Standards for Surgical Respirators and Masks: Relevance for Protecting Healthcare Workers and the Public During Pandemics

Rachael M. Jones and David Rempel

1Department of Family and Preventive Medicine, School of Medicine, University of Utah, Salt Lake City, UT 84108, USA 2Rocky Mountain Center for Occupational and Environmental Health, University of Utah, Salt Lake, UT 84108, USA 3Division of Occupational and Environmental Medicine, University of California, San Francisco, CA 94115, USA

*Author to whom correspondence should be addressed. Tel: +1-510-703-2484; e-mail: david.rempel@ucsf.edu

Submitted 2 October 2020; revised 2 November 2020; editorial decision 3 November 2020; revised version accepted 20 January 2021.

Abstract

National standards for surgical respirators and masks are written and enforced to protect healthcare workers from particles and microorganisms such as Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). In addition to the ability to filter particles (e.g. filtration efficiency, FE), the standards address breathability (e.g. differential pressure), how well the mask seals to a worker’s face (e.g. fit test), the level of protection from a fluid splash, and other factors. Standards used in the USA, European Union (EU), and China were compared with respect to testing methods and certification criteria. Although there are substantial similarities in standards for respirators, such as surgical N95, FFP2, and KN95 filtering facepiece respirators (FFRs), there are differences with respect to who performs that testing and fit-testing requirements that influence certification. There is greater variation in test methods between countries for surgical (USA) or medical (EU and China) masks than for FFRs. Surgical/medical masks can be certified to different levels of protection. The impact of the similarities and differences in testing methods and certification criteria on FFR and mask performance for protecting healthcare workers from SARS-CoV-2 are discussed, as well as the value of a new standard in the EU for testing fabrics for masks used by the public. Health and safety personnel in healthcare settings must understand the differences between standards so that they can select respirators and masks that provide appropriate protection for healthcare workers.

Keywords: COVID-19; healthcare workers; hospital; pandemic; respiratory protection
Introduction

The Coronavirus Disease 2019 (COVID-19) pandemic overwhelmed the global supply of personal protective equipment for healthcare workers, including respiratory protective devices, and led to the widespread use of face coverings among the public. Never have there been more eyes turned toward respirators, surgical masks, and cloth masks, and many saw a confusing array of jargon, testing methods, and performance standards. The first objective of this paper is to describe the testing methods and performance criteria in the USA, the European Union (EU), and China for the most commonly used type of respirators in healthcare settings—filtering facepiece respirators (FFRs), and surgical/medical masks. While other nations have performance criteria, we focus on these three regions owing to their large populations and influence on the marketplace. Testing methods and performance criteria were identified through iterative Internet searches for governmental policy documents and testing standards, and cross-referencing from identified documents. The second objective of this paper is to discuss the impact of the COVID-19 pandemic with respect to performance criteria for these devices, and research needs.

Owing to the variety of names used globally, some definitions are provided. A respirator is a piece of personal protective equipment that is designed to fit tightly to the face and prevent airborne contaminants from being inhaled by the wearer. Among the many types of respirators, FFRs feature a facepiece comprised entirely of the filter material, though they are available in many different designs. The phrase FFR, however, is a technical term predominantly used in the USA; healthcare workers often call these devices N95 masks, where N95 refers to the performance standard for the filter material specified by the National Institute for Occupational Safety and Health (NIOSH), the organization in the USA that certifies respiratory protective devices. In other countries, these devices may be called filtering half masks (EU EN 149+A1, 2009). A surgical or medical mask, in contrast, fits loosely over the face and is designed to prevent the emission of respiratory droplets and aerosols from the wearer (source control) and to prevent the exposure of droplets or spray onto the mouth or nose of the wearer (Brosseau et al. 2021; Garcia Godoy et al., 2020). Herein, the phrases FFR and surgical masks will be used.

Testing methods

There are numerous testing methods used to evaluate the performance of FFRs and surgical masks. The focus of this summary is on tests most relevant to the ability of the devices to prevent the transmission of respiratory infectious disease and wearability, including filtration efficiency (FE), pressure differential, fluid barrier, and fit testing.

