



The Norfolk Group presents

**QUESTIONS FOR A
COVID-19
COMMISSION**

INTRODUCTION

America's response to the COVID-19 pandemic failed on many levels of government and in many aspects. Certainly, deaths are unavoidable during a pandemic. However, too many U.S. policy makers concentrated efforts on ineffective or actively harmful and divisive measures such as school closures that generated enormous societal damage without significantly lowering COVID-19 mortality, while failing to protect high-risk Americans. As a result, Americans were hard hit both by the disease and by collateral damage generated by misguided pandemic strategies and decisions that ignored years of pandemic preparation guidance crafted by numerous public health agencies, nationally and internationally.

Many crucial mistakes were made early on, in January, February, and early March 2020, and not corrected later. Mistakes made during this early critical window at the beginning of the pandemic affected our ability to collect data about COVID-19 and protect those most at risk and laid the groundwork for loss of public trust and confusion. These oversights led to unnecessary morbidity and mortality, particularly in nursing homes, and a lack of much-needed medical supplies, reagents for testing, and required medications. Delays in initiating research on key questions such as effectiveness of therapeutics, modes of transmission, length of infective periods, and other questions, meant that policy decisions were based on assumptions rather than on solid data. To this day, many of these questions have not been adequately addressed through robust trials.

At hospitals, morbidity and mortality (M&Ms) conferences are used to examine errors or omissions in order to improve medical care. Aviation agencies conduct detailed investigations after airplane accidents and incidents. Pandemics are recurring events throughout history, and there will be future pandemics. It is thus critically important that we thoroughly examine federal pandemic responses and decisions so that we can identify and learn from mistakes. Individual states should take on the responsibility of conducting similar processes to analyze their own responses to the pandemic. Other countries have conducted such inquiries ([Norway](#), [Sweden](#), [The Netherlands](#), the [United Kingdom](#), and [Denmark](#)) and made results available to the public and to decision makers. The United States is notably absent from this list. These inquiries pose important questions to key decision makers during the pandemic, including (i) politicians, (ii) leaders of the Centers of Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH) and the National Institute of Allergy and Infectious Disease (NIAID), (iii) state health departments, (iv) university presidents, medical school deans, hospital executives, medical journal editors, and leading public health scientists, as well as (iv) news media and technology/media companies.

This document is not a report from such an inquiry. Rather, we present a blueprint containing key public health questions for a COVID-19 commission. In separate chapters we summarize key background information and propose specific questions about failures to protect older high-risk Americans, about school closures, collateral lockdown harms, lack of robust public health data collected and/or made available, misleading risk communication, downplaying infection-acquired immunity, masks, testing, vaccine efficacy and safety, therapeutics, and epidemiological modeling.

We chose not to discuss economic issues, although we recognize that negative effects on the economy have long-term negative effects on public health. We have also chosen not to engage in issues regarding media

handling of the pandemic, nor questions of how, when and why the SARS-CoV-2 virus originated. Public health responses to a pandemic are devised and implemented independently of viral origin.

This document was prepared and written solely by its eight authors. No other person discussed its content, or saw a draft or the final version before publication. Seven of us started the work at an in-person meeting in Norfolk, Connecticut, organized by the Brownstone Institute in May of 2022. We wrote and edited the bulk of this document during the subsequent six months. In honor of the place where we met, we call ourselves the Norfolk Group.

The eight of us hold a wide range of political views and are not united by any particular political viewpoints. All the authors have voiced criticisms of how the pandemic was handled by government agencies and individuals appointed by and serving in both Republican and Democratic administrations. This is a public-health document, and we write it as scientists with different specific areas of expertise, but sharing the same views regarding the [basic principles of public health](#). Our work on this document was not on behalf of any institution, public or private. Further, the statements written in these articles by the Norfolk Group represent their personal interpretations and do not necessarily represent those of their employers. Last, as data are collected and new studies emerge, some of these documents and statements may become out of date or less accurate. These documents are based on current information as of January 2023 and may not have been updated past that date.

- The Norfolk Group



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EXECUTIVE SUMMARY

In this document we list specific questions on specific topics related to COVID-19 pandemic responses in the United States. We believe these questions are vital for the nation to ask the White House, the CDC, the FDA, and other government officials, as well as state health departments, scientists, and the media. The public deserves answers to these questions so we can learn from our mistakes. Key issues include:

1. What could have been done to better protect older high-risk Americans, so that fewer of them died or were hospitalized due to COVID-19?
2. Why was there widespread questioning of infection-acquired immunity by government officials and some prominent scientists? How did this hinder our fight against the virus?
3. Why were schools and universities closed despite early evidence about the enormous age-gradient in COVID-19 mortality, early data showing that schools were not major sources of spread, and early evidence that school closures would cause enormous collateral damage to the education and mental health of children and young adults?
4. Why was there an almost exclusive focus on COVID-19 to the detriment of recognizing and mitigating collateral damage on other aspects of public health, including but not limited to, cancer screening and treatment, diabetes, cardio-vascular diseases, childhood vaccinations, and mental health?
5. Why did the CDC fail to collect timely data to properly monitor and understand the pandemic? Why did we have to rely on studies from private initiatives and from other countries to understand the behavior of the virus and the effects of therapeutics, including vaccines?
6. Why was there so much emphasis and trust in complex epidemiological models, which are by nature unreliable during the middle of an epidemic, with unknown input parameters and questionable assumptions?
7. Could therapeutic trials have been run in a more timely manner? How was information on drug effectiveness and safety disseminated to doctors and clinicians? Were effective therapeutics easily accessible across the population? How did certain drugs become heavily politicized?
8. Why did vaccine randomized trials not evaluate mortality, hospitalization, and transmission as primary endpoints? Why were they terminated early? Why were there so few studies from the highest-quality CDC and FDA vaccine safety systems?
9. Why was the USA slow to approve and roll out critical COVID-19 testing capacity? Why was there more emphasis on testing young asymptomatic individuals than on testing to better protect older high-risk Americans? Why was so much effort spent on contact-tracing efforts?
10. Why was there an emphasis on community masking and mask mandates, which had weak or no data to support them, at the expense of efficient and critical COVID-19 mitigation efforts? Why did the CDC or NIH not fund large randomized trials to evaluate the efficacy and potential harms of mask wearing? Why didn't policy recommendations change after the publication of randomized trial data from Denmark and Bangladesh which showed no or minimal efficacy of mask wearing by the public?

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CHAPTER 1

PROTECTING HIGH-RISK AMERICANS



- › Long-Term Care Facilities
- › Older People Living Outside of Residential Facilities
- › High-Risk People in the Workforce
- › Multi-Generational Homes
- › Information Exchange

Background

COVID-19 does not harm all people equally. Age is the single most important risk factor in predicting hospitalization or death from SARS-CoV-2 infection, with more than a thousand-fold higher risk of poor outcomes for older people relative to young children, a [fact known from the beginning](#) of the pandemic. Others with chronic conditions such as [obesity](#), and some [immunocompromised](#) populations, also face elevated mortality and morbidity risk. Early on, particularly pre-vaccination, institutionalized populations, including those in nursing homes and jails, also faced specific challenges, as did high-risk indigenous populations.

Given these epidemiological facts, it was a critically important public health priority to properly protect these high-risk populations in order to reduce their risk of infection. It is therefore vital to conduct an honest evaluation of the successes and failures of state, local, and national public health agencies to protect the most vulnerable Americans.

Long-Term Care Facilities

Residents of long-term care facilities constituted [40% of COVID-19-attributed deaths in the US](#), and in some states it reached as [high as 80%](#), highlighting the lack of proper protection of this population. While partially due to frailty and declining health of nursing-home residents, the high mortality rate was also due to a failure to limit transmission from other residents, staff, and visitors.

- › Why did some state governors order hospitals to discharge infectious COVID-19 patients to long-term care facilities causing infection to spread to other residents? Specifically, what decisions led to nursing-home disasters in [New York](#), [Pennsylvania](#) and [Michigan](#)? How many people died from COVID-19 because of these decisions?
- › To minimize risk of infection, residents should be cared for by a static, rather than rotating, group of staff members. This infection control policy is essential during a pandemic. However, it was common for staff to work multiple jobs at different facilities during the same day or week. Why were there no efforts to change this practice during the pandemic? Did care facilities have financial incentives, such as avoiding overtime pay? Were there any efforts from care companies, state health departments, or the CDC to reduce staff rotation?
- › Protective services such as rehabilitation and physical therapy were severely restricted or discontinued, as were [visits from family](#) and friends, even post vaccination. Such activities [would have helped](#) older people maintain [physical and mental health](#) and reduced [dementia](#) due to isolation. Were the effects of severe isolation and lack of services taken into consideration in this population, particularly post-vaccination?

- › [Very low reinfection rates](#) ([peer reviewed](#) by Dec 14, 2020) early on in the pandemic, including evidence documented in Pfizer’s trial data ([Table 8](#) page 27), suggested that infection-acquired immunity was protective against reinfection, severe disease, and death from COVID-19. Within several months, immunological studies confirmed robust and long-lasting protection (See Infection-Acquired Immunity, Chapter 7). Why did the CDC not release data on reinfection rates during the first 6-8 months of the pandemic? Were long-term care facilities encouraged to hire COVID-19-recovered individuals?
- › In her 2022 [testimony](#) to Congress, released in June, 2022, Dr. Deborah Birx, former White House COVID-19 Response Coordinator, stated *“I knew all of these infection loopholes that existed not only in nursing homes and in the country, and I felt strongly that there was no way to protect the vulnerable of America without stopping community spread.”* Did policy experts know about [pre](#) and [early](#) pandemic statements in which experts cast doubt on the ability of quarantine and lockdown measures to stop community spread without excessive collateral damage? Why did Dr. Birx [purposely avoid](#) meeting with public health experts who had specifically proposed such measures?

Older People Living Outside of Residential Facilities

During the pandemic, protecting older people living at home should have been an urgent priority.

- › To protect seniors, some civic organizations organized grocery delivery so that older people would not have to be exposed in supermarkets. This type of protection was also implemented among family, friends and neighbors. Was this strategy effective? If so, why was it not used more widely?
- › Some supermarkets offered apps for ordering food online, either for home delivery or curbside pick-up. How widespread was this practice, both in terms of availability and use, and what barriers prevented greater implementation and use among those at highest risk?
- › Senior-only hours in grocery stores were used to try and protect older high-risk people. While seniors can be infected by anyone, including other seniors, the rationale was that such restricted hours would reduce crowds. Was this effective? Have there been any studies evaluating the effectiveness of these and other measures? Is there evidence that older people are less likely to transmit the virus to others?
- › The immune system benefits from overall good health, including exercise. Why were many physical activity spaces, particularly outdoor spaces, closed during lockdowns? Why did some locations ban or discourage outdoor physical activities, such as going to the beach or the park, when there was little evidence of outdoor transmission?
- › When schools closed, some low-income parents had to leave their children with grandparents during normal school hours. To what extent did this increase the exposure of older people, by, for example, having to take the bus to and from their

grandchildren's home and doing activities with the children? When schools were closed, did local, state, and federal leaders consider these negative consequences of school closures? Were there CDC warnings about these risks?

High-Risk People in the Workforce

Many older Americans work, especially immigrants and low-income people. While some older people were able to work from home, many had to continue in high-exposure jobs such as working as cab drivers, health care workers/aides, and supermarket clerks. Some older day care workers also had to care for large numbers of children who normally would have been in school.

- › Why were work-from-home orders and opportunities not age-dependent? More specifically, why were all teachers working from home rather than only those over 60?
- › What role did teachers unions play in shifting the burden of risk to grandparents and day care workers (who may have been older) to care for children during school days?
- › Why were there only limited efforts to replace older high-risk essential workers in high exposure settings with young low-risk workers? Why did the CDC not launch such efforts? Why did the federal or state government not provide financial incentives to accomplish this?
- › Taxi drivers were one of the professions most exposed to the virus. Why did some hospitals send COVID-19 patients home in taxis driven by older drivers in high-risk groups instead of providing safer forms of transportation?
- › Protection of older high-risk Americans was especially important during higher-risk seasonal time periods of two or three months every year. Why did the federal government not make accommodations to offer those over 60 years of age the ability to [temporarily use](#) social security benefits or sick leave so that they could stay at home during peak infection periods?

Multi-Generational Homes

Some older Americans live with their adult children and grandchildren in multi-generational households. In [Sweden](#), living with a working-age adult increased the risk of infection for older people compared to living with other older people, but living with a child under the age of 12 did not further increase that risk. Another [study in California](#) found that exposure to children actually *decreased* the risk of severe COVID-19 in adults.

- › Why did university presidents create additional multi-generational homes by abruptly closing campuses, sometimes with only a week's notice, and sending young people back home to live with older parents and/or grandparents rather than keeping them at school with their low-risk peers? How many older Americans died because of these actions by universities?

- › Why did the CDC not initiate a public campaign to encourage older retired people in multi-generational homes to temporarily relocate to live with a same-age sibling, or with a relative or friends instead of with their working-age children?
- › During the height of the pandemic, many hotel rooms were empty. Why were these not offered as temporary housing for older people from multi-generational homes?
- › Israel and other countries created facilities for people hospitalized with COVID-19 to prevent early release and subsequent exposure to other family members. Why did the CDC and federal health authorities not work with city and county governments to ensure that such facilities were free and available? This would have been particularly important for essential workers who lived in multigenerational families in small apartments in crowded urban environments such as New York City and Los Angeles.

Information Exchange

Policies to protect at-risk populations must necessarily be implemented at the local level because the needs of vulnerable populations differ by community. It was thus vital for public health officials to freely share information about best practices derived from the successes and failures of local public health policies. However, the failure to communicate these lessons from the local level to national level resulted in slow dissemination of critical information that communities could have used to keep their vulnerable populations safer.

- › Why was there no strategy for evaluating local efforts to specifically protect the vulnerable, and to share success stories across the nation?
- › When [specific proposals](#) for targeted protection of high-risk Americans were proposed, why were they dismissed and ruled out as impossible without discussion or debate?
- › Why did the CDC continue to focus on masks for protection of high-risk populations even when randomized studies found they were unreliable for protection. Did some very high-risk people acquire severe or fatal Covid-19 because they believed a mask would provide reliable protection in indoor gatherings? What are the implications of the CDC not being entirely transparent about disease-mitigation data?
- › When infection rates were high, why were most governmental efforts focused on community-wide suppression efforts and few efforts focused on protecting high-risk Americans through strategies outlined here (hotels for quarantining, use of extra sick leave/social security benefits for older people, keeping university campuses open, etcetera)?

CHAPTER 2

INFECTION-ACQUIRED IMMUNITY



- › Denial and Questioning of Infection-Acquired Immunity
- › Infection-Acquired Immunity in the Workforce
- › Infection-Acquired vs Vaccine-Acquired Immunity
- › Herd Immunity: Policy Implications and Messaging Failures

Background

It has been [known since the Athenian plague](#) of 430 BC that [recovered individuals are protected when re-exposed](#) to an infectious disease, at least for some amount of time. This is called infection-acquired immunity or natural immunity, as opposed to vaccine-acquired immunity. Protection may be absolute or partial, resulting in sterilizing immunity that prevents reinfection or in non-sterilizing immunity that decreases severity of disease if reinfected. With few individuals becoming reinfected early in the pandemic, it was obvious that most recovered individuals mounted robust and protective immune responses. Although sterilizing immunity may wane over time, protection from severe disease post-COVID-19 infection is, so far, long-lasting, similar to other coronaviruses that cause common colds.

The issue of infection-acquired immunity was and is at the core of many disputed pandemic policies. Without durable infection-acquired immunity, herd immunity¹ cannot be reached, there would be no effective vaccines, and high-risk individuals would have to be sheltered forever unless the virus was eradicated. However, evidence existed early on that prior infection conferred durable protective immunity in the case of SARS-CoV2, meaning that efforts should have been aimed at protecting high-risk individuals until sufficient immunity could be reached in the population through a combination of infection-acquired and vaccine-acquired immunity.

Another reason that denial of natural immunity led to misguided COVID-19 policies is that vaccines were assumed to have superior immunity compared to natural infection, an assumption that led to widespread vaccine mandates even in previously infected people. Prior infection and vaccines both provide a form of immunity. Acknowledgement of infection-acquired immunity is not an argument against vaccines. For example, the purpose of the measles vaccine is to prevent measles, but those who have already had measles do not need the vaccine.

¹ The term “herd immunity” refers to a threshold where a sufficient portion of people in a population have acquired immune protection against a specific infectious agent, either through recovery from infection or vaccination, so that the virus can no longer circulate at epidemic levels. It does not refer to eradication.

Denial and Questioning of Infection-Acquired Immunity

Contrary to vaccine-acquired immunity, which was overemphasized, infection-acquired immunity was consistently downplayed during the pandemic.

- › In October 2020, a widely circulated [Memorandum](#)² published in *The Lancet*, a top British medical journal, questioned infection-acquired immunity. It stated that “*there is no evidence for lasting protective immunity to SARS-CoV-2 following natural infection*”, claiming “*scientific consensus*” for this view. The Memorandum was co-authored by several senior US scientists, including Drs. Marc Lipsitch (Harvard), Ali Nouri³ (president, American Federation of Scientists) and Rochelle Walensky⁴ (Harvard). With extremely [few reinfections](#) at the time, clear evidence for the existence of infection-acquired immunity, and despite what we know about other coronaviruses, on what basis did these scientists question that infection with SARS-CoV-2 provided lasting protection from severe disease for recovered individuals and, early on, from reinfection? What was the rationale for *The Lancet* editor-in-chief, Dr. Richard Horton’s⁵, decision to publish the [Lancet Memorandum](#) that questioned infection-acquired immunity after SARS-CoV-2 infection without citing supporting data and which ran in opposition to well established immunologic principles?
- › In the same week as he co-authored the Lancet Memorandum, the president of the American Federation of Scientists, Dr. Ali Nouri, published an [article in Scientific American](#) arguing for stronger efforts to combat COVID-19 misinformation. Why did *Scientific American* publish a piece arguing for combatting COVID-19 misinformation authored by a scientist questioning infection-acquired immunity?
- › In 2020, prior to availability of COVID-19 vaccines, there was very little information about infection-acquired immunity on the [CDC.gov website](#). This was in spite of much robust [international](#) data [already](#) being available. One exception was the page discussing antibody tests: “*Having antibodies to the virus that causes COVID-19 may provide protection from getting infected with the virus again. If it*

² The authors called it the John Snow Memorandum, but John Snow was a great epidemiologist and it is inappropriate to connect his name to this document. Hence, we will call it the Lancet Memorandum.

³ Dr. Nouri was later appointed as the Assistant Secretary in the Department of Energy.

⁴ Dr. Walensky was later appointed as the Director of the Centers for Disease Control and Prevention.

⁵ This is the same editor who published the controversial 2020 Lancet letter denouncing “rumours and misinformation around its origins” and condemning “conspiracy theories suggesting that COVID-19 does not have a natural origin”.

does, we do not know how much protection the antibodies may provide or how long this protection may last.” Why did the CDC downplay infection-acquired immunity, despite robust evidence for it?

- › In the summer of 2021, all references on the CDC.gov website to immunity after infection with SARS-CoV-2 were removed. Vaccination was recommended even in recovered individuals: *“Get vaccinated regardless of whether you already had COVID-19. Studies have shown that vaccination provides a strong boost in protection in people who have recovered from COVID-19.”* With no evidence cited in support of this statement, what was the evidence supporting the CDC’s claim when the prior six months had produced [several additional studies showing that infection-acquired immunity was](#) protective, robust, and long-lasting?
- › On August 6, 2021, the CDC published a Kentucky-based study as an [MMWR early release article](#). Among people with infection-acquired immunity from 2020, the study reported that people who were subsequently vaccinated were less likely to test positive for COVID-19 than those with only infection-acquired immunity. However, the study did not evaluate differences in hospitalization and death or even symptomatic disease. Why did CDC Director Rochelle Walensky cite this study to support her statement [that](#) *“if you have had COVID-19 before, please still get vaccinated”* ?
- › By October 2021, there was [substantial evidence of robust immunity in persons with](#) a history of [only mild or asymptomatic](#) infections. Despite this, the [CDC claimed](#) that *“there are insufficient data to extend the findings related to infection-induced immunity at this time to persons with very mild or asymptomatic infection or children”*. In light of the scientific evidence, why did the CDC claim that individuals with immunity after recovery remained unprotected from severe reinfection? Why was substantial scientific literature on this topic ignored? Who was involved in those discussions and decisions?
- › The concept of infection-acquired immunity is well understood by the public, and has been for hundreds of years. By questioning this well-known concept, how much damage did the CDC, other public health officials and public health scientists do to public health’s credibility, and to vaccine confidence and adherence to mitigation policies?
- › Through the [CDC Foundation](#), the CDC [receives funding from pharmaceutical companies](#) and other organizations. Over the years, has it received donations from vaccine-related interests such as Astra-Zeneca, Johnson & Johnson, Pfizer, Moderna, the GAVI Alliance and/or the Gates Foundation? Did CDC decision makers have conflicts of interest in questioning the role of infection-acquired immunity in protection from severe COVID-19?

