

# COVID-19: THE EVIDENCE FOR MASKS

A new epitaph has surfaced: “Mask Denier,” akin to “Climate-Change Denier.” As in the case of climate, a mask denier is someone who denies “settled science.”

This study reviews the science and data supporting the use of masks to reduce the transmission of COVID-19. It does not conclude whether masks should be worn, but only what the science says. What are the numbers? And the limits of the numbers?

For this study the term “masks” refers to all masks—face shields, N95 respirators, surgical masks, homemade or purchased cloth masks, bandanas, etc. When referring to a unique type of mask that type is specified.

## FACTORS THAT MATTER.

Masks perform one or both of two basic functions: (1) source control, and/or (2) personal protective equipment (PPE). Source control seeks to limit infection of others by the wearer; PPE seeks to protect the wearer from infection by others.

In the case of COVID-19, source control seeks to limit transmission by infected individuals—i.e., prevent virus from escaping into the

air others breath: PPE seeks to filter virus from the air non-infected people breath.

In both source control and PPE applications masks act as filters. Filter effectiveness is a function of filter efficiency—how well the filter media removes target particles from air, fit—how much contaminated air leaks around the filter, and duration—how long can the filter do its job.



worn loosely on the face. These are regulated by the FDA.

**Cloth masks** are any cover over the mouth and nose. These have no NIOSH-recognized consistent purpose, nor standard.

**EVOLVING ADVICE.** On February 29, Dr Jerome Adams (US Surgeon General) tweeted, “Seriously people- STOP BUYING MASKS! They are NOT effective in preventing [the] general public from catching #Coronavirus, but if healthcare providers can’t get them to care for sick patients, it puts them and our communities at risk!”

During a March 8 episode of *60 Minutes*, Dr Anthony Fauci told viewers, “There’s no reason to be walking around with a mask...” He later changed directions and said his comments were intended to avoid a shortage of masks for healthcare workers. More recently he claimed new evidence of transmission by pre-symptomatic and asymptomatic contact as a reason to wear masks, and conceded prior concerns about potential mask shortages were unfounded.

April 3, the CDC reversed its earlier guidance by recommending that

Understanding the Difference		
	 Surgical Mask	 N95 Respirator
<b>Testing and Approval</b>	Cleared by the U.S. Food and Drug Administration (FDA)	Evaluated, tested, and approved by NIOSH as per the requirements in 42 CFR Part 84
<b>Intended Use and Purpose</b>	Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer’s respiratory emissions.	Reduces wearer’s exposure to particles including small particle aerosols and large droplets (only non-oil aerosols).
<b>Face Seal Fit</b>	Loose-fitting	Tight-fitting
<b>Fit Testing Requirement</b>	No	Yes
<b>User Seal Check Requirement</b>	No	Yes. Required each time the respirator is donned (put on)
<b>Filtration</b>	Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection	Filters out at least 95% of airborne particles including large and small particles
<b>Leakage</b>	Leakage occurs around the edge of the mask when user inhales	When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales
<b>Use Limitations</b>	Disposable. Discard after each patient encounter.	Ideally should be discarded after each patient encounter and after aerosol-generating procedures. It should also be discarded when it becomes damaged or deformed; no longer forms an effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult; or if it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.

**N95 masks** are intended to reduce the wearer’s exposure to small particle aerosols and large droplets—i.e., as PPE. Close fit is critical to effectiveness. These are evaluated, tested and approved by [NIOSH](#), a division of the CDC.

