

Filtration Efficiency of Hospital Face Mask Alternatives Available for Use During the COVID-19 Pandemic

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IMPORTANCE Procuring respiratory protection for clinicians and other health care workers has become a major challenge of the coronavirus disease 2019 (COVID-19) pandemic and has resulted in nonstandard practices such as the use of expired respirators and various decontamination processes to prolong the useful life of respirators in health care settings. In addition, imported, non-National Institute for Occupational Safety and Health (NIOSH)-approved respirators have been donated or acquired by hospitals as a potential replacement for limited NIOSH-approved N95 respirators.

OBJECTIVE To assess fitted filtration efficiencies (FfEs) for face mask alternatives used during the COVID-19 pandemic.

DESIGN, SETTING, AND PARTICIPANTS For this quality-improvement study conducted between April and June 2020, we used the Occupational Safety and Health Administration's Quantitative Fit Testing Protocol for Filtering Facepiece Respirators in a laboratory atmosphere supplemented with sodium chloride particles to assess the FfEs of a variety of respirators worn by a male volunteer and female volunteer.

MAIN OUTCOMES AND MEASURES The FfEs of respirators commonly worn by clinicians and other health care workers and available respirator alternatives during the COVID-19 pandemic.

RESULTS Of the 29 different fitted face mask alternatives tested on 1 man and 1 woman, expired N95 respirators with intact elastic straps and respirators subjected to ethylene oxide and hydrogen peroxide sterilization had unchanged FfE (>95%). The performance of N95 respirators in the wrong size had slightly decreased performance (90%-95% FfE). All of the respirators not listed as approved in this evaluation (n = 6) failed to achieve 95% FfE. Neither of the 2 imported respirators authorized for use by the Centers for Disease Control and Prevention that were not NIOSH-approved tested in this study achieved 95% FfE, and the more effective of the 2 functioned at approximately 80% FfE. Surgical and procedural face masks had filtering performance that was lower relative to that of N95 respirators (98.5% overall FfE), with procedural face masks secured with elastic ear loops showing the lowest efficiency (38.1% overall FfE).

CONCLUSIONS AND RELEVANCE This quality-improvement study evaluating 29 face mask alternatives for use by clinicians interacting with patients during the COVID-19 pandemic found that expired N95 respirators and sterilized, used N95 respirators can be used when new N95 respirators are not available. Other alternatives may provide less effective filtration.

JAMA Intern Med. 2020;180(12):1607-1612. doi:10.1001/jamainternmed.2020.4221
Published online August 11, 2020.

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A major concern during the coronavirus disease 2019 (COVID-19) pandemic has been protection of clinicians and other health care workers from severe acute respiratory syndrome coronavirus (SARS-CoV-2) infection by respiratory aerosol and contact transmission. A widespread, acute shortage in personal protective equipment, primarily filtering facepiece respirators (henceforth referred to as respirators), has prompted the implementation of nonstandard practices to fill the need for protection in health care settings. The Centers for Disease Control and Prevention (CDC) has developed contingency and crisis strategies to provide alternatives for respirators, including use beyond expiration dates, decontamination and reuse, and use of non-National Institute for Occupational Safety and Health (NIOSH)-approved respirators.¹

Comparative fitted filtration efficiencies (FfEs), combined intrinsic filtering efficiency of material and efficacy of fit to the face, for respirator alternatives have not previously been quantified in a comprehensive manner, and health care facilities are faced with prioritization of their available options without clear data to guide decision-making. To address this need, we have performed a series of FFE evaluations for a wide range of 29 respirators and face masks used by health care facilities, including expired N95 respirators, N95 respirators that have undergone sterilization, CDC-approved imported respirators, respirators not listed as approved, and surgical or procedure masks with ties and ear loops.

