HB 699
FAV / FWA

STATEMENT OF PIERRE KORY, M.D., MPA AND THE FRONT LINE COVID-19 CRITICAL CARE ALLIANCE ("FLCCC") BEFORE THE MARYLAND ASSEMBLY

Health and Government Operations Committee

In Support of HB 699 - State and Local Government- Proof of Vaccination for Employees and Applicants for Employment- Prohibition (Vaccination by Choice Act)

and Delegate M. Morgan's Amendment to Include Public Institutions of Higher Learning

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INTRODUCTION

As new data emerges from continuing publication, government data such as V-Safe reporting begrudgingly released via litigation and the views of once respected physicians finding their way into the light of day, it is increasingly clear that the mRNA vaccine benefits have been exaggerated and its risks hidden from view. Policymakers do not have clear data upon which to rely because a narrative that the vaccines were safe and effective was locked in from the beginning, even before data from this large experiment became available. Given the public health view that vaccination success required wide adoption and the pressing need to demonstrate a path toward economic normalcy, claiming victory and suppressing adverse data became instruments in and of themselves of public health policy. While the CDC has had to admit that reductions in transmission and illness are not as advertised, the public health community stubbornly refuses to acknowledge the limitations of the vaccine and seriousness of vaccine injuries solely to maintain vaccine policies that have not worked well, the glowing reporting notwithstanding.

Reasonable people can and do disagree about the wisdom of continuing to press for widespread mRNA vaccination; what is not reasonable is to remove essential autonomy and force anyone to expose themselves to a risk that, unlike COVID-19, they have no ability to manage. How many people realize that 7.7% of those receiving the mRNA vaccine have had to seek urgent care, including hospitalization for a host of serious adverse events, of which myocarditis is only the most well-known? Imposing a choice between maintaining employment or education against risks that have been minimized and aggressively ignored because it is inconvenient to high stakes health care policy is deeply troubling. To impose such force, contrary to every medical and legal doctrine of informed consent, without notice of what the science actually says about the limited benefits and serious potential health risks imposed violates the State's essential agreement with its citizens.

The public health community, led by the pharmaceutical industry, has gotten so far over their collective skis on vaccination that it has employed multiple means of stilting the evidence toward its holy but empty grail of herd immunity. In the light of what we know now, for government to force any person to accept vaccination is not defensible. To mandate young adults and children, given the significant risks they face with little possible benefit, is unconscionable. The reason that this is not widely recognized is because of unprecedented interference in access to data, including litigation by CDC opposing the release of V-Safe data, publication biases and statistical manipulation in favorable studies while suppressing publications whose conclusions differ from the allowed narrative. Social media and credentialing bodies have been weaponized to stifle, *a priori*, any critical reporting that calls into question the validity of vaccination policies, as this instrument of public health requires it to squelch its own critique.

This discussion requires a word about politics. As should be evident, this testimony is offered from a scientific perspective and is not grounded in any political view about government. It does not stem from any party affiliation or view of electoral politics. Due to a perfect storm of events, views about the management of COVID-19 rapidly became highly politicized. Anyone questioning the developed public health narrative has been quickly labeled as anti-science and in favor of anti-government sentiments. This has led to legitimate concerns being squelched and important conversations shunted aside. In the case of vaccine mandates, this has made it a difficult environment for legislators to make thoughtful decisions. We offer this detailed testimony in an effort to assist legislators with the data they need to make an informed choice.

The Work of the FLCCC; Your Witness' Credentials and Expertise

This testimony is grounded in medical experience in the trenches with COVID-19 patients and in many state houses on medical policies for addressing the pandemic. It is submitted on behalf of the Front Line COVID-19 Critical Care Alliance ("FLCCC").

Pierre Kory, MD, MPA Credentials

Dr. Kory's is Board Certified in Internal Medicine (currently), Pulmonary Diseases, and Critical Care Medicine and is a former Associate Professor and Chief of the Critical Care Service at the University of Wisconsin. To date, Dr. Kory has published over 50 peer-reviewed papers, 17 book chapters, and served as senior editor of an award-winning textbook now published in its 2nd edition and translated into 7 languages. He is currently the founder and Medical Director of a private telehealth practice opened 8 months ago called the Advanced Covid-19 Care Center (drpierrekory.com), which is solely focused on treating patients with COVID and its complications including "long haul" and post-COVID-mRNA vaccine injury syndromes. Most pertinently, he has published over 12 research papers on numerous aspects of COVID-19. Dr. Kory's CV attached.

The Front Line COVID-19 Critical Care Alliance ("FLCCC")

FLCCC was founded by a group of highly published, world-renowned Critical Care physicians and scholars, including Dr. Kory and Dr. Marik, who have held leadership positions in large medical center ICUs. Its MATH+ Hospital Treatment Protocol was introduced in March 2020 and has saved tens of thousands of patients who were critically ill with COVID-19. The expertise in clinical research can be seen just in the fact FLCCC member physicians have nearly 2,000 published peer-reviewed publications among them. These eminent, well-recognized physicians have extensive experience with COVID-19, and, despite being overtime at bedside throughout this emergency, have put remarkable efforts into studying, documenting, and educating the professions and the public about the clinical value of ivermectin in COVID-19.

One of FLCCC's initial efforts, consistent with WHO guidelines, was to explore the re-purposing of existing drugs, an effort that received too little global effort as financial resources focused on developing new patented medications. A rapidly growing published medical evidence base demonstrating ivermectin's unique and highly potent ability to inhibit SARS-CoV-2 replication and to suppress inflammation included not only multiple in-vitro and animal models, but numerous clinical trials from centers and countries around the world showing repeated, consistent, large magnitude improvements in clinical outcomes when ivermectin is used, not only as a prophylactic agent, but also in mild and moderate cases and even has some positive effects in severe disease states. FLCCC developed consensus-based standards among its global physician members, issued them for use by interested medical professionals worldwide, and advocated for their adoption and public discussion by physicians who recognize the need to inform the public about the value and availability of its protocols. The Alliance has the academic

support of allied physicians from around the world to research and develop lifesaving protocols for the prevention and treatment of COVID-19 in all stages of illness. The website cites a large number of peer-reviewed publications, some of which were authored by FLCCC's founding physicians.

EXECUTIVE SUMMARY

There is Significant Evidence That the Contribution of mRNA Vaccines to Reduction in Transmission, Prevention and Severity and Duration of Illness Is Over-reported and that it Presents Significant Risks; A Summary of Clinical and Public Health Policy Issues

The Scientific Evidence: An examination of evidence regarding the relative risks and benefits of vaccination, excess mortality data suggesting significant cost in life, data about natural immunity in post-COVID-19 patients, and other markers of effectiveness and safety reveals a picture that requires ending vaccine mandates for all, but especially in university and school aged adults and children:[1]

Transmission: Current data do not support the claim that the COVID-19 mRNA vaccine is effective in preventing transmission. The CDC Director herself has reported[2] that vaccinated individuals are now well known to carry equal or greater viral loads than the unvaccinated, and thus transmit at equal or higher rates, for physiologic reasons detailed below, most concerning being the negative efficacy of the vaccines against Omicron. This has also been reported by seminal nosocomial outbreak papers by Chau et al.[3] (Health care workers (HCW) in Vietnam), the Finland hospital outbreak[4] (spread among HCWs and patients), and the Israel hospital outbreak[5] (spread among HCWs and patients).

A large new study from Qatar in the New England Journal of Medicine by Weil Cornell Medicine[6] found that the Pfizer vaccine protection waned after four months. By seven months, when adjusted for those who already had prior infection, the Pfizer shot had a negative 4% effectiveness against transmission. Also, effectiveness against asymptomatic infection was negative 33% after seven months, which suggests that the vaccinated become more likely to

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[1] Note that our interpretation of the data is consistent with the long-held (but pandemic-ignored) Federal regulatory standard that considers any adverse event or death reported in temporal association with receipt of a novel and/or experimental therapy to be caused by the intervention until proven otherwise. We recognize this practice departs from the recently adopted, ethically and morally troubling pandemic standard whereby U.S. federal and state health agencies dismiss adverse event reports as unrelated to the vaccines until proven otherwise.

[2] https://sfist.com/2021/07/27/cdc-confirms-that-viral-loads-in-vaccinated-people-with-delta-are-indistinguishable-from-unvaccinated/

[3] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733

[4] https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.30.2100636

[5] https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.39.2100822

[6] https://www.nejm.org/doi/full/10.1056/NEJMoa2114114

spread COVID-19 over time.

Prevention: The claim that COVID-19 mRNA vaccine is effective in preventing illness is also not well-supported by the data. Using up-to-date data (i.e., last 3-6 months to today) from a wide selection of public health sources including the U.S, Denmark, Israel, Australia, and the UK, the current estimate of the protective efficacy from contracting COVID-19 is one of either "negative efficacy" or rapidly waning efficacy such that potential benefits, if any, are demonstrably short-lived and instead rapidly transition into an increased risk (i.e., negative efficacy) of contracting COVID-19.

Preventing Severe Disease: Similarly, the efficacy of the COVID-19 mRNA vaccine in preventing severe disease is also questionable. CDC data shows that there is no statistically valid evidence that they prevent severe disease or deaths in children. See below corresponding section which more fully details the data supporting this conclusion

Preventing Long Haul COVID: Finally, the efficacy of the COVID-19 mRNA vaccine in the prevention of "long-haul" COVID does not appear to be supported. A large Veterans Administration study recently reported disturbing evidence: by month six after a SARS-CoV-2 infection, vaccinated persons with breakthrough infections were at higher risk of long COVID (HR = 1.50, 95% CI: 1.46, 1.54). When including the earlier time periods, the COVID-19 vaccines only reduced the risk of long COVID by approximately 15% compared to the unvaccinated, a level of estimated protection far less than the increased risk of death found in the same study as mentioned above.

Significant Risk: The risks of myocarditis, neurological conditions, sudden death, and other adverse effects directly related to the mRNA vaccine are significant. In addition to the many published studies noted here, the government's own V-Safe and VAERS data raise significant concerns.

Overreported COVID-19 Mortality: On the other side of the equation, errors in antigen and PCR testing, and the problem of dying "with" COVID-19 rather than "from" COVID-19, exaggerate the public health importance of attempting to enforce universal compliance.

Legal and Policy Context:

The Exemption System Necessitated by Mandates is Unworkable: The only clear medical exemption, according to the CDC, is for people who can demonstrate a reaction to the ingredients of the vaccine or have a history of a reaction to an ingredient of the vaccine. This brutal logic is intrinsic to a mandate which attempts to gain universal compliance. Medical physicians are under scrutiny and fear discipline if they write exemptions, even for sound reasons such as prior history of myocarditis. The system also compounds class inequities because those with means are less affected by the economic duress imposed by mandates.

Active Suppression of Evidence and Divergent Viewpoints: Medical journal editors, professional associations and regulatory bodies, social and news media all took on adherence to the vaccine narrative as an instrument of public health policy, not only in what they publish but in aggressively taking down scientifically grounded concerns of well-credentialed physicians and scientists solely because it might encourage thoughtful reconsideration of the approach. Reporting of vaccine injuries to VAERS was made intentionally difficult and discouraged by institutions.

Mandates Impose a Profound Lack of Informed Consent: In the absence of overwhelming evidence that the vaccine is safe and effective and that there is compelling public health interest necessitating such action, overcoming individual choice by use of a mandate is contrary to democratic principles of autonomy and cannot be justified. We include information about a recent Citizen's Petition to the FDA asking that the mRNA vaccine labels be amended to include factual limitations on their known safety and effectiveness; in addition to the evidence contained in this testimony, the inadequacy of the labeling further illuminates the gulf between the narrative circulated about the safety and effectiveness of the mRNA vaccine and what is actually known to recipients, and the policy makers who hold their well-being in their hands.

DISCUSSION
The Clinical Evidence

I. Clinical Evidence for mRNA Vaccine Risks Are Significant and Have Been Underplayed.

A. There is substantial data that "all-cause" mortality has been elevated by the mRNA vaccine.

There is ample evidence supporting concerns that mRNA vaccines bear some responsibility for excess mortality. In this published paper[7] analyzing data from the pivotal clinical trials used to support the novel mRNA vaccines (i.e., Moderna, Pfizer, and Janssen), Classen compared "all-cause severe morbidity," defined as "severe infections with COVID-19 and all other severe adverse events between the treatment arms and control arms, respectively." His analysis found a statically significant increase in all-cause severe morbidity occurred in the vaccinated group compared to the placebo group.

A shift in the basis for excess mortality is also cause for concern. As a result of a FOIA application in the state of Massachusetts, an analysis of the now publicly available death

[7] https://www.scivisionpub.com/pdfs/us-COVID-1919-vaccines-proven-to-cause-more-harm-than-good-based-on-pivotal-clinical-trial-data-analyzed-using-the-proper-scientific--1811.pdf

certificate data[8] found that during 2020, the predominant causes of rises in all-cause mortality were due to "**respiratory causes**," (i.e., excess mortality from COVID-19) while in 2021, the predominant causes were "**cardiovascular**." The analyst concluded, "the official Massachusetts database of death certificates contains proof that COVID-19 vaccines killed thousands of people in Massachusetts in 2021."

The CDC data[9] shows the timing of the start and the steady rise in all-cause mortality of working-age adults in the U.S., both overlapping with the start of the mass vaccination campaign. Although alternate causes of this historic rise in death have been considered, (i.e., COVID-19 deaths, deaths of despair, etc.), the number of deaths from these causes is insufficient to explain the overall rise.

Florida Surgeon General Joe Ladapo published a study entitled "Exploring the relationship between all-cause and cardiac-related mortality following COVID-19 vaccination or infection in Florida residents: a self-controlled case series study."[10] Reviewing the literature, Dr. Ladapo went against CDC recommendations by recommending "against males aged 18 to 39 from receiving mRNA Covid-19 vaccines." The basis for this recommendation is discussed in a helpful Forbes article.[11]

When the FDA took the extraordinary step of approving mRNA vaccination for infants, Surgeon General Ladapo firmly came out against this step: "Ladapo opposes COVID vaccines for children younger than 5."[12] *See also* "Florida surgeon general at odds with FDA panel decision on COVID-19 vaccine for children under 5."[13] The official Florida state guidance is found on the Florida government website.

B. V-Safe Data Shows Significant Safety Concerns that Public Health Authorities have not Communicated to the Public.

The CDC V-Safe[14] data show that 33.1% of the people who got the vaccine suffered from a significant adverse event and 7.7% had to seek urgent professional medical care. The CDC created this smartphone-based program to collect health assessments after COVID-19

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8 https://coquindechien.substack.com/p/c19-vaccine-the-cause-of-causes?s=r

9 https://rescue.substack.com/p/chilling-pandemic-data-from-the-insurance?s=r

10 https://floridahealthCOVID-1919.gov/wp-content/uploads/2022/10/20221007-guidance-mrna-COVID-1919-vaccines-analysis.pdf?utm_medium=email&utm_source=govdelivery

11 https://www.forbes.com/sites/brucelee/2022/10/09/florida-surgeon-general-warns-against-young-men-getting-covid-19-mrna-vaccines-whats-his-justification/?sh

12 https://health.wusf.usf.edu/health-news-florida/2022-06-15/ladapo-opposes-covid-vaccines-for-children-younger-than-5

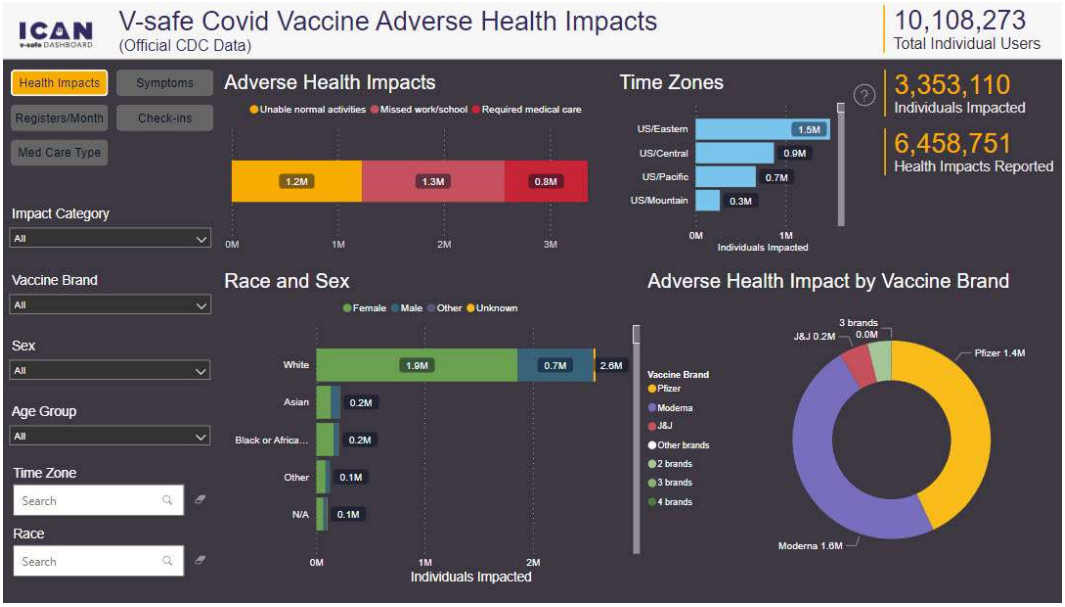
13 https://www.foxnews.com/health/florida-surgeon-general-odds-fda-panel-covid-19-vaccine-children-5.

14 https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html#:~:text=What%20is%20v%2Dsafe%3F,vaccines%20in%20near%20real%20time.

vaccination. Approximately 10 million people signed up and submitted health reports after COVID-19 vaccination.[15] Significantly, death is not a reportable category in V-safe as these are self-reports, and particularly given data about likely mortality from the vaccine set forth below, the 7.7% of respondents who sought urgent care is a concerning figure of which the public is largely unaware. The CDC evidently did not want to share this data because of its likely impact on compliance. The Informed Consent Action Network ("ICAN") legal team sued the CDC twice;[16] the CDC spent 463 days resisting ICAN's efforts to obtain the data and make it public.

These extraordinary numbers clearly raise substantial questions about mRNA vaccine safety and the conduct of the CDC in resisting making this public data available to the American public. The contrast between this data and that reported in the clinical trials raises legitimate areas of inquiry.

ICAN has taken the CDC's official raw data and created a dashboard interface that allows users to graphically view the 144+ million health entries.[17] This data is based on self-reports of approximately 10 million V-Safe users. Note that the data is limited to only pre-populated fields checked by V-Safe users (for example, selecting from a list of pre-populated symptoms). Information captured in free-form fields has not yet been released by CDC and litigation continues to obtain that information.



15 https://icandecide.org/article/v-safe/

16 Informed Consent Action Network V. Centers for Disease Control and Prevention and Health and Human Services Civil Action No. 1:21-cv-1179 filed 12/28/21in the Western District of Texas; Informed Consent Action Network V. Centers for Disease Control and Prevention and Health and Human Services Civil Action No. 1:22-cv-481filed 5/17/22 in the Western District of Texas leading to a court order requiring release of the data.

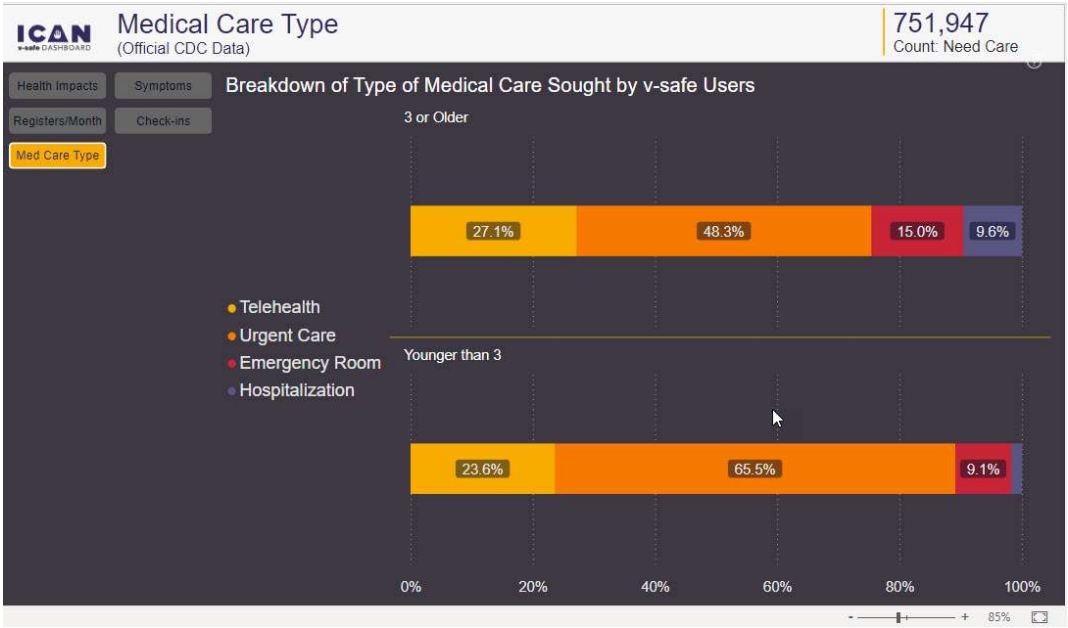
17 https://icandecide.org/article/v-safe/

A Rasmussen Report using polling methods lines up closely with V-Safe, finding that 7% of vaccinated Americans have suffered major side effects from mRNA vaccine.[18]

The CDC claims it took so long to release the data because they did not have enough resources to write the program to display the data, though plaintiffs were able to write that program in a day. It also does not explain why they opposed the release of data in court. The following figures taken from the ICAN Dashboard provide an overview of self-reported impacts, including the fact that of 10.1 million V-Safe users, over 751,000 required care, and of these, 73% felt the need to go to an urgent care center, ED or hospital.

C. VAERS Data Reveals Significant Safety Concerns.

As of May 27, 2022, in the United States alone, 5,309 cases of myocarditis, 782,665



adverse events, 151,796 severe adverse events, and 14,613 deaths have been recorded in the Vaccine Adverse Event Reporting System[19] following COVID-19 vaccination in the U.S. It should be appreciated that the VAERS database's main limitation is that of underreporting, with a recent pre-print analysis suggesting VAERS deaths are underreported by a factor of 20[20]. The

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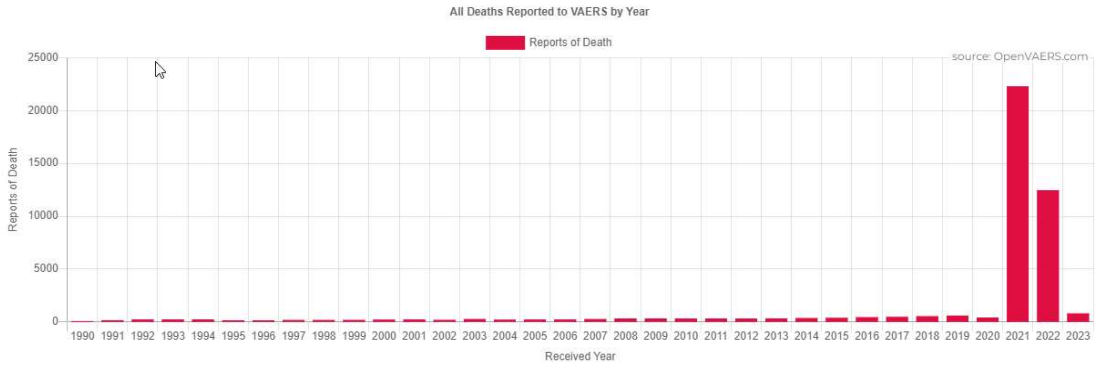
18 https://www.rasmussenreports.com/public_content/lifestyle/covid_19/concerns_about_covid_19_vaccines_remain_high. Of note, "Democrats and Republicans reported almost the same exact level of side effects, so, it's not politicized."

19 https://vaers.hhs.gov/

20 https://www.researchgate.net/publication/355581860_COVID-19_vaccination_and_age-stratified_all-cause_mortality_risk

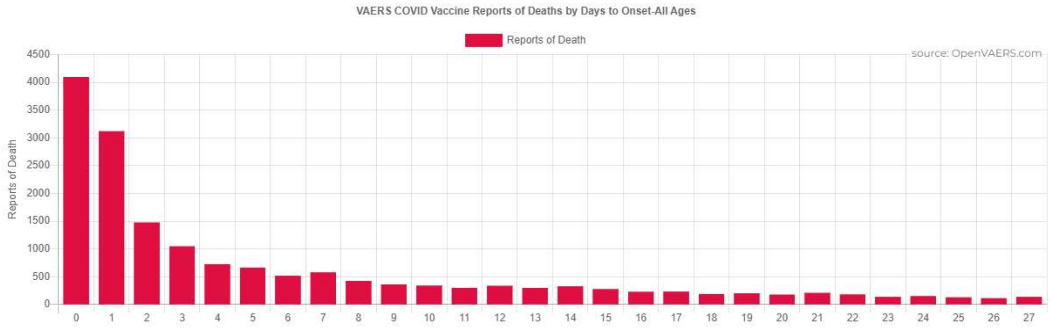
most concerning implication of under-reporting regarding the exponential increases in actual reports of death after vaccination in the past year compared to prior years of all vaccines combined.

VAERS COVID VACCINE MORTALITY REPORTS



Source: https://openvaers.com/covid-data

Even more damning is the temporal relationship of these reports to the date of the individual's vaccination, which some authorities have attempted to dismiss as simply representing "background" deaths. The fact that the reporting of deaths decrease over time from date of vaccination (shown below), infers a worrying causal relationship whereas erroneously reported "background deaths" would instead appear in similar numbers each subsequent day after the date of vaccination.



