HEALTH & MEDICINE

How Effective Are Cloth Face Masks?

More than a century after the 1918 influenza pandemic, claims of the masks' effectiveness continue to lack a firm foundation.

BY IAN T.T. LIU, VINAY PRASAD, AND JONATHAN J. DARROW

Since the emergence of the COVID-19 pandemic, many public health officials, political and social leaders, and major news media have urged people to wear face masks to reduce the transmission of the SARS-CoV-2 virus. In the United States, masking has become a flashpoint of controversy, with school boards and local governments facing fervent—and sometimes even threatening—demands either for or against mask mandates.

By September 2020, the U.S. government had distributed 600 million facemasks for use by the public as part of its response to the pandemic. At the local level, 32 states and numerous municipalities implemented mask mandates at some point, and some political and social figures called for a nationwide mask mandate. At the height of the pandemic, New York City instituted a $1,000 fine for those who refused to wear face masks in public, and then-presidential candidate Joe Biden proclaimed in a speech, "Wearing masks is not a political statement, it is a scientific imperative." Over 40% of the global population lives in countries that at one time or another mandated mask-wearing in public areas to fight the pandemic.

Yet, there is little consensus that masking—at least as commonly practiced in the United States, using cloth masks—is effective at suppressing various types of respiratory infection. In the surgical operating room context, a review by the Cochrane Collaboration—a widely respected nonprofit that provides comprehensive,

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evidence-based summaries on various medical topics—found "no statistically significant difference in infection rates between the masked and unmasked group in any of the trials." Another Cochrane review, of masking and influenza-like illness, found "that wearing a mask may make little or no difference to the outcome of influenza-like illness … compared to not wearing a mask."

Given that background, the World Health Organization was initially skeptical of encouraging the general public to wear cloth masks in an effort to slow the pandemic. The WHO's initial COVID-19 guidelines stated that "cloth (e.g., cotton or gauze) masks are not recommended under any circumstance," and a subsequent update noted "the widespread use of masks by healthy people in the community setting is not yet supported by high quality or direct scientific evidence."

So, are masking requirements just "public health theater," providing baseless assurance to a fearful public? Or has new evidence emerged to confirm the belief that masks—or, at least, the cloth masks that are commonly used—reduce respiratory virus transmission? Below is a summary of the scientific literature on the effectiveness of masking, both against respiratory infection generally and against COVID-19.

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MASKS INTERRUPT DROPLET TRANSMISSION, BUT DOES THAT SLOW COVID?

Among the hallmark memes of the COVID-19 pandemic have been videos using special lighting and high-speed photography to visualize the dramatic differences in droplets emitted when a person sneezes with and without a mask. As if subtitling the visuals, an article in the *New York Times* explained that mask fibers "create a haphazard obstacle course through which air—and any infectious cargo—must navigate."

Such vivid imagery promotes a misconception that the emission of infectious particles primarily occurs during forceful expiration such as sneezing. In fact, respiratory particles are emitted even when breathing. Little evidence suggests that frequent public sneezing during the pandemic has been a key driver of the virus's spread.

It is debated whether larger "droplets" (greater than about 10 micrometers) or smaller "aerosols" containing the virus are more infectious. But aerosol transmission has been demonstrated or is considered likely for other respiratory infections such as H1N1 influenza, Middle East Respiratory Syndrome (MERS), respiratory syncytial virus (a common virus among infants), and the 2003 SARS virus. When smaller particles evaporate, they can stay suspended in the air for long periods of time and be inhaled, potentially causing infection deeper in the respiratory tract and at lower concentrations. SARS-CoV-2 viral particles have been detected in low-touch areas such as under beds and in air samples taken from hallways outside patient rooms, consistent with sustained aerosol distribution.

The greater the role of aerosols in spreading SARS-CoV-2, the less important is the filtering capability of masks, because exhaled air easily flows around a mask's edges. The extent to which droplets penetrate a mask has not been established as a reliable surrogate for the prevention of disease transmission.

RANDOMIZED CONTROLLED MASK TRIALS AND COVID-19

The best evidence to establish the effectiveness of cloth face masks would be from cluster-randomized controlled trials (RCTs) showing that communities tasked with wearing cloth masks have lower viral spread than those assigned to not wear cloth masks, with high participation and protocol adherence. The endpoint of such studies should be laboratory-confirmed SARS-CoV-2 infection and not just symptoms of illness, because mask wearing could affect a user's perception of symptoms, creating bias.

The only two sizeable studies evaluating masks in the context of COVID-19 failed to demonstrate statistically significant reductions in confirmed viral transmission either for surgical masks (one study) or for cloth masks (the other).