Methods

Fitted filtration efficiency tests were conducted between April and June 2020 in a custom-built exposure chamber (US Environmental Protection Agency Human Studies Facility in Chapel Hill, North Carolina). The institutional review board at the University of North Carolina at Chapel Hill waived the need for study approval as well as individual consent needed for device testing. Face masks available by purchase or contribution to the local UNC Health Care facility were fitted on an adult male volunteer (weight, 75 kg; height, 178 cm; head circumference, 58.5 cm) with no beard. For sex comparison of small and regular-sized face masks commonly used in health care facilities, an adult female volunteer was also tested (weight, 53 kg; height, 160 cm; head circumference, 56.0 cm). Fitted filtration efficiency tests were conducted as prescribed by the Occupational Safety and Health Administration's Modified Ambient Aerosol CNC Quantitative Fit Testing Protocol For Filtering Facepiece, Table A-2.²

Accordingly, FFE was measured during a series of repeated movements of the torso, head, and facial muscles to simulate typical occupational activities experienced by a mask wearer. A Particle Generator 8026 (TSI) was used to supplement ambient particle counts in the chamber, with sodium chloride particles having a count median diameter of 0.05 μm , as measured by a scanning mobility particle sizer. Particle concentration in the chamber was allowed to stabilize for 30 minutes prior to testing. All face masks were fitted with sampling probes using a Fit Test Probe Kit for Disposable Facepieces 8025-N95 (TSI) to allow sampling of aerosol inside of the face

Key Points

Question How effective are the aerosol filtration efficiencies for fitted face mask alternatives used during the coronavirus disease 2019 pandemic?

Findings In this quality-improvement study of 29 fitted face mask alternatives, expired N95 respirators with intact elastic bands and masks that had been subjected to ethylene oxide and hydrogen peroxide sterilization had unchanged fitted filtration efficiencies (FfEs) of more than 95%, while the performance of N95 respirators in the wrong size resulted in decreased FfEs between 90% and 95%. As a group, surgical and procedure masks had lower FfEs relative to N95 respirators, with masks secured with elastic ear loops showing the lowest performance.

Meaning When new N95 respirators are unavailable, N95 respirators past their expiration date; sterilized, used N95 respirators; and other less common respirators can be acceptable alternatives.

