

## Invited Commentary

# Filtration Efficiency, Effectiveness, and Availability of N95 Face Masks for COVID-19 Prevention

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**In March 2020**, the soaring number of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections resulted in an unprecedented shortage of personal protective equipment (PPE) for clinicians and essential health care workers.<sup>1</sup> The shortage was most profound among N95 masks.

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N95 respirators, named for their ability to filter 95% or more of tiny 0.3- $\mu$ m particles, are the mainstay of protection against airborne pathogens.<sup>2</sup> Airborne transmission results from contact with infectious particles contained within small (<5  $\mu$ m) droplet nuclei (ie, aerosols) that can linger in the air for hours and be dispersed over great distances.<sup>2</sup> In contrast, SARS-CoV-2 is primarily spread by large (>5-10  $\mu$ m) respiratory droplets that can be expelled up to 6 feet horizontally and drop to the ground within seconds, against which surgical masks generally offer adequate protection.<sup>2,3</sup> Nonetheless, the Centers for Disease Control and Prevention recommends that health care workers use N95 masks when caring for patients with confirmed or suspected coronavirus disease 2019 (COVID-19) out of concern for airborne transmission, particularly during exposure to procedures that produce high concentrations of aerosols (eg, intubation, extubation, noninvasive ventilation).<sup>2</sup> To mitigate the shortage of N95 respirators, many health care facilities are pursuing nonstandard approaches to maintaining an adequate supply, including mask decontamination and reprocessing for reuse, which extend the wearable life of the mask beyond the expiration date, and procuring KN95 masks (N95 masks that are regulated in China).

In this issue of *JAMA Internal Medicine*, Sickbert-Bennett and colleagues<sup>4</sup> provide reassuring evidence of the performance of nonstandard approaches to preserving the N95 mask supply. The authors' laboratory-based evaluation of a broad array of nonstandard face masks demonstrates that National Institute for Occupational Safety and Health (NIOSH)-approved N95 respirators outperform alternatives in terms of filtration efficiency. Results of the study demonstrated that N95 masks reprocessed using ethylene oxide sterilization, as well as masks that are up to 11 years past expiration, maintain very high filtration efficiency under laboratory conditions. N95 masks with suboptimal fit still had comparable filtration efficiency of more than 90%. Their KN95 counterparts, millions of which have been purchased by or donated to US hospitals, performed less well, with filtration efficiency ranging from 53% to 85%. Surgical masks secured with either ties or ear loops also had much lower filtration efficiency of 37% to 69%, as might be expected by their more comfortable, thinner filter and looser fit.

Despite the apparent imperfect filtration efficiency of non-NIOSH approved respirators and surgical masks in the laboratory, there is reason for optimism regarding their real-world effectiveness. Although surgical masks have lower

filtration efficiency than N95 respirators, observational studies have shown no significant benefit of N95 masks over surgical masks for prevention of severe acute respiratory syndrome coronavirus 1 (odds ratio, 0.86; 95% CI, 0.22-3.33) or other respiratory viruses (odds ratio, 0.96; 95% CI, 0.85-1.08).<sup>3</sup> For health care workers, routine care for a patient with COVID-19 if both are wearing surgical masks is not considered to be a high-risk occupational exposure.<sup>3</sup> Yet, SARS-CoV-2 viral particles have been identified in the air for several hours after an aerosolizing event simulated in a laboratory and near air vents in a clinical setting.<sup>3</sup> A group of 239 scientists recently signed an open letter urging the World Health Organization and other international public health bodies to recommend additional precautions (though not N95 masks specifically) to protect against potential airborne transmission, highlighting several recent superspreading events in which SARS-CoV-2 transmission occurred in poorly ventilated areas.<sup>5</sup> These instances raise concern for the possibility of SARS-CoV-2 airborne transmission; however, the viability and infectiousness of SARS-CoV-2 viral particles in aerosol form remains unknown. Importantly, no documented SARS-CoV-2 outbreaks have been linked to settings in which surgical masks were assiduously used in lieu of N95 masks, which suggests that even if airborne transmission is a considerable contributor to SARS-CoV-2 transmission, surgical masks are likely sufficient to prevent it.<sup>3</sup> Because the infectious dose of virus required to cause clinical infection also remains unknown, it is possible that blocking most, even if not all, viral particles through masks with lower filtration efficiencies of submicron particles is sufficient to prevent disease in the vast majority of cases.