Infection-Acquired Immunity in the Workforce

Infection control is very important in hospitals and nursing homes in order to protect elderly frail patients and others with weakened immune systems. Minimizing risk of infection by hospital and nursing home staff is important.

When vaccines became available, hospital and nursing home staff were prioritized to reduce transmission risk to their elderly high-risk patients and residents. Before vaccines were available, COVID-19 risk to older high-risk nursing home residents and hospital patients could be reduced if patients were cared for by staff with infection-acquired immunity.

- › Why did hospital and nursing homes not pursue such focused protection of the most vulnerable? Why did they not try to hire staff with infection-acquired immunity? Why was this not recommended by the CDC?
- › Since infection-acquired immunity offered superior protection compared to vaccine-acquired immunity, why did hospitals fire rather than hire unvaccinated nurses, physicians and other staff who had infection-acquired immunity? Why did hospitals implement vaccine mandates without providing exceptions for staff with infection acquired immunity?
- › After [firing many unvaccinated nurses and physicians](#), some hospitals experienced severe staff shortages in late 2021 and into 2022, many which persist today. How did this affect the quality of healthcare? How many patients did not receive healthcare because of this? What did governors and state health departments do to avoid these self-imposed problems? Has there been any discussions of or plans to compensate staff who lost their jobs due to vaccine mandates?

Infection-Acquired vs Vaccine-Acquired Immunity

Vaccines are designed to mimic the immune response from a disease while avoiding the risks involved with being infected. Individuals are capable of understanding risks when given accurate information and acknowledging that infection-acquired immunity is superior to vaccine-acquired immunity is not equivalent to promoting infection over vaccination. On its [website](#), the CDC wrote that *“the risk of severe illness and death from COVID-19 far outweighs any benefits of natural immunity.”* However, for people that have already survived an infection, the relevant question is whether they have acquired immunity, which they do in the vast majority of cases. For people without a prior COVID-19 infection, the relevant comparison is vaccine efficacy versus adverse reactions. Did the CDC damage vaccine confidence when they conflated these two issues?

- › The CDC [Kentucky study](#) from August 2021 did not evaluate symptomatic disease, hospitalizations or death, but it showed fewer positive COVID-19 tests in people

who had combined immunity (from both Covid-19 infection and vaccination), compared to COVID-19 infection alone (both were very low, however). Since all participants in the study had infection-acquired immunity, why did the title of the [CDC press release](#) for this study falsely claim that “*Vaccination Offers Higher Protection than Previous COVID-19 Infection.*”? That question was not evaluated in the Kentucky study. Why did [NIH director](#) Francis Collins use this study to falsely claim that “*it was more than two-fold better from the people who had the vaccine, in terms of protection, than people who had had the natural infection*”?

- › It is important to know if the vaccines can provide the same or similar level of immunity as infection-acquired immunity. Early important studies on that topic were conducted in [Israel](#), [Sweden](#) and [Qatar](#). Why did the CDC or NIH not fund or conduct such studies in the United States until [January 2022](#)? Why were the results of Israeli and Swedish studies largely ignored by public health authorities in the United States?
- › In September 2021, why did Health and Human Services Secretary [Xavier Becerra](#) refuse to acknowledge that infection-acquired immunity is superior to vaccine-induced immunity?
- › In October 2021, CDC released a [methodologically flawed study](#) claiming that vaccine-induced immunity was 5.3 times more effective than infection-acquired immunity. Did CDC officials know about high quality studies from other countries that showed opposite results? In the [CDC press release](#) about the study, why did Dr. Rochelle Walensky falsely claim that “*we now have additional evidence that reaffirms the importance of COVID-19 vaccines, even if you have had prior infection*”?
- › In January 2022, the CDC published a [study](#) using statewide data from New York and California confirming that infection-acquired immunity was superior to vaccine induced immunity. What was the impetus for this new study? After this study was published, and after the methodological flaws in the previous CDC study were pointed out by various scientists, why did the CDC not retract the prior flawed study? To date, this newer article has not been cited in any CDC press release and is not mentioned by the CDC on any of its informational web pages. Why did CDC not publicize this study as much as their prior flawed study?
- › In a September 2021 [Munk Debate](#), Dr. Paul Offit argued for general vaccine mandates. In a subsequent January 2022 [podcast](#), he described a meeting where CDC Director Rochelle Walensky, NIH Director Francis Collins, NIAID Director Anthony Fauci, and surgeon general Vivek Murthy, asked the advice from four experts whether “*natural immunity should count as a vaccine*”. The outcome of the meeting was that it should not. In the podcast Dr. Offit acknowledged that infection-

acquired immunity is strong “as you would expect, it is true for every other virus ... except the flu ... [and that] you’ve been vaccinated essentially”. He then described the decision as “probably more bureaucratic than anything else.” Is Dr. Offitt correct that the denial of infection-acquired immunity was a bureaucratic rather than a science-based decision? Were vaccine mandates also a bureaucratic rather than a science-based decision? Who were the other three “experts” consulted on this matter and how did they vote? If important public health decisions are taken for bureaucratic rather than scientific reasons, how does that affect the public's trust in public health?

Herd Immunity: Policy Implications and Messaging Failures

The term “herd immunity” refers to a threshold where a sufficient portion of people in a population have acquired immune protection to a specific infectious agent, either through recovery from infection or vaccination, so that the virus can no longer circulate at epidemic levels. At that time, there is some protection for those who have not yet acquired immunity, protecting high-risk individuals from severe disease and death. It does not mean that the disease has been eradicated. On the contrary, once herd immunity is reached, an endemic equilibrium stage is reached in which the infection rate is related to the rate of waning immunity and the birth of susceptible individuals. Because of seasonality, it is possible to reach herd immunity during summer months with the epidemic reemerging when seasonality raises the reproductive number during the fall or winter.

For some infectious diseases such as measles, recovery or vaccination results in lifelong protection. For others, such as common cold coronaviruses, immune protection against reinfection (usually mild) is not long lasting. This does not mean that herd immunity is invalid, but rather that periodic mild reinfections or vaccination will restore community protection while protection from severe disease is maintained.

Public comments from health officials in the U.S. have demonstrated that this concept was poorly understood at the highest levels during the COVID-19 pandemic. In a 2022 paper by Dr. Anthony Fauci and colleagues, “[The Concept of Classical Herd Immunity May Not Apply to COVID-19](#)”, the authors questioned whether the natural and well-established phenomenon of herd immunity applies to SARS-CoV-2, due to waning of immunity and the rate of mutation. However, herd immunity limits transmission and protects against serious disease outcomes, even as sterilizing immunity wanes. Like other pandemic viruses, the SARS-CoV-2 virus becomes endemic as a result of sufficient population immunity. In 2022, former White House Coronavirus Task Force Response Coordinator Dr. Deborah Birx [testified](#) to Congress that “*herd immunity is not usually discussed as it comes to humans. Herd immunity comes out of vaccinating your cows and your pigs...So that’s how herd immunity is discussed. We don’t discuss that usually about humans.*” A 2022 [search](#) for “herd immunity humans” on PubMed generated over

2,900 scientific articles on the topic. Former CDC Director Robert Redfield has [stated](#) that: *“I thought for COVID-19, that there is no herd immunity”*.

- › Why do three of the architects of the U.S. government’s COVID-19 policy seem to be questioning such an important epidemiological concept? How did their beliefs about herd immunity affect the nation’s COVID-19 response? Why did they question whether herd immunity applies to SARS-CoV-2, at least for severe disease?
- › Did any or all of them consult with infectious disease epidemiologists who specifically study this topic?

CHAPTER 3

SCHOOL CLOSURES

- › Closing Schools
- › Keeping Schools Closed
- › CDC Reopening Guidelines
- › Lobbying for School Closures
- › Harms from School Closures
- › Children with Special Needs
- › Inequity of School Closures
- › Extra-Curricular Activities

Background

Schools closed in March 2020 across the USA, initially for 2 weeks, but then extended for the vast majority until the end of the school year, with in-person teaching replaced by online instruction. Some schools opened in the fall of 2020 while other schools remained virtual throughout the 2020/21 academic year. Some schools were even virtual or experienced brief closures during the 2021/22 academic year, while many others went remote during surges. In some school districts, a hybrid approach was used, with in-person schools on some days and online schools on other days. In other districts school was entirely remote with little in person synchronous instruction for most of the 2020/2021 year. In contrast, most European children returned to school after a short shut down while Sweden never closed schools for children under the age of 15.

Closing Schools

Children readily spread influenza A, both to adults and among themselves, and readily become ill due to influenza A. Early [data from Wuhan](#), however, showed that there is more than a thousand-fold difference in the risk of COVID-19 mortality between the old and young, and that children were largely spared from serious illness and death. Early studies also indicated that children were relatively poor spreaders of infection.

- › With such small risks to children, why did some states, such as [Oregon](#), cite the “*health of children*” as a reason to close schools?
- › There were concerns that children would spread to adults and very few schools reopened in the USA through spring of 2020. However, in April 2020, [data from Iceland](#) showed that young children are less likely than adults to transmit the virus. Rather than closing schools, why were schools not reorganized to permit in-person instruction so that low risk teachers under the age of 60 could be in the classroom?

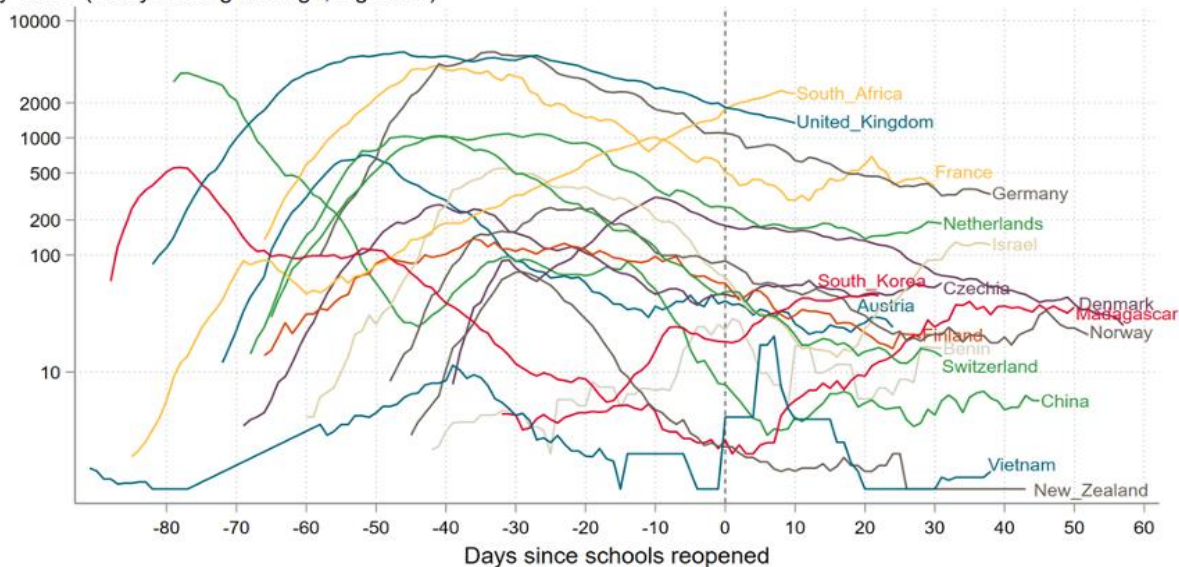
Keeping Schools Closed

In fall of 2020, the USA was a patchwork of closed and open schools, even though a great deal of reassuring data had become available here and abroad. Sweden kept daycare and schools open throughout the spring of 2020, for all children ages 1 to 15, without social distancing, masks, or testing. As of June 2020, among the [1.8 million children](#) in this age group, zero died from COVID-19 and only a few were hospitalized. Early data also indicated teachers did not have a higher risk of serious COVID-19 than other professionals. On July 7, 2020, Swedish and Finnish Public Health Agencies issued a [public report](#) comparing the two countries, concluding that “*closure or not of schools has had little if any impact on the number of laboratory confirmed cases in school aged*

children in Finland and Sweden. The negative effects of closing schools must be weighed against the positive effects, if any."

- › Sweden's and Finland's report should have ensured that all American children returned to in-person teaching in the fall of 2020. Why were these results ignored by the CDC and many governors and state health departments?
- › On July 29, 2020, the New England Journal of Medicine (NEJM) published an [article](#) concerning "reopening primary schools during the pandemic", without mentioning data from the only major western country that kept schools open throughout the 2020 spring semester. Were they aware of Sweden's and Finland's report?
- › Except for [CNN-Español](#), we are not aware of any major U.S. media covering the positive results from Sweden. Why did journalists not report on the safety of the open schools in Sweden?
- › On August 7, 2020, the CDC published an [MMWR study](#) based on COVID-Net data from March 1, 2020 through July 25, 2020, which clearly established the low risk to American children. In the analysis, children comprised less than 0.01% of hospitalizations and 0.0005% of associated COVID-19 mortality. Why did the CDC not use these data to reassure concerned parents that in-person schools were safe for children?
- › In [Australia](#) and [South Korea](#) in August 2020, data showed that secondary infection rates were very low in schools. [The UK](#), as well as [Norway](#) and other [Scandinavian countries](#), showed that in-school spread was low and that teachers were at no higher risk of infection than the general population. In fact, schools tended to have *lower* transmission rates than the general community. Similarly, in May 2020, the Center for Global Development released [a report](#) that failed to find any increase in community COVID-19 case rates related to school reopenings internationally. Why did US policy makers and the CDC ignore data from the US and Europe showing COVID-19 transmission in schools was low and teachers had [lower risk of contracting COVID-19](#) or [having severe outcomes](#) from COVID-19 than other essential workers?

Daily cases (7-day moving average, log scale)



- › [California data](#) on preschools and daycares were similar, with 33,773 preschools and daycares remaining open, and state data through July 2020 showing that only about 450 students had tested positive for the virus in the preceding six months. Were US policy makers and the CDC aware of these data from daycare centers that had stayed open and which showed low rates of COVID-19 transmission?
- › In the USA, a large-scale analysis from [Brown University](#) using fall 2020 data found that school opening did not raise transmission significantly, if at all, and that schools reflected community rates. Data from [New York City](#) schools, the largest and most diverse district in the USA, identified only 28 cases after random testing of 16,000 staff and students. In 2021, two large-scale studies in [Wisconsin](#) and [North Carolina](#) showed very low within-school transmission rates in public and private schools, no transmission to teachers and lower case rates within the school than in the surrounding community. Were policy makers aware of these data? If they were, why did they not take these data into account when making recommendations around school openings and closures?

CDC Reopening Guidelines

The CDC originally set reopening guidelines for fall 2020 with a recommendation of staying remote when cases exceeded 20 per 100,000. While these were recommendations and not requirements, many county health departments adopted them as requirements and school boards and district officials turned them into preconditions for re-opening. Under these conditions, 99% of American schools could not reopen in fall 2020. As a result of these guidelines, public schools in e.g., San Francisco, Atlanta, Seattle, Chicago, Portland, OR, and other cities did not reopen for in person instruction until April 2021, and then for only a few hours per week, with attendance often limited to 50% capacity.

- › Why did the CDC use community transmission rates as a metric for school guidance given available data showing schools were not meaningfully driving spread?
- › Data from states that reopened schools in August 2020, such as Florida, showed low rates of severe COVID-19 in children. Why did the CDC not adjust guidelines given these data?
- › Why were outdoor school options not explored in the warmer southern parts of the US as they [were in parts of Europe](#)?
- › There were [no data](#) indicating differences in transmission rates between social distancing of [6 feet or 3 feet \(or fewer\)](#). Why was the CDC slow to decrease distancing requirements, which kept millions of children at home due to the 6 foot requirement? Even with 6 foot distancing, why did the CDC provide [classroom diagrams](#) that severely underutilized classroom space instead of giving guidance that would have maximized the number of students that could have returned?
- › Why were privately-funded [academic centers](#) collecting data on school transmission and the effectiveness of mitigation measures instead of the CDC? Why did the CDC not offer to fund these projects after they were established and were clearly providing useful and important information?

Lobbying for School Closures

Released emails have shown that leaders of [teacher unions provided input](#) on and previewed CDC guidance on school closures and opening.

- › Why did the CDC incorporate policy language proposed by leaders of teachers unions on the scientific and public health aspects of school reopening [without soliciting](#) expertise of outside scientists in public health, infectious diseases, or other related fields?
- › As a result of educator union heads' input, social distancing with evidence-free metrics, such as 6 feet of distance, were maintained into spring of 2021. Why did the CDC follow requests from teacher union leaders instead of examining the epidemiological evidence?
- › Some school districts created in-person "hubs" which were opened for students but staffed by low-wage workers while teachers worked remotely. What was the rationale for having "hubs" instead of in-person teaching? Were these low-wage workers assumed to be at less risk for COVID-19 than teachers? Having to pay both teachers and hub workers, how much money did school districts spend to transfer minimal COVID-19 risks from teachers to low-wage workers? Was the fact that many of the lower-wage workers in school buildings are nonunionized a factor in creating this set up?

Harms from School Closures

Decades of research established that remote learning provides worse academic outcomes, and that low-income students rely more heavily on the social services and safety net resources that public schools provide. Several pre-pandemic studies showed that students relegated to [online learning](#) performed worse than their [in-person](#) peers and that even students who used [computers in the classroom](#) had lower test scores than those learning without them. Absence rates are well known to predict graduation rates and even [snow days](#) can significantly impact academic performance. In districts such as the Los Angeles Unified School District, [more than half of students never logged on at all in spring 2020 and fall 2021](#) and nearly half continue to be [chronically absent](#) in 2022.

- › Why were lessons ignored about the negative effects of prior school closures, such as during the [polio pandemic](#), the floods in [Thailand](#) in 2011, teacher strikes in [Argentina](#) in the 1980s, and the earthquake in [Pakistan](#) in 2005?
- › Why were plans to avert and ameliorate learning loss not immediately put in place and rolled out aggressively?
- › Removing school sports and extracurricular activities led to predictable weight gain, development of sedentary behaviors, increased screen time, and a loss of the mental health benefits of exercise and sports participation. Why were these activities canceled? Are there plans to ameliorate the resulting damage to children's physical health?
- › [Standardized](#) tests [show](#) that children have lost decades worth of academic progress due to school closures. What plans are in place, nationally and locally, to help students recover some of these academic losses?
- › Three million students are thought to have [left the public education system](#) altogether during the pandemic. What efforts are being made to find those students and bring them back into the system?
- › Children's anxiety, health care utilization for suicidality, and depression, and eating disorders [are at an all time high](#). Why were plans to avert and ameliorate mental health effects not in place? What is being done to provide mental health care to these children?
- › What are the short-term and long-term effects of missed school screenings for vision, hearing, and dental problems?
- › What were the short- and long-term consequences of the unavailability of school-based health education programs, including preventive health, mental health counseling, wellness education, physical education, reproductive health services and alcohol and drug counseling?
- › Schools are important for detecting child abuse. How many child abuse cases went undetected and how many children experienced continued [abuse](#) because of school closures?
- › Childhood vaccination rates fell during the pandemic. How much of this was due to school closures, such as a [lack of school vaccine clinic](#) or school vaccine requirements, versus other factors?

Children with Special Needs

Millions of children received no special education services during school closures, and students with learning disabilities, autism, and other neurodiverse issues, and English as a Second Language (ELL) students experienced disproportional harms due to remote school and mask mandates.

- › What effect did school closures have on autistic children, children with other learning disabilities, and their families? How were the needs of these children weighed in the decision to close their schools?
- › What effects did school closures have on English language learners, not only in terms of the lack of in-person ELL teaching, but also in missed opportunities to interact with and speak English with their peers?
- › Why were school districts allowed to suspend Free Appropriate Public Education (FAPE, section 504) requirements?
- › Were there requirements for districts to use Elementary and Secondary School Emergency Relief (ESSER) funds to help these students to catch up? If not, why not?
- › Why were districts not required by the Department of Education to let students unable to learn remotely come into school buildings for in-person instruction?