Filtration efficiency

FE is the proportion of particles that are intercepted by the filtration material. It is measured by challenging the material with particles of known size, carried at a known flow rate or velocity, and measuring the particle concentration upstream of the material, \( C_{\text{up}} \), and downstream of the material, \( C_{\text{down}} \). Particle penetration through the filter material, \( P_{\text{filter}} \), is the ratio of the downstream concentration to the upstream concentration, multiplied by 100%. FE is the complement of particle penetration: FE = 100% − \( P_{\text{filter}} \). A filter material through which 5% of particles penetrates (\( P_{\text{filter}} = 5\% \)) has 95% FE. FE is influenced by multiple factors, including the filter material; size, shape, and charge of the challenge particles, airflow rate, temperature and humidity, loading, and other factors.

It is well known that the FE of filter material may vary for particles of different sizes and shapes. This is because filtration occurs through multiple physical processes—straining or sieving, inertial impaction, interception,
diffusion, gravitational settling, and electrostatic attraction (Hinds, 1999), and the efficiency of these processes varies by particle size. The particle size for which a filter material has the lowest FE is termed the most penetrating particle size (MPPS). Ideally, the MPPS is used to test filter performance, as the filter efficiency for all other particles will be better than that obtained with the MPPS. MPPS varies with filtration material and air velocity through the filter. Early studies reported MPPS for respirators of 0.3 μm, but more recent studies have shown that MPPS is in the 0.04–0.06 μm range (Rengasamy et al. 2012).

Table 1 summarizes common FE testing methods used in the USA, EU, and China for FFRs and surgical masks. All FE test methods for FFRs use sodium chloride particles with a count median diameter (CMD) of 0.075 μm [mass median aerodynamic diameter approximately 0.3 μm (Eninger et al. 2008)]. The FE test methods for surgical masks use larger particles and lower airflow rates than the test methods for FFRs. Filter material will generally show higher FE with larger particles than the MPPS, and with lower airflow rates than the MPPS, with the airflow rate generally showing a strong correlation with filter efficiency. The airflow rates, or face velocity, for testing are selected based on the expected upper end of flow rates by workers performing typical tasks. The airflow of 85 l/min was selected to represent a workers’ inhalation at a high work rate. The airflow during rest or rapid walking will be between 10 and 40 l/min (Louhevaara et al. 1986).

Particles are charged neutralized in most tests for FFRs because such particles generally have a lower FE than charged particles (Eninger et al. 2008). The ASTM F2299 method was recently altered to require charged neutralized particles for testing. A study completed prior to this change found that the ASTM F2299 method produced higher FE values than the NIOSH TEB-APR-STP-0059 method for the same filter materials (Rengasamy et al., 2017; NIOSH, 2019). Of note, bacteria FE tests expose the interior of the mask to the particles, while tests used for FFRs expose the exterior of the mask to the particles. S. aureus bacteria will generally show higher FE with larger particles than the MPPS, and with lower airflow rates than the MPPS, with the airflow rate generally showing a strong correlation with filter efficiency. The airflow rates, or face velocity, for testing are selected based on the expected upper end of flow rates by workers performing typical tasks. The airflow of 85 l/min was selected to represent a workers’ inhalation at a high work rate. The airflow during rest or rapid walking will be between 10 and 40 l/min (Louhevaara et al. 1986).

The pressure differential, or pressure drop, reflects how easy it is to breathe through the filter material. The pressure differential is generally determined by measuring the air pressure on both sides of the filter material while the air flows at a known velocity through the filter material. The pressure differential is the difference between the two air pressures. A low-pressure differential means air easily passes through the filter material, making it easier for the wearer to breathe.
to breathe through. For a given experimental set-up, decreasing the air velocity will decrease the pressure differential and increasing the thickness of the filter material will increase the pressure differential. Table 2 summarizes methods used to measure pressure differential for filter materials.

The pressure differential is typically reported in the units of pascal (Pa) \((1.0 \, \text{Pa} = 0.102 \, \text{mmH}_2\text{O})\). Some pressure differential standards for surgical masks use the unit of Pa/cm\(^2\), which has no physical meaning. These tests, however, specify the surface area of the mask material tested, so the values have been multiplied by the surface area tested to obtain a physically meaningful unit, Pa.