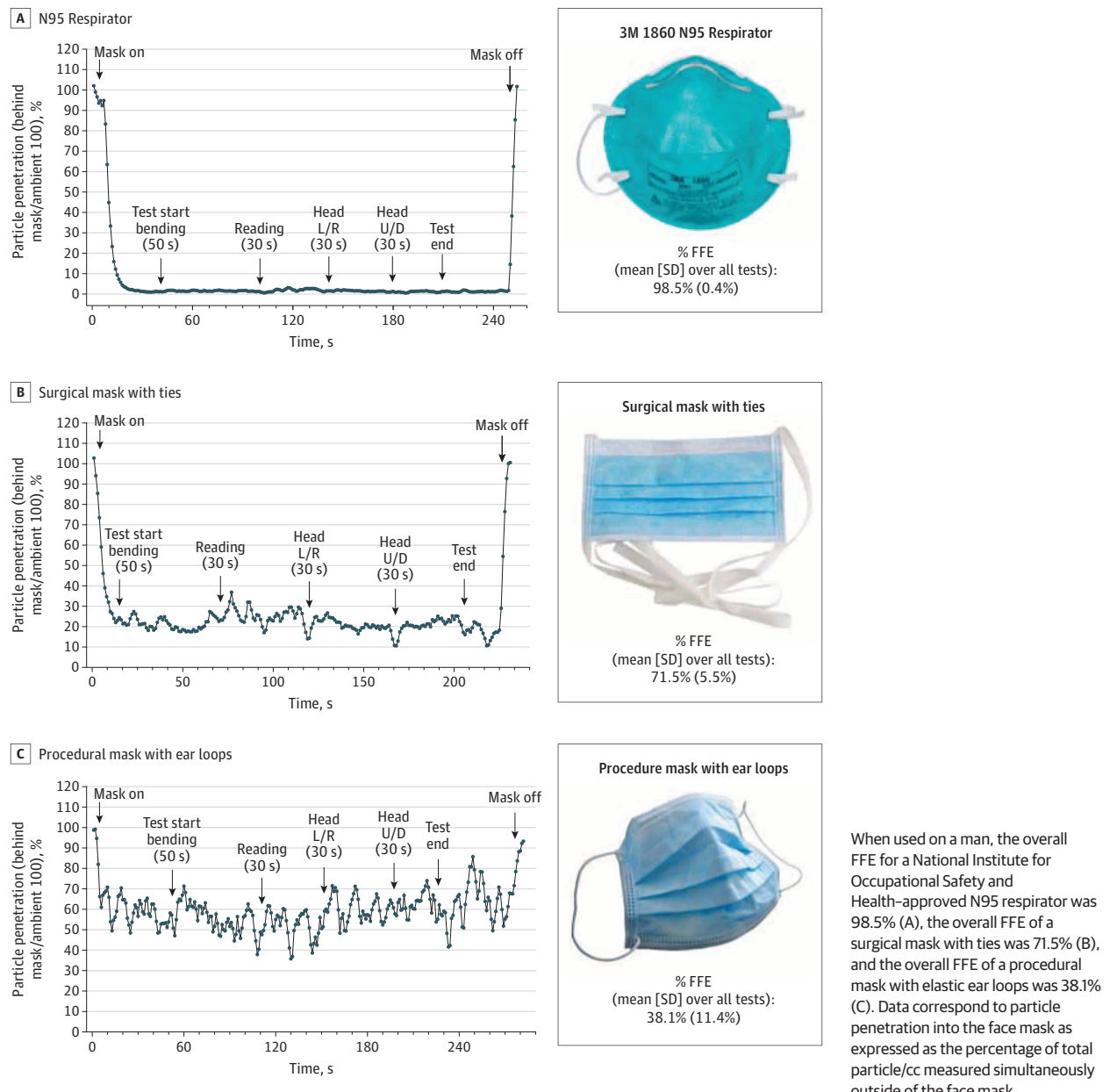
mask. Face masks fitted with sampling probes can be seen in the **Figure**. A pair of Condensation Particle Counters 3775 (TSI) was run in single particle analysis mode to continuously monitor particles (0.02-3.00 μm) in the chamber just outside of the face mask (ambient) and behind the face mask at a sampling rate of 1 second. Ambient particle counts/cc were typically in the range of 2000 to 5000. Ten feet of 0.25-inch conductive rubber tubing was used for each sampling line, and a small piece of nonconductive tubing and stopcock served as a connector between the sampling port and the conductive tubing sampling line. The ambient sampling line and masks sampling line were made identical to reduce variability in the system.

The temperature during testing ranged from 23 °C to 29.5 °C, and the relative humidity was 10% to 50%. The overall FFE was averaged from start to end of the testing period, and the average standard deviation over the period of sampling was computed (total testing time was about 3 minutes). Three respirator sterilization methods were tested on used masks: ethylene oxide (EtO) (500 mg/L-hours at 50 °C, 16-hour cycle), steam (121 °C, 15 minutes), and vaporized hydrogen peroxide (8 g/min, 260 PPM, 100-minute cycle). Each sterilization load was monitored with mechanical, chemical, and biological indicators specific to the sterilizer manufacturer's instructions. The FFE of these sterilized, used masks was measured after a single sterilization cycle as described above.