Source: https://openvaers.com/covid-data

Statisticians and analysts working with the Vaccine Safety Research Foundation (VSRF) have estimated the total number of deaths in the U.S. caused by the COVID-19 vaccines based on the numbers that were reported to the U.S. Vaccine Adverse Event Reporting System. In their

white paper,[21] they employed 9 different statistical prediction models, including estimates of under-reporting to VAERS and found that as of December 2021, total deaths associated with the vaccines ranged from 148,000 to 216,000. Using the same methodology for the 14,613 COVID-19 vaccine associated deaths in the U.S. reported as of May 16, 2022, the updated point estimate is approximately 599,000 deaths. The data and conclusions from these publications above provide support for identifying the vaccination campaign as the primary cause of the massive increases in Life Insurance claims among working age Americans beginning in the second half of 2021, as will be detailed below.

Further, VAERS likely significantly underestimates adverse events. React19, a patient advocacy organization that represents thousands of people injured following COVID-19 vaccines, recently conducted an audit of the Vaccine Adverse Event Reporting System (VAERS) database. It shared the results of this audit with ICAN and its legal team. Based on its audit of 126 verified VAERS reports randomly collected from its members, React19 found that 5% never made it into the VAERS system, another 22% made it into the system but were not publicly visible, and incredibly another 15% of VAERS reports made it into the system but then were outright deleted. Even more concerning, the majority of the deleted reports consisted of permanent disabilities and emergency room visits. In total, the team found that 42% of reports were not accessible in the VAERS system used by many across this country to assess vaccine safety.[22]

It has also been widely reported that medical institutions have discouraged providers from reporting adverse events. As one brief example, Deborah Conrad, a hospitalist physician's assistant on the frontlines of the pandemic, has spoken out about the complete disregard in her hospital for reporting Covid vaccine injury to VAERS. In riveting detail, including emails and recorded phone conversations, Conrad exposes the internal push to turn a blind eye to injuries and "tow the company line" that this vaccine is safe.[23] Instructions by hospitals to staff not to report, and the difficulty in successfully completing a VAERS report if attempted, are well-known throughout medicine.

D. Epidemiologic Data Demonstrates Highly Alarming Safety Signals.

An article published in the journal Nature[24] reported[25]:

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[21] https://www.skirsch.com/COVID-19/Deaths.pdf

[22] https://icandecide.org/press-release/ican-confronts-cdc-and-fda-about-hiding-important-vaccine-adverse-event-reports-from-public-view/

[23] https://www.reddit.com/r/DebateVaccines/comments/zvtp6q/7_of_vaccinated_americans_have_suffered_major/

[24] https://www.nature.com/articles/s41598-022-10928-z

[25] It must be acknowledged that accurately interpreting epidemiologic data to determine the relationship between vaccination status and the risk of contracting COVID-19 is both challenging and complicated given;

1) the unmeasured confounding variables associated with an individual's vaccination

- increases of over 25% in the number of ambulance calls in response to cardiac arrests (CA) and acute coronary syndromes (ACS or "heart attacks") for young people in the 16–39 age group during the COVID-19 vaccination rollout in Israel (January–May, 2021) compared with the same period of time in prior years (2019 and 2020).
- a robust and statistically significant association between the weekly CA and ACS ambulance call counts and the rates of 1st and 2nd vaccine doses administered to this age group. Note they found no observed statistically significant association between COVID-19 infection rates and the CA and ACS call counts.
- findings that aligned with previous studies showing that increases in overall CA incidence were not always associated with higher COVID-19 infections rates at a population level, and that the stability of hospitalization rates related to myocardial infarction throughout the initial COVID-19 wave compared to pre-pandemic baselines in Israel.
- findings that mirrored reports of increased emergency department visits with cardiovascular complaints during the vaccination rollout in Germany as well as increased EMS calls for cardiac incidents in Scotland. [26]

Equally alarming is the massive rise in deaths among healthy, young professional athletes from around the world. Since the vaccination campaign was initiated, and as of June 4, 2022, there were approximately 1,616 athletes that suffered a cardiac arrest, with 1,114 of them dying as a result.[27] The majority of arrests occurred in competition or training. The frequency of these events in comparison to historical data is highly concerning. In a 2009 review of professional athletes deaths,[28] published in a prominent European Cardiology journal, researchers found that from 1966 to 2004, there was an average of only 29 sudden athlete deaths ***per year worldwide***. A

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status (i.e., age, co-morbidities, behaviors)
2) the rapidly changing and often inconsistent definitions of what it means to be vaccinated (dependent upon varying numbers of vaccinations during different periods, varied vaccine types and schedules, and varied time windows from last vaccination).
3) the definition of a COVID-19 case (tested, untested, false positive, false negative), the definition of a COVID-19 death ("with COVID-19" vs. "from COVID-19," with the latter likely overestimated due to hospital financial incentives created during the Pandemic).
4) the exclusion from efficacy calculations of the surprisingly large numbers of COVID-19 infections and deaths suffered by the recently vaccinated (i.e., within 14 days of vaccination).

[26] https://scotland.shinyapps.io/phs-COVID-19-wider-impact/, see also https://www.opendata.nhs.scot/dataset/covid-19-wider-impacts-scottish-ambulance-services/resource/d1d2d098-193f-489c-940a-a828fdcfc357

[27] https://goodsciencing.com/COVID-19/athletes-suffer-cardiac-arrest-die-after-COVID-19-sh

[28] https://pubmed.ncbi.nlm.nih.gov/17143117/

study by Maron *et al* in 2009 found that there were 66 deaths per year in the previous 6 years.[29] Compare this number to just the month of January 2022 alone where 127 collapses and 87 deaths among professional athletes were reported. Overall, these athlete deaths reflect an approximately 22-fold increase in the year after the introduction of COVID-19 vaccines, to date unexplained by other identifiable causes.

On February 10, 2020, the Israeli Health Ministry published the results of a survey of adverse events[30] [31] among roughly 2,000 random Israelis who received booster shots. Although many could be thought of as minor, it is concerning that 51% of the women and 35% of the men who experienced a side effect reported that, as a result, they had difficulty performing daily activities. A total of 4.5% of those who received booster doses reported neurological side effects.

E. There are substantial risks associated with receipt of a COVID-19 mRNA vaccination, particularly in younger patients, which has been globally recognized by a number of governments who are at odds with the CDC position.

Seven nations have suspended COVID-19 vaccines for younger age groups due to risks of myocarditis. Sweden, Finland, France, and Germany suspended Moderna for under 30 years old. Denmark suspended the Moderna vaccine for under 18 years old and now no longer recommends vaccination for low-risk individuals under 50 years old. Taiwan suspended 2nd Pfizer vaccine for ages 12-17 (please see below for detailed references to all risks of morbidity and mortality among those receiving COVID-19 mRNA vaccination compiled from Life Insurance Industry reports, VAERS database, U.S. Disability statistics and peer reviewed publications.)

A recent study[32] in The Journal of Medical Ethics, an affiliate of the British Medical Journal, shows that getting a COVID-19 "booster shot" is at least 18 times more dangerous for young people than getting COVID-19. According to the study's authors, "[t]o prevent one COVID-19 hospitalisation over a six-month period, we estimate that 31,207–42,836 young adults aged 18–29 years must receive a third mRNA vaccine. Booster mandates in young adults are expected to cause a net harm: per COVID-19 hospitalisation prevented, we anticipate at least 18.5 serious adverse events from mRNA vaccines, including 1.5-4.6 booster-associated myopericarditis cases in males (typically requiring hospitalisation)."

It is important to understand why these adverse events were only picked up in post-surveillance:

First, it must be recognized that the pediatric clinical trials[33] for the COVID-19 vaccines were too small (the booster trial for 5-to-11-year olds had 140 participants) to detect safety

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29 https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.108.804617.

30 https://drive.google.com/file/d/1NyMrHRTO-SLvygWtPmA39QlgqCE_GbsP/view

31 https://rtmag.co.il/?view=article&id=238&catid=2

32 https://jme.bmj.com/content/early/2022/12/05/jme-2022-108449

33 https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-data-demonstrating-high-immune

signals for serious adverse events–especially for a recipient population in the tens of millions. It is difficult to understand how the FDA allowed trials to be conducted with so few children enrolled, knowing they were inadequate to assure safety with a specific inability to assess long-term safety.

Secondly, the Pfizer data presented to the FDA in support of an Emergency Use Authorization for vaccinating children from 6 months to 4 years old includes deeply concerning data regarding safety and efficacy. In a review by the diagnostic pathologist[34] Dr. Clair Craig, Co-Chair of the HART group[35] (HART is a group of highly qualified UK doctors, scientists, economists, psychologists, and other academic experts that came together over shared concerns about policy and guidance recommendations relating to the COVID-19 pandemic), she reports that:

- The trial recruited 4,526 children from 6 months to 4 years old. *3,000 did not make it to the end of the trial.* This is a highly disturbing finding and is almost unprecedented to have this number of subjects (2/3) drop out of any trial. This level of drop-out essentially negates the value of any findings.
- They defined "severe COVID-19" as an increased heart or respiratory rate. There were 6 cases in the vaccinated group and only one in the unvaccinated group. *The only child hospitalized in the trial had a fever and a seizure. They were in the vaccinated group*.
- In the 3-week period between the first and 2nd doses in this trial, *34 of the vaccinated children contracted COVID-19, while only 13 in the unvaccinated group contracted COVID-19*.
- In the 8-week gap between the 2nd and 3rd dose, again more subjects in the vaccinated group fell ill with COVID-19. These data were ignored.
- In the several weeks after the 3rd dose, again more subjects in the vaccinated group fell ill with COVID-19. These data were ignored.
- In the end they compared the 3 children in the vaccine group who ultimately got COVID-19 post the 3-dose with the 7 children in the unvaccinated group.
- This was the basis for their claim of efficacy; however, it must be noted they ignored 97% of the cases of COVID-19 prior to this point.
- Further, of the 11 children who contracted COVID-19 twice during the trial, only one was unvaccinated. Many of the vaccinated children who contracted COVID-19 twice had received three doses already.

Furthermore, multiple case reports[36] [37] have suggested that vaccinating after infection increases the risk of vaccine-induced side effects such as myocarditis. Most concerning is this

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[34] https://rumble.com/v18s66i-bombshell-dr.-clare-craig-exposes-how-pfizer-twisted-t
[35] https://www.hartgroup.org/bios/
[36] https://www.cureus.com/articles/96445-a-rare-case-of-myocarditis-after-the-first-
[37] https://www.cureus.com/articles/93217-COVID-19-vaccination-induced-cardiomyopathy

nationwide survey of myocarditis incidence in Finland from 2017 found that there were 4 cases per million[38].

A CDC study of 12-29 year-olds with heart inflammation following mRNA vaccination, published last week in *The Lancet Child & Adolescent Health*, found that 1 in 6 still had not "fully recovered" at least 90 days after myocarditis onset, including 1 in 100 who hadn't improved at all.[39]

Myocarditis has increased so markedly among youth since COVID-19 vaccines were authorized for them that an Ivy League-affiliated hospital started running TV ads for its treatment in children. New York Presbyterian marked the ad's Sept. 6 YouTube video private less than two weeks later, following criticism that it was trying to "normalize" a vaccine-induced condition. The CDC's COVID-19 Response Team found more than 800 myocarditis reports to the VAERS from Jan. 12 to Nov. 5, 2021 that matched the parameters for age and time since onset.[40]

The risks demonstrably outweigh the benefits of COVID-19 vaccination in children. A study out of Hong Kong[41] showed one out of every 2,700 12-17-year-old boys are diagnosed with myocarditis following the second dose of Comirnaty vaccine (37 per 100,000 vaccinated). A study from Kaiser found the same rate of myocarditis in 12-17-year-old American boys, 1/2700.[42] While CDC is saying that myocarditis is a mild disease, cardiologists know otherwise.[43] The CDC's own preliminary data[44] reported at the February 4 ACIP meeting, revealed that nearly half of the young people diagnosed with myocarditis still had symptoms 3 months later, and 39% had their activity restricted by their physician. We know this serious

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38 https://jamanetwork.com/journals/jamacardiology/fullarticle/2791253

39 Kracalik I, Oster ME, Broder KR, Cortese MM, Glover M, Shields K, Creech CB, Romanson B, Novosad S, Soslow J, Walter EB, Marquez P, Dendy JM, Woo J, Valderrama AL, Ramirez-Cardenas A, Assefa A, Campbell MJ, Su JR, Magill SS, Shay DK, Shimabukuro TT, Basavaraju SV; Myocarditis Outcomes After mRNA COVID-19 Vaccination Investigators and the CDC COVID-19 Response Team. Outcomes at least 90 days since onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults in the USA: a follow-up surveillance study. Lancet Child Adolesc Health. 2022 Nov;6(11):788-798. doi: 10.1016/S2352-4642(22)00244-9. Epub 2022 Sep 22. Erratum in: Lancet Child Adolesc Health. 2022 Dec;6(12):e28. Erratum in: Lancet Child Adolesc Health. 2023 Jan;7(1):e1. PMID: 36152650; PMCID: PMC9555956.

40 https://en-volve.com/2022/09/28/cdc-now-admits-that-covid-vaccine-is-causing-lasting-post-jab-heart-problems-in-young-adults/

41 https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab989/6445179

42 https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/04-COVID-19-klein-508.pdf

43 https://onlinelibrary.wiley.com/doi/10.1002/pds.5439

44 https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/summary-2022-02-04-508.pdf

adverse event frequently occurs in teenagers. But no one knows how often it occurs in younger children. This is of significant concern for babies and younger children.

There is no available care for children injured by COVID-19 shots. There is no way to remove the spike protein and other toxic byproducts of vaccination, which may be produced for a considerable period of time following inoculation of messenger RNA.[45] The science and medicine have not yet developed, and most families will be unable to cover the costs of potential catastrophic injuries. The federal government's Countermeasures Injury Compensation Program has not compensated a single person injured by COVID-19 vaccines. [46]

Several months ago, the FDA authorized booster doses of the Pfizer vaccine for 5-11-year-olds without convening a VRBPAC meeting[47] or providing any public discussion of the evidence supporting the booster. Dr. Peter Marks, the Director of FDA's Center for Biologics, told the VRBPAC in April that the FDA's issuance of an EUA for a second booster in adults was a "stopgap measure" [48]– the implication being there was no scientific evidence to support that booster. Has the FDA given up even the appearance of a scientific evaluation before issuing more EUAs for COVID-19 vaccines?

In the documents related to a recent FOIA request, in the Pfizer informed consent document[49] it was revealed that the company recognized the risk of myocarditis to be as high as 1 in 10,000. In 2022, with many fewer vaccines administered compared to 2021, the rate of myocarditis reports to VAERS[50] is averaging 245% higher than last year. The myocarditis is overwhelmingly found in children.

In a paper by Walach et al.,[51] the authors calculated the Number Needed to Vaccinate (NNTV) to prevent one death from a large Israeli field study. They then accessed the Adverse Drug Reactions database of the Dutch National Register (Lareb) to extract the number of cases reporting severe side effects and the number of cases reporting fatal side effects.

- They found the NNTV to be between 200 and 700 to prevent one case of COVID-19 by Pfizer's mRNA vaccine product.
- The NNTV to prevent one death was between 9,000 and 100,000 (95% confidence interval), with 16,000 as a point estimate (as you will see below, for younger healthy people, this estimate would tend to the higher end of a NNTV of 90,000-100,000 to prevent a single death).
- They calculated that for every 6 deaths prevented by vaccination, there were approximately 4 deaths reported associated with vaccination, yielding a potential

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45 https://www.cell.com/cell/fulltext/S0092-8674(22)00076-9?_returnURL=https%3A%2F%252

46 https://www.hrsa.gov/cicp/cicp-data

47 https://www.fda.gov/news-events/press-announcements/coronavirus-COVID-19-update-fda-expands-eligibility-pfizer-biontech-COVID-19-vaccine-booster-dose

48 https://www.npr.org/sections/health-shots/2022/04/06/1091242252/advisers-to-fda-w

49 https://www.icandecide.org/wp-content/uploads/2022/02/Substudy-C.pdf at page 2.

50 https://openvaers.com/COVID-19-data/myo-pericarditis

51 https://www.mdpi.com/2076-393X/9/7/693

risk/benefit ratio of 2:3 (note that deaths are consistently under-reported to such databases, thus a more accurate risk/benefit ratio for death would likely be inverted).
- The authors concluded that, "although causality between individual reports of adverse events and vaccination has not been established, these data indicate a lack of clear benefit, which should cause governments to rethink their vaccination policy."

In a published paper by Jessica Rose,[52] a world expert analyst of the VAERS database, she found that, based on the ratio of expected severe adverse events to observed adverse events in VAERS for a number of conditions, the "underreporting factor (URF)" for COVID-19 vaccine-associated deaths was 31. Using this URF for all VAERS-classified severe adverse events, as of October 2021, vaccines were associated with 205,809 deaths, 818,462 hospitalizations, 1,830,891 ER visits, 230,113 life-threatening events, 212,691 disabled and 7,998 birth defects."

A paper by Ronald Kostoff et al.[53] was retracted despite passing peer review. However, in a personal review of the correspondence between the author and Journal Editor, neither I nor my colleagues were able to find a valid criticism of the underlying data analysis or conclusions. Therefore, I have incorporated this valuable study whereby they used a novel, best-case scenario, cost-benefit analysis which showed conservatively that there were five times the number of deaths attributable to each inoculation vs. those attributable to COVID-19 in the most vulnerable 65+ demographic. The risk of death from COVID-19 decreased drastically as age decreases, and the longer-term effects of the inoculations on lower age groups "may increase" their risk-benefit ratio (although this has not been demonstrated to date as can be seen below).

Current data shows that children have a 99.995% recovery rate, and a body of medical literature indicates that near nil healthy children under five years old have died from COVID-19. Further, only a fraction of the rare child deaths were due to COVID-19 and these do not accord with pediatric COVID-19 death rates from other countries. The *New York Times* has reported that the CDC has chosen to conceal the number of Americans[54] who died due to COVID-19, even though the data are found on death certificates.

A study from Johns Hopkins[55] that monitored 48,000 children diagnosed with COVID-19 showed a zero-mortality rate in children under 18 without comorbidities. *The Wall Street Journal* reported on this in their editorial comment "The Flimsy Evidence Behind the CDC's Push to Vaccinate Children."[56]

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[52] https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864_0490c898f7514df4b6fbc5935da07322.pdf

[53] https://www.sciencedirect.com/science/article/pii/S221475002100161X

[54] https://www.nytimes.com/2022/02/20/health/COVID-19-cdc-data.html

[55] See reporting at https://thefederalist.com/2021/07/21/johns-hopkins-study-found-zero-COVID-19-deaths-among-healthy-kids/

[56] https://www.wsj.com/articles/cdc-COVID-19-coronavirus-vaccine-side-effects-hospitalization-kids-11626706868

A study in *Nature* demonstrated that children under 18 with no comorbidities have virtually no risk of death.[57]

Data from England and Wales,[58] published by the UK Office of National Statistics on January 17, 2022, revealed that throughout 2020 and 2021, only one (1) child under the age of 5, without comorbidities, had died from COVID-19 in the two countries, whose total population is 60 million.

A large study conducted in Germany[59] showed zero deaths for children ages 5-11 and a case fatality rate of three per million in all children without comorbidities. A study published in December in *Nature*[60] demonstrated how children efficiently mount effective, robust, and sustained immune responses.

The CDC published data[61] stating that not one death occurred in children aged 6 months through 4 years old that was associated with COVID-19 during the late Delta through early Omicron wave from December 2021 through March 2022.

It is well known that hospitalizations and deaths with COVID-19 have been misattributed as hospitalizations and deaths due to COVID-19 by federal health agencies, leading to numbers of severe cases and deaths that have been disputed by US physicians investigating them, and which do not accord with the mortality rates for children in other nations. CDC now publishes its COVID-19 mortality data as deaths *with* COVID-19,[62] blatantly exaggerating COVID-19-caused morbidity and mortality.

According to CDC and the *New York Times,*[63] sampling data over a three-month term beginning on February 28, 2022, during which there has been fewer than one U.S. child per 100,000 children hospitalized daily for COVID-19. Contrast this number with the 37 children per 1000,00 who will contract myocarditis from the vaccine as referenced above.

According to the CDC data tracker, less than 0.1% of all US deaths that have occurred "with" COVID-19 have occurred in children aged 0 through 4.[64]

Strong evidence that newer variants of COVID-19 (Omicron) pose dramatically reduced risks to young children was published in the April 1, 2022, JAMA Pediatrics by Wang et al.[65] Using a huge U.S. medical database, they were able to match children aged under 5 who were

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57 https://www.nature.com/articles/s41591-021-01578-1

58 From search conducted at: https://www.ons.gov.uk/aboutus/transparencyandgovernance/freedomofinformationfoi/

59 https://www.medrxiv.org/content/10.1101/2021.11.30.21267048v1

60 *https://www.nature.com/articles/s41590-021-01089-8*

61 https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-17-18/02-COVID-19-fleming-dutra-508.pdf (at Slide 19).

62 https://data.cdc.gov/NCHS/Provisional-COVID-19-Death-Counts-by-Age-in-Years-/3apk-4u4f

63 *https://www.nytimes.com/interactive/2021/us/COVID-19-cases.html*

64 https://COVID-19.cdc.gov/COVID-19-data-tracker/?CDC_AA_refVal=https://www.cdc.gov/coron

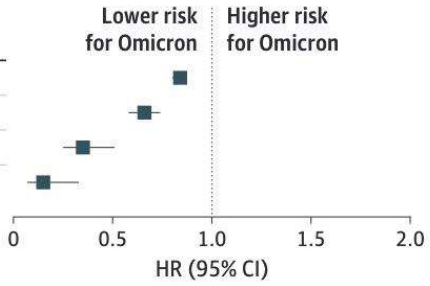
65 https://jamanetwork.com/journals/jamapediatrics/fullarticle/2790793

infected with an Omicron variant with those who were infected with a Delta variant. Children with Omicron were only 35% as likely to require an ICU admission and only 15% as likely to require mechanical ventilation as same-aged children who had been sick due to earlier Delta variants.

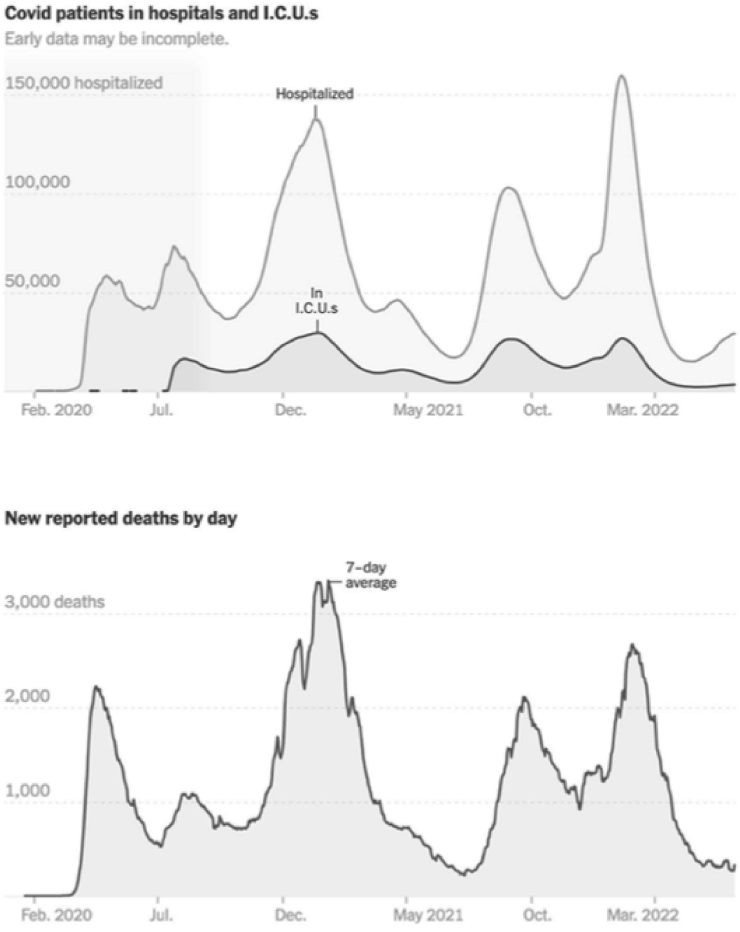
Figure. Comparison of Risks of Clinical Outcomes of SARS-CoV-2 Infection in Children Younger Than 5 Years

A Omicron vs Delta cohorts

Outcome	Matched Omicron cohort, No. (%)	Matched Delta cohort, No. (%)	HR (95% CI)
ED visits	4637 (20.36)	5602 (24.60)	0.84 (0.80-0.87)
Hospitalizations	401 (1.76)	741 (3.25)	0.66 (0.58-0.74)
ICU admissions	38 (0.17)	115 (0.51)	0.35 (0.25-0.51)
Mechanical ventilation	10 (0.04)	51 (0.22)	0.15 (0.07-0.33)



Below are shown the June 8, 2022, *New York Times* graphs for the current number of US patients in hospitals, ICUs, and suffering deaths attributed to COVID-19. The number of patients in ICUs dying each day ascribed to COVID-19 are close to the lowest numbers since the start of the pandemic. Given that CDC extrapolated that 95% of Americans already have partial to complete immunity, while we are at historic low levels for severe COVID-19 disease, it should be clear that there is no need to vaccinate anyone now.



The Pfizer clinical trials for children 2 through 4 years old failed to meet FDA-specified requirements for COVID-19 vaccine EUAs.[66] The vaccines did not show 50% efficacy nor meet the required 30% lower bound with a 95% confidence interval[67] Given these data, there is no support for the proposal to use a product and schedule that failed FDA's established criteria in its clinical trials should not be allowed.