**Fluid barrier**

Fluid barrier tests evaluate how well the material prevents the penetration of liquid, such as might be splashed onto the device during healthcare activities. A primary test for the fluid barrier is ASTM F1862. ASTM F1862 is a qualitative test in which synthetic blood is projected onto the exterior of the mask at a specific pressure (80, 120, or 160 mmHg), and the interior of the mask is visually inspected for penetration (ASTM International, 2017b). The test seeks to represent the event of blood splatter exiting from a small arterial puncture.

**Fit testing**

Respirator fit testing is performed to determine how well the respirator fits the face of the wearer or the inward leakage of particles. In a quantitative fit test, the general approach is to measure the particle number concentration inside and outside of the respirator facepiece while the wearer performs a series of exercises; often sodium chloride or other particles are released outside the respirator to ensure that quantifiable particle concentrations penetrate the facepiece. The fit of the respirator is described by the fit factor, the ratio of the particle concentration outside the respirator to that inside the respirator facepiece. The fit test measures total inward leakage—the leakage of particulates through the face seal, valves, and gaskets, as well as penetration through the filter. Use of high-efficiency particulate filters, for example, N100 or P100 in the USA or KN100 in China, functionally eliminates penetration through the filters, so that the fit test measures leakage of particulates through the face seal, valves, and gaskets. Total inward leakage is calculated as 100% divided by the fit factor (Rengasamy et al., 2014), but in the EU, the fit factor is adjusted by the duration of inhalation and exhalation to determine total inward leakage (EU EN 149+A1, 2009). In the USA, respirator
fit testing is the responsibility of the employer (29 CFR 1910.134), and is not part of the respirator certification process. In the EU (EU EN 149+A1, 2009) and China (China National Standard GB 2626-2006, 2006), however, total inward leakage tests are required as part of the respirator certification process.

**Product certification**

**Filtering facepiece respirators**

The performance criteria for FFRs (e.g. filtering half masks) are shown in Table 3. In the USA, surgical N95 FFRs are required by the Food and Drug Administration (FDA) to undergo the same testing required for surgical masks—particle FE, bacteria FE, fluid penetration, pressure differential, and flammability (e.g. Table 4). Although these tests are reported by the manufacturer, the manufacturer may report results from the particle filtration and pressure differential tests performed by NIOSH as part of the respirator certification process to the FDA (NIOSH STP-0003, 2019; NIOSH STP-0007, 2019; NIOSH STP-0059, 2019). Fluid penetration testing is not required for certification of FFP1, FFP2, FFP3 filtering half masks in the EU, but is required in China (China National Standard GB 19083-2010, 2010) for devices worn in healthcare settings.

Respirator certification in the EU requires that 46 of 50 individual respirator fit-testing exercises (10 subjects × 5 exercises) have total inward leakage ≤25, 11, or 5% for FFP1, FFP2, and FFP3, respectively (EU EN 149+A1, 2009); and that at least 8 of 10 subjects have mean inward leakage ≤22, 8, and 2% for FFP1, FFP2, and FFP3, respectively (EU EN 149+A1, 2009; EU EN 13274-7, 2019). Similar criteria are used in China, where 46 of 50 individual respirator fit-testing exercises (10 subjects × 5 exercises) must have total inward leakage <13, 11, or 5% for KN90, KN95 and KN100 devices, respectively; and that at least 8 of 10 subjects have overall total inward leakage <10, 8, or 2% for KN90, KN95, and KN100 devices, respectively (China National Standard GB 2626-2006, 2006).

**Surgical/medical masks**

In the USA, surgical masks are cleared by the FDA through the premarket notification process (CFR 878.4040; 21CFR807.81; FDA, 2004, 2020). Manufacturers must submit data regarding particle FE, bacteria FE, fluid penetration, flammability, and pressure differential, but the FDA does not specify which test

