COVID-19 Interim Guidance: Elastomeric Half Face Respirator Source Control in Pre-Hospital and Health-Care Settings

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Situation
Reusable elastomeric half-face respirators (EHFR) have been used primarily in hospital and pre-hospital health-care settings (such as emergency health services) and may be considered in other community-based settings during the COVID-19 pandemic. EHFRs are used as an alternative when N95 respirator supply is limited or a health-care provider is unable to be successfully fitted to available N95 respirator models and sizes. Respirators with exhalation valves protect the wearer from SARS-CoV-2 but may not prevent the wearer from spreading the virus to others. The concern is whether the use of EHFR with unfiltered exhalation valves worn by asymptomatic staff members may expose co-workers or patients to infectious agents including SARS-CoV-2 and variant strains.

The Ministry of Health’s Mask Use in Health-Care Facilities during the COVID-19 Pandemic Policy requires all health-care workers (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). It is important to note that medical grade masks are not designed to fit tightly to the face and have gaps normally along the sides. When the wearer breathes in and out, air could potentially leak through those gaps, and may include respiratory droplets and aerosols. Therefore, it is important to implement all mitigation strategies on the hierarchy of IPC to prevent the spread of respiratory pathogens (e.g., physical distancing wherever possible, screening, ventilation, environmental cleaning, hand hygiene, etc.).

For respirators with exhalation valves, the direction of the exhaled airflow will vary depending on the design (for example, downward/forward for EHFR with exhalation valves). The exhaled unfiltered air poses a risk of environmental contamination and clean/sterile field contamination.

Any changes in EHFR use within health-care settings during the pandemic should reflect other control measures in place such as appropriate ventilation, COVID-19 screening, physical distancing, hand hygiene and the use of medical masks.

Recommendations
The following recommendations aim to address potential concerns about EHFR with unfiltered exhalation valves. In the context of the pandemic the EHFR with exhalation valves continue to be part of the provincial personal protective equipment (PPE) strategy to extend the use of N95 respirators as well as provide an alternative for HCWs who cannot be

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1 HCWs includes paramedics.
fitted for an N95 respirator. The following recommendations align with current U.S. Centers for Disease Control and Prevention (CDC) recommendations. These recommendations will be revisited and amended in the future, as required:

1. **EHFR with unfiltered exhalation valves should be covered, with a medical grade mask or other source control mechanism deemed acceptable by the National Institute for Occupational Safety and Health (NIOSH), during use.** Medical grade masks should be applied to the EHFR in a way that does not interfere with the respirator seal, by attaching the ear loops around filter cartridges. Where a sterile field is required (e.g., operating room), an N95 respirator is the preferred option; however, if EHFR is the only option available, the exhalation valve must be covered. Users of EHFR are responsible for self-screening prior to each shift and must follow the reusable EFHR cleaning and disinfection protocols.

2. In non-patient care areas where HCWs use EHFRs to protect themselves from hazards other than infectious agents (e.g., dust/particulates, chemical handling or spill clean-ups), the exhalation valve does not have to be covered if other people in the area are wearing a respirator. Refer to site work procedures for additional task-specific PPE requirements (e.g., remove EHFR and wear surgical mask when transitioning to patient care areas).

**Additional Notes**

- N95 filtering face-piece respirators with an exhalation valve are not recommended in patient interactions in health authority facilities as they cannot be safely covered. Using a medical mask to cover N95 respirators with an exhalation valve can affect the seal and therefore is not acceptable.
  
  Consult with workplace health and safety for health authority specific guidance.

**Literature Review Findings**

There is a lack of published peer-reviewed literature on the effectiveness of respirators with exhalation valves (e.g., EHFR) in preventing the spread of SARS-CoV-2 from the wearer to others. A literature search review was performed on University of British Columbia’s library databases online using a combination of keywords and PPE terms: “respirator with exhalation valve” OR “exhalation valves” AND “SARS-CoV-2” OR “COVID-19” OR “coronavirus 19.”

There is limited scientific evidence to support or warn against covering unfiltered exhalation valves on EHFRs and the risk of SARS-CoV-2 transmission by pre-symptomatic or asymptomatic individuals through droplets expelled from EHFR exhalation valves in relation to patient and staff safety.