66 https://www.nytimes.com/2022/02/01/us/politics/pfizer-vaccine-kids.html

67 Id.

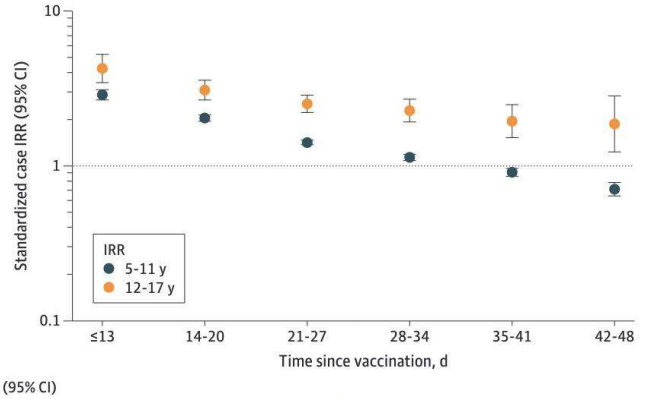
II. Real World Efficacy Data Raises Serious Concerns about the Benefit of mRNA Vaccines and Demonstrates that Vaccinated Individuals Are Likely at Higher Risk.

A. Numerous Studies Demonstrate Negative Efficacy.

Delving deeper into specific concerns about efficacy and further addressing the statements that "vaccination status, when you combine the benefits and the risks of it, it actually favors the unvaccinated" and that "all-cause mortality" is higher for vaccinated people than for non-vaccinated people, there are a number of proposed mechanisms for negative efficacy in the vaccinated. Dr. Paul Offit, Chair of the FDA Vaccine Advisory Board, for example conceded in a letter to the New England Journal of Medicine[68] that there is a real concern of the shots inducing a form of immune suppression known as original antigenic sin. More recently, Dr. Offit has flatly said that young people should not be vaccinated because the risks outweigh the likely benefits.[69]

Some of the evidence for negative efficacy comes from booster data, which have fleeting efficacy, as one data point the fact that the Pfizer shots in the 5-11 year range led to very poor efficacy; 31% according to the CDC and 12% after 7 weeks according to a massive database comprising over 1.3 million children (365,000 of whom were vaccinated) from the NY Department of Health.[70] Five to 11-year-old children dropped into the negative efficacy range by 8 weeks after receiving the second dose. See Figure below.

Figure. New COVID-19 Cases Among Unvaccinated Children vs Fully Vaccinated Children by Time Since Vaccination and Age Group



IRR (95% CI)						
12-17 y	4.3 (3.4-5.3)	3.1 (2.7-3.6)	2.5 (2.2-2.9)	2.3 (1.9-2.7)	1.9 (1.5-2.5)	1.9 (1.2-2.8)
5-11 y	2.9 (2.7-3.1)	2.0 (1.9-2.1)	1.4 (1.4-1.5)	1.1 (1.1-1.2)	0.9 (0.9-1.0)	0.7 (0.6-0.8)

Time since full vaccination was defined as days subsequent to 14 days after completion of the primary 2-dose series. Incidence rate ratio (IRR) values less than 1 observed in later times likely reflect estimator instability, residual confounding, or both as opposed to true relative increased risk for those vaccinated.

68 https://www.nejm.org/doi/full/10.1056/NEJMe2203329
69 https://twitter.com/MaxBlumenthal/status/1573768095633653760
70 https://www.medrxiv.org/content/10.1101/2022.02.25.22271454v1.full.pdf

This is the largest COVID-19 vaccine efficacy study in children ever published, using the highest quality, official data from NY state. There was a large, linear drop in efficacy seen with each successive week following full vaccination. Extremely narrow confidence intervals confirm the validity of these data. By 8 weeks following their second dose, vaccinated children were placed at higher risk of developing COVID-19 than unvaccinated children. By 9 weeks, their risk was even higher. Despite data-free theories offered to minimize this finding, the indisputable fact is that being vaccinated placed these children in a higher risk category for a COVID-19 infection than if they had never been vaccinated.

The original Moderna clinical trial data,[71] which should have been available to regulatory agencies at least since the Moderna package was presented for licensure, reveals that while 93% of unvaccinated controls produced detectable SARS-CoV-2 anti-nucleocapsid antibody after infection, only 40% of the vaccinated produced this antibody after infection. Most of the vaccinated failed to mount the expected immune response. This is probably why Dr. Marco Cavaleri of the European Medicines Agency warned that frequent COVID-19 booster shots could adversely affect the immune response and may not be feasible. "Repeat booster doses every four months could eventually weaken the immune response and tire out people," Bloomberg reported, quoting the European Medicines Agency.[72] It is probable that the more doses of these vaccines you receive, the less broad immunity you will develop, even after getting infected.

Also notable, the CDC was asked pursuant to FOIA to provide "all data concerning or reflecting the efficacy of COVID-19 'booster shots' for people 12-49 years of age." The CDC's rather chilling response was that a "search of our records failed to reveal any documents pertaining to your request."[73] The FOIA request referred to a *New York Times* article entitled "The C.D.C. Isn't Publishing Large Portions of the Portions of the Covid Data it Collects"[74] and the *New York Post* also published a story called "CDC withholding COVID data over fears of misinterpretation."[75] When presented with a FOIA request raising this issue, CDC demurred and said they had no such data. While this might be written off as errors in judgment and legal compliance on the part of a FOIA Office, the consistency with which the CDC has failed to provide data, and that it could or would not identify studies in support of booster shots for those 12-49 years of age, means that policy makers are deprived of supportive data under which any mandate might be reasonable.

Walgreens pharmacies perform rapid antigen COVID-19 tests and report weekly on the results, based on the number of vaccine doses received and the date the most recent vaccination was obtained. In June 2022, their data revealed that receiving a 2nd or 3d dose within the past 5

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71 https://www.medrxiv.org/content/10.1101/2022.04.18.22271936v1

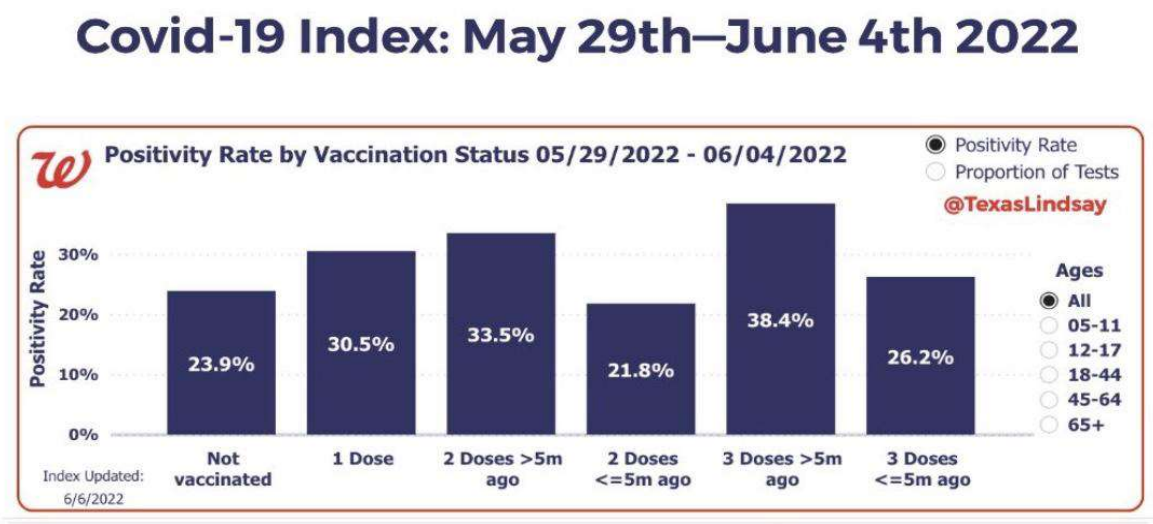
72 https://www.bloomberg.com/news/articles/2022-01-11/repeat-booster-shots-risk-overloading-immune-system-ema-says

73 https://icandecide.org/wp-content/uploads/2023/01/Final-Response-No-Records.pdf

74 https://www.nytimes.com/2022/02/20/health/covid-cdc-data.html

75 https://nypost.com/2022/02/22/cdc-withholding-covid-data-over-fears-of-misinterpretation/

months leads to a comparable positivity rate as being unvaccinated (21.8-26.2%). However, receiving 2 or 3 doses more than 5 months ago leads to the highest positivity rates (33.5-38.4%). This is further supportive evidence that efficacy falls into negative territory several months after vaccination. See the chart below.



With the above caveats in mind, the data indicates that vaccinated individuals are more likely to fall ill with the variants now in circulation. This may not have been the case earlier in the global vaccination campaign but is unfortunately the case now. There are several possible explanations for this finding. Chief among them is that the current mRNA vaccines were formulated using the genetic sequences of the original "Wuhan" strain of SARS-CoV2 from over 2 years ago. Given SARS-CoV2 is a highly mutagenic virus, many dozens of variants have since emerged, with several strains exhibiting sudden, multiple, and major pathogenically important mutations, particularly within the original spike protein to which the mRNA sequences are directed.

The major mutations have been "named" and each have many subvariants. The Delta variant phase in the U.S. ran from approximately June of 2021 to January 2022, after which the Omicron variant has predominated, and we are currently seeing rising cases from sub-variants of this strain. Omicron deserves mention as it is phylogenetically different from both Delta and the original Wuhan strain. This is likely the most accurate explanation as to why, in the setting of what are now "non-neutralizing" antibodies, this paradoxically makes "Wuhan strain" vaccinated individuals more susceptible as follows;

Stanford researchers found that "prior vaccination with Wuhan-Hu-1-like antigens followed by infection with Alpha or Delta variants gives rise to plasma antibody responses with apparent Wuhan-Hu-1-specific imprinting manifesting as relatively decreased responses to the

variant virus epitopes compared with unvaccinated patients infected with those variant viruses."[76]

From a Public Health England vaccine surveillance report in the U.K., government researchers asserted[77] that their serology tests were underestimating the number of people with prior infection due to recent observations from UK Health Security Agency (UKHSA) surveillance data that "N antibody levels appear to be lower in individuals who acquire infection following 2 doses of vaccination."

In this peer-reviewed paper[78] they found that at the country-level (and U.S. county level), there appears to be no discernable relationship between the percentage of the population fully vaccinated and new COVID-19 cases as seen below. In fact, the rising slope of the relationship in both graphs below suggest that mass vaccination policies may paradoxically lead to more cases, with Israel serving as a worrying outlier.

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[76] https://www.cell.com/action/showPdf?pii=S0092-8674%2822%2900076-9

[77] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1027511/Vaccine-surveillance-report-week-42.pdf at page 23.

[78] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8481107/

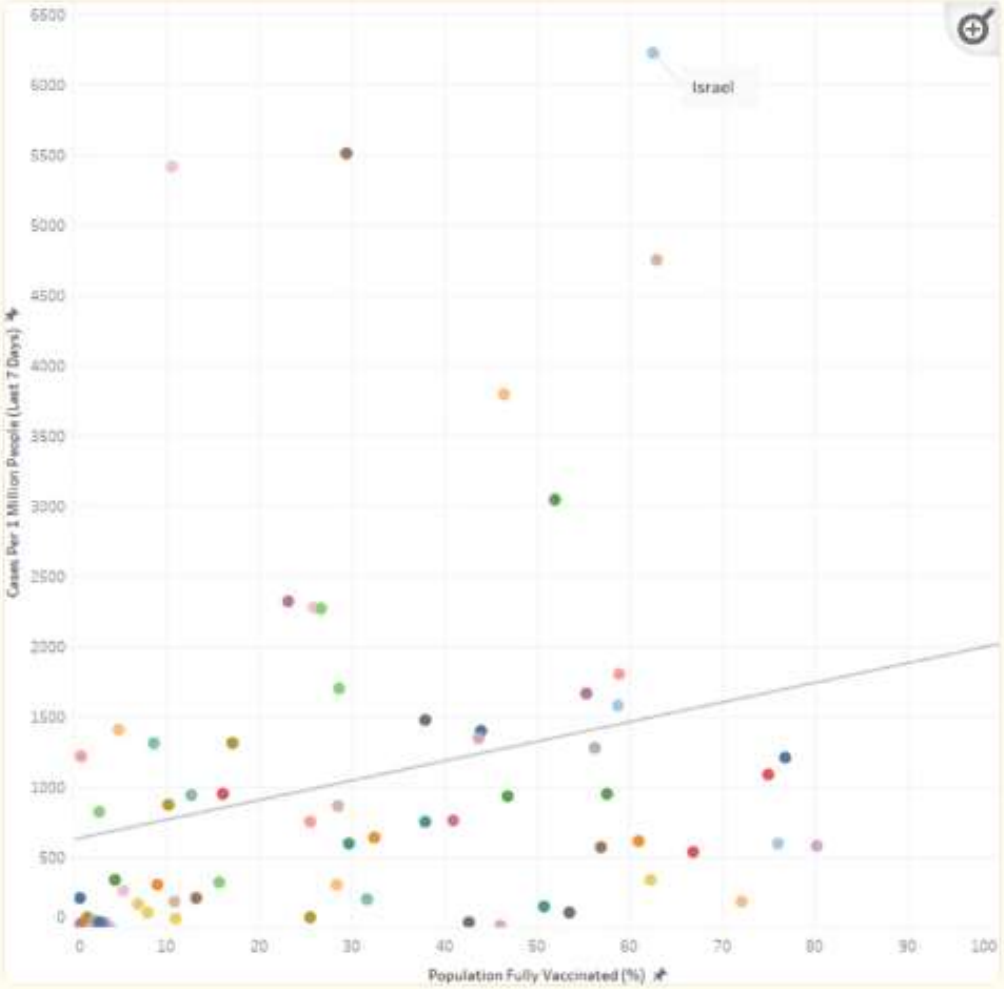

Fig. 1

Relationship between cases per 1 million people (last 7 days) and percentage of population fully vaccinated across 68 countries as of September 3, 2021 (See Table S1 for the underlying data)

This is also seen in a European Journal of Epidemiology study[79] that found that at the country-level, there appears to be no discernable relationship between percentage of population fully vaccinated and new COVID-19 cases in the last 7 days (Fig. 1). In fact, the trend line

[79] Subramanian SV, Kumar A. Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States. Eur J Epidemiol. 2021 Dec;36(12):1237-1240. doi: 10.1007/s10654-021-00808-7. Epub 2021 Sep 30. PMID: 34591202; PMCID: PMC8481107.

suggests a marginally positive association such that countries with higher percentage of population fully vaccinated have higher COVID-19 cases per 1 million people."

A study prepared by Humetrix[80] for the Department of Defense called "Project Salus," monitored 20 million Medicare beneficiaries from January to August of 2021 and found that the vaccinated share of the COVID-19 hospitalizations rose steadily with both vaccines after three to four months and sharply after six months (as the Israelis found). By late July, 71% of all cases and 61% of all hospitalizations were among vaccinated individuals.

More current data from the Walgreens chain of pharmacies[81] finds that in the U.S., over the last several months, fully or partially vaccinated individuals are testing positive at higher relative rates than the unvaccinated.

According to Cornell University's faculty, an outbreak in December of 2021[82] that forced the school to switch to online learning was driven exclusively by the vaccinated. "Virtually every case of the Omicron variant to date has been found in fully vaccinated students, a portion of whom had also received a booster shot," said Vice President for University Relations Joel Malina in a statement.

On December 31, 2021, the UK's Office of National Statistics [83]released an "Infection Survey" of 1,701 individuals who tested positive for COVID-19 between Nov. 29 and Dec. 12, of whom 115 tested positive for the Omicron variant. The agency found a clear correlation between the number of vaccinations and the likelihood of an Omicron-positive result. The odds ratio of testing positive for Omicron with two vaccinations was 2.26; for the triple-vaccinated, it was 4.45.

According to the[84] latest U.K. health surveillance report, roughly 95% of those over 70 are double-vaccinated and about 90%-93% of the age cohorts over 70 are boosted. Just 1.6% of the senior cases between weeks 7 and 10 of this year were among the unvaccinated, which is below the 5% share of the population they compose. The triple-boosted actually made up 90% of the cases.

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[80] https://web.archive.org/web/20210924082828/https:/www.humetrix.com/powerpoint-vaccine.htm

[81] https://www.walgreens.com/businesssolutions/COVID-19-index.jsp

[82] https://www.cnn.com/2021/12/14/us/cornell-university-COVID-19-cases/index.html

[83] https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/adhocs/14107coronavirusCOVID-1919infectionsurveyukcharacteristicsrelatedtohavinganomicroncompatibleresultinthosewhotestpositiveforCOVID-1919

[84] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1061532/Vaccine_surveillance_report_-_week_11.pdf

Table 13: PCR-confirmed COVID-19 age-standardised case rate per 100,000 individuals by vaccine status, seven-day rolling average from 15 January 2022 to 11 February 2022

	Unvaccinated			1 Dose		
Week	No. tested positive by PCR	Population	Age-standardised case rate per 100,000 with 95% confidence intervals	No. tested positive by PCR	Population	Age-standardised case rate per 100,000 with 95% confidence intervals
15 January - 21 January 2022	5,320	976,941	**439.48** (416.28 - 462.67)	1,962	318,871	**481.31** (443.73 - 518.89)
22 January - 28 January 2022	4,956	970,309	**381.51** (362.44 - 400.59)	1,664	302,843	**422.99** (388.50 - 457.49)
29 January - 04 February 2022	4,757	962,727	**393.55** (374.97 - 412.13)	1,444	275,689	**383.99** (353.98 - 413.99)
05 February - 11 February 2022	3,834	956,449	**340.79** (321.48 - 360.10)	1,152	262,647	**343.90** (315.71 - 372.08)
	2 Doses*			Booster or 3 Doses		
Week	No. tested positive by PCR	Population	Age-standardised case rate per 100,000 with 95% confidence intervals	No. tested positive by PCR	Population	Age-standardised case rate per 100,000 with 95% confidence intervals
15 January - 21 January 2022	6,522	934,811	**617.62** (596.83 - 638.40)	10,772	3,070,303	**428.00** (401.48 - 454.51)
22 January - 28 January 2022	5,411	855,982	**569.85** (548.82 - 590.87)	11,123	3,170,692	**446.83** (415.17 - 478.49)
29 January - 04 February 2022	5,079	830,753	**525.86** (505.59 - 546.13)	12,052	3,229,937	**500.21** (474.93 - 525.49)
05 February - 11 February 2022	5,201	809,783	**549.69** (529.08 - 570.31)	13,833	3,270,226	**527.98** (508.76 - 547.21)

* 1 Dose and 2 Dose populations include individuals who have exceeded the recommended dose schedule and may be subject to vaccine waning. Data in this table should not be used as a measure of vaccine effectiveness due to unaccounted for biases and risk factors in different populations. For more information, please see the interpretation of data and vaccine effectiveness summary sections above.

The respected Robert Koch Institute reported that among the 4,206 Germans infected with Omicron for whom their vaccination status was known, 95.58% were fully vaccinated.[85] More than a quarter of them had booster shots. Given that the overall background rate for vaccination in Germany is 70%, this suggests an -87% effectiveness rate against Omicron. As of Dec. 31, 2021, in Denmark, 89.7% of all Omicron cases were among the fully vaccinated with just 8.5% of all cases in Denmark among the unvaccinated,[86] according to the Statens Serum Institut. Overall, 77.9% of Denmark was fully vaccinated at the time[87], and Omicron is more prevalent among younger people for whom there is a greater unvaccinated pool, which again support a negative efficacy.[88] Even for non-Omicron variants, the unvaccinated composed

[85] https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Situationsberichte/Wochenbericht/Wochenbericht_2021-12-30.pdf?__blob=publicationFile
[86] https://www.coronaheadsup.com/europe/denmark/denmark-85-of-omicron-cases-are-doub
[87] https://files.ssi.dk/COVID-1919/omikron/statusrapport/rapport-omikronvarianten-31122021-ct18
[88] https://www.telegraph.co.uk/global-health/science-and-disease/omicron-wave-driven-young-healthy-vaccinated-population

only 23.7% of the cases.

Vaccination status (12+ year olds)	Other variants (No. of cases)	Other variants (%)	Omicron (No. of cases)	Omicron (%)
Not vaccinated	21,390	23.7	3,500	8.5
Received first dose	2,813	3.1	731	1.8
Completed primary vaccination schedule	56,532	62.5	29,781	72.0
Revaccinated	9,704	10.7	7,330	17.7
Total	90,439	100.0	41,342	100.0

B. The Evidence Alleging to Show Significant Reduction in Severity and Mortality from the mRNA Vaccine Is Overstated.

There have been numerous reports that large numbers of COVID-19 deaths are preventable using mRNA vaccines, an element in the support for the use of coercion against medical professionals via licensing and credentialing actions to ensure compliance. An example is a 2021 analysis[89] that utilized a number of questionable assumptions to conclude that higher vaccination rates could have saved over 200,000 lives. The impact of mRNA vaccination on longevity is discussed throughout this section, but it is useful to highlight some of the faults in such studies:

- Since so many deaths not caused by COVID-19 have been classified as COVID-19 deaths, we don't actually know how many people died from the illness, including deaths that could have been caused by mRNA vaccination (this study just assumed the official but inflated figure as accurate).[90]This is a complex topic about which there are professional differences of opinion and the evidence is not yet fully clear, in part because of difficulties obtaining data from CDC and FDA as they have opposed release of information in court and were concerned that the data would be "misinterpreted" as showing unacceptable risks of vaccination.[91]
- The study ignores numerous confounding variables that could account for different death rates such as differences in implementation and compliance with other public health measures, along with other limitations noted in the study.
- In Pfizer's trial, the survival benefit from the vaccine worsened with time (this has also been observed outside the trials), and at 6 months follow-up[92] (where the trial was

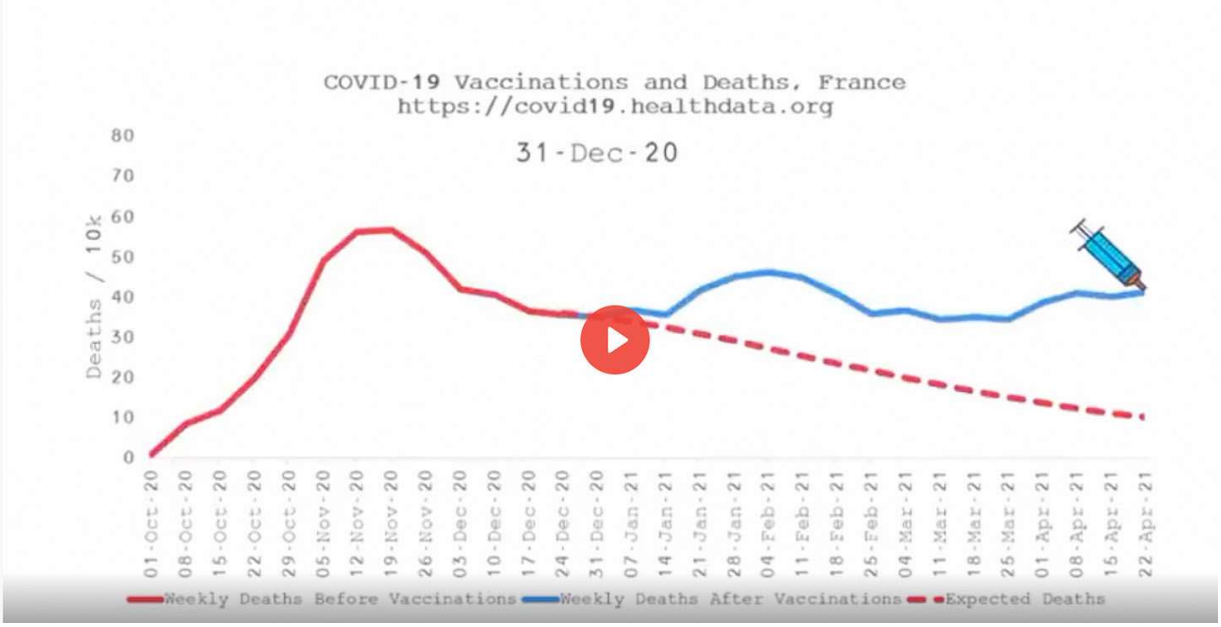
[89] https://www.healthsystemtracker.org/brief/covid19-and-other-leading-causes-of-death-in-the-us/

[90] See for e.g. https://stevekirsch.substack.com/p/how-to-assess-whether-a-death-was?utm_source=post-email-title&publication_id=548354&post_id=90896546&isFreemail=true&utm_medium=email

[91] https://www.nytimes.com/2022/02/20/health/covid-cdc-data.html

[92] https://www.nejm.org/doi/full/10.1056/nejmoa2110345

abruptly terminated), more people who were vaccinated died than those who were unvaccinated (which means that it is impossible that there could have been a net gain of life through vaccinating). Since this is the longest clinical trial that was performed on the vaccines, its conclusion must stand until a longer trial is conducted.
- The vaccines we are using have caused SARS-CoV-2 to rapidly evolve into variants for which it no longer offers protection. For this reason, the alleged benefits of the vaccine have had to be continually modified[93] because the vaccine failed to meet each of its previously promised metrics (i.e., it does not prevent transmission of COVID-19)[94].
- The study fails to account for the fact that national death rates consistently increased or stayed the same (but never decrease) following COVID vaccination campaigns:



- The estimate fails to account for studies like the recent one from the Cleveland clinic,[95] which have found that the risk of contracting COVID-19 increases with the number of vaccines received:

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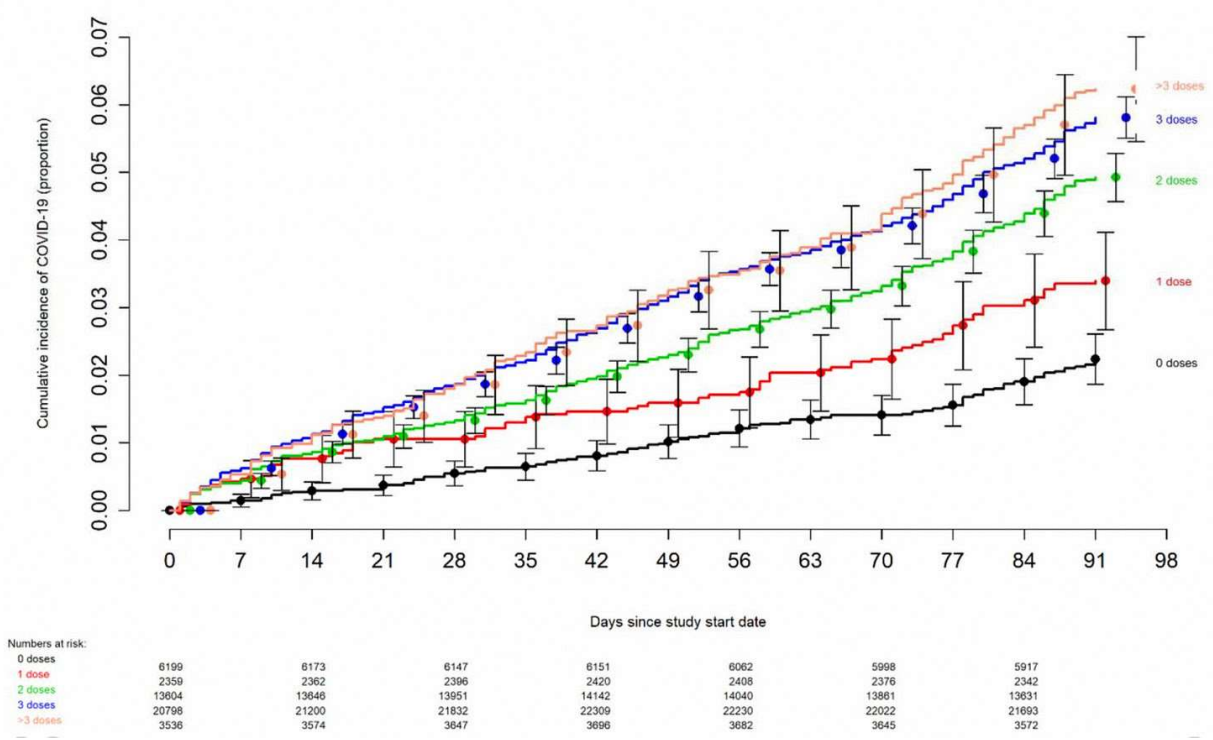
93 https://www.bmj.com/content/371/bmj.m4037

94 https://www.factcheck.org/2022/10/scicheck-its-not-news-nor-scandalous-that-pfizer-trial-didnt-test-transmission/

95 https://www.medrxiv.org/content/10.1101/2022.12.17.22283625v1.full



- The estimate also fails to account for the fact that life insurance data have shown an unprecedented spike in deaths following the mass vaccination campaigns for age groups rarely expected to otherwise die.[96]
- Because any immunity derived from mRNA vaccination is so short-lived, and unlike original expectations continual boosters are required[97], the risks presented by vaccination are increased.