Inequity of School Closures

Children with more affluent parents, with parents with flexible work schedules, and who had better access to high-speed internet did better, for the most part, with online learning. Affluent families were also better equipped to hire tutors, to set up pod schools and to pay for enrichment. Some could afford to move their children from public to private schools that were still offering in-person teaching, thus exacerbating the equity gap in education. Low-income students and students from racial minorities, who already suffer from low graduation rates and lower college enrollment, came back to school at lower rates when schools finally reopened. Students who were in [remote learning longer](#), students of lower socioeconomic status, and students of color were all [found](#) to have greater educational losses during the pandemic, widening racial and socioeconomic divides in the United States.

- › While governors closed public schools, many private schools continued with in-person teaching. Why were public schools in some states closed while private schools were not? Why did public schools not open when private schools were opening successfully?
- › Why were concerns about differential impacts of school closures dismissed when schools were closed and remained closed?
- › Why did the Department of Education not require districts to have a plan to retain the most at-risk students in order to receive Elementary and Secondary School Emergency Relief (ESSER) funds? How are ESSER funds monitored and accounted for to ensure that the most at-risk students receive more of the money?

- › Studies emerged in fall 2020 that women were [leaving the workforce](#) and that the burden of overseeing their children's education at home was [falling disproportionately](#) on women while the burden of maintaining the family income was falling disproportionately on men. Were the disproportionate and long-term impacts of school closures on gender equality, women's careers considered when school closures were implemented?

Extra-Curricular Activities

School closures not only affected class-room education but also extra-curricular activities that form a very important part in the lives of children in terms of social life, physical exercise, and social bonding. Even after schools were re-opened, some extracurricular activities remained in lockdown.

- › To what extent did the canceling of extracurricular contributions contribute to the increasing mental health problems that children experienced during the pandemic?
- › How did the lockdown of extracurricular sports activities harm children's physical health? What was its effect on obesity?
- › Were differential effects of extracurricular activity cancellations on low-income children considered, for example since wealthier families could move to states where their children could compete, or travel for club sports?

CHAPTER 4

COLLATERAL LOCKDOWN HARMS

- › Lockdown Philosophy
- › Health-Care Utilization
- › Cancer
- › Cardiovascular Disease
- › Other Chronic Diseases
- › Infectious Diseases & Childhood Vaccinations
- › Mental Health
- › Homicides and Domestic Violence
- › Physical Activity
- › The Microbiota & Human Immune System
- › Excess Deaths
- › Business Closures & Unemployment
- › Housing
- › Food Insecurity
- › Cultural & Sports Activities
- › Religious Gatherings
- › The Environment
- › Community-Wide Suppression

Background

The collateral damage associated with pandemic lockdown policies is enormous, cutting across multiple areas of physical and mental health, education, culture, religion, the economy, and the social fabric of society. In this document, we use the term ‘lockdowns’ broadly to refer to a suite of policies ranging from school and university closures, mandatory online education, health-care and travel restrictions, business closures, stay-at-home and work-from-home orders, COVID-19-related firings, and the canceling and prevention of cultural, social and religious events. Collateral public health damage has affected all segments of society, but children, low-income people, manual laborers, the elderly, and people with chronic health problems have been hardest hit, resulting in increased wealth and health inequalities.

Some of the consequences of lockdowns were immediate, such as the deterioration of cardiovascular disease outcomes and mental health, while other negative consequences, due to, for example, delayed cancer screenings and school closures, may not be realized or fully felt for decades. States, counties, and the federal government will continue to collect data and compare outcomes in states with prolonged deep lockdowns (OR, CA, MD, e.g.) versus in states that had fewer COVID-19 restrictions (SD, NE, IA, FL e.g.). [Early reports](#) indicate profound differences, with [estimates](#) suggesting that 75-80% of the excess deaths during the pandemic were not attributable to COVID-19 but to pandemic policies that led people to miss addiction treatment, to stay home when they were experiencing symptoms of a heart attack, and others.

Lockdown Philosophy

In 2006, a small group of Bush-administration health officials and computer modelers suggested lockdowns as a response to a future pandemic. Dr. Donald Henderson, a 78 year-old world-renowned epidemiologist who led the eradication of smallpox, went into action, [responding](#) that: *‘Experience has shown that communities faced with epidemics or other adverse events respond best and with the least anxiety when the normal social functioning of the community is least disrupted. Strong political and public health leadership to provide reassurance and to ensure that needed medical care services are provided are critical elements. If either is seen to be less than optimal, a manageable epidemic could move toward catastrophe.’*

- › Why did lab scientists such as NIH Director Francis Collins, NIAID Director Anthony Fauci and CDC Director Robert Redfield ignore the important knowledge, insights, experiences and warnings from Dr. Henderson, a public health giant?

- › Early in the pandemic, another preeminent infectious disease epidemiologist, Dr. Sunetra Gupta at Oxford University, voiced similar early warnings as Dr. Henderson. Why were her concerns dismissed and ignored?
- › Why was so much influence on public health policy accorded to Drs. Collins and Fauci? They control the largest source of infectious disease research funding in the world. How many infectious disease scientists, who should have been strong voices during the pandemic, kept quiet for fear of losing the research funding on which their livelihood depends?

Health-Care Utilization

Health-care utilization declined during lockdowns. Visits to emergency departments [dropped](#), and childhood vaccinations [plummeted](#). These declines likely will lead to deteriorating short and/or long-term health.

- › In April 2020, emergency department visits [dropped](#) by 50%. They recovered somewhat in subsequent months but were still 34% below normal at the end of 2020. How many people died because they did not go to an emergency department when they needed treatment?
- › A fundamental [principle of public health](#) is to consider all of health rather than focus on a single disease such as COVID-19. Why were lockdowns implemented without consideration of their negative effects on other diseases and health states? Why did the government not conduct either a formal or informal cost-benefit analysis of lockdown strategies?
- › Are there any systematic attempts by the CDC or NIH to collate deaths and other health consequences of deferred or missed health care during the pandemic?

Cancer

The pandemic saw a decrease in new cancer cases, but not because of less cancer. There was a [significant decrease](#) in the number of patients undergoing screening tests for cancer and thus in the number of diagnoses of cancerous and precancerous lesions during the pandemic. This inevitably means there will be more cancer deaths and later-stage diagnoses in the future. There were also decreases and delays in cancer treatments.

- › How many people had a cancer diagnosis delayed during the pandemic? What did the CDC and state health departments do to avoid this problem? What have they done to ensure catch ups with cancer screenings?
- › What will be the toll on future cancer mortality due to delayed cancer diagnoses?
- › What is the toll in terms of longer and more expensive cancer treatment due to delayed cancer diagnoses?

Cardiovascular Disease

Both lockdowns and fear reduced hospital visits while [increasing](#) cardiovascular deaths at home.

- › In 2020 there was an [increase](#) in deaths from both heart disease and stroke. The increase was especially pronounced among Black, Hispanic and Asian Americans. How much of this increase was collateral lockdown damage? Why was this problem not foreseen by the health agencies and politicians implementing lockdowns?

Other Chronic Diseases

Pandemic restrictions have also had a negative impact on other chronic diseases such as diabetes and auto-immune diseases.

- › Diabetes care was [interrupted during the pandemic](#). How many Americans did this affect? What will be the long-term consequences and who will be responsible for defining and collating them?
- › Physical exercise is important for preventing diabetes. How did closing exercise venues such as parks and gyms, affect diabetes incidence?
- › What were the effects of COVID-19 restrictions on people with lupus, rheumatoid arthritis, Sjögren's syndrome, and other auto-immune diseases?
- › People with dementia have suffered extraordinarily during the pandemic. Why were there not more efforts to ensure the well-being of dementia patients? To what extent did isolation protocols, cessation of physical therapy, cessation of group activities and restriction of mobility contribute to [increases](#) in dementia and to dementia deaths?

Infectious Diseases & Childhood Vaccinations

Social distancing and other pandemic measures affected COVID-19 and spread of other infectious diseases.

- › Many older people with weakened immune systems die from commonly circulating viruses. Did lockdowns have secondary beneficial effects on the transmission and pathology of other viruses?
- › Children need to build up their immune systems against common viruses in order to be protected later in life. Will pandemic-era children and babies have immune systems that are less robust than their slightly older and younger cohorts?
- › Childhood vaccination rates [plummeted](#) in March 2020. For example, the administration of the second dose of the measles vaccine fell by more than 90%. Vaccinations [rebounded](#) later in the year but were still below baseline and the necessary catch-up did not materialize. How many American children did not get their scheduled vaccinations due to pandemic restrictions? What are the short- and long-term consequences of this?
- › Vaccine skepticism has increased during the pandemic [because of inaccurate and overly broad messaging around COVID-19 vaccines](#). How has this affected

childhood vaccination rates during the pandemic and how will it affect childhood vaccination rates in the future?

Mental Health

The combined effects of increased social isolation, loss of safety net services traditionally delivered in schools for young people, increased screen time, decreased addiction and therapeutic services, loss of access to religion and social events, and increased anxiety due to the pandemic and/or pandemic policies, have had a devastating toll on the mental health of Americans, including [increased](#) anxiety, depression, substance abuse and suicidal ideation. Young people and older people have suffered disproportionately due to imposed isolation.

- › Why were mental health and addiction services suspended without considering potential consequences of service removal?
- › Why were activities and sports for low-risk young people suspended without considering the harms of isolation and lack of physical activity?
- › Why were known harms of increased screen time for young people ignored?
- › Why was poor availability of mental health services not taken into account when imposing isolation on children, young adults and the elderly?
- › During the pandemic, why were there so few attempts to measure mental health parameters that are more sensitive than suicidality and suicide?
- › How will we evaluate and compare short- and long-term mental health and longevity of people in low versus high lockdown areas?
- › Anxiety and depression [increased](#) during the 2020 lockdowns. [CDC data](#) show that, in 2021, 37% of American high school students reported experiencing poor mental health during the COVID-19 pandemic, and 44% reported they persistently felt sad or hopeless during the past year compared to 36.7% in 2019. Why did public health authorities not consider such adverse effects? What is now being done to address and treat this problem?
- › There have been substantial [increases](#) in substance abuse during the pandemic, with especially devastating impacts on [underserved communities](#). How much did social isolation, unemployment, and termination or online only availability of support groups such as Alcoholics Anonymous contribute to this?
- › Eating disorders [increased during lockdowns, at least through the end of 2021](#). Why were treatment centers for eating disorders closed or virtual only for so long in many states? What are CDC and state health departments doing to alleviate this problem?

Homicides and Domestic Violence

In the United States, the overall crime rate decreased during the first lockdown spring of 2020. Homicides later stayed constant or in some cities rose precipitously while [domestic violence](#) increased.

- › What proportion of these positive and negative changes were attributable to psychosocial and economic stresses of lockdowns, versus other factors such as social unrest or economic factors?

Physical Activity

General health and physical activity is important for the immune system's ability to fight off infections, including COVID-19. Obesity is an important risk factor for COVID-19 mortality. [Multiple studies](#) have shown that physical activity and fitness decreased significantly during the pandemic including in [children and young adults](#). Conversely, studies have demonstrated [improved COVID-19 outcomes with activity](#) for any given risk cohort. The prevalence of type 2 diabetes increased during the pandemic. Estimates of increase in Type 2 diabetes [among children are as high as 182%](#) during the first year of the pandemic, disproportionately affecting Black youth.

- › Why were people discouraged from going outside to exercise?
- › Why were beaches, basketball courts, playgrounds, and similar venues closed, preventing people from exercising and socializing in low-risk environments?
- › Why were many gyms closed by local and state governments?
- › Why were sports programs for children terminated?
- › In children ages 2-19, the [rate of BMI increase approximately doubled](#) during the pandemic compared to the pre pandemic period. What are the long term consequences on childhood obesity and diabetes? Was this taken into account when local governments restricted physical activity?
- › As of March of 2021, 42% of adults [reported gaining weight](#) during the pandemic with an average weight gain of 29 lbs. What are the long-term consequences on adult obesity, diabetes, cardiovascular disease, etc? Was this taken into account when local governments restricted physical activity?

The Microbiota & Human Immune System

Lockdowns and other social distancing measures not only affected COVID-19, but also other viruses and infectious diseases. Young children [need to be exposed to viruses](#) in order to build up the immune system that will protect them for the rest of their lives.

- › What effect did the lockdowns have on children's immune systems and long term ability to fight off a variety of diseases?
- › The pandemic and media messaging increased use of disinfectants. What consequences does this have on our microbiota? Has it led to more gut dysbiosis (a reduction in microbial diversity)?

- › Gut dysbiosis is linked to an [increased risk](#) of viral hepatitis. Did use of disinfectants during the pandemic do more good than harm? Are there efforts underway at NIH to find out?

Excess Deaths

A fundamental principle of public health is concern about all aspects of health and not only a single disease. Total excess deaths is therefore an important metric when evaluating the pandemic response.

- › Between April of 2020 and December of 2021, excess deaths not due to COVID-19 [exceeded](#) excess deaths due to COVID-19 (29,000 vs 20,000) for ages 18-44. Why were more concerted efforts not made to anticipate and prevent non-COVID-19 excess deaths?
- › The US had around [170,000](#) excess non-COVID-19 deaths through 2021 while countries with fewer restrictions such as Sweden and Denmark had negative excess deaths during the same time period. Why did the United States focus almost exclusively on COVID-19, while Scandinavia took a more balanced approach that considered all aspects of public health? Why did most media outlets seek to discredit Sweden in 2020 for following fundamental principles of public health, leading to one of the lowest excess mortality rates in the world when measured cumulatively from the start of the pandemic until 2022?
- › According to [CDC data](#), there were more than 200,000 additional American deaths at home in 2020 and more than 250,000 additional deaths at home in 2021 (provisional) compared to 2019, even while hospice deaths dropped in those years versus 2019. This can be compared to only ~19,000 COVID-19 deaths at home in 2020. What caused all these additional home deaths? How could they have been avoided?

Business Closures & Unemployment

Our pandemic response [created economic problems](#), and public health is [intrinsically linked](#) to the economy. As people rise out of poverty their health improves, both in the short and long term. When people fall into poverty, the opposite occurs. The collateral economic harms from pandemic restrictions are of course much wider than the public health aspects discussed below, and such harms should be taken equally seriously. But, that is outside of our public health expertise and the scope of this report.

- › After staying at or below 4% throughout 2018, 2019, and early 2020, [U.S. unemployment](#) rose to 15% in April 2020. It gradually declined thereafter, taking until the last month of 2021 to dip below 4% again. Pre-pandemic studies show that unemployment is linked to [increased mortality in men](#). One [study](#) estimates a 6% increased mortality risk for each percentage point increase in unemployment. Did lockdown-induced rise in unemployment increase mortality in 2020 and 2021? Does this explain some of the excess mortality seen among Americans below the age of 65?

- › The number of women working outside the home has steadily increased over the past decades but declined during lockdowns. Some politicians who have long championed better childcare options for working parents suddenly supported closing childcare centers and schools and leaving parents scrambling. [Women](#) disproportionately provided the necessary childcare at home. How has this affected the short- and long-term economic situation for working mothers and their families? How has it affected the mental and social health of women? How has this affected women's career advancement and salary trajectories?
- › Lockdowns forced many small businesses to close permanently. How did this affect the health and well-being of small business owners and their employees? When small businesses were forced to close, much of their business was taken over by large corporations that were allowed to operate when small businesses couldn't. Why were larger businesses provided this competitive advantage? Can this be reversed? If not, what are the long-term health consequences of having fewer small businesses?
- › In 2020, one pro-lockdown argument was that it was more important to save lives than to save the economy. However, a healthy economy is important for public health, especially among lower income populations. Did this view prevail because the people making it were mostly work-from-home professionals, who themselves did not suffer economically?

Housing

Many people who lost their jobs were evicted from their homes when they were no longer able to pay rent. Some people were protected by eviction moratoria.

- › To what extent did lockdown related home evictions or eviction moratoria exacerbate or alleviate this problem? How many Americans were evicted from their homes because of COVID-19 restrictions? How many older Americans, some of whom rely on rental income, were harmed by eviction moratoria?
- › Together with university closures, were house evictions one of the primary drivers of increased multi-generational living during the pandemic? How much did this increase COVID-19 mortality for older high-risk people?
- › In March 2020, the CARES Act [temporarily prohibited](#) landlords of federally subsidized housing units from evicting tenants for failure to pay rent during the pandemic, protecting about 25% of tenants. In September 2020, the CDC issued an [agency order](#) preventing COVID-19 related evictions. Some states implemented further prohibitions on evictions. How many people were protected by these policies? How many were able to catch up with rent, and how many were eventually evicted? How many landlords suffered economic hardship as a result?
- › How much did increased addiction contribute to increased homelessness?

Food Insecurity

Food insecurity [increased](#) during lockdowns, especially among families with children. With closed schools, some children lost their best source of nutritious food. In fall 2020, media outlets were full of images of [thousands of people waiting in line for food](#) in many states.

- › Did those implementing COVID-19 restrictions consider the fact that some people would not have enough food to eat because of lockdowns? Were there sufficient state and local remediation efforts to ensure that no American would go hungry and how well did they work?
- › Some school programs alleviated problems by supplying food pick-up for children in need, to be picked up by parents or other caregivers. How successful were these programs? What proportion of children in need did they reach? How many schools and districts delivered food to homes and at what cost?

Cultural & Sports Activities

Art, music, dance, theater, museums, libraries, food festivals, county fairs, sports, and other cultural activities are important for mental, emotional and social health and well-being.

- › Were the importance of cultural and religious activities considered when closing them?
- › How many children were deprived of cultural and athletic activities?
- › With a few notable exceptions, why were professionals working in cultural organizations not more outspoken against the closure of cultural activities? What long-term effects will these closures have on culture and society?
- › How many arts organizations closed their doors during the period when live performances were not allowed? What efforts are being made to revive them?

Religious Gatherings

During the pandemic, governments prevented churches, mosques, synagogues, and temples from in-person gatherings for religious worship. These closures had profound consequences on society from a multitude of perspectives. To stay within the scope of this report, we cover its public health consequences.

- › For many people, religious and spiritual activities are important for their mental health, whether it is partaking in mass at their church or doing yoga with a group of friends. To what extent did closing religious institutions and preventing spiritual activities contribute to increases in the nation's mental health problems? How can religious organizations step in and help us recover?
- › Religious gatherings provide spiritual support as well as critical community support for emotional, mental and physical health. Why were religious gatherings closed down when many have no alternatives for social and spiritual support?
- › Many religious institutions provide essential services such as funerals and weddings. Marriage can also increase family income. How will we measure

whether social bonds that help society function were weakened in the long-term by failing to observe such rituals?

The Environment

A healthy environment is important for long term public health and well-being.

- › With work-from-home orders, [less car traffic](#) reduced street congestion and [air pollution](#) in cities in 2020. What benefits did this have on asthma and other respiratory conditions? Are there ways to achieve similar improvements in air quality without pandemic lockdowns?
- › Did mask requirements, COVID-19 fears, and public transit restrictions push people from public transportation to increased car use? In the long run, will such fear reduce public transit use and increase traffic congestion and air pollution in large cities?
- › The pollution from billions of disposable face masks has harmed [birds](#) and [other wildlife](#). What is being done to mitigate this problem? Are there other negative public health consequences from this environmental damage such as increased microplastics in the environment for humans?
- › Despite no evidence that COVID-19 is spread by fomites, hundreds of millions of people [increased](#) their use of disinfectants. What are the environmental effects of increased disinfectant exposures?