Results

Table 1^{3,4} shows FfEs for all face masks tested. A Controlled Air Purifying Respirator system (MAXAIR) fitted with a face shield supplied by the device manufacturer prevented more than 99% of particles from entering the test individual's breathing space. N95 respirators up to 11 years past their expiration (expired in 2009 and 2011) and N95 respirators subjected to EtO and vaporized hydrogen peroxide sterilization retained FfEs more than 95%. Although N95 respirators with exhalation valves (Particulate Respirator 8511 [3M]) are not generally used in health care settings because the expired air is not

Figure. Evaluation of Fitted Filtration Efficiency (FFE) Using the Occupational Safety and Health Administration Modified Ambient Aerosol CNC Quantitative Fit Testing Protocol for Filtering Facepiece



filtered by the face mask, their FFE was also more than 95%. All of the respirators not listed as approved (eg, KN95 [Guangdong Fei Fan]) and the 2 CDC-approved, imported, non-NIOSH-approved respirators (DTC-3X-1 and DTC-3X-2 [Dasheng]) in this evaluation failed to achieve 95% FFE. As expected, surgical and procedure masks had substantially lower average FFEs than the N95 respirators, and the variability in their performances was observed to be largely dependent on the tightness of the contact between the material and the test individual's facial skin. In all tests, the FFE of masks with ties outperformed those with ear loops.

Finally, **Table 2** compares respirator and face mask FFEs for the man and woman. The small 1860 N95 respirator (3M)

on the man and the regular 1860 N95 respirator on the woman failed to achieve an FFE more than 95%; however, both were more than 90% efficient. All other single-sized N95 face masks reached more than 95% FFE on both the man and woman. The mask with ear loops was less efficient on the woman's face relative to the man's face.

Discussion

While Controlled Air Purifying Respirator systems and new NIOSH-approved N95 respirators fitted to the face are clearly the preferred choice of protection from bioaerosols, the avail-

Table 1. Face Mask Fitted Filtration Efficiency (FFE) Against Submicron Particle Penetration

Face mask	Condition	Approved	% FFE (SD) ^a	No. of masks tested on male test individual
Commonly used				
MAXAIR Controlled Air Purifying Respirator system ^b	New	NA	99.6 (0.1)	1
3M 8210 N95 ^b	New	Yes ^c	97.9 (0.5)	2
3M 8210 N95 ^b	Expired in 2011	NA	98.5 (0.4)	3
3M 1860 N95 ^b	New	Yes ^c	98.5 (0.4)	1
3M 1860 N95 ^b	Expired in 2009	NA	97.0 (1.0)	3
3M 1860 N95 ^b	EtO sterilized	NA	98.1 (0.5)	3
3M 1860 N95 ^b	H ₂ O ₂ sterilized	NA	96.8 (0.7)	1
3M 1870+ Aura N95 ^b	New	Yes ^c	99.2 (0.3)	1
3M 1870+ Aura N95 ^b	Autoclaved	NA	98.0 (0.4)	3
Halyard Health 46827 N95 ^b	New	Yes ^c	99.5 (0.1)	1
Surgical mask				
With ties	New	NA	71.5 (5.5)	4
With ear loops	New	NA	38.1 (11.4)	3
Less commonly used				
Dasheng DTC-3Z with head straps ^b	New	Yes ^c	99.2 (0.3)	1
3M 8511 N95 with exhaust valve ^b	New	Yes ^c	98.0 (0.5)	1
Moldex 2200 N95 ^b	New	Yes ^c	97.8 (0.5)	1
One Sperian HC-NB295F Duckbill ^b	New	Yes ^c	97.7 (0.7)	1
3M 9010 CN N95 ^b	New	Yes ^c	97.6 (0.8)	1
Dasheng DTC-3W with head straps ^b	New	Yes ^c	95.5 (1.2)	1
Safemark Magic City 6950 Duckbill ^b	New	Yes ^c	95.2 (1.3)	1
U-Line S-9632	New	Yes ^c	94.2 (1.4)	1
SAS Safetycorp 8617 Duckbill	New	Not listed	93.2 (1.4)	1
Willson Saf-T Fit N1105 medium/large (Honeywell)	New	Yes ^c	93.0 (1.8)	1
Fangtian Duckbill FT-032 with exhaust valve	New	Not listed	86.2 (2.8)	1
Safe-Life N95 B150	New	Not listed	85.9 (2.0)	1
Jia Hu Kang KN95 mask with ear loops	New	Not listed	85.1 (2.2)	1
Dasheng DTC-3X1 with ear loops	New	Yes (CDC only) ^d	79.7 (4.4)	1
Zhongshan Dongfeng Huangshang GM700	New	Not listed	79.2 (6.8)	1
Dasheng DTC-3X2 with ear loops	New	Yes (CDC only) ^d	76.8 (5.5)	1
Guangdong Fei Fan KN95	New	Not listed	53.2 (6.8)	1

