the stay-at-home and business closure components of defendants' orders violate the due process clause of the Fourteenth

Amendment; and (3) that the business closure components of defendants' orders violate the Equal Protection Clause of the Fourteenth Amendment…" (Attached and link provided. Not Printed.)

https://www.courthousenews.com/wp-content/uploads/2020/09/butler-v-wolf.pdf

Additional Considerations Regarding the Administrative Procedures Act (APA)

Did *COVID-19 Alert No. 2* and the *Guidance for Certifying Deaths Due to Coronavirus Disease 2019 (COVID-19)* create a new rule that required APA informal rulemaking procedure?

APA §551(4) defines a rule as "…any agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy…"

COVID-19 Alert No. 2 adopted a new ICD-10 code for COVID-19 as well as the *Guidance for Certifying Deaths Due to Coronavirus Disease 2019 (COVID-19)* which changed the death certificate recording such that, **"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… 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."**

This is a fundamental change in policy in the way deaths are recorded on certificates. Under the guidance of the 2003 death registration handbooks, the chronic conditions mentioned in the example in the paragraph above would be reported in Part I of the death certificate and not Part II.

This change in policy should have required the APA §553 rulemaking steps to be followed.

Was APA §553 properly followed?

Under APA §553, three steps must be followed. The first step involves publishing notice of the proposed rulemaking in the Federal Register except if "the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest."

APA §553 does not specifically mention emergency rules, instead mentioning "good cause." A pandemic does not necessarily qualify as "good cause" for immediate policy change relating to data collection for infectious disease when data collection rules for other infectious diseases already exists and is used nationwide. By declaring "good cause," the CDC would be exempt from providing notice for public opportunity to comment but not from federal oversight for data accuracy. The CDC would be able to unilaterally make changes they determined to be

necessary, even if they understood proposed changes may compromise the integrity and accuracy of COVID-19 data.

The CDC is required to provide a brief statement of notice, prior to enacting the changes that elucidate the medical and statistical rationale for “good cause.” This notice should state the rationale for the enactment of changes and why notifying the Federal Register to initiate federal oversight, independent peer-review, and public comment is impracticable, unnecessary, or contrary to the public interest. The CDC is also required to publish their rule changes in final form within the Federal Register. The CDC appears to have failed to provide this brief statement of notice or report their changes in final form to the Federal Register.

People Worthy of Our Remembrance

Tom Keveney Died Alone

“My younger brother, Tom Keveney, died last month. My family’s deep sadness was understandable and unavoidable, but the coronavirus pandemic ravaged our ability to mourn his death.

We’re all feeling loss resulting from the pandemic. It could be a graduation ceremony or a job; it’s likely to be freedom of movement and a basic sense of security. The fallout from COVID-19 makes the death of a family member inestimably worse.

My family’s experience isn’t unique; if anything, it’s too common in these unprecedented times. Many families’ losses have been crueler; each death cuts to the bone. They all need to be remembered.”

https://www.usatoday.com/story/life/2020/05/07/covid-19-made-my-brothers-death-harder-grieve/5170437002/

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All authors disclose no financial conflicts of interest and state no desire to profit from this work individually. This work is intended to be public domain and therefore accessible at no cost for access to the information presented herein. This work is a volunteer effort and a labor of love on behalf of all people who have suffered during this crisis so that we may collaborate with public health policy makers to arrive at solutions that serve all concerned citizens.

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