Community-Wide Suppression

The World Health Organization's October 2019 publication "[Non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza](#)" stated that *"home quarantine of exposed individuals to reduce transmission is not recommended because there is no obvious rationale for this measure, and there would be considerable difficulties in implementing it."*

In a Johns Hopkins document, "[Preparedness for a High-Impact Respiratory Pathogen Pandemic](#)", the authors stated in September 2019 that *"In the context of a high-impact respiratory pathogen, quarantine may be the least likely NPI to be effective in controlling the spread due to high transmissibility."* They also stated that *"During an emergency, it should be expected that implementation of some NPIs, such as travel restrictions and quarantine, might be pursued for social or political purposes by political leaders, rather than pursued because of public health evidence."*

On January 24, 2020, NIH/NIAID Director Dr. Anthony Fauci [told reporters](#), *"That's something that I don't think we could possibly do in the United States, I can't imagine shutting down New York or Los Angeles, but the judgement on the part of the Chinese health authorities is that given the fact that it's spreading throughout the provinces...it's their judgement that this is something that in fact is going to help in containing it. Whether or not it does or does not is really open to question because historically when you shut things down it doesn't have a major effect."*

- › Why did Dr. Fauci later change his positions to become a [proponent](#) of school closures and other pandemic restrictions?
- › On March 21, 2020, Dr. Michael Osterholm, Director of the Center for Infectious Disease Research and Policy, and subsequent COVID-19 advisor to President Biden, advocated against lockdowns and for focused protection in an [Op-Ed published by the Washington Post](#). Why did he later [advocate for lockdowns](#) in the New York Times while [criticizing](#) focused protection?
- › In March 2020, more than 800 epidemiologists and other medical professionals [sent a letter to Vice President Pence](#), warning that *“Mandatory quarantine, regional lockdowns, and travel bans have been used to address the risk of COVID-19 in the US and abroad. But they are difficult to implement, can undermine public trust, have large societal costs and, importantly, disproportionately affect the most vulnerable segments in our communities.”* Why did the Vice President and other government officials ignore this letter?
- › Why did some public health scientists reverse previous positions when federal and state governments implemented lockdowns in the spring of 2020, while others did not? One example was changing levels of evidence expected for safety and efficacy of COVID-19 vaccines depending on which administration was in the White House.
- › In October 2020, tens of thousands of scientists and medical professionals signed the [Great Barrington Declaration](#), advocating for focused protection instead of school closures and other lockdown measures. Why did the NIH director attempt to [reduce](#) support for this document rather than encourage debate at a time when debate was critical?
- › Why did some highly influential public health scientists believe that SARS-CoV-2 could be permanently suppressed or eradicated when epidemiologic history did not support this conclusion?
- › Community-wide efforts can partially and temporarily suppress community spread, prolonging the length of the pandemic and, therefore, prolonging the period of time that older vulnerable people must isolate to protect themselves. Why did the CDC and state health departments not consider fatigue when advocating for community suppression rather than focused protection? How many additional COVID-19 deaths resulted from this failure?

CHAPTER 5

PUBLIC HEALTH DATA & RISK COMMUNICATION

- ›
- › Incidence and Hospitalizations
- › Seroprevalence
- › COVID-19 Case Definitions
- › COVID-19 Comorbidities
- › Infection Fatality Rate
- › Risk Communication
- › Long COVID
- › Data Sharing

Background

Disease surveillance is a primary duty of public health agencies, to monitor the spread, prevalence, and seriousness of diseases in different geographical regions and population groups. This task includes gathering and disseminating basic information about incidence, hospitalizations, mortality, infection-fatality rates, sero-prevalence/antibodies, T-cell immunity, vaccinations, vaccine efficacy, vaccine adverse events, variants, and other parameters. Such knowledge lays the foundation for public health recommendations. Without reliable disease surveillance data, public health agencies, politicians, scientists and the public are operating blindly. For influenza, salmonella, e.coli and dozens of other infectious diseases, the CDC has reliable disease surveillance systems in place. For COVID-19, there was a profound lack of reliable and unbiased data, even after the first few confusing months of the pandemic. The lack of accurate data persists to this day.

Incidence and Hospitalizations

Incidence refers to the number of new cases of a disease in a specified time period.

- › For COVID-19, the CDC relied on its influenza-like illness surveillance system as a main data source for respiratory illness identification. This led to underestimation of SARS-CoV-2 transmission because it didn't count asymptomatic or mildly symptomatic individuals. Why were COVID-specific surveillance systems not quickly put in place by the CDC to monitor spread?
- › Why was the CDC unable to accurately record hospitalizations due to COVID-19? Why is there still no consistent system in place to separate actual COVID-19 hospitalizations, due to COVID-19, from incidental COVID-19 hospitalizations that are due to some other condition in people who also happened to have either asymptomatic or mildly symptomatic COVID-19?

Seroprevalence

To understand transmission and severity of COVID-19, we must know how many people have already been infected. If 100 people were infected, 100 sought health care and 10 died, mortality is high and contact tracing is both feasible and important. If 100,000 people were infected, 100 sought health care and 10 died, mortality is low and contact tracing is futile. A seroprevalence survey tests a selection of representative people to determine how many people have developed antibodies to the virus, by age-group and geographical regions over time. Public health agencies in other countries, such as [Spain](#) and [Sweden](#), quickly conducted such surveys. The United States had to rely on small local surveys such as one done by Stanford University in [Santa Clara County, California](#).

- › In early 2020, it was critical to quickly estimate disease prevalence. Why did the CDC fail to conduct seroprevalence surveys in key communities?
- › Why did the CDC not conduct a national seroprevalence survey using a random sample from different regions and age-groups, continuously updated by week or month?
- › The CDC [did conduct a national seroprevalence study](#) in February 2022. Why was it not done earlier?

COVID-19 Case Definitions

COVID-19 hospitalizations and deaths and associated comorbidities are important statistics for policy considerations. However, throughout the pandemic, these statistics were not consistently reported by the CDC. For a virus who clinical manifestation ranges from asymptomatic or mildly symptomatic to fatal, the percent of reported COVID-19 hospitalizations and deaths that were due to COVID-19 versus with COVID-19 should be separated out, i.e., when a patient was hospitalized or died due to another cause after testing positive for COVID-19. Over time, incidental COVID-19 positive cases were magnified by PCR testing, which is highly sensitive for the presence of viral genome, and by increasingly contagious variants. The more contagious and ubiquitous the variant, the more likely a COVID positive patient was hospitalized for an unrelated reason. By mid-late 2021, some U.S. hospitals reported that the majority of COVID-19 patients in their hospitals were hospitalized with COVID-19 as an incidental diagnosis. One [audit](#) of death data in Alameda County, CA, found that 25% of COVID-19 deaths reported were not due to COVID. Most concerning, the CDC has not reported accurate data on COVID-19 deaths in young people. A review of the [WONDER](#) database for Underlying Cause of Death (UCoD) and Multiple Cause of Death (MCoD) through December 2021 indicates that the vast majority of reported pediatric COVID-19 deaths were in children with other serious conditions.

- › Why did the CDC or other federal agencies not conduct random surveys to determine the proportion of reported COVID-19 deaths that were due to COVID-19 as the primary cause of death versus deaths with COVID-19 that were unrelated to the virus?
- › COVID-19 mortality is very low in children. While every pediatric death from any cause is a unique tragedy, collecting data on which children are at risk would have been invaluable to parents and policy makers. Why did the CDC not conduct a complete evaluation of every child with a reported COVID-19 death, to determine how many were actually due to COVID-19 and what comorbidities those children had? Why did they ignore [suggestions](#) to do so?
- › [FluNet data analysis](#) indicates that COVID-19 presents a lower level of risk than influenza does for children under 12. Why was this information not incorporated into recommendations and policies?

COVID-19 Comorbidities

While age is the most important risk factor for COVID-19 hospitalization and death, it is important to know about other risk factors in order to more precisely define the vulnerable population and provide advice about modifiable risk factors. This is true for both adults and children.

- › Why did the CDC or NIH not immediately conduct or fund large studies to evaluate the effects of comorbidities on COVID-19 mortality?
- › Knowing that general health is important to fight off infections, and with obesity as a major risk-factor, why did the CDC and state health officials not encourage healthier eating and more exercise, instead of closing both outdoor and indoor recreational spaces?
- › When more detailed [data appeared](#) on COVID-19 comorbidities from other sources, why did the CDC not use these data to create better focused protection strategies for high-risk populations?
- › When CDC Director Rochelle Walensky was asked how many of the approximately 300 pediatric COVID-19 deaths in the U.S. at the time had a medical comorbidity, she was unable to answer. Why didn't the CDC collect or provide comorbidity data for all 300 COVID-19 deaths in children? Did most of these deaths occur in children with severe comorbidities, such as leukemia or kidney disease?
- › COVID-19 comorbidity information can inform a targeted approach rather than subjecting healthy children to the mental and physical health consequences of educational loss, reduced physical activity, and profound social isolation. Why did the CDC recommend severe restrictions on the lives of more than 50 million children in the U.S., rather than collecting and utilizing data needed to craft appropriate recommendations to protect higher-risk children specifically?

Infection Fatality Rate

The infection fatality rate (IFR) is the risk that an infected person will die from a disease. Since not all infected persons are diagnosed, it is different from the case fatality rate (CFR), which is the risk of dying among those that have been diagnosed with the disease. The latter changes over time depending on the amount of testing done. During the beginning of the pandemic, public health officials and scientists [conflated](#) these two basic epidemiological concepts.

- › To accurately estimate an IFR, it is necessary to have accurate cause-of-death data but the CDC reports included deaths with an incidental COVID-19 infection. Why did the CDC consistently provide inaccurate IFR estimates?
- › The IFR is often given as a single number, even though there can be more than a thousandfold difference in IFR depending on age. Since different states and countries can have very different age structures, combined IFRs cannot be compared between different geographical regions. In light of this, why did scientists and the media continuously emphasize a single national number?

Risk Communication

Without accurate data, assessment of risk and perception of risk by the public was misleading, and national surveys showed that public perception of COVID-19 infection fatality rate was [wildly](#) inaccurate. Young people, particularly, [thought that their risk of COVID-19 mortality was much higher](#) than their actual risk, while some older people underestimated their mortality risk.

- › Why was public perception of hospitalization and mortality risk due to COVID-19 so different from the actual risk?
- › What actions, if any, did CDC take to help the public better and more accurately understand COVID-19 risk?
- › Why did public health officials not continuously update their risk figures as the population gained immunity, which caused risk to decrease over time?
- › How did the CDC and State Health Departments communicate about other risk factors for COVID-19 mortality, such as general health, obesity, and being immunocompromised?
- › One risk factor is obesity, [especially in those under the age of 60](#). Would accurate and unapologetic communication of this risk have improved vaccine uptake before the Delta wave hit the Sun Belt in 2021? No other region has such high obesity rates and no other region suffered as large a Delta wave.
- › A long-established public health principle is to combat excess fear among the public. Yet, on March 29, 2021, after vaccines were widely available to vulnerable populations, CDC Director Rochelle Walensky [spoke to the nation](#) about her *“feeling of impending doom”*. Were the CDC and State Health Departments using fear to drive behavior change, in contradiction with most established public health principles?
- › As the experiences and observations of most Americans became dissonant with stated CDC statistics, there was an increasing loss of trust in CDC and public health officials. When parts of the public realize that the communicated risks are overblown, there can be a counter reaction where they dismiss any risk at all. Has this contributed to suboptimal vaccine uptake in high-risk individuals? Did some older high-risk Americans not take necessary precautions to avoid being infected? Will this affect how the public responds to future health crises?

Long COVID

For infectious diseases, there can be long term consequences lasting beyond the infection period. This phenomenon has received wide public attention during the pandemic, with widespread concerns about “long COVID”. It is important to understand potential long term effects after COVID-19 infection. So far, we lack robust [scientific evidence that it is more common after COVID-19](#) than after other infectious diseases.

- › Why is long-COVID-19 of greater concern than e.g., “long influenza” or “long norovirus disease”? [Is it a distinct clinical entity](#)? In February 2021, [NIH allocated 1.15 billion dollars](#) in funding for long COVID-19 research over a four year period.

Is this a reasonable amount? Historically, how much has NIH spent on research concerning long term effects after other infectious diseases?

Data Sharing

Federal and state agencies, including the CDC, failed to merge real-time Medicare and Medicaid data and state vaccination data. Failure to do so impeded population-wide analyses on natural immunity, comorbidity risk factors for COVID-19 death and hospitalization, and the study of vaccine adverse reactions.

- › Why were data not readily shared between different federal agencies such as CDC, FDA, Medicare and Medicaid?
- › While states had the most accurate vaccination data, Medicare and Medicaid had accurate clinical outcome data. Why were such data and collection strategies not shared between agencies to better evaluate vaccine uptake, efficacy, and safety? Combining such data could have saved lives and enabled a wiser vaccine rollout strategy between December 2020 and April 2021, when many Americans were dying each day because they could not get vaccinated in time.
- › Furthermore, ignoring population and large institutional data on infection acquired immunity also resulted in the redundant immunization of many people who were already protected from severe outcomes while high-risk unvaccinated seniors died waiting for a vaccine. How many Americans died because of this?

CHAPTER 6

EPIDEMIOLOGIC MODELING



- › Infectious Disease Forecasts
- › Pandemic Concepts and Parameters
- › Modeling Collateral Lockdown Damage

Background

Throughout the pandemic, policy makers from local levels (county and state health officials, school boards, and governors) to national and federal levels such as CDC directors and White House officials, relied on modeling to guide decisions. Public health has a long history of using epidemiologic models for a variety of purposes: (i) To gain understanding of infectious disease dynamics, (ii) to predict future health care needs to ensure sufficient capacity, and (iii) to fill in for missing real world data. When using models to make public-health policy decisions, it is crucial that politicians, policy makers, and public health officials clearly understand data weaknesses, underlying assumptions used to generate models and forecasts, the nature of input parameters, and uncertainties inherent in any model.

At the outset, models from the Institute of Health Metrics and Evaluation at the University of Washington (IHME) and Imperial College in London, as well as models generated by the [CDC](#), were influential both locally and nationally. These models tried to forecast COVID-19 cases, hospitalizations, and deaths under different pandemic lockdown strategies, by modeling the effects on COVID-19 from school closures, public gathering restrictions, suspension of health care services, business closures, limiting restaurant capacity, quarantining people, travel restrictions, and mass asymptomatic testing. Mask models were used as support for mask mandates and models assuming that vaccination halted transmission were used when approving, recommending and mandating vaccines.

Infectious Disease Forecasts

Models used to forecast infectious disease cases, hospitalizations, and deaths are complex, with arcane assumptions built into mathematical formulas. These models are sensitive to assumptions about input parameters that violate real-world conditions. Assumptions and limitations are not always understood by the ultimate consumers of the model, including policy makers. It is important to conduct sensitivity analyses, because if model parameters are overly reliant on specific inputs, this greatly limits their usefulness and predictive ability at forecasting using real-world data, which tend to be messy and variable.

In March 2020, professor Neil Ferguson and colleagues at Imperial College [published](#) alarming COVID-19 mortality forecasts. At the same time professor Sunetra Gupta, an infectious disease epidemiologist at Oxford University, [suggested](#) that various scenarios of spread were compatible with available COVID-19 data. The Gupta model highlighted three key sources of uncertainty in these forecast models: (1) the date of initial seeding of the virus in populations; (2) the inherent infectivity of the virus; and (3) the infection fatality rate. These sources of uncertainty are related, meaning that a virus with both high

infectivity and high infection fatality rate is highly unlikely. Gupta and colleagues called for these uncertainties to be resolved before policy makers relied heavily on these models to craft policy.

- › Why did world leaders overly rely on models that made unverified assumptions about the pandemic's trajectory rather than trying to verify these assumptions and their implications? Did politicians and public health officials understand inherent limitations in epidemiologic COVID-19 models?
- › [While technical](#) aspects of modeling are complex, it is important to understand that any model, in order to make accurate predictions, must be based on accurate data on initial disease prevalence in the population. Why did the CDC not conduct seroprevalence surveys? Why did policy makers assume that Chinese reports about initial disease spread, released in December 2019, were accurate? Published in the fall of 2020, antibody detection assays in [Italy](#) and [France](#) indicated a late summer 2019 spread. Why were these data not factored into subsequent models?
- › Once it became obvious it would be very difficult to limit COVID transmission in the general community, why didn't policy makers prioritize models focusing on the age gradient in risk?
- › Why were the most influential models from IHME, Imperial College, and CDC, only accompanied by limited sensitivity analyses, instead of by an extensive evaluation with many different possible input parameters? Were experts with relevant knowledge included in discussions of model parameters?
- › Why didn't more modelers speak up about the difficulty of accurately predicting COVID-19 cases, hospitalizations, and deaths? Did epidemiological disease modelers sufficiently explain inherent model limitations to politicians and other consumers?
- › Websites to enable open-source modeling exist and are critical to promote transparency and peer-review of model assumptions. Were influential models, particularly at the state level, critiqued transparently?
- › Around 15 years ago, to prepare for a potential pandemic NIH launched the [Models of Infectious Disease Agent Study](#) (MIDAS), funding a network of more than one hundred infectious disease modelers, including Neil Ferguson and six of his colleagues at Imperial College. Considering how poorly their models performed at predicting the behavior of the COVID-19 pandemic, will NIH continue to fund MIDAS?
- › After forecasting models failed for COVID-19, the CDC launched the [Center for Forecasting and outbreak Analysis](#) (CFA). How does CFA plan to avoid repeating the modeling failures during the pandemic?
- › Why did some states and governors [rely on local models to shut down](#) schools and businesses when those models were not vetted or made transparent and the model creators did not necessarily have experience in epidemiological modeling?

- › Why did many models appear to ignore aspects of human nature, such as the desire to gather?
- › Did models consider the disparate impacts that lockdowns would have on different socioeconomic groups?

Pandemic Concepts and Parameters

Epidemiological models are important for estimating pandemic parameters such as infection fatality rate, case fatality rate, person-to-person transmission, and reproductive number.

- › In 2020, health agencies and the media [confused the case fatality rate \(CFR\) with the infection fatality rate \(IFR\)](#). The former is the risk of death among known cases. The latter is the risk of death if infected, which, in the case of SARS-CoV2, is much lower since many cases are asymptomatic or mild and go undetected by health officials. Why was there confusion about these basic epidemiological concepts? Why did the CDC and NIH not clarify this misunderstanding? How did confusing the two concepts drive panic in the general population?
- › Studying transmission on the Diamond Princess cruise ship demonstrated that the asymptomatic [transmission rate](#) was around 18%. Furthermore, data collected on the Diamond Princess cruise ship [suggested age stratification of severe disease](#). While the exact numbers are debatable, as they have been adjusted by reported Chinese data, the IFR from this outbreak was significantly lower than initial calculations from the WHO, and should have raised questions about the high IFR used to instigate restrictions such as school closures. Were policy makers aware of these data and of the major age-stratified risk from COVID-19?

Modeling Collateral Lockdown Damage

Nearly all the modeling efforts used by public health officials during the pandemic focused on predicting COVID-19-related parameters, such as trajectories of cases, hospitalizations, and COVID-19-related mortality, as well as on predicting effects of non-pharmaceutical interventions such as masking and distancing in schools. However, public health measures had a broad range of collateral consequences beyond COVID-19, such as learning loss from closed schools, worsening mental health from fewer social contacts, canceled cultural events and religious services, more substance use and weight gain due to isolation and depression, and worse cancer outcomes from delayed cancer screenings and missed cancer treatments, to name a few.

- › Why did public health scientists develop models to forecast COVID-19 but not to forecast health and economic outcomes resulting from collateral damage due to non-pharmaceutical interventions?
- › Why did public health authorities accept models forecasting health consequences from COVID-19, without insisting on models also forecasting collateral public health damage due to pandemic mitigations?

CHAPTER 7

THERAPEUTICS AND CLINICAL INTERVENTIONS

- › Exploring Potential COVID-19 Treatments
- › Clinical Guidelines
- › Mechanical Ventilators
- › Anticoagulation Therapy
- › Monoclonal Antibodies
- › Convalescent Plasma
- › Remdesivir
- › Fluvoxamine (Luvox)
- › Paxlovid (Nirmatrelvir)
- › Dexamethasone (Decadron)
- › Budesonide (Pulmicort) and Other Inhaled Steroids
- › Hydroxychloroquine
- › Ivermectin

Background

Since it quickly became evident that SARS-CoV2 spread rapidly and could not be eradicated, it was critically important to promptly find treatments to minimize mortality and reduce hospitalizations. Because developing new pharmaceutical drugs from scratch is a lengthy and expensive process, it was important to quickly evaluate existing drugs to see if they could be repurposed as COVID-19 treatments. In addition, the clinical medicine community urgently needed data and guidance concerning costs and benefits of proposed and widely used treatments.

The NIH rapidly initiated preclinical and clinical trials to evaluate hundreds of new and repurposed drugs for potential antiviral effects. The difficulty of this task may explain why there are few drugs to treat COVID-19. Even to treat influenza, which is not a novel virus, there are few effective approved antiviral drugs.

Below we discuss the most notable drugs and interventions, and those that were most widely used. We also address issues surrounding data collection timeliness, information dissemination, drug accessibility, and politicization of certain therapeutics.

Exploring Potential COVID-19 Treatments

By April 2020, NIH had launched the [Accelerating COVID-19 Therapeutic Interventions and Vaccines \(ACTIV\)](#) partnership between US and European health agencies and pharmaceutical companies in order to evaluate hundreds of existing [drugs](#) as potential COVID-19 treatments. These drugs spanned a variety of classes, including immune modulators, monoclonal and polyclonal antibodies, and blood thinners. These studies were also used to inform [vaccine development](#). Later, other drug classes such as antidepressants and antiparasitic drugs were included for study as potential therapies.

