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Technical Bulletin

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Possible Alternatives to Surgical Filtering Facepiece Respirators: Healthcare

Background

The purpose of this document is to highlight possible alternatives to surgical filtering facepiece respirators for use in healthcare workplaces to help protect workers from infectious airborne biological particles, such viruses and bacteria.

When respiratory protection is recommended to help reduce exposure to biological hazards, the U.S. Centers for Disease Control and Prevention (CDC), the European Centre for Disease Prevention and Control (ECDC), and the World Health Organization (WHO) often recommend respirators at least as protective as an N95, FFP2, or similar particulate respirator. All filtering facepiece respirators that are certified as N95, FFP2, KN95, or similar can, when properly selected and worn, effectively filter airborne biological particles such as viruses and bacteria.[2-5] Surgical filtering facepiece respirators are also cleared as surgical masks by the U.S. Food and Drug Administration (FDA), the European Union Notified Bodies, or an equivalent authority in other countries.

Healthcare facilities often standardize on approved surgical filtering facepiece particulate respirators, sometimes also referred to as surgical N95s, healthcare respirators or medical respirators, for workers providing patient care. However, during disease outbreaks, or public health disasters, availability of approved surgical filtering facepiece respirators may become limited and organizations should evaluate whether other, more readily available, respirators would be appropriate for use. In many situations, it can be appropriate for healthcare workers to use respirators other than surgical or standard filtering facepiece respirators. The CDC indicates that healthcare facilities should consider and use alternatives to N95 respirators where feasible and appropriate. These include other classes of filtering facepiece respirators, elastomeric half-facepiece and full facepiece air purifying respirators and powered air purifying respirators (PAPRs).[1] All of these alternatives will provide equivalent or higher respiratory protection than N95 respirators when properly selected and worn (see Table 1 for some respiratory protection options).

Prioritizing Respirator Use

Prioritization of respirator use can help promote availability of surgical respirators when needed for specific clinical situations. Surgical respirators are meant to be used during surgery and for other clinical procedures during which both of the following are true: the wearer requires respiratory protection and fluid resistance (as defined by the ASTM F1862 or EN14683 standard).

The healthcare organization must determine what are considered "surgical procedures", if respiratory protection is required for these surgical procedures, and whether it's necessary to use surgical filtering facepiece respirators or whether a different type of respirator may be acceptable and/or preferred.

Considerations for use of Alternatives to Surgical FFRs

During the COVID-19 pandemic, the CDC published tiered recommendations in their Strategies for Optimizing the Supply of N95 Respirators. Under the Conventional Capacity Strategies tier, CDC states, "If surgical N95 respirators are not available, and there is a risk that the worker may be exposed to splashes, sprays, or splatters of blood or body fluids, then a faceshield or surgical facemask should be worn over the standard N95 respirator. Care should be taken not to compromise the fit of the respirator if a facemask is placed over the respirator."[1]

Some FFRs feature an exhalation valve, which is intended as a comfort feature to help release the wearer's warm exhaled breath. According to the CDC, "as source control, findings from NIOSH research suggest that all NIOSH approved filtering facepiece respirators with exhalation valves, even without covering the valve, perform the same or better than surgical masks, procedure masks, cloth masks, or fabric."[1]

"In general, individuals wearing NIOSH-approved N95s with an exhalation valve should not be asked to use one without an exhalation valve or to cover it with a face covering or mask."[6] "If there is a risk that the worker may be exposed to splashes, sprays, or splatters of blood or body fluids, then a faceshield or surgical facemask should be worn over the standard N95 respirator. Care should be taken not to compromise the fit of the respirator if a facemask is placed over the respirator."[1]

Many elastomeric respirators also have an exhalation valve. The CDC states that elastomeric respirators with unfiltered exhalation valves should not be used in surgical settings due to concerns that air coming out of the exhalation valve may contaminate the sterile field. The NIOSH Certified Equipment List identifies the elastomeric respirators without exhalation valves or with filtered exhalation valves that may be used in surgical settings.[1]

CDC goes on to say that PAPRs should not be used in surgical settings due to concerns that the blower exhaust and exhaled air may contaminate the sterile field.[1] There is no regulatory agency that evaluates respirators or surgical masks for outward leakage of particles exhaled by the wearer. Such tests are not required by the FDA nor by NIOSH. Howard et. al, 2020, investigated sterile field contamination from both PAPRs and surgical masks and found no statistical difference between their effectiveness in reducing aerosol contamination.[7] Further research is needed on the topic of outward leakage from masks and respirators.

Table 1: 3M Respiratory Protection Options

Examples of respirator types, other than surgical N95 FFRs, that may be appropriate for use in healthcare include:

		
Non-surgical filtering facepiece respirators	Reusable (elastomeric) respirators	Powered air-purifying respirators (PAPRs)

Here are some considerations to help healthcare organizations determine whether these other respirator types might work within their respiratory protection program.