| Table 3. Selected performance criteria for filtering facepiece respirators. |
|---------------------------------------------------------------|
| **N95 FFR** | **FFP1** | **FFP2** | **FFP3** | **KN95** |
| Filtration efficiency testing method | NIOSH | TEB-APR-STP-0059 | EN 149+A1 | EN 149+A1 | EN 149+A1 |
| Minimum filtration efficiency | ≥95% | ≥80% | ≥94% | ≥99% | ≥95% |
| Maximum test challenge load | 200 mg | Not specified | Not specified | Not specified | 200 mg |
| Tested by | NIOSH | Manufacturer | Manufacturer | Manufacturer | Manufacturer |
| Number of respirators tested | 20 | 9 | 20 | 20 | 20 |
| Mean total inward leakagea | ≤22% | ≤8% | <2% | ≤8% | ≤8% |
| Maximum pressure differential on inhalation | 343 Pa | 210 Pa at 95 l/min | 240 Pa at 95 l/min, 70 Pa at 30 l/min | 300 Pa at 95 l/min | 290 Pa at 95 l/min |
| Mean total inward leakage on exhalation | 245 Pa | 300 Pa at 160 l/min | 250 Pa | 343 Pa | 350 Pa |
| Maximum pressure differential on exhalation | 245 Pa | Not specified | Not specified | Not specified | Not specified |
| Carbon dioxide | <1% by volume | <1% by volume | <1% by volume | <1% by volume | <1% by volume |

a Observed for 8 of 10 subjects evaluated.
methods must be used. However, the FDA recommends ASTM 2299 for particulate FE, using 0.1 μm latex spheres that have not been charge-neutralized, but there is no specified flow rate. For bacteria FE, the FDA recommends ASTM F2101, Mil-M369454C, or the modified method of Greene and Vesley (1962). Once cleared by the FDA, surgical masks are often marketed based on their barrier performance level (e.g. 1, 2, or 3) as defined by ASTM International (Table 4).

The EU criteria also define three barrier levels for medical masks (EU EN 14683+C1, 2019), as shown in Table 5. The standards for testing and requirements for medical face masks (EU EN 14683+C1, 2019) are similar to the FDA requirements for surgical masks (Table 4). Only Type IIR requires splash protection/ fluid resistance. Type II and IIR are intended to protect hospital staff from patients during surgical and other procedures. Type I are only for patients and the public during epidemics. The testing methods for BFE (Annex B) require preconditioning with 85% RH and 21°C for 4 h. The method is otherwise similar to ASTM F2101.

In China, the standard for surgical masks used in the pharmaceutical industry (China International Pharmaceutical Standard YY 0469-2011, 2011) provides for only one performance level. Performance requirements include, but are not limited to ≥95% bacterial FE (ASTM F2101), ≥30% particle FE (GB 2626-2006), no visible fluid penetration when synthetic blood is applied with 120 mmHg to the mask exterior, pressure differential ≤49 Pa, and noncombustible.

### Table 4. ASTM criteria (F2100-19e1) for three barrier levels for surgical masks, as used in the USA.

| Test method | Metric | Barrier level |
|-------------|--------|---------------|
| ASTM F1862  | Fluid resistance (mmHg) | 80 | 120 | 160 |
| ASTM F2299  | Filtration efficiency (%) | ≥95 | ≥98 | ≥98 |
| or F2101    | Pressure (Pa/cm²) | <50 | <60 | <60 |
| EU EN 14683:2019 | Pressure differential (Pa/cm²) | ≤245 | ≤294 | ≤294 |
| Annex C    | Fluid resistance (kPa) | ≤16 |

* Flow rate of 8 l/min. Pa calculated assuming 4.9 cm² material tested.

### Table 5. Selected European Union criteria for three barrier levels for medical masks (EU EN 14683).

| Metric                        | Type I Not required | Type II Not required | Type IIR ≥16 |
|-------------------------------|--------------------|----------------------|--------------|
| Fluid resistance (kPa)        | ≥95                | ≥98                  | ≥98          |
| Pressure differential (Pa/cm²)| <40                | <40                  | <60          |

{\textit{a}} Flow rate of 8 l/min. Pa calculated assuming 4.9 cm² material tested.

which has led to confusion and concern about performance equivalence. One source of confusion is the use of various terms globally to refer to similar devices—for example, N95 FFRs and filtering half masks, or protective face masks. In addition, while testing methods and criteria for respirators are relatively similar (Tables 1–3), their performance in the field may vary. In particular, the ability of respirators to protect workers is dependent upon the quality of the respirator fit; FFRs may not fit a large segment of the population (Lee et al., 2008; Zhang et al., 2020).