**Current Precautionary Measures**

HCW self-screening before each shift is in place in all health authority facilities. If a staff member becomes symptomatic during their shift, they are required to notify their supervisor/manager, leave the workplace, use the self-assessment tool and go for COVID-19 testing if required. Staff should self-isolate as recommended by public health.

All visitors, patients, staff and HCWs in B.C. health-care facilities and patient care areas are required to wear medical grade (procedure/surgical) masks at all times. In addition, HCWs are required to wear eye/facial protection (e.g., face shield, safety goggles) during patient interactions.
Discussion / Conclusion

Literature regarding the level of source control offered by EHFRs is extremely limited and there is a lack of evidence-based research at this time. Only Howard et al. (2020) have studied sterile field contamination of EHFRs, finding no difference compared to other masks.

Expanding the literature search to include N95 respirators with valves, the NIOSH technical report (2020) offers corroborating evidence, indicating that a valved respirator provides source control similar to surgical masks but less than an N95 respirator without an exhalation valve. Verma et al. (2020) and Staymates (2020), through their visualization methods, show that aerosols can be released from medical masks as well as through the exhalation valves and the direction of this release is impacted by the exhaust valves on the N95 respirator. However, the clinical implications are unknown.

BC Emergency Health Services has conducted a validation of practice (fit test) to determine if covering the exhalation valve with a procedure mask compromises the seal. Medical grade masks were applied to EHFR in a way not interfering with the respirator seal, by attaching ear loops around the filter cartridges. Quantitative fit testing (using a PortaCount) resulted in 100% pass (N = 42) and did not demonstrate a negative impact on the respirator seal/fit. (Average fit factor2: EHFR with exhalation valve = 4977; EHFR with exhalation valve covered with a medical grade mask = 4042; EHFR with exhalation valve covered with a pediatric medical grade mask = 4984)

The provincial mask use in health-care facilities policy requires all health-care workers, clients/patients and visitors to wear medical grade masks to contain liquid droplets from mouths and noses when they cough, sneeze, and/or talk. However, medical grade masks are not designed to seal tightly to the face, so some unfiltered air can escape through and around the edges (Verma et al., NIOSH Technical Report, and Howard et al). While some air can escape through and around the edges, medical masks still offer better protection from direct droplets from coughs or sneezes than other masks or no masks.

Research on exhalation valves on N95s has shown that droplets pass through the exhalation valve unfiltered in a more focused and directional manner. When wearing a face shield in conjunction with these respirators with exhaust valves, the combination may lower the droplet concentration in front of the HCW’s face by blocking the forward motion of the jet and dispersing it over a wider area (to the side and downward back toward the user). Given that there is little evidence to support that the amount of infectious particulates released from these EHFRs is greater than that released through medical masks, there may be situations where a full face shield may be used with these EHFR. This practice could further minimize the potential droplets released from being exhaled directly towards other staff and/or patients who are in close proximity to the wearer. It could also alleviate the risk of potential medical mask impact on the respirator seal and/or potential physiological impact to the HCWs wearing the respiratory protection for extended periods of time and often at higher work rates (during emergency response, etc.).

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2 A fit factor is a number that is the direct result of a quantitative respirator fit test. It is a measurement made by an instrument during a simulation of workplace activities (the exercises). It is expressed as the challenge aerosol concentration outside the respirator divided by the challenge aerosol concentration that leaks inside the respirator during a fit test.
The evidence regarding the risk of transmission from EHFR and whether an unfiltered exhaust valve needs to be covered is inconclusive at this time. According to the Public Health Agency of Canada (2021) and the World Health Organization (2020), use of respirators with exhaust valves are not recommended because the exhalation valve can allow virus particulates to pass through the exhalation valve opening. This makes the respirator ineffective at preventing the spread of SARS-CoV-2 or other respiratory viruses. Covering any unfiltered exhalation valve with a medical grade mask covering can be implemented to mitigate risk and is recommended by the U.S. (2020). However, respirator manufacturers do not endorse this practice.

Acknowledgements
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References


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