The first study, conducted from April to June 2020 in Denmark, found that 42 (1.8%) of 2,392 subjects provided with more than four dozen three-layer surgical masks reported SARS-CoV-2 infection, versus 53 (2.1%) of 2,470 in the control group. That is a difference of only 0.3%, which is not statistically significant (p = 0.38). Although adherence to masking instructions was imperfect, an analysis of only those self-reporting that they did adhere to the protocol also failed to find a benefit. The Danish study evaluated only the ability of masks to protect the wearer and did not test their ability to prevent infection to others ("source control").

A much larger study in Bangladesh examined the ability of masks to reduce community-wide infection rates, including as source control. Six hundred cluster-randomized villages were studied between November 2020 and January 2021. Including the data of only the 40% of those reporting symptoms who consented to blood collection, the laboratory-confirmed SARS-CoV-2 rate was 0.76% in control villages (n = 146,783) versus 0.74% in villages cross-randomized to wear cloth masks (n = 54,122), a difference of just 0.02% that was not statistically significant (p = 0.540). On the other hand, in surgical mask villages, there was a statistically significant difference (p = 0.043), but it was small, just 0.09%. Extrapolating the study's data, 406 people had to wear masks for eight weeks to prevent one lab-confirmed case of SARS-CoV-2. Also of interest, five-month follow-up surveillance revealed that proper mask use dramatically declined within intervention villages from approximately 28% to 14%, raising questions about long-term feasibility.

It should be noted that this study is sensitive to the unique conditions of Bangladesh, which essentially had no pre-existing natural immunity nor vaccination during the study period, and children and schools were not included as study subjects. A third RCT, in Guinea–Bissau, is ongoing.

OBSERVATIONAL EVIDENCE AND COVID-19

The remainder of the real-world evidence regarding masks and COVID-19 is primarily limited to observational data, which are not randomized, controlled, or blinded. A number of studies, for example, have compared locations with and without mask mandates at the county, state, and country levels, generally concluding that masks are highly effective. One of the most highly cited such studies estimated that mask mandates prevented up to 450,000 cases by May 22, 2020, a figure that was widely reported in news media.

Because of their strong potential for confounding, however, observational data provide only weak evidence of effectiveness. For example, in locations where legislators have sufficient political support to enact mask mandates, populations may have different attitudes about COVID-19 that could affect behavior other than mask-wearing. Among those are hand hygiene, physical distancing, eating separately from ill family members, voluntary business restrictions such as waiting-line spacing or "senior" hours, use of curbside pickup or disinfectants, installation of transparent barriers, adjustments to ventilation settings, school closures (or parental decisions to keep children home), gathering-size limitations, curfews, reduced participation in large political rallies and other "outlier" activities, opening of home windows to improve ventilation, selective mobility reductions by those with symptoms, reductions in verbal communications when in public, differing efforts in contact tracing, greater use of diagnostic tests, and so on.

Despite the efforts of some researchers to control for potential confounders, it is unlikely that all relevant confounders could be adequately accounted for or even known. Most observational studies also examined mask mandates (or self-reported usage) rather than actual mask wearing.

RANDOMIZED CONTROLLED MASK TRIALS AND OTHER DISEASES

At least 14 RCTs have assessed the relationship between mask-wearing and non-SARS-CoV-2 respiratory infections, 13 of which failed to find a statistically significant benefit in the main treatment group. For example, a 2012 cluster-randomized study at the University of Michigan found 46 (11.7%) of 392 students in the mask group tested positive for influenza-like illness compared to 51 (13.8%) of 370 in the unmasked control group, a difference that was not statistically significant.

The one study finding a significant benefit to mask wearing was a small pilot study of 164 pilgrims during the 2002 Hajj season, in which 28 (53%) of 53 no-mask contacts sleeping immediately adjacent to patients with known influenza-like illness became symptomatic, compared to only 11 (31%) of 36 masked contacts (P = 0.04). However, a follow-up randomized controlled study by the same researchers that was more than 45 times larger (n = 7,687) not only failed to show a statistically significant benefit to masks, but a per-protocol sub-analysis (i.e., considering only the 828 participants from the mask arm who self-reported using a mask and the 1,497 from the control arm who self-reported not using a mask) found *higher* point estimates of clinical respiratory infection among mask wearers (12% [97 ÷ 828]) than unmasked participants (9% [141 ÷ 1,497]), although the difference was not statistically significant at the 95% confidence level (p = 0.06).

