EXHIBIT Q

COMMENTARY: Masks-for-all for COVID-19 not based on sound data

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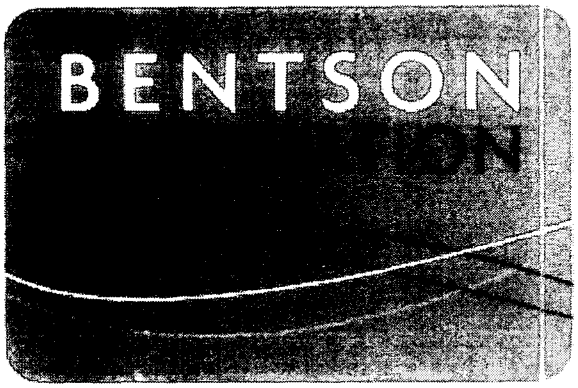

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In response to the stream of misinformation and misunderstanding about the nature and role of masks and respirators as source control or personal protective equipment (PPE), we critically review the topic to inform ongoing COVID-19 decision-making that relies on science-based data and professional expertise.

As noted in a previous commentary, the limited data we have for COVID-19 strongly support the possibility that SARS-CoV-2—the virus that causes COVID-19—is transmitted by inhalation of both droplets and aerosols near the source. It is also likely that people who are pre-symptomatic or asymptomatic throughout the duration of their infection are spreading the disease in this way.

Data lacking to recommend broad mask use

We do not recommend requiring the general public who do not have symptoms of COVID-19-like illness to routinely wear cloth or surgical masks because:

- There is no scientific evidence they are effective in reducing the risk of SARS-CoV-2 transmission

- Their use may result in those wearing the masks to relax other distancing efforts because they have a sense of protection
- We need to preserve the supply of surgical masks for at-risk healthcare workers.

Sweeping mask recommendations—as many have proposed—will not reduce SARS-CoV-2 transmission, as evidenced by the widespread practice of wearing such masks in Hubei province, China, before and during its mass COVID-19 transmission experience earlier this year. Our review of relevant studies indicates that cloth masks will be ineffective at preventing SARS-CoV-2 transmission, whether worn as source control or as PPE.

Surgical masks likely have some utility as source control (meaning the wearer limits virus dispersal to another person) from a symptomatic patient in a healthcare setting to stop the spread of large cough particles and limit the lateral dispersion of cough particles. They may also have very limited utility as source control or PPE in households.

Respirators, though, are the only option that can ensure protection for frontline workers dealing with COVID-19 cases, once all of the strategies for optimizing respirator supply have been implemented.

We do not know whether respirators are an effective intervention as source control for the public. A non-fit-tested respirator may not offer any better protection than a surgical mask. Respirators work as PPE only when they are the right size and have been fit-tested to demonstrate they achieve an adequate protection factor. In a time when respirator supplies are limited, we should be saving them for frontline workers to prevent infection and remain in their jobs.

These recommendations are based on a review of available literature and informed by professional expertise and consultation. We outline our review criteria, summarize the literature that best addresses these criteria, and describe some activities the public can do to help "flatten the curve" and to protect frontline workers and the general public.

We realize that the public yearns to help protect medical professionals by contributing homemade masks, but there are better ways to help.

Filter efficiency and fit are key for masks, respirators

The best evidence of mask and respirator performance starts with testing filter efficiency and then evaluating fit (facepiece leakage). Filter efficiency must be measured first. If the filter is inefficient, then fit will be a measure of filter efficiency only and not what is being leaked around the facepiece.

Filter efficiency

Masks and respirators work by collecting particles through several physical mechanisms, including diffusion (small particles) and interception and impaction (large particles).[1] N95 filtering facepiece respirators (FFRs) are constructed from electret filter material, with electrostatic attraction for additional collection of all particle sizes.[2]

Every filter has a particle size range that it collects inefficiently. *Above and below this range, particles will be collected with greater efficiency*. For fibrous non-electret filters, this size is about 0.3 micrometers (μm); for electret filters, it ranges from 0.06 to 0.1 μm. When testing, we care most about the point of inefficiency. As flow increases, particles in this range will be collected less efficiently.

The best filter tests use worst-case conditions: high flow rates (80 to 90 liters per minute [L/min]) with particle sizes in the least efficiency range. This guarantees that filter efficiency will be high at typical, lower flow rates for all particle sizes. Respirator filter certification tests use 84 L/min, well above the typical 10 to 30 L/min breathing rates. The N95 designation means the filter exhibits at least 95% efficiency in the least efficient particle size range.

Studies should also use well-characterized inert particles (not biological, anthropogenic, or naturogenic ones) and instruments that quantify concentrations in narrow size categories, and they should include an N95 FFR or similar respirator as a positive control.

Fit

Fit should be a measure of how well the mask or respirator prevents leakage around the facepiece, as noted earlier. Panels of representative human subjects reveal more about fit than tests on a few individuals or mannequins.

Quantitative fit tests that measure concentrations inside and outside of the facepiece are more discriminating than qualitative ones that rely on taste or odor.

