One doctor's take on masks . . .

A literature review of masks and their use in pandemic settings

By Braxton DeGarmo, MD

Over the course of the COVID-19 "crisis," I've been asked numerous times about my take on masks and all of these mandates for wearing them. I had my initial thoughts on them, based upon what I was taught in medical school and what was considered standard practice. That recommendation was that those who were symptomatic with a respiratory illness could help prevent transmission to others by wearing a mask when around others, and that those in high risk occupations such as healthcare should wear them. There was no need for the healthy to wear a mask, and numerous studies existed to show that not only did they offer no protection for the healthy, they could be harmful when worn for extended periods of time. This was the standard of care prior to COVID-19. What changed? In reality, nothing.

So, what are my qualifications, besides four years of medical school and a three-year residency in Emergency Medicine? After all, I'm not a trained virologist or immunologist. So, why should my opinion count for anything? Well, as an ER doctor, we are considered "experts" in personal protective equipment (PPE). However, in addition to that training, I have a BSE in BioMedical Engineering from Duke. We were well educated on the scientific method, biostatistics, how to analyze a problem, and more. I also did a brief stint as a medical researcher in the Army, where the lab division I directed redesigned military body armor and created the first head's up displays for aviator helmets. Again, not virology, but I mention it because I'm not a stranger to reading and analyzing medical studies. As an Army ER doctor, I also led mass casualty and MOPP4 (biological and/or chemical warfare) exercises for training. Talk about PPE, try doing anything useful in full MOPP4 gear.

One of the things I've observed over the years is that there are well-designed studies, and a lot more that aren't. A good study is randomized and has a control group. Being double-blinded is even better, but not always possible. In this situation, it's not like you can have the equivalent of sugar-pill placebo for a mask. But if you want accurate testing for masks, you need to control other variables, such as hand washing, touching the face, and exposure to potentially contaminated surfaces such as shopping cart handles. There are so many possible variables, it's basically impossible to control them all. As a result, most papers in favor of masks lumped them into a group of such primary infection control practices and didn't truly control the study for mask use. I came across no studies that actually attempted such controls. Their results all need to be seen in that light.

Also, despite touting "evidence-based medicine," a lot of what medicine does is out of

tradition, not based upon science, the evidence. This has led to what I like to call "sounds right" science. In other words, the results of a study are massaged to fit a tradition because the researcher believes the tradition to be correct. The results "sound right" because they fit a particular belief. Some would also call this scientism, or pseudoscientific. Here's an article that looked at just this topic with critical-care nurses:
https://www.sciencedaily.com/releases/2014/04/140401101847.htm
They found that fewer than 15% of clinicians followed evidence-based practices and that it took up to 20 years for them to catch up.

A good example of this was the use of steroid shots for poison ivy. In the 1970s, we were taught that someone with a bad case of rhus dermatitis should get a regimen of hydrocorticoid steroid to clear it up. After all, the rash is an inflammatory reaction and these steroids are potent anti-inflammatories. Sounds right that a shot and pills would help. One problem—no one had ever studied the issue. Steroids were given out of "tradition." When randomized, double-blind studies were actually done for the first time in the 1990s, they disproved the accepted belief that steroids helped.

Another example of "sounds right" science involves circular reasoning. An example of this, that I discovered when researching vaccines, involves the studies of vaccines and SIDS (Sudden Infant Death Syndrome). Even though the results of these studies showed peaks in SIDS cases at 2, 4, and 6 months—the exact times when infants get a plethora of immunizations—the researchers did not conclude that vaccines *might* be the cause, or even call for additional study. Instead, they concluded that since they *knew* vaccines weren't a cause of SIDS, there had to be another cause. Circular reasoning: vaccines can't be the cause of SIDS because we know SIDS isn't caused by vaccines.

I bring up the concept of "sounds right" science because many of the studies in favor of masks are just that. Several recent papers supporting masks have headlines that masks prevent the spread of coronavirus. Seems intuitive. Sounds right. Yet, their conclusions are that masks, **in conjunction with** hand washing, social distancing, and more will help prevent the spread. Not that masks alone can do that. The headlines are misleading. They've not actually delved deep into the science. As I mentioned, it also shows they didn't control the variables of hand washing, etc. In fact, frequent hand washing is still likely the best preventive measure one can take, as we've advised for decades. If you think about it, where does all that virus purportedly trapped by a mask go? Onto your hands each time you handle the mask.

As a side note here, while I'm not investigating the idea of social distancing, it is another tradition, one that goes back to the 1930s when it was first thought that germs spread by droplets in coughs and sneezes and that those droplets would hit the floor by the six-foot mark.

While, yes, such droplets carry viruses and bacteria (germs), we now understand that viruses are also carried in aerosols that can travel across a large room. The idea of social distancing is outdated and not supported by new science . . . a tradition.

So, as I mentioned above, when I was first asked my opinion, I fell back onto my own training and experience. However, I realized that my own "education" on the topic might be improved. Maybe there was new research available that I was unaware of and that now showed our previous practice to be outdated. As such, I embarked on a search and review of pertinent studies on masks related to respiratory illnesses, such as COVID-19. What follows is a compilation of dozens of published medical studies on the topic. Where available, I reprinted the abstract of the study. But abstracts are just that, and don't always reveal the biases and finer points of the study. Those can be quite revealing. Because of that, I provide my own note on each study, trying to be as objective as I can, but you can probably already tell that I have my own bias and opinion—largely because as I write this, I already know what the studies show.

Clearly, you can use the links to find and read the studies on your own. Your opinion of the study might differ from mine, and that's okay. We all come into this "crisis" from different life experiences, education levels, etc.

In this paper, I'm simply trying to provide a resource to educate people about masks. BTW, in the abstracts, words emphasized in bold are my emphasis, not the original author's, unless so stated. I do so to highlight something I then mention in my own note.

Starting with the CDC . . .

I decided that the CDC's own page on masks would be as good a starting point as any: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html. The following are the articles used on the CDC's page to support their claim that masks are helpful in preventing spread and to support their mandate for masks. Their references might change over time, just as their recommendation on masks has flip-flopped. The references below were those being used in mid-July 2020 when I started this review. Also, the references I'm citing are to the full article, while those on the CDC site usually link only to an abstract.

I should note that most of the journals in which these studies are published request "conflict of interest" information. In many articles where this request was made, the typical statement was "Competing interests: None declared." Not that there were no competing interests or conflicts, just that the authors did not "declare" any. As such, we have no idea who funded said studies and whether or not any real conflicts exist. One of the first things I learned about analyzing a

study was to know who funded it. Follow the money, as they say. That gives you your first clue as to any biases the authors might have.

Let's begin.

- Rothe C, Schunk M, Sothmann P, et al. Transmission of 2019-nCoV Infection from an Asymptomatic Contact in Germany. The New England journal of medicine. 2020;382(10):970-971. https://www.nejm.org/doi/10.1056/NEJMc2001468

[***NOTE:*** Case study, so no abstract. This article simply shows that COVID-19 is no different than influenza or other coronaviruses in being transmissible to others at some undetermined period prior to symptoms arising. The index patient, from China, became sick on her flight home from Germany and two of the German patients were exposed to her in the two days prior to that. The other two German patients were exposed to the first German patient in the few days before he became symptomatic. In all cases, the incubation period was quite short (3-4 days) and each had only mild cases. It's important to realize that this is a case study involving only five people, and its intent, I suppose, is to show that asymptomatic spread is possible. Therefore, the inference is that masks will help prevent that spread, although there is zero mention of masks and asymptomatic spread is assumed. There is a difference between asymptomatic carriers and **pre**symptomatic patients. The two are often treated as being the same.

In addition, this is not a randomized, double-blind study of hundreds or thousands of people. If I presented a case report on, say, hydroxychloroquine, to the CDC that involved only five people, they would dismiss it out of hand as having too small a test sample. Speculation on my part? No, in fact, Dr. Fauci and CDC leaders did just that on studies involving hundreds of people that used hydroxychloroquine successfully for COVID-19. Larger test populations provide more useful data and better statistical results. Later in this paper, you'll see some studies, one involving 455 people, that refute the idea of asymptomatic spread.]

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- Zou L, Ruan F, Huang M, et al. SARS-CoV-2 Viral Load in Upper Respiratory Specimens of Infected Patients. The New England Journal of Medicine. 2020;382(12):1177-1179. https://www.nejm.org/doi/10.1056/NEJMc2001737

[***NOTE:*** Case study, so no abstract. This study looked at only 17 patients in China in the early days of COVID-19. Only two required ICU care. The others had mild-to-moderate illnesses. The

nasal viral load in asymptomatic cases were similar to those who were ill. The main conclusion of the article was that more study was needed. This study talks of nasal viral loads, a quantitative factor. Later, I'll discuss the issue of qualitative versus quantitative testing.]

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- Pan X, Chen D, Xia Y, et al. Asymptomatic cases in a family cluster with SARS-CoV-2 infection. The Lancet Infectious diseases. 2020. https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30114-6/fulltext

[***NOTE:*** Case study, so no abstract. This case report looked at a **single family of three**, one of which (the father) became ill while the wife and child remained asymptomatic but tested positive. As in the first article above, this shows COVID-19 to be no different than influenza and other cold viruses in that these patients were either asymptomatic or had only mild-to-moderate symptoms.]

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- Bai Y, Yao L, Wei T, et al. Presumed Asymptomatic Carrier Transmission of COVID-19. JAMA. 2020. https://jamanetwork.com/journals/jama/fullarticle/2762028

[***NOTE:*** Case study, so no abstract. This case study looked at a single family cluster of five people in China. The five family members became ill after contact with an allegedly asymptomatic family member from Wuhan. That person was negative on testing initially, positive two days later, and negative again eight and 11 days later. All of her other lab tests and chest CT were normal. First, this calls into question the validity of her tests. The flaws in testing have been well shown and discussed in the media. Second, she is presumed to be the "carrier" simply by the fact that she came from Wuhan and that there were no other reported cases in Anyang where this family resided. Any search for other potential sources, if investigated, were not reported. Guilt by association? I'm surprised JAMA (the Journal of the American Medical Association) even accepted this.]

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- Kimball A HK, Arons M, et al. Asymptomatic and Presymptomatic SARS-CoV-2 Infections in Residents of a Long-Term Care Skilled Nursing Facility — King County, Washington, March 2020. MMWR Morbidity and mortality weekly report. 2020; ePub: 27 March 2020. https://pubmed.ncbi.nlm.nih.gov/32240128/ -- https://www.cdc.gov/mmwr/volumes/69/wr/mm6913e1.htm?s_cid=mm6913e1_w

Abstract:

Older adults are susceptible to severe coronavirus disease 2019 (COVID-19) outcomes as a consequence of their age and, in some cases, underlying health conditions (1). A COVID-19 outbreak in a long-term care skilled nursing facility (SNF) in King County, Washington that was first identified on February 28, 2020, highlighted the potential for rapid spread among residents of these types of facilities (2). On March 1, a health care provider at a second long-term care skilled nursing facility (facility A) in King County, Washington, had a positive test result for SARS-CoV-2, the novel coronavirus that causes COVID-19, after working while symptomatic on February 26 and 28. By March 6, seven residents of this second facility were symptomatic and had positive test results for SARS-CoV-2. On March 13, CDC performed symptom assessments and SARS-CoV-2 testing for 76 (93%) of the 82 facility A residents to evaluate the utility of symptom screening for identification of COVID-19 in SNF residents. Residents were categorized as asymptomatic or symptomatic at the time of testing, based on the absence or presence of fever, cough, shortness of breath, or other symptoms on the day of testing or during the preceding 14 days. Among 23 (30%) residents with positive test results, 10 (43%) had symptoms on the date of testing, and 13 (57%) were asymptomatic. Seven days after testing, 10 of these 13 previously asymptomatic residents had developed symptoms and were recategorized as presymptomatic at the time of testing. The reverse transcription-polymerase chain reaction (RT-PCR) testing cycle threshold (Ct) values indicated large quantities of viral RNA in asymptomatic, presymptomatic, and symptomatic residents, suggesting the potential for transmission regardless of symptoms. Symptom-based screening in SNFs could fail to identify approximately half of residents with COVID-19. Long-term care facilities should take proactive steps to prevent introduction of SARS-CoV-2 (3). Once a confirmed case is identified in an SNF, all residents should be placed on isolation precautions if possible (3), with considerations for extended use or reuse of personal protective equipment (PPE) as needed (4).

[***NOTE:*** Influenza and other viral illnesses also spread quickly in these environments (nursing homes) because there are poor controls. In the case of the second facility where the residents were tested, the health care provider worked **while symptomatic**. Little wonder the illness spread quickly there. Also, it should be recognized that the residents of a skilled nursing facility are there because they have comorbid health problems requiring *skilled* nursing. Special care is needed to protect these most vulnerable patients, as concluded by the article. There are differences between the need for masks in a medical setting and in the community at large. As we'll see, even studies that show no support for masks in the community tend to support their use in medical settings. This is clearly a situation where masks are recommended, but it's not reflective of the community at large.]

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- Wei WE LZ, Chiew CJ, Yong SE, Toh MP, Lee VJ. Presymptomatic Transmission of SARS-CoV-2 — Singapore, January 23–March 16, 2020. MMWR Morbidity and Mortality Weekly Report. 2020; ePub: 1 April 2020. PMID: 32271722external icon -- https://www.cdc.gov/mmwr/volumes/69/wr/mm6914e1.htm?s_cid=mm6914e1_w

  Abstract:

  Presymptomatic transmission of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), might pose challenges for disease control. The first case of COVID-19 in Singapore was detected on January 23, 2020, and by March 16, a total of 243 cases had been confirmed, including 157 locally acquired cases. Clinical and epidemiologic findings of all COVID-19 cases in Singapore through March 16 were reviewed to determine whether presymptomatic transmission might have occurred. Presymptomatic transmission was defined as the transmission of SARS-CoV-2 from an infected person (source patient) to a secondary patient before the source patient developed symptoms, as ascertained by exposure and symptom onset dates, with no evidence that the secondary patient had been exposed to anyone else with COVID-19. Seven COVID-19 epidemiologic clusters in which presymptomatic transmission **likely occurred** were identified, and 10 such cases within these clusters accounted for 6.4% of the 157 locally acquired cases. In the four clusters for which the date of exposure could be determined, presymptomatic transmission occurred 1-3 days before symptom onset in the presymptomatic source patient. To account for the possibility of presymptomatic transmission, officials developing contact tracing protocols should strongly consider including a period before symptom onset. Evidence of presymptomatic transmission of SARS-CoV-2 underscores the critical role social distancing, including avoidance of congregate settings, plays in controlling the COVID-19 pandemic.

