

Possible Alternatives to Surgical Filtering Facepiece Respirators: Healthcare

Background

This is a general document that is not specific to any particular airborne contaminant, including viruses and bacteria, and that is intended for a sophisticated occupational audience.

During disease outbreaks recommendations are often made to provide healthcare workers with respirators at least as protective as an N95, FFP2, or equivalent filtering facepiece particulate respirator. Healthcare facilities often standardize on approved surgical N95 respirators, sometimes also referred to as healthcare respirators or medical respirators, during typical operations. However, during outbreaks availability of approved surgical N95 respirators may become limited, and organizations should evaluate whether other, more readily available, respirators would be appropriate for use. • When respiratory protection is recommended, 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) recommend respirators at least as protective as an N95, FFP2, or equivalent particulate respirator, and the CDC indicates that reusable respirators and powered air purifying respirators should be used “where feasible.”¹ These recommendations from the CDC, ECDC, and WHO do not specify the need for a surgical N95 respirator.

All filtering facepiece respirators that are certified as N95, FFP2, KN95, or [equivalent](#) can, when properly selected and worn, effectively filter airborne biological particles such as viruses and bacteria.¹²³⁴ There is no difference in the filtration effectiveness between comparable standard N95 respirators and surgical N95 respirators. Both are approved as particulate respirators by the U.S. National Institute for Occupational Safety and Health (NIOSH), European Union Notified Bodies, or an equivalent agency in other countries.¹ Surgical N95 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. Surgical respirators are meant to be used during surgery and other tasks during which both of the following are true: the wearer requires respiratory protection and either fluid resistance (as defined by the ASTM F1862 or EN14683 standard) is required or expelled particles must be contained (to help maintain a sterile field, for example).

[3M Technical Bulletin - Surgical N95 vs. Standard N95 - Which to Consider?](#) offers a comparison of surgical and standard N95 filtering facepiece respirators based on U.S. regulatory requirements. Slight differences exist among different countries' requirements for surgical respirators' performance. Table 1 contains details for how surgical respirators are evaluated and regulated in a variety of countries.

In normal circumstances when disease outbreak is not a concern, most healthcare facilities do not have high usage rates for respirators and often choose to standardize across one or two models of surgical N95 respirators for all tasks. While these respirators typically have wide availability in normal conditions, unusually high demand for surgical N95 respirators during outbreaks can result in the availability of these respirators becoming limited. During times when organizations are not able to obtain surgical N95 respirators, alternative respirator options may need to be considered for certain healthcare tasks.

1. Particulate respirators are designed to help reduce the wearer's exposure to airborne particulate hazards. NIOSH tests and certifies respirators based on their physical and performance characteristics, including filtration efficiency. N95-rated filtering facepiece respirators have a filtration efficiency of at least 95% against non-oily particles when tested using the NIOSH criteria. The particles used to test the filtration are in a size range that is considered the most penetrating. Therefore, the test methods ensure that the filter media can filter particles of all sizes with at least 95% efficiency.

Table 1: 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

Prioritizing Respirator Use

Prioritization of respirator use can help promote availability of surgical that surgical N95 respirators for those healthcare workers who are in surgery, need to work in a sterile field, or may be exposed to high-velocity streams of bodily fluid. If a healthcare facility is prioritizing respirator use, workers' expected tasks and exposures should be evaluated to determine whether it's necessary for them to use surgical N95 respirators or whether a different type of respirator may be acceptable instead. **All certified N95 or higher-rated particulate respirators can filter airborne biological particles such as viruses and bacteria when properly selected and worn.**²³⁴

It may be appropriate for healthcare workers who will not be performing medical procedures or do not need to maintain a sterile field to use respirators other than surgical N95 respirators. During the COVID-19 pandemic, the CDC published tiered recommendations in their February 2020 [Strategies for Optimizing the Supply of N95 Respirators](#). Under the [Conventional](#)

[Capacity Strategies](#) tier, CDC indicates that “in times of shortage, only HCP who are working in a sterile field or who may be exposed to high velocity splashes, sprays, or splatters of blood or body fluids should be provided these [surgical] respirators. Other HCP can use standard N95 respirators.” CDC goes on to say, “Use alternatives to N95 respirators where feasible. These include other classes of filtering facepiece respirators, elastomeric half-mask and full facepiece air purifying respirators, powered air purifying respirators (PAPRs) where feasible. All of these alternatives will provide equivalent or higher protection than N95 respirators when properly worn.”

Examples of tasks requiring respiratory protection, but likely not requiring a surgical respirator model, include triage and evaluating patients with respiratory symptoms, as well as caring for patients with known viral or bacterial infections. Below is an example of selection guidelines that healthcare organizations may choose to consider adding to their respiratory protection program.