Mask, N95 respirator filtering performance

Following a recommendation that cloth masks be explored for use in healthcare settings during the next influenza pandemic,[3] The National Institute for Occupational Safety and Health (NIOSH) conducted a study of the filter performance on clothing materials and articles, including commercial cloth masks marketed for air pollution and allergens, sweatshirts, t-shirts, and scarfs.[4]

Filter efficiency was measured across a wide range of small particle sizes (0.02 to 1 μm) at 33 and 99 L/min. N95 respirators had efficiencies greater than 95% (as expected). For the entire range of particles tested, t-shirts had 10% efficiency, scarves 10% to 20%, cloth masks 10% to 30%, sweatshirts 20% to 40%, and towels 40%. All of the cloth masks and materials had near zero efficiency at 0.3 μm, a particle size that easily penetrates into the lungs.[4]

Another study evaluated 44 masks, respirators, and other materials with similar methods and small aerosols (0.08 and 0.22 μm).[5] N95 FFR filter efficiency was greater than 95%. Medical masks exhibited 55% efficiency, general masks 38% and handkerchiefs 2% (one layer) to 13% (four layers).

These studies demonstrate that cloth or homemade masks will have very low filter efficiency (2% to 38%). Medical masks are made from a wide range of materials, and studies have found a wide range of filter efficiency (2% to 98%), with most exhibiting 30% to 50% efficiency.[6-12]

We reviewed other filter efficiency studies of makeshift cloth masks made with various materials. Limitations included challenge aerosols that were poorly characterized[13] or too large[14-16] or flow rates that were too low.[17]

Mask and respirator fit

Regulators have not developed guidelines for cloth or surgical mask fit. N95 FFRs must achieve a fit factor (outside divided by inside concentration) of at least 100, which means that the facepiece must lower the outside concentration by 99%, according to the OSHA respiratory protection standard. When fit is measured on a mask with inefficient filters, it is really a measure of the collection of particles by the filter plus how well the mask prevents particles from leaking around the facepiece.

Several studies have measured the fit of masks made of cloth and other homemade materials.[13,18,19] We have not used their results to evaluate mask performance, because none measured filter efficiency or included respirators as positive controls.

One study of surgical masks showing relatively high efficiencies of 70% to 95% using NIOSH test methods measured total mask efficiencies (filter plus facepiece) of 67% to 90%.[7] These results illustrate that surgical masks, even with relatively efficient filters, do not fit well against the face.

In sum, cloth masks exhibit very low filter efficiency. Thus, even masks that fit well against the face will not prevent inhalation of small particles by the wearer or emission of small particles from the wearer.

One study of surgical mask fit described above suggests that poor fit can be somewhat offset by good filter collection, but will not approach the level of protection offered by a respirator. The problem is, however, that many surgical masks have very poor filter performance. Surgical masks are not evaluated using worst-case filter tests, so there is no way to know which ones offer better filter efficiency.

Studies of performance in real-world settings

Before recommending them, it's important to understand how masks and respirators perform in households, healthcare, and other settings.

Cloth masks as source control

A historical overview of cloth masks notes their use in US healthcare settings starting in the late 1800s, first as source control on patients and nurses and later as PPE by nurses.[20]

Kellogg,[21] seeking a reason for the failure of cloth masks required for the public in stopping the 1918 influenza pandemic, found that the number of cloth layers needed to achieve acceptable efficiency made them difficult to breathe through and caused leakage around the mask. We found no well-designed studies of cloth masks as source control in household or healthcare settings.

In sum, given the paucity of information about their performance as source control in real-world settings, along with the extremely low efficiency of cloth masks as filters and their poor fit, there is no evidence to support their use by the public or healthcare workers to control the emission of particles from the wearer.

Surgical masks as source control

Household studies find very limited effectiveness of surgical masks at reducing respiratory illness in other household members.[22-25]

Clinical trials in the surgery theater have found no difference in wound infection rates with and without surgical masks.[26-29] Despite these findings, it has been difficult for surgeons to give up a long-standing practice.[30]

There is evidence from laboratory studies with coughing infectious subjects that surgical masks are effective at preventing emission of large particles[31-34] and minimizing lateral dispersion of cough particles, but with simultaneous displacement of aerosol emission upward and downward from the mask.[35]

There is some evidence that surgical masks can be effective at reducing overall particle emission from patients who have multidrug-resistant tuberculosis,[36] cystic fibrosis,[34] and influenza.[33] The latter found surgical masks decreased emission of large particles (larger than 5 μm) by 25-fold and small particles by threefold from flu-infected patients.[33] Sung[37] found a 43% reduction in respiratory viral infections in stem-cell patients when everyone, including patients, visitors, and healthcare workers, wore surgical masks.

In sum, wearing surgical masks in households appears to have very little impact on transmission of respiratory disease. One possible reason may be that masks are not likely worn continuously in households. These data suggest that surgical masks worn by the public will have no or very low impact on disease transmission during a pandemic.