[***NOTE:*** Notice the words “likely occurred” when presenting the seven clusters of patients, from which only ten patients were in the 157 confirmed locally acquired cases. No mention is made of the severity of any of the cases. And while it is “recognized” that presymptomatic spread is possible with all viral illnesses, there is, in reality, no way to actually test and prove that. We don’t live in sterile environments where we can control every potential avenue of exposure. But it sounds right. Hand to face contact is still considered the primary track of spread for colds and flu. These studies always conclude that you caught the illness after contact with a carrier, whether asymptomatic or presymptomatic, and contact can mean simply sitting in the same room together. However, opening a door or using a grocery cart after it’s been used by a symptomatic stranger can load your hands with virus, which can then infect you after you touch your face, etc. Essentially, in the strictest sense, all such studies are flawed, basing their conclusions on an assumption. Even if we accept the assumption that pre- or asymptomatic people can pass it on to others, to then say that this study “underscores the critical role social distancing, including avoidance of congregate settings, plays in controlling the COVID-19 pandemic” is deceptive, as they didn’t actually control and test such precautions. Besides, this

article is being used to support a mask mandate and yet does not even include masks in its conclusion.]

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- Li R, Pei S, Chen B, et al. Substantial undocumented infection facilitates the rapid dissemination of novel coronavirus (SARS-CoV2). Science (New York, NY). 2020. PMID: 32179701external icon -- https://science.sciencemag.org/content/368/6490/489

  Abstract:

  Estimation of the prevalence and contagiousness of undocumented novel coronavirus [severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2)] infections is critical for understanding the overall prevalence and pandemic potential of this disease. Here, we use observations of reported infection within China, in conjunction with mobility data, a networked dynamic metapopulation model, and Bayesian inference, to infer critical epidemiological characteristics associated with SARS-CoV-2, including the fraction of undocumented infections and their contagiousness. We estimate that 86% of all infections were undocumented [95% credible interval (CI): 82-90%] before the 23 January 2020 travel restrictions. The transmission rate of undocumented infections per person was 55% the transmission rate of documented infections (95% CI: 46-62%), yet, because of their greater numbers, undocumented infections were the source of 79% of the documented cases. These findings explain the rapid geographic spread of SARS-CoV-2 and indicate that containment of this virus will be particularly challenging.

[***NOTE:*** this whole article is based upon a computer model, not real-life data. And computer models are based upon assumptions made by their designers. In this case, one likely assumption is that the disease first started in December 2019 in Wuhan. Modeling forward in time to January 2020 would get them certain results. And yet, sewage testing in a number of countries (Spain, Italy, and Brazil) has revealed that COVID-19 was in those countries in December 2019 (before its alleged outbreak in Wuhan) [https://www.iss.it/web/guest/primo-piano/-/asset_publisher/o4oGR9qmvUz9/content/id/5422725], or even as early of March 2019. [https://www.medrxiv.org/content/10.1101/2020.06.13.20129627v1] That alters the entire scenario of spread and makes this model invalid.]

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- Furukawa NW, Brooks JT, Sobel J. Evidence Supporting Transmission of Severe Acute Respiratory Syndrome Coronavirus 2 While Presymptomatic or Asymptomatic [published online ahead of print, 2020 May 4]. Emerg Infect Dis. 2020; 26(7):10.3201. https://wwwnc.cdc.gov/eid/article/26/7/20-1595_article

Abstract:

Recent epidemiologic, virologic, and modeling reports support the possibility of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission from persons who are presymptomatic (SARS-CoV-2 detected before symptom onset) or asymptomatic (SARS-CoV-2 detected but symptoms never develop). SARS-CoV-2 transmission in the absence of symptoms **reinforces the value of measures that prevent the spread** of SARS-CoV-2 by infected persons who may not exhibit illness despite being infectious. **Critical knowledge gaps include the relative incidence of asymptomatic and symptomatic SARS-CoV-2 infection, the public health interventions that prevent asymptomatic transmission, and the question of whether asymptomatic SARS-CoV-2 infection confers protective immunity.**

[***NOTE:*** This article, too, is based upon the assumption that asymptomatic spread is possible. But even if we accept that critical assumption, this article goes on and seems to contradict itself. How can it "*reinforce the value of measures that prevent*" asymptomatic spread while admitting to "*critical knowledge gaps*" that "*include the relative incidence of asymptomatic and symptomatic SARS-CoV-2 infection,* (and) *the public health interventions that prevent asymptomatic transmission.*" With such critical knowledge gaps how do we know that such prevention measures are actually doing anything?]

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- Oran DP, Topol Prevalence of Asymptomatic SARS-CoV-2 Infection: A Narrative Review [published online ahead of print, 2020 Jun 3]. Ann Intern Med. 2020; M20-3012. https://www.acpjournals.org/doi/10.7326/M20-3012

  Abstract:

  Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has spread rapidly throughout the world since the first cases of coronavirus disease 2019 (COVID-19) were observed in December 2019 in Wuhan, China. It has been suspected that infected persons who remain asymptomatic play a significant role in the ongoing pandemic, but their relative number and effect have been uncertain. The authors sought to review and synthesize the available evidence on asymptomatic SARS-CoV-2 infection. **Asymptomatic persons seem to account for** approximately 40% to 45% of SARS-CoV-2 infections, and they can transmit the virus to others for an extended period, perhaps longer than 14 days. Asymptomatic infection may be associated with subclinical lung abnormalities, as detected by computed tomography. Because of the high risk for silent spread by asymptomatic persons, it is imperative that testing programs include those without symptoms. To supplement conventional diagnostic testing, which is constrained

by capacity, cost, and its one-off nature, innovative tactics for public health surveillance, such as crowdsourcing digital wearable data and monitoring sewage sludge, might be helpful.

[***NOTE:*** Perhaps the key phrase from this abstract is "*Asymptomatic persons **seem** to account …*" Many authors will couch their conclusions in terms such as: been suspected that, seem to, likely to, may cause, along with, suggest that etc. They're being intellectually honest in doing so because they can't make any statement of causality with absolute certainty. However, most readers will read right past these terms to see the conclusion as fact. If you actually read the article, the following limitations are stated:

"The prevalence of asymptomatic SARS-CoV-2 infection, however, has remained uncertain."

"Most data from the 16 cohorts in this narrative review are not the output of large, carefully designed studies with randomly selected, representative samples. They do not generally purport to depict anything more than certain circumscribed cohorts at specific moments in time. We have not attempted to pool them for the purposes of statistical analysis."

"The difficulty of distinguishing asymptomatic persons from those who are merely presymptomatic is a stumbling block."

Clearly, this article was written to support certain assumptions and biases and not based on actual data. Do you see the trend here? The first eight (of 19) studies purport to show the asymptomatic spread of COVID-19 as presenting the need for the healthy to wear masks. And yet, they don't truly prove that, or use case reports of such small numbers that it makes it easier to make their claim. However, when you really look at studies that tried to determine such an infectivity rate, the idea is disproven. In "A Study on infectivity of asymptomatic SARS-CoV-2 carriers" (Ming Gao, et al. Respir Med. 2020 Aug; 169: 106026) they actually had an asymptomatic patient in a controlled hospital setting and could study the concept. Of 455 people who came into contact with her, ZERO developed COVID-19. BTW, if you go to the above link in *Respiratory Medicine*, you'll see a link to a rebuttal. In the rebuttal, they argue that the patient was not asymptomatic but had been in the hospital with symptoms for almost a month. The reality is that she was in the hospital for problems related to an atrial-septal heart defect and surprised the doctors by being COVID-19 positive on testing. That gave them the opportunity to follow her as an asymptomatic carrier.]

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- National Academies of Sciences, Engineering, and Medicine. 2020. Rapid Expert Consultation on the Possibility of Bioaerosol Spread of SARS-CoV-2 for the COVID-19 Pandemic (April 1, 2020). Washington, DC: The National Academies Press. https://www.nap.edu/catalog/25769/rapid-expert-consultation-on-the-possibility-of-bioaerosol-spread-of-sars-cov-2-for-the-covid-19-pandemic-april-1-2020

[***NOTE:*** This three-page letter was written in response to questions from a physician about aerosolized spread of COVID. In it, the writer states:

*"Currently available research supports the **possibility** that SARS-CoV-2 could be spread via bioaerosols generated directly by patients' exhalation."*

"A recent study of SARS-CoV-2 aerosolization at the University of Nebraska Medical Center showed widespread presence of viral RNA in isolation rooms where patients with SARS-CoV-2 were receiving care." – note where the samples were being taken, in hospital rooms of ill patients in isolation.

*"While this research indicates that viral particles can be spread via bioaerosols, the authors stated that **finding infectious virus has proved elusive** and experiments are ongoing to determine viral activity in the collected samples."*

The letter cites two studies that showed aerosol transmission of viral RNA particles is reduced with surgical masks, but neither could confirm that such RNA particles were actually infectious. The letter also states that one Wuhan study showed that the highest level of contamination was of surfaces. In medical staff areas, these levels were highest in the rooms where PPE was removed. Wouldn't that pose a great risk of contaminating someone who has just taken off their protective gear? The letter also goes on to state:

"However, for no respiratory virus is the exact proportion of infections due to air droplet, aerosol, or fomite transmission fully established, and many individual factors and situations may contribute to the importance of each route of transmission."

In other words, no one has any idea as to what comprises an infectious particle or what viral load is required to cause illness, and there's no data to support one route of transmission as being more infectious than another.]

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- Schwartz KL, Murti M, Finkelstein M, et al. Lack of COVID-19 transmission on an international flight. CMAJ. 2020;192(15): E410. https://www.cmaj.ca/content/192/15/E410

[***NOTE:*** Two patients traveled from Wuhan to Guangzhou, then Guangzhou to Toronto in Jan 2020. Both were mildly symptomatic and proved to be COVID-19 positive on testing. The 25 passengers (out of 350 on the flight) within 6 ft of them, plus the flight crew and one other close contact, were followed. Six became mildly symptomatic but proved to be negative for COVID-19. I don't see how this article supports the mandate for masks? It appears to me to show that masks are unnecessary.]

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- Anfinrud P, Stadnytskyi V, Bax CE, Bax A. Visualizing Speech-Generated Oral Fluid Droplets with Laser Light Scattering. N Engl J Med. 2020 Apr 15. doi:10.1056/NEJMc2007800. https://www.nejm.org/doi/10.1056/NEJMc2007800

[***NOTE:*** This was an interesting study showing the flow of water droplets produced by someone speaking. Using a laser to light up the droplets, they recorded results at various volumes and also with a "slightly damp washcloth" over the mouth. As intuitively expected, the washcloth reduced the number of droplets recorded. However, a major limitation of the study design was that the speaker spoke into a 53x46x62 cm (19x22x26 in.) box where the laser scattering and recording was done. The box would have the effect of focusing the droplets along the path provided by the walls of the box. In real life, we don't speak into boxes and such droplets would dissipate much differently. In addition, air currents, even in a seemingly still room, also have an effect on the droplets. And, while the damp washrag reduced the number of droplets, as common sense would lead us, the study made no comment on what happens to the droplets caught by the cloth. As to be shown in studies cited further on in this paper, these droplets begin to "clog" the pores of the cloth contributing to hypoxia, hypercapnia, and rebreathing of any viruses and bacteria in the droplets. Those studies show that people wearing cloth masks who then become ill, get sicker than those using other types of masks, as well as those not wearing masks at all. The following study: Bahl P, Bhattacharjee S, de Silva C, et al. Face coverings and mask to minimise droplet dispersion and aerosolisation: a video case study. Thorax http://press.psprings.co.uk/thx/july/thx215748.R.pdf did a better job of showing the dispersion of droplets and looked at no mask, 1-layer mask, 2-layer mask, and surgical mask. Its limitation is that it looked at only one person.]

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- Davies A, Thompson KA, Giri K, Kafatos G, Walker J, Bennett A. Testing the efficacy of homemade masks: would they protect in an influenza pandemic? Disaster Med Public Health Prep. 2013;7(4):413-8. PMID: 24229526external icon -- https://www.cambridge.org/core/journals/disaster-medicine-and-public-health-preparedness/article/testing-the-efficacy-of-homemade-masks-would-they-protect-in-an-influenza-pandemic/0921A05A69A9419C862FA2F35F819D55

  Abstract:

  Objective--This study examined homemade masks as an alternative to commercial face masks.

  Methods--Several household materials were evaluated for the capacity to block bacterial and viral aerosols. Twenty-one healthy volunteers made their own face masks from cotton t-shirts; the masks were then tested for fit. The number of microorganisms isolated from coughs of healthy volunteers wearing their homemade mask, a surgical mask, or no mask was compared using several air-sampling techniques.

  Results--The median-fit factor of the homemade masks was one-half that of the surgical masks. Both masks significantly reduced the number of microorganisms expelled by volunteers, although the surgical mask was 3 times more effective in blocking transmission than the homemade mask.

  Conclusion--Our findings suggest that a homemade mask should only be considered as a last resort to prevent droplet transmission from infected individuals, but it would be better than no protection.

[***NOTE:*** This 2013 study looked at homemade cloth (tee-shirt) masks, surgical masks, and no masks. They used various air-sampling methods to capture microorganisms expelled in the coughs of 21 healthy subjects using the masks and without. As expected, the counts were lowest using surgical masks, then the cloth masks, and highest with no mask in place. They then conclude: *"Our findings suggest that a homemade mask should only be considered as a last resort to prevent droplet transmission from infected individuals, but it would be better than no protection."* The healthy need protection, but how do you go from testing forcefully expelled air (a cough) in an infected subject to concluding a level of protection for the healthy in inhaled air? As I stated in the beginnings of this paper, for decades we've advised the ill to wear a mask to help prevent spread. A closer look at the great majority of these studies shows that they focus on using masks to block droplet transmission from coughs or sneezes—forceful exhalation—not routine inhalation, or even routine exhalation. The mechanisms of air flow through a mask are different for a forceful exhalation and a typical inhalation. You really cannot

imply protection during inhalation from the results of these studies, which at best support the use of masks only by the sick.]