- › Hundreds or even thousands of drugs must be evaluated to find a few that may work. By nature, most drugs evaluated will fail, but studies of failed drugs still provide important data. How many drugs were evaluated in pre-clinical *in-vitro* and *in-vivo* animal studies?
- › How many preclinical studies were sufficiently promising to be promoted to evaluation in humans? How many progressed to a randomized clinical trial?
- › How was this information disseminated to the larger scientific community?
- › Was the US-Europe-industry collaboration smooth and effective? Did other countries, in Asia, Africa or Latin America, also engage in this type of work?
- › Data mining of electronic health records can be used to explore potential treatments, by comparing outcomes among COVID-19 patients who happen to be

on existing drugs for other reasons. To what extent were such data and methods utilized?

Clinical Guidelines

With limited knowledge and weak or no evidence about efficacy of existing drugs against COVID-19, physicians had to make treatment decisions in the absence of complete knowledge. This information void led to many controversies and disagreements among doctors, between patients and their doctors, and between the public and health authorities as to best practices for treating COVID-19. Even as post-vaccination infections mounted in the summer of 2021, trials to evaluate existing medications with unresolved potential for efficacy were not accelerated and some, even today, remain incomplete.

- › In early 2020, what clinical guidance, if any, did we glean from Asia and Europe, where the virus was spreading before reaching North America?
- › Many randomized trials were quickly funded and conducted by NIH and others. Were these study results disseminated to practicing clinicians and if so by what means?
- › At times, individual doctors and hospitals were left without solid guidance as to how to treat COVID-19 patients at various stages of illness. Who was responsible for assembling and updating best practice clinical guidelines? The CDC, NIH, FDA, the American Medical Association, the American College of Physicians, or leading academic hospitals? Who, if anybody, stepped up to the plate to support floundering front line doctors?

Mechanical Ventilators

Mechanical ventilation with intubation can be a life-saving intervention. However, during prolonged use, as occurred for many COVID-19 patients, it is associated with serious and potentially life-threatening complications. By February 2020, physicians in countries such as [Hong Kong](#) and [China](#) argued for the benefits of early intubation to reduce virus aerosolization. However, [by March 2020](#), clinicians actively treating COVID-19, across multiple countries, [concurred](#) that the rush to mechanical ventilation needed to be rethought. By June 2020, many were [urging](#) providers not to routinely intubate COVID-19 patients, citing [emerging data](#) that [non-invasive](#) methods [were](#) no more [aerosolizing](#) than [mechanical ventilation](#).

- › Was there sufficient evidence for providers to implement an invasive medical intervention to treat COVID-19 patients? Should there have been a randomized trial to evaluate the benefits versus risks of ventilating patients?
- › Did the CDC, NIH, or a medical society convene an expert panel to discuss the matter? Were there policy makers on the COVID-19 task force or at the CDC with [clinical experience treating](#) COVID-19 patients that could advise on this matter?
- › In March 2020, the federal government [invoked](#) the Defense Production Act to force General Motors to produce more ventilators. At the same time, the New York State and City governments [demanded](#) more ventilators, even though current

supply was not exhausted, claiming that *‘without a ventilator, doctors cannot save lives’*. Did government officials ask for clinical evidence to support this intervention? If not, why not? Physicians in New York [stated](#) that they intubated patients early to “control the spread”. How many patients were intubated in New York City in March/April 2020 and what were their outcomes stratified by age and comorbidities? Could rapid gathering of such data have ended the practice earlier?

Anticoagulation Therapy

Anticoagulants such as heparin and apixaban are used as blood thinners to treat and prevent blood clots. Heparin is on the WHO list of essential medicines. Early on in the pandemic, there was an [increase in use of anticoagulants](#) in COVID-19 patients after [observing](#) that some patients developed blood clots in their lungs (pulmonary emboli) and/or deep peripheral veins (deep venous thrombi). However, while anticoagulation therapy can save lives in patients with blood clots, they can also have dangerous effects when used on patients that do not need them.

- › In 2020, some care-providers were starting potentially dangerous anticoagulant treatments on patients without blood clots. Were doctors considering the dangers of these drugs when they prescribed them for COVID-19? How were significant and complex clinical controversies around COVID-19 treatment, which required coordination of prescriptions, blood draws, and laboratory tests, addressed and resolved? Should the CDC, NIH, medical associations and/or the FDA have provided clinical guidance about using these medications for COVID-19 patients? If not, whose job was it to disseminate best-practices data and address clinical gray areas around treatment?

Monoclonal Antibodies

For more than 20 years, monoclonal antibodies (mAbs) have been used to mitigate the severity of viral infections such as [Respiratory Syncytial Virus \(RSV\)](#). Various [monoclonal preparations](#) have been effective against COVID-19, [mitigating the severity of disease](#) in both primary and vaccine-breakthrough infections. The FDA approved the first mAb treatments for COVID-19 in November 2020.

- › As one of the few proven early treatments for COVID-19, should the federal government have invested more resources to increase the supply of monoclonal antibodies? Should state governments have invested more resources to increase the distribution, awareness, and availability of this treatment? Did lack of funding or resources primarily harm poor and working-class Americans with inferior access to medical care?
- › During the Delta wave that spread through the Sun Belt in the summer of 2021, the federal government [curtailed shipments](#) of mAbs to southern states, preventing many Americans from receiving this life saving medical treatment. By the time the northern states had their 2021/22 seasonal winter surge, Omicron had largely displaced Delta, for which the same mAbs were of little use. How many Americans died because they were unable to obtain mAbs? How many mAb treatments went

unused because they were not needed in the locations to which they had been allocated?

- › Currently, mAbs are only [authorized](#) for use in patients with mild-to-moderate COVID-19, but not in hospitalized patients. Are there data supporting this guideline?

Convalescent Plasma

In contrast to monoclonal antibodies, convalescent plasma contains “polyclonal antibodies” obtained from individuals who have recovered from a COVID-19 infection. The FDA issued an emergency use authorization in August 2020, which is ongoing with several subsequent [modifications](#).

- › The [largest RCT](#), from India in October 2020, did not demonstrate any benefit from inpatient convalescent plasma treatment. A February 2021 [meta-analysis of ten RCTs](#) also did not show any benefit. [Subsequent RCTs](#) evaluating higher levels of antibodies were also disappointing. Why is there an ongoing EUA for convalescent plasma from the FDA when multiple RCTs have demonstrated no benefit?

Remdesivir

Remdesivir is a patented anti-viral medication made by pharmaceutical company Gilead. On May 1, 2020, FDA [approved](#) its use for treating COVID-19 under an emergency use authorization. It received regular approval on October 22, 2020.

- › The efficacy of Remdesivir for hospitalized COVID-19 patients was evaluated in randomized controlled trials on 158 patients in a [Chinese study](#) (April 29, 2020); on 541 patients in an [NIAID funded](#) study (May 22, 2020); and on 2743 patients in the WHO [Signature Trial \(October 15, 2020\)](#). The Chinese and WHO trials showed no reduction in mortality, while the NIAID trials showed a modest non-statistically-significant reduction in mortality and a modest statistically significant reduction in time to recovery. Considering that the larger Signature Trial did not show a mortality benefit, should the FDA have given [regular approval](#) of Remdesivir for treating COVID-19? Why did the FDA approve Remdesivir without the [customary consulting](#) of their Antimicrobial Drugs Advisory Committee?
- › On October 8, 2022, Gilead signed a billion dollar [contract](#) to supply Remdesivir to the European Union, before the WHO Signature Trial results were publicly released on October 15, [but after Gilead knew the results](#). Why was this contract approved before results were released? Was this process different from usual processes for such contracts?
- › Remdesivir requires continuous daily infusion at roughly [\\$500/day](#). How does this high cost affect the cost-benefit ratio of this treatment?

Fluvoxamine (Luvox)

Fluvoxamine was approved by the FDA in 1994. It is a low toxicity, generic, and low cost medication with decades of use in non-infectious settings, primarily as an antidepressant. It is on the WHO list of essential medicines.

In November 2020, a small [randomized trial](#) showed a statistically significant decrease in progression to severe disease after Fluvoxamine administration compared to placebo (0% versus 8.3%, respectively). In October 2021, a Brazilian [randomized controlled trial](#) showed a statistically significant reduction using the primary endpoint of time in hospital, with varying results for secondary endpoints. However, a [trial](#) evaluating early out-patient use did not find a statistically significant reduction in hypoxemia, emergency department visit, hospitalization, or death.

- › After a December 2021 submission, in May 2022 [the FDA rejected a EUA](#) for Fluvoxamine for early treatment of COVID-19. Considering the positive clinical trial data, why was Fluvoxamine rejected? Was the decision based upon the lack of a known plausible mechanism of action for the anti-inflammatory effects? In contrast, Remdesivir was approved based on a plausible mechanism despite unimpressive clinical trial data. Who decides when to prioritize plausible biological mechanisms instead of clinical endpoints, and on what basis?
- › The NIH is currently funding an [RCT](#) to evaluate Fluvoxamine, to be completed in March 2023. Three years into the pandemic and with most of the population having some form of immunity, should there have been a larger effort to conduct this trial earlier?

Paxlovid (Nirmatrelvir)

Paxlovid is a patented antiviral made by Pfizer that was evaluated in a [randomized controlled trial](#) of *high-risk unvaccinated* patients during the Delta variant period (EPIC-HR). When started within 3 days of symptom onset, it reduced hospitalization or death with an absolute risk reduction of 6.3% and a relative risk reduction of 89%. There was [no reduction in household transmission](#). It was authorized in December 2021 for treatment of mild-to-moderate disease in patients 12 years of age and older (who weigh at least 40 kg) and who are at high risk for progression to severe COVID-19.

A [subsequent RCT](#) in *vaccinated and other low-risk patients* (EPIC-SR) was terminated early by Pfizer as there was no statistically significant evidence of benefit. However, several [subsequent retrospective cohort studies](#) (not RCTs) showed a benefit in vaccinated patients and/or those with natural immunity, specifically older cohorts.

- › Despite the negative trial result for the EPIC-SR RCT, Pfizer [contended](#) that there was a trend towards disease reduction in these populations. Considering this trend, why did Pfizer not continue the trial to resolve this important question? Will there be an RCT to evaluate Paxlovid in low-risk populations?
- › Should Paxlovid have been authorized to treat lower risk and/or vaccinated patients before randomized trial data were available showing efficacy? Considering that by mid-2022, 95% of Americans had a [prior COVID-19 infection](#), should this cohort have been evaluated in earlier trials? Should Paxlovid be

available for 12-17 year olds since this age group has not been included in any study?

- › The CDC's [definition](#) of an underlying health condition that exacerbates risk for severe disease is extremely broad, including mental health conditions, pregnancy, and being a former or current smoker. Will there be further evaluation to determine which specific groups benefit from taking Paxlovid, particularly for young people?
- › How many Paxlovid doses have been prescribed for low-risk patients despite lack of evidence of effectiveness?
- › In October 2022, why did White House COVID-19 coordinator Ashish Jha use a low-quality unadjusted [observational study](#) to [promote](#) Paxlovid for use in vaccinated patients and patients with infection-acquired immunity?
- › "[Viral rebound](#)" occurs in about 2-5% of [patients](#), with some studies showing [less](#) or [more](#). Is viral rebound taken into account when creating guidelines for Paxlovid use? In a May 2022 [report](#), the CDC did not advise further Paxlovid courses after rebound. What contributed to this decision?
- › In April 2022, at a cost of \$530 per treatment course, the Federal Government [purchased](#) 20 million courses of Paxlovid from Pfizer, at a total cost of around \$10 billion. How did the US government assess the need for this drug, given that most older high-risk Americans had already been vaccinated or recovered from the disease by then? Was this investment cost effective?

Dexamethasone (Decadron)

Dexamethasone is a generic drug on the WHO list of essential medicines. In 2020, UK researchers conducted the large randomized [RECOVERY Trial](#), showing that dexamethasone improved survival of hospitalized patients. It is widely used in the US to [treat](#) very severe COVID illness.

A US [randomized trial](#), however, did not find a difference in hospitalized patients receiving dexamethasone plus remdesivir versus baricitinib plus remdesivir. An [observational study](#) of hospital patients not receiving supplemental oxygen found increased mortality after receiving dexamethasone, which could be an accurate finding or an artifact due to more serious COVID-19 patients being more likely to receive dexamethasone.

- › Considering the wide use of dexamethasone in treating hospitalized COVID patients, should there have been a large randomized-trial of dexamethasone to determine for whom the drug was effective and safe?
- › Is dexamethasone helpful in outpatients and/or patients with less severe COVID-19 patients? Should there have been randomized trials of effectiveness of dexamethasone in a wider range of patients, such as in [outpatients with moderate illness](#)?

Budesonide (Pulmicort) and Other Inhaled Steroids

Early reports from Italy noted that patients with chronic respiratory illness were under-represented among hospitalized COVID-19 patients. Some investigators hypothesized that use of chronic inhaled steroids such as budesonide, common in this population, may be protective against COVID. Budesonide was developed in the 1970s and is on the WHO list of essential medicines.

Several countries, including [Spain](#), [Argentina](#), and the [UK](#), ran trials in 2020 to evaluate budesonide treatment in hospitalized patients as well as in the [outpatient setting](#). These early trials showed a decrease in disease progression for both populations. However, an outpatient RCT (part of ACTIV-6) conducted in the US during the Delta and Omicron waves and after vaccination was available, found that the generic inhaled steroid, Fluticasone, did not significantly reduce time to recovery in [interim results](#).

- › In the early days of the pandemic, did clinicians understand the potential benefits of starting inhaled steroids early in disease? How were the budesonide results disseminated to American clinicians?
- › Trials conducted in populations with high immunity, through vaccination or prior infection, such as the Fluticasone ACTIV-6 trial, are going to yield very different results than trials conducted in immune naive populations. Should there have been studies of budesonide and/or other inhaled steroids earlier in the pandemic?

Hydroxychloroquine

Hydroxychloroquine is an anti-malarial drug that can also be used to treat arthritis and lupus. It is on the WHO list of essential medicines, and its safety profile is well known. In March 2020, the FDA granted emergency use [authorization](#) of the drug to treat hospitalized COVID-19 patients. However, that approval was [revoked in](#) June 2020.

In June 2020, an NIH [RCT](#) of hydroxychloroquine was halted early after concluding that the drug was safe but ineffective for hospitalized COVID-19 patients. In October 2020, the larger WHO [Solidarity Trial](#) also showed that hydroxychloroquine does not benefit hospitalized COVID-19 patients if given during their hospitalization. In February 2021, an evidence-based [Cochrane Review](#) of these and other RCTs concluded that hydroxychloroquine had *'little or no effect on the risk of death'* for hospitalized COVID-19 patients. A [meta analysis](#) of randomized trials found hydroxychloroquine to cause increased mortality in hospitalized patients with COVID-19. Globally, many other [trials](#) were [conducted](#) which [produced](#) negative [results](#) in patients both in the hospital and outpatient settings. An important medical question was studied in a timely manner and hydroxychloroquine is no longer used to treat hospitalized COVID-19 patients.

- › What was the rationale for the March 2020 FDA approval? What were the key factors leading to the rapid gathering of RCT evidence? How was this information disseminated to the public and medical community?
- › In 2020, some physicians [promoted](#) early outpatient hydroxychloroquine treatment for mild to medium severe COVID-19 to prevent hospitalization and subsequent mortality. This was based on [retrospective](#) studies, prospective observational studies and larger case series. Observational studies generally suffer from confounding differences between the treatment and control group making

definitive conclusions more difficult than with randomized studies. For case series, one cannot know whether the high survival rate is due to the treatment or to a low infection mortality rate. Was it appropriate to promote the outpatient use of hydroxychloroquine without high quality RCT evidence?

Ivermectin

Approved [by the FDA in 1996](#), ivermectin is an anti-parasitic drug that is on the WHO list of essential medicines. In 2020, it was proposed as a potential drug for COVID.

A systematic review published in June 2020 showed ivermectin to be effective against several viruses in [in vitro](#) experiments using cultured cells, including SARS-CoV2. A few smaller human [trials](#) published in 2021-2022 showed [faster](#) SARS-CoV2 viral clearance in patients taking ivermectin compared to a placebo, but clinical endpoints were unaffected or not measured.

In July 2021, an evidence-based [Cochrane Review](#) used available RCTs to conclude that ‘based on the current very low- to low-certainty evidence,’ they were “uncertain about the efficacy and safety of ivermectin used to treat or prevent COVID-19. The completed studies were “small and few are considered high quality.”

The largest RCT on ivermectin as an early outpatient treatment against COVID-19 is the Brazilian [Together Trial](#). It was published in March 2022 and found ivermectin to be safe but with a statistically insignificant mortality reduction.

Another [systematic review and meta-analysis](#) of 19 RCTs published in June 2022 reached similar conclusions: that “ivermectin did not have any significant effect on outcomes of COVID-19 patients.” The authors failed to identify a benefit against severe disease, recovery time, or viral load or clearance but found, based on low certainty, that it may reduce mortality. Published in August 2022, another [RCT](#) conducted in the US found that the early treatment with ivermectin was safe but did not provide a statistically significant reduction in hypoxia, emergency visits, hospitalization, or death. Similar results were found in an NIH funded [ACTIV-6 RCT](#) published in late 2022 which evaluated both [low](#) and [high](#) dosing.

- › Considering the *in vitro* plausibility, early positive clinical data, and the politicization and controversy surrounding ivermectin, should there have been a large randomized controlled trial in early 2020 to evaluate whether ivermectin reduces COVID-19 mortality for hospital and/or outpatient use?
- › The NIH concluded their high dose ACTIV-6 ivermectin trial nearly 3 years into the pandemic when there was already a high (>95%) level of immunity from either prior infection or vaccination. Were these trials completed in a timely manner?
- › Because of the controversy and [repeated warnings from the CDC](#), [NIH](#) and [FDA](#) on the dangers of taking ivermectin, physicians were hesitant to prescribe it and pharmacies were hesitant to dispense it. However, ivermectin is a useful and safe drug to treat diseases and conditions such as ascariasis, head lice, lymphatic filariasis, river blindness, scabies, strongyloidiasis, and trichuriasis. Were Americans denied appropriate use of ivermectin for these conditions because of

controversies surrounding ivermectin for COVID-19? Were side effects of ivermectin of COVID-19 exaggerated by some media outlets and some health providers?

CHAPTER 8

VACCINES

- › Randomized Vaccine Trials in Adults
- › Vaccine Prioritization and Distribution
- › Vaccine Safety
- › Vaccines and COVID-19 Transmission
- › Vaccine Mandates and Passports
- › Randomized Vaccine Trials in Children
- › Vaccine Safety in Children
- › Effects on Confidence in Other Vaccines
- › Waning Vaccine Efficacy and Boosters

Background

COVID-19 vaccines were developed and given emergency use authorization (EUA) in record time. In late 2020, the Food and Drug Administration (FDA) granted EUA to three COVID-19 vaccines for adults: Pfizer (2 doses), Moderna (2 doses) and Johnson & Johnson (1 dose). Subsequently, the Pfizer and Moderna vaccines also received EUA approval for use in children as young as 6 months of age. Pfizer, Moderna and Johnson & Johnson boosters were also approved. Federal, state, and local governments, as well as many companies, hospitals, restaurants, universities, and a few K-12 school systems, imposed vaccine mandates for work, business, education, travel and cultural events. As of December 2022, only vaccinated visitors can enter the USA.

Vaccination policies were some of the most divisive elements of the pandemic, engendering protests at various times and termination of employment for some professions or government employees over their refusal to get vaccinated. Because mandates were initially based on the assumption that vaccines were capable of halting transmission, it is important to delve into the trials in detail.

Randomized Vaccine Trials in Adults

The [Pfizer randomized trial](#) showed 95% efficacy against symptomatic COVID-19 infection, the trial's primary endpoint. The [Moderna randomized trial](#) showed 94% efficacy against symptomatic COVID-19 infection, that trial's primary endpoint. The [Johnson & Johnson randomized trial](#) showed 67% efficacy against moderate or severe COVID-19 infection, the trial's primary endpoint, and 67% efficacy against any symptomatic infection, a secondary endpoint.

Despite roughly 37,000, 28,000 and 40,000 participants, respectively, only 5% of patients were in the >75 age group, the group at highest risk for a severe outcome due to age. Thus, none of the Pfizer, Moderna or the Johnson & Johnson trials were sufficiently powered to evaluate efficacy against hospitalization and death, and none could determine efficacy against transmission.

While the trial designs allowed rapid deployment to the public, the limitations in knowledge they produced— particularly about absolute risk reduction for hospitalization and death, vaccine adverse reactions, and about the fact that trials did not study whether vaccines limited transmission – were not clearly conveyed to the public.

- › Should pharmaceutical companies have designed trials using COVID-19 death and/or COVID-19 hospitalizations as primary end points? Why were more older patients not enrolled in order to achieve that?