There is no evidence that surgical masks worn by healthcare workers are effective at limiting the emission of small particles or in preventing contamination of wounds during surgery.

There is moderate evidence that surgical masks worn by patients in healthcare settings can lower the emission of large particles generated during coughing and limited evidence that small particle emission may also be reduced.

N95 FFRs as source control

Respirator use by the public was reviewed by NIOSH: (1) untrained users will not wear respirators correctly, (2) non-fit tested respirators are not likely to fit, and (3) improvised cloth masks do not provide the level of protection of a fit-tested respirator.

There are few studies examining the effectiveness of respirators on patients. An N95 FFR on coughing human subjects showed greater effectiveness at limiting lateral particle dispersion than surgical masks (15 cm and 30 cm dispersion, respectively) in comparison to no mask (68 cm). [35] Cystic fibrosis patients reported that surgical masks were tolerable for short periods, but N95 FFRs were not.[34]

In summary, N95 FFRs on patients will not be effective and may not be appropriate, particularly if they have respiratory illness or other underlying health conditions. Given the current extreme shortages of respirators needed in healthcare, we do not recommend the use of N95 FFRs in public or household settings.

Cloth masks as PPE

A randomized trial comparing the effect of medical and cloth masks on healthcare worker illness found that those wearing cloth masks were 13 times more likely to experience influenza-like illness than those wearing medical masks.[38]

In sum, very poor filter and fit performance of cloth masks described earlier and very low effectiveness for cloth masks in healthcare settings lead us conclude that cloth masks offer no protection for healthcare workers inhaling infectious particles near an infected or confirmed patient.

Surgical masks as PPE

Several randomized trials have not found any statistical difference in the efficacy of surgical masks versus N95 FFRs at lowering infectious respiratory disease outcomes for healthcare workers.[39-43]

Most reviews have failed to find any advantage of one intervention over the other.[23,44-48] Recent meta-analyses found that N95 FFRs offered higher protection against clinical respiratory illness[49,50] and lab-confirmed bacterial infections,[49] but not viral infections or influenza-like illness.[49]

A recent pooled analysis of two earlier trials comparing medical masks and N95 filtering facepiece respirators **with controls** (no protection) found that healthcare workers continuously wearing N95 FFRs were 54% less likely to experience respiratory viral infections than controls ($P = 0.03$), while those wearing medical masks were only 12% less likely than controls ($P = 0.48$; result is not significantly different from zero).[51]

While the data supporting the use of surgical masks as PPE in real-world settings are limited, the two meta-analyses and the most recent randomized controlled study[51] combined with evidence of moderate filter efficiency and complete lack of facepiece fit lead us to conclude that surgical masks offer very low levels of protection for the wearer from aerosol inhalation. There may be some protection from droplets and liquids propelled directly onto the mask, but a faceshield would be a better choice if this is a concern.

N95 FFRs as PPE

A retrospective cohort study found that nurses' risk of SARS (severe acute respiratory syndrome, also caused by a coronavirus) was lower with consistent use of N95 FFRs than with consistent use of a surgical mask.[52]

In sum, this study, the meta-analyses, randomized controlled trial described above,[49,51] and laboratory data showing high filter efficiency and high achievable fit factors lead us to conclude that N95 FFRs offer superior protection from inhalable infectious aerosols likely to be encountered when caring for suspected or confirmed COVID-19 patients.

The precautionary principle supports higher levels of respiratory protection, such as powered air-purifying respirators, for aerosol-generating procedures such as intubation, bronchoscopy, and acquiring respiratory specimens.

Conclusions

While this is not an exhaustive review of masks and respirators as source control and PPE, we made our best effort to locate and review the most relevant studies of laboratory and real-world performance to inform our recommendations. Results from laboratory studies of filter and fit performance inform and support the findings in real-world settings.

Cloth masks are ineffective as source control and PPE, surgical masks have some role to play in preventing emissions from infected patients, and respirators are the best choice for protecting healthcare and other frontline workers, but not recommended for source control. These recommendations apply to pandemic and non-pandemic situations.

Leaving aside the fact that they are ineffective, telling the public to wear cloth or surgical masks could be interpreted by some to mean that people are safe to stop isolating at home. It's too late now for anything but stopping as much person-to-person interaction as possible.

Masks may confuse that message and give people a false sense of security. If masks had been the solution in Asia, shouldn't they have stopped the pandemic before it spread elsewhere?

Ways to best protect health workers

We recommend that healthcare organizations follow US Centers for Disease Control and Prevention (CDC) guidance by moving first through conventional, then contingency, and finally crisis scenarios to optimize the supply of respirators. We recommend using the CDC's burn rate calculator to help identify areas to reduce N95 consumption and working down the CDC checklist for a strategic approach to extend N95 supply.

For readers who are disappointed in our recommendations to stop making cloth masks for themselves or healthcare workers, we recommend instead pitching in to locate N95 FFRs and other types of respirators for healthcare organizations. Encourage your local or state government to organize and reach out to industries to locate respirators not currently being used in the non-healthcare sector and coordinate donation efforts to frontline health workers.

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