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- Konda A, Prakash A, Moss GA, Schmoldt M, Grant GD, Guha S. Aerosol Filtration Efficiency of Common Fabrics Used in Respiratory Cloth Masks. ACS Nano. 2020 Apr 24. PMID: 32329337external icon -- https://pubs.acs.org/doi/10.1021/acsnano.0c03252

  Abstract:

  The emergence of a pandemic affecting the respiratory system can result in a significant demand for face masks. This includes the use of cloth masks by large sections of the public, as can be seen during the current global spread of COVID-19. However, there is limited knowledge available on the performance of various commonly available fabrics used in cloth masks. Importantly, there is a need to evaluate filtration efficiencies as a function of aerosol particulate sizes in the 10 nm to 10 μm range, which is particularly relevant for respiratory virus transmission. We have carried out these studies for several common fabrics including cotton, silk, chiffon, flannel, various synthetics, and their combinations. Although the filtration efficiencies for various fabrics when a single layer was used ranged from 5 to 80% and 5 to 95% for particle sizes of **<300 nm and >300 nm**, respectively, the efficiencies improved when multiple layers were used and when using a specific combination of different fabrics. Filtration efficiencies of the hybrids (such as cotton-silk, cotton-chiffon, cotton-flannel) was >80% (for particles <300 nm) and >90% (for particles >300 nm). We speculate that the enhanced performance of the hybrids is likely due to the combined effect of mechanical and electrostatic-based filtration. Cotton, the most widely used material for cloth masks performs better at higher weave densities (i.e., thread count) and can make a significant difference in filtration efficiencies. Our studies also imply that **gaps (as caused by an improper fit of the mask) can result in over a 60% decrease in the filtration efficiency**, implying the need for future cloth mask design studies to take into account issues of "fit" and leakage, while allowing the exhaled air to vent efficiently. Overall, we find that combinations of various commonly available fabrics used in cloth masks can potentially provide significant protection against the transmission of aerosol particles.

[***NOTE:*** While they note a need to evaluate filtration efficiencies of various materials for aerosol particulates as small as 10 nm, they limited their study to particulates <300nm and >300nm. Maybe this was because the popular N95 mask is rated to 300nm (0.3μm). Since the coronavirus is 125nm, perhaps they should have determined efficiencies to that level. (And maybe they did, but the results weren't what they hoped to show. I know. I shouldn't be so cynical, but fudging results is far too common.) Their results showed that a hybrid mask (eg, cotton-silk) was more efficient than either alone because the silk layer became electrostatically

charged. An electrostatic charge is what helps make N95 masks more efficient. But such a charge wanes over time, which is why reuse of N95 masks is discouraged. They also noted that poorly fitting masks reduce their efficiency over 60%. In the ER, we had specially fitted masks. In real life, people's masks are half falling off, not covering the nose, etc.

Masks experts say that filtration for 100nm particles isn't necessary because viruses don't "travel" alone. They bind to droplets, mucus, or other larger particles that will be filtered out. They also point out that such small particles travel via Brownian motion—that is, very erratically—making them more likely to get caught in the fibers of the mask. Add in an electrostatic charge, and N95 masks reportedly are 95% efficient at blocking such small particles. Thus, their name.

However, these same experts study droplets, not aerosols, when talking about masks. It was once accepted that viruses did not aerosolize. We now know viral RNA particles do indeed aerosolize. We just don't know what that really means. Are such fragments infectious? We don't know. Also, missing in this discussion, as I've pointed out before, what happens to the viral particles caught in the mask? The virus load builds up within the mask and rebreathing of those particles can increase your viral exposure, potentially leading to a more serious illness if you do become symptomatic. Does the way people handle and reuse their masks, getting the virus all over their hands and faces, contribute to their eventually getting ill? Is this why we saw strict mask mandates having no effect on containing COVID-19 in Wuhan?

Also, when we talk about aerosolized viral particles, why are we not talking about protecting our eyes? Masks don't cover our eyes, and yet, aerosolized particles are caught by the tears that constantly wash our eyes. It's ironic that clear plastic face shields that protect eyes, nose, and mouth are theoretically better PPE than simple masks, and yet if I wore that to my local Walmart, without a mask, I'd be denied admission or asked to leave.]

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- Aydin O, Emon B, Saif MTA. Performance of fabrics for home-made masks against spread of respiratory infection through droplets: a quantitative mechanistic study. Originally published as a preprint article in medRxiv: https://www.medrxiv.org/content/10.1101/2020.04.19.20071779v2
  Formally published in Elsevier's ScienceDirect in October 2020: https://www.sciencedirect.com/science/article/pii/S2352431620301802?via%3Dihub

  Abstract:

Coronavirus Disease 2019 (COVID-19) may spread through respiratory droplets released by infected individuals during coughing, sneezing, or speaking. Given the limited supply of professional respirators and face masks, the U.S. Centers for Disease Control and Prevention (CDC) has recommended home-made cloth face coverings for use by the general public. While there have been several studies on aerosol filtration performance of household fabrics, their effectiveness at blocking larger droplets has not been investigated. Here, we ascertained the performance of 11 common household fabrics at blocking large, high-velocity droplets, using a commercial medical mask as a benchmark. We also assessed the breathability (air permeability), texture, fiber composition, and water absorption properties of the fabrics. We found that most fabrics have substantial blocking efficiency (median values >70%). In particular, two layers of highly permeable fabric, such as T-shirt cloth, blocks droplets with an efficiency (>94%) similar to that of medical masks, while being approximately twice as breathable. The first layer allows about 17% of the droplet volume to transmit, but it significantly reduces their velocity. This allows the second layer to trap the transmitted droplets resulting in high blocking efficacy. Overall, our study suggests that cloth face coverings, especially with multiple layers, may help reduce droplet transmission of respiratory infections. Furthermore, face coverings made from materials such as cotton fabrics allow washing and reusing, and can help reduce the adverse environmental effects of widespread use of commercial disposable and non-biodegradable facemasks.

[***NOTE:*** While not specifically mentioned in the abstract, the study looked at the ability of various materials to block large droplets at high velocity, ie when sneezed or coughed, by repurposing a metered-dose inhaler to produce the droplets and velocity. The article lumps in breathing with coughing and sneezing, but routine breathing does not produce **high velocity** transmission of droplets. As such, while this study might support the wearing of masks by those who are sick/symptomatic, it does NOT offer any proof that masks prevent the healthy from picking up the virus. Plus, the article also does not address aerosols, many of which can go right through these masks.

One study I recall, but could not relocate to offer you the citation, involved a video study of what actually happens when someone coughs with a mask on. Yes, the forward projection of those droplets is markedly reduced. However, significant puffs of droplets jetted out the sides, under the bottom, and out the top of the mask. These droplets will fall somewhere, leading to the potential for contaminating nearby surfaces, such as countertops, the handle of the shopping cart you're pushing, etc. This, to me, again emphasizes the need for hand washing, as well as the cleaning of potentially contaminated surfaces, as pointed out earlier.]

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- Ma QX, Shan H, Zhang HL, Li GM, Yang RM, Chen JM. Potential utilities of mask-wearing and instant hand hygiene for fighting SARS-CoV-2. J Med Virol. 2020. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7228401/

  Abstract:

  The surge of patients in the pandemic of COVID-19 caused by the novel coronavirus SARS-CoV-2 may overwhelm the medical systems of many countries. Mask-wearing and handwashing can slow the spread of the virus, but currently, masks are in shortage in many countries, and timely handwashing is often impossible. In this study, the efficacy of three types of masks and instant hand wiping was evaluated using the avian influenza virus to mock the coronavirus. Virus quantification was performed using real-time reverse transcription-polymerase chain reaction. Previous studies on mask-wearing were reviewed. The results showed that instant hand wiping using a wet towel soaked in water containing 1.00% soap powder, 0.05% active chlorine, or 0.25% active chlorine from sodium hypochlorite removed 98.36%, 96.62%, and 99.98% of the virus from hands, respectively. N95 masks, medical masks, and homemade masks made of four-layer kitchen paper and one-layer cloth could block 99.98%, 97.14%, and 95.15% of the virus in aerosols. Medical mask-wearing which was supported by many studies was opposed by other studies possibly due to erroneous judgment. With these data, we propose the approach of mask-wearing plus instant hand hygiene (MIH) to slow the exponential spread of the virus. This MIH approach has been supported by the experiences of seven countries in fighting against COVID-19. Collectively, a simple approach to slow the exponential spread of SARS-CoV-2 was proposed with the support of experiments, literature review, and control experiences.

[***Note:*** First, the abstract talks about aerosols, but, in fact, the study was done using a nebulizer to produce particles in the 3.9 – 5.0µm range, which is in line with other studies of droplets. The definition of aerosols in other studies is particles under 3µm (<3000nm), typically measured in nanometers, not micrometers. COVID-19 is 125nm in size. The design of this study was interesting in how they tested their mask materials to the same viral load, and in that they attempted to mimic inhalation rather than a cough or sneeze (finally). What I didn't see was a measurement of that "inhalation" air flow/pressure to confirm that it did indeed copy typical inhalation air flow. That could dramatically alter their results. A slower air flow would give more time for viral trapping by the materials, improving their results, while faster air flow could decrease the time and efficacy. That said, their reported efficacy of their mask materials was far better than other studies. However, they also state that cloth alone as a mask *"may be unable to block the virus and thus confer no protection against the virus."* And yet the WHO and CDC promote cloth masks.

Their hand washing results further support the benefits of hand washing in preventing viral spread. The statistical difference between using soap or using a .25% active chlorine solution is insignificant. Again, as we've advised for years, wash your hands! Frequently, in cold and flu season.

Earlier, I mentioned the issue of qualitative versus quantitative testing. This group, like all the others, used RT-PCR (reverse transcription-polymerase chain reaction) to test their viral loads. There are still questions as to the validity of such testing. PCR testing was originally designed specifically for DNA, not RNA. Thus, the need to add the reverse transcriptase component to the test. Also, Dr. Kary Mullis, who won the Nobel prize in Science for inventing the PCR test, has reportedly stated "*Quantitative PCR is an oxymoron.*"
http://www.virusmyth.org/aids/hiv/jlprotease.htm

Did he say really that? The Reuters Fact Check team looked at the claim: "COVID-19 TEST A FRAUD." (https://www.reuters.com/article/uk-factcheck-pcr-idUSKBN24420X) Their verdict? "*False. The quote undermining PCR tests is misattributed to Mullis and taken out of context. PCR tests are being used widely in England to show that SARS-CoV-2 viral genetic material* ***is present*** *in the patient."* Who checks the "fact checkers?" Per their quoted source, it only shows the genetic material's *presence*, not how much. Dr. Mullis' comment was about quantitative testing and the "fact checkers" are talking about qualitative testing, a simple yes/no about the presence of viral material. Their own page also quotes Public Health England as saying *"It is important to note that detecting viral material by PCR does not indicate that the virus is fully intact and infectious, i.e. able to cause infection in other people."*

In reality, the test only shows the presence of viral RNA material, can't be used to quantify that material, and can't determine infectivity. We also don't know just what portions of genetic material it detects. It's a coronavirus. All coronaviruses share a large portion (90+%) of genetic material. Even though the genetic sequence of COVID-19 has now been detailed, are these tests detecting material unique to COVID-19, or could anyone who has had a coronavirus cold in the past also test positive? From what I've read so far, the jury's still out on that one, but more specific tests are supposedly in the works.

So, in looking again at this study, if RT-PCR testing can't quantify viral loads or determine infectivity, what do we make of their results?]

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- Leung, N.H.L., Chu, D.K.W., Shiu, E.Y.C. *et al.* Respiratory virus shedding in exhaled breath and efficacy of face masks. *Nat Med*. 2020. https://www.nature.com/articles/s41591-020-0843-2

  Abstract:

  We identified seasonal human coronaviruses, influenza viruses and rhinoviruses in exhaled breath and coughs of children and adults with acute respiratory illness. Surgical face masks significantly reduced detection of influenza virus RNA in respiratory droplets and coronavirus RNA in aerosols, with a trend toward reduced detection of coronavirus RNA in respiratory droplets. Our results indicate that surgical face masks could prevent transmission of human coronaviruses and influenza viruses from symptomatic individuals.

[***Note:*** This is a well done study that screened 3,363 people between March 2013 and May 2016 (pre-COVID-19), and ultimately studied 111 who tested positive for coronavirus (OC43, HKU1, or NL63), influenza, and/or rhinovirus. Again, though, they're using RT-PCR testing to try to quantify viral loads (See previous study's note). Also, it tested the emissions of viral particles, and in so doing only supports the concept that the sick should wear masks, not the healthy.

Of the tests done on masked subjects, they report *"Our findings indicate that surgical masks can efficaciously reduce the emission of influenza virus particles into the environment in respiratory droplets, but not in aerosols..."* as well as *"We also demonstrated the efficacy of surgical masks to reduce coronavirus detection and viral copies in large respiratory droplets and in aerosols."*

In the next paragraph, though, they state *"Among the samples collected* ***without*** *a face mask, we found that the* ***majority*** *of participants with influenza virus and coronavirus infection* ***did not shed detectable virus in respiratory droplets or aerosols****, whereas for rhinovirus we detected virus in aerosols in 19 of 34 (56%) participants (compared to 4 of 10 (40%) for coronavirus and 8 of 23 (35%) for influenza).* ***For those who did shed virus in respiratory droplets and aerosols****,* ***viral load in both tended to be low*** *(Fig. 1)."* Curiously, they considered this—undetectable viral shedding—"the major limitation of their study." Might it be that there were no viral particles to detect? I guess those results didn't sound right to them. Maybe we don't all shed these viruses as much as they think we should.]

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- Johnson DF, Druce JD, Birch C, Grayson ML. A quantitative assessment of the efficacy of surgical and N95 masks to filter influenza virus in patients with acute influenza infection.

Clin Infect Dis. 2009 Jul 15;49(2):275-7.
https://academic.oup.com/cid/article/49/2/275/405108

Abstract:

We assessed the in vivo efficacy of surgical and N95 (respirator) masks to filter reverse transcription-polymerase chain reaction (RT-PCR)-detectable virus when worn correctly by patients with laboratory-confirmed acute influenza. Of 26 patients with a clinical diagnosis of influenza, 19 had the diagnosis confirmed by RT-PCR, and 9 went on to complete the study. Surgical and N95 masks were equally effective in preventing the spread of PCR-detectable influenza.

[***Note:*** This is a 2009 study of the flu that tested the emission of influenza virus in a cough and enrolled only 26 patients, of which only 19 were confirmed to have influenza by RT-PCR of nasal swabs and only ten of those 19 were confirmed to have it by point-of-care assay. One of the ten couldn't complete the protocol. So, only nine people were actually used in the study. Their results showed N95 and surgical masks to be equally efficient. Besides being a really tiny study, however, they *"did not formally demonstrate that the virus detected in the study participants was infectious and could be transmitted to other individuals."* Yet, they go on to say "*…it is **likely** that the virus quantitated by real-time PCR was infectious.*" Was it, or wasn't it? No proof, but it sounds right. Oh, and there's that RT-PCR test again, being used as a quantitative test.]