Importantly, the effectiveness of any mask also depends heavily on its real-world use; variability in mask filtration during clinical care may fluctuate more by mask adherence and fit than by marginal differences in laboratory-based filtration efficiency. In practicality, when worn properly, N95 masks are suffocating, uncomfortable, and difficult to tolerate for long durations. Best practices for N95 use require intermittent, individualized fit testing and a seal check on donning. Mask fit varies by facial shape and body habitus, and thus, once fit tested, ensuring fidelity to the same manufacturer and size is essential. Filtration efficiency of an N95 mask can also be compromised by even small amounts of facial hair in the area of the seal. Prolonged use of tightly fitting masks may result in facial bruising and abrasions, but bandages over these areas, such as the commonly seen wound barriers over the nasal bridge, interrupt the mask seal. Although a recent clinical trial<sup>6</sup> reported similar and suboptimal self-reported adherence between outpatient health care personnel randomized to wear N95 masks vs medical masks (89% vs 90%), the study also demonstrated no difference in cases of laboratory-

documented influenza—albeit a different respiratory virus—between the 2 groups. Acknowledging that adherence is likely higher amid the COVID-19 pandemic, mask efficiency observed in the laboratory likely reflects an upper bound of the effectiveness that would be observed in clinical settings.

Beyond N95 laboratory-based efficacy and ensuring proper fit-tested use, costs have been a major challenge in procurement of adequate mask supply, with prices increasing in some cases up to 30- to 100-fold.<sup>7</sup> Outside of pandemic conditions, surgical and N95 masks generally cost approximately \$0.08 and \$0.50 each, respectively. Standard pricing for KN95 masks, which are generally not sold in the United States, is unavailable, but they have been sold during the crisis from \$2 to \$4 per mask. Expired masks, which would otherwise be discarded, should be cost free. While competition and price gouging for masks has certainly hindered access, supply has been the biggest problem. Reprocessed masks, which can cost up to 6 times the original price of the mask itself, are among the few solutions to continued inadequate supply. Until we have a better understanding of how filtration efficacy translates to improved protection against SARS-CoV-2 transmission, health care systems are left to pay top dollar to keep their most valuable resources—clinicians and health care workers—safe.

Supply chain breakdowns and skyrocketing costs underscore the importance of investment in pandemic prepared-

ness to prevent future PPE shortfalls. Meanwhile, it is critically important that the health care community continues to find innovative ways to overcome PPE shortages. In the setting of severe supply-demand mismatch, we must match supply to risk. Frontline clinicians and essential health care workers who engage in the highest risk procedures should be afforded the highest level of protection with NIOSH-approved N95 respirators; Sickbert-Bennett and colleagues<sup>4</sup> demonstrate that reprocessed use and expired supply of N95 masks are safe and offer excellent alternatives to standard single-use N95 masks. Despite lower filtration efficiencies of submicron particles, surgical masks and other N95 alternatives likely provide adequate protection against transmission for routine care.

We endorse the health care community's cry for the best possible protection for all frontline clinicians and essential health care workers. We are further reassured by the cross-sectional study from Long Island, New York, also in this issue of *JAMA Internal Medicine*,<sup>8</sup> demonstrating that the effectiveness of PPE; the frequency of SARS-CoV-2 antibody positivity among hospital employees required to use PPE was no higher than that of the general population in that area. Taken together, these and other emerging data suggest that surgical masks and N95 alternatives will continue to keep clinicians and health care workers safe.

#### ARTICLE INFORMATION

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