The 95% bacteria FE required for surgical masks (Tables 4 and 5) may lead some to consider that these devices offer protection to workers that are equivalent to respirators, since most respirators used in healthcare settings have filters with a FE of 95% (e.g. N95, FFP2, and KN95). Since filtration occurs through multiple physical processes, FE and the MPPS is influenced by the air velocity, particle size, particle charge, as well as charge of the filter material (Balazy et al., 2006). FE tests for surgical masks and FFRs differ across many of these variables (Table 1). The size of the Staphylococcus aureus particles (3 μm) and the air velocity used to test bacteria FE mean that the bacteria FE tests are less stringent than the use of smaller sized NaCl particles to test respirators (Rengasamy et al., 2017). Oberg and Brosseau (2008) tested nine surgical masks reported to have bacteria FE ≥95% and found filter efficiencies measured using the NIOSH NaCl respirator test methods to be much lower, for example, 10–90%. Because respiratory viruses are found in the air in particles with diameters <3.0 μm (Phan et al., 2020; Chia et al., 2020), it is important for healthcare workers to have FFRs and masks capable of filtering particles in this size range with high efficiency. Another flaw arises from the ease with which particles can by-pass the filtration material of a surgical mask owing to the loose fit of the mask against the face (Oberg and Brosseau, 2008; Lee et al., 2008). It is interesting

### Discussion

Shortages of respirators and surgical masks during the COVID-19 pandemic have required many healthcare organizations to use new supply chains and products,
to note that a recent FDA Emergency Use Authorization (EUA) created a new term ‘Authorized Surgical Masks’ that they designate as PPE for healthcare personnel in healthcare settings, but the criteria for testing is not changed.

There is a need to improve the fit of FFRs. It is routine to find that FFRs fail to fit a substantial number of people (Lee et al., 2008; Zhang et al., 2020). It is difficult to find data about the quality of fit from manufacturers and distributors (Lofgren, 2018), and many peer-reviewed studies do not detail the models tested. As a result, employers must have multiple respirator models available and fit test workers with more than one model and more than one size per model. Fit testing of FFRs is required for respirator certification prior to sales in the EU and China, and the standards require testing of at least ten individuals (China National Standard GB 2626-2006, 2006; EU EN 149+A1, 2009), but it is not clear how well this requirement yields well-fitting FFRs (Foereland et al., 2019). In the USA, there have been calls to require fit-testing as part of the NIOSH certification process and to generally improve the fit of FFRs (Lofgren, 2018). Toward that goal, a voluntary standard is under development that would incorporate respirator fit into conformity assessment (Coffey and Miller, 2019). Such a standard, along with improved face seal designs, may improve the effectiveness of FFRs.

The use of masks by the general public is now widely recommended as a COVID-19 control strategy. While the FE of cloth masks is highly variable (Rengasamy et al., 2010; N95DECON et al., 2020), human experimental studies demonstrate that cloth masks can decrease the emission of respiratory droplets and epidemiologic studies demonstrate an impact of public mask-wearing on COVID-19 transmission (Davies et al., 2013; Chu et al. 2020). Yet, there remains a need for further research about cloth mask performance as worn by the public as well as performance criteria. The European Committee on Standardization has proposed minimum requirements for face coverings used by the general public (CWA 17553, 2020), which includes FE testing with 3.0 μm particles (≥90% or ≥70% FE) and a pressure differential of less than 60 Pa/cm². This recommendation is consistent with the World Health Organization, which recommends a pressure differential of 100 Pa over the whole mask (WHO, 2020). Unfortunately, pressure differential and FE can work against one another. It is important to avoid cloth masks with pressure differentials high enough that the wearer finds the mask so uncomfortable as to wear it incorrectly, decreasing the effectiveness of the mask. Hopefully, this new guideline will enhance consumer decision making and improve the consistency of cloth mask performance. In general, cloth masks made of multiple layers of tightly woven fabric offer the best FE and should be worn tight to the face (N95DECON et al. 2020).