This short discussion does not do this topic justice, the interpretation of vaccine effectiveness data is highly complex and by no means is the full story known. Much of the risk/benefit discussion, for example, conflates relative with absolute risk which skews the apparent benefit at the same time that much of the literature underplay the risks.

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96 https://amidwesterndoctor.substack.com/p/what-can-we-learn-from-cause-unknown

97 *See for e.g.* https://www.kff.org/policy-watch/why-do-vaccinated-people-represent-most-covid-19-deaths-right-now/

C. The Evidence Also Demonstrates that Vaccination is Not Effective in Preventing Severe Disease.

The efficacy of the COVID-19 mRNA vaccine in preventing severe disease is also questionable.[98] CDC data shows that there is no statistically valid evidence that they prevent severe disease or deaths in children. Current mRNA injections were formulated based on the original Wuhan strain and were not tested for benefits against current variants in clinical trials. Which raises the question as to what can be accomplished by vaccinating small children with an outdated vaccine.

In Ireland, in March of 2022, during the milder Omicron variant wave, there were[99] more people in Irish hospitals than at any point in the previous 12 months. This occurred despite the fact that nearly 95% of all adults in Ireland are fully vaccinated, and [100]nearly 100% of seniors are vaccinated and boosted.

In Israel, the Director of a major hospital recently declared that the fully vaccinated[101] are not protected against severe illness.

NSW Health[102] in New South Wales, the most populated of Australian states at 8.1 million inhabitants, reported that 97 out of 98 COVID-19 deaths[103] occurring over the previous two weeks involved fully vaccinated persons. Moreover, those that had three doses appeared most at risk for hospitalization admission, ICU transfer, and death.

These data are consistent with the recent report published in the *New York Times*,[104] which stated, "despite strong levels of vaccination among older people, COVID-19 killed them at vastly higher rates during this winter's Omicron wave than did last year, preying on long delays since their last shots and the variant's ability to skirt immune defenses."

The conclusion of a recent Danish study[105] in the prestigious Lancet a pre-print study found that in long-term follow-up of over 74,000 adult participants in the Moderna and Pfizer trials there was no all-cause mortality benefit from the two mRNA shots.

In a recent, large Veterans Administration study,[106] investigators discovered disturbing evidence: by month six after a SARS-CoV-2 infection, beyond the first 30 days of illness, vaccinated persons with breakthrough infections were at higher risk of death (hazard ratio (HR) = 1.75, 95% confidence interval: 1.59,1.93).

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98 https://pubs.acs.org/doi/10.1021/acsinfecdis.1c00557

99 https://www.irishtimes.com/news/health/COVID-19-cases-surge-63-954-cases-reported-in-last-five-days-1.4832219

100 https://COVID-1919ireland-geohive.hub.arcgis.com/pages/vaccinations

101 https://www.israelnationalnews.com/news/321674

102 https://www.health.nsw.gov.au/

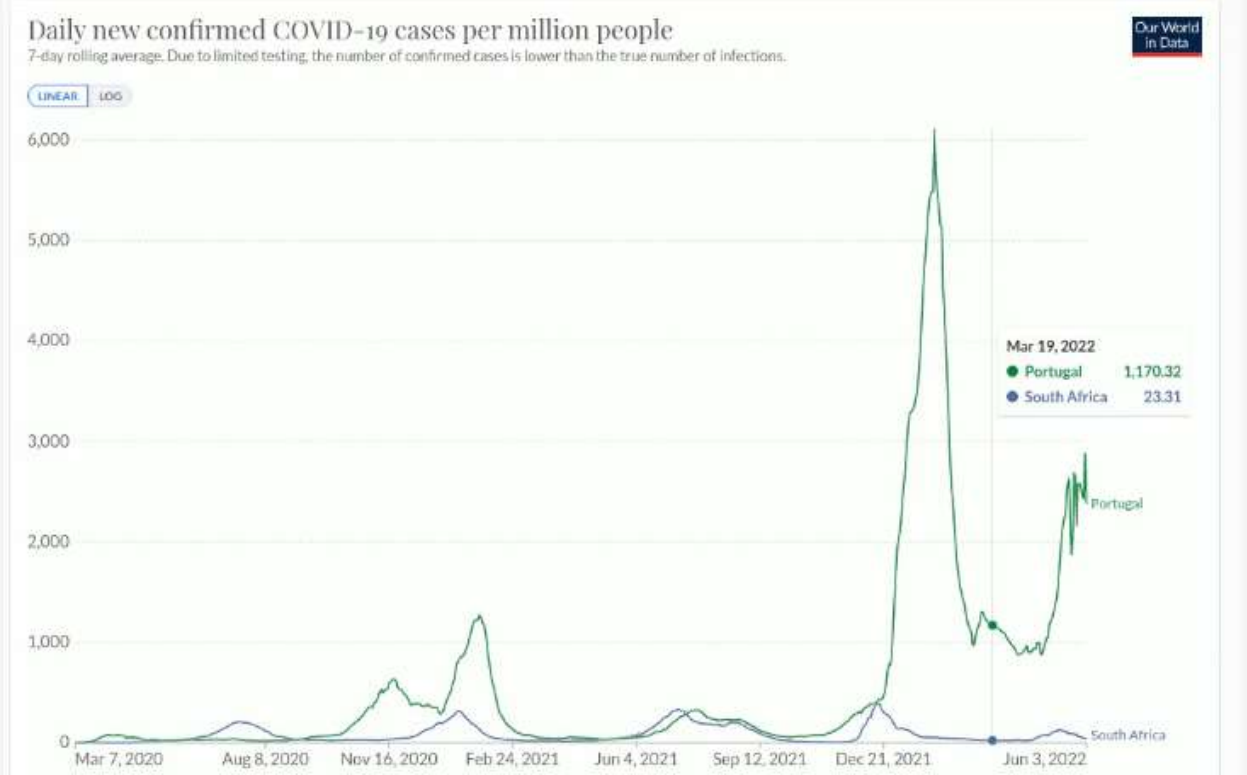
103 https://www.conservativereview.com/horowitz-COVID-19-deaths-vaccinated-australia-2657732814.html

104 https://www.nytimes.com/2022/05/31/health/omicron-deaths-age-65-elderly.html

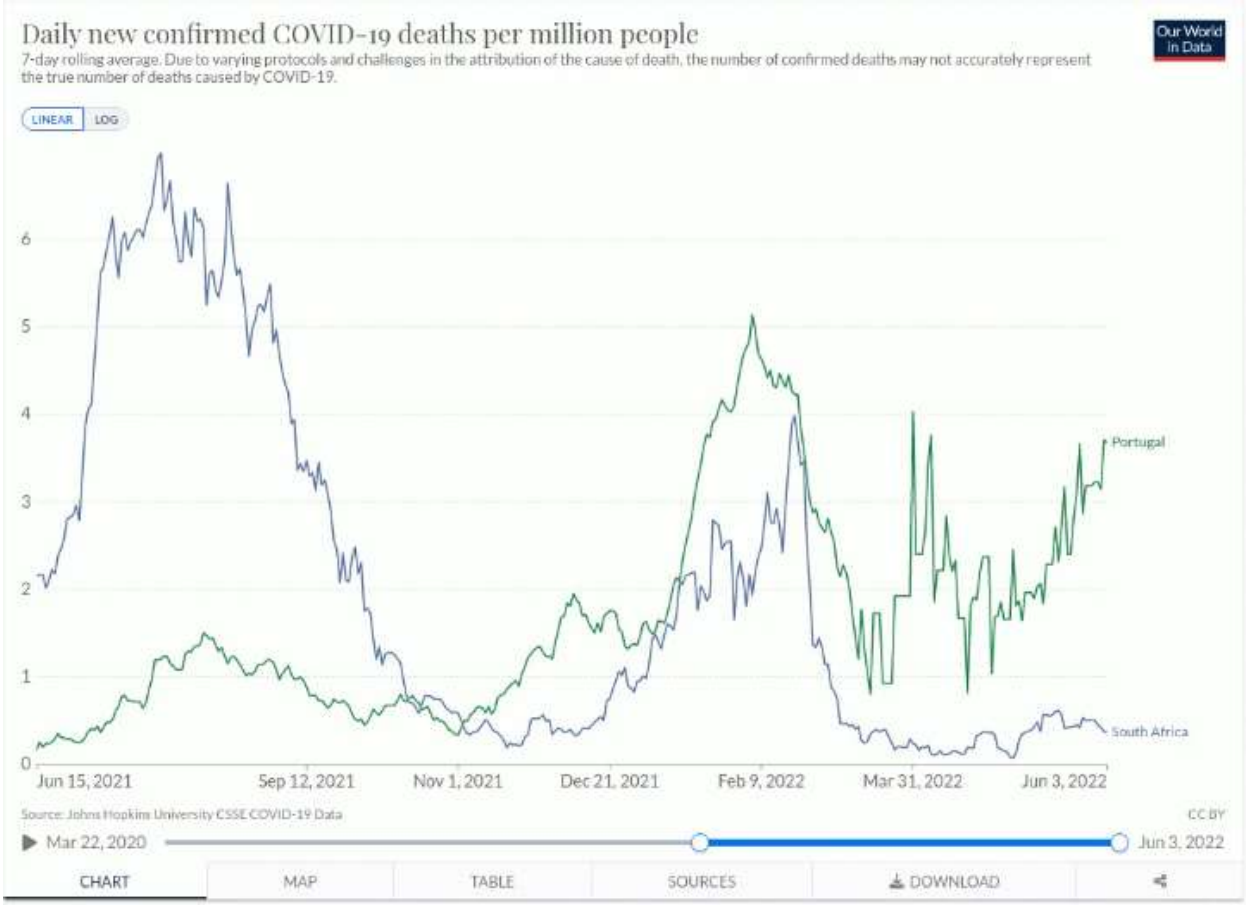
105 https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4072489

106 https://medicine.wustl.edu/news/long-COVID-19-poses-risks-to-vaccinated-people-too/

The implications of the vaccine's diminished ability to protect against severe disease among more recent variants is now playing out in real-time. On June 5th, 2022, analyst Igor Chudov posted a 2 country comparison[107] of the current cases and deaths being reported from Portugal and S. Africa, two countries undergoing similar waves of infection from the emerging B4/5 sister variants. South Africa is only 35% vaccinated and 5% boosted whereas Portugal is 95% vaccinated and 70% boosted. These variants are now driving a deadly wave of COVID-19 in highly vaccinated Portugal, with deaths among the Portuguese nearing their January peak and still rising as seen below.



107 https://igorchudov.substack.com/p/ba5-is-a-variant-for-boosted-people?s=r



Thus, in terms of benefits, based on the most up-to-date data, the current crop of mRNA vaccines against Omicron confer either rapidly waning efficacy or negative efficacy, and not only do they no longer protect against severe disease, but it appears to be raising the risk of severe disease and death.

D. Vaccination Also Does Not Appear to Prevent Long-Haul COVID-19.

Finally, the efficacy of the COVID-19 mRNA vaccine in the prevention of "long-haul" COVID-19 does not appear to be supported. A large Veterans Administration study[108] recently reported disturbing evidence: by month six after a SARS-CoV-2 infection, vaccinated persons with breakthrough infections were at higher risk of long COVID-19 (HR = 1.50, 95% CI: 1.46, 1.54). When including the earlier time periods, the COVID-19 vaccines only reduced the risk of long COVID by approximately 15% compared to the unvaccinated, a level of estimated protection far less than the increased risk of death found in the same study as mentioned above.

108 https://medicine.wustl.edu/news/long-COVID-19-poses-risks-to-vaccinated-people-too/

Again, from the large Veterans Administration study, investigators discovered disturbing evidence: by month six after a SARS-CoV-2 infection, vaccinated persons with breakthrough infections were at higher risk of long COVID-19 (HR = 1.50, 95% CI: 1.46, 1.54). When including the earlier time periods, the COVID-19 vaccines only reduced the risk of long COVID by approximately 15% compared to the unvaccinated, a level of estimated protection far less than the increased risk of death found in the same study as mentioned above.

III. Vaccination Under Duress is Particularly Unsupportable in Patients with a COVID-19 Positive History Given these Risks, as Natural Immunity Appears to Be Superior than mRNA Vaccination.

Natural immunity provides robust protection, not only from contracting the COVID-19 a second time, but also against hospitalization and death. Given the adverse events noted in this Section, this calls the policy of those with a prior COVID-19 history into serious question.

Beginning with the concern for the young, most children are already immune. Natural immunity is superior to vaccine-induced immunity and vaccinating the already immune is superfluous and potentially harmful as per this study.[109] Further, CNBC reported in March 2022, "an estimated 95% of Americans ages 16 and older have developed identifiable COVID-19 antibodies."[110] CDC earlier said over 75% of children already have partial or full immunity to COVID-19.

The most recent review of data supporting the protection of natural immunity, compiled from over 160 research studies, found that natural immunity provided equal or superior protection against not only contracting the disease, but also against hospitalization and death.[111]

Further, vaccinated individuals are far more likely to get re-infected with COVID-19 compared to those with natural immunity. A new preprint[112] study from Bangladesh found that among 404 people re-infected with COVID-19, having been vaccinated made someone 2.45 times more likely to get re-infected with a mild infection, 16.1 times more likely to get a moderate infection, and 3.9 times more likely to be re-infected severely, relative to someone with prior infection who was not vaccinated. Although overall re-infections were rare, vaccination was a greater risk factor of re-infection than co-morbidities.

A new study from Harvard, Continued Effectiveness of COVID-19 Vaccination among Urban Healthcare Workers during Delta Variant Predominance[113] tracked vaccinated and unvaccinated Massachusetts healthcare workers and showed 0 infections in 74,557 person-days

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109 https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e1.htm

110 https://www.cnbc.com/2022/03/29/cdc-majority-of-us-has-COVID-19-antibodies-what-that-means-for-you.html

111 https://brownstone.org/articles/research-studies-affirm-naturally-acquired-immunity/

112 https://www.medrxiv.org/content/10.1101/2021.12.26.21268408v1.full.pdf

113 https://www.medrxiv.org/content/10.1101/2021.11.15.21265753v1.full-text

for previously infected patients compared to 49 infections out of 830,084 person-days for fully vaccinated patients.

A study published in the New England Journal of Medicine[114] assessed a cohort of 1,304 patients meeting a very strict definition of "re-infection." In this cohort, there were no deaths and no ICU admissions during reinfections while 7 deaths and 28 ICU admissions occurred during the primary infections. Overall, there was a statistically significant 90% reduction in the composite outcome of severe, critical, or fatal disease during reinfections.

In summary, if a previously infected person were to contract COVID-19, the illness would be mild with near nil probability of any severe outcome. This would, as is expected from numerous childhood illnesses, provide him or her with robust natural immunity which would far exceed the duration and protection given by the COVID-19 vaccines.

IV. The Inflated Mortality Reporting of COVID-19 Deaths Substantially Overstates the Need for Mandatory Vaccination.

On the other side of the equation, there is considerable evidence that the number of COVID-19 cases have been grossly exaggerated.[115] As a physician who has treated a considerable number of COVID-19 patients, I do not mean to downplay the seriousness of the pandemic, I have seen it firsthand. In order to make sensible vaccine policies, however, it's important to have a proper understanding of risks and benefits. Imposing exposure to the vaccine, and I have also seen many cases of vaccine injury, requires consideration of the extent to which the pandemic numbers have exaggerated the risks.

First, antigen tests have a very high percentage of false positives, according to the FDA, especially when of screening at a low 0.1% active disease prevalence, a level we have been at or near for most of the pandemic.[116] Virologists warned in an August 2020 *New York Times* article that the gold standard for COVID-19 testing, PCR tests, were being run with too many amplification cycles with the potential that 90% of the tests were false positives.[117] In a cross check of COVID-19 diagnosis during vaccine trials, Pfizer noted when using the full genetic sequencing needed to study COVID-19 variants, 91% of the PCR test positives were false positives.[118] Second, the case definition for a positive case has too often been based solely on a

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114 https://www.nejm.org/doi/full/10.1056/NEJMc2108120

115 https://tamhunt.medium.com/how-covid-19-stats-are-grossly-exaggerated-a-brief-summary-of-the-arguments-53a5b4237c4c

116 https://www.fda.gov/medical-devices/letters-health-care-providers/potential-false-positive-results-antigen-tests-rapid-detection-sars-cov-2-letter-clinical-laboratory?utm_medium=email&utm_source=govdelivery

117 https://www.nytimes.com/2020/08/29/health/coronavirus-testing.html?searchResultPosition=10

118 https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02183-8/fulltext

positive lab result,[119] a matter called out in the literature.[120] *See* Cohen, A., Kessel B, Milgroom M. Diagnosing SARS-CoV-2 infection: the danger of over-reliance on positive test results: False positive test results impact clinical and policy decisions. medRxiv preprint (not peer-reviewed) doi: https://doi.org/10.1101/2020.04.26.20080911; this version posted September 28, 2020. Attachment B. ("The high specificities (usually 100%) reported in PCR-based tests for SARS-CoV-2 infection do not represent the real-world use of these tests, where contamination and human error produce significant rates of false positives. Widespread lack of awareness of the real-world false positive rates affects an array of clinical, case management and health policy decisions. Similarly, health authorities' guidance on interpreting test results is often wrong.")

Dying with COVID-19 rather than from COVID-19 remains a concern even though the CDC has stated that "COVID-19 should not be reported on the death certificate if it did not cause or contribute to the death."[121] yet the CDC's definition of a death "involving" Covid-19 is as follows: "Deaths with confirmed or presumed COVID-19, coded to ICD–10 code U07.1."[122] And while that continues, other coding errors have led to an overcount of deaths.[123]

The Massachusetts Department of Public Health (DPH), as a clear example, updated its criteria for identifying COVID-19 deaths in March of 2022. It notes that "[c]urrently, the COVID death definition includes anyone who has COVID listed as a cause of death on their death certificate, and any individual who has had a COVID-19 diagnosis within 60 days but does not have COVID listed as a cause of death on their death certificate. The updated definition reduces this timeframe from 60 days to 30 days for individuals without a COVID diagnosis on their death certificate." Under the DPH definition, in other words, the mere fact of a contemporaneous occurrence of COVID-19, whether 30 or 60 days, is sufficient to list it as cause of death.[124] Dying with, rather than from COVID-19, is still counted as a COVID-19 death.

In Maryland, the Department of Health states that a "confirmed COVID-19 death lists COVID-19 or SARS-COV-2 as a cause of death on the death certificate. A death is classified as probable if the person's death certificate notes COVID-19 to be a probable, suspect or presumed cause or condition. Probable deaths have not yet been confirmed by a laboratory test."[125] The breakdown of death data states that a COVID-19 death includes a confirmed death, laboratory-

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[119] https://tamhunt.medium.com/how-are-covid-19-cases-and-hospitalizations-defined-6775a86d25c2

[120] *See, for e.g.*, https://www.medrxiv.org/content/10.1101/2020.04.26.20080911v4.full.pdf

[121] https://www.cdc.gov/nchs/data/nvss/coronavirus/cause-of-death-data-quality.pdf

[122] https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm (see footnote 1 to Table 1).

[123] https://www.theguardian.com/world/2022/mar/24/cdc-coding-error-overcount-covid-deaths

[124] https://www.mass.gov/news/department-of-public-health-updates-covid-19-death-definition

[125] https://health.maryland.gov/phpa/Documents/faq_covid19_data_dashboard_083120pdf.pdf

confirmed positive COVID-19 test result.[126] It does not specify criteria for determining that the death was caused by COVID-19.

A peer-reviewed study of pediatric (under 22 year olds) COVID-19 hospitalizations at a hospital serving 12 million people in Southern California found that most hospitalized patients who test positive for SARS-CoV-2 are asymptomatic or have a reason for hospitalization other than coronavirus disease 2019.[127] Classification schemes for level of risk developed for mask use, for example, have included wide state-by-state variations in protocols, such as testing asymptomatic patients, drive up reported numbers.[128] Coroners have raised concerns, one citing that two of their five deaths "related to COVID-19" were people who died of gunshot wounds.[129]

A host of exaggerated figures creates a significant risk of overreactions on the part of policymakers, who are left with stilted information upon which to make such critical decisions as whether to impose a mandate. The *Washington Post* editorialized just a few months ago that our counting of patient with COVID-19 as dying from COVID-19 has created false information and can lead to bad policy.[130]

Legal and Policy Context

I. The Exemption System Necessitated by Mandates is Unworkable

The only clear medical exemption, according to the CDC, is for people who can demonstrate a reaction to the ingredients of the vaccine. The only listed contraindications for mRNA vaccination are specifically "a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine or a known diagnosed allergy to a component of the COVID-19 vaccine."[131] Given that one of the only exposures to an injection with any of these ingredients is polyethylene glycol (PEG), an additive in cosmetics, medicines, and food which is rarely identified as the causative compound, there are thus effectively few recognized medical indications for an exemption to the first dose. Further, in regard to receiving Novavax which is a non-mRNA vaccine that contains spike protein, it should be noted the Asthma and Allergy Network site states that: "Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen's

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126 https://coronavirus.maryland.gov

127 https://pubmed.ncbi.nlm.nih.gov/34011567/

128 https://thehill.com/opinion/healthcare/3837892-why-misleading-covid-19-hospitalization-data-shouldnt-influence-local-policy-decisions/

129 https://www.cbsnews.com/colorado/news/grand-county-covid-deaths/

130 https://www.washingtonpost.com/opinions/2023/01/13/covid-pandemic-deaths-hospitalizations-overcounting/

131 https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf; https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

Novavax COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur."[132]

Given the limited ability for people to track such exposures, there is effectively no recognized medical basis for an exemption to the first dose. The CDC's limited recognition of allowed exemptions poses a serious risk to a not insignificant number of recipients. And while vaccine-induced myocarditis is recognized, the CDC still recommends that patients with previous myocarditis that has resolved continue to receive additional doses.[133] The CDC's view imposes a brutal logic when applied to a mandate.

Physicians who are open to wider concerns can identify a number of patients who are likely vulnerable given drug or environmental sensitivities, previous experience with other vaccines, immunological conditions, detoxification system deficits or chronic illness. But intrinsic to the calculus of a mandate, strict limitations on clinical bases for exemptions is necessary.

Medical physicians are under scrutiny and fear discipline if they write exemptions, even for sound reasons such as prior history of myocarditis. A Maryland attorney who works with FLCCC has noted that a number of physicians have contacted him with serious concerns about providing requested exemption letters, even when the physician thinks the need is serious, and many have chosen not to provide exemptions for fear of disciplinary proceedings in the climate created by public health agencies. The Federation of State Medical Boards (FSMB) has called for discipline against physicians who spread vaccine "misinformation,"[134] a call that is understood to discourage exemption letters for any cause other than the CDC's very limited allowance.

The system also compounds class inequities because those with means are less affected by the economic duress imposed by mandates. Those living from paycheck to paycheck or students who often have fewer resources are not in a position to walk away from their work or University and thus are more likely to expose themselves to vaccination even if they are at heightened risk or it proffers little benefit.

II. Active Suppression of Evidence and Divergent Viewpoints Has Created A False Picture of the Need to Mandate Vaccination.

Assessing the mainstream view that mRNA vaccination has a record of safety and effectiveness sufficient to justify mandates requires understanding the validity of the underlying

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[132] https://allergyasthmanetwork.org/news/statement-on-covid-vaccine/#:~:text=%23Polyethylene%20glycol%20(PEG)%20is,between%20these%20compounds%20may%20occur.