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- Green CF, Davidson CS, Panlilio AL, et al. Effectiveness of selected surgical masks in arresting vegetative cells and endospores when worn by simulated contagious patients. Infect Control Hosp Epidemiol. 2012;33(5):487-494.
https://www.cambridge.org/core/journals/infection-control-and-hospital-epidemiology/article/effectiveness-of-selected-surgical-masks-in-arresting-vegetative-cells-and-endospores-when-worn-by-simulated-contagious-patients/BFC344C8AF4D992EB843B1FF0644BC84#

Abstract:

Objective: The objective of this study was to quantify the effectiveness of selected surgical masks in arresting vegetative cells and endospores in an experimental model that simulated contagious patients.

Setting: Laboratory.

Methods: Five commercially available surgical masks were tested for their ability to arrest infectious agents. Surgical masks were placed over the nose and mouth of

mannequin head forms (Simulaids adult model Brad CPR torso). The mannequins were retrofitted with a nebulizer attached to an automated breathing simulator calibrated to a tidal volume of 500 mL/breath and a breathing rate of 20 breaths/min, for a minute respiratory volume of 10 L/min. Aerosols of endospores or vegetative cells were generated with a modified microbiological research establishment-type 6-jet collision nebulizer, while air samples were taken with all-glass impinger (AGI-30) samplers downstream of the point source. All experiments were conducted in a horizontal bioaerosol chamber.

Results: Mean arrestance of bioaerosols by the surgical masks ranged from 48% to 68% when the masks were challenged with endospores and from 66% to 76% when they were challenged with vegetative cells. When the arrestance of endospores was evaluated, statistical differences were observed between some pairs, though not all, of the models evaluated. There were no statistically significant differences in arrestance observed between models of surgical masks challenged with vegetative cells.

Conclusions: The arrestance of airborne vegetative cells and endospores by surgical masks worn by simulated contagious patients supports surgical mask use as one of the recommended cough etiquette interventions to limit the transmission of airborne infectious agents.

[Note: So, where to start in this one? First, they used mannequin heads and nebulizers, not real people. Second, they tested for bacterial endospores and vegetative cells, which are HUGE compared to viruses. Even with this, their results for stopping these large bodies are not encouraging. If the masks only stop 48-68% of endospores, would they stop a droplet with virus at all?]

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These are the studies used by the CDC to support the extended wearing of masks. If I were to summarize these studies, I would have to say that

1) they used statistically insignificant subject sample sizes—only 2 of 19 studies had more than 100 test subjects and none exceeded 200
2) they tested for forceful exhalation (ie, cough and sneezes) and only one study attempted to study inhalation
3) they relied upon RT-PCR to quantify viral loads, when the use of RT-PCR for quantitative testing is problematic at best
4) they assumed pre-/asymptomatic people can be infectious carriers while admitting that they don't even know if the viral particles shown by RT-PCR are infectious

At the very best, a few of these studies **suggest** support for the use of masks in symptomatic (sick) patients, but none support the use of masks in the healthy. As has been advised for decades, hand washing remains the best preventive measure against viral illnesses, while unfitted, simple cloth masks—as currently advised by the CDC—are useless against viruses. I should also note that Dr. Fauci, in a video conversation with students of Georgetown University's Institute of Politics and Public Service, came out **against** doing a real, randomized controlled study on masks (https://www.breitbart.com/politics/2020/07/16/dr-anthony-fauci-opposes-controlled-study-effectiveness-masks/ and https://www.thenewamerican.com/usnews/health-care/item/36451-does-fauci-oppose-mask-studies-because-he-knows). He cited the meta-analyses I've reviewed above as all the study needed to show the efficacy of masks. As we've seen, they do nothing of the sort.

More to the story . . .

Now that we've looked at the 19 studies/reports that the CDC believes best support its recommendations on masks, let's look at other studies.

- Molinari, JA and Nelson, P. Face Mask Performance: Are You Protected? Oral Health, March 16, 2016. https://www.oralhealthgroup.com/features/face-mask-performance-protected/

[Note: This is a good review article on masks in general, written for the dental profession. It discusses performance standards, proper use and misuse, and more. That includes proper fit, the use-life of a mask, the need to change them frequently in a dental (healthcare) setting, and other basic considerations—few, if any, of which we see being performed by the community mask user. He ends by saying that "*One should also understand that no mask can filter out 100 percent of aerosolized particles*."]

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- Streeck H, Schulte B, et al. Infection fatality rate of SARS-CoV-2 infection in a German community with a super-spreading event. medRxiv May 4, 2020. https://doi.org/10.1101/2020.05.04.20090076

Abstract:

Results: Of the 919 individuals with evaluable infection status (out of 1,007; 405 households) 15.5% (95% CI: [12.3%; 19.0%]) were infected. This is 5-fold higher than the number of officially reported cases for this community (3.1%). Infection was associated with characteristic symptoms such as loss of smell and taste. 22.2% of all infected individuals were asymptomatic. With the seven SARS-CoV-2-associated reported deaths the **estimated IFR was 0.36%** [0.29%; 0.45%]. Age and sex were not found to be associated with the infection rate. **Participation in carnival festivities increased both the infection rate** (21.3% vs. 9.5%, p<0.001) and the number of symptoms in the infected (estimated relative mean increase 1.6, p=0.007). The risk of a person being infected was not found to be associated with the number of study participants in the household this person lived in. The secondary infection risk for study participants living in the same household increased from 15.5% to 43.6%, to 35.5% and to 18.3% for households with two, three or four people respectively (p<0.001). Conclusions: While the number of infections in this high prevalence community is not representative for other parts of the world, the IFR calculated on the basis of the infection rate in this community can be utilized to estimate the percentage of infected based on the number of reported fatalities in other places with similar population characteristics. Whether the specific circumstances of a super-spreading event not only have an impact on the infection rate and number of symptoms but also on the IFR requires further investigation. **The unexpectedly low secondary infection risk among persons living in the same household has important implications** for measures installed to contain the SARS-CoV-2 virus pandemic.

[***Note:*** This study is in preprint status, awaiting peer review and formal publication. Because of the length of the abstract, I'm reprinting only the results and conclusion. Heinsberg, Germany is one of the country's hardest hit areas with COVID-19. The super-spreading event is a large carnival held annually there, which gave them an opportunity to study the concept of super-spreading events. The infection fatality rate of .36% is higher than some other studies of IFR but still within the range seen with influenza. Participation in the carnival did increase the infection rate. However, the very low p-value shows this increase to be insignificant. Likewise with secondary infections among members of the same household. In fact, they reported the low secondary infection risk as "unexpected" in light of having 5x the number of positive tests than officially reported in the region and 22% of those being asymptomatic. While mask usage is not discussed, this again shows that COVID-19 is not spread as readily as described by WHO and the CDC, particularly among asymptomatic individuals. As with the previously mentioned study by Ming Gao ("A Study on infectivity of asymptomatic SARS-CoV-2 carriers"), this larger study counters the CDC's arguments for asymptomatic spread.]

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- bin-Reza F et al. The use of mask and respirators to prevent transmission of influenza: A systematic review of the scientific evidence. Resp Viruses 2012;6(4):257-67 https://onlinelibrary.wiley.com/doi/full/10.1111/j.1750-2659.2011.00307.x

  Abstract:

  There are limited data on the use of masks and respirators to reduce transmission of influenza. A systematic review was undertaken to help inform pandemic influenza guidance in the United Kingdom. The initial review was performed in November 2009 and updated in June 2010 and January 2011. Inclusion criteria included randomised controlled trials and quasi-experimental and observational studies of humans published in English with an outcome of laboratory-confirmed or clinically-diagnosed influenza and other viral respiratory infections. There were 17 eligible studies. Six of eight randomised controlled trials found no significant differences between control and intervention groups (masks with or without hand hygiene; N95/P2 respirators). One household trial found that mask wearing coupled with hand sanitiser use reduced secondary transmission of upper respiratory infection/influenza-like illness/laboratory-confirmed influenza compared with education; hand sanitiser alone resulted in no reduction. One hospital-based trial found a lower rate of clinical respiratory illness associated with non-fit-tested N95 respirator use compared with medical masks. Eight of nine retrospective observational studies found that mask and/or respirator use was independently associated with a reduced risk of severe acute respiratory syndrome (SARS). Findings, however, may not be applicable to influenza and **many studies were suboptimal**. **None of the studies established a conclusive relationship between mask/respirator use and protection against influenza infection**. Some evidence **suggests** that mask use is best undertaken as part of a package of personal protection **especially hand hygiene**. The effectiveness of masks and respirators is likely linked to early, consistent and correct usage.

[***Note:*** This paper actually is a review of 17 studies on the use of masks, a group gleaned from 6,015 articles. Of these 17, only 8 were randomized, controlled studies and six of those found no benefit to using masks. The other nine were retrospective, observational studies, two of which also included use of hand sanitizer. Eight of the nine suggested that masks/respirators were associated with a reduced risk to SARS, but the authors rightfully note that differences between SARS, MERS, and influenza might alter findings and that results for one virus might not translate to others. Also, notice the comment about *"many studies were suboptimal."* Actually, Table 2 of the paper gives a synopsis of each of the 17 studies, including their limitations. In reviewing that, **all 17** studies were suboptimal for more than one reason. These reasons included being underpowered, small sample sizes, recall bias, lack of serologic testing in controls, and more. One interesting result that emerged from the review involves the timing in the use of masks. A study of U.S. university students showed efficacy in using masks against

influenza, but they started their protocol at the very beginning of flu season and continued through the season. This study also involved hand sanitizer, which significantly reduced the spread if both mask and sanitizer use were started within 36 hours of identifying an index case. Again, hand hygiene made a big difference and they stressed its use. What does this say about the current COVID-19 pandemic? We certainly aren't at the beginning of the pandemic and hand hygiene is hardly mentioned, while mandates for masks are pushed.]

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- Oberg, T and Brosseau, LM. Surgical mask filter and fit performance. Am J Infect Control. 2008 May;36(4):276-82
  https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7115281/pdf/main.pdf

  Abstract:

  Background: Surgical masks have been used since the early 1900s to minimize infection of surgical wounds from wearer-generated bacteria. There is ongoing debate, however, whether surgical masks can meet the expectations of respiratory protection devices. The goal of this study was to evaluate the filter performance and facial fit of a sample of surgical masks.

  Methods: Filter penetration was measured for at least 3 replicates of 9 surgical masks using monodisperse latex sphere aerosols (0.895, 2.0, and 3.1 mm) at 6 L/min and 0.075-mm sodium chloride particles at 84 L/min. Facial fit was measured on 20 subjects for the 5 masks with lowest particle penetration, using both qualitative and quantitative fit tests.

  Results: Masks typically used in dental settings collected particles with significantly lower efficiency than those typically used in hospital settings. All subjects failed the unassisted qualitative fit test on the first exercise (normal breathing). Eighteen subjects failed the assisted qualitative fit tests; 60% failed on the first exercise. Quantitative fit factors ranged from 2.5 to 9.6.

  Conclusion: None of these surgical masks exhibited adequate filter performance and facial fit characteristics to be considered respiratory protection devices.

[***Note:*** While this study looked at penetration of various-sized particles (but very large in comparison to other studies) with a variety of masks, its primary results are related to mask fit. Even healthcare workers experienced in using masks were not able to properly fit their masks the majority of the time. Their conclusion is that improper fit essentially made the masks useless in preventing the spread of an infectious respiratory illness.]

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- Desai, AN and Mehrotra, P. Medical Masks, JAMA. 2020;323(15):1517-1518 https://jamanetwork.com/journals/jama/fullarticle/2762694

  "When Should a Mask Be Used?

  Face masks should be used only by individuals who have symptoms of respiratory infection such as coughing, sneezing, or, in some cases, fever. Face masks should also be worn by healthcare workers, by individuals who are taking care of or are in close contact with people who have respiratory infections, or otherwise as directed by a doctor. Face masks should not be worn by healthy individuals to protect themselves from acquiring respiratory infection because there is **no evidence to suggest that face masks worn by healthy individuals are effective in preventing people from becoming ill**. Face masks should be reserved for those who need them because masks can be in short supply during periods of widespread respiratory infection. **Because N95 respirators require special fit testing, they are not recommended for use by the general public**."

[***Note:*** This is a patient information page for the public produced by JAMA in April 2020. It, too, mentions the need for proper fitting of N95 respirators. How many people do you know who have properly fitted masks? Also, of note, it **stresses** the need for hand washing when using a mask—washing hands before and after touching the mask, washing them after discarding a mask, and washing frequently during the day. The paper says as much about hand hygiene as it does masks.]

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- Michael Klompas, M.D., M.P.H., Charles A. Morris, M.D., M.P.H Universal Masking in Hospitals in the Covid-19 Era. N Engl J Med 2020; 382:e63 https://www.nejm.org/doi/full/10.1056/NEJMp2006372

[Note: No abstract, but here are a few significant quotes:

"We know that wearing a mask outside health care facilities offers little, if any, protection from infection. Public health authorities define a significant exposure to Covid-19 as face-to-face contact within 6 feet with a patient with symptomatic Covid-19 that is sustained for at least a few minutes (and some say more than 10 minutes or even 30 minutes). The chance of catching Covid-19 from a passing interaction in a public space is therefore minimal."

"*What is clear, however, is that universal masking alone is not a panacea. A mask will not protect providers caring for a patient with active Covid-19 if it's not accompanied by meticulous hand hygiene, eye protection, gloves, and a gown. A mask alone will not prevent health care workers with early Covid-19 from contaminating their hands and spreading the virus to patients and colleagues. Focusing on universal masking alone may, paradoxically, lead to more transmission of Covid-19 if it diverts attention from implementing more fundamental infection-control measures.*"

and,

"*It is also clear that masks serve symbolic roles. Masks are not only tools, they are also talismans that may help increase health care workers' perceived sense of safety, well-being, and trust in their hospitals*."

Hmmm, now we're dealing not with science but with talismans. Is it a "*perceived sense of safety …*" or a false sense of security? Also, did you notice the concern about contaminating hands in the second quote? We're back to hand washing as a "*fundamental infection-control measure.*"]

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- MacIntyre CR, Seale H, Dung TC, et al. A cluster randomised trial of cloth masks compared with medical masks in healthcare workers *BMJ* Open 2015; 5:e006577 https://bmjopen.bmj.com/content/5/4/e006577

  Results: The rates of all infection outcomes were highest in the cloth mask arm, with the rate of ILI statistically significantly higher in the cloth mask arm (relative risk (RR)=13.00, 95% CI 1.69 to 100.07) compared with the medical mask arm. Cloth masks also had significantly higher rates of ILI compared with the control arm. An analysis by mask use showed ILI (RR=6.64, 95% CI 1.45 to 28.65) and laboratory-confirmed virus (RR=1.72, 95% CI 1.01 to 2.94) were significantly higher in the cloth masks group compared with the medical masks group. Penetration of cloth masks by particles was almost 97% and medical masks 44%.