It should be a great concern to occupational hygienists, however, that surgical masks and cloth masks, rather than respirators, are widely used to protect workers from COVID-19 transmission in workplaces. In the US state of Utah, approximately 12% of confirmed COVID-19 cases were associated with workplace outbreaks: 58% of workplace outbreaks occurred in the manufacturing, construction and wholesale trade sectors and 73% of the affected workers identified as Hispanic or nonwhite (Bui et al., 2020). Morally and ethically, workers—in particular, essential workers—should be provided with the safest working conditions possible. The hierarchy of controls recommends personal protective equipment as a last resort, but engineering controls to prevent aerosol transmissible diseases can take time to implement (Brosseau et al., 2021). In the absence of other effective controls, workers should be provided with respirators rather than surgical masks or cloth masks given the role of respirable infectious aerosols in COVID-19 transmission (Brosseau et al., 2021; Tang et al., 2020). As indicated by the testing methods and performance criteria reviewed herein, cloth masks and surgical masks provide inferior protection relative to FFRs for bioaerosols.

Historically, surgical masks were designed to prevent the emission of respiratory droplets from the wearer (e.g. source control) while respirators were designed to prevent the inhalation of airborne contaminants by the wearer (e.g. receptor control; personal protection). These uses have morphed over time. Surgical masks, for example, as worn by health care workers protect them from droplets from patients but when worn by patients will control emissions (Siegel et al., 2007). With respect to respirators, asymptomatic shedding of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) by COVID-19 cases has led to questions about the performance of some respirators for source control. In particular, there is concern that the exhalation valves present on some FFRs (and all elastomeric respirators) may enable the release of SARS-CoV-2 from an infected wearer. Research is ongoing to quantify such emission (Ippolito et al., 2020). There is a need to better characterize the effectiveness of respirators and surgical masks for these dual functions.

It is not clear that the current testing methods and criteria applied to respirators and surgical masks are appropriate for the use of these devices in healthcare settings. Herein, we have highlighted performance criteria most relevant to healthcare settings and which contrast
respirators and surgical masks, but standards may require other tests that are more relevant to industrial uses for the devices. For example, in the USA, NIOSH has developed alternate performance standards for a new class of powered air-purifying respirators (the PAPR100 class) that will undergo a sodium chloride aerosol test instead of the silica dust test, because it has been recognized that the devices are not subject to heavy dust loading in healthcare settings. The high airflow rate used for the NIOSH N95 test is extreme relative to the breathing rate of the person using a mask for source control, and, therefore, overestimates the pressure drop and underestimates the FE as actually worn. Fluid barrier performance may not be necessary for all healthcare activities, but is definitely important for surgical, wound, or emergency procedures that generate splashes and sprays of body fluids. In addition, the design of most FFRs is such that the majority of the filter material is held away from the nose and mouth, such that when splashed, the material is unlikely to penetrate to the facial mucous membranes before the wearer can safely egress to remove the device, even if the device is not fluid resistant.

The COVID-19 pandemic has highlighted a number of challenges related to testing and communication about respirators, surgical masks and cloth masks that should be addressed by the occupational hygiene and public health communities, some of which were discussed at an August 2020 workshop held by the National Academies of Sciences, Current Issues in the Assessment of Respiratory Protective Devices: Non-Traditional Workers and Public Use. The severe shortage of respirators has led to emergency guidelines issued by the CDC for extended use, re-use, and decontamination of respirators. Other issues previously discussed herein include the emission of respiratory aerosols through exhalation valves and the requirement of fit testing of respirators during the design, testing, and certification process. An area of public concern has been the measurement of carbon dioxide inside of masks and respirators, which is considered when certifying respirators in the EU and China, but not in the USA (Table 3). Another emerging issue is the design of standards for masks worn by the public for source control, especially in the setting of asymptomatic transmission. Given the similarity in performance standards between countries, consideration could be given for exchangeability of certification, the development of international standards, or the harmonization of standards as a long-term strategy to improve supply chains in emergencies, rather than addressing emergency requests.

Conclusions

Test methods and performance criteria for FFRs and surgical/medical masks are relatively similar among the USA, the EU and China but there are differences with respect to fit testing and whether or not independent laboratories perform the testing. The test methods for FFRs ensure that these devices provide better protection to the wearer than surgical/medical masks. The new EU guideline for evaluation of cloth masks worn by the general public is the start of a process to also develop parallel North American or international guidelines on cloth masks for source control. These guidelines should improve consumer knowledge and access to higher-performing products. The COVID-19 pandemic has highlighted the need for education about the performance and use of respirators and surgical masks beyond the community of occupational health professionals. There is also a need for additional research to improve FFR fit and the performance of surgical/medical masks as both source and receptor controls for infectious diseases.