[133] https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#myocarditis-pericarditis

[134] https://www.fsmb.org/advocacy/news-releases/fsmb-spreading-covid-19-vaccine-misinformation-may-put-medical-license-at-risk/

data and how the discussion itself has been skewed. Efforts to actively quash adverse information, labeled "misinformation" in the Orwellian fight this has become, is being increasingly recognized. Some peer-reviewed publications are beginning to print articles addressing this issue:

> The COVID-19 pandemic is one of the most manipulated infectious disease events in history, characterized by official lies in an unending stream lead by government bureaucracies, medical associations, medical boards, the media, and international agencies.
>
> For the first time in American history a president, governors, mayors, hospital administrators and federal bureaucrats are determining medical treatments based not on accurate scientifically based or even experience based information, but rather to force the acceptance [of] ... a series of essentially untested messenger RNA vaccines. For the first time in history of medical treatment, protocols are not being formulated based on the experience of the physicians treating the largest number of patients successfully, but rather individuals and bureaucracies that have never treated a single patient—including Anthony Fauci, Bill Gates, EcoHealth Alliance, the CDC, WHO, state public health officers and hospital administrators.
>
> The media (TV, newspapers, magazines, etc), medical societies, state medical boards and the owners of social media have appointed themselves to be the sole source of information concerning this so-called "pandemic". Websites have been removed, highly credentialed and experienced clinical doctors and scientific experts in the field of infectious diseases have been demonized, careers have been destroyed and all dissenting information has been labeled "misinformation" and "dangerous lies", even when sourced from top experts in the fields of virology, infectious diseases, pulmonary critical care, and epidemiology. These blackouts of truth occur even when this information is backed by extensive scientific citations from some of the most qualified medical specialists in the world. Incredibly, even individuals, such as Dr. Michael Yeadon, a retired ex-Chief Scientist, and vice-president for the science division of Pfizer Pharmaceutical company in the UK, who charged the company with making an extremely dangerous vaccine, is ignored and demonized. Further, he, along with other highly qualified scientists have stated that no one should take this vaccine.[135]

Florida Surgeon General Joseph Ladapo echoes this, saying there has been a "propaganda campaign where bad news about [the COVID injections'] safety has been suppressed." Ladapo

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[135] Blaylock RL. COVID UPDATE: What is the truth? Surg Neurol Int. 2022 Apr 22;13:167. doi: 10.25259/SNI_150_2022. PMID: 35509555; PMCID: PMC9062939. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9062939/ Attachment X.

also says regulatory organizations "are not being honest" and that sub-clinical myocarditis from the COVID "vaccines" is likely a much larger problem than has been acknowledged. https://sensereceptornews.com/?p=13841

These efforts have been global, as has the intent; the opposition to any indication of harm has even prevented the public from dealing with their own experience, as can be seen in a comment by BBC that it triggered the removal of a Facebook vaccine injury support group with over 250,000 members. Once the BBC alerted Facebook's parent company, Meta, the groups were removed:

> We have removed this group for violating our harmful misinformation policies and will review any other similar content in line with this policy. We continue to work closely with public health experts and the U.K. Government to further tackle Covid vaccine misinformation," the firm said in a statement.[136]

This is part of a wide-spread and global pattern. Australia's drug regulator admitted that it hid vaccine deaths from the public, concerned that "disclosure could undermine public confidence,"[137] pinpointing the motives that have prevented an honest appraisal. The hidden deaths include two children, seven and nine years old, who both suffered fatal cardiac arrests which the Therapeutic Goods Administration (TGA) assessed as causally linked to Covid vaccination.

Things are certainly no different in the U.S. Efforts to raise concerns have also been squelched by the Biden Administration, which invested extraordinary funding in an effort to create acceptance of the COVID-19 vaccine. Judicial Watch received 249 pages of records from the Department of Health and Human Services (HHS) detailing extensive media plans to push the COVID-19 vaccine. The records were received in response to an August 2021 Freedom of Information Act (FOIA). As has been the consistent experience on COVID-19 information, Judicial Watch of course had to file a lawsuit after HHS failed to respond to an April 19, 2021 request for records related to the Biden HHS COVID-19 Community Corp Program (Judicial Watch v. U.S. Department of Health and Human Services (No. 1:22-cv-02315)).[138]

The White House invested $13 billion in this campaign, including monies to the American Medical Association, American Public Health Association, Infectious Disease Society and other professional organizations[139] who then attacked physicians raising any contrary information. This is not merely the appearance of a conflict but actually compromised the ability of these organizations to act independently and explore means to help the vaccine injured. The program included vaccine engagement packages to all entertainment talent and management

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136 https://dailysceptic.org/2022/09/16/bbc-boasts-it-got-vaccine-injured-support-group-with-250000-members-removed-from-facebook/

137 https://dailysceptic.org/2023/02/15/australias-drug-regulator-hid-child-vaccine-deaths-to-maintain-public-confidence/

138 https://www.judicialwatch.org/covid-19-vaccine-campaign/

139 https://www.pcpcc.org/fr/node/209742

agencies, media companies and show producers, outreach to major culture event producers, a late night hosts vaccination video, extensive digital media using celebrities and influencers, physicians, YouTube special productions and other major social and other media, and not only included pro-vaccine messages but intentionally chided and denigrated the "unvaccinated" as anti-science, to focus on one of the milder epithets.

As a result, anyone raising concerns that are well-founded, pays a high social cost and censure, as well as suppression by the censor, in attempting to raise these concerns. One of the unfortunate side effects has been the politicization of vaccination, so that it has been governed by what political tribe one is in rather than a full view of the science.

III. The Profound Violation of Informed Consent Imposed by a Mandate Under These Circumstances is Unconscionable.

The suppression of minority scientific viewpoint has been necessary to maintain a mandate, which overides both information and consent. Even if only a portion of the scientific record laid out in this testimony is valid, it undercuts the assumptions that the State has a valid interest in being so intrusive. Or that it would want to do so.

One way to frame this issue is to question what the proper labeling of mRNA vaccines would be given even a conservative understanding of risk. The Coalition Advocating for Adequately Labeled Medicines has petitioned the FDA to change the labeling on the mRNA COVID-19 vaccines to lawfully and accurately reflect its risks.[140] The Petition expressly requests that the FDA make specific amendments to the current labeling of Pfizer and Moderna COVID-19 vaccines (for all authorized or approved indications and populations). This petition, signed by physicians, professors of epidemiology and biostatistics, include substantive support for these statements the Petition, includes scientific support for the veracity of the following requested additions to the label:

1. Add language clarifying that phase III trials were not designed to determine and failed to provide substantial evidence of vaccine efficacy against SARS-CoV-2 transmission or death.
2. Add language clarifying that the immunobridging surrogate endpoint used in multiple authorized indications has not been validated to predict clinical efficacy.
3. Add safety and efficacy results data from manufacturer randomized trials of current bivalent boosters that reported results after EUA was granted.
4. Add a clear statement that FDA authorized a new Pfizer vaccine formulation containing Tris buffer without requiring clinical studies to evaluate efficacy, safety or bioequivalence to the formulation containing phosphate buffer.

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140 https://www.regulations.gov/document/FDA-2023-P-0360-0001

5. Add a clear statement disclosing that a Pfizer phase III randomized trial in pregnant women (NCT04754594) was completed as of July 2022 but there have been no results reported.
6. Add a clear statement that Pfizer vaccine efficacy wanes after 2 months following dose 2 according to the Pfizer phase III randomized trial.
7. The following adverse event types should be added to the Adverse Reactions section of labeling:
    a. multisystem inflammatory syndrome (MIS) in children;
    b. pulmonary embolism;
    c. sudden cardiac death;
    d. neuropathic and autonomic disorders.
8. The following reproductive health and lactation related adverse event types should be added to the Adverse Reactions section of labeling:
    a. decreased sperm concentration;
    b. heavy menstrual bleeding;
    c. detection of vaccine mRNA in breastmilk.
9. Add frequency data for clinical and subclinical myocarditis.
10. Labeling should present trial results on serious adverse events in tables with statistics, as is done for non-serious adverse events.

These requests raise central questions about the approval process and what is in fact known about the vaccines. Even for those not subject to a mandate, data needed for an informed judgment is not readily available. Mandating that individuals expose themselves to risk of harm when the benefit rapidly wanes over a few months (Item 6), as one example, is not sensible health policy.

The purpose of a label is to provide information needed for the prescribing physician to make an informed medical judgment, and to explain risks and benefits to enable their patient to make an informed treatment choice. The issues raised in the Petition make it clear not only that critical information is not being provided but that the information gap is substantial and does not support an imposition with this magnitude of uncertainty and risk.

CONCLUSION

Of course, in this case, there is not even a physician. The "physician" is the State of Maryland. By allowing a mandate to stand, the State is imposing direct medical choices on individuals with potentially dire consequences. There may be public health situations in which a truly safe and effective vaccine is needed to build herd immunity that could justify a properly constructed mandate. I can find no data to suggest that is the case in the COVID-19 pandemic and the mRNA vaccines.

Attachments:
Attachment 1: Curriculum Vitae of Pierre Kory, MD, MPA
Attachment 2: Cohen, A., Kessel B, Milgroom M. Diagnosing SARS-CoV-2 infection: the danger of over-reliance on positive test results: False positive test results impact clinical and policy decisions. medRxiv preprint (not peer-reviewed) doi: https://doi.org/10.1101/2020.04.26.20080911

Exhibit A

Dr. Pierre Kory

M.P.A., M.D.

Founding member of the FLCCC Alliance and co-author of the MATH+ and I-MASK+ Prophylaxis and Treatment Protocols for COVID-19

Contributions to the Field of Medicine

Pierre Kory is the former Chief of the Critical Care Service and Medical Director of the Trauma and Life Support Center at the University of Wisconsin. He is considered one of the world pioneers in the use of ultrasound by physicians in the diagnosis and treatment of critically ill patients. He helped develop and run the first national courses in Critical Care Ultrasonography in the U.S., and served as a Director of these courses with the American College of Chest Physicians for several years. He is also the senior editor of the most popular textbook in the field titled "Point of Care Ultrasound," a book that is now in its 2nd edition and that has been translated into 7 languages worldwide. He has led over 100 courses nationally and internationally teaching physicians this now-standard skill in his specialty.

Dr. Kory was also one of the pioneers in the United States in the research, development, and teaching of performing therapeutic hypothermia to treat post-cardiac arrest patients. In 2005, his hospital was the first in New York City to begin regularly treating patients with therapeutic hypothermia. He then served as an expert panel member for New York City's Project Hypothermia, a collaborative project between the Fire Department of New York and Emergency Medical Services that created cooling protocols within a network of 44 regional hospitals along with a triage and transport system that directed patients to centers of excellence in hypothermia treatment, of which his hospital was one of the first.

Known as a Master Educator, Dr. Kory has won numerous departmental and divisional teaching awards in every hospital he has worked and has delivered hundreds of courses and invited lectures throughout his career.

In collaboration with Dr. Paul Marik, Dr. Kory pioneered the research and treatment of septic shock patients with high doses of intravenous ascorbic acid. His work was the first to identify the critical relationship between the time of initiation of therapy and survival in septic shock patients, an aspect of the therapy that led to understanding all the failed randomized controlled trials that employed delayed therapy.

Dr. Kory has led ICU's in multiple COVID-19 hotspots throughout the pandemic, having led his old ICU in New York City during their initial surge in May for 5 straight weeks, he then travelled to other COVID-19 hotspots to run COVID ICU's in Greenville, South Carolina and Milwaukee, WI during their surges. He has co-authored 5 influential papers on COVID-19 with the most impactful being a paper that was the first to support the diagnosis of early COVID-19 respiratory disease as an organizing pneumonia, thus explaining the critical response of the disease to corticosteroids.

Education

1988–1994	B.A. **University of Colorado,** Boulder, Colorado Major Mathematics
1994–1996	M.P.A. **New York University,** New York, NY Health Policy and Administration
1998–2002	M.D. **St. George's University** Grenada, West Indies
2002–2005	Residency Internal Medicine**, Columbia College of Physicians and Surgeons**, New York, NY, St. Luke's–Roosevelt Hospital, New York
2005–2008	Fellowship Pulmonary Disease and Critical Care **Medicine Albert Einstein College of Medicine**, Beth Israel Medical Center, New York

Certification and Licensure

2015	Wisconsin Medical License (exp. 10/31/2021)
2015	Illinois Medical License (exp. 11/19/2021)
2005, 2015	Internal Medicine
2008, 2019	Pulmonary Diseases
2008, 2018	Critical Care Medicine
2008	National Board Exam in Echocardiography - Pass
2009	Healthcare Simulation Training - Instructor Certification

Present Appointment/Position

December 2020 President, **Front Line Covid-19 Critical Care Alliance**

Past Appointments/Positions

1995–1997	Project Coordinator - Study of Incentives to Improve Medicaid Immunization Coverage Rates, **NYC Dept. of Health and Centers for Disease Control**
1997–1998	Project Director - Study of Incentives to Improve Medicaid Immunization Coverage Rates, **NYC Dept. of Health and Centers for Disease Control**
2008–2015	Attending Physician - MICU, Pulmonary Consultation Service, Faculty Practice **Beth Israel Medical Center**, NY, NY
2008–2012	Assistant Professor of Clinical Medicine **Albert Einstein College of Medicine**, New York, NY
2008–2015	Director of Simulation Training–Department of Medicine **Beth Israel Medical Center**, New York
2012–2015	Program Director - Pulmonary Disease and Critical Care Medicine Fellowship - **Mount Sinai Beth Israel**, New York
2013–2015	Associate Professor of Clinical Medicine **Icahn School of Medicine** at Mount Sinai, New York, NY
2016–2020	Associate Professor of Medicine, Clinical Health Scientist **Track University of Wisconsin School of Medicine and Public Health**

2015–2020	Critical Care Service Chief, Medical Director, Trauma and **Life Support Center University of Wisconsin** Hospital and Clinics, Madison, WI
May 2020	COVID-19 Emergency Critical Care Attending **Mount Sinai Beth Israel Medical Center**, New York, NY
8/20–10/20	Weatherby Health Care, Locums Critical Care Specialist **Greenville Memorial Hospital**, Greenville, SC
10/20–12/20	**Aurora St. Luke's Medical Center**, Milwaukee, WI Intensivist, Advocate Critical Care Service

Professional Society Memberships

2006–2012	American College of Chest Physicians
2008–2010	Medical Society of the State of New York
2008–2011	Society of Critical Care Medicine
2010–present	American Thoracic Society

Honors and Awards

1999–2002	Iota Epsilon Alpha International Medical Honor Society
2003	Best Internal Medicine Resident in Primary Care Award, PGY1
2004	Best Internal Medicine Resident Award, PGY2
2007	"Feature Article" in November 2007 issue of *Chest*
2008	Teaching Faculty of the Year, Dept. Of Medicine, Beth Israel Med. Ctr
2008	Health Care Association of New York Quality Institute "Profiles in QI"
2008	Modern Healthcare - 16th Annual Spirit of Excellence Award Nominee
2009	Young Investigator Award Semifinalist-DVT Study - *Chest* 2009
2009	Young Investigator Award Semifinalist-Hypothermia - *Chest* 2009
2010	1st Prize - Beth Israel Medical Center Research Fair
2013	Super Doctors - "Rising Stars" of New York City
2013	Anesthesia and Analgesia Article Featured in *Journal Watch, MDLinx*
2013	1st Prize - Beth Israel Research Fair-RCT of Videolaryngoscopy
2013	Honorable Mention BI Research Fair 2013-IVC Analysis Study
2013	Young Investigator Award Semi-Finalist - *Chest* Annual Meeting 2013
2013	Critical Care Smart Brief, Nov. 2013 - Videolaryngoscopy Abstract
2013	Medscape Medical News Feature, Nov. 2013 - Videolaryngoscopy
2015	University of Wisconsin Hospital and Clinic's Trauma and Life Support Center Team Member of the Month, June 2015
2015	President's Choice Award, British Medical Association Book Awards
2015	Highly Commended in Internal Medicine, British Medical Association Book Awards
2016	Madison Magazine Dane County "Top Docs"- Critical Care
2016	James B. Skatrud Teaching Award - UW PCCM Fellowship
2016	Outstanding Off–Service Faculty Teaching Award -UW Dept. Emergency Medicine
2017	Madison Magazine Dane County "Top Docs"- Critical Care
2018	Faculty Excellence in Teaching Award, UW Department of Medicine

2018	Madison Magazine Dane County "Top Docs"- Critical Care
2019	Department of Medicine - Tribute from a Patient
2019	Gold Medal Award - Highest Abstract Score - 2019 Annual Meeting
2019	UW Health Physician Excellence Award Nominee
2020	Founding Member, Front-Line Critical Care Working Group, www.flccc.net

Grant Support

2018	University of Wisconsin Internal Medicine Residency Committee Education Committee Grant - $20,000
2012	Principal Investigator - Impact of housestaff performed lung ultrasonography using a hand-carried ultrasound device General Electric - $80,000 in equipment support

Publications

KEY: a) Concept Development and Design
b) Mentoring
c) Data Acquisition
d) Analysis
e) Writing

***indicates five most noteworthy publications**

Refereed Articles

1. **Kory P**, Meduri GU, Iglesias J, Varon J, Marik PE. Clinical and Scientific Rationale for the MATH+ Hospital Treatment Protocol for COVID-19. J Int Care Med, in production, 2020
2. Sadd C, Rowe T, Nazeef M**, Kory P**, Sultan S, Faust H. Thromboelastography to detect Hypercoagulability and Reduced Fibrinolysis in COVID-19 ARDS Patients. Crit Care Explorations 2020;2:e0192. DOI: 10.1097/CCE.0000000000000192
3. Wiseman D, **Kory P**, Mazzucco D, Ramesh MS, Zervos M. Treatment and prevention of early disease before and after exposure to COVID-19 using hydroxychloroquine: A protocol for exploratory re-analysis of age and time-nuanced effects: Update based on initial dataset review. medRxiv, 2020. **doi:** https://doi.org/10.1101/2020.08.19.20178376
4. Griffin DO, Brennan-Rieder D, Ngo B, **Kory P** et al. The importance of Understanding the Stages of COVID-19 in Treatment and Trials. *Under Peer Review*, Annals Int Med. 2020
5. Marik PE, **Kory P,** Varon J. Treatment of COVID-19 is critically phase specific. Crit Care Shock (2020) 23:10-12
6. **Kory P**, Kanne J. Sars-CoV-2 Organizing Pneumonia: "Has there been a widespread Failure to diagnose this prevalent condition in COVId-19". BMJ Open Resp Rsrch. 2020:Sept;

7. Marik PE, **Kory P**, Varon J, Iglesias J, Meduri GU. MATH+ protocol for the treatment of SARS-CoV-2 infection: the scientific rationale. Published online ahead of print. Expert Review of Anti-Infective Therapy - 18 Aug 2020.
8. Marik PE, **Kory P**, Varon J. Does Vitamin D status impact mortality from SARS-CoV2 infection? Medicine in Drug Discovery, 2020 dx.doi.org/10.1016/j.medidd.2020.100041
9. Long M, **Kory P**, Marik PE. Vitamin C, Hydrocortisone, and Thiamine for Septic Shock. JAMA. 2020 Jun 2; 323(21):2203-2204
10. Marik PE, **Kory P,** Varon J. Does Vitamin D status impact mortality from SARS-COV-2 Infection? Med Drug. Discov. 2020 Apr 29;6:100041 10.1016/j.medidd.2020.100041
11. Frommelt, **Kory**, Long. Letter On Update to the Vitamin C, Thiamine and Steroids in Sepsis (VICTAS) protocol. Trials. March 2020
12. Kruser J, Schmidt G, **Kory P**. REBUTTAL: Should the use of diagnostic point of care ultrasound in patient care require hospital privileging/credentialing? NO" Chest 2019 – in press
13. Kruser J, Schmidt G, **Kory P.** COUNTERPOINT: Should the use of diagnostic point of care ultrasound in patient care require hospital privileging/credentialing? NO" Chest 2019 – in press
14. Long MT, Frommelt M, Ries M, Osman F, **Kory PD**. Efficacy of intravenous hydrocortisone, ascorbic acid and thiamine in septic shock: a retrospective cohort analysis. Critical Care and Shock, 2020 February
15. Long MT, **Kory PD**, Steuerwald MT, Joffe AM, Galgon RE. VL and DL Equal for Air Medical Intubation? The Operator Matters. Crit Care Med. 2020 Mar;48(3):e254-e255
16. Bondarsky E, Rothman A, Ramesh N, **Kory P**, Lee YI. "Influence of Head-of-Bed Elevation on the Measurement of Inferior Vena Cava Diameter and Collapsibility" J Clinic Ultrasound, 2020 Feb 4. Epub ahead of print
17. Islam M, Nesheim D, Ascquah SO, **Kory P**, Kouroni I, Ramesh N, Erhlich, Bajpayee G, Steiger D, Filopei J. Author's Response to "Factors Related with Outcomes in Patients with Intracardiac Thrombus". J Intensive Care Med, 2019
18. Restrepo M, Banach G, Boivin M, **Kory P**, Sarkar P, Banauch GI, Halpern S, Mayo PH. Effectiveness of a Transesophageal Echocardiography Course. JICM, 2019 Epub ahead of print
    a) 25% b) 0% c) 25% d) 25% e) 25
19. Islam M, Nesheim D, Ascquah SO, **Kory P**, Kouroni I, Ramesh N, Erhlich, Bajpayee G, Steiger D, Filopei J. Right Hearth Thrombi: Patient Outcomes by Treatment Modality and Predictors of Mortality: A pooled Analysis. J Intensive Care Med. 2019 Nov-Dec;34(11-12):930-937
20. Wang AW, Appel HJ, Bennest SC, Forsyth LH, Glasser SK, Jarka MA, **Kory PD**, Malik AN, Martonffy AI, Wahlin LK, Willaims TT, Woodin NA, LienC Miller IKT, Miller LG. Trial By Fire: Barriers To Timely Care Of PANS/PANDAS In Children of Healthcare Providers. JAACP, Under Review.
21. Millington S, Arntfield R, Jie Guo R, Koenig S, **Kory P**, Noble V, Mallemat H, Schoenherr R. Expert Agreement in the Interpretation of Lung Ultrasound Studies Performed on Mechanically Ventilated Patients. J Ultrasound Med. 2018
22. Millington S, Arntfield R, Jie Guo R, Koenig S, **Kory P**, Mayo P, Schoenherr JR. The Assessment of Competency in Thoracic Sonography (ACTS) Scale: Validation of a Tool for Point-of-care Ultrasound, Critical Ultrasound Journal 2017 Nov 22;9(1):25
23. Millington SJ, Hewak M, Arntfield RT, Beaulieu Y, Hibbert B, Koneig S, **Kory P**, Mayo P, Schoenherr JR. Outcomes from extensive training in critical care echocardiography: Identifying the optimal number of practice studies required to achieve competency. J Crit Care. 2017 Mar;40:99-102

24. Mayo PH, Arntfield R, Balik M, **Kory P** et al. The ICM Research Agenda on Critical Care Ultrasonography. Intensive Care Med, 2017 Mar 7
25. **Kory P.** Counterpoint: Should acute fluid resuscitation be guided primarily by inferior vena cava ultrasound for patients in shock? No, CHEST (2016), doi: 10.1016/j.chest.2016.11.017. Concept/Design- 100, Mentoring-100, Data-100, Analysis-100, Writing-100)
26. **Kory P**. Rebuttal From Dr Kory, CHEST (2016), doi: 10.1016/j.chest.2016.11.020. (Concept/Design- 100, Mentoring-100, Data-100, Analysis-100, Writing-100)
27. Millington SJ, Arntfield RT, Hewak M, Hamstra SJ, Beaulieu Y, Hibbert B, Koenig S, **Kory P**, Mayo P, Schoenherr JR. The Rapid Assessment of Competency in Echocardiography Scale: Validation of a Tool for Point of Care Ultrasound. J Ultrasound Med. 2016 Jul;35(7):1457-63. (Concept/Design -20, Mentoring-20, Data-60, Analysis-20, Writing-20)
28. Silverberg M, Li N, Acquah SO**, Kory P.** Reply: Comparing Performance of Video and Direct Laryngoscopes for Urgent Endotracheal Intubation. Crit Care Med. 2015 Apr;43(3):636-41 (Concept/Design -80, Mentoring-100, Data-70, Analysis-80, Writing-80)
29. Corrigendum 'Development of a fluid resuscitation protocol using inferior vena cava and lung ultrasound. . Journal of Critical Care. 2016 Jun;33:267
30. Lee, C, **Kory P**, Arntfield R. Development of a Fluid Resuscitation Protocol Using Inferior Vena Cava and Lung Ultrasound. Journal of Critical Care. 2016 Feb;31(1) 96-100 (Concept/Design -40, Mentoring-40, Data-0, Analysis-80, Writing-60)
31. Lee CW, **Kory PD**, Arntfield RT. Corrigendum 'Development of a fluid resuscitation protocol using inferior vena cava and lung ultrasound' Journal of Critical Care 31(2016) 96-100. J Crit Care. 2016 Jun;33:267. (Concept/Design -40, Mentoring-40, Data-0, Analysis-80, Writing-60)
32. Silverberg MJ, **Kory P**. Reply: Airway training for critical care fellows: more than just video laryngoscopy. Ann Am Thorac Soc. 2014 Dec;11(10):1671. (Concept/Design -100, Mentoring-100, Data-0, Analysis-80, Writing-80)
33. *****Silverberg M, Li N, Acquah SO, **Kory P**. Comparison of Video Laryngoscopy Versus Direct Laryngoscopy During Urgent Endotracheal Intubation: A Randomized Controlled Trial. *Crit Care Med*. 2015 Mar;43(3):636-41 (Concept/Design -100, Mentoring-100, Data-30, Analysis-80, Writing-80)
34. Tofts R, **Kory P**, Acquah SO. A 72 year old man presenting with melena and multiple falls becomes acutely decompensated. *Chest.* 2014 Oct 1;146(4):e130-3 (Concept/Design -100, Mentoring-100, Data-30, Analysis-80, Writing-70)
35. Silberberg M, **Kory P**. Use of Videolaryngoscopy in Urgent Endotracheal Intubation; A Survey. *Ann Am Thorac Soc*. 2014 Oct;11(8):1225-9 (Concept/Design-90, Mentoring-100, Data-30, Analysis-80, Writing-80)
36. *****Filopei J, Siedenberg H, Rattner P, Fukaya E, **Kory P**. Impact of Pocket Ultrasound Use by Internal Medicine Housestaff in the Diagnosis of Dyspnea. *J Hosp Med*. 2014 Sep;9(9):594-7 (Concept/Design -90, Mentoring-100, Data-30, Analysis-70, Writing-70)
37. Schmidt GA, **Kory P**. Ultrasound-Guided Central Venous Catheter Insertion: Teaching and Learning. *Intensive Care Med.* 2014 Jan;40(1):111-3 ((Concept/Design-40, Mentoring-0, Data-50, Analysis-50, Writing-40)
38. Silverberg M, **Kory P**. Ultrasound Guided Vascular Access Insertion and Deep Venous Thrombosis Examinations. *Annals ATS.* 2013 Oct;10(5):549-56 (Concept/Design -100, Mentoring-100, Data-60, Analysis-70, Writing-80)