  Conclusions: This study is the first RCT of cloth masks, and the results caution against the use of cloth masks. This is an important finding to inform occupational health and safety. Moisture retention, reuse of cloth masks and poor filtration **may result in increased risk of infection**. Further research is needed to inform the widespread use of cloth masks globally. However, as a precautionary measure, cloth masks should not be

recommended for HCWs, particularly in high-risk situations, and guidelines need to be updated.

[***Note:*** The conclusion above pretty much says it all for this study. Of course, this doesn't address the community use of cloth masks, but the efficacy of such won't improve just because they're used in a different setting. Notice that they also conclude that cloth masks may **increase** the risk of infection. As we'll see, this isn't just because the prolonged use of a cloth mask causes it to become overladen with virus (if exposed); there are physiologic changes in the body that contribute as well.]

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- Xiao J, Shiu E, Gao H, et al. Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures. Emerging Infectious Diseases. 2020;26(5):967-975. https://wwwnc.cdc.gov/eid/article/26/5/19-0994_article

  Abstract:

  There were 3 influenza pandemics in the 20th century, and there has been 1 so far in the 21st century. Local, national, and international health authorities regularly update their plans for mitigating the next influenza pandemic in light of the latest available evidence on the effectiveness of various control measures in reducing transmission. Here, we review the evidence base on the effectiveness of nonpharmaceutical personal protective measures and environmental hygiene measures in nonhealthcare settings and discuss their potential inclusion in pandemic plans. Although mechanistic studies support the potential effect of hand hygiene or face masks, evidence from 14 randomized controlled trials of these measures did not support a substantial effect on transmission of laboratory-confirmed influenza. We similarly found limited evidence on the effectiveness of improved hygiene and environmental cleaning. We identified several major knowledge gaps requiring further research, most fundamentally an improved characterization of the modes of person-to-person transmission.

[Note: The abstract says it well: hand hygiene and face masks offer no substantial effect on transmission of influenza and more study on the "modes of person-to-person transmission" is needed.

With regards to masks, the article states: "*In our systematic review, we identified 10 RCTs that reported estimates of the effectiveness of face masks in reducing laboratory-confirmed influenza virus infections in the community from literature published during 1946–July 27, 2018.*

In pooled analysis, we found no significant reduction in influenza transmission with the use of face masks *(RR 0.78, 95% CI 0.51–1.20; I2 = 30%, p = 0.25)"*

Notice the dates. This meta-analysis went back into the literature to 1946 and looked at all of the studies done up to July 2018. They could only identify 10 randomized, controlled studies from which to make their conclusions. That's not to say there were only 10 studies over 72 years. There are many, many case reports, letters, and reviews on the topic, but randomized, controlled tests (RCT) are a gold standard for testing. Curiously, if you notice the hyperlink, this article is housed on the CDC's own website, yet contradicts the advice from the CDC. Perhaps, that's why it wasn't included in the CDC's bibliography on their mask page.

Also, in you look again at the bin-Reza, et al. study mentioned a few pages earlier, at the beginning of this section, you'll note that they, too, looked specifically at RCTs. They reviewed over 6,000 articles from which they gleaned 17 papers worth analyzing. Of those, only 8 were RCTs, but their conclusions were the same. In plain English, masks don't work.]

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- MacIntyre CR, Cauchemez S, Dwyer DE, et al. Face mask use and control of respiratory virus transmission in households. *Emerg Infect Dis*. 2009;15(2):233-241. https://wwwnc.cdc.gov/eid/article/15/2/08-1167_article

  Abstract:

  Many countries are stockpiling face masks for use as a nonpharmaceutical intervention to control virus transmission during an influenza pandemic. We conducted a prospective cluster-randomized trial comparing surgical masks, non–fit-tested P2 masks, and no masks in prevention of influenza-like illness (ILI) in households. Mask use adherence was self-reported. During the 2006 and 2007 winter seasons, 286 exposed adults from 143 households who had been exposed to a child with clinical respiratory illness were recruited. We found that adherence to mask use significantly reduced the risk for ILI-associated infection, but <50% of participants wore masks most of the time. We concluded that household use of face masks is associated with low adherence and is ineffective for controlling seasonal respiratory disease. However, during a severe pandemic when use of face masks might be greater, pandemic transmission in households could be reduced. Many countries are stockpiling face masks for use as nonpharmaceutical interventions to reduce viral transmission during an influenza pandemic. We conducted a prospective cluster-randomized trial comparing surgical masks, non–fit-tested P2 masks, and no masks in prevention of influenza-like illness (ILI) in households. During the 2006 and 2007 winter seasons, 286 exposed adults from 143 households who had been exposed to a child with clinical respiratory illness were recruited. Intent-to-treat analysis showed no significant difference in the relative risk of ILI in the mask use groups compared with the control group; however, <50% of those in the mask use groups reported wearing masks most of the time. Adherence to mask use

was associated with a significantly reduced risk of ILI-associated infection. We concluded that household use of masks is associated with low adherence and is ineffective in controlling seasonal ILI. If adherence were greater, mask use might reduce transmission during a severe influenza pandemic.

[***Note:*** Their final conclusion is that masks don't help control the spread of seasonal flu-like illnesses (ILI) due to poor compliance in using them. It should also be noted that "*Although we found no significant difference in handwashing practices between adherent and non-adherent mask users, it is possible that adherent mask use is correlated with other, unobserved variables that reduce the risk of infection*." In other words, they didn't control their study for hand washing practices, although a third of their citations were for studies on hand washing. They also did not look at practices for cleansing contaminated surfaces, which has been found to have a high correlation with the spread of ILI. Also, this is an article housed on the CDC website that contradicts their recommendations and isn't used on their mask page. Is there a pattern developing?]

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- Jacobs JL, Ohde S, Takahashi O, Tokuda Y, Omata F, Fukui T. Use of surgical face masks to reduce the incidence of the common cold among health care workers in Japan: a randomized controlled trial. Am J Infect Control. 2009;37(5):417-419.

  Abstract:

  Background: Health care workers outside surgical suites in Asia use surgical-type face masks commonly. Prevention of upper respiratory infection is one reason given, although evidence of effectiveness is lacking.

  Methods: Health care workers in a tertiary care hospital in Japan were randomized into 2 groups: 1 that wore face masks and 1 that did not. They provided information about demographics, health habits, and quality of life. Participants recorded symptoms daily for 77 consecutive days, starting in January 2008. Presence of a cold was determined based on a previously validated measure of self-reported symptoms. The number of colds between groups was compared, as were risk factors for experiencing cold symptoms.

  Results: Thirty-two health care workers completed the study, resulting in 2464 subject days. There were 2 colds during this time period, 1 in each group. Of the 8 symptoms recorded daily, subjects in the mask group were significantly more likely to experience

headache during the study period (P < .05). Subjects living with children were more likely to have high cold severity scores over the course of the study.

Conclusion: Face mask use in health care workers has not been demonstrated to provide benefit in terms of cold symptoms or getting colds. A larger study is needed to definitively establish noninferiority of no mask use.

[***Note:*** Again, a relatively small test group that was followed for common cold symptoms, not COVID-19. Like many of these studies, they were done pre-COVID-19, but after SARS-CoV. Their conclusion: masks don't help.]

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- Cowling BJ, Zhou Y, Ip DK, Leung GM, Aiello AE. Face masks to prevent transmission of influenza virus: a systematic review. Epidemiol Infect. 2010;138(4):449-456. https://www.cambridge.org/core/journals/epidemiology-and-infection/article/face-masks-to-prevent-transmission-of-influenza-virus-a-systematic-review/64D368496EBDE0AFCC6639CCC9D8BC05

  Abstract:

  Influenza viruses circulate around the world every year. From time to time new strains emerge and cause global pandemics. Many national and international health agencies recommended the use of face masks during the 2009 influenza A (H1N1) pandemic. We reviewed the English-language literature on this subject to inform public health preparedness. There is some evidence to support the wearing of masks or respirators during illness to protect others, and public health emphasis on mask wearing during illness may help to reduce influenza virus transmission. There are fewer data to support the use of masks or respirators to prevent becoming infected. Further studies in controlled settings and studies of natural infections in healthcare and community settings are required to better define the effectiveness of face masks and respirators in preventing influenza virus transmission.

[***Note:*** Some data to suggest that masks worn by those who are sick will help prevent spread, but nothing in their data suggests that masks help protect the healthy. See Summary Table 1 & 2., if you can find the full article. It seems to have been recently pulled from the internet. Curious.]

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- Smith, J.D. et al. "Effectiveness of N95 respirators versus surgical masks in protecting health care workers from acute respiratory infection: a systematic review and meta-

analysis," CMAJ Mar 2016 https://www.cmaj.ca/content/188/8/567

[Note: The abstract for this 2016 paper was a bit longer than I wished to duplicate here, but here's a quote from their results:

"We identified 6 clinical studies (3 RCTs, 1 cohort study and 2 case–control studies) and 23 surrogate exposure studies. In the meta-analysis of the clinical studies, **we found no significant difference between N95 respirators and surgical masks in associated risk of (a) laboratory-confirmed respiratory infection** (RCTs: odds ratio [OR] 0.89, 95% confidence interval [CI] 0.64–1.24; cohort study: OR 0.43, 95% CI 0.03–6.41; case–control studies: OR 0.91, 95% CI 0.25–3.36); **(b) influenza-like illness** (RCTs: OR 0.51, 95% CI 0.19–1.41); **or (c) reported workplace absenteeism** (RCT: OR 0.92, 95% CI 0.57–1.50)."

They reviewed 8,962 titles, excluded 8,855 just from the title, and looked at the other 107 full-text papers. From this group, they selected the six studies mentioned. Since all of these studies were done in healthcare workers, who were required to wear masks at work, there appears to be no control arms for subjects not wearing a mask. Thus, they could only compare between the two styles of masks and could not assess the efficacy of masks compared to no masks at all.]

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- Offeddu, V. et al. "Effectiveness of Masks and Respirators Against Respiratory Infections in Healthcare Workers: A Systematic Review and Meta-Analysis," Clinical Infectious Diseases, Volume 65, Issue 11, 1 December 2017, Pages 1934–1942, https://academic.oup.com/cid/article/65/11/1934/4068747

  Abstract:

  This systematic review and meta-analysis quantified the protective effect of facemasks and respirators against respiratory infections among healthcare workers. Relevant articles were retrieved from Pubmed, EMBASE, and Web of Science. Meta-analyses were conducted to calculate pooled estimates. Meta-analysis of randomized controlled trials (RCTs) indicated a protective effect of masks and respirators against clinical respiratory illness (CRI) (risk ratio [RR] = 0.59; 95% confidence interval [CI]:0.46–0.77) and influenza-like illness (ILI) (RR = 0.34; 95% CI:0.14–0.82). Compared to masks, N95 respirators conferred superior protection against CRI (RR = 0.47; 95% CI: 0.36–0.62) and laboratory-confirmed bacterial (RR = 0.46; 95% CI: 0.34–0.62), but not viral infections or ILI. Meta-analysis of observational studies provided evidence of a protective effect of masks (OR = 0.13; 95% CI: 0.03–0.62) and respirators (OR = 0.12; 95% CI: 0.06–0.26) against severe acute respiratory syndrome (SARS). This systematic review and meta-

analysis supports the use of respiratory protection. However, the existing evidence is sparse and findings are inconsistent within and across studies. Multicentre RCTs with standardized protocols conducted outside epidemic periods would help to clarify the circumstances under which the use of masks or respirators is most warranted.

[***Note:*** This 2017 paper looked at over 2,300 articles and ultimately selected six RCTs and 23 observational studies for review. While the abstract says their meta-analysis supports the use of masks for protection, they also admit that the evidence for such was "*sparse and findings are inconsistent within and across studies.*" Not sure how sparse and inconsistent findings lend support to their conclusion. In fact, in their discussion they mention that, in the RCTs, the clinical assessments were self-reported by HCWs and prone to bias and that the sources of reported infections were not ascertained. Those who got sick could have picked up the illness from any source. Four of the six RCTs were done in China by the same research team, which makes it difficult to generalize their findings to other settings. In all of these studies, the evidence for protection against viral respiratory illness was not statistically significant. Of the observational studies, their results point to protection from SARS in a hospital setting, but for H1N1 influenza the results were inconsistent.

In their full conclusion, they state:
"We found evidence to support universal medical mask use in hospital settings ***as part of*** *infection control measures to reduce the risk of CRI and ILI among HCWs. Overall, N95 respirators may convey greater protection, but universal use throughout a work shift is likely to be less acceptable due to greater discomfort.*

Our analysis confirms the effectiveness of medical masks and respirators against SARS. Disposable, cotton, or paper masks are not recommended."

"We found no clear benefit of either medical masks or N95 respirators against pH1N1."

"Overall, the evidence to inform policies on mask use in HCWs is poor, with a small number of studies that is prone to reporting biases and lack of statistical power."

Why didn't they say that in their abstract?]

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- Jefferson T, Foxlee R, et al. Physical interventions to interrupt or reduce the spread of respiratory viruses: systematic review. BMJ 2008 Jan 12;336(7635):77-80 https://www.bmj.com/content/336/7635/77

  Abstract:

Conclusion-- Routine long-term implementation of some physical measures to interrupt or reduce the spread of respiratory viruses might be difficult but many simple and low cost interventions **could be** useful in reducing the spread.

[***Note:*** I found over a dozen similar papers that looked at a host of preventive interventions: hand washing, masks, gowns, etc. All had essentially the same conclusion, that the interventions **could** be useful. Again, this abstract was long, so I reprinted only the conclusion. This study looked specifically at hand washing (>10 times a day), N95 masks, and protective gowns. Their comment that such interventions could be helpful applied to using **all three** together. They also stated "*The lack of proper evaluation of global measures such as screening at entry ports and social distancing* ***prevent firm conclusions being drawn***." So, no firm conclusions from this study . . . or the dozen-plus like it.]