Acknowledgements

We would like to thank Laura Kwong and Sylvia Smullin and other members of N95DECON.org for their contributions to early versions of the manuscript.

Funding

The authors received no funding for the preparation of the manuscript.

Conflict of interest

The author declares no conflict of interest.

References

ASTM F2100-19e1. (2019) Standard specification for performance of materials used in medical face masks. West Conshohocken, PA. ASTM Committee F23. ASTM International. https://doi.org/10.1520/F2100-19E01.

ASTM F2101-19e1. (2019) Standard test method for evaluating the bacterial filtration efficiency of medical face mask materials, using a biological aerosol of Staphylococcus aureus. West Conshohocken, PA: ASTM Committee F23. ASTM International.

ASTM International. (2014) F2101-14: standard test method for evaluating the bacterial filtration efficiency (BFE) of medical face mask materials, using a biological aerosol of
Staphylococcus aureus. West Conshohocken, PA: ASTM Committee F23. ASTM International.

ASTM International. (2017a) F2299/F2299M-03: standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particles using latex spheres. West Conshohocken, PA: ASTM Committee F23. ASTM International.

ASTM International. (2017b) F1862-17/F1862M-17: standard test method for resistance of medical face masks to penetration by synthetic blood (horizontal projection of fixed volume at a known velocity). West Conshohocken, PA: ASTM International. https://doi.org/10.1520/F1862_F1862M-17.

Balazy A, Toivola M, Reponen T et al. (2006) Manikin-based performance evaluation of N95 filtering-facepiece respirators challenged with nanoparticles. Ann Occup Hyg; 50: 259-69.

Brosseau LM, Rosen J, Harrison R. (2021). Selecting controls for minimizing SARS-CoV-2 aerosol transmission in workplaces and conserving respiratory protective equipment supplies. Ann Work Exp and Health; 65: 53-62. doi: 10.1093/annweh/wxa083.

Bui DP, McCaffrey K, Friedrichs M et al. (2020) Racial and ethnic disparities among COVID-19 cases in workplace outbreaks by industry sector - Utah, March 6–June 5, 2020. MMWR Morb Mortal Wkly Rep; 69: 1133-8.

Chia PY, Coleman KK, Tan YK, et al. (2020) Detection of air and surface contamination from SARS-CoV-2 in hospital rooms of infected patients. Nat Commun; 11: 2800.

China National Pharmaceutical Industry Standard YY 0469-2010. (2010) Respiratory protective equipment. Beijing: People's Republic of China.

China National Standard GB 19083-2010. (2010) Respiratory protective equipment – filtering facepiece respirator. ICS 13.300.30 C73. People's Republic of China.

China National Standard GB 19083-2010. (2010) Technical requirements for protective face mask for medical use. ICS 11.100 C44. People’s Republic of China.

Chu DK, AkI EA, Duda S et al; COVID-19 Systematic Urgent Review Group Effort (SURGE) study authors. (2020) Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis. Lancet; 395: 1973-87.

Coffey C, Miller C. (2019) The respirator fit capability test: enhancing the efficacy of filtering facepiece respirators. Synergist; 2019(9): 2019. PMID: 32336905

CWA 17553 (2020). Community face coverings – guide to minimum requirements, methods of testing and use. CEN Workshop Agreement. ICS. 13.340.20. Available at ftp://ftp.cenelec.eu/EN/ResearchInnovation/CWA/CWA17553_2020.pdf. Accessed on 9 February 2021.

Davies A, Kafatos G, Thompson KA S et al. (2013) Testing the efficacy of homemade masks: Would they protect in an influenza pandemic. Dis Med Public Health Prepared. 7(4): 413-418.

Eninger RM, Honda T, Reponen T et al. (2008) What does respirator certification tell us about filtration of ultrafine particles? J Occup Environ Hyg; 5: 286-95.

European Union. EN 149+A1. (2009) Respiratory protective devices: filtering half masks to protect against particles: Requirements, testing, marketing. Brussels: CEN, Technical Committee CEN/TC 79, S 76-014. ISSN 0335-3931, ICS: 13.340.30.