39. **Kory P**, Guevarra, K, Mathew JP, Hegde A, Mayo PH. Impact of Videolaryngoscopy Use During Urgent Endotracheal Intubation in the Critically Ill. *Anesth Analg.* 2013 Jul;117(1):144-9 (Concept/Design -100, Mentoring-100, Data-50, Analysis-80, Writing-90)
40. Glen C, Acquah SO, **Kory P**. Ultrasound Corner -"Beyond Belief" – *Chest.* 2013 Mar;143(3):e1-4 (Concept/Design -90, Mentoring-100, Data-60, Analysis-80, Writing-80)
41. Glen C, Acquah SO, **Kory P**. Ultrasound Corner -"Sliding to Safety." *Chest*. 2013 Feb 1;143(2):e1-3 (Concept/Design -90, Mentoring-80, Data-60, Analysis-80, Writing-80)
42. ***Kory P**, Fukunaga M, Mathew J, Singh B, et al. Outcomes of Mild Therapeutic Hypothermia (MTH) After In-Hospital Cardiac Arrest (IHCA). *Neurocrit Care* 2012; 16(3):406-412 (Concept/Design -100, Mentoring-100, Data-60, Analysis-80, Writing-80)
43. Greenstein Y, Lakticova V, **Kory P**, Mayo PH. Adequacy of Chest Compressions Performed by Medical Housestaff. *Hospital Practice* 2011; 39: 44-49 (Concept/Design -20, Mentoring-20, Data-20, Analysis-20, Writing-10)
44. ***Kory P**, Pellecchia C, Shiloh AL, Mayo PH, Koenig S. Accuracy of Ultrasonography Performed by Critical Care Physicians for the Diagnosis of Deep Venous Thrombosis. *Chest 2011*; 139: 538-42 (Concept/Design -80, Mentoring-50, Data-40, Analysis-70, Writing-70)
45. **Kory P**, Weiner J, Mathew JP, Fukunaga M, Palmero P, Singh B, Haimowitz S, Clark ET, Fischer A, Mayo PH. A Rapid, Safe, and Low Cost Technique for the Induction of Mild Therapeutic Hypothermia in Post-Cardiac Arrest Patients. *Resuscitation* 2011; 82: 15-20 (Concept/Design -100, Mentoring-100, Data-40, Analysis-80, Writing-80)
46. Mayo PH, Hegde A, Eisen LA, **Kory P,** Doelken P. A Program to Improve the Quality of Emergency Endotracheal Intubation. *J Int Care Med* 2011; 26(1):50-6 (Concept/Design -10, Mentoring-0, Data-10, Analysis-10, Writing-10)
47. ***Kory P**, Adachi M, Ribaudo V, Eisen LA, Mayo PH. Initial Airway Management of Senior Residents: Comparison of Simulation Training compared with Traditional Training. *Chest* 2007; 132:1927-1931 (Concept/Design -30, Mentoring-0, Data-50, Analysis-40, Writing-70)
48. Fairbrother G, Siegel M, **Kory P**, Hanson K, Butts GC**.** Impact of Financial Incentives on documented immunization rates in the inner city: results of a randomized controlled trial. *J Amb Pediatrics 2001;* 1:206-212 (Concept/Design -20, Mentoring-0, Data-60, Analysis-30, Writing-0)
49. Hanson KL, Fairbrother G, **Kory P**, Butts GC, Friedman S. The transition from Mdicaid fee-for-service to managed care among private practitioners in New York City: effect on immunization and screening rates. *Maternal and Child Health Journal* 1998; 2(1):5-14 (Concept/Design -20, Mentoring-0, Data-60, Analysis-30, Writing-0)
50. Foley M, **Kory P**, Fairbrother G**.** Evaluation of Hope for a Million Kids Immunization Event in New York City: Process, Outcome, and Costs. *J Pub Health Mgmt Pract* 4(4):97-105, 1998 (Concept/Design -20, Mentoring-0, Data-60, Analysis-30, Writing-0)

Non-Refereed Articles – N/A

USA Today Editorial – "More of Us Need to Wear N95 Masks" – July 5, 2020

Media Interviews/Profiles, Panel Speaker, Medical Podcasts Invitations

ATS Facebook Podcast Interview – ATS Fellow Symposium, 2018

Podcast – Chest Journal Podcast Series, March 13, 2017 - Kyle Hogarth, MD and Greg Schmidt, MD

Social Media Event – ATS Fellow Symposium, 2017

US Senate Homeland Security Committee Expert Testimony, "How Emerging Data Should Drive Policy" – May 7, 2020

US Senate Homeland Security Committee Expert Testimony, "Early At-Home Treatment" – December 8, 2020

David Kolbaba Radio Show – May 2020

The American Spectator, "A Report from the Front" – May 1, 2020

Sean Burke Show – COVID-19 Care, October 9, 2020, July 2020

NYT Magazine August "The Covid Drug Wars that Pitted Doctor vs. Doctor" – August 5, 2020

Lee Cowden Group – Medical Care for COVID-19 , July 2020

Medscape.com: "Doctors Say Their COVID-19 Protocol Saves Lives. Others Want Proof" 7/16/20

John Anderson Radio Show, New Zealand – August 2020

Vicki Mckenna –October 30, 2020 – "Landmark New Discovery2020, May 2020

National Public Radio Rob Ferret "Drive Time" – May 2020

Update Productions Documentary on Innovators in Medicine – Interview October 7, 2002

Jim Bohannon Radio Show

National Fox News Interview, Dec 8th, 2020

Charles Adler Radio Show, Canada

George Russell "Nashua This Morning"– 11-12-20, 10-12-20

Lars Larson Radio Show, 12-11-20

Sam Dube – Toronto Business Morning 12-16-20

Chapters in Books

1. Ramesh N, Mayo PH, **Kory P**. Lung and Pleural Ultrasonography. In Irwin R, Rippe M, Mayo PH (Eds.), *Ultrasound for the Management of the Critically Ill*. Wolters Kluwer Health, Philadelphia PA, 2020 (submitted). (Concept/Design -100, Mentoring-100, Data-50, Analysis-60, Writing-40)
2. Arntfield R, Walsh SD, **Kory P**, Soni, N. Left Ventricular Function. In Soni NJ, Artnfield R, Kory P (Eds.), *Point of Care Ultrasonography 2nd ed.*. Elsevier Saunders, Philadelphia, PA 2019. (Concept/Design -20, Mentoring-10, Data-30, Analysis-30, Writing-20)

3. Ramesh N, **Kory P**. Lung and Pleural Ultrasonography. In Irwin R, Rippe M, Mayo PH (Eds.), *Intensive Care Medicine*, Seventh Edition. Wolters Kluwer Health, Philadelphia PA, 2016 (submitted). (Concept/Design -100, Mentoring-100, Data-50, Analysis-80, Writing-70)
4. **Kory P**. Utility of Ultrasonography in the Diagnosis of DVT and PE. In Irwin R, Rippe M, Mayo PH (Eds.), Intensive Care Medicine, Seventh Edition. Wolters Kluwer Health, Philadelphia PA, 2016 (submitted). (Concept/Design -100, Mentoring-N/A, Data-100, Analysis-100, Writing-1000)
5. Nair G, **Kory P,** Mathew J (2015). Acute Left Ventricular and Valvular Dysfunction. In M. Jankowich, E. Gartman (Eds.), *Ultrasound in the Intensive Care Unit,* Respiratory Medicine, Springer Science + Business Media, New York, NY (Concept/Design -70, Mentoring-70, Data-50, Analysis-50, Writing-40)
6. Soni N, Arntfield R, **Kory P** (2015). The Rise of Point-of-Care Ultrasonography. In Soni NJ, Artnfield R, Kory P (Eds.), *Point of Care Ultrasonography*. Elsevier Saunders, Philadelphia, PA. (Concept/Design -20, Mentoring-10, Data-30, Analysis-30, Writing-20)
7. Lyn-Kew K, **Kory P (**2015). Evolution of Lung Ultrasonography. In Soni NJ, Artnfield R, Kory P (Eds.), *Point of Care Ultrasonography*. Elsevier Saunders, Philadelphia, PA. (Concept/Design -80, Mentoring-100, Data-50, Analysis-70, Writing-50)
8. Fein D, **Kory P** (2015). Image Acquisition – Lung Ultrasonography. In Soni NJ, Arntfield R, Kory P (Eds.), *Point of Care Ultrasonography*. Elsevier Saunders, Philadelphia, PA. (Concept/Design -80, Mentoring-100, Data-50, Analysis-70, Writing-70)
9. Arntfield R, **Kory P,** Soni N (2015). Assessment of Left Ventricular Function. In Soni NJ, Arntfield R, Kory P (Eds.), *Point of Care Ultrasonography*. Elsevier Saunders, Philadelphia, PA. (Concept/Design -20, Mentoring-10, Data-20, Analysis-20, Writing-10)
10. Lee P, **Kory P** (2015). Image Interpretation – Lung Ultrasonography**.** In Soni NJ, Arntfield R, Kory P (Eds.), *Point of Care Ultrasonography*. Elsevier Saunders, Philadelphia, PA. (Concept/Design -80, Mentoring-100, Data-50, Analysis-70, Writing-70)
11. Tofts RP, **Kory P** (2015). Lung Ultrasonography – Pearls and Pitfalls. In Soni NJ, Arntfield R, Kory P (Eds.), *Point of Care Ultrasonography*. Elsevier Saunders, Philadelphia, PA. (Concept/Design -80, Mentoring-100, Data-50, Analysis-70, Writing-70)
12. **Kory P,** Mayo PH**.** Lung Ultrasonography (2014). In Levitov A, Mayo PH, Slonim A (Eds.), *Critical Care Ultrasonography, 2nd Ed,* Mcgraw Hill, New York, NY (Concept/Design -60, Mentoring-N/A, Data-80, Analysis-70, Writing-60)
13. Mathew J**, Kory P** (2012). Assessment of Left Ventricular Function. In Walker D, Clements F, Jones, N. (Eds.), *Clinical Echocardiography for Critical Care Physicians. University Press*, Oxford University Press, Oxford, England (submitted). (Concept/Design -60, Mentoring-70, Data-50, Analysis-50, Writing-50)
14. **Kory P,** Kaplan AE (2009). Venous Ultrasonography. In Feller-Kopman D, Moore C, Carmody K. (Eds.), *Handbook of Critical Care and Emergency Ultrasound*. McGraw Hill, New York, NY (Concept/Design -50, Mentoring-N/A, Data-50, Analysis-60, Writing-50)
15. Kaplan AE, **Kory P** (2009). Use of Ultrasonography for the Diagnosis of Venous Thromboembolic Disease. In Bolliger CT et al (eds.), *Clinical Chest Ultrasound: from the ICU to the Bronchoscopy suite. Progress in Respiratory Research, Volume 37*. Karger, Basel, Switzerland (Concept/Design -50, Mentoring-N/A, Data-50, Analysis-60, Writing-50)
16. **Kory P,** Mayo PH (2009)**.** Transesophageal Echocardiography - Technique, Orientation, and Views. In Levitov A, Mayo PH, Slonim A (Eds.), *Critical Care Ultrasonography,* Mcgraw Hill, New York, NY (Concept/Design -20, Mentoring-N/A, Data-40, Analysis-30, Writing-40)

17. Foley M, **Kory P**, Fairbrother G (1999)**.** "Evaluation of Hope for a Million Kids Immunization Even. In Brownson R et al. (eds.), *New York City: Process, Outcome, and Costs". Community Based Prevention-Programs that Work,* Aspen Publishers, Frederick, MA (Concept/Design -20, Mentoring-0, Data-60, Analysis-10, Writing-0)

Monographs or Books

1. Soni NJ, Arntfield R, **Kory P**. *Point-of-care Ultrasound (Japanese).* 2nd ed. Tokyo: Elsevier Japan. (translation in preparation)

2. Soni NJ, Arntfield R, **Kory P**. *Ecografía a Pie de Cama: Fundamentos de la Ecografía Clínica (Spanish).*2nd ed. Madrid: Elsevier España. (translation in preparation)
3. Soni NJ, Arntfield R, **Kory P**. *Point-of-care Ultrasound (Korean).* 1st ed. Seoul: Koonja Publishing Inc; 2019. (in press)
4. Soni NJ, Arntfield R, **Kory P**. *Point-of-care Ultrasound.* 2nd ed. Philadelphia, PA: Elsevier/Saunders; 2019, ISBN: 978-0-323-54470-2.
5. Soni NJ, Arntfield R, **Kory P**. *Ecografía a Pie de Cama: Fundamentos de la Ecografía Clínica (Spanish).*1st ed. Madrid: Elsevier España; 2016, ISBN: 978-84-9113-030-7. (Responsible for 1/3 of chapters, thus: Concept/Design -30, Mentoring-30, Data-30, Analysis-30, Writing-30)
6. Soni NJ, Arntfield R, **Kory P**. *Point-of-care Ultrasound (Chinese).* 1st ed. Beijing: People's Medical Publishing House; 2015, ISBN: 978-7117212724.
7. Soni NJ, Arntfield R, **Kory P**. *Point-of-care Ultrasound.* 1st ed. Philadelphia, PA: Elsevier/Saunders; 2015, ISBN: 978-1455775699. (Responsible for 1/3 of chapters, thus: Concept/Design -30, Mentoring-30, Data-30, Analysis-30, Writing-30)

Technical reports/Other publications

Abstracts

1. Thurber, MI, Doss G, **Kory P**, Tarula E, Sladky K. Medical management of a presumed tetanus infection and associated medical complications in a northwest bornean orangutan (*pONGO pYGMAEUS pYGMAEUS*) – Under Review
2. Efficacy of the Early Adoption of iHAT Therapy in Septic Shock: A Retrospective Cohort Analysis. December 2019. Critical Care Medicine 48:807
3. DeSanti R, Al-Sabu A, Cowan E, Lasarev M, **Kory P**, Use of Point-of-Care Ultrasound to Diagnose the Etiology of Acute Respiratory Failure in the PICU
4. DeSanti R**, Kory P**, Cowan E, Lasarev M, Al-Sabu A The Interrater Reliability of Pediatric Point-of-Care Lung Ultrasound in the PICU. December 2019. Critical Care Medicine 48:483
5. DeSanti R, Al-Subu AM, Cowan E, Lasarev M, **Kory P**. Use of point-of-care lung ultrasound to diagnose the etiology of acute respiratory failure in a pediatric intensive care unit. Wisconsin PICU Regional Meeting 2019
6. Fish J, Baxa J, Willenborg et al (**Kory P Senior Author**). 5 Year Outcomes After Implementing A Pain, Agitation, and Delirium Guideline in A Mixed ICU. December 2018. Critical Care Medicine 47:18

7. Murray M, Frommelt M, Ries M, Long M, **Kory P**. Outcomes of HAT therapy use in Septic Shock Patients. A Retrospective Cohort Study. Wisconsin ACP 2019 Meeting
8. Jordan CP, Fein D, Acquah SO, **Kory P**. A Prospective Study of Inferior Vena Cava Parameters to Predict Fluid Responsiveness, Chest 2015 Annual Meeting
9. Bergman M, **Kory P** - Steroid Responsive Pneumonia after Breast Radiation - New entity or Old News? American Thoracic Society Meeting 2015
10. Eisen L, Yip E, **Kory P**, Gross B, Pickering B, Herasevich V, Gong M. Informational Needs During Intensive Care Unit Physician Handovers: A Multicenter Survey. American Medical Informatics Association 2014
11. Ban H, **Kory P,** Takeryu T, Silverberg M. The efficacy of anaerobe specific antibiotics in patients with aspiration pneumonia. Infectious Disease Society of America, 2014
12. Kobayashi A, **Kory P**. The importance of pre-embolectomy CT pulmonary angiography in suspected massive pulmonary embolism. Society of General Internal Medicine, 2014
13. Silverberg M, Li N, **Kory P**. Efficacy of Video Laryngoscopy vs. Direct Laryngoscopy during Urgent Endotracheal Intubation Performed By Pulmonary/Critical Care Physicians: a Randomized Controlled Trial. Slide Presentation, Annual Meeting of the ACCP, Chicago, IL, 2013
14. Lee MP, Gupta K, Ahuja J, Love A, **Kory P**. Influence of Head-of-Bed Elevation on the Measurement of IVC Diameter and Collapsibility. Poster Presentation, Annual Meeting of the ACCP. Chicago, IL 2013
15. Lee C, Seidenberg H, Mann S, **Kory P**. Outcomes of Mild Therapeutic Hypothermia after In-Hospital Cardiac Arrest: A Systematic Review of the Literature. Slide Presentation, Annual Meeting of the ACCP, Chicago, IL, 2013
16. Fein D, Lee P, Peng C, **Kory P**. Implementation and Results of a Critical Care Ultrasound Program for Fellows Using Cloud-Based Image Review Software. Slide Presentation, Annual Meeting of the ACCP, Chicago, IL, 2013
17. Acquah SO, **Kory P**, Rizk D, Cuban Cruz, E. Preliminary Data on Reasons for Failure to Recognize Early Warning Signs Prior to Rapid Response Events. Oral Presentation, American Thoracic Society Annual Conference, 2012
18. Oleng NA, Ahuja JS, Sharif MU, Annan EL, **Kory P.** Bilateral Intraparenchymal Fat Nodules with Pneumothoraces: A Novel Complication of Mastopexy. Poster Presentation, American Thoracic Society Annual Conference, 2012
19. Palmero V, Klatchko T, Aslam H, **Kory P,** Acquah S. Diagnostic Accuracy of Cytopathologic Patterns found on EBUS FNA in Patients with Suspected Pulmonary Sarcoidosis. Poster Presentation, Annual Meeting of the ACCP, 2011
20. **Kory P,** Hwang C, Pellechia C, Acquah S. Team Performance Assessment during Rapid Response Events, Oral Presentation, Annual Meeting of the ACCP, 2011
21. Koenig S, Lacticova V, Hegde A, **Kory P**, Narasimhan M, Doelken P, Mayo PH. Safety of urgent endotracheal intubation performed without a paralytic agent. Oral Presentation, Annual Meeting of the ACCP, 2011
22. Ahuja J, Mathew J, Sharif M, Annan E, **Kory P**, Walker P. Pleural Fluid Analysis in a Patient with Pleuro-myopericarditis Secondary to Crohns Disease. Oral Presentation, Annual Meeting of the ACCP, 2011
23. Annan E, Guevarra KP, Mathew J, Ahuja J, Sharif M, Acquah S, **Kory P.** Primary Videolaryngoscopy Improves First Pass Success during Emergency Endotracheal Intubation by First Year Fellows. Oral Presentation, Annual Meeting of the ACCP, 2011

24. NYC Project Hypothermia Working Group. Intra-arrest Induction Of Therapeutic Hypothermia Via Large-volume Ice-cold Saline Infusion Improves Immediate Outcomes For Out-of-hospital Cardiac Arrest. Poster Presentation, Resuscitation Science Symposium 2011
25. NYC Project Hypothermia Working Group. Intra-Arrest Induction of Therapeutic Hypothermia Via Large-Volume, Ice-Cold Saline Infusion Results in Improved Outcomes Among Out-of-hospital Cardiac Arrests of Cardiac Etiology. Poster Presentation, Resuscitation Science Symposium 2011
26. NYC Project Hypothermia Working Group. Incidence And Relevance Of Pulmonary Edema As A Result Of Large-volume, Ice-cold Saline Infusion For The Induction Of Hypothermia During Out-of-hospital Cardiopulmonary Resuscitation. Poster Presentation, Resuscitation Science Symposium 2011
27. NYC Project Hypothermia Working Group. Initiation Of Large-volume, Ice-cold Saline Infusion During Initial Resuscitation Attempts For Out-of-hospital Cardiac Arrest Results In Near-target Temperatures For Therapeutic Hypothermia Upon Emergency Department Arrival. Poster Presentation, Resuscitation Science Symposium 2011
28. Fukunaga M, Singh B, Mosak J, Szainwald L, Mathew J, Pellecia C, Berg D, Katz A, Marks M, Saadia M, Friedmann P, **Kory P.** Outcomes of Mild Therapeutic Hypothermia (MTH) After In-Hospital Cardiac Arrest (IHCA): A Historical Controlled Trial. Oral Presentation, Annual Meeting of the ACCP, 2010
29. Mathew J, Pellecchia C, Guevarra KP, Palmero V, Acquah S, **Kory P.** Safety and Efficacy of a Novel Glidescope-Assisted Percutaneous Dilational Tracheotomy Technique**.** Poster Presentation, Annual Meeting of the ACCP, 2010
30. Guevarra KP, Mathew JP, Sharif M, Palmero V, Mayo PH, Hegde A, Eisen LA, Doelken P, **Kory P.** Safety and Efficacy of Emergency Endotracheal Intubation Using The Glidescope® Video-Laryngoscope, A Historical Controlled Trial. Oral Presentation, Annual Meeting of the ACCP, 2010
31. Szainwald L, Ahuja J, **Kory P**. Mild Therapeutic Hypothermia after In-Hospital Cardiac Arrest – A Nationwide Survey of Current Practice. Oral Presentation, Annual Meeting of the ACCP, 2010
32. Ahuja JS, Fukunaga, M, Pellecchia C, Mathew, J, Weiner J, **Kory P**. Safety of Mild Therapeutic Hypothermia after In-Hospital Cardiac Arrest, A Comparison with Historical Controls. Poster Presentation, Annual Meeting of the ACCP, 2010
33. Fukunaga M, Mosak J, Singh B, Szainwald L, Palmero V, Weiner J, Marks M, Berg D, Saadia M, Katz A, Friedman P, **Kory P**. Predictors of Neurological Outcome in Medical Intensive Care Unit Patients Admitted After In-Hospital Cardiac Arrest. Oral Presentation, Annual Meeting of the ACCP 2010
34. Koenig S, Lakticova V, Hegde A, **Kory P**, Narasimhan M, Doelken P, Mayo PH. The Safety of Emergency Endotracheal Intubation Without the Use of A Paralytic Agent. Oral Presentation, Annual Meeting of the ACCP, 2010
35. Fisher N, Goffman D, Dulu A, Bayya J, Bernstein PS, **Kory P**, Kvetan V, Eisen LA. Maternal Cardiac Arrest Simulation: Critical Care Fellows' Knowledge, Performance and Self-confidence. Poster Presentation, Annual International Meeting on Simulation in Healthcare, 2010
36. Nayya J, Goffman, D, Eisen LA, Fisher N, Bernstein PS, **Kory P**, Dulu A. Resuscitating a Pregnant Patient: Use of Simulation to Compare Performance and Knowledge Among Maternal Fetal Medicine and Critical Care Medicine Fellows. Poster Presentation, Annual International Meeting on Simulation in Healthcare, 2010

37. Pellecchia C, **Kory P**, Koenig S, Shiloh A, Chandra S, Alaverdian A, Dibello C, Mayo PH. et al. Accuracy of Critical Care Physicians in the Ultrasound Diagnosis of Deep Venous Thrombosis in the ICU. Oral Presentation, Annual Meeting of the ACCP, 2009
38. Mathew J, **Kory P**, Fukunaga M, Pellecchia C, Weiner J, Mayo PH. Outcomes of Mild Therapeutic Hypothermia in In-Hospital Cardiac Arrest Patients. Oral Presentation, Annual Meeting of the ACCP, 2009
39. **Kory P**, Pellecchia C, Mathew J, Fukunaga M, Weiner J, Mayo, PH. Safety of Mild Therapeutic Hypothermia after In-Hospital Cardiac Arrest". Poster Presentation, Annual Meeting of the ACCP, 2009
40. Eisen LA, **Kory P**, Malik A, Yunen J, Ardilles E, Kline M, Mayo P. Training and Assessment of Fellows in Critical Care Ultrasonography: A New Paradigm. Poster Presentation, Annual Meeting of the ACCP, 2008.
41. Koenig S, **Kory P**, Lakticova V, Chandra S, et al. Simultaneous training in initial airway management and chest compressions using simulation based technology improves house staff competency over that learned in ACLS. Oral Presentation, Annual Meeting of the ACCP, 2008
42. Greenstein Y, Lakticova V, **Kory P**, Mayo PH. Adequate Chest Compressions: Are Gender and Duration of Compression Important Variables? Poster Presentation, Annual Meeting of the ACCP, 2008.
43. **Kory P**, Mayo PH. "Mild Therapeutic Hypothermia; a Rapid, Inexpensive Technique for the ICU". Oral Presentation, Annual Meeting of the ACCP, 2007.