	Key Attributes	Key Potential Advantages	Key Potential Limitations	Select Examples
Non-surgical filtering facepiece respirators 	• Effectively filter airborne biological particles such as viruses and bacteria • Designed to fit tightly to the face • Certified as a particulate respirator	• Low Cost • Minimal care and maintenance • Wide variety available	• Wearer must be clean shaven in area of the face-seal • Fit with certain safety glasses	**All 3M filtering facepiece respirators can filter biological particles, including these classes:** • N95 • P95 • P100
Elastomeric respirators 	• Effectively filter airborne biological parti-cles such as viruses and bacteria • Designed to fit tightly to the face • Multiple sizes • Can be cleaned, disinfected and reused	• Low Cost • Reusable • Eye protection (Full-face only)	• Wearer must be clean shaven in area of the face-seal • Fit with certain safety glasses (half-face) • Storage, cleaning, and maintenance required • Fit with Prescription eyewear (Full-face)	**Any 3M elastomeric facepiece equipped with appropriate 3M particulate filters, per applicable regulatory approvals, including:** • 7093, 7093C filters, P100 filters • 5N11 & 5P71 pre-filter assemblies • 2000 series disc filters • 6092X Series filters - cartridges

	Key Attributes	Key Potential Advantages	Key Potential Limitations	Select Examples
Powered air-purifying respirators (PAPRs) 	• Effectively filter airborne biological particles such as viruses and bacteria • Designed to fit over some facial hair • Variety of styles and facepiece/head top offerings • Can be cleaned, disinfected and reused	• Wide variety of head-tops • Limited facial hair permitted for loose-fitting head- gear • Eye/face protection (certain headgear) • More of face visible • Low breathing burden and increased comfort	• Storage, cleaning, maintenance required • Care, charging, and life of PAPR batteries • Weight and size	• All 3M PAPR particulate filters can filter biological particles

References

1) U.S. Centers for Disease Control and Prevention (CDC). Strategies for Optimizing the Supply of N95 Respirators: Conventional Capacity Strategies. Updated April 9, 2021. Accessed April 19, 2021. https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/conventional-capacity-strategies.html
2) Brosseau LM, Schaffer R. Do We Need to Challenge Respirator Filters With Biological Aerosols? NIOSH Blog; 2014.
3) Chen SK, Vesley D, Brosseau LM, Vincent JH. Evaluation of single-use masks and respirators for protection of health care workers against mycobacterial aerosols. *AM J Infect Control*. 1994; 22: 65-74.
4) Brosseau LM, McCullough NV, Vesley D. Mycobacterial aerosol collection efficiency of respirator and surgical mask filters under varying conditions of flow and humidity. *Appl Occup Environ Hyg*. 1997; 12(6): 435-445.
5) McCullough NV, Brosseau LM, Vesley D. Collection of three bacterial aerosols by respirator and surgical mask filters under varying conditions of flow and relative humidity. *Ann Occup Hyg*. 1997; 41(6): 677-690 .
6) U.S. Centers for Disease Control and Prevention (CDC), "Coronavirus Disease 2019 (COVID-19) Personal Protective Equipment: Questions and Answers." Updated April 9, 2021. Accessed April 19, 2021. https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html
7) Howard RA, Lathrop GW, Powell N. Sterile field contamination from powered air-purifying respirators (PAPRs) versus contamination from surgical masks. *Am J Infect Control.* 2020; 48(2): 153-156.

Appendix A: Global Regulatory Requirements for Surgical Respirators

	United States	Europe	China	Australia/ New Zealand
Term frequently used	Surgical N95	Medical respirator or healthcare respirator	Medical protective respirator	Surgical respirator or healthcare respirator
Agency issuing respirator certifications (See 3M Technical Bulletin on Global Certification for more details.)	National Institute for Occupational Safety and Health (NIOSH)	EU Notified Bodies certify compliance with the requirements of EU PPE Regulations	National Medical Products Administration (NMPA) Note: NMPA is the former CFDA	Products are expected to meet requirements of AS/NZS 1716 or NIOSH N95. Products may be certified by 3rd party companies.
Respirator approval for surgical respirators	N95 or higher, with appropriate fluid resistance rating	FFP2 and FFP3, with appropriate fluid resistance rating	Medical protective respirator (GB 19083, PFE ≥ 95%)	N95/P2 rating or higher, with appropriate fluid resistance rating
Agency clearing/approving products to be sold as surgical masks	Food and Drug Administration (FDA)	EU Notified Bodies certify compliance with the requirements of the EU Medical Devices Directive	NMPA	Therapeutic Goods Administration (TGA)
Test for fluid resistance (high-velocity stream of liquid)	ASTM F1862	EN14683 refers to test method ISO 22609	YY/T 0691-2008	AS 4381 refers to ASTM F1862 or ISO 22609
Test for biological filtration efficiency (BFE)	ASTM F2101	EN14683 contains the test for BFE	No requirement	AS 4381 refers to ASTM F2101 or EN 14683
Microbial cleanliness (Bioburden)	No requirement	When tested according to EN ISO 11737-1 the bioburden of the medical mask shall be ≤ 30 CFU/g	Total bacterial colony count ≤ 200CFU/g; total number of fungal colonies ≤ 100 CFU/g	No requirement
Sterilization	No requirement	No requirement	No requirement. If claim, it should be marked on the package	No requirement

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