Several RCTs found promising point estimates supporting masks and some sub-analyses were statistically significant. For example, an Australian study of 145 families compared surgical masks, N95-equivalent masks, and no masks in suppressing influenza-like illness. In a sub-analysis of those self-reporting adherence, a significant benefit was found when surgical and N95 masks were grouped together. However, adherent mask wearers reported higher rates of handwashing than non-adherent mask users (45% vs. 34%)—a reminder that adherence could be confounded by other behaviors—and the main analysis of all randomized participants found no benefit.

META-ANALYSES

Trying to make sense of the many studies assessing mask efficacy is a daunting task. Variations in the disease under study, diagnosis methods, mask types, subgroup analyses, adjustments for baseline characteristics, adherence rates, potential biases, unknown confounders, and other factors produced a confusing array of numbers and significance levels, often allowing multiple bites at the statistical significance apple. For more on this, see our working paper, available at www.cato.org.

Fortunately, a number of scholars have integrated the findings of primary research studies into at least 31 systematic reviews and meta-analyses. These generally confirm an absence of clear benefit and conclude that, if present, benefits are small to modest. For example, in a 2020 publication, Nishant Aggarwal et al. assessed 17 mask studies, concluding there was "no significant association between mask use and decrease in events of [influenza-like illness]." Another meta-analysis by Jingyi Xiao et al., supported by the WHO and available on the website of the U.S. Centers for Disease Control and Prevention, concluded that "evidence from RCTs of … face masks did not support a substantial effect on transmission of laboratory-confirmed influenza." Under direction from the White House Office of Science and Technology Policy, the National Academies of Sciences, Engineering, and Medicine considered the benefits of homemade fabric masks in the COVID-19 context, concluding that the "level of benefit, if any, is not possible to assess."

Some reviews nevertheless recommend masks based on a version of the precautionary principle, i.e., that masks might help and are unlikely to harm. (See "The Paralyzing Principle," Winter 2002–2003.) Among these is a publication from the European Centers for Disease Control, which acknowledges that only "very low" certainty of evidence is available to show that non-medical face masks have a "small to moderate" benefit for the prevention of COVID-19.

DO FACE MASKS HAVE DOWNSIDES?

High-quality evidence may eventually better demonstrate mask effectiveness. However, it is important to consider that community use of cloth masks may accelerate rather than slow disease transmission. The WHO has noted the possibility that mask wearing could provide a false sense of security that induces individuals to forgo standard sanitary measures, although this concern is contested and the evidence is mixed.

In one study, mask wearing was associated with reductions of physical distancing when the experimenter asked 2,722 randomly selected pedestrians in Paris for directions, particularly if the investigator was wearing high-status clothes. A study of pedestrians in Venice, however, found passersby increased distance from a masked versus unmasked person standing on the side of a pathway, particularly if the mask was homemade and accompanied by goggles.

A review of U.S. location data aggregated from multiple phone apps found that mask mandates were associated with 20–30 minutes of increased daily time outside the home and increased restaurant visitation. On the other hand, in Germany a review of Google location data showed reductions in visits to grocery stores and decreases in time spent outside the home following mask mandates.

Regardless of their more nuanced effects, masks could accelerate disease spread in a much more striking manner: Inflated beliefs in mask efficacy provide government leaders with political cover to "reopen the economy safely," dramatically increasing the volume of people visiting restaurants, bars, health facilities, schools, and other locations that might otherwise remain closed or implement alternate safety precautions such as increased ventilation.

Other concerns are more subtle and their effects are unknown. In the community setting, masks are repeatedly reused and infrequently washed, leading to the possibility that they are inadvertently serving as homemade disease cultures; in contrast, mask studies usually provide participants with multiple clean masks per day. Auditory difficulties engendered by masks combined with their obfuscation of lip movements could cause wearers to talk more loudly (which yields more droplets), lean to the side of plastic barriers, or approach more closely to hear or be heard, undermining any benefits masks provide.

The possibility that masks cause harm is not merely theoretical. Several studies have found higher point estimates of infection among mask wearers, a few of which were statistically significant. In the large follow-up study of Hajj pilgrims described above, a subset of unvaccinated pilgrims in the facemask group had a higher rate of clinical respiratory infection than unvaccinated pilgrims in the control group," a difference that was small but statistically significant (13% versus 10%, $p = 0.03$). In a cluster-randomized trial of healthcare workers, rates of influenza-like illness in the cloth mask arm were more than three times higher than in the "standard practice" control arm (2.3% [13 ÷ 569] vs. 0.7% [3 ÷ 458]), even though mask wearing rates were more than twice as high in the mask arm as the control arm. (The Institutional Review Board deemed it unethical to ask control arm participants not to wear a mask, and 23.6% did wear one most of the time versus 56.8% in the mask arm.) In a study led by researchers at Columbia University of 2,788 people in 509 households, those in the no-mask group included significantly more members without any reported upper respiratory symptoms compared to the mask group (57.6% [545 ÷ 946] vs. 38.7% [363 ÷ 938], $p < 0.01$).

