



Respiratory Protection Options for Operating Room Settings: N95s, Powered Air Purifying Respirators and Elastomeric Half-Face Respirators

January 10, 2022

Scope

This document provides respiratory protection options for use in operating room (OR) settings in the event that a supply of N95 respirators becomes unavailable or a health-care worker (HCW) is unable to be successfully fitted for an available N95 respirator. This document evaluates appropriate respiratory protection options for use in the OR setting, including considerations for the use of reusable elastomeric half-face respirators (EHFRs) and powered air purifying respirators (PAPRs) while working in the sterile field and for source control.

Background

A review of respiratory protection options for use in the OR setting was completed to identify any use limitations or other considerations.

EHFRs are tight-fitting respirators that require fit-testing. Inhaled air passes through HEPA filters attached to inhalation valves/gaskets and exhaled air is released through the exhalation valve located on the front of the respirators (in 3M and Honeywell models currently used in B.C. health authorities).

PAPRs do not require fit-testing as long as they use loose-fitting hoods and air is under positive pressure in the hood. Air that enters the hood and breathing zone of the HCW passes through HEPA filters prior to entering the hood. Exhaled breath enters directly into the hood and then dissipates out the bottom of the hood through ventilation openings normally located below the chin of the user.

For the EHFRs and PAPRs currently in use, exhaled breath is not filtered before it passes into the environment.

To protect both the health-care worker and the patient, any droplets and/or infectious agents that might be in the health-care practitioner's exhaled breath must be captured. The [Ministry of Health's Mask Use in Health-Care Facilities during the COVID-19 Pandemic Policy](#) requires all HCWs to wear a medical grade mask (surgical or procedure) to contain droplets from the mouth and nose as a method of infection prevention and control (IPC).



For [EHFRs](#), a medical mask or an exhalation valve filter must be worn overtop of the exhalation valve (through which exhaled breath passes out of the respirator).

To evaluate the potential use of EHFRs and PAPRs in the OR, the following was completed:

- Review of the literature and other information sources (e.g., health and safety regulations, manufacturer recommendations) related to use of EHFRs and PAPRs in the OR environment.
- Assessments of adverse physiological impacts associated with use of an EHFR in combination with a medical mask.

PAPR

Literature Review Findings

The following information was obtained from a review of literature specific to use of PAPRs in the OR setting (see [Appendix A](#) for literature search method):

Methodology Summary	Observations and Findings	Reference
Aerosolized droplet contamination onto a sterile field was compared for: 1) Full facepiece PAPR, 2) Full facepiece PAPR with a shoulder-length hood, 3) A surgical mask.	No significant difference between configurations. All had significant reduction of contamination versus wearing no mask.	RA Howard, GW Lathrop & N. Powell. Sterile field contamination from powered air-purifying respirators (PAPRs) versus contamination from surgical masks . <i>American Journal of Infection Control</i> 48, no. 2 (February 2020), 153-156.
Reviewed OR response to COVID-19 pandemic in a tertiary hospital in Singapore. The hospital provided anesthesiology staff who could not fit an N95 respirator with a CleanSpace HALO PAPR (mask fitting done). This type of respirator was chosen due to better protection than loose-fitting facepiece PAPR. A review of the personal protective equipment (PPE) donning procedures appears to show that the PAPR were used in combination with an N95.	No mention of contamination. However, authors did comment on the need to consider increased challenges in communication once PPE donned and especially once the PAPR was donned.	Jolin Wong et al. Preparing for a COVID-19 pandemic: a review of operating room outbreak response measures in a large tertiary hospital in Singapore . <i>Canadian Journal of Anaesthesia</i> 67, no. 6 (March 2020), 732-745.
HCW fitted with helmet PAPR with hood tucked underneath sterile gown. PAPR was turned on for 10 minutes then off. Particulate count was tested around the table, around HCW head/front/below the gown.	Result found no measurable differences in particulate counts at the surgical table when the PAPR was turned on vs. off. Authors concluded this may be an acceptable alternative to N95 in OR.	Yoojin Kim & Molly Hale. Pilot Study to Examine the Use of Powered Air Purifying Respirator (PAPR) in the Operating Room . <i>American Journal of Infection Control</i> 45, no. 6 (June 2017).



