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America's response to the COVID-19 pandemic and its misguided strategies failed on many levels. While not to minimize the tragic and unavoidable deaths associated with a pandemic, many formally trusted public health agencies including the CDC, WHO and NIH failed to follow the many years of trusted science.

While the COVID cover-up began in China, COVID chaos continued in the United States. Unchecked government tyranny can never happen again. On many levels even the Rhode Island Department of Health failed to "follow the science". Pseudoscience and unlawfully enacted mandates can never again be imposed on the citizens of Rhode Island. Finally, a pandemic does not preclude the United States Constitution. It is imperative that false government narratives be appropriately challenged.

With permission I have included Chapter 10 of the Norfolk Group's questions for a COVID-19 Commission recently presented to Congress. This Chapter reviews the science of masking mandates.

Please feel free to contact me should any questions remain.

Respectfully Submitted,

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Chapter Ten | Masks

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?