- › Who was responsible for conveying uncertainty about the trials in terms of benefits against hospitalization, death, transmission and long-term effectiveness? The manufacturers, the FDA, the CDC, or all of them?
- › As of November 2022, the CDC [website](#) states that vaccines are “effective at protecting people from getting seriously ill, being hospitalized, and dying”, but does not mention that the presented data about the current benefit was based on observational data rather than randomized clinical trial data, which had [not been updated](#) since [2021](#). Observational data is very likely to be confounded by differences in underlying health between vaccinated and unvaccinated. Why does the CDC’s messaging not contain nuance around these issues and why are they not transparent about the limitations in our knowledge when relying on non-randomized data?
- › If the follow up period had been longer in the randomized trials, robust risk benefit analysis could have been performed and stratified for different age groups and among those with and without infection-acquired immunity. Why were the trials terminated after a short period of follow up for young and middle-aged adults?
- › In the Pfizer trial, 567 patients in the placebo group and 526 in the treatment arms had evidence of prior COVID-19 infection. In each arm, there was only 1 reinfection (or <0.2% for both), according to the primary endpoint definition ([Table 8](#) page 27), which was roughly 5 times less than symptomatic infection in the placebo arm (n=164/17720 or 0.9%) for those without evidence of prior infection. Why wasn’t this low rate of reinfection in both the treatment and placebo arms acknowledged in vaccine recommendations? Why did the CDC not make it clear to the public that previously infected people, per Pfizer’s own RCT, demonstrated a much lower risk of reinfection? Would official acknowledgement of these data have decreased the push to require low risk individuals to be vaccinated in work and school settings?
- › Why was a longer and larger randomized trial not performed to assess the benefits and risks of the booster for young adults, when there was no longer an emergency? [One observational study](#) found an unfavorable risk-benefit analysis for use of boosters in adults 18-29. Why were the FDA and CDC not more transparent and concerned about unfavorable risk-benefit analysis in young adults, especially when it became clear vaccines did not stop transmission?
- › The Moderna trial included [prespecified](#) secondary endpoints of asymptomatic infections and seroconversion but did not report any seroconversion results in their initial publication in [December of 2020](#). In November of 2021, results [were published](#) demonstrating only 63% efficacy against asymptomatic PCR-confirmed infection by the end of the study period and 59% efficacy against seroconversion (or asymptomatic infection detected) at day 57 ([Supplement Table S28](#)). As a prespecified endpoint, the latter information should have been available at the time of publication in December of 2020. Why did the FDA allow Moderna not to disclose these seroconversion data? Why was it not communicated better to the public that vaccine efficacy at the time of initial publication against symptomatic and asymptomatic PCR positive infections together was less than 90%? Whose responsibility is it to communicate these results to the public? Should the FDA have

demanded data on seroprevalence in the initial trial results, given that Moderna specified seroprevalence as a primary endpoint?

- › Why did the FDA remain silent on these results while vaccine mandates and vaccine passports were supported by the government, leading to many Americans losing their jobs [and health-care staff shortages during the Delta and Omicron waves of 2021](#)?
- › Why were Pfizer's trial protocol criteria for documenting an infection so different from how infections were documented in many Western countries, including the United States? Specifically, "evidence of infection" in the Pfizer trial pooled two different methods for determining SARS-CoV-2 positivity (PCR and anti-nucleocapsid). Doing so could significantly overestimate vaccine efficacy due to the lower rate of anti-nucleocapsid conversion in vaccine recipients when compared to placebo. This is because people who are infected but vaccinated are less likely to develop evidence of seroconversion (by producing anti-nucleocapsid antibodies) than those who are unvaccinated. Specifically [NIH and Moderna researchers noted that 93% of placebo recipients generated measurable anti-nucleocapsid antibodies, while only 40% of vaccine recipients did so](#). Did the use of anti-nucleocapsid conversion for evidence of infection underestimate infections in the vaccine recipient cohort?
- › In early 2022, [Christine Stabell Benn et al.](#) published pooled clinical trial results showing a reduction in all-cause mortality for the adenovirus-based vaccines (J&J, AstraZeneca, and Sputnik) but not for the mRNA vaccines (Pfizer and Moderna). Why did the FDA not do these pooled analyses in 2021? Considering these results, is it possible that some people could have benefited more from receiving a different, non-mRNA, vaccine?
- › Why did pharmaceutical companies not design trials to evaluate all-cause mortality? If older participants had been enrolled or if the trial had lasted longer, randomized studies could have helped determine if there were all-cause mortality and COVID-19-specific mortality benefits from vaccination with mRNA vaccines. Why did the FDA not insist on having trials with the above-mentioned endpoints? Why did the FDA instead accept symptomatic disease as an endpoint?
- › Vaccines were developed and approved in record time. What contributed to this remarkable accomplishment?
- › The Pfizer and Moderna randomized trials ended after [less than 6 months](#) when those who had received the placebo were offered vaccination. This meant there was no randomized information on long term efficacy and adverse reactions. An argument can be made for ending the trial for older high-risk participants, but why was this time-frame selected for younger participants with low mortality risk?
- › Why were only three vaccines available in the United States in 2020 and 2021? Why did other vaccine manufacturers not submit applications and/or receive FDA approval?
- › Why was the Johnson & Johnson vaccine paused for central venous sinus thrombosis for all ages when the risk-benefit ratio was [clearly most unfavorable](#) for

women under 50? Why were there no similar pauses or suspension due to Pfizer- and Moderna-associated myocarditis in young males?

- › In September of 2022, a [study](#) used data from the Pfizer and Moderna randomized trials to show an excess serious adverse event rate post Pfizer of 1/990 and post Moderna of 1/662 compared with controls who received placebo. Why was a study such as this performed by independent scientists and not requested by the FDA or from the manufacturers in 2020 or 2021? Why were individual level data, which were requested by the authors not [made public](#) by the FDA, Pfizer or Moderna? Why was an age-gradient risk-benefit analysis not performed?
- › There were [early indications](#) that prior infection provided significant protection against reinfection and [even more robust protection](#) against future severe disease. Why, in all age groups and demographics, did the FDA and the CDC assume that the benefits of two doses of vaccine in previously infected people would exceed the potential risks of vaccine adverse reactions?
- › For previously infected people, why were no randomized trials done with sufficient sample size, and thus power, to assess vaccine efficacy against severe disease? Without evidence from such a trial, why were previously infected individuals told to get vaccinated?

Vaccine Prioritization and Distribution

Some states prioritized older highest-risk adults for early vaccination in the winter and spring of 2021, when vaccines were in short supply, together with health care workers. In other states, a large number of young adults got vaccinated through their employers while those over 65 years had difficulty getting vaccinated.

- › Why were many younger low-risk adults given the vaccine before high-risk older adults? Did this cause unnecessary deaths, and if so, how many?
- › The [United Kingdom](#) and other [European countries](#) implemented strict risk-based vaccine prioritization. By contrast, the CDC [prioritized](#) young health care workers with or without natural immunity before Americans over the age of 75, who had the same priority as frontline essential non-healthcare workers of all ages, such as store clerks, teachers and transit workers. What led some states, such as Florida and Texas, to [reject the CDC guidelines](#) and instead prioritize by age?
- › In April and May 2021, Michigan had a regional COVID-19 spike while COVID-19 was on the seasonal decline in most other states. The [federal government](#) refused to send additional vaccine doses and resources to Michigan during this regional emergency. Why did they not send vaccines where they were most acutely needed? How many people died because of this?
- › US states have different seasonal patterns for COVID-19 disease, with the north having a large winter peak while the south has both a winter and a summer peak. Should seasonal patterns have been taken into account for timing vaccine dose distribution for different states?

- › People [who have recovered](#) from COVID-19 infection [already have excellent immunity](#). Why were they given the same vaccine priority as those without immunity? How many people died unnecessarily because those with natural immunity got the vaccine before susceptible older Americans with high mortality risk?
- › With a global vaccine shortage throughout 2021, young adults in first world countries were vaccinated before much higher risk elderly in low- and middle-income nations. Was this public health policy appropriate given disease risk gradient by age, with over a thousand-fold difference in the mortality risk between old and the young? Why did universities in the United States mandate vaccines for students while millions of older high-risk adults in the developing world desperately needed the vaccine? Globally, how many [excess deaths](#) were caused by such policies?

Vaccine Safety

When a drug or vaccine is approved, there is often not enough safety data from clinical trials to provide data about potentially rare adverse reactions or even common adverse reactions in specific subpopulations. In the United States, there are several post-market vaccine safety surveillance systems run by the CDC and FDA. The three most important are (i) CDC's [Vaccine Safety Datalink](#) (VSD), which uses electronic health records from integrated health systems such as Kaiser Permanente and Health Partners, (ii) the FDA [Biologics Effectiveness and Safety System](#) (BEST), which uses health insurance claim data and Medicare data, and (iii) the [Vaccine Adverse Event Reporting System](#) (VAERS), run jointly by CDC and FDA, which uses spontaneous reports from the public and health care providers about potential or suspicious adverse reactions. Pharmaceutical companies are legally obligated to report any adverse reactions to the VAERS system, so pharmaceutical companies should not have data above and beyond the data recorded in VAERS.

The purpose of these vaccine safety systems is not only to detect and report vaccine safety problems but to demonstrate to the public when vaccines are safe. If relevant analyses are withheld, the public does not know if the vaccines are safe or not.

- › Not all VAERS reports are causal, as there will be some adverse events after vaccination simply due to chance. The raw unanalyzed VAERS data is publicly available, and it has been widely used by vaccine critics to publicize adverse events that may or may not be causal or occurring at a rate which is higher than expected in the absence of the vaccine. Along with the raw data, why did the CDC and FDA not publish the VAERS analyses they routinely conduct to help determine if the observed adverse events are more than one would expect by chance?
- › Because VSD data are based on electronic health records, have well-defined denominators for total number vaccinated, and contain other relevant health information, VSD data are higher quality than VAERS data. A September 2021 [VSD report](#) for mRNA vaccines showed good safety for many outcomes. When specific concerns about COVID-19 vaccine safety arose among the public, why

were there not more reports from the VSD system to either refute or confirm those concerns?

- › Why have there been so few public reports on COVID-19 vaccine safety using the FDA BEST system?
- › In April 2021, there were reports of blood clots after the J&J vaccine, primarily among women under 50. There were no reports among anyone above 50. Despite this, CDC paused the vaccine for everyone, including the high-risk older people for whom the vaccine is most important. The pause led to a sharp decline in J&J vaccinations at a time when vaccines were still in short supply. How many older people died because of this pause? How did the pause affect hard to reach populations, such as rural residents and the homeless, for which one-dose vaccines may have advantages over two-dose vaccines?
- › A vaccine scientist with expertise in the early evaluation of safety data objected publicly to pausing the J&J vaccine for older Americans (Dr. Martin Kulldorff, who was on the faculty of Harvard Medical School and is one of the authors of this document). After voicing [his concerns](#), he [was fired from the CDC](#) working group on COVID-19 vaccine safety. Who made that decision? Will such terminations affect willingness of other public health scientists to voice their views when those views are [contrary to the views of the CDC](#)?
- › In April/May 2021, Israel [reported](#) an increased risk of myocarditis after the Pfizer vaccine, predominantly in young males after dose 2, putting the risk at somewhere between 1/3000 to 1/6000 for males 16-24. The [first published study](#) to assess subclinical myocarditis following the second dose of Pfizer in adolescent boys 13-18 found a rate of clinical and subclinical myo/pericarditis of 3.5%. VSD data [confirmed excess](#) myocarditis [risk](#), especially after the second dose and boosters. Data from [France](#) and [Nordic countries](#) found post-vaccination myocarditis rates to be 3-4 times higher post-Moderna than post-Pfizer. Why did it take so long for the CDC and FDA to [identify](#) and quantify the myocarditis signal and perform a cost-benefit analysis? On their Biologics License Application (BLA) approval of Moderna, FDA [required](#) a US post-market analysis of myo/pericarditis and subclinical myocarditis to be completed in 2025. Why not sooner or before approval for younger ages? The BLA approval also [required](#) measuring long term consequences of post-vaccination myocarditis in affected individuals.
- › In September of 2021, why were non-stratified data [published](#) in one of the United States premier medical journals, the *New England Journal of Medicine*, which gave a false impression of a very low rate of post-vaccination myocarditis in young males by grouping all ages and both sexes together resulting in an overall rate of 1-5/100,000 vaccinations when we knew from [CDC](#) and [FDA data](#) that the main safety signal was in young males? Why has it not been made well known that the Pfizer-Moderna combination has the [highest rate](#) of post-vaccination myocarditis? Why are many young males still mandated to get vaccine doses, including those who already have immunity from a prior COVID-19 infection?
- › Why were no studies run to look at other co-risk factors for myocarditis, such as previous infection or other risk factors such as exercise following vaccination?

- › Given the [clear relationship](#) in this demographic between myocarditis and the second dose of Pfizer, why was Pfizer not questioned further when they [stated](#) they had not seen a higher than expected rate?
- › In the fall of 2021, [much of Northern Europe](#) placed restrictions on use of Moderna in those under age 30. In the US, why were the mRNA vaccines, or at least the two-dose regimen, not paused or suspended in males <30, to perform a thorough risk-benefit analysis and to determine if spacing doses, omitting the second dose, or using lower doses could minimize harm? Why was there no discussion of preferentially giving Johnson & Johnson or other vaccines than Moderna to young males due to increased risk of myocarditis?
- › In the summer of 2021, the FDA [reported](#) that they saw a “signal” of a potential increase in heart problems after the mRNA vaccines. Why was this presented in a press release without any actual data? Why were there no timely follow-up reports to determine whether this was a causal relationship or not?
- › The FDA BEST system has [reported](#) safety signals for acute myocarditis/pericarditis, myocardial infarction, Bell’s Palsy, pulmonary embolism and immune thrombocytopenia after mRNA vaccines. Have these risks been formally communicated to the public?

Vaccines and COVID-19 Transmission

The randomized controlled vaccine trials did not evaluate the ability of the vaccines to reduce or prevent transmission.

- › Why did Pfizer, Moderna and Johnson & Johnson not evaluate transmission as part of their vaccine trials?
- › In 2021, without supporting evidence, the [CDC claimed](#) that the COVID-19 vaccines “*can keep you from getting and spreading the virus that causes COVID-19.*” Was this messaging deliberate or an honest mistake by the CDC?
- › When the public learns that CDC is making inaccurate claims about COVID-19 vaccines, how does that affect the trust in the benefits of this and other vaccines? How does this affect trust in our public health agencies?
- › Why did it take so long to correct this information? Were CDC officials with knowledge of the shortcomings of the vaccine [afraid to speak](#) against official CDC views?

Vaccine Mandates and Passports

In 2021, universities, hospitals, governments and private employers started requiring proof of vaccination, often firing those who would not or could not comply. The vaccine mandates included people who had infection-acquired immunity, despite [substantial evidence of robust immunity in](#) recovered [persons](#), even [those](#) who [had mild or asymptomatic](#) infections. Furthermore, the vaccine trials did not assess the ability of the vaccine to reduce transmission.

- › Why were mandates pursued without carve-outs for those with immunity due to prior infection? Why were people fired, destroying careers and reducing healthcare capacity?
- › Why were there mandates for low risk working age employees and students?
- › What was the intent of the vaccine mandates? If it was to prevent transmission, why was it not made clear that we did not yet know whether or not the vaccines prevented transmission?
- › Why did many organizations continue with mandates through summer and fall of 2021, despite data demonstrating both waning efficacy of symptomatic infection and reduced long term ability to curb viral spread?
- › Was it appropriate to have vaccine mandates in demographics, such as young students, in which it was not certain that the benefits of the vaccine would outweigh the risk?
- › To what extent have COVID-19 vaccine mandates reduced long term trust and uptake of other vaccines?
- › In August 2022, the [CDC changed its COVID-19 prevention guidelines](#) so that “*vaccinated people now have the same guidance as unvaccinated people*”. What caused this change? Why did it not happen sooner?
- › As of November 2022, the United States continues to demand proof of vaccination from international visitors. What is the rationale for this? How does this affect immigrant families in the United States and the tourism industry?

Randomized Vaccine Trials in Children

Pfizer included 16–17-year-old adolescents as part of its adult trial. For both Pfizer and Moderna vaccines, separate randomized trials were subsequently conducted for 12-15- and 12–17-year-olds respectively, for 5-11 year olds and for children between 6 months and 5 years old. The pediatric trials were small and participants were followed for fewer than 4 months. The Pfizer and Moderna trials were not powered to detect vaccine efficacy against severe disease, nor rare but serious adverse events. There was no assessment of the impacts of the vaccine on viral acquisition or transmission. It thus was impossible to perform a reliable risk benefit analysis for this very low risk population.

Pfizer failed to demonstrate significant efficacy against symptomatic infection (page 53 of [the FDA submission](#)) after either 2 or 3 doses of vaccine in either the 6-month to 2-year olds or in 2-5 year olds. While not statistically significant, the rate of severe disease was [twice as high](#) in vaccinated (0.33%) compared to unvaccinated (0.11%) 2-5 year olds. Moderna found a non-statistically significant [vaccine efficacy \(table 84\)](#) against asymptomatic infection of 4% in children aged six months to two years and 23% in children between two and six years old. Compared to the ~90% efficacy for adults, Moderna has low efficacy against symptomatic infections in children: 50% in children aged six months to two years, and 42% in children between two and six years old. From multiple observational studies in 5-11 year olds, it is clear efficacy against infection wanes quickly, [in a matter of weeks to months](#).

- › Given that healthy children are at such low risk for severe COVID-19 disease, why did the FDA approve these vaccines with such weak evidence on efficacy and little knowledge about potential adverse reactions?
- › For the Pfizer vaccine, should the fact that the point estimate of severe disease was *higher* in the vaccinated arm have been cause for concern or reason for a larger study to look at severe disease as an endpoint?
- › Why did regulators choose the [Emergency Use Authorization \(EUA\)](#) pathway when a child's overall risk of serious disease is [less than that for influenza](#) during an average year?
- › Should randomized vaccine trials in children have been powered and lengthened to evaluate severe disease, waning efficacy, and rare but serious adverse events?
- › Some have argued that the primary purpose of vaccinating children is to protect adults around them. If so, why were the trials not designed to evaluate child-to-adult transmission?
- › Why were children with prior infection not studied separately?
- › Should trials have been designed with stratification, to separately evaluate vaccine efficacy and risk among children with comorbidities who may be at higher risk for severe COVID-19 versus children without any comorbidities?
- › In an [FDA meeting on June 28, 2022](#), Pfizer Vice President for Viral Vaccines Kena Swanson [acknowledged that](#) “there is no established correlate of protection” between antibody levels and protection from disease. Was a surrogate endpoint of antibody titres appropriate for a booster vaccine in children when the risk to children of severe disease after 1 dose, let alone two doses, of mRNA vaccination is incredibly low?
- › There were multiple data points (See **Section G** points 4 & 5, below) in the trials to suggest a possible signal for increased susceptibility to other infections in vaccine recipients in both the Moderna and Pfizer Pediatric trials. With such low risk from COVID-19 in children, why was this signal ignored as it trended to more overall harm than benefit? Is post-authorization surveillance data currently being collected?
- › Has the CDC made attempts to calculate risks vs benefits of each dose of the vaccine in children and adolescents? Using observational data, one [study](#) estimated benefits and risks of vaccination in adolescents stratified by health status and prior infection. It found 2 doses of vaccination to carry more risks than benefits (considering myocarditis risks only) for every adolescent group except non-immune girls with risk factors. Why was this not addressed by the CDC? Why did they not perform or publish their own similar analyses?
- › The recommendations for vaccinating and boosting children against COVID-19 currently vary internationally. Multiple European countries, including [Sweden](#), [Denmark](#), [Norway](#) and [Finland](#) are only recommending fall bivalent booster doses for those over 50-65 years or otherwise considered to belong to a high-risk group.

Denmark [specifically stated](#) in June of 2022 that children (under 18) cannot get vaccinated against COVID-19 unless they have a medical evaluation from a physician who deems it advisable. [Sweden, the UK](#), and [Finland](#) do not routinely recommend vaccination for healthy children under 12. Why is the United States still recommending COVID-19 vaccines, including boosters, for all healthy children 6 months and up?

- › The EMA\ECDC recommended in [a joint statement](#) in September of 2022 that the bivalent booster “be directed as a priority to people who are more at risk of progressing to severe disease” and gave more nuanced guidance than the CDC. Why is the CDC recommending a bivalent booster dose to all children regardless of previous infection or health status? Why does the CDC differ from the EMA\ECDC in this recommendation?
- › Vaccines recommended by the CDC for “routine administration” are [eligible to be covered](#) under the Health Resources & Services Administration, protecting the manufacturers from liability. Did this play a role in the ACIP’s [decision to endorse](#) adding the COVID-19 vaccination to the recommended [vaccine schedule](#)? Was this appropriate without evidence that benefits of additional COVID-19 vaccinations in children outweigh the risks?