Methodology Summary	Observations and Findings	Reference
<p>Used agar plate in a small room and compared colony growths after using three models of PAPR, N95, surgical N95 and surgical masks.</p>	<p>Two of the PAPR tested with comparable contamination as using N95, while one (Versaflo) was higher and deemed not suitable. However, results of Versaflo were still lower than surgical N95 respirators and surgical masks (2/3 PAPR & N95 < 1/3 PAPR < surgical N95 < surgical mask).</p> <p>Unpublished study quoted in thesis (University of Cincinnati) conducted a similar study comparing an N-95 to a PAPR vs. empty room. Agar plates were used and a colony forming unit (CFU) was counted. Result: no significant difference in CFU between the N95 and the control, while the PAPR produced a significantly higher CFU than the control. Authors concluded PAPR did result in an over contamination of the sterile field.</p>	<p>T Church. Bacterial Contamination Study of Loose-Fitting Power Air Purifying Respirators (PAPR) Compared to N-95 FFR and Surgical Mask, in a Simulated Sterile Environment. <i>Graduate Theses, Dissertations and Problem Reports</i>. (2019).</p>
<p>Workshop Summary Paper on the Use of PAPRs in Health Care.</p>	<p>Noted some facilities have tried using surgical masks under loose-fitting head coverings or placing the ends of the PAPR hood under the surgical gown, but neither is a tested or certified configuration. There appears to be little reliable information on infection risks from using a standard surgical ensemble as compared to PAPR. Other concerns of using PAPR in the OR include possibility of dislodged parts, different work postures and challenges in disinfecting the parts within an OR setting.</p>	<p>Board on Health Sciences Policy; Institute of Medicine. The Use and Effectiveness of Powered Air Purifying Respirators in Health Care: Workshop Summary. National Academies Press: Washington DC. May 7 2015.</p>

Information available from other trusted sources (including health and safety regulators, National Institute for Occupational Safety and Health (NIOSH) and respirator manufacturers) state that PAPRs should not be worn when a sterile field is required due to unfiltered air. Specifically:



- [NIOSH](#) – Does not recommend PAPR use in an OR due to a lack of scientific evidence to support safe usage and the possible impact of exhaled, unfiltered air onto the sterile field. Scientific studies are under way and prudent practice suggests use of an N95 respirator until more evidence is available.
- 3M - 3M PAPRs are not approved or cleared by the Food and Drug Administration as medical devices for use in health-care surgical settings. As such, 3M does not market or recommend these PAPRs for use in a sterile surgical field.

In general, there is a theoretical risk of biological contamination of the sterile environment from using a PAPR in an OR setting. However, there is limited and inconclusive scientific data to support the risk. As well, other configurations (e.g., tucking the hood beneath gowns, wearing a mask underneath it) can limit risk associated with unfiltered exhaled breath entering the sterile field as noted in some of the studies referenced.

EHFR/Reusable Respirators

Literature Review Findings

There is a lack of published peer-reviewed literature specific to EHFR use in the OR setting.

Information available from other trusted sources (including health and safety regulators, the Centers of Disease Control and Prevention (CDC) and respirator manufacturers) state that EHFRs should not be worn when a sterile field is required due to unfiltered air. However, no details or references are provided. It is likely that these recommendations are made based on theoretical risks. The language used is vague:

- [3M](#):
 - “there is **concern** that any bacteria or viruses expelled from the wearer may travel through the exhalation valve;”
 - “wearer-generated droplets, exhaled through the valve, **might** contaminate a sterile field;”
 - “there is a **possibility** that exhaled particles may leave the respirator via the valve.”
- [OSHA](#):
 - “there is **some concern** that exhaled air from wearers of PAPRs or APRs [air purifying respirators] with exhalation valves can flow into and potentially contaminate...”
- [CDC](#):
 - “Elastomeric respirators with exhalation valves should not be used in surgical settings due to **concerns** that unfiltered air coming out of the exhalation valve may contaminate the surgical field.” For the same reason, most trusted sources also recommend that those with symptoms should not wear respirators with valves.
 - “The wearer’s respiratory secretions and moist exhaled breath can lead to moisture build-up in a respirator. While it is possible for moisture to build-up in a respirator with or without an exhalation valve, preliminary research shows that this is **unlikely**.”