European Union. EN 14683+C1. (2019) Medical face masks – requirements and test methods. November 2018. Brussels: CEN, Technical Committee CEN/TC 79. ICS:11.140.

European Union. EN 13274-7. (2019). Surgical mask. ICS 11.100 C44. People’s Republic of China.

European Union. EN 13274+C1. (2019). Medical face masks. ICS 13.340.30. November 2018. Brussels: CEN, Technical Committee CEN/TC 79. ICS:11.140.

Foerel S, Robertsen O, Hegseth MN. (2019) Do various respirator models fit the workers in the Norwegian Smelting Industry? Saf Health Work; 10: 370-6.

Food & Drug Administration (FDA). (2020, August 5). EUA letter of authorization – umbrella EUA for surgical masks. Available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#surgicalmasks. Accessed 1 October 2020.

Food & Drug Administration (FDA). (2020, May) Enforcement policy for face masks and respirators during the coronavirus disease (COVID-19) public health emergency (revised). Rockville, MD: US Department of Health and Human Services.

Food & Drug Administration (FDA). (2004, July 14) Guidance for industry and FDA staff: surgical masks – premarket notification [501(k)] submissions. Rockville, MD: US Department of Health and Human Services.

Garcia Godoy LR, Jones AE, Anderson TN, et al. (2020) Facial protection for healthcare workers during pandemics: a scoping review. BMJ Glob Health; 5(5):e002553. doi:10.1136/bmjgh-2020-002553.

Greene VW, Vesley D. (1962) Method for evaluating effectiveness of surgical masks. J Bacteriol; 83: 663-7.

He X, Reponen T, McKay RT et al. (2013) Effect of particle size on the performance of an N95 filtering facepiece respirator and a surgical mask at various breathing conditions. Aerosol Sci Technol; 47: 1180-7.

Hinds WC. (1999) Filtration. In Aerosol technology: properties, behavior, and measurement of airborne particles. 2nd edn. New York: John Wiley & Sons.

Ippolito M, Iozzo P, Gregoretti C et al. (2020) Facepiece filtering respirators with exhalation valve should not be used in the community to limit SARS-CoV-2 diffusion. Infect Control Hosp Epidemiol. doi: 10.1017/ice.2020.244.

Lee SA, Grinshpun SA, Reponen T. (2008) Respiratory performance offered by N95 respirators and surgical masks: human subject evaluation with NaCl aerosol representing bacterial and viral particle size range. Ann Occup Hyg; 52: 177-85.

Lofgren DJ. (2018) Disclosure and fit capability of the filtering facepiece respirator. New Soluta; 28: 24-32.

Louhevaara V, Smolander J, Korhonen O et al. (1986) Effects of industrial respirators on breathing pattern at different levels of work. Eur J Appl Physiol, 55: 142-146.
N95DECON.org. (2020) Cloth mask breathability and filtration efficiency technical report, V1.0, August 6, 2020. Available at www.n95decon.org. Accessed on 15 December 2020.

National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory. (2019a). Determination of exhalation resistance. Available at https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0003-508.pdf. Accessed on 15 December 2020.

National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory. (2019b) Determination of inhalation resistance. Available at https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0007-508.pdf. Accessed on 15 December 2020.

National Institute for Occupational Safety and Health [NIOSH]. (2019) Determination of particulate filter efficiency level for N95 series filters against solid particulates for non-powered, air purifying respirators standard testing procedure (STP). Available at https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0059-508.pdf. Accessed on 15 December 2020.

Oberg T, Brosseau LM. (2008) Surgical mask filter and fit performance. Ann J Infect Control; 36: 276-82.

Phan LT, Sweeney DM, Maita D et al; CDC Prevention Epicenters Program. (2020) Respiratory viruses in the patient environment. Infect Control Hosp Epidemiol; 41: 259-66.

Rengasamy S, Eimer B, Shaffer RE. (2010) Simple respiratory protection—evaluation of the filtration performance of cloth masks and common fabric materials against 20–1000 nm size particles. Ann Occup Hyg; 54: 789-98.

Zhang X, Jia N, Wang Z. (2020) The relationship between the filtering facepiece respirator fit and the facial anthropometric dimensions among Chinese people. Ind Health; 58: 318-24.