Invited Research Presentations

Local

Department of Neurology Grand Rounds, Beth Israel Medical Center
"Treatment of Anoxia in the Post-Cardiac Arrest Patient", August 2008

Department of Emergency Medicine Grand Rounds, Beth Israel Medical Center
"Techniques for Induction of Therapeutic Hypothermia", September 2008

Department of Medicine Grand Rounds, Beth Israel Medical Center
"Therapeutic Hypothermia – The BI Experience", December 2009

Division of Cardiology, Beth Israel Medical Center
"Therapeutic Hypothermia in the Post-Arrest Patient" - 2009, 2010, 2011

Department of Family Medicine, Beth Israel Medical Center
"Overview of Pulmonary Function Testing", April 2009
"Obstructive and Restrictive Spirometry", May 2009

Division of Cardiology, Beth Israel Medical Center
Cardiology Nurse Practitioner Service Simulation Training Series,
Basic Airway Management and Code Leadership Skills, April 2011

NYU Downtown Hospital, Dept. of Medicine Noon Conference, August 1, 2011
"Overview of Lung Ultrasonography"

Regional

Fire Department of New York/Greater New York Hospital Association,
"Project Hypothermia", March 2009
Speaker Panel Member "Experience in Development of an Institutional Hypothermia Protocol"

New York City Regional Emergency Ultrasound Symposium, Mount Sinai Roosevelt Hospital, March 18, 2015
"Using Ultrasound for Fluid Responsiveness"

National/International

Cardiothoracic Surgical Critical Care Association Annual Meeting
Washington, DC, May 4-8, 2008
Keynote Speaker - "Applications of Critical Care Ultrasonography"

American Institute of Ultrasound Medicine Annual Meeting,
New York, NY, April 24, 2008
General Session Lecture – "Ultrasonography for the Diagnosis of Dyspnea"

American College of Chest Physicians 73rd Annual International Assembly.
Philadelphia, PA, October 25-October 30, 2008
Highlight Session - "Therapeutic Hypothermia: Review of the Evidence"

American College of Chest Physicians 74th Annual International Assembly.
San Diego, CA, October 31-November 5, 2009
General Session – "Update in Therapeutic Hypothermia"

Patents

2012 U.S. Patent Serial No. 61/181,324 – Touchless Isolation Gown Dispenser. Sole Inventor. Device engineered to allow rapid entry of health care providers into isolation gowns without contamination of exterior surfaces.

Educational Activities & Presentations

Classroom Teaching

1. MEDICAL STUDENTS

University of Wisconsin School of Medicine and Public Health - UWHC
2015 - Respiratory Pathophysiology Small Group Sessions– 2 sessions
2016-- Trauma and Life Support Morning Conference Series – 2 hours/month

2016 – Ultrasound Integration into Physical Diagnosis – the role of Echocardiography
2016 - Respiratory Pathophysiology, Small Group Sessions (ILD)– 2 sessions
2017- Video Lecture Series, New Curriculum, "Respiratory Support Devices"
2017 - Respiratory Pathophysiology, Small Group Sessions (ILD)– 2 sessions
2018 – Acute Care Teacher - Coach – Acute Care Course
2018 - Respiratory Pathophysiology, Small Group Sessions (ILD) – 2 sessions

Albert Einstein College of Medicine - Beth Israel Medical Center
2007-2010 – Summer Research Scholar Program, Simulation Training Center
Taught 10-15hrs/week, accepted 1-4 students/summer
2007-Yonatan Greenstein
2008- Matthew Marks, Dana Berg, Meir Saadia, Annie Katz
2009- Elena Clark, Stephanie Haimowitz, Alyssa Fischer
2010- Dovi Ettinger, Melissa Iamatteo, Abby Ettinger
2008-2015 Dept. of Medicine Noon Conference Series–5 lectures/year, 8-10 students/lecture

2. PHYSICIAN ASSISTANT STUDENTS

University of Wisconsin Physician Assistant Program
2019 – ARDS/Acute Respiratory Failure Lecture

3. RESIDENTS

University of Wisconsin Residency Programs
2015 – November - Internal Medicine Residency Morning Report – Pleural Effusions
2015 – August – Emergency Medicine Residency M & M
2016 –Trauma and Life Support Morning Conference Series – 2 hours/month
2017- Trauma and Life Support Morning Conference Series – 2 hours/month
2018 - Trauma and Life Support Morning Conference Series – 2 hours/month
2019 - Trauma and Life Support Morning Conference Series – 2 hours/month

American Family Children's Hospital
Pediatric Intensive Care Unit Point of Care Ultrasound Program
2015- Present, Director, Lung Ultrasonography Curriculum
2015- Present Co-Director, Faculty Member –Point of Care Ultrasound Curriculum

Albert Einstein College of Medicine - Beth Israel Medical Center
2008-15

• Noon Conference Lectures	5 hr/yr	5 hr/yr
• Journal Club Resident Mentor	3-4 hr/yr	4 hr/yr
• Basic Airway Mgmt. Skills	15hr/wk, 3wk/yr	45 hr/yr
• Chest Compression Skills	5hr/wk, 3wk/yr	15 hr/yr
• Code/RRT Leadership Skills	20 hr/wk, 3wk/yr	60 hr/yr
• Code Team Practice	1 hr/month	12 hr/yr
• Ultrasound Elective	15 hr/wk,4 wk/yr	60 hr/yr
• Simulation Training Elective	10hr/wk, 2wk/yr	20 hr/yr

4. FELLOWS

LOCAL:
University of Wisconsin School of Medicine and Public Health – PCCM Fellowship
2015 - 2019- Advanced Airway Management Simulation Training – Four hours
2015 - 2019- Critical Care Ultrasonography Course– 16 hours
2016-19 – Critical Care Trans-Esophageal Echocardiography Simulation Training
2016-18 – Critical Care Ultrasound Cases and Clip Review Sessions– 4 hours/year
2017-19 – "Ventilator School" – Lecture Series to Cardiology, Pulmonary, Anesthesia, RT

Albert Einstein College of Medicine - Beth Israel Medical Center,
2008-2015

Advanced Airway Management	10 hr/yr	10 hr/year
Ventilator Management	5 hr/yr	5 hr/yr
Morning Case Conference	3/wk, 48 wk/yr	156 hr/yr
Core Conference Lectures	10 lectures/yr	10 hr/yr
Fellows Ultrasound Course	3 days/year	25 hr/yr

REGIONAL:
Annual Midwest Regional Fellows Course in Critical Care Ultrasonography – A collaborative of Midwest PCCM Fellowships
Senior Faculty, Co-Organizer, Main Lecturer
Chicago IL, July 30,31 2015
Chicago, IL July 24,25 2016
Iowa City IA, July 23, 24 2017
Iowa City, IA, July 16,17, 2018

Regional Fellows Classroom Instruction – New York
Greater New York Hospital Association/United Hospital Fund, Senior Faculty, Annual Critical Care Fellows Ultrasound 2 Day Training Course, New York, NY
October 20-26, 2007
September 24-26, 2008
September 30-Oct 2, 2009
July 28-30, 2010
July 18-20, 2011

New York City Fellows Bronchoscopy Course – Beth Israel Medical Center
"Indications/Contraindications to Fiberoptic Bronchoscopy", July 2009

New York City Fellows Course in Advanced Bronchoscopic Techniques, July 26, 2010
Lecturer– "Indications and Contraindications to Bronchoscopy"
Hands-On Training Faculty – "Foreign Body Removal Techniques"

NATIONAL:
American Thoracic Society International Conference - Pulmonary and Critical Care Fellows Symposium 2012-2019 Annual Dinner Highlight Session Speaker
"Overview of Critical Care Ultrasonography"

Co-Director, West Coast Regional Fellows Course in Critical Care Ultrasonography
University of Southern California, November 13,14, 2015
University of California, Los Angeles September 8,9 2016
Cedars-Sinai Medical Center, Los Angeles Sept 9,10 2017
University of Southern California, November 13,14, 2018

University of Southern California, Keck School of Medicine, Division of Pulmonary and Critical Care Grand Rounds, Los Angeles, CA, June 20, 2014
Visiting Professor, Fellows Symposium
"Performing a General Critical Care Ultrasound Exam"

5. FACULTY INSTRUCTION

Course Director, National Jewish Health Center, Denver, CO, November, 2010
Critical Care Division – 2-Day Intensive Course in Critical Care Ultrasonography

Course Director, St. Luke's-Roosevelt Pulmonary and Critical Care Division,
Sept 25-26, 2011 "Ultrasonography for the Critical Care Attending"

Greater New York Hospital Association, November 4, 2011
Clinical Controversies in Critical Care Symposium, Debater, Con Argument –
"Paralytics are the Standard of Care for ARDS"

Course Director, Winthrop University Hospital and St. Luke's-Roosevelt Medical Center
Pulmonary and Critical Care Divisions 2-Day Course in Critical Care Ultrasonography,
January 9-10, 2012 "Intensive Ultrasonography Training for the Critical Care Attending"

Course Director, University of Medicine and Dentistry of New Jersey, Pulmonary and Critical Care Division, Critical Care Ultrasonography Course,
"Intensive Ultrasonography Training for the Critical Care Attending"
Jan 15-17, 2013
April 18-19, 2015
May 29, 30 2016
March 15,16 2017

Department of Obstetrics and Gynecology, Beth Israel Medical Center
"M&M – Afferent/Efferent Limbs of the RRT System", September 2011

Beth Israel Medical Center Board of Overseers Meeting –
"Case Presentation and Overview of Therapeutic Hypothermia Program Data, May 2013

UWSMPH/Hospital Regional CME Courses:

Course Director, Lecturer (10-12 Lectures): "Fundamentals of Point of Care Ultrasonography in Critical Care and Acute Cate Settings" – hosted by the Division of Allergy, Pulmonary, and Critical Care

August 8,9, 2015 - ,– Faculty, Fellows, Residents**,**
January 8,9,2016 – Faculty, Fellows, APP's, Residents
February 10,11, 2017 - Faculty, Fellows, Nurse Practitioners, Residents, Students
May 4,5 2018 - Faculty, Fellows, Nurse Practitioners, Residents, Students
May 3,4, 2019 - Faculty, Fellows, Nurse Practitioners, Residents, Students

Regional Course Faculty - Arndt Airway Course, Department of Anesthesia, UWSMPH
"Ultrasound Use in Anesthetic Emergencies" - Lecture and Hands-on Sessions
October 1,2016
Sept 29, 2017
Sept 28, 2018

Regional Course Faculty – Dept of Nursing Spring 2019
Faculty Lecturer – "updates in Sepsis Management

Same for Fall 2019

OPRo-con debate – asystole/Pea
Pro-con debate – Myoclonus – should we cool?

CME Presentations – Departmental:

University of Wisconsin AFCH - Childrens Hospital of Philadelphia Pediatric Ultrasound Course
Faculty, Hands-On Sessions – September 26, 2018

University of Wisconsin Hospital and Clinics, Division of Hospital Medicine CME Lecture Series
June 6, 2019 -"Metabolic Resuscitation, A Major Therapeutic Advance and the Future of Critical Care"
October 12, 2016 - "CPAP, BPAP, HiFlow – Which One When?"

Department of Medicine Grand Rounds, Beth Israel Medical Center
2009 - "Bornholm's Disease" – Clinicopathologic Conference Clinician,

Departments of Respiratory Therapy and Nursing, Beth Israel Medical Center, NY, NY
July 2010 CME Lecture - -"Airway Pressure Release Ventilation"

Institute of Urban and Family Health Medicine, Grand Rounds, Beth Israel Medical Center
December 2011 - "Overview of the Diagnosis and Management of COPD", December, 2011

Division of Hospitalists, CME Lecture Series, Beth Israel Medical Center, NY, NY
"Simulation Training at Beth Israel – Past, Present, and Future", July 2010
"Applying Medical Ethical Principles to CPR Decisions", April 2012

Invited Extramural Grand Rounds Lectures:

Medical College of Wisconsin, Division of Nephrology Grand Rounds, Visiting Professor Session
December 17, 2019 “Ultrasonography applications in Clinical Nephrology”

University of Louisville, Louisville, KY- Department of Medicine Grand Rounds
April 16, 2019 - “Ultrasound in the Management of Cardiopulmonary Failure”

New York University Winthrop Hospital, Mineola, NY – Pulmonary/Critical Care Grand Rounds
January 7, 2019 - “Metabolic Resuscitation – A Major Therapeutic Advance, Future of Critical Care”

North Shore University Hospital, Manhasset, NY. Pulmonary and Critical Care Grand Rounds
January18, 2019 - “The Importance of Avoiding Hyperoxia in the Critically Ill”

Medical College of Wisconsin, Milwaukee, WI Department of Anesthesia Grand Rounds, Visiting Professor Session
“Ultrasonography in the Management of Cardiopulmonary Failure”

University of Kansas, Kansas City, KS Department of Medicine Grand Rounds Visiting Professor Sessions
April 8, 2018 - “Developing a Point-of-Care Ultrasound Curriculum for Internal Medicine Residents”

University of Southern California, Los Angeles, CA - Hastings Center for Pulmonary Research Grand Rounds
Pulmonary and Critical Care Research Symposium, April, 2018
“Echocardiography in the Differentiation and Management of Shock States”

Lankenau Medical Center, Philadelphia, PA Department of Medicine Grand Rounds, Visiting Professor
March 6, 2018 - “Ultrasound in the Management of Cardiopulmonary Failure”

Mount Sinai Beth Israel Medical Center, NY, NY Department of Medicine Grand Rounds
New York City, NY December 19, 2017
“Lung Ultrasonography to Improve Diagnostic Accuracy”

Cedars-Sinai Medical Center, Los Angeles, CA Department of Medicine Grand Rounds
Los Angeles, CA September 8, 2017
“Echocardiography in the Differentiation and Management of Shock States”

University of California, Los Angeles Department of Medicine Grand Rounds, Sept 8, 2016
“Lung Ultrasound in the Differentiation of Acute Respiratory Failure”

Mt. Sinai West Department of Medicine Grand Rounds, NY, NY January 22, 2016
"Ultrasonography in the Management of Cardiopulmonary Failure"

University of Wisconsin Hospital and Clinics, Division of Allergy, Pulmonary and Critical Care Medicine, Critical Care Grand Rounds, Madison, WI, October 2, 2014
"Improving Diagnostic Accuracy in Acute Respiratory Failure - Role of Lung Ultrasonography"

University of Southern California, Keck School of Medicine, Division of Pulmonary and Critical Care Grand Rounds, Los Angeles, CA, September 9, 2015
Will Rogers Foundation Sponsored Grand Rounds - "Improving Diagnostic Accuracy of Dyspnea"

University of Southern California, Keck School of Medicine, Division of Pulmonary and Critical Care Grand Rounds, Los Angeles, CA, June 20, 2014
Grand Rounds Presentation - "Echocardiography in the Management of Shock States"

Invited Intramural Grand Rounds Lectures – University of Wisconsin:

Department of Hospital Medicine
2019**:** "Metabolic Resuscitation – A Major Therapeutic Advance and the Future of Critical Care"
2018 – Hi-FLOW, CPAP, BPAP –"Which one when and how?"

Division of Hematology and Oncology, Bone Marrow Transplant Service (not a CME though)
"Metabolic Resuscitation – A Major Therapeutic Advance and the Future of Sepsis Therapy"

University of Wisconsin Department of Nursing
February 2019 – Sepsis Grand Rounds - Case Presentations

Department of Anesthesia Grand Rounds
2019, January – "The Harms of Hyperoxia in the ICU: Stop Being an Oxy-Moron"

Division of Allergy, Pulmonary and Critical Care Grand Rounds
2019**:** "Metabolic Resuscitation – A Major Therapeutic Advance and the Future of Critical Care"
2018: The Harms of Hyperoxia in the ICU: Stop Being an Oxy-Moron
2017: Goal-Directed TEE in the ICU – Utility and Applications
2016: Accuracy of Lung Ultrasound in Acute Respiratory Failure

Department of Emergency Medicine
2018 -"Metabolic Resuscitation – A Major Therapeutic Advance and the Future of Critical Care"
2017 "Ultrasound in the Differentiation of Shock States",
2016 - "Ultrasound in the Differentiation of Respiratory Failure States"
2015 – Emergency Department M & M Guest Lecturer/Presenter

Division of Nephrology Grand Rounds
2016- "Fluid Balance Evaluation and Ultrasound Techniques"

Division of Pulmonary and Critical Care Grand Rounds, Beth Israel Medical Center –
2012- "Echocardiography in the Diagnosis and Management of Shock States "-
2013 - "Lung Ultrasonography in the Intensive Care Unit – Case Based Illustration", Sept 19, 2013

Institute of Urban and Family Health Medicine Grand Rounds, Beth Israel Medical Center
2014, June 6 - "Update in the Outpatient Management of COPD"

State & Regional Invited CME Lectures:

Wisconsin
University of Wisconsin Update in Medical-Surgical Nursing Conference, EPIC Campus
April 2019 – "Update in Sepsis Diagnosis and Treatment"

Wisconsin Department of Health COVID-19 Webinar
June 1, 2020 - "Care of the Critically Ill COVID-19 Patient"

Wisconsin Department of Health COVID-19 Webinar
July 30, 2020 - "Update in COVID-19 Care"

New York
9th Annual Mid-Atlantic Hospital Medicine Symposium, "Mastering the Care of the Hospitalized Patient", Icahn School of Medicine at Mount Sinai,
New York, New York, October 24, 2014
Senior Faculty "Skills Symposium – Arterial Blood Gas Analysis"

Mount Sinai Beth Israel Medical Center, Division of Hospitalists
Faculty Development Lectures- July 8, 2020
"The ABC's of ABG's"
"Achieving Oxygenation and Ventilation without Intubation"

National Conference Invited Lectures:

Senior Faculty/Lecturer- American College of Chest Physicians, “Fundamentals of Critical Care Ultrasonography” 3 Day National Training Courses
April 28-30, 2007, Orlando, FL
December 7-9, 2007, Scottsdale, AZ
April 16-18, 2008, St. Louis, MO
April 23-25, 2009, Fort Lauderdale, FL
May 1-3, 2010, Austin, TX
April 15-17, 2011, Baltimore, MD

Senior Faculty, American College of Chest Physicians, “Focused Critical Care Echocardiography”, 2-Day National Training Course, Chicago, IL
September 17-18, 2008
September 19-20, 2009
September 18-19, 2010
September 24-25, 2011

Senior Faculty, American College of Chest Physicians, “Focused Pleural-Vascular Ultrasonography Course”, Chicago, IL
September 19-20, 2008
September 18-19, 2009
September 16-17, 2010
September 22-23, 2011

American College of Chest Physicians Annual International Assembly
Simulation Training Center Faculty – Critical Care Ultrasonography Section
Chicago, IL October 20-October 26, 2007
Philadelphia, PA October 25-October 30, 2008
San Diego, CA October 31-November 5, 2009
Vancouver, Canada October 30-November 5, 2010
Honolulu, HI October 22-October 26, 2011
Atlanta, GA, October 20-25, 2012
Chicago, IL, October 26- 31, 2013

American College of Chest Physicians 75^{tt} Annual International Assembly,
Vancouver, Canada. October 30 - November 5, 2010
Lecturer, Post-Graduate Course in Critical Care Ultrasonography - “DVT”
Lecturer, Symposium on Advanced ICU Echocardiography - “Use of Doppler”
General Session - “Ultrasound for the Pulmonary Consultant”

American College of Chest Physicians 76th Annual International Assembly,
Honolulu, HI, October 30 - November 5, 2011
Lecturer, Panel Session - “Abdominal and Vascular Ultrasonography in the Diagnosis and Management of Cardiorespiratory failure”

American Thoracic Society International Conference 2011, Denver, CO
Pulmonary and Critical Care Fellows Symposium, Highlight Presentation Speaker
"Overview of Critical Care Ultrasonography"

American Thoracic Society International Conference 2012, San Francisco, CA
Program Chair – "Impact of Ultrasonography in Assessing Cardiorespiratory Failure"
Clinicians Center Luncheon Program, "Introduction to Critical Care Ultrasonography"
Pulmonary and Critical Care Fellows Symposium, Highlight Session Speaker
"Overview of Critical Care Ultrasonography"
Faculty Hands-On Training, Post-Graduate Course – "Incorporating Ultrasound and Echocardiography into Intensive Care Unit Practice"
Lecturer, Post-Graduate Course – "Ultrasonography for Deep Venous Thrombosis"

Course Director, American College of Chest Physicians, "Focused Pleural Vascular Ultrasonography", Chicago, IL, May 3-4, 2012

Course Director, American College of Chest Physicians, "Focused Critical Care Echocardiography, Chicago, IL, May 5-6, 2012

Course Director, American College of Chest Physicians, "Focused Pleural Vascular Ultrasonography", Chicago, IL, Sept. 20-21, 2012

Course Director, American College of Chest Physicians, "Focused Critical Care Echocardiography, Chicago, IL, Sept. 22-23, 2012

American Thoracic Society International Conference 2012, San Francisco, CA
Pulmonary and Critical Care Fellows Symposium, Highlight Session Speaker
"Overview of Critical Care Ultrasonography"
Program Chair – "Impact of Ultrasonography in Assessing Cardiorespiratory Failure"
Clinicians Center Luncheon Program, "Introduction to Critical Care Ultrasonography"
Faculty Hands-On Training, Post-Graduate Course – "Incorporating Ultrasound and Echocardiography into Intensive Care Unit Practice"
Lecturer, Post-Graduate Course – "Ultrasonography for Deep Venous Thrombosis"
Center for Career Development Session Senior Faculty Networking –
Career Development Mentor for Junior Attendees

American College of Chest Physicians 77th Annual International Assembly,
Atlanta, GA, October 30 - November 5, 2012
Simulation Enhanced General Sessions – Daily Lecture (3) on
"Ultrasound Assessment of Cardiopulmonary Failure"
Critical Care Ultrasound Certificate Exam – Exam Proctor, Hands-On Training Section
Simulation Center General Sessions – Critical Care Ultrasonography Overview – Hands-On Faculty
Simulation Center General Sessions – Critical Care Ultrasonography Overview – Interpretation Session Moderator

Faculty – Post-Graduate Course in Advanced Critical Care Echocardiography – Lecture on “Principles of Doppler Ultrasonography”

Senior Course Faculty and Institutional Host,
“Advanced Critical Care Echocardiography”, American College of Chest Physicians, Beth Israel Medical Center, NY, NY, May 29-31, 2013

American Thoracic Society International Conference 2013, Philadelphia, PA
Dinner Highlight Session Speaker - Pulmonary and Critical Care Fellows Symposium - “Overview of Critical Care Ultrasonography”
Program Chair – “Ultrasonography in the Assessment of Cardiopulmonary Failure”
Clinicians Center Luncheon Program, “Applications of Critical Care Ultrasonography”
Faculty Hands-On Training, Post-Graduate Course – “Incorporating Ultrasound and Echocardiography into Intensive Care Unit Practice”
Lecturer, Post-Graduate Course – “Ultrasonography for Deep Venous Thrombosis”
Center for Career Development Session Senior Faculty Networking –Career Development Mentor for Junior Attendees

American College of Chest Physicians 78th Annual International Assembly,
Chicago, IL, October 25- October 30, 2013
Faculty – Post-Graduate Course in Advanced Critical Care Echocardiography – Lecture on “Principles of Doppler Ultrasonography”
Simulation Enhanced General Sessions – Daily Lecture (3) on “Ultrasound Assessment of Cardiopulmonary Failure”
Critical Care Ultrasound Certificate Exam – Exam Proctor, Hands-On Training
SectionSimulation Center General Sessions – Critical Care Ultrasonography Overview – Hands-On Faculty
Simulation Center General Sessions – Critical Care Ultrasonography Overview – Interpretation Session Moderator
Speaker Panel Member – “Ultrasonography in the Rapid Assessment of Cardiopulmonary Failure”

National Jewish Critical Care Conference, Course Director - Ultrasonography Track,
Keystone, CO, Feb 5-8, 2014
“Lung Ultrasonography in the Management of Respiratory Failure”
“Critical Care Echocardiography Interpretation Practice Session”
“Ultrasound in the Assessment of Intravascular Volume Status”

Greater New York Hospital Association
“Care of the Critically Ill COVID-19 Patient”
Panel Speaker – April 22, 2020

Virtual 15th Annual Mid-Atlantic Hospital Medicine Symposium
October 16, 2020
“Oxygen Support Devices”

International Conference Invited Lectures:

European Society of Respirologists/Chest World Congress. 2014, Madrid, Spain
Faculty, Thoracic Ultrasonography for the Pulmonary Specialist, March 20-24
Moderator, Poster Session, Critical Care Section, March 22

Western University Critical Care Ultrasonography 2015, London, Ontario, Canada - August 20,21, 2015 - Guest Lecturer, Interpretation Session Faculty

American College of Chest Physicians World Congress, 2016, Shanghai, China, April 14-18 2016 – Senior Faculty and Lecturer for "Ultrasonography in the Intensive Care Unit"

CLINICAL TEACHING
2012-present Daily supervision and teaching of general and advanced cardiology fellows in the adult cardiac catheterization laboratory. (Audience: fellows)

Mentoring:

UWSMPH – Trainee Mentoring, Other Divisions
Pediatric Critical Care Fellow - Ryan DeSanti, PICU Ultrasound Mentor 2017-18
Nephrology Fellow - Sayee Algandaruswamy, Nephrology Ultrasound Mentor, 2017-19
Mark Frommelt
Amy Jaeger

Faculty Promotions Committee Member
Ryan Thompson – Department of Emergency Medicine
Benjamin Seides, MD – Division of Pulmonary and Critical Care
Micah Long, MD – Department of Anesthesiology
Josh Glazer – Department of Emergency Medicine

Albert Einstein College of Medicine
Independent Scholar Mentor: Dovi Ettinger, Hypothermia Therapy, Medical Student, 2011
Independent Scholar Mentor: Yonatan Greenstein, Simulation Training Medical Student, 2010

Other Educational Initiatives:

Critical Care Ultrasound Curriculum – regular over-reading with written feedback of all interpreted ultrasound studies performed by PCCM fellows – approximately 300 studies/year
2012-15 - Beth Israel Medical Center
2015-19- University of Wisconsin Hospital and Clinics, Trauma and Life Support Center
Fellows, Residents, Nurse Practitioner Participation (approx. 50 -100 studies/yr)