Health Authority EHFR-Related Assessments

1. *Qualitative fit-test of EHFR with medical masks on top as used in OR setting*
 - Purpose: To assess if there is any impact of wearing a medical mask on respirator seal.



- Vancouver Coastal Health conducted a small trial for EHFRs with medical masks on top using qualitative fit-tests. Two staff were tested and passed, indicating adding a medical mask over an EHFR does not affect the seal. After implementation of EHFRs within a department, and having them use a medical mask overtop, a few staff said they felt light-headed. Most staff using the EHFR also mentioned it was difficult to communicate.



2. *Assessment of potential for CO₂ re-breathing and adverse physiological impacts on the HCW when using medical mask overtop of EHFR*

Interior Health conducted a study with four respiratory therapists using various EHFR and mask combinations to investigate CO₂ re-breathing, corresponding physiological changes and user experience. Results showed that physiological changes were similar for EHFR alone and EHFR-mask combinations, although participants noted increased humidity and heat when using an EHFR with a medical mask.

Findings from the Interior Health study and existing literature (Kim, Benson, & Roberge, Raymond J., MD, MPH, 2013) suggests that there are likely negligible differences in CO₂ levels between all configurations while performing quiet standing work. Fraser Health also did an additional study to expand on the Interior Health study and to explore the interaction between respirator types and/or mask combinations on CO₂ rebreathing, respiratory rate and SPO₂ (i.e., blood oxygen saturation) levels over a longer period of time. The Fraser Health Study included seven subjects that had successfully passed a fit-test on both the N95 and EHFRs utilized and collected measurements during four different mask use combinations (medical mask alone, EHFR alone, EFHR with medical mask overtop and N95 alone). Physiological measurements were taken using an end tidal monitor to measure end tidal CO₂, respiratory rate and saturated oxygen levels in each participant over time.

Both assessments found that levels of CO₂ remained within healthy ranges (35-45 mmHg) as did the respiratory rates (12-20 breaths/minute) and the saturated oxygen level (SPO₂ = 95-100%).

As a result, it is recommended that EHFRs could be utilized in combination with medical masks within the sterile field. A limitation of these studies is that longest period monitored was 60 minutes.

Conclusion

There was no literature found to clearly demonstrate whether wearing EHFR will increase post-operative infection rates. As most trusted sources recommend against the use of EHFR in a sterile field (and at least one



HCW confirmed droplet formation on exhalation valve), it is recommended that EHFRs be used in combination with a medical mask worn on top of it or, when available from manufacturer, with an exhalation valve filter. Ensure applicable [donning and doffing procedures](#) are followed.

The literature regarding risk in relation to the use of PAPRs in the OR was inconsistent. Some referred to the use of a medical mask with PAPRs (but had not specifically tested its effectiveness) and some highlighted using PAPRs with a hood tucked into their gowns. Additional considerations for the PAPR include that proper use is more time-consuming (e.g., proper donning, doffing, cleaning, disinfecting), it requires more training and a buddy system, and increases communication challenges due to noise produced by the PAPR blowers and is dependent on hood style and fit.

Recommendation

In summary, the preference for respiratory protection is to utilize N95 respirators when they are readily available and HCWs have a successful fit-test for an available model. For users unable to fit a N95 respirator, follow your health authority's established process for alternative respiratory protection options.

The following respiratory options remain for consideration and are noted in **descending order of recommendation**, by OR position:

OR Position	Work Zone	Respirator Type (in descending order of preference)	Medical Mask (or exhalation valve filter) required
Anesthesia	Non-Sterile	N95	No
		EHFR	Yes (over top)
		PAPR	Yes (underneath)
	Sterile	Surgical rated N95*	No
		EHFR	Yes (over top)
		PAPR	Yes (underneath)
Surgeon	Sterile	Surgical rated N95*	No
		EHFR	Yes (over top)
		PAPR	Yes (underneath)
Circulating Nurse	Non-Sterile	N95	No
		EHFR or PAPR	Yes
Scrub Nurse	Sterile	Surgical rated N95*	No
		EHFR	Yes (over top)
		PAPR	Yes (underneath)

*N95 with medical masks on top is **NOT** recommended as it can more easily impact effectiveness of the N95 respirator seal and leave user unprotected.