**Surgical masks** are fluid resistant and intended to protect from large droplets, splashes, or sprays of bodily or other hazardous fluids—i.e., as PPE—and others from the wearer’s respiratory emissions. These are typically



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### TIMELINE OF ADVICE (2020)

- Jan 9:** WHO notes pneumonia-like cases Wuhan (Hubei province of China)
- Jan 21:** CDC confirms first US cases; Chinese begin to confirm human-to-human transmission
- Feb 3:** US declares Public Health Emergency
- Feb 29:** USSG tweets, “STOP BUYING MASKS!...”
- Mar 8:** Fauci says, “There’s no reason to be walking around with a mask...”
- April 1:** CIDRAP published mask & respirator review recommending against wide-spread public use
- Apr 3:** CDC reverses prior advice, now recommending face coverings for public
- Apr 8:** NAS Rapid Expert Consultation concludes there is little evidence that cloth masks block infection by asymptomatic or pre-symptomatic individuals
- May 20:** CDC publishes Policy Review, concluding masks are not effective in reducing virus spread
- Jun16:** Fauci recommends masks; earlier advice was to avoid shortages for healthcare workers
- Jul 16:** CIDRAP updates its Commentary and shares readers’ comments
- Jul 18:** Redfield claims masks could end pandemic in 4 to 8 weeks; JAMA publishes Mass General Study
- Jun 24:** Fauci says masks can block asymptomatic and pre-symptomatic transmission; concedes prior concerns about shortages were unfounded

people should wear face coverings in public. Their “emerging evidence” focused primarily on the transmission by pre-symptomatic and asymptomatic contact—as did Fauci’s evolved view, but also included several papers that consider homemade masks. One (Davies et al.) concluded homemade masks “should only be considered as a last resort to prevent droplet transmission from infected individuals, but it would be better than no protection.”

A July 18, 2020 [article](#) in the Wall Street Journal (updated August 10) announced, “Face Masks Really Do Matter. The Scientific Evidence is Growing.” The subtitle hedges: “New research suggests that face coverings help reduce the transmission of droplets, though some masks are more protective than others.”

A [commentary](#) authored by two industrial hygiene experts—Lisa Brosseau and Margaret Sietsema—a published April 1, 2020 by the University of Minnesota Center for Infectious Research and Policy (CIDRAP) began with an Editor’s Note. “The authors and CIDRAP have received requests in recent weeks to remove this article from the CIDRAP website. Reasons have included: (1) we don’t truly know that cloth masks (face coverings) *are not effective*, since the data are so limited, (2) wearing a cloth mask or face covering is better than doing nothing, (3) *the article is being used by individuals and groups to support non-mask wearing where mandated* [italics added] and (4) there are now many modeling studies suggesting that cloth masks or face coverings could be effective at flattening the curve and preventing many cases of infection.

**SCIENTIFIC EVIDENCE.** The July 18 Wall Street Journal [article](#) by Caitlin McCabe cited Robert Redfield, director of the CDC claiming the COVID-19 pandemic could be stopped “over the next four to eight weeks if ‘we could get everybody to wear a mask right now.’” It goes on to mention an [editorial](#) in the Journal of the American Medical Association

(JAMA) that concluded “universal masking of health care workers (HCWs) and patients can help reduce transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections.”

To support their assertion, Dr Redfield and his follow authors cite a [study](#), also in JAMA, relating the experience of Mass General Brigham (the largest health care system in Massachusetts). The system instituted a “universal mask policy” that required all patients, visitors and HCWs to wear surgical masks. Prior to the intervention the system saw an increase in the rate of positive CCOVID-19 tests of 1.16% per day, with case counts doubling every 3.6 days. The intervention—i.e., implementing the policy—positivity rate decreased 0.49% per day. It proposed that the mask policy was associated with the reduce positivity rates.

In the discussion section the authors explained, “The decrease in HCW infections could be confounded by other interventions inside and outside of the health care system, such as restrictions on elective procedures, social distancing measures, and increased masking in public spaces, which are limitations of this study.” Association is not necessarily causation.

In their summary of the study Redfield’s team opined, “Others may think it is premature to promote community masking until research has been completed that measures the effectiveness of cloth face coverings to prevent exposure specifically to SARS-CoV-2.



Laboratory studies will be difficult and costly because they require capacity to safely manage this biosafety level 3 pathogen. Any type of community-based randomized trial will be complex to deploy in the right setting (a community with active infection) at the right time (when infections are increasing) to produce actionable results quickly. In the absence of such data, it has been persuasively argued *the precautionary principle be applied to promote community masking because there is little to lose and potentially much to be gained* [italics added].”