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- Neupane BB, et al. Optical microscopic study of surface morphology and filtering efficiency of face masks. PeerJ. 2019; 7: e7142
  https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6599448/

  Results

  The pore size of masks ranged from 80 to 500 µm, which was much bigger than particular matter having diameter of 2.5 µm or less ($PM_{2.5}$) and 10 µm or less (PM_{10}) size. The PM_{10} filtering efficiency of four of the selected masks ranged from 63% to 84%. The poor filtering efficiency may have arisen from larger and open pores present in the masks. Interestingly, we found that efficiency dropped by 20% after the 4th washing and drying cycle. We observed a change in pore size and shape and a decrease in microfibers within the pores after washing. Stretching of CM surface also altered the pore size and potentially decreased the filtering efficiency. As compared to CMs, the less frequently used surgical/paper masks had complicated networks of fibers and much smaller pores in multiple layers in comparison to CMs, and therefore had better filtering efficiency. **This study showed that the filtering efficiency of cloth face masks were relatively lower, and washing and drying practices deteriorated the efficiency**. We believe that the findings of this study will be very helpful for increasing public awareness and help governmental agencies to make proper guidelines and policies for use of face mask.

[Note: The recommendation of those promoting cloth masks is to wash and dry them often to keep them clean and reduce the viral load that builds up with use. However, this study shows that such routine cleaning actually degrades the already low efficiency of these masks.]

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- Robert Levin, MD, Medical Director, Ventura County Public Health, *COVID-19 and the Use of Cloth Face Masks* https://www.simivalley.org/home/showdocument?id=22324

  Issues:
  Should cloth masks be worn during this COVID-19 pandemic in either the community setting or in places of business where food is sold?

  Conclusions:
  1. There is no incontrovertible, compelling or even a preponderance of evidence to support an Order to wear a cloth mask in the community setting at this time.
  2. I am supportive of cashiers and customers wearing cloth masks inside a grocery store or any essential business where social distancing is difficult to maintain. Supporting evidence is not strong enough to issue an Order to mandate the use of cloth masks at this time; consumer preference is already accomplishing this in most parts of the County.

[Note: This is the Ventura County (CA) Public Health Department's published statement, dated April 27, 2020. This is actually a good resource listing a Pros/Cons section of 19 arguments for and against the use of masks, along with references. It does not, however, delve into the issues of potential harm from masks, as we'll investigate in the next section of this paper.]

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You can find thousands of articles on masks from news services, medical journals, and online resources. A good many of them are little more than opinion pieces. Most of these other articles offer no additional insights than the ones I've discussed already. Of those that "cite" RCTs, they appear to cherry pick the studies which state in their conclusions that masks might help, without looking at the actual results of the studies. Many of these are the studies I've actually presented in this paper so you can see for yourself what is stated, and what it left out, in their conclusions. Here's a sampling of some of these other articles I've looked at, should you want to refer to them.

- Harriman KH, Brosseau LM. Controversy: Respiratory Protection for Healthcare Workers. April, 2011. http://www.medscape.com/viewarticle/741245_print
- Respirators and Surgical Masks: A Comparison. 3 M Occupational Health and Environment Safety Division. May, 2020 https://multimedia.3m.com/mws/media/957730O/respirators-and-surgical-masks-contrast-technical-bulletin.pdf
- Brosseau L. N95 Respirators and Surgical Masks. Centers for Disease Control and Prevention. Oct. 2009. https://blogs.cdc.gov/niosh-science-blog/2009/10/14/n95/

- Weber A, Willeke K, Marchioni R, et al. Aerosol penetration and leakage characteristics of masks used in the health care industry. *Am J Infect Control*. 1993;21(4):167-173. https://www.ajicjournal.org/article/0196-6553(93)90027-2/pdf
- Lipp A. The effectiveness of surgical face masks: what the literature shows. *Nurs Times*. 2003;99(39):22-24. https://pubmed.ncbi.nlm.nih.gov/14562656/
- Chen CC, Willeke K. Characteristics of face seal leakage in filtering facepieces. *Am Ind Hyg Assoc J*. 1992;53(9):533-539. https://pubmed.ncbi.nlm.nih.gov/1524028/
- COVID-19: How much protection do face masks offer? Mayo Clinic Patient Health Info page. https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-mask/art-20485449
- Radonovich, L.J. et al. N95 Respirators vs Medical Masks for Preventing Influenza Among Health Care Personnel: A Randomized Clinical Trial, JAMA. 2019; 322(9): 824–833. https://jamanetwork.com/journals/jama/fullarticle/2749214
- Long, Y. et al. Effectiveness of N95 respirators versus surgical masks against influenza: A systematic review and meta-analysis, J Evid Based Med. 2020; 1- 9. https://onlinelibrary.wiley.com/doi/epdf/10.1111/jebm.12381
- MacIntyre CR, Seale H, Dung TC, et al A cluster randomised trial of cloth masks compared with medical masks in healthcare workers BMJ Open 2015;5:e006577 https://bmjopen.bmj.com/content/5/4/e006577
- Brainard J, Jones N, et al. Facemasks and similar barriers to prevent respiratory illness such as COVID-19: A rapid systematic review. https://www.medrxiv.org/content/10.1101/2020.04.01.20049528v1
- Jefferson T, Jones M, et al. Physical interventions to interrupt or reduce the spread of respiratory viruses. Part 1 - Face masks, eye protection and person distancing: systematic review and meta-analysis. https://www.medrxiv.org/content/10.1101/2020.03.30.20047217v2
- Hyejung Jung, et al. Comparison of Filtration Efficiency and Pressure Drop in Anti-Yellow Sand Masks, Quarantine Masks, Medical Masks, General Masks, and Handkerchiefs. Aerosol and Air Quality Research, 14: 991–1002, 2014 https://aaqr.org/articles/aaqr-13-06-oa-0201.pdf
- Tunevall, T.G. Postoperative wound infections and surgical face masks: A controlled study. World J. Surg. 15, 383–387 (1991). https://doi.org/10.1007/BF01658736
- Mitchell NJ and Hunt S, Surgical face masks in modern operating rooms—a costly and unnecessary ritual? Hosp Infect Vol 18: Issue 3, p239-242, July 01,1991 https://www.journalofhospitalinfection.com/article/0195-6701(91)90148-2/pdf
- Da Zhou C, at al. Unmasking the surgeons: the evidence base behind the use of facemasks in surgery. J R Soc Med. 2015 Jun; 108(6): 223–228. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4480558/
- Samy Rengasamy, Benjamin Eimer, Ronald E. Shaffer, Simple Respiratory Protection—Evaluation of the Filtration Performance of Cloth Masks and Common Fabric Materials Against 20–1000 nm Size Particles, The Annals of Occupational Hygiene, Volume 54, Issue 7, October 2010, Pages 789–798, https://academic.oup.com/annweh/article/54/7/789/202744

- Person E, et al. [Effect of a surgical mask on six minute walking distance] Rev Mal Respir 2018 Mar;35(3):264-268 https://pubmed.ncbi.nlm.nih.gov/29395560/
- Chughtai AA, Stelzer-Braid S, Rawlinson W, Pontivivo G, Wang Q, Pan Y, Zhang D, Zhang Y, Li L, MacIntyre CR. Contamination by respiratory viruses on outer surface of medical masks used by hospital healthcare workers. BMC Infect Dis. 2019 Jun 3;19(1):491. https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-019-4109-x

More harm than good?

Earlier, I mentioned that masks could be harmful when worn for prolonged periods of time. Since I looked at the articles listed by the CDC to support their position, I felt it only appropriate to do the same for the other side. Here are some of the articles, papers, and studies supporting that statement.

- Russell Blaylock, MD, Face Masks Pose Serious Risks to The Healthy https://www.technocracy.news/blaylock-face-masks-pose-serious-risks-to-the-healthy/

[***Note:*** This online article provides a summary of the physiologic changes (lowered O2, elevated CO2, etc.) of prolonged mask wearing and the harmful effects of prolonged use. The author cites his sources, most of which I've reviewed and included here in order to verify his statements, or not. I do so because this article is frequently used by those standing against the general use of masks in this pandemic. There have been those who have tried to refute the science behind some of his statements, too. Some of those attempts are laughable, such as a Mayo Clinic article where one doctor used a fingertip oximeter to monitor his oxygen saturation levels while taking a walk with a mask on. The fact that his oxygen saturation level didn't fall significantly (it dropped a point or two) was his proof that masks don't cause hypoxia (low O2). One man. One walk. I'm convinced. Sorry, I'm being sarcastic, but I am seriously looking for at least one good study to refute the hypoxia claim that you'll find in a study below, which Dr. Blaylock cited.

He also discusses the dangers of rebreathing viruses caught in a mask:

"*Newer evidence suggests that in some cases the virus can enter the brain. In most instances it enters the brain by way of the olfactory nerves (smell nerves), which connect directly with the area of the brain dealing with recent memory and memory consolidation. By wearing a mask,*

the exhaled viruses will not be able to escape and will concentrate in the nasal passages, enter the olfactory nerves and travel into the brain."

Again, we'll look at all of these claims of the harmful effects of masks by looking at the studies Dr. Blaylock cited.]

* * * * *

Let's look at the claims of respiratory changes first.

- Zhu, JH, Lee, SJ, Wang, DY, Lee, HP. Effects of long-duration wearing of N95 respirator and surgical facemask: a pilot study; J Lung Pulm Resp Res, 2014: 4: 97-100 https://medcraveonline.com/JLPRR/JLPRR-01-00021.pdf

  Abstract:

  The protection efficacy of facemasks and respirators has been well documented. The change of human nasal functions after wearing N95 respirator and surgical facemask is not known. In a parallel group study, we recruited 87 healthy healthcare workers. Each of the volunteers attended two sessions, and wore N95 respirator in session 1 (S1) and surgical facemask in session 2 (S2) for 3hours. Mean minimum cross-sectional area (mMCA) of the two nasal airways via acoustic rhinometry and nasal resistance via rhinomanometry were measured before and immediately after the mask wearing. Rhinomanometry was repeated every 30minutes for 1.5hours after the removal of masks. A questionnaire was distributed to each of the volunteers, during the 3hours mask wearing period, to report subjective feelings on discomfort level of breathing activity. Among 77 volunteers who completed both two sessions, the mean nasal resistance immediately increased upon the removal of surgical facemask and N95 respirator. The mean nasal resistance was significantly higher in S1 than S2 at 0.5 hour and 1.5 hours after removal of the masks ($p<0.01$). There is no statistical difference on mMCA before and after mask wearing in both sessions ($p=0.85$). The discomfort level was increasing with time while wearing masks, with significantly higher magnitude in S1 ($p<0.001$). There is an increase of nasal resistance upon removal of N95 respirator and surgical facemask potentially due to nasal physiological changes. N95 respirator caused higher post-wearing nasal resistance than surgical facemask with different recovering routines.

[***Note:*** While the number of test subjects in this study was small, it shows that prolonged wearing of masks causes measurable changes in nasal function that extends for hours after removal of the mask. Increased nasal resistance is of little concern in healthy individuals, but could be significant is those with asthma, COPD, and other pulmonary disorders. I also found the first statement of the abstract somewhat presumptive. I have yet to read one study that

well documents the protection efficacy of masks/respirators. Even the CDC website couldn't offer one for review. I'm still looking.]

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- Beder A et al. Preliminary report on surgical mask induced deoxygenation during major surgery. Neurocirugia 2008; 19(2):121-6. https://www.sciencedirect.com/science/article/abs/pii/S1130147308702355?via%3Dihub

  Abstract:

  Objectives: This study was undertaken to evaluate whether the surgeons' oxygen saturation of hemoglobin was affected by the surgical mask or not during major operations.

  Methods: Repeated measures, longitudinal and prospective observational study was performed on 53 surgeons using a pulse oximeter pre and postoperatively.

  Results: Our study revealed a decrease in the oxygen saturation of arterial pulsations (SpO2) and a slight increase in pulse rates compared to preoperative values in all surgeon groups. The decrease was more prominent in the surgeons aged over 35.

  Conclusions: Considering our findings, pulse rates of the surgeons increase and SpO2 decrease after the first hour. This early change in SpO2 may be either due to the facial mask or the operational stress. Since a very small decrease in saturation at this level, reflects a large decrease in PaO2, our findings may have a clinical value for the health workers and the surgeons.

[***Note:*** While this is a small study, size-wise, the data was repeatable. The authors fudge their conclusion a bit, IMO. I can see heart rate increasing due to operational stress, but stress would increase respiratory rate as well, and that would increase SpO2, not decrease it. The reduced SpO2 is likely mask related. Yes, I said *likely*, as it's not fully provable even though no other explanation is suggested. Also note the comment about *"a very small decrease in saturation at this level, reflects a large decrease in PaO2."* That's why using a fingertip oximeter while taking a walk in a mask to prove that hypoxia doesn't occur is laughable. A drop in the partial pressure of oxygen in arterial blood (PaO2) can cause hypoxia at the tissue level well before it's reflected in the oxygen saturation (SpO2) reading.]

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- Kao TW, Huang KC, Huang YL, Tsai TJ, Hsieh BS, Wu MS. The physiological impact of wearing an N95 mask during hemodialysis as a precaution against SARS in patients with end-stage renal disease. J Formos Med Assoc. 2004;103(8):624-628. https://pubmed.ncbi.nlm.nih.gov/15340662/

  Abstract:

  Background and purpose: Most patients with end-stage renal disease (ERSD) visiting our hospital for hemodialysis treatment during the SARS outbreak wore an N95 mask. Data on the physiological stress imposed by the wearing of N95 masks remains limited. This study investigated the physiological impact of wearing an N95 mask during hemodialysis (HD) on patients with ESRD.

  Methods: ESRD patients who received regular HD at National Taiwan University Hospital between April to June 2003 were enrolled. Each patient wore a new N95 mask (3M Model 8210) during HD (4 hours). Vital signs, clinical symptoms and arterial blood gas measured before and at the end of HD were compared.

  Results: Thirty-nine patients (23 men; mean age, 57.2 years) were recruited for participation in the study. Seventy percent of the patients showed a reduction in partial pressure of oxygen (PaO2), and 19% developed various degrees of hypoxemia. Wearing an N95 mask significantly reduced the PaO2 level (101.7 +/- 12.6 to 92.7 +/- 15.8 mm Hg, $p = 0.006$), increased the respiratory rate (16.8 +/- 2.8 to 18.8 +/- 2.7/min, $p < 0.001$), and increased the occurrence of chest discomfort (3 to 11 patients, $p = 0.014$) and respiratory distress (1 to 17 patients, $p < 0.001$). Baseline PaO2 level was the only significant predictor of the magnitude of PaO2 reduction ($p < 0.001$).

  Conclusion: Wearing an N95 mask for 4 hours during HD significantly reduced PaO2 and increased respiratory adverse effects in ESRD patients.