Vaccine Safety in Children

For drugs and vaccines with a large absolute risk reduction in mortality, the benefits outweigh the risks even if there is a small risk of serious adverse reactions. Since children have a very small risk for serious COVID-19 outcomes, the absolute risk reduction is, by default, at most very small, and even a small risk for serious adverse reactions can tip the benefit-risk balance against the vaccine. It is therefore critical to have a precise and thorough understanding of COVID-19 vaccine adverse events in children. For concerns about myocarditis in children, see **Section C** above. Here we discuss vaccine safety concerns specific to children.

- › For the Pfizer vaccine, 16-17 years olds were [included](#) in the adult clinical trial, with 76 participants in the treatment arm and 77 in the placebo arm. For 12-15 year olds, a new randomized trial was conducted with [49 and 51 participants](#) respectively, for a total of 125 participants in the treatment arm. In April 2021, Pfizer submitted an [amendment](#) to their application with an additional 1,131 and 1,129 participants respectively. These numbers are less than for many other childhood vaccine trials, and not sufficient for a thorough evaluation of potential adverse events. Considering their very low risk for hospitalization and mortality, why did the FDA approve the Pfizer vaccine for children based on such small numbers?
- › In the [randomized trial](#) for 5-11 year olds, Pfizer enrolled 1,518 children in the treatment arm and 750 in the placebo arm. Were these numbers of participants sufficient for pre-approval evaluation of vaccine safety?
- › In the Pfizer trial, 2/3 of the treatment arm population did not remain in the trial through completion. Why did so many participants in the Pfizer under-5-year-old trial fail to complete the trial? For the 6-month to 23-month age group, there were

3,031 treatment participants in the [Moderna trial](#) and 1,178 treatment participants in the [Pfizer trial](#). For the 2-year-old to under 5-year-old age group, there were 1,761 treatment participants in the Moderna trial and 1,835 treatment participants in the Pfizer trial. Was this a sufficient sample size to answer important questions?

- › Although absolute numbers are too small to reach significance, there were more instances of other respiratory tract infections in the vaccine arm in pediatric mRNA trials. In the [Pfizer](#) 6-month-old to 23-month-old group, there were 5 episodes of RSV bronchiolitis, 2 episodes of pneumonia and an episode of gastroenteritis in the treatment arm. By comparison, there were 3 episodes of RSV bronchiolitis in the placebo arm. In the [Moderna](#) 6-month-old to 23-month-old cohort, there were increased events of croup (1.3% of vaccine recipients and 0.3% of placebo recipients), RSV (0.8% vs 0.5%), and pneumonia (0.2% vs 0%) in trial participants. In the Moderna 6-11 year-old trial, increased rates of respiratory tract infection were noted in the treatment arm. RSV infection was increased (0.3% vs 0%) and other upper respiratory tract infections were increased (3.9% vs 2.5%). Should these events have been investigated as potentially vaccine related?
- › Why was leukopenia, or low white blood cell count, not studied in the pediatric trials despite its [presence \(Supplement: figure S3\)](#) in adult trials? There was at least one case of moderate leukopenia with mild thrombocytopenia with fever in the 2-year-old-to-under-5-year-old Pfizer treatment arm.
- › In the Moderna trial for the 2-5-year-old cohort, fever was reported more frequently after each dose among participants with positive SARS-CoV-2 antibodies at baseline compared to those with negative SARS-CoV-2 status: 13% vs 8% after dose 1 and 21% vs 17% after dose 2. In the [absence of clear benefit against severe disease or infection](#) with no reduction in severe cases even in the absence of a prior infection in the randomized trials, should this have been considered before recommending the vaccine to children with infection-acquired immunity?

Effects on Confidence in Other Vaccines

During the pandemic, vaccinations against [common childhood diseases decreased](#). The purpose of transparent vaccine safety surveillance systems is not only to find vaccine adverse reactions, when they exist, but also to ensure trust in vaccines when they are efficacious and safe. Since the COVID-19 vaccines were approved, we have seen increasing vaccine skepticism and hesitance in the population.

- › How much of the reduction in childhood vaccination rates were due to less access to medical care during lockdowns? Did school closures affect vaccine uptake? Was this a temporary effect? What proportion of children were able to catch up with their missed vaccinations after lockdowns lifted and schools reopened?
- › Since excess risk of myocarditis after mRNA vaccines is well established for young men, why was it considered “anti-vaccine” to discuss this adverse reaction to the vaccine, when such evaluations and discussions have been considered “pro vaccine” [for other vaccines](#), such as intussusception after rotavirus vaccines and febrile seizures after measles containing vaccines?

- › What are the public health implications of not being thorough and transparent about known but rare vaccine adverse reactions? Is the [loss of trust](#) in the FDA and CDC partly related to a lack of transparency about COVID-19 vaccine adverse events? To what extent has this led to [potentially deadly decreases](#) in vaccination rates for other childhood vaccinations such as polio and measles? How much of the reduction in childhood vaccination rates is due to increased vaccine hesitancy because of increasing distrust in the medical and public health establishment and lack of full transparency about COVID-19 vaccines? How might this have been prevented or mitigated?
- › How have COVID-19 vaccine mandates and coercion affected trust in and uptake of other vaccines?

Waning Vaccine Efficacy and Boosters

In the summer of 2021, studies showed that vaccine induced immunity was rapidly decreasing. In a study from [Qatar](#), vaccine effectiveness against infection went to 0% after 20-24 weeks. This led to the introduction of booster shots in late 2021. Rather than using randomized trials, boosters were evaluated using observational data, which are confounded because people who choose to get a booster dose will likely have different health status, behaviors, and/or attitudes towards vaccination than those who do not choose to boost.

- › Early information about waning vaccine efficacy came from countries such as [Israel](#) and [Qatar](#). Why did the United States not collect its own data on this in a timely manner?
- › Why did the FDA approve boosters without randomized trials to evaluate the efficacy and safety of COVID-19 booster vaccines? In particular, why were there no randomized booster trials in people under 65, for whom there was no longer an emergency?
- › Using a database of 4.7 million people, an [Israeli study](#) failed to identify any benefit of Pfizer booster doses against hospitalization in people <40. Why were boosters recommended for those under 50 without accompanying data showing efficacy?
- › Why was [evidence](#) of quickly waning vaccine effectiveness against hospitalization not widely communicated to the public until after the bivalent booster was available?
- › Why did the CDC and the FDA not conduct a proper benefit-risk evaluation of boosters in young adults and children? Why was the very low absolute risk reduction against severe disease not considered? An independent [analysis](#) anticipated that for every one COVID-19 hospitalization prevented in previously uninfected young adults <30, there would be more than 18 serious adverse events, including 1.7 to 3.0 booster-associated myocarditis cases in males, and 1,373 to 3,234 cases of grade ≥ 3 reactogenicity (defined as interfering with daily activities). Why did the CDC and the FDA ignore such information? How might risks of myocarditis and other side effects after a booster with an unknown and at most modest benefit erode public trust in vaccines?

- › A Danish household transmission [study](#)⁶ found no difference in secondary transmission rates in boosted vs vaccinated vs unvaccinated people. Why are boosters being mandated by universities, hospitals and other employers, without any proof of lasting efficacy against transmission? Are there harms that might arise from suggesting that boosting will make school and college campuses “safe” without reliable evidence that boosters can reliably prevent infection and transmission?
- › In the [absence of transparent](#) COVID-19 data collected and released in the US, Americans have had to repeatedly look to other countries for reliable information. In an Israeli [study](#) using a head-to-head comparison between boosted vs. non-boosted people, in people under age 30 the risk of COVID-19 death among non-boosted people was zero, the same as in boosted people. In people <40 there was no detected benefit of the booster against severe COVID-19. Considering known adverse reactions, why did the CDC recommend boosters to this age group?
- › When the FDA authorized boosters for young people, on three separate occasions, why did they [bypass](#) the recommendation of their own Vaccines and Related Biological Products Advisory Committee (VRBPAC), consisting of external advisory experts?
- › Recommendations for the bivalent COVID-19 vaccine were based on small sample sizes yet made for everyone “12 and up”. Director Walensky cited the reason for the overly broad recommendation as the need to [“simplify messaging”](#) to the public. Why did the CDC choose this strategy instead of focusing the messaging on the importance of boosters to those truly at risk of infection?
- › Some emerging [data](#) suggest that the monovalent and bivalent boosters elicit similar neutralizing antibody responses against all viral variants. Data from Qatar also show [no difference in severe disease](#) regardless of prior infection and number of vaccine doses, but show [increased susceptibility to infection after boosting](#). Is the CDC tracking this concerning signal for “imprinting”? Is the CDC or NIH conducting or funding any studies on this topic? Why is Qatar but not the United States able to maintain and run robust national data analyses that provide rapid feedback for these types of policy decisions?
- › Multiple European countries, including [Sweden](#), [Denmark](#), [Norway](#) and [Finland](#), now only recommend bivalent booster doses for those over 50 or 65 years old, or those belonging to a high-risk group. The European CDC and European Medicine Agency released a [joint statement](#) saying updated boosters should be “directed as a priority” to those 60 years and older or high risk groups. Why did the US deviate

⁶ See Table S8 in the linked study.

from this and recommend a booster for young healthy people who face very low risks from COVID-19, most of whom have already been infected, when the benefits and risks of the new bivalent vaccine were not known, and no risk-benefit calculation had been performed?

- › While it is the responsibility of the FDA to license a vaccine, recommendations for vaccine use are developed by the ACIP (which advises the CDC). In the [ACIP meeting discussing the bivalent booster recommendations](#), Dr. Sara Oliver stated that, “*It is a PREP Act liability if the ACIP recommendations are different than the [FDA’s] EUA recommendations*”. Rather than providing guidance based on the clinical expertise of its members, did the ACIP recommendations simply mimic the FDA’s EUA recommendations in order to avoid Prep Act Liability⁷, as [alluded to](#) by Dr. Oliver? Did mentioning the PREP Act during the ACIP meeting by Dr. Oliver or others contribute to bivalent booster recommendations that were not nuanced based on age, health conditions or prior infection? Does it affect trust in public health if the CDC is not, or believes they are not, legally able to provide recommendations that are appropriately individualized and nuanced because they are focused on avoiding liability for the vaccine manufacturer?

⁷ “When the Secretary determines that a threat or condition constitutes a present or credible risk of a future public health emergency, the Secretary may issue a [PREP Act declaration](#). The declaration provides immunity from liability (except for willful misconduct) for claims of loss caused by, arising out of, relating to, or resulting from the administration or use of covered countermeasures to diseases, threats and conditions identified in the declaration.”

CHAPTER 9

TESTING & CONTACT TRACING

- › Development, Approval, and Production of COVID-19 Tests
- › Testing in Hospitals and Nursing Homes
- › Mass Asymptomatic Testing of Low-Risk Populations
- › Contact Tracing
- › Testing for Travel
- › Home Testing
- › Polymerase Chain Reaction Test Cycle Thresholds

Background

Testing for SARS-CoV-2 is important for multiple reasons. At the clinical level, when someone has COVID-like symptoms, it is important to find out whether they have COVID-19 or something else, in order to provide effective treatment. To prevent COVID-19 spread, it is important to test hospital and nursing home staff and visitors, so they do not infect frail elderly high-risk individuals. It is also important for disease surveillance and sero-prevalence estimation. This latter topic is covered in Chapter 5 on Public Health Data.

As early as February 2020, public health agencies emphasized testing in combination with contact tracing as interventions to suppress COVID-19 spread. To the extent that this was a policy position, large-scale rapid testing was needed. When it became clear COVID-19 could not be eradicated, testing was still important to guide treatment and to protect those who were at high risk of severe disease. However, testing continued to be used and recommended for the general population, including in very low risk children, without evidence of individual or community-wide benefit from doing so. Positive tests forced children to miss school and adults to miss work without evidence of these strategies effectively decreasing community transmission or benefiting the health of the community.

COVID-19 testing in the U.S. was marked by periods of significant under-testing, over-testing, and socioeconomic inequities in access to testing due to hoarding of tests by wealthy institutions such as elite universities.

Development, Approval, and Production of COVID-19 Tests

Because SARS-CoV-2 was a novel pathogen, COVID-19 tests were not available at the beginning of the pandemic. For the purposes described above, it was important to quickly develop, evaluate, and approve such tests and get them to market.

The SARS-CoV-2 viral genome sequence was made available worldwide on January 10th, 2020. On January 23, 2020, Europe [released](#) the first diagnostic PCR test and rapidly shipped worldwide to 57 countries by the end of February. However, the US declined to use it, [stalling testing](#) here [for around 6 weeks](#). While millions of tests were performed weekly across the developed world, the US had only done 549 tests by February 28, 2020 because the CDC declined PCR “recipes” available from the WHO and China, choosing instead to develop its own test. This led to health-care [facilities](#) facing test shortages. After the CDC developed its own COVID-19 test, the agency [was slow](#) to distribute it to state and local health departments.

While other [countries](#) quickly established working PCR assays to identify the virus in patient samples, after February 4th, when the state of emergency was declared, laboratories in the U.S. were not permitted to replicate these tests. After this date, laboratories were required to gain FDA approval to run tests, severely delaying the ability to identify cases and attempts to limit spread. This is because of a pre-pandemic regulation stating that, in a state of emergency, the FDA regulates who is approved to conduct pathogen testing. This strict [FDA policy](#) slowed development of new PCR tests by university laboratories and commercial vendors.

- › Why did the US decline to use the validated European test when it became available or to use the WHO test?
- › How many health-care facilities lacked sufficient tests? How many suspected positive patients were denied treatment?
- › Why was this FDA regulation not [amended](#)? Why were pathways to deliver testing not smoothed quickly, nor regulatory burdens removed?
- › How many lives of nursing home residents and other elderly high risk could have been saved by more rapid deployment/use/creation of tests during the 6 weeks that the US lagged the rest of the developed world?

Testing in Hospitals and Nursing Homes

Testing staff in hospitals and nursing homes is important to minimize the risk that staff unwittingly infect older frail and other high-risk patients and residents. When tests were in short supply, testing in high-risk populations was not prioritized. Particularly early on, when restrictions on testing had not been lifted, the CDC failed to surge tests to the most high-risk populations such as long-term care patients and their caregivers. Instead, many tests were used on close contacts of patients, even when those contacts were low risk and not in danger of infecting high-risk populations.

- › Why did the CDC fail to roll out to governors and state health departments a testing distribution strategy that prioritized the highest risk populations, older people, long term care patients and their caregivers, and hospital patients? Did sub-optimal use of limited resources result in unnecessary nursing home and long-term care facility deaths?
- › During the spring and summer of 2020, there was limited testing of nursing home staff. Why was that? Was there a shortage of available tests? Were there regional differences in testing availability?
- › In the fall of 2020, testing frequency at nursing homes increased. How did this come about? Where did the resources come from? Could it have happened earlier?

Mass Asymptomatic Testing of Low-Risk Populations

COVID-19 tests have been widely used for mass testing asymptomatic individuals in schools, universities, and workplaces, but there have been very few attempts to measure the efficacy of such testing. One [study](#), conducted prior to the Delta wave in the spring of

2021 and published in April 2022, showed that weekly asymptomatic testing in schools did little to reduce viral spread either in schools or in the community. Several [studies](#) show dwindling sensitivity of antigen tests at recognizing new variants; antigen tests remain particularly inaccurate at detecting infection in the absence of symptoms. Despite this, many schools continued to conduct asymptomatic surveillance testing at the behest of the CDC at enormous great expense of money and staff time, and causing test-positive students and staff and their close contacts to be excluded from school, all without giving adequate consideration to the limitations (false positives or negatives) and downsides of these tests.

- › In light of the above, why did the [CDC](#) stress that mass asymptomatic testing was a vital part of a strategy to reduce viral spread in schools and universities [through August of 2022](#), especially when [numerous European countries](#) had largely abandoned mass testing of children? Was the purpose of continued testing in K-12 schools to reassure parents and teachers that in person learning was “safe” despite a lack of data to support this intervention and without acknowledging the drawbacks of lost school days?
- › Was the continued push for testing of low-risk individuals in the US a result of lobbying from testing companies? Were some of those pushing mass testing financially benefiting from testing companies?
- › Why did most universities insist on testing low-risk asymptomatic students, sometimes as much as three times per week? Did White House officials and CDC officials urge them to do so? Did they do it because of fear of litigation?
- › Why did the CDC or NIH not conduct group randomized trials to determine whether mass asymptomatic testing in schools and universities had any positive effect?
- › Test [accuracy](#) is lower for the omicron variant. Why was/is mass testing still recommended in some places even with decreasing accuracy of the tests?
- › What is the decision-making process that goes into determining when to discontinue a policy such as asymptomatic testing in schools and universities when data supporting its use have not been generated?
- › In late 2021 and early 2022, the CDC issued [broad testing recommendations](#) while there was [a limited testing supply](#). As a result, a testing grab ensued, with wealthier and more powerful communities securing tests for low-risk Americans while poor and minority communities struggled to get tests. Why did the CDC recommend mass testing while COVID-19 tests were in scarce supply? Why was the testing guidance not modified so that the limited number of tests available were rationed wisely?

Contact Tracing

Testing and contact tracing is important for containing many infectious diseases, such as sexually transmitted diseases, but it is ultimately [futile](#) for reducing the spread of respiratory diseases such as influenza or SARS-CoV2 that have an infectious period during an asymptomatic or mildly symptomatic phase. Furthermore, by the time COVID-

19 tests were widely available, the disease was [widespread](#) across the globe, as already [demonstrated](#) in April of 2020, and not amenable to eradication by quarantine. Also, COVID-19 can infect multiple species of animals, making it even more unlikely it could ever be eradicated, even if it had been possible to quarantine all infected humans (which it was not). In 2021, for example, surveillance studies showed that SARS-CoV-2 was present in [white tailed deer](#).

- › Why did federal and state governments spend large amounts of effort and money on futile testing and contact tracing activities? Why were funds not instead prioritized for more important activities, such as increased testing in nursing homes, better ventilation in schools, or ensuring that older high-risk people did not have to work in high-risk occupations such as taxi drivers or store clerks?
- › In early 2021, when the New York City Department of Health [asked Dr. Fauci](#) to divert federal funds from contact tracing to vaccine delivery, what was the reaction from the federal government? How many state and local health departments lacked sufficient resources for vaccine delivery to older high-risk Americans while federal funds were earmarked for contact tracing?

Testing for Travel

Until June 2022, the United States required pre-departure testing for air-travel into the country, and after that, for unvaccinated travelers. The CDC stated that the [policy's goals](#) were to preserve human life; prevent spread and introduction of new variants; keep airline crew, passengers, and personnel safe; and preserve healthcare resources. Notably, domestic airline travel, of which there is significantly more than international travel, required no such testing, nor did international arrivals via land or water.

- › Why did the CDC require testing for international air travel, but not for domestic?
- › Why did the CDC require testing for international arrivals by air, but not by land or sea?
- › In 2015, the [CDC evaluated effectiveness of border entry screening](#) during the SARS1 and H1N1 influenza outbreaks, and concluded that both were heavily resource intensive, unlikely to be successful in preventing entry of disease, and should not be used. Why did the CDC not follow its 2015 conclusions?
- › Rapid antigen tests are not reliable [early during an infection](#), which alone rendered the intervention aimed at a highly transmissible virus futile. Furthermore, the rapid spread of omicron around the world, including in the USA, after its discovery in South Africa in November 2021, at a time when arrival testing was in heavy use internationally, clearly demonstrated that such testing programs were not effective and spread of the variant was inevitable. Nearly all [countries](#) dropped air travel testing requirements before the US did in [June of 2022](#). Why was international pre-departure testing required for so long for entry into the US?
- › Why was so little consideration given to the harms of such a futile intervention, such as the negative impacts on travel and tourism which many cities rely upon for revenue, or the fact that many Americans living abroad were denied the last

opportunity to be with loved ones? Why was a principle so fundamental to public health as Bayes' Theorem ignored, which states that the utility of a diagnostic test dwindles as the likelihood of a tested person being positive decreases?

Home Testing

Home testing has been an effective strategy to enable rapid results when people want to know if they can safely visit an older relative. The medical profession has a long history of resisting home testing, evidenced by resistance to home pregnancy tests for women, which were not available until 1977 despite being developed in the 1920s. Similar resistance delayed the introduction of home HIV tests.