References



3M. **Technical Bulletin: Filtering Facepiece Respirators FAQ: Healthcare.** July 2021. Retrieved November 12, 2021. <https://multimedia.3m.com/mws/media/17927320/respiratory-protection-faq-healthcare.pdf>.

3M. **Technical Bulletin: Filtering Facepiece Respirators FAQ: General Public.** August 2021. Retrieved November 12, 2021. <https://multimedia.3m.com/mws/media/17915260/respiratory-protection-faq-general-public-tb.pdf>.

3M. **Technical Data Bulletin: Respiratory Protection for Airborne Exposures to Biohazards.** June 2020. Retrieved July 7, 2020. <https://multimedia.3m.com/mws/media/4099030/respiratory-protection-against-biohazards.pdf>.

BC Centre for Disease Control & BC Ministry of Health. **COVID-19 Interim Guidance: Elastomeric Half-Face Respirator Source Control in Pre-Hospital and Health-Care Settings.** June 9, 2021 Retrieved November 12, 2021. http://www.bccdc.ca/Health-Professionals-Site/Documents/COVID-19-PPE/EHFR_GuidanceSourceControl.pdf.

Centers for Disease Control and Prevention. **Elastomeric Respirators: Strategies During Conventional and Surge Demand Situations.** October 13, 2020. Retrieved November 12, 2021. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/elastomeric-respirators-strategy/index.html>.

Kim J., Benson S. and Roberge R. "Pulmonary and heart rate responses to wearing N95 filtering facepiece respirators." *American Journal of Infection Control*, 41(2013): 24-27. [doi: 10.1016/j.ajic.2012.02.037](https://doi.org/10.1016/j.ajic.2012.02.037).

Licina, A., Silvers, A. & Stuart, R.L. "Use of powered air-purifying respirator (PAPR) by healthcare workers for preventing highly infectious viral diseases—a systematic review of evidence." *Systematic Reviews* 9, 173 (2020). <https://doi.org/10.1186/s13643-020-01431-5>.

National Institute for Occupational Safety and Health, Centres for Disease Control and Prevention . **Healthcare Setting Specific FAQs.** September 3, 2021. Retrieved November 12, 2021. https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/resresource3healthcare.html.

Occupational Safety and Health Administration. **Hospital Respiratory Protection Program Toolkit.** 2015. Retrieved November 12, 2021. <https://fddocuments.in/download/hospital-respiratory-protection-program-toolkit-resources-for->.

Wang, Z., Reponen, T., Willeke, K and Sergey, A.G. "Survival of Bacteria on Respirator Filters". *Aerosol Science & Technology* 30, 3 (1999): 300-308. Retrieved July 5, 2020. <https://www.tandfonline.com/doi/pdf/10.1080/027868299304651>.



Radonovich, L.J., Yanke, R., Cheng, J. and B.Bender. "Diminished Speech Intelligibility Associated with Certain Types of Respirators Worn by Healthcare Workers." *Journal of Occupational and Environmental Hygiene* 7(2010): 63-70. <https://pubmed.ncbi.nlm.nih.gov/19904661/>.



Ministry of
Health



BC Centre for Disease Control

If you have fever, a new cough, or are
having difficulty breathing, call 8-1-1.



Appendix A: Literature Search Method

1. Date Completed: 2020-05-08

Search Strategy:

Databases Searched:

CINAHL
EMBASE
Medline
UpToDate
Cochrane Central Register of Controlled Trials
Cochrane Database of Systematic Reviews

Other Sources:

PubMed
TRIP
CADTH
Google Scholar

Terms searched/Keywords:

elastomeric respirator, elastomer*, respirator*, infect*, exhalation valve, sterile field, PAPR

2. Date Completed: 2021.09.10

Search period: November 2020 – Current; Selected abstracts and titles

Purpose – determine if any additional publications available specific to use of PAPRs in Operating Room

Search Strategy:

Databases Searched:

EMBASE
Medline
Cochrane Database of Systematic Reviews
FHA COVID-19 Portal (The Lancet)
FHA COVID-19 portal (JAMA)

Other Sources:

Google Scholar

Terms searched/Keywords: Powered air purifying respirator AND (operating room OR operating theatre), COVID-19, SARS-CoV-2