[***Note:*** Here's a study that looked at end-stage renal disease patients on dialysis. As with the surgeons, they, too, became significantly hypoxic with the prolonged wearing of a mask. I should point out that another study, from 2016—Campos I, Chan L, Zhang H, et al. Intradialytic Hypoxemia in Chronic Hemodialysis Patients. *Blood Purif*. 2016;41(1-3):177-187 (https://www.karger.com/Article/FullText/441271)—shows that hemodialysis in itself produces some hypoxemia, which is a lesser degree of hypoxia by most definitions. Kao at al recognized this and accounted for it in their study with the N95 masks.

I should also note that I found only two other similar studies: one looking at surgical mask use by pregnant women and one study that looked at using a surgical mask over a N95 mask in healthcare workers. Among their results, they reported no changes in oxygen saturation (SpO2), which as I said above, is not the same as the partial pressure of oxygen in the blood

(PaO2). Another reason that I have not included those is that they both limited the time wearing a mask to an hour or less, which is not the scenario we see with workers being required to wear masks for hours.]

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- Shehade H et al. Cutting edge: Hypoxia-Inducible Factor-1 negatively regulates Th1 function. J Immunol 2015; 195:1372-1376. 2. https://ratical.org/PandemicParallaxView/1372.full.pdf

  Abstract:

  Tissue hypoxia can occur in physiological and pathological conditions. When O2 availability decreases, the transcription factor hypoxia-inducible factor (HIF)-1a is stabilized and regulates cellular adaptation to hypoxia. The objective of this study was to test whether HIF-1a regulates T cell fate and to define the molecular mechanisms of this control. Our data demonstrate that Th1 cells lose their capacity to produce IFN-g when cultured under hypoxia. HIF-1a2/2 Th1 cells were insensitive to hypoxia, underlining a critical role for HIF-1a. Our results point to a role for IL-10, as suggested by the increased IL-10 expression at low O2 levels and the unchanged IFN-g production by IL-10–deficient Th1 cells stimulated in hypoxic conditions. Accordingly, STAT3 phosphorylation is increased in Th1 cells under hypoxia, leading to enhanced HIF-1a transcription, which, in turn, may inhibit suppressor of cytokine signaling 3 transcription. This positive-feedback loop reinforces STAT3 activation and downregulates Th1 responses that may cause collateral damage to the host.

[***Note:*** While this is a *very* technical article, it basically shows a biochemical pathway in which hypoxia can harm the body. In a nutshell, hypoxia increases interleukin-10 (IL-10) which causes inflammation, causes T cells (one of our defensive white blood cells) to lose the ability to produce interferon (IFN-g), and reduces the activation of those T cells. This means a reduced immune function that affects not only our ability to fight off infections but to ward off cancerous cells as well.]

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- Westendorf, A, et al. Hypoxia enhances immunosuppression by inhibiting CD4+ effector T cell function and promoting Treg activity. *Cell Physiol Biochem 2017; 41:1271-84. 3.* https://www.karger.com/Article/FullText/464429

  Abstract:

Background/aims: Hypoxia occurs in many pathological conditions, including inflammation and cancer. Within this context, hypoxia was shown to inhibit but also to promote T cell responses. Due to this controversial function, we aimed to explore whether an insufficient anti-tumour response during colitis-associated colon cancer could be ascribed to a hypoxic microenvironment.

Methods: Colitis-associated colon cancer was induced in wildtype mice, and hypoxia as well as T cell immunity were analysed in the colonic tumour tissues. In addition, CD4+ effector T cells and regulatory T cells were cultured under normoxic and hypoxic conditions and examined regarding their phenotype and function.

Results: We observed severe hypoxia in the colon of mice suffering from colitis-associated colon cancer that was accompanied by a reduced differentiation of CD4+ effector T cells and an enhanced number and suppressive activity of regulatory T cells. Complementary ex vivo and in vitro studies revealed that T cell stimulation under hypoxic conditions inhibited the differentiation, proliferation and IFN-γ production of TH1 cells and enhanced the suppressive capacity of regulatory T cells. Moreover, we identified an active role for HIF-1α in the modulation of CD4+ T cell functions under hypoxic conditions.

Conclusion: Our data indicate that oxygen availability can function as a local modulator of CD4+ T cell responses and thus influences tumour immune surveillance in inflammation-associated colon cancer.

[***Note:*** This is another article that shows altered immune response related to hypoxia.]

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- Sceneay, J, et al. Hypoxia-driven immunosuppression contributes to the pre-metastatic niche. Oncoimmunology. 2013 Jan 1; 2(1): e22355
  https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3583916/

  Abstract:

  Primary tumor cells create favorable microenvironments in secondary organs, termed pre-metastatic niches, that promote the formation of metastases. Using immune competent syngenic breast cancer mouse models, we have recently demonstrated that factors secreted by hypoxic tumor cells condition pre-metastatic niches by recruiting CD11b+/Ly6Cmed/Ly6G+ myeloid cells and suppressing natural killer cell functions.

[***Note:*** This is a third study showing reduced immune function secondary to hypoxia. The last thing we need in fighting off COVID-19, or any other virus, is a compromised immune system, and yet it appears evident that these mask mandates are contributing to just that.]

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- Savransky V et al. Chronic intermittent hypoxia induces atherosclerosis. Am J Resp Crit Care Med 2007; 175:1290-1297. https://www.atsjournals.org/doi/full/10.1164/rccm.200612-1771OC

  Abstract:

  Rationale: Obstructive sleep apnea, a condition leading to chronic intermittent hypoxia (CIH), is associated with hyperlipidemia, atherosclerosis, and a high cardiovascular risk. A causal link between obstructive sleep apnea and atherosclerosis has not been established.

  Objectives: The objective of the present study was to examine whether CIH may induce atherosclerosis in C57BL/6J mice.

  Methods: Forty male C57BL/6J mice, 8 weeks of age, were fed either a high-cholesterol diet or a regular chow diet and subjected either to CIH or intermittent air (control conditions) for 12 weeks.

  Measurements and main results: Nine of 10 mice simultaneously exposed to CIH and high-cholesterol diet developed atherosclerotic lesions in the aortic origin and descending aorta. In contrast, atherosclerosis was not observed in mice exposed to intermittent air and a high-cholesterol diet or in mice exposed to CIH and a regular diet. A high-cholesterol diet resulted in significant increases in serum total and low-density lipoprotein cholesterol levels and a decrease in high-density lipoprotein cholesterol. Compared with mice exposed to intermittent air and a high-cholesterol diet, combined exposure to CIH and a high-cholesterol diet resulted in marked progression of dyslipidemia with further increases in serum total cholesterol and low-density lipoprotein cholesterol (124 +/- 4 vs. 106 +/- 6 mg/dl; $p < 0.05$), a twofold increase in serum lipid peroxidation, and up-regulation of an important hepatic enzyme of lipoprotein secretion, stearoyl-coenzyme A desaturase-1.

  Conclusions: CIH causes atherosclerosis in the presence of diet-induced dyslipidemia

[***Note:*** Okay, yes, this was done in mice and may or may not extrapolate well into humans. But it shows yet another potential risk to mask-induced hypoxia. Will we see a surge in atherosclerotic heart disease in ten years because of this? Time will tell.]

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- Matuschek C, Moll F, Fangerau H, et al. Face masks: benefits and risks during the COVID-19 crisis. *Eur J Med Res*. 2020;25(1):32. Published 2020 Aug 12. doi:10.1186/s40001-

020-00430-5 https://eurjmedres.biomedcentral.com/articles/10.1186/s40001-020-00430-5

Abstract:

Background: The German government has made it mandatory to wear respiratory masks covering mouth and nose (MNC) as an effective strategy to fight SARS-CoV-2 infections. In many countries, this directive has been extended on shopping malls or public transportation. The aim of this paper is to critically analyze the statutory regulation to wear protective masks during the COVID-19 crisis from a medical standpoint.

Methods: We performed an extensive query of the most recent publications addressing the prevention of viral infections including the use of face masks in the community as a method to prevent the spread of the infection. We addressed the issues of practicability, professional use, and acceptability based on the community and the environment where the user resided.

Results: **Upon our critical review of the available literature, we found only weak evidence for wearing a face mask as an efficient hygienic tool to prevent the spread of a viral infection.** However, the use of MNC seems to be linked to relevant protection during close contact scenarios by limiting pathogen-containing aerosol and liquid droplet dissemination. Importantly, **we found evidence for significant respiratory compromise in patients with severe obstructive pulmonary disease, secondary to the development of hypercapnia.** This could also happen in patients with lung infections, with or without SARS-CoV-2.

Conclusion: Epidemiologists currently emphasize that wearing MNC will effectively interrupt airborne infections in the community. The government and the politicians have followed these recommendations and used them to both advise and, in some cases, mandate the general population to wear MNC in public locations. Overall, the results seem to suggest that there are some clinically relevant scenarios where the use of MNC necessitates more defined recommendations. Our critical evaluation of the literature both highlights the protective effects of certain types of face masks in defined risk groups, and emphasizes their potential risks.

[***Note:*** This paper reviewed eight current studies on face masks. Some of these studies looked at masks for everyday use, some at N95 masks specifically, others at surgical masks, and two compared surgical and N95 masks. One only surveyed healthcare workers on their perceptions of PPE. One looked at surgical masks and wound infections, not viral illnesses. Of those that looked specifically at viral illness, they again tested the mask's ability to reduce droplet transmission from coughs. One of the studies reviewed has been presented earlier in this paper— Konda A, et al. Aerosol Filtration Efficiency of Common Fabrics Used in Respiratory Cloth Masks.

While their conclusion really is no conclusion at all and seems written to satisfy their medical authorities, their results are telling: "*weak evidence for wearing a face mask*" and "*significant compromise*" in COPD patients due to hypercapnia. In most cases, the development of hypercapnia is related to an increase in respiratory dead space created by the mask. This dead space is an area where the air flows in both directions. Normally, that's the nasal cavity, trachea, and portions of the alveoli in the lungs. Adding dead space increases the work required to breathe in and out and get the same amount of usable air. It is also a space in which exhaled CO2 can accumulate, only to be rebreathed. Hypercapnia has numerous deleterious effects on the body: headache, vertigo, double vision, brain fog (inability to concentrate), tinnitus (ringing or buzzing in the ears), seizures, or suffocation due to displacement of air.

The claim that masks cause hypercapnia has also been challenged by the "fact checkers." Reuters, Snopes, USAToday and others all have reports on this. They typically report that, yes, CO2 can build up in a mask, but, no, most people won't be affected because most people only wear their mask for short periods. They don't address people who are required to wear a mask for hours, or even all day, at work. They do comment on the fact that people with lung disorders will be affected more. But they only give a cursory glance at the science. True, most healthy people are unlikely to pass out behind the wheel of their car (a few have) or have a seizure, but many report headaches and brain fog. They also don't look deeply into the physiologic changes in the body at the biochemical level that result from hypercapnia. The following study looks at the effect hypercapnia has on our immune system.]

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- Casalino-Matsuda, SM, et al. Hypercapnia Alters Expression of Immune Response, Nucleosome Assembly and Lipid Metabolism Genes in Differentiated Human Bronchial Epithelial Cells. Scientific Reports, 2018; 8:13508
  https://www.nature.com/articles/s41598-018-32008-x.pdf

  Abstract:

  Hypercapnia, the elevation of CO2 in blood and tissues, commonly occurs in severe acute and chronic respiratory diseases, and is associated with increased risk of mortality. Recent studies have shown that hypercapnia adversely affects innate immunity, host defense, lung edema clearance and cell proliferation. Airway epithelial dysfunction is a feature of advanced lung disease, but the effect of hypercapnia on airway epithelium is unknown. Thus, in the current study we examined the effect of normoxic hypercapnia (20% CO2 for 24h) vs normocapnia (5% CO2), on global gene expression in differentiated normal human airway epithelial cells. Gene expression was assessed on Afymetrix microarrays, and subjected to gene ontology analysis for biological process and cluster-network representation. We found that hypercapnia downregulated the expression of 183 genes and upregulated 126. Among these, major gene clusters linked to immune responses and nucleosome assembly were largely downregulated, while lipid metabolism genes were largely upregulated. The

overwhelming majority of these genes were not previously known to be regulated by CO2. These changes in gene expression indicate the potential for hypercapnia to impact bronchial epithelial cell function in ways that may contribute to poor clinical outcomes in patients with severe acute or advanced chronic lung diseases.

[***Note:*** This study shows that hypercapnia actually causes changes at a genetic level and that the affected genes are linked to our immune response or lipid (fat and cholesterol) metabolism. Prior to this study, the effects of CO2 on most of the affected genes was unknown. After reading through the technical data, the effect, in simple English, is a negative one on our immune system in two main ways: chemotaxis—the ability of white blood cells to detect and attack foreign material, such as a virus—is reduced, and the ability of a virus to attach itself to cells in our airways is increased. The paper reports "*Taken together, these observations indicate that the airway epithelium is an important target for hypercapnic suppression of innate immune gene expression. This, along with the suppressive effects of elevated CO2 on macrophage, neutrophil, alveolar epithelial cell functions likely contribute to the deleterious impact of elevated CO2 on lung injury and host defense."*

Whether or not this is a long-term effect that outlasts the period of hypercapnia is unknown. However, whether it's short- or long-term, it's not what our bodies need during a pandemic.]

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- Samannan R, Holt G; Calderon-Candelario R; Mirsaeidi M; Campos M; Effect of Face Masks on Gas Exchange in Healthy Persons and Patients with COPD, Annals of the American Thoracic Society, 0(ja), pp. https://www.atsjournals.org/doi/abs/10.1513/AnnalsATS.202007-812RL

[Note: This study, released 2 October 2020, looks at 30 individuals—15 healthy housestaff members at their institution, and 15 veterans with severe COPD. They acknowledge the small number of subjects, but justify it as being larger than some other studies. Hardly good justification, for them or the smaller studies. The article is being widely touted as disproving the claims that hypercapnia occurs with masks (ex, https://www.foxnews.com/health/face-masks-dont-cause-carbon-dioxide-build-up-or-restrict-breathing). They used only surgical masks, no N95 or cloth masks, had the subjects wear the mask for only 30 minutes, and had them walk for six minutes before testing their blood. They report no changes in the healthy subjects, and state, "We focused in severe COPD subjects as they are at a higher risk of CO2 retention compared with subjects of milder severity or other pulmonary conditions. As shown, we observed a small drop in pO2 in this group, expected based on their disease severity, but not a rise in pCO2 after walking." They then state, "An ideal setting would have been to walk these

individuals without a mask, however, due the current epidemic this was not allowed in our institution at the time of the evaluation."