Abbreviations: CDC, Centers for Disease Control and Prevention; EtO, ethylene oxide; H₂O₂, vaporized hydrogen peroxide; NA, not applicable; NIOSH, National Institute of Occupational Safety and Health.

^a The FFE percentage corresponds to the mask condensation particle counter counts/ambient condensation particle counter counts × 100. The FFE percentage and SD were calculated across the length of the test.

^b Mask functioned at or above 95% FFE.

^c Denotes NIOSH-approved N95 particulate filtering facepiece respirators.³

^d Denotes CDC-approved, imported, non-NIOSH-approved respirators manufactured in China.⁴

ability of these items may be compromised during periods of high demand, such as a pandemic. The current study provides a comparative evaluation of particle penetration for commonly available face masks and alternatives while fitted to the face at baseline and under nonstandard conditions (eg, expired, sterilized) using a worst-case scenario of exposure to very small aerosols. Results of this study show that, despite an 11-year expiration, N95 respirators with intact headbands exceeded 95% FFE. Recently, sterilization and decontamination of face masks has emerged as a novel method to prolong the limited supply of existing respirators.⁵ Both EtO and vaporized hydrogen peroxide, which are effective sterilization agents and well known for material compatibility, had no deleterious effect on FFE after a single sterilization. A potential disadvantage of EtO sterilization is that the wearer may be exposed to residual EtO within the face mask. We also evaluated steam sterilization for 2 respirator models. Steam visibly

distorted the 1860 N95 respirators, making them unsuitable for reuse. However, 1870+ Aura face masks (3M) were not visibly altered and maintained more than 95% FFE when subjected to a single cycle of steam autoclaving.

Neither of the CDC-approved, imported respirators lacking NIOSH certification functioned at or above 95% efficiency, and the most effective face mask achieved only 79.7% FFE. These respirators, which have elastic ear loops and a vertical fold design, were least effective when the test individual bent at the waist and looked up and down. Procedure masks with ear loops performed at 38.1% FFE and were the least effective when moving the head left and right (21.2% FFE), and created visible gaps between the face mask and the wearer. Taken together, these data suggest that elastic ear loops may not provide adequate tension to maintain a tight fit during a typical range of motions. Moreover, these findings illustrate the importance of fit for maximizing the overall effectiveness of both respirators and masks.

Table 2. Face Mask Fitted Filtration Efficiency (FFE) Against Submicron Particle Penetration

Face mask	% FFE (SD) ^a	
	Man	Woman
3M 1860 N95		
Small	91.1 (4.0)	98.6 (0.4)
Regular	98.4 (0.5)	93.1 (1.6)
3M 8210 N95 (one size only) ^b	99.4 (0.3)	98.2 (0.7)
3M 8511 N95 with exhalation valve ^b	98.1 (0.7)	98.3 (0.9)
Surgical mask		
With ties	69.8 (5.1)	68.9 (10.9)
With ear loops	39.7 (10.5)	26.5 (14.0)

^a The FFE percentage corresponds to the mask condensation particle counter counts/ambient condensation particle counter counts × 100. The FFE percentage and SD were calculated across the length of the test.

^b Mask functioned at or above 95% FFE.