To be clear, these studies do not establish that masks cause harm. Statistically significant results occasionally occur by chance, a risk that increases with the number of trials or analyses within each trial. Cluster-randomized trials are often plagued by poor adherence and self-reported adherence may be inaccurate. Unmeasured confounders rather than the presence of masks could explain negative outcomes. Even when results are valid and reproducible, idiosyncrasies of a given study could mean that those results cannot be generalized beyond their particular circumstances. For example, the Columbia University study was conducted in the unusually dense upper Manhattan area, where mean household size was 4.5 people per one-bedroom apartment, possibly leading to modes of transmission not common to other environments.

Such caveats, however, apply with equal force to findings of mask benefit. Yet, suggestive point estimates of benefit have frequently been rationalized as supporting mask efficacy by downplaying study limitations and explaining away any lack of significance on the grounds that those trials lacked sufficient statistical power. These rationalizations, if adopted, should not be selectively invoked depending on study outcome.

MAKING SENSE OF THE AVAILABLE EVIDENCE

Taken as a whole, the available mechanistic and clinical evidence leaves substantial uncertainty as to whether, to what extent, and under what circumstances community-wide use of cloth face masks helps to reduce infection rates of SARS-CoV-2. The voluminous mechanistic evidence clearly demonstrates that masks reduce some measures of droplet transmission, such as the distance that larger droplets travel, and it is known that such droplets can contain SARS-CoV-2. However, such surrogates of efficacy have not been demonstrated to correlate with infection outcomes and therefore fail to show that masks reduce the true measure of interest.

Scholars who have meta-analyzed the primary data have mostly concluded that evidence of mask benefit is weak and that benefit is modest at best. Uncontrolled observational studies suggesting larger benefits are hopelessly confounded. The best available evidence—the RCT—has largely failed to demonstrate mask effectiveness, particularly of cloth masks, despite trial sizes with thousands or even hundreds of thousands of participants.

THE PATH FORWARD

Notwithstanding the lack of evidence, amid a pandemic, government officials may not be able to wait until high-quality evidence is generated. If they determine, based on limited evidence, that community masking policies are appropriate, it is an ethical imperative to truthfully communicate what the evidence actually shows and to update disclosures as higher-quality evidence is gathered. In their zeal to do good, scientists and public health officials must take care not to apply a double standard to available studies, emphasizing projections of lives saved when evidence suggests benefit, while focusing on study limitations when the evidence suggests harm or fails to show any effect at all.

The well-known distinction between absence of evidence and evidence of absence applies to the COVID-19 context. If face masks save lives—or even if it is reasonably likely that they do—such measures are appropriate and compassionate. This rationale applies to all unproven interventions and has served as a basis for the Food and Drug Administration's expanded access program and the various state and federal Right-to-Try laws, which facilitate access to experimental drugs that are not yet FDA-approved.

Yet, as with medicines, the use of unproven non-drug technologies is not without potential harm. Overconfident portrayal of evidence could stifle research agendas, making it difficult to reevaluate previously held positions. Faith in the technology could cause its substitution for interventions supported by better evidence, such as vaccination. If later evidence proves the intervention useless or harmful, the experience can undermine public trust. Although masks are individually inexpensive, the costs of indefinitely producing and distributing masks to a global community of 7.8 billion people are not trivial, nor are the environmental harms that result when they are eventually discarded. Finally, masking has taken on political dimensions, fueled strong passions, and is clearly an animating issue for many. Masks have proven socially divisive, sparking disputes and, in a few tragic cases, violent and even lethal acts. The full implications for mask mandates throughout the pandemic are unknown but may extend far beyond viral effects.

More than a century after the 1918 influenza pandemic, examination of the efficacy of cloth masks has produced a large volume of mostly low-quality evidence that has generally failed to demonstrate their value in most settings. When repeated attempts are undertaken to demonstrate an expected or desired outcome, there is a risk of declaring the effort resolved once results consistent with preconceived notions are generated, regardless of the number or extent of previous failures. Scientists and public health officials should exercise caution to ensure that this potential bias does not lead to a cessation of research as the first studies demonstrating mask efficacy are reported. R

READINGS

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