Ironically, the “precautionary principle” argues the exact opposite: lacking data—i.e., negative effects and effectiveness of community masking—the action should be paused to avoid problems.

Other studies by a team at Duke University and Florida Atlantic University have appeared recently demonstrating that masks of all sorts restrict the spread of droplets (source control). All concluded that materials and fit are important factors. None considered spread of respiratory droplets in general and viruses in particular.

A [Policy Review](#) published by the CDC in May 2020 used meta-analysis techniques to evaluate the effectiveness of masks and environmental hygiene on transmission of influenza virus, spread by respiratory droplets. It concluded:

- In 10 randomized clinical trials (1946 through 2018) involving laboratory-conformed

influenza virus infections, face mask yielded no statistically significant reduction in transmission;

- In 7 household studies none reported significant reduction in secondary infections (i.e., transmission)
- Disposable medical masks (i.e., surgical masks) yielded no statistically significant decrease in effect on transmission.

N95 and P2 masks were not included in the meta-analysis.

In the case of cloth masks likely to be used in low-income areas, the authors concluded, “Proper use of face masks is essential because improper use might increase the risk for transmission.”

Industrial Hygiene. Interesting and compelling research on masks comes from the industrial hygiene community, which has been studying and testing masks for generations.

The Brosseau and Sietsema [commentary](#) (mentioned above) brings their expertise, experience and perspective to the question of masks.

They DO NOT recommend requiring the non-symptomatic general public to wear masks:

- There is no scientific evidence they are effective in reducing the risk of COVID-19 transmission;
- Mask use provides a sense of protection, and may interfere with distancing initiatives; and

- Surgical (and other high efficiency masks) should be reserved for at-risk health-care workers.

They point-out that cloth masks were widely deployed in Hubei province (China)—the source of COVID-19—before and during its mass transmission event—i.e., masks did not arrest the now pandemic. Brosseau and Sietsema concluded cloth masks were ineffective in both source control and PPE applications.

Surgical masks may have some utility as source controls—limiting the spread of larger particles present in coughs and sneezes—but are probably less effective as PPE.

Properly fitted and maintained respirators (e.g., N95 units) offer the greatest protection in both source control and PPE applications, but the effect of inadequate fit, prolonged use (beyond the rated time) is difficult to quantify.

In their July 16 revision Brosseau and Sietsema respond to comments and critiques of their prior commentary. They share that initial CDC mask guidelines did not cite supporting studies. While revised guidelines do include citations, the additions “employ very crude, non-standardized methods... or are not relevant to cloth face coverings because they evaluate respirators or surgical masks.” They also point-out, “The CDC failed to reference the National Academies of Sciences Rapid Expert Consultation on the Effectiveness of Fabric Masks for the COVID-19 Pandemic (NAS 2020), which



concludes, ‘The evidence from...laboratory filtration studies suggests that such fabric masks may reduce the transmission of larger respiratory droplets. There is little evidence regarding the transmission of small aerosolized particulates of the size potentially exhaled by asymptomatic or pre-symptomatic individuals with COVID-19.’”

In their revision, Brosseau and Sietsema concluded, “...though we support mask wearing by the general public, we continue to conclude that cloth masks and face coverings are likely to have limited impact on lowering COVID-19 transmission, because they have minimal ability to prevent the emission of small particles, offer limited personal protection with respect to small particle inhalation, and should not be recommended as a replacement for physical distancing or reducing time in enclosed spaces with many potentially infectious people.”

In April 2015 a public health team from the University of New South Wales publish [results](#) from their randomized clinical trial (RCT) in BMJ. It was the first RCT of the use of cloth masks.

Intervention wards were supplied with medical masks or cloth masks. Control wards used routine masking procedures and types.

The team found statistically significant increases in influenza-like illnesses (ILIs), and respiratory infections among cloth masks wearers compared to medical mask wearers and controls.