Clinicians and other health care workers are exposed to polydispersed aerosols when caring for patients, particularly during aerosol-generating procedures. SARS-CoV-2 virions are 50 to 200 nm in diameter⁶ but can be transported and transmitted on much larger droplets, which may be the major source of transmission. The count median diameter of particles in the test atmosphere was measured at 50 nm, likely smaller than SARS-CoV-2 virions or droplets containing the virus. However, the particle size of the test atmosphere was very similar to the sodium chloride particle size used to test and certify N95 respirators (75 ± 20 nm), which is deemed appropriate by the US Code of Federal Regulations (42 CFR §84, subpart K). Based on the mechanisms of particle deposition that govern filtration by face masks (ie, diffusion, impaction, interception, and sedimentation), it is clear that protection against aerosols with a count median diameter of 50 nm would also confer similar

or better protection against much larger aerosols or droplets larger than 3 μm.⁷ In fact, for masks with an electric charge (such as those manufactured by 3M), the most penetrating particle size was found to be 30 to 60 nm,⁸ which is similar in size to those used for measurements in this study.

Limitations

A limitation of this study is the decision to test each mask on a single man (and woman for a few comparisons) rather than a large number of individuals with a full range of facial configurations. On the other hand, the use of 1 common individual allowed for testing of a larger quantity of masks in a short period of time, which addressed the urgent need for hospital infection prevention decision-making.

Conclusions

Evidence from previous studies suggests that even face masks with less than 95% FFE (eg, surgical masks) are effective in preventing acquisition of epidemic coronaviruses (ie, severe acute respiratory syndrome coronavirus 1, SARS-CoV-2) by clinicians and other health care workers except possibly during aerosol-generating procedures.⁹⁻¹¹ For prevention of a related coronavirus, severe acute respiratory syndrome coronavirus 1, N95 respirators had no increased prevention benefit over surgical masks.¹⁰ However, the CDC and Infectious Diseases Society of America has recommended the use of N95 respirators especially during aerosol-generating procedures as long as the supplies are available. This evaluation provides quantitative results on which health care administrators, supply chain leaders, and hospital epidemiologists can make evidence-based decisions to protect clinicians and other health care workers during a pandemic or long-term mask shortage.

ARTICLE INFORMATION

Accepted for Publication: July 7, 2020.

Published Online: August 11, 2020.

doi:10.1001/jamainternmed.2020.4221

Author Contributions: Dr Sickbert-Bennett had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Drs Sickbert-Bennett, Samet, and Clapp served as co-first authors and contributed equally to the work.

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Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Clapp.

Administrative, technical, or material support: Sickbert-Bennett, Samet, Zeman, Tong, Weber.

Study supervision: Sickbert-Bennett, Samet, Weber, Bennett.

Conflict of Interest Disclosures:

Dr Sickbert-Bennett reports receiving consultation fees from PDI and Johnson & Johnson. No other disclosures are reported.

Funding/Support: This study was supported by a cooperative agreement between the University of North Carolina at Chapel Hill and the US Environmental Protection Agency (CR 83578501).

Role of the Funder/Sponsor: The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Disclaimer: The research described in this article has been reviewed by the Center for Public Health and Environmental Assessment, and the US Environmental Protection Agency and approved for publication. The contents of this article should not be construed to represent US Environmental Protection Agency policy nor does mention of trade names or commercial products constitute endorsement or recommendation for use.

Additional Contributions: We would like to acknowledge David Diaz-Sanchez, PhD, of the US Environmental Protection Agency, and Philip Bromberg, PhD, of the University of North Carolina at Chapel Hill, for their invaluable assistance in the collection of study data and the review of the article. They were not compensated for their contributions.

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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.¹



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The shortage was most profound among N95 masks. N95 respirators, named for their ability to filter 95% or more of

tiny 0.3- μm particles, are the mainstay of protection against airborne pathogens.² Airborne transmission results from contact with infectious particles contained within small (<5 μm) droplet nuclei (ie, aerosols) that can linger in the air for hours and be dispersed over great distances.² In contrast, SARS-CoV-2 is primarily spread by large (>5-10 μm) 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.^{2,3} 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).² 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 colleagues⁴ 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).³ 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.³ 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.³ 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.⁵ 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.³ 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 efficiency