PICU POCUS Curriculum

Family Medicine POCUS Mentoring

Internal Medicine Residency Ultrasound Curriculum

Critcaresono.org (Founder, Developer): Medical education website with over 600 visitors/month and over 60,000 clips viewed to date (2009 - 2016)

POCUS Website – UW Division of Nephrology, 2019 – tutorials, cases, interpretation practice clips covering a range of pathologies and applications with a specific emphasis on the differentiation of Shock states

Service Activities

Departmental:

2010–2015	ABIM/ACGME House Staff Committee Member Beth Israel Medical Center
2011–2015	Director Simulation Training, Dept. of Medicine Beth Israel Medical Center
2014–2015	Clinical Competency Committee Member, Internal Medicine Residency - Mount Sinai Beth Israel Medical Center Clinical Competency Committee Member, Internal Medicine Residency - Mount Sinai Beth Israel Medical Center
2014–2015	Clinical Competency Committee Member, Pulmonary and Critical Care Fellowship - Mount Sinai Beth Israel Medical Center
2016–2018	Clinical Competency Committee Member, Pulmonary and Critical Care Fellowship - University of Wisconsin Hospital and Clinics
2016–2018	Program Evaluation Committee, Pulmonary and Critical Care Fellowship - University of Wisconsin Hospital and Clinics

UWSMPH/Hospital:

2005–2015	Ethics Committee Member, Beth Israel Medical Center
2006–2015	Clinician Founder and Director - Beth Israel Hypothermia Protocol
2006–2015	CPR Committee Member - Beth Israel Medical Center
2009–2015	Rapid Response Team Committee Member - Beth Israel Medical Center
2010–2011	Simulation Center Design Committee Member
2011–2015	Simulation Center Governance Committee Member - Beth Israel Medical Center
2011	Founder, Director of Hospital RRT Management Protocol, Beth Israel
2015	Trauma and Life Support Center Quality Improvement, UWHC
2015–present	Respiratory Care Committee, UWHC
2015–present	Critical Care Committee Member, UWHC
2015–present	Critical Care Operations Council, UWHC
2016	Inpatient Operations Council, UWHC

2015–17	C.Diff Control Initiative Committee Member, UWHC
2015	Sepsis Guideline Creation Committee, UWHC
2015	Procalcitonin Guideline Committee, UWHC
2015	Unit Council Member –Trauma and Life Support Center, UWHC
2015	QI Committee Member–Trauma and Life Support Center, UWHC
2016	Ventilator Policy Test of Change Committee Member, UWHC
2016	HAP/VAP Guideline Committee
2016	Albumin Guideline Committee Member, UWHC
2017–2018	Sepsis Surveillance System Initiative Committee, UWHC
2017–2018	Critical Care Services Committee–TAC, Meriter, UWHC
2017–2018	PERT Committee, UWHC
2017–2018	CTICU Critical Care Service Collaboration Committee, UWHC
2017	Post–Cardiac Arrest Care Guideline Committee
2018–2019	TAC ICU Policy Committee
2019	Alcohol Withdrawal Guideline Committee
	University of Wisconsin –Pulmonary Embolism Response Team–Provide consultative care and endovascular therapy for acute pulmonary embolism.
	Sepsis Guideline Committee
	C.Diff prevention committee
	Sepsis Early warning Committee

Community:

2009–2012	Fire Department of New York, *Project Hypothermia* Clinician leadership team - planning, implementation, and data collection

Regional:

2008–2014 Greater New York Hospital Association/United Hospital Fund – Senior Faculty, Fellows Course in Critical Care Ultrasonography

National/International:

2006–2013	American College of Chest Physicians - Senior Faculty and Lecturer, National Courses in Fundamentals of Critical Care Ultrasonography
2008–2013	American College of Chest Physicians Annual Conference - Simulation Training Center Faculty - Critical Care Ultrasonography Section
2009–present	*Journal of Intensive Care Medicine*, Reviewer
2010	American College of Chest Physicians - Co-author, Critical Care Ultrasonography Certificate Exam - Practical and Written Components
2010	*Respiration*, Reviewer
2011–2013	American College of Chest Physicians - Director, National Course in Advanced Critical Care Echocardiography
2011–2013	American College of Chest Physicians - Director, National Course in Advanced Pleural and Vascular Ultrasonography

2011–2014	American College of Chest Physicians - Proctor and Grader, Critical Care Ultrasonography Certificate Exam
2012–present	*American Journal of Critical Care*, Reviewer
2012–present	*Critical Care Medicine*, Reviewer
2012	American College of Chest Physicians-Faculty, Simulation Training in Fundamentals of Trans-Esophageal Echocardiography
2012–present	American College of Chest Physicians - Ultrasound Portfolio Reviewer, Certificate Program in Critical Care Ultrasonography
2012	External Reader, Research Grants - Michael Smith Foundation for Health Research, Toronto, CA
2012,2013	American Thoracic Society - Faculty Member, Lecturer, Postgraduate Course in Critical Care Ultrasonography
2013	*Annals of the American Thoracic Society*, Reviewer
2013	*Chest,* Reviewer
2013	Advanced Critical Care Echocardiography Certification Planning Committee - National Board of Echocardiography and ACCP
2014	*Thrombosis and Thrombolysis*, Reviewer
2015–present	*Annals of Intensive Care Medicine,* Reviewer

Exhibit B

Diagnosing SARS-CoV-2 infection: the danger of over-reliance on positive test results

False positive test results impact clinical and policy decisions.

Andrew N. Cohen, Ph.D.[1]*, Bruce Kessel, M.D.[2], Michael G. Milgroom, Ph.D.[3]

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Abstract: Contrary to the practice during previous epidemics, with COVID-19 health authorities have treated a single positive result from a PCR-based test as confirmation of infection, irrespective of signs, symptoms and exposure. This is based on a widespread belief that positive results in these tests are highly reliable. However, evidence from external quality assessments and real-world data indicate enough a high enough false positive rate to make positive results highly unreliable over a broad range of scenarios. This has clinical and case management implications, and affects an array of epidemiological statistics, including the asymptomatic ratio, prevalence, and hospitalization and death rates, as well as epidemiologic models. Steps should be taken to raise awareness of false positives and reduce their frequency. The most important immediate action is to check positive results with additional tests, at least when prevalence is low.

Key messages

The high specificities (usually 100%) reported in PCR-based tests for SARS-CoV-2 infection do not represent the real-world use of these tests, where contamination and human error produce significant rates of false positives.

Widespread lack of awareness of the real-world false positive rates affects an array of clinical, case management and health policy decisions. Similarly, health authorities' guidance on interpreting test results is often wrong.

Steps should be taken immediately to reduce the frequency and impacts of false positive results, including checking positive results with additional tests at least when prevalence is low.

Most tests for active SARS-CoV-2 infection use the polymerase chain reaction (PCR) to amplify and detect diagnostic sequences within the virus' RNA. According to leading health authorities, while negative results from these tests are frequently wrong, positive results are highly reliable.[1-4] Accordingly, the World Health Organization (WHO) and most government health ministries diagnose SARS-CoV-2 infection on the basis of a single positive PCR result, even in asymptomatic persons without any history of exposure.[5-11] For example, WHO defines a confirmed case as a person with a positive test result, "irrespective of clinical signs and symptoms."[5]

This is a departure from historical practice. In previous epidemics case definitions required individuals to be symptomatic, and health authorities voiced concerns that false positive results from PCR-based tests could harm both the individuals tested and the ability of agencies to monitor outbreaks. National and international health agencies adopted measures to limit the occurrence of false positives, recommending that PCR-based testing be limited to individuals with a high probability of infection (those with symptoms and/or significant exposure), and often requiring confirmation of positive results by a second, independent test (Box 1). These warnings and requirements are absent from the same agencies' current guidance on SARS-CoV-2 testing.

In this Analysis we argue that basing diagnoses on unrestricted PCR-based testing freed from clinical context has created serious problems. PCR-based tests produce a significant number of false positive results, making positive results unreliable over a broad range of real-world scenarios. Consequently, the frequent assertion that positive test results for SARS-CoV-2 are more reliable than negative results[4] is wrong most of the time, and the widespread reliance on a single positive PCR result as a sufficient basis for diagnosis has been a mistake. The general misunderstanding of the rate of false positives in SARS-CoV-2 testing affects clinical and case management decisions, and through flawed interpretations of test statistics, has affected policy decisions. As an immediate, minimum step we recommend checking positive PCR results for asymptomatic individuals with a second independent test; over the longer term, we should work on eliminating the underlying causes of false positives.

False positives

The accuracy of a diagnostic test is measured by sensitivity, which is the proportion of infected individuals that test positive, and specificity, the proportion of uninfected individuals that test negative. Although SARS-CoV-2 PCR assays are widely reported to have 100% specificity[4]—that is, a false positive rate of 0%—this refers only to the tests' lack of reaction with substances other than SARS-CoV-2 RNA (analytical specificity), and not to the potential for incorrect results in real-world testing (clinical specificity) where contamination and human error can generate false positives during sample collection, transport and analysis.[4]

The only published data on the full false positive rate of SARS-CoV-2 tests in real-world settings appear to be from two studies that found rates of 0.3% and 3% in presurgical patients.[24 25] Rates within laboratories can be assessed by challenging participating laboratories with prepared samples that either contain or are free of the virus' RNA. We are aware of seven such assessments, known as external quality assessments or proficiency tests, for SARS-CoV-2. Four studies tested a total of 119 South Korean laboratories, and reported no positive results for 47, 33, 16 and 236 negative samples.[26 27] Another study assessed 52 Austrian laboratories, and reported no positive results for 67 negative samples.[28] The absolute lower detection limit for false positive rates in these studies ranged from 0.4% to 6.3%. A German study of 463 laboratories found an overall false positive rate of 1.9% by gene target, but did not report results

Box 1: Measures minimizing false positive results in PCR-based tests

Then:

SARS-CoV-1

US CDC: "To decrease the possibility of a false-positive result, testing should be limited to patients with a high index of suspicion for having SARS-CoV disease...In addition, any positive specimen should be retested in a reference laboratory to confirm that the specimen is positive. To be confident that a positive PCR specimen indicates that the patient is infected with SARS-CoV, a second specimen should also be confirmed positive."[12]

WHO: "[R]equirements for the laboratory diagnosis of SARS...almost always involves two or more different tests or the same assay on two or more occasions during the course of the illness or from different clinical sites...A single test result is insufficient for the definitive diagnosis of SARS-CoV infection."[13]

H1N1 Influenza Virus

US CDC: Case confirmation requires presentation with an influenza-like illness in addition to a single positive PCR test.[14]

MERS-CoV

US CDC: Requirements for testing include both specific clinical features and epidemiologic risk,[15] and positive results must be confirmed by the CDC.[16]

WHO: Testing should be limited to persons with specified symptoms and, in most cases, elevated risk of exposure.[17]

Ebola Virus

US CDC: "CDC recommends that Ebola testing be conducted only for persons who...[have] both consistent signs or symptoms and risk factors...Any presumptive positive Ebola test result must be confirmed at the CDC...CDC considers a single diagnostic test...insufficient for public health decision-making."[18]

WHO: Case confirmation requires specific clinical signs in addition to a single positive PCR test.[19]

Zika Virus

US CDC: Testing is recommended only for pregnant women with symptoms and recent exposure, or asymptomatic pregnant women with ongoing exposure. "[B]ecause of the potential for false-positive...results, updated recommendations include [PCR] testing of both serum and urine and concurrent Zika virus IgM antibody testing to confirm the diagnosis...with more than one test."[20]

WHO: Testing is recommended only for symptomatic patients.[21]

Now:

SARS-CoV-2

Except for validation of a laboratory's first few results, we found no requirement or recommendation for a second confirmatory test in guidance documents from the World Health Organization, the US Centers for Disease Control and Prevention, the European Centre for Disease Prevention and Control, Public Health England, the Public Health Agency of Canada, the Pan American Health Organization, or South Korea's Centers for Disease Control and Prevention; instead these entities require only a single positive PCR result to confirm infection in symptomatic or asymptomatic persons.[5-11] The Chinese Centers for Disease Control and Prevention requires clinical manifestations and usually exposure history in addition to a positive PCR result to confirm a case.[22] On May 27 the Norwegian Institute of Public Health amended its guidance to recommend confirmatory tests of positive results in persons who are both asymptomatic and without exposure history.[23]

In most regions testing was initially restricted to persons with specified clinical signs and symptoms and exposure history, but as more tests became available many authorities allowed broader use of PCR-based tests, including testing of individuals with no symptoms or known exposure risk.

for samples.[29] A study of 365 laboratories in 36 countries reported 11 positive results for 1,529 negative samples, yielding a false positive rate of 0.7%.[30] These results are generally consistent with data from 43 external quality assessments of similar PCR assays of other RNA viruses conducted in 2004-2019. Out of 10,538 negative samples, 336 (3.2%) were reported as positive. The median false positive rate was 2.3%, and the interquartile range was 0.8-4.0% (Table 1).

Table 1. False positive rates in external quality assessments of PCR tests for RNA viruses[a]

Virus	Number of EQAs	Dates of EQAs	Laboratories per EQA	Negative samples per EQA	False positive rates[b]
SARS-CoV	1	2004?	58	174	2.3-6.9%
MERS-CoV	3	2014-17	49-99	49-1134	<0.6-1.0%
Influenza A viruses	17	2007-2019	64-174	114-332	<0.6-7.0%
Hepatitis C virus	8	2005-07	5-104	21-728	2.1-7.0%
Hepatitis Delta virus	1	2015?	28	112	5.4%
Chikungunya virus	2	2007, 2014	31-56	108-297	1.9-8.1%
Chikungunya, Dengue	1	2015	20	40	2.5%
Dengue virus	1	2013	16	16	6.3%
Zika virus	1	2016	50	504	2.8%
Rift Valley Fever virus	1	2012	30	117	3.4%
Measles virus	1	2014	41	123	0.8%
Ebola virus	5	2014-16	3-82	3-317	0.3-16.7%
4 arboviruses	1	2017	51	204	4.9%

[a] See Reference 4 for references and limitations.
[b] "<" indicates a false positive rate below the detection limit.
EQA = external quality assessment

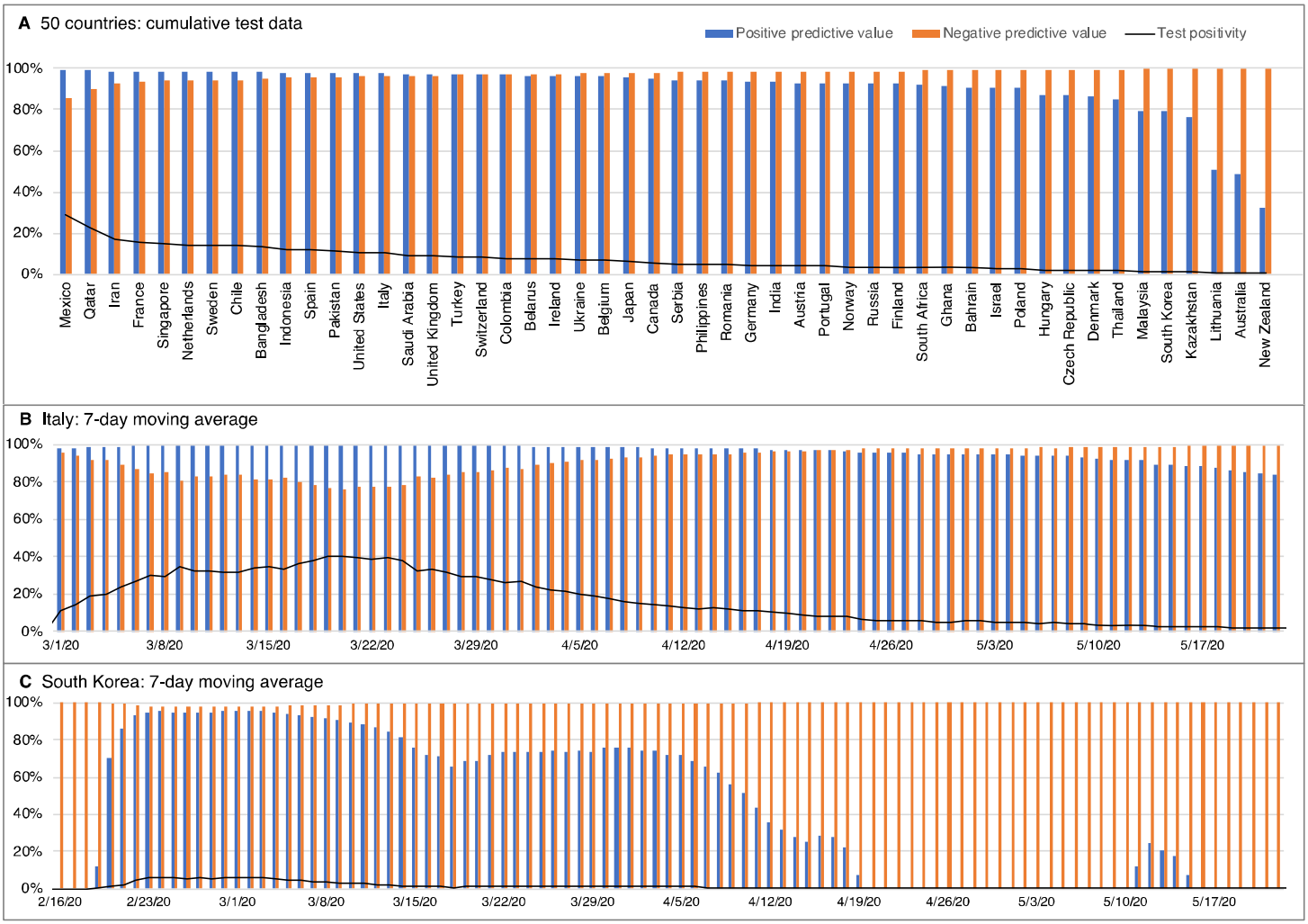
At low prevalence, the reliability of positive results declines

Figure 1 shows that even a false positive rate of 0.3% (the lowest rate from studies in real-world settings) can greatly reduce the reliability of test results. At that rate, in countries with a low test positivity rate, overly broad testing has produced results that are too unreliable to be useful (toward the right side of panel A, which shows measures of reliability calculated from countries' cumulative test data). Reliability measures calculated from daily test data contrast the time course in Italy (in Panel B), which suffered a catastrophic outbreak, with that in South Korea (Panel C), which avoided one. These calculations show that in South Korea after April 20th most of the positive test results in asymptomatic individuals could have been false positives, even as the country continued to conduct over 6,000 tests a day.

The reliability of positive results falls to near zero when the test positivity rate approaches the false positive rate. However, even with positivities up to ten times the false positive rate, a significant proportion of positive results will be false. For example, with a false positive rate of 0.3% and a test positivity rate of 1% nearly 1 in 3 positive results will be false, and with a positivity rate of 3% nearly 1 in 10 will be false. Most of these false-positive individuals would likely be asymptomatic, which could at least partially explain the reports of large numbers of asymptomatic carriers of SARS-CoV-2.

Public health authorities often state that positive results from SARS-CoV-2 tests are more trustworthy than negative results.[1-4] However, over a wide range of likely scenarios, the opposite is true: for example, in figure 1 wherever the blue columns (positive predictive values) are lower than the orange columns (negative predictive values), positive results are more likely to be wrong than are negative results. This is because the false positive rate affects samples from uninfected people, while the false negative rate affects samples from people that are infected. When prevalence is low, there are many more uninfected than infected people, so even a low false positive rate can have a larger effect than a high false negative rate.

Figure 1. Reliability of SARS-CoV-2 test results in different countries. Positive predictive value (the probability that a positive result is true) and negative predictive value (the probability that a negative result is true) calculated with a false negative rate of 26% (midpoint of published estimates of 0-52%)[4] and a false positive rate of 0.3%. (A) Results for the 50 countries with the greatest reported number of tests based on cumulative test data through 24 May 2020. Countries arranged left to right in order of decreasing test positivity. (B, C) Reliability trajectories based on the previous-7-day moving average, showing a country with (Italy) and without (South Korea) a major outbreak. Cumulative test data are from Our World in Data (https://github.com/owid/covid-19-data/tree/master/public/data/ accessed 24 May 2020). Daily test data are from the Italian Ministry of Health (http://www.salute.gov.it/portale/nuovocoronavirus/archivioNotizieNuovoCoronavirus.jsp?lingua=italiano&menu=notizie&p=dalministero&area=nuovocoronavirus&notizie.page=0 accessed 24 May 2020) and the South Korean Centers for Disease Control and Prevention (https://www.cdc.go.kr/board/board.es?mid=&bid=0030 accessed 24 May 2020).



Sources of false positives

As with other PCR-based diagnostic tests, most false positives in SARS-CoV-2 tests are probably due to contamination, derived from such sources as positive samples, positive controls, contaminated reagents, or infected workers.[4 12] Massive amplification of nucleic acids makes PCR-based assays highly sensitive, but also highly vulnerable to minute levels of contamination which can produce false positives that are indistinguishable from true positives. Even the most highly-regarded laboratories struggle to avoid contamination problems when using PCR, and sometimes fail.[31 32] False positives can also be produced by sample mix-ups, software problems or data errors.[4]

Impacts from false positives

Considerable attention has been paid to *false negative rates* in SARS-CoV-2 PCR testing[4] and to false positive rates in *antibody* testing,[33] but there has been little discussion in the scientific or medical literature of false positive rates in SARS-CoV-2 PCR testing.[4] Failing to anticipate and correct for false positive results has numerous clinical and case management consequences. These include waste of personal protective equipment, waste of human resources in contact tracing,[35] unnecessary delays in surgical procedures,[25 35] prolongation of hospital stays,[25 35] and potentially dangerous sequestering of uninfected individuals with infected individuals.[25 32] A false positive test result can impede a correct diagnosis, delaying or depriving patients of appropriate treatment. False-positive patients introduce noise into clinical observations, which may hinder the development of improved medical care based on clinical experience. False-positive individuals or their close contacts could be subjected to medically inappropriate therapies,[34] including prophylactic or antiviral medications and antibody therapy. Individuals that have falsely tested positive may be less likely to avoid future exposure to infected individuals, believing they have immunity, and for the same reason may not seek vaccination when it becomes available. Clinical trials could lose statistical power by unwittingly enrolling false-positive individuals, who would be exposed to potentially harmful side effects without any mitigating potential for benefit. False positives also distort the estimates of an array of epidemiological statistics that affect policy decisions including the asymptomatic ratio, prevalence estimates, and hospitalization and death rates, as well as many modeling studies.

Fixing the problem

The impact of false positives in SARS-CoV-2 testing would be somewhat mitigated by merely increasing the awareness of false positives. This would introduce an appropriate note of caution into clinical and management decisions where patients might be harmed if not already infected, and would promote the inclusion of reasonable estimates of false positive rates into analyses of test data, substantially changing results in some cases. These would be helped by improved estimates of false positive rates, either from external quality assessments designed to realistically estimate false positive rates, or retrospective confirmation of PCR results with serological tests.

But more importantly, we should reduce false positive rates. Long-term, this can be done by investigating and improving laboratory and sampling practices. Shorter-term solutions, all of which involve tradeoffs between specificity and sensitivity, include raising the criteria for positive results in PCR tests by lowering the cutoff known as the maximum threshold cycle (Ct), or by selecting tests with primer-probe sets that are less sensitive, which would reduce false positives that result from a low-concentration contamination. Pooled sampling also reduces false positives. However, a simpler and immediately available approach is to check positive results with additional tests, at least when prevalence is low, such as in the mass-testing of

asymptomatic individuals. In such circumstances, requiring two independent positive test results to diagnose an individual as infected greatly reduces the effective false positive rate at the cost of a minimal, often insignificant, increase in the false negative rate.

There is evidence that this works. This past spring, the provincial government of Ontario, Canada decided to test all residents and staff at long-term care homes. Medical officers overseeing three counties, anticipating the possibility of false positives, retested all positive results. Eight specimens initially tested positive, from eight asymptomatic residents and staff at eight separate homes. The individuals and their families were informed of the results but told that they were tentative pending confirmation, and the eight homes were put on lockdown in the interim. Second aliquots taken from the eight original samples all tested negative, as did second and third swabs from the eight individuals. This additional testing increased the total number of tests used by 0.5%. The medical officers concluded that the initial positive results were false, informed the eight individuals, and ended the lockdowns (I. Arra, personal communication; D. Colby, personal communication).

Now imagine what would have happened without retesting. The initial results would be accepted as proof of infection, the individuals would be told they have a disease that stands a good chance of killing them in short order, and the 558 residents of the eight homes would be put in lockdown, restricted to their rooms without visitors or activities, for 14 days. Residents, staff and their families would be subject to greater and longer-endured levels of anxiety, with potentially greater physical and mental health impacts on the isolated residents. During that time, the residents with false positive results would be attended only by staff in full PPE, causing unnecessary consumption of these supplies and further isolation of the residents. Unnecessary contact tracing would be conducted for any of the eight that had outside contacts, potentially resulting in additional, unnecessary tests. In some localities the eight false positives would require two additional, negative tests in order to leave isolation. In this case there were no infected individuals in the homes for the false-positive residents to be sequestered with; however, in some localities they would be transferred to a common facility with infected individuals, significantly elevating the risk of infection and, for the elderly or vulnerable, the risk of death.

Like all tests, PCR-based assays are subject to error that includes both false negative *and* false positive results. A successful testing program must understand the error rates of both and use tests appropriately. While SARS-CoV-2 testing to date has clearly missed the mark, we can course-correct: we can reassess plans for mass-testing using realistic estimates of false-positive rates, reconsider the conclusions of studies that implicitly assumed a zero false positive rate, and reduce misdiagnoses and statistical miscounts by checking positive results with follow-up tests, especially in asymptomatic persons and in areas where test positivity is low. In the interim, where testing has been conducted without regard to symptoms or exposure—notably in certain localities, congregate-living facilities, workplaces and sports leagues—positive results in healthy individuals should be considered doubtful unless confirmed by a second test.

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