Measurements demonstrated that cloth masks prevented penetration of between 3% and 56% of particles, depending on mask construction and particle size. They advised caution in the use of cloth masks, and identified moisture retention, reuse and poor filtration as the likely sources of poor performance.

**THE WHO.** The World Health Organization recently recommended that patients delay non-emergency dental care until the current pandemic abates.

"WHO guidance recommends in case of community transmission to give priority to urgent or emergency oral cases, to avoid or minimize procedures that may generate aerosol, prioritize a set of clinical interventions that are performed using an instrument and of course to delay routine non-essential oral health care..."

Benoit Varenne, a WHO dental officer, added, "The likelihood of COVID-19 being transmitted through aerosol, micro-particles or airborne particles ... today I think is unknown, it's open to question at least. This means that more research is needed."

**OPEN QUESTIONS.** Current CDC mask guidelines do not address several important questions as people consider the advice and develop their plans.

- **Construction:** What materials are effective for cloth masks? Which are ineffective? Are all medical/surgical masks the same? How can I know which to make or buy?

- **Fit:** How can I know if my mask (or my child's mask) fits properly?
- **Duration:** How long can I wear my mask before it should be replaced? How frequently should I replace it? How can I know when it is inefficient or contaminated? (Note: surgical masks are intended for single use)
- **Reconditioning:** Can I wash my mask? How?
- **Disposal:** What is the proper way to discard a used or contaminated mask? (Note: the federal government considers used medical masks hazardous waste)

**OUR ANALYSIS.** As we take a step back for our review of the data and opinions, we are struck by the paucity of data and wealth of opinions.

The most clear-headed review of data seems to be Brosseau's and Sietsema's. It is well worth reading. We were also impressed by the CDC's May Policy Review (above). Both these papers were long on relevant data and common-sense interpretations.

We remain perplexed by Dr Redfield's position that universal masks are justified by the potential for virus spread by non-symptomatic and asymptomatic people, when these are precisely the people for whom data suggest cloth masks will be likely least effective.

In healthcare settings, clinicians remove disposable masks when finished with an examination or procedure, wash their hands carefully and don a new mask



before moving on to the next potential exposure. Individual masks are not worn day after day; masks are seldom worn for hours on end without a break, except during extended surgeries. And when they are removed, proper disposal, hand washing and a new mask follow. We are skeptical that the general public exercise these precautions in daily mask use.

The Who's position that "The likelihood of COVID-19 being transmitted through aerosol, micro-particles or airborne particles ... today I think is unknown, it's open to question at least..." flies in the face of nearly all current public health guidance.

As we have highlighted before, neither the CDC nor state public health departments are reporting interim measures of suicide, depression, substance abuse, etc. Likewise, no data are available about whether community masking contributes to isolation-related (unfavorable) outcomes.

**OUR CONCLUSIONS.** There is little, if any clinical evidence that universal use of *cloth masks of any type* will arrest the spread of COVID-19 by symptomatic patients. There is strong evidence that universal use of N95—properly fitted and handled—might arrest such spread. Surgical masks fall between these extremes, but proper fit and handling are critical. Little effort has been put into instructing the public about the importance of fit, handling and disposal of masks.

There is less evidence that cloth or surgical masks reduce transmission by asymptomatic and pre-symptomatic sources.

The RCT trial in Hanoi (above) demonstrated that respiratory infections and ILIs are a real, potential unfavorable outcome from regular, prolonged use of cloth masks. No contrary evidence was found.

Many of the papers we reviewed mention the importance of consistent messaging about masks. We think those messages should rely on data; and it should be clear when they do not. To do otherwise risks the credibility of leaders and public health scientists. We also think asking that legitimate analysis—e.g., Brosseau's and Sietsema's—be withdrawn because it interferes with messaging is wrong and violates the public's trust.

*Note: This work was completed without commercial sponsorship of any kind from any source. We established a GoFundMe site (<https://gofundme.com/f/just-the-numbers>) to help underwrite our effort to develop independent, politics-free analyses.*

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