- › The FDA first [authorized](#) a home COVID-19 self-test on Nov. 17, 2020, but at-home tests were not widely available for home and business use [until early 2022](#). During the omicron surge of 2021, test supply did not meet demand. Why did public health officials take so long to embrace home COVID-19 testing and stall in providing tests to the places they were needed most?
- › In the late winter and early spring, when Europe had widespread access to free COVID-19 tests, there was a serious supply shortage in the US through winter of 2021; available tests were expensive and difficult to find, again placing the poor at higher risk of exposure and continuing isolation for the elderly with fewer resources. What were the primary drivers of the shortage?

Polymerase Chain Reaction Test Cycle Thresholds

Nucleic acid amplification tests, such as polymerase chain reaction (PCR) tests, are used to detect the presence of SARS-CoV-2 genetic material in individual samples. However, a positive result does not indicate the presence of live virus or an ability of a positive person to transmit the virus to others. The cycle threshold (Ct) is the number of amplification cycles that are needed to detect viral RNA, with higher values corresponding to lower viral loads. In August, 2020, the FDA [replied](#) to an inquiry that *“it does not specify the cycle threshold ranges used to determine who is positive”*, and that *“commercial manufacturers and laboratories set their own.”* Some laboratories defined samples with a Ct value of 40 as a positive test result.

- › Why did the FDA or CDC not define a national standard to set the PCR cycle threshold?
- › Why did diagnostic laboratories not report Ct values? Should the FDA or hospitals require that it be provided? Why did [CDC guidance](#) state that *“specific Ct values should not be included in a person’s health record or used to influence a person’s individual care”*?
- › Why were testing protocols used by different diagnostic laboratories not made available to scientists and the public?
- › An August 21, 2020 [review](#) by the Center for Evidence-Based Medicine at Oxford concluded that *“lower cycle threshold values may be associated with worse course of illness and outcomes and threshold values may be useful in predicting the*

clinical course and prognosis of patients.” Why did the CDC [assert](#) that “RT-PCR tests are used to identify and diagnose an active infection and cannot be used to show how infectious an individual person is?”

- › In a June 2021 [report](#), only 3% of patient samples with Ct values >35 contained live virus. For Ct >35, the European Center for Disease Control [suggested](#) that PCR testing be repeated to minimize false positive test results and unnecessary quarantines. Why did the CDC or FDA not make such a recommendation? How many American school children, students and workers were subjected to isolation protocols despite not harboring any infectious viruses?
- › Different PCR thresholds should be used for different purposes. For example, for nursing home staff, false negatives are worse than false positives, so it makes sense to use a higher threshold than for asymptomatic school children. Why did the CDC not develop such purpose specific threshold recommendations?

CHAPTER 10

MASKS



- › Randomized Mask Studies
- › Observational Mask Studies
- › Exaggerating Mask Effectiveness
- › Mask Mandates
- › Harms of Masking Children

Background

Public mask use was rare in the United States before the COVID-19 pandemic. On April 3, 2020, the CDC began recommending face coverings, including both cloth and surgical masks, for everyone two years old and up. The CDC cited no evidence for the efficacy of masks and the previous lack of evidence on efficacy of mask wearing for other respiratory viruses was ignored or distorted. During the pandemic, universal and school-masking became increasingly controversial and polarized.

In supporting mask mandates for people ages 2 and up, the CDC and other government officials: 1) Exaggerated the benefits of masks based on pre-pandemic studies, 2) Promoted studies that supported masking recommendations/mandates, while ignoring or censoring those that did not, 3) Did not fund randomized controlled trials to determine the efficacy of masking, 4) Failed to explain why masking recommendations were not aligned with many European countries, especially for children, and 5) Failed to acknowledge potential harms of masking, especially for children.

Randomized Mask Studies

Randomized controlled trials (RCTs) are the gold standard in medical research.

- › Prior to the COVID-19 pandemic, the [evidence](#) that masks did little if anything to stop the spread of respiratory viruses was uncontroversial. A [meta-analysis](#) of 14 randomized controlled trials *“did not find evidence that surgical-type face masks are effective in reducing laboratory-confirmed influenza transmission, either when worn by infected persons (source control) or by persons in the general community to reduce their susceptibility.”* A [Cochrane analysis](#) of nine trials stated that *“the pooled results of randomized trials did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks during seasonal influenza.”* [RCTs](#) conducted in healthcare workers found that surgical masks provided questionable benefit against respiratory pathogens, including the [common cold](#). Another [RCT](#) published in 2010 investigating the use of masks as source control found no difference in infection rates of household contacts between masked and unmasked groups. In light of this research, why did public health officials and agencies promote the idea that masks would be effective against SARS-CoV2? Why did they start recommending and mandating surgical masks to prevent SARS-CoV2 transmission?
- › Few RCTs have evaluated the effectiveness of cloth masks. The results from the first [concluded](#) that *“cloth masks should not be recommended for health care workers”*. If they are not effective for hospital staff, why were they recommended for the public?

- › In March 2021, a research team in Denmark [published](#) the first RCT of mask effectiveness against SARS-CoV2 transmission. To the extent that the study was powered, there was no significant reduction in SARS-CoV2 and other respiratory viral infections for those wearing surgical masks compared to unmasked controls. Why was this study ignored or dismissed by the CDC and other U.S. public health agencies?
- › In August, 2021, a second randomized mask [study](#) was published, eventually appearing in [Science](#). Rural Bangladeshi villagers were randomized to wear cloth masks, surgical masks or no masks. With a p-value slightly below 0.05, masks reduced short-term transmission by between 0% and 18% (95% confidence intervals), suggesting that the masks had marginal or no impact on COVID-19 transmission. A subsequent [reanalysis](#) of the data found an even weaker effect. Why was this study used to justify the continuation of mask policies? Why did mainstream [media outlets](#) exaggerate the [results](#) of this study to claim that masks are highly effective against SARS-CoV-2 transmission?
- › Why did neither CDC nor NIH/NIAID conduct or fund large RCTs to compare transmission rates between masked individuals, households, schools and/or workplaces to unmasked controls groups and to groups wearing different mask types? This would have provided strong evidence as to whether masks prevent viral transmission in different community settings, which masks (if any) were most effective, and whether mask wearing was warranted.

Observational Mask Studies

Observational studies of individuals can provide valuable information when they are well conducted and properly adjust for potential confounders. Non-randomized research studies based on geographically related groups (ecological data) rather than individuals are prone to bias, and more suitable for hypothesis generation than hypothesis evaluation.

- › Before the pandemic, there was not much evidence that cloth masks were effective against respiratory viruses. One [study](#) concluded that *“the use of fabric materials may provide only minimal levels of respiratory protection to a wearer against virus-size submicron aerosol particles (e.g. droplet nuclei). This is partly because fabric materials show only marginal filtration performance against virus-size particles when sealed around the edges. Face seal leakage will further decrease the respiratory protection offered by fabric materials.”* Despite such evidence, why were cloth masks encouraged rather than discouraged as protection against Covid-19?
- › In a May 2020 [paper](#) about masking in hospital settings, Dr. Mike Klompas, a Harvard professor and hospital epidemiologist, wrote that *“we know that wearing a mask outside health care facilities offers little, if any, protection from infection...In many cases, the desire for wide spread masking is a reflexive reaction to anxiety over the pandemic.”* Why did Dr. Anthony Fauci and the CDC come to a different conclusion? Did they recommend and mandate masks to reduce anxiety amongst the public?

- › In July, 2020, CDC published its first [study](#) on mask efficacy against COVID-19. In this study, two hairstylists tested positive for SARS-CoV2 yet did not infect any of their patrons. The authors concluded that the lack of transmission was due to consistent adherence to masking on the part of the hairstylists. However, viral loads were not tested, and in an [early study of household transmission](#), the secondary attack rate was only 19%. Therefore, regardless of masking, there was a low probability of spread and, despite the positive test, it is possible that viral levels were too low to be infectious. Furthermore, this study consisted of a sample size of two and no control group. Why was this report considered strong evidence of mask effectiveness?
- › In January 2021, the CDC published a [study](#) from Wood County, Wisconsin, which found lower transmission rates in schools, where masks were commonly used, compared to the community at large. Despite the lack of a comparative unmasked control group, why did the CDC and the [Secretary of Education](#) use this study as evidence that masks are effective? [Schools in Norway](#) that did not mask students <12 also saw similarly low transmission levels during the same time period. Was the possibility that [children transmit less frequently](#) than adults, rather than mask mandates, considered as an explanation to why schools had relatively low transmission rates?
- › In the summer of 2021, Duke University produced a [report](#) claiming that “*widespread use of masks in schools can effectively prevent COVID-19 transmission*”, which was then promoted by *The New York Times*. The study found that within-school transmission was very low, which the authors concluded was due to universally implemented mask mandates. However, the study had no control group of schools that did not mandate masks. Considering that [Sweden](#) had very low in-school transmission without masking children, a more plausible explanation is that children are [less prone](#) to spread COVID-19 than adults. Why did Duke University and *The New York Times* promote such a fundamentally flawed study?
- › In September 2021, the CDC published a [mask study](#) conducted in Arizona, comparing school districts with and without mask mandates. The study was not randomized and did not control for important confounders such as vaccination rates in the community; it used a longer period of data collection time for masked districts (14% longer); and, it used an inappropriate definition of “outbreak” (2 or more cases in 14 days) that biased numbers against large school districts, of which only 11% had mask mandates, and in favor of small district, of which 52% had mask mandates. Despite its obvious and serious methodological flaws, why did [Dr. Walensky and the media use](#) this study to claim that unmasked districts had higher rates of COVID?
- › A [CDC study](#) published in October, 2021, compared U.S. counties with and without school mask mandates, concluding that masking reduced pediatric infection rates. Such ecological studies are very prone to bias, since both mask mandates and the seasonality of COVID-19 are regional. Therefore, it was not surprising that [a follow up study](#) that used the same methodology as the original study, but simply

extended the study period and included more counties, concluded that masks did not affect pediatric case rates. Why did the CDC publish this heavily flawed study and base public health policy on it? When the extended follow-up study was [published](#), why did CDC ignore it?

- › In November 2021, the British Medical Journal published a [systematic review](#) of observational mask studies conducted during the pandemic. From their meta-analysis, the authors concluded that mask wearing reduced COVID-19 infection by 53%. However, this conclusion was based on six studies with moderate to critical bias because they did not control for variables such as simultaneous changes in behavior, activities, and the use of other mitigation measures. Why were these studies frequently used as support for implementing mask mandates?
- › Ecological studies are slightly better when comparing neighboring districts, such as (i) an earlier CDC study conducted in the fall of 2020 in [Georgia](#) that showed that student masking did not significantly reduce transmission in school, or (ii) a 2022 [study](#) in Fargo, North Dakota, that “*suggests school-based mask mandates have limited to no impact on the case rates of COVID-19 among K-12 students.*” Did the CDC set masking policies based on cherry-picked studies while ignoring others that did not have the desired outcome?
- › The best [observational study](#) of masks in children was published in March 2022. Using a quasi-experimental design, Spanish researchers compared school children aged 6, who were subject to a mask mandate, with children aged 5, for whom masks were not mandated. They found no significant difference in COVID-19 rates and concluded that “*mask mandates in schools were not associated with lower SARS-CoV-2 incidence or transmission, suggesting that this intervention was not effective.*” In April 2022, in another [study](#) looking at mask mandates, in Finland, there was no difference in pediatric case rates between children in communities with and without mask mandates. Why did the CDC ignore these studies?
- › In May 2022, another Duke University [study](#) evaluated whether schools with or without mask mandates had a higher proportion of secondary (school acquired) versus primary (community acquired) COVID infections. The classification of primary versus secondary transmission was conducted by school health staff. Masked school districts, however, did not generally consider masked students to be potential contacts during tracing because of CDC [guidelines](#) which stated that “*the close contact definition excludes students who were between 3 to 6 feet of an infected student if both the infected student and the exposed student(s) correctly and consistently wore well-fitting masks the entire time.*” This would lead to in-school transmission cases in districts with mask mandates being overlooked by contact tracers and incorrectly considered community transmission, giving falsely low rates of secondary transmission in districts with mask requirements. Despite its obvious and serious methodological flaws, why did the NIH [promote](#) this study, claiming that mandatory masking in schools reduced COVID-19 cases?
- › In November 2022, the New England Journal of Medicine published a [study](#) claiming that the lifting of masking requirements was associated with additional

COVID-19 cases. The study compared COVID-19 incidence in two school districts with sustained mask mandates throughout the school year, with 70 school districts that ended mask mandates during the first, second or third week of March, 2022. Districts that ended mask mandates on the second week (n=17) had many more cases than those ending mandates on the first (n=46) or third week (n=7) of March, which in turn had more than the two districts that kept mandates in place (n=2). The difference between the 2nd and 1st/3rd week can only be explained by confounding, and in the presence of such major confounding, no reliable conclusions can be made about the districts with continued mask mandates. While the authors' difference in difference technique can be useful to adjust for covariates that remain constant over time to infer causality, it does not adjust for critical time-varying confounders such as population immunity levels, which have different temporal patterns in different locations in this study. Further, since observations within the same school district are dependent, the statistical analysis should have been done at the district level rather than individual student/staff level. With n=2 city districts still masking and n=70 more suburban districts no longer masking, it was epidemiologically inappropriate to conclusively attribute district case rate differences to a change in mask policy. Why did the journal publish such a [flawed study](#)? Why did [media promote](#) this flawed research study [uncritically](#)?

Exaggerating Mask Effectiveness

In February-March 2020, mask use began to [increase](#) among the general public. Unless they had COVID-19, public health officials were quick to discourage this trend, including CDC Director [Robert Redfield](#), NIH/NIAID Director [Anthony Fauci](#) and the U.S. Surgeon General [Jerome Adams](#). Dr. Anthony Fauci gave the same [advice](#) to close associates in private, saying that *“the typical mask you buy in the drug store is not really effective in keeping out virus, which is small enough to pass through the material.”* In April 2020, the official public health message suddenly changed.

On April 3rd, 2020, CDC [recommended](#) face masks for people who were confirmed or suspected to have COVID-19: *“You should wear a facemask when you are around other people (e.g., sharing a room or vehicle) or pets and before you enter a healthcare provider’s office. If you are not able to wear a facemask (for example, because it causes trouble breathing), then people who live with you should not stay in the same room with you, or they should wear a facemask if they enter your room.”* Why did they make this recommendation without citing any high quality evidence in support of the efficacy of face masks for prevention or transmission of respiratory viral infections?

- › CDC [information](#) guidance provided to healthcare workers continued to contradict recommendations for the general public, for example stating that *“face masks protect the wearer from splashes and sprays.”* while *“respirators, which filter inspired air, offer respiratory protection.”* Why did the CDC recommend surgical and cloth face masks for the [general public](#) while at the same time informing healthcare workers that facemasks do little to filter inspired air or offer protection from respiratory viral infection?

- › On September 17, 2020, CDC director Robert Redfield [said](#) *“I might even go so far as to say that this face mask is more guaranteed to protect me against COVID than when I take a COVID vaccine”*. Why did Dr. Redfield exaggerate the benefits of masks? Why did the CDC Director lower confidence in COVID-19 vaccines before vaccine trial data were even available?
- › Double masking was endorsed by NIH/NIAID Director [Anthony Fauci](#) and CDC Director [Rochelle Walensky](#), presumably based on a single [study](#) published by CDC in March, 2021, in which the authors cautioned that *“the findings of these simulations should neither be generalized to the effectiveness of all medical procedure masks or cloth masks nor interpreted as being representative of the effectiveness of these masks when worn in real-world settings.”* Why did Drs. Fauci and Walensky recommend double masking based only on simulated rather than real-world data?
- › On October 29, 2021, CDC director Rochelle Walensky [stated](#) that *“the evidence is clear”* that masking *“can reduce your chance of infection by more than 80%, whether it’s from the flu, the coronavirus or even just the common cold.”* What evidence did she use to make this conclusion, which appears to greatly exaggerate the benefits of masks?
- › CDC [promoted](#) a 350% reduction in “outbreaks” based on their [flawed](#) Arizona school mask mandate study whereas other positive studies have shown at most a 2% to 25% reduction in transmission rates. Why did health officials continue to cite low quality studies instead of citing the only two randomized COVID mask trials from [Denmark](#) and [Bangladesh](#), both conducted pre-vaccination, which showed zero or minimal efficacy of public mask use against SARS-CoV2?
- › Why were some studies showing masks as not effective at curbing viral spread, such as Cochrane influenza studies, [censored](#)?
- › Did people engage in behavior that increased their chances of contracting the virus because they had a false sense of security that they would be fully protected by masking?

Mask Mandates

In addition to mask recommendations, many governments, schools, universities, and businesses instituted mask mandates.

- › Why did some American schools mandate masks for children two and up, while WHO recommended against masking children under the age 6 and the European Centers for Disease Control [recommended against](#) masks for children 12 and under?
- › Why did Head Start, a federal program serving preschool-age children from low-income families, [maintain a mask requirement longer than any other setting](#)?
- › Why were masks [mandated on public transportation](#) such as buses, trains and airplanes without any scientific studies showing their efficacy in such settings?

- › Were there any discussions about the ethics and wisdom of imposing mask mandates based on weak studies while ignoring higher quality studies showing that masks made little or no difference in COVID-19 spread?
- › When the legality of Connecticut school mask mandates were questioned in court, the State [argued](#) and the Connecticut Supreme Court “wrestled” over whether the legal challenge was moot since the governor had subsequently ended the mandate. Will State Governments continue to attempt to dismiss legal challenges to pandemic restrictions on the grounds that the restrictions are no longer in place?

Harms of Masking Children

Mitigations that limit children’s observations of faces due to masking of teachers and peers [should not](#) be discounted as harmless, [especially in](#) young children and those with special needs. We know from [studies](#) of children who are blind that language and emotional development may be hindered by lack of visual cues, though this may be multifactorial. Without [specific interventions](#), blind children are slower to learn language and emotional fluency unrelated to level of intelligence. Evidence [suggests young children](#) learn [basic emotions and interact with others](#) by focusing on faces. Lip reading and visual cues can be particularly important to [children with developmental challenges](#) in language and speech development.

Seeing faces is crucial for communication in children with hearing loss, who may have [hampered word recognition](#) in settings where people are masked. Children without hearing impairment may also have [reduced word identification](#), particularly in noisy environments when the speaker is masked. Face masks also appear to impair recognition of [emotions](#), trustworthiness and perceived closeness and may “undermine the success of our social interactions.” Another [study](#) found mask use limits the ability to read facially expressed emotions in people of all ages, particularly in 3-5- years-old.

WHO [recommended](#) against masking children ages 5 and younger, because this age group is at low risk of illness, because masks are not “in the overall interest of the child,” and because many children are unable to wear masks properly. Even for children ages 6 to 11, the WHO did not routinely recommend masks, because of the “potential impact of wearing a mask on learning and psychosocial development.”

- › Why did the CDC recommend masks for all children two and up?
- › An Italian [study](#) published in March 2021, found that masking is a barrier to speech recognition, hearing, and communication, and that masks impede children’s ability to decode facial expressions, dampening children’s perceived trustworthiness of faces. Why was this not considered when implementing mask mandates in children?
- › [Research](#) has suggested that hearing-impaired children have difficulty discerning individual sounds; opaque masks, of course, prevent lip-reading. Why were masks frequently used on these children and their teachers?
- › Some teachers, parents, and speech pathologists have reported that masks can make learning difficult for some of America’s most vulnerable children, including

those with cognitive delays, [speech issues](#), and [autism](#). Masks may also hinder language and speech development—especially important for students who do not speak English at home. Why were masks frequently used on these children and their teachers?

- › Masks may [impede emotion recognition](#), even in adults, but particularly in [children](#). When children were asked, many [said](#) that prolonged mask wearing is uncomfortable and that they dislike it. By the summer of 2022, [babies](#) and young children were suffering [developmental delays](#), behavioral issues, and [speaking less](#) which some experts have attributed, at least partially, to mask wearing of children and their teachers. Why were masks used on very young children under the age of five?
- › Mask wearing may cause [physiological harm](#), [including](#) breathing difficulties, headaches, dermatitis, and general discomfort which may have several negative downstream effects, including reduced time and intensity of exercise, additional sick days, reduced learning capacity, and increased anxiety. Were these factors considered when implementing mask mandates?
- › Public health interventions with clear downsides in children were implemented for long periods of time in the absence of high quality evidence such as randomized trials in children. There were also no clear endpoints or metrics given to end mandates. Why were known, expected and potential harms to children from masking not taken into account in the recommendation and implementation process?
- › Children face the least risk of COVID-19 and face the highest risk of harm from prolonged masking. Why were the youngest and most vulnerable children in the Head Start programs, overseen by the Department of Health and Human Services, some of the very [last to be allowed](#) to remove their masks in the Fall of 2022?