Besides being so small as to being statistically insignificant, this study appears deceptive. They only followed their subjects for 30 minutes, with six minutes of walking. That's hardly realistic in today's world of mask mandates. Other studies show the O2 and CO2 changes beginning to kick in after an hour, so why didn't these people follow their subjects for one, two, or even three hours? These researchers also failed to do any form of control, to the point they didn't even test their subjects without a mask. I'm surprised this study was accepted for publication. Maybe I shouldn't be.]

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- Ong, JJY, et al. Headaches Associated With Personal Protective Equipment – A Cross-Sectional Study Among Frontline Healthcare Workers During COVID-19. Headache 2020;60:864-877
  https://headachejournal.onlinelibrary.wiley.com/doi/epdf/10.1111/head.13811

  Results—A total of 158 healthcare workers participated in the study. Majority [126/158 (77.8%)] were aged 21-35 years. Participants included nurses [102/158 (64.6%)], doctors [51/158 (32.3%)], and paramedical staff [5/158 (3.2%)]. Pre-existing primary headache diagnosis was present in about a third [46/158 (29.1%)] of respondents. Those based at the emergency department had higher average daily duration of combined PPE exposure compared to those working in isolation wards [7.0 (SD 2.2) vs 5.2 (SD 2.4) hours, P < .0001] or medical ICU [7.0 (SD 2.2) vs 2.2 (SD 0.41) hours, P < .0001]. Out of 158 respondents, 128 (81.0%) respondents developed de novo PPE-associated headaches. A pre-existing primary headache diagnosis (OR = 4.20, 95% CI 1.48-15.40; P = .030) and combined PPE usage for >4 hours per day (OR 3.91, 95% CI 1.35-11.31; P = .012) were independently associated with de novo PPE-associated headaches. Since COVID-19 outbreak, 42/46 (91.3%) of respondents with pre-existing headache diagnosis either "agreed" or "strongly agreed" that the increased PPE usage had affected the control of their background headaches, which affected their level of work performance.

  Conclusion—Most healthcare workers develop de novo PPE-associated headaches or exacerbation of their pre-existing headache disorders.

[***Note:*** This study confirms my earlier statement about many people reporting headaches related to wearing PPE. There was no investigation or comment as to the potential causes of these headaches, such as hypoxia and/or hypercapnia.]

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Now, we'll look at the issue of increased risks of viral infection of the central nervous system (CNS) due to rebreathing the viruses in a mask.

- Baig AM et al. Evidence of the COVID-19 virus targeting the CNS: Tissue distribution, host-virus interaction, and proposed neurotropic mechanisms. ACS Chem Neurosci 2020; 11:7:995-998. https://pubs.acs.org/doi/10.1021/acschemneuro.0c00122

  Abstract

  The recent outbreak of coronavirus infectious disease 2019 (COVID-19) has gripped the world with apprehension and has evoked a scare of epic proportion regarding its potential to spread and infect humans worldwide. As we are in the midst of an ongoing pandemic of COVID-19, scientists are struggling to understand how it resembles and differs from the severe acute respiratory syndrome coronavirus (SARS-CoV) at the genomic and transcriptomic level. In a short time following the outbreak, it has been shown that, similar to SARS-CoV, COVID-19 virus exploits the angiotensin-converting enzyme 2 (ACE2) receptor to gain entry inside the cells. This finding raises the curiosity of investigating the expression of ACE2 in neurological tissue and determining the possible contribution of neurological tissue damage to the morbidity and mortality caused by COIVD-19. Here, we investigate the density of the expression levels of ACE2 in the CNS, the host-virus interaction and relate it to the pathogenesis and complications seen in the recent cases resulting from the COVID-19 outbreak. Also, we debate the need for a model for staging COVID-19 based on neurological tissue involvement.

[***Note:*** This article looks at how COVID-19 is similar to SARS-CoV in gaining access to cells through a particular enzyme receptor (ACE2) on the cell wall. Central nervous system and nerve cells in general are rich in these receptors and the author suggests that CNS involvement by COVID-19 could be a critical factor in mortality, while also acknowledging that it is "*widespread dysregulation of homeostasis caused by pulmonary, renal, cardiac, and circulatory damage that proves fatal in COVID-19 patients.*" Based upon a previous study the author performed (cited in this article) showing that the amoeba *Naegleria fowleri* gains access to the CNS through the cribiform plate and olfactory nerves, he proposes that COVID-19 could also access the brain via the transcribrial route but provides no proof. He suggests that autopsies should take a look at this area for COVID-19 in order to study this possibility. As such, this study does not actually provide evidence that COVID-19 infects the brain through the nose, but presents that possibility.]

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- Wu Y, Xu X, Chen Z, et al. Nervous system involvement after infection with COVID-19 and other coronaviruses. *Brain Behav Immun*. 2020; 87:18-22. https://www.sciencedirect.com/science/article/pii/S0889159120303573?via%3Dihub

  Abstract:

  Viral infections have detrimental impacts on neurological functions, and even to cause severe neurological damage. Very recently, coronaviruses (CoV), especially severe acute respiratory syndrome CoV 2 (SARS-CoV-2), exhibit neurotropic properties and may also cause neurological diseases. It is reported that CoV can be found in the brain or cerebrospinal fluid. The pathobiology of these neuroinvasive viruses is still incompletely known, and it is therefore important to explore the impact of CoV infections on the nervous system. Here, we review the research into neurological complications in CoV infections and the possible mechanisms of damage to the nervous system.

[*Note:* In this study, they state "*that, in addition to systemic and respiratory symptoms, 36.4% (78/214) of patients with COVID-19 develop neurological symptoms, including headache, disturbed consciousness, and paresthesia.*" Also, in March 2020, Beijing Ditan Hospital reported the first case of COVID-19 viral encephalitis. COVID-19 has been documented in cerebrospinal fluid. Other studies report that a sudden loss of smell and/or taste can be a marker of COVID-19:

1. Hopkins, C., Kumar, N., 2020. Loss of sense of smell as marker of COVID-19 infection. https://www.entuk.org/sites/default/files/files/Loss%20of%20sense%20of%20smell%20as%20marker%20of%20COVID.pdf.
2. Ryan W.M., 2020. There's a new symptom of coronavirus, doctors say: Sudden loss of smell or taste. https://www.usatoday.com/story/news/health/2020/03/24/coronavirus-symptoms-loss-smell-taste/2897385001/.
3. Giacomelli, A., Pezzati, L., Conti, F., Bernacchia, D., Siano, M., Oreni, L., et al., 2020. Self-reported olfactory and taste disorders in SARS-CoV-2 patients: a cross-sectional study [published online ahead of print, 2020 Mar 26]. Clin Infect Dis ciaa330.

This paper suggests two potential routes for direct infection of the CNS: blood circulation through the blood-brain barrier (although there is rare evidence of this with coronaviruses) and a neuronal pathway, such as the olfactory nerves through the cribiform plate. The latter has been documented with the SARS virus, and a mouse study—K. Bohmwald, N.M.S. Galvez, M. Rios, A.M. Kalergis. Neurologic alterations due to respiratory virus infections. Front Cell Neurosci., 12 (2018), p. 386—shows that removal of the olfactory bulb restricts the invasion of SARS-CoV into the brain. The loss of smell also implicates involvement of the olfactory neurons.]

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- Perlman, S, et al. Spread of a neurotropic murine coronavirus into the CNS via the trigeminal and olfactory nerves. Virology 170: 2, June 1989; 556-560 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7130896/

  Abstract:

  The route of entry into the central nervous system (CNS) of most neurotropic viruses has not been established. The coronavirus, mouse hepatitis virus strain JHM (MHV-JHM), causes acute encephalomyelitis and acute and chronic demyelinating diseases and is an important model system for virus-induced neurological disease. Suckling C578L/6 mice infected intranasally with MHV-JHM develop either the acute encephalomyelitis or a late onset, symptomatic demyelinating encephalomyelitis, depending on whether they are nursed by unimmunized or immunized dams. Analysis by in situ hybridization was used to determine the route of entry of MHV-JHM into the CNS in these mice. At early times, viral RNA was detected only in the trigeminal and olfactory nerves and in their immediate connections in all mice. A few days later, MHV-JHM RNA was found throughout the brain in mice dying of the acute encephalomyelitis, but remained confined to the entry sites in mice which did not develop acute disease. These results suggest that MHV-JHM enters the CNS via an interneuronal route in all mice, but that the presence of maternal antibody prevents the dissemination of virus via extracellular fluid. In addition, MHV-JHM may establish low-level persistence in the trigeminal or olfactory nerve or in one of its connections in mice that do not develop acute encephalomyelitis.

[***Note:*** Again, a mouse study, but this work would never get approved on humans, except maybe government lawyers. Sorry, couldn't resist. This study actually showed viral RNA in the olfactory nerves and bulb prior to development of acute encephalitis. Pretty definitive, IMO. But, how would masks affect this? Some have suggested that the rebreathing of viral particles caught in a mask can lead to increasing levels of virus within the nasal cavity, which in turn could lead to a greater risk of the virus traveling along the olfactory nerves into the brain. While that sounds plausible (sounds right, right?), I could find no studies corroborating the claim. In fact, that would be a difficult study to do, requiring frequent nasal swabs over not just hours but days because we have no idea what time frame to test. Also, since there is no reliable *quantitative* test for viruses, how could we know whether or not the viral particles are increasing? Still, it is apparent that viruses can travel into the brain via the olfactory nerves and that is the likely route for the development of the encephalitis sometimes seen with COVID-19.]

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One other topic not covered by the media has to do with the cloth used to make the masks we typically see worn by those around us in retail establishments. Textiles often contain harmful dyes and chemicals, specifically formaldehyde. No research is available to show whether or not breathing through cloth masks, and the moisture retention that occurs, will release such chemicals into the air we're breathing through them. We do know, however, that formaldehyde is a gas that can irritate a person's eyes, nose, throat and lungs, or trigger an asthma attack, even at low concentrations. Prolonged exposure to formaldehyde can cause cancer. Here are two sources for information on formaldehyde: https://ww2.arb.ca.gov/resources/fact-sheets/formaldehyde and https://www.gao.gov/new.items/d10875.pdf.

Also not discussed is the dramatic rise in suicides, domestic abuse, depression, child abuse and other psychological issues we've seen related to this "crisis." Masks per se are only a part of those issues. There's something about not being to "read" others' faces that contributes to the sense of social isolation being foisted on society.

Conclusion

At this point, I've presented the 19 articles used by the CDC to support their stance on face masks, as well as more than twice that many articles that show no real benefit to the healthy wearing masks, plus the potential harm from the prolonged wearing of masks. I've read over a hundred studies, articles, and reviews on masks, of which I've presented those cited most often by other papers or are representative of many similar studies. My original stance on the use of masks—by those who are sick and those working in high-risk occupations such as healthcare—has not changed, even though the studies only *suggest* that masks can help in those two situations.

If we are to follow evidence-based medicine, then the widespread use of masks, and certainly the mandates for masks, should end. There is zero support for the use of masks by the healthy, outdoors, or for casual indoor exposures such as passing by someone in the store. Masks provide a false sense of security that may even cause people to ignore other common-sense preventive measures such as hand washing, which remains at the top of my list for prevention.

I understand that no mayor, health department director, governor, or business leader/owner wants to be that person who is seen as lax on public health issues. However, if they wish to use evidence-based medicine as their justification for a mandate, they need to use the *actual* evidence. Most are simply walking lock-step with the CDC and WHO, whose recommendations

are suspect and not following the evidence, even results in studies hosted on their own websites. They follow numbers of new cases (ie, new positive tests, not people who are actually sick) and ignore the falling death rate numbers (https://www.cdc.gov/nchs/nvss/vsrr/COVID19/index.htm). Imagine the hysteria that could be created by initiating such an aggressive testing program for influenza and then reporting the daily increases in positive tests. Well, actually, people know and understand the flu, and the hysteria would never materialize. But COVID-19 is new—novel they call it—and easy to make scary, even though its infection fatality rate (IFR) is no different from that of influenza.

Is there an agenda behind these mask mandates? Certainly, there are those who believe so (https://childrenshealthdefense.org/ and others). The Great Barrington Declaration (https://gbdeclaration.org) expressly refutes the stances of Dr. Fauci, the CDC, and WHO, and has been signed by over 3,000 medical and public health scientists and over 4,500 medical practitioners in its first two days. And if you follow the money, such concerns seem justified. As with any viral pandemic, a societal goal should be to reach "herd immunity" as quickly as possible in order to allow the pandemic to die out on its own. But if you have a $3,200-per-dose drug (Remdesivir) and a new vaccine, not yet available but from which billions of dollars are to be made, you don't want herd immunity reached quickly. By allegedly slowing the spread, masks, together with other interventions, will draw out the process of reaching herd immunity and ensure a second wave, while continuing the hype and fear mongering and making people eager to take your unproven, and likely unsafe, fast-tracked vaccine. Add in the fact that prolonged mask usage weakens the immune system through hypoxia and hypercapnia, and you're likely to see your drug and vaccine profits soar. Then, enforce your mandates on children, and the physical and psychological damage done to them guarantees new future customers. Indeed. Follow the money.

At the beginning of the pandemic, before we had a handle on COVID-19, the call to "flatten the curve" was a good one. More should have been done to protect the vulnerable. Sending active COVID-19 cases to nursing homes was the wrong move and borders on criminal, IMO. At that time, the CDC advised against the healthy wearing masks, until it became clear that we were racing toward herd immunity faster than they'd estimated. Then, their mantra changed, and mandates were created. Now, Dr. Fauci and his CDC counterparts warn of a second wave (pretty much guaranteed in people with compromised immune systems from wearing masks). Yet, if you look at the numbers, the curve was flattened months ago and the death rate continues to fall. Note, that I say the *rate*, not the absolute number. Using absolute numbers is far scarier than using the rate. Whether or not we've already reached herd immunity levels, as some believe, or will see a second wave is yet to be seen. Either way, masks have no proven

role in preventing spread, can have long-term detrimental effects, and should once again be limited in their use.

We live in an “ocean” of viruses and bacteria. They’re all around us and inside us. To think that any one of us will escape exposure to COVID-19 is naïve. Many of us likely have already “caught” it and will never have any symptoms. As Sweden has shown us with COVID-19, continuing on with life, while protecting the vulnerable, leads to the faster acquisition of herd immunity. Instead, our “leaders” and the media have promoted fear and caused more death (by lack of care of other health issues and mental health problems) than would have occurred if we had taken a more sensible route. They’ve sowed lasting damage to our economy and millions of people’s lives. We need to accept that COVID-19 is with us to stay and get back to life as we knew it.

[Updated 7 October 2020]