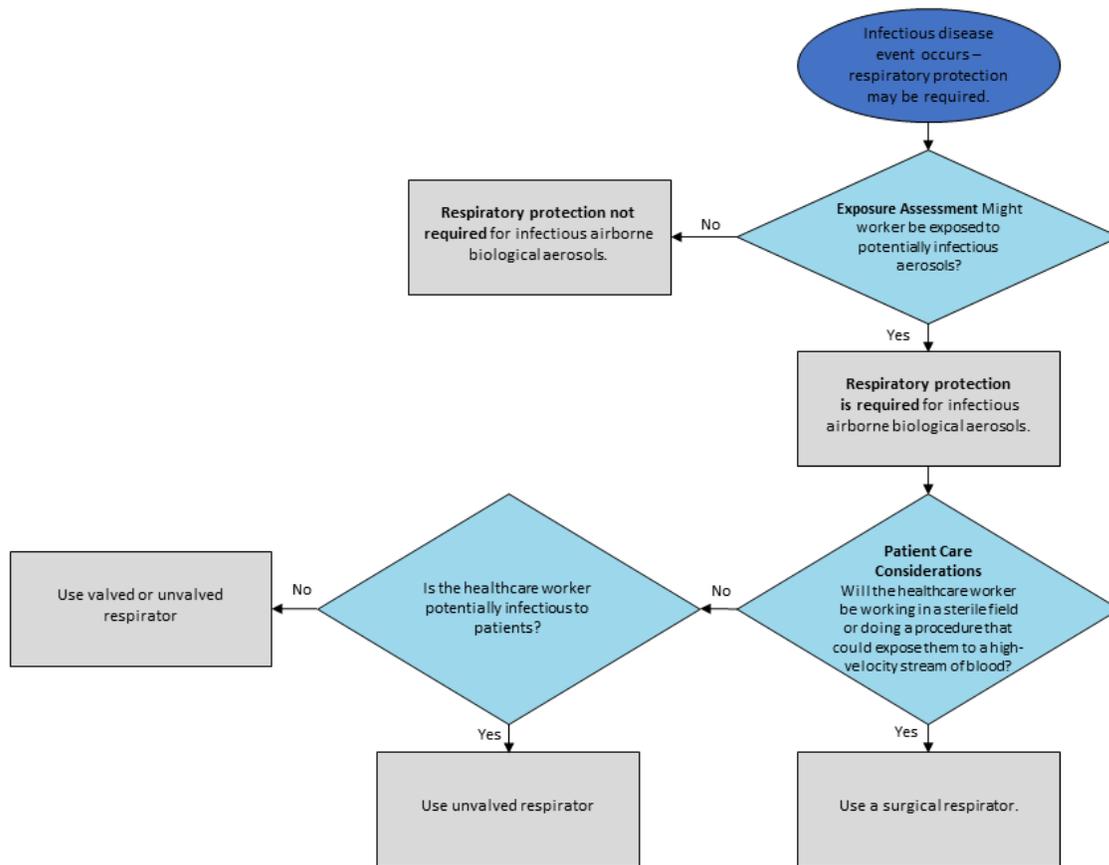


Figure 1: Flowchart: Respiratory Protection Considerations for Infectious Airborne Biological Aerosols

Evaluating Available Respiratory Protection Options

Examples of respirator types that may be available when availability of surgical N95 respirators is limited include:

		
<p>Non-surgical filtering facepiece respirators</p>	<p>Reusable (elastomeric) respirators</p>	<p>Powered air-purifying respirators (PAPRs)</p>

Here are some considerations to help organizations determine whether any of these other respirator types might work within their respiratory protection program. Please note that none of these have the additional properties required of a surgical respirator, and so would not be appropriate for use in a surgical setting.

	Key Attributes	Key Potential Advantages	Key Potential Limitations
<p>Non-surgical filtering facepiece respirators</p> 	<ul style="list-style-type: none"> Effectively filter airborne biological particles such as viruses and bacteria Designed to fit tightly to the face Wide variety Certified as particulate respirator 	<ul style="list-style-type: none"> Low Cost Minimal care and maintenance 	<ul style="list-style-type: none"> Wearer to be clean shaven in area of the face seal Fit with certain safety glasses
<p>Elastomeric respirators</p> 	<ul style="list-style-type: none"> Effectively filter airborne biological particles such as viruses and bacteria Designed to fit tightly to the face Multiple sizes Cleaned and reused 	<ul style="list-style-type: none"> Low Cost Reusable – longevity / replacement parts Eye protection (Full-face only) 	<ul style="list-style-type: none"> Wearer to be clean shaven in area of the face seal Fit with certain safety glasses (half face) Communication Storage, cleaning, maintenance Prescription in-facepiece eyewear (Full-face)

	Key Attributes	Key Potential Advantages	Key Potential Limitations
<p>Powered air-purifying respirators (PAPRs)</p> 	<ul style="list-style-type: none"> Effectively filter airborne biological particles such as viruses and bacteria Designed to fit over some facial hair Variety of styles and facepiece/headtop offerings 	<ul style="list-style-type: none"> Wide variety of head-tops <ul style="list-style-type: none"> Limited facial hair permitted for loose-fitting headgear Eye protection (certain head-gear) More of face visible Low breathing burden and increased comfort for longer wear time 	<ul style="list-style-type: none"> Storage, cleaning, maintenance Care, charging, and life of PAPR batteries Weight and size Communication

References

- 1) Brosseau, L.M., Schaffer, R. [Do We Need to Challenge Respirator Filters With Biological Aerosols?](#) NIOSH Blog; 2014.
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- 3) Brosseau, L.M., McCullough, N.V. and D. Vesley. Mycobacterial aerosol collection efficiency of respirator and surgical mask filters under varying conditions of flow and humidity. *Appl. Occup. Environ. Hyg.* 12(6):435-445; 1997.
- 4) McCullough, N.V., Brosseau, L.M. and D. Vesley. Collection of three bacterial aerosols by respirator and surgical mask filters under varying conditions of flow and relative humidity. *Ann. Occup. Hyg.* 41(6):677-690; 1997.
- 5) EN 14683:2019 Medical face masks - Requirements and test methods. European Committee for Standardization, Brussels

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