McMaster University | HEALTH FORUM

COVID-END COVID-19 Evidence Network to support Decision-making ... in Canada

# Appendices for COVID-19 Rapid Evidence Profile #28

(10 January 2022)

## Appendix 1: Methodological details

We use a standard protocol for preparing rapid evidence profiles (REP) to ensure that our approach to identifying research evidence as well as experiences from other countries and from Canadian provinces and territories are as systematic and transparent as possible in the time we were given to prepare the profile.

### Identifying research evidence

For this REP, we searched our continually updated inventory of best evidence syntheses and guide to key COVID-19 evidence sources for:

1) guidelines (defined as providing recommendations or other normative statements derived from an explicit process for evidence synthesis);
2) full systematic reviews;
3) rapid reviews;
4) protocols for reviews or rapid reviews that are underway;
5) titles/questions for reviews that are being planned; and
6) single studies (when no guidelines, systematic reviews or rapid reviews are identified).

Each source for these documents is assigned to one team member who conducts hand searches (when a source contains a smaller number of documents) or keyword searches to identify potentially relevant documents. A final inclusion assessment is performed both by the person who did the initial screening and the lead author of the rapid evidence profile, with disagreements resolved by consensus or with the input of a third reviewer on the team. The team uses a dedicated virtual channel to discuss and iteratively refine inclusion/exclusion criteria throughout the process, which provides a running list of considerations that all members can consult during the first stages of assessment.

During this process we include published, pre-print and grey literature. We do not exclude documents based on the language of a document. However, we are not able to extract key findings from documents that are written in languages other than Chinese, English, French or Spanish. We provide any documents that do not have content available in these languages in an appendix containing documents excluded at the final stages of reviewing.

### Identifying experiences from other countries and from Canadian provinces and territories

For each REP, we collectively decide on what countries to examine based on the question posed. For other countries we search relevant sources included in our continually updated guide to key COVID-19 evidence sources. These sources include government-response trackers that document national responses to the pandemic. In addition, we conduct searches of relevant government and ministry websites. In Canada, we search websites from relevant federal and provincial governments, ministries and agencies (e.g., Public Health Agency of Canada).

While we do not exclude countries based on language, where information is not available through the government-response trackers, we are unable to extract information about countries that do not use English, Chinese, French or Spanish as an official language.

**Assessing relevance and quality of evidence**

We assess the relevance of each included evidence document as being of high, moderate or low relevance to the question. We then use a colour gradient to reflect high (darkest blue) to low (lightest blue) relevance.

Two reviewers independently appraised the quality of the guidelines we identified as being highly relevant using AGREE II. We used three domains in the tool (stakeholder involvement, rigour of development and editorial independence) and classified guidelines as high quality if they were scored as 60% or higher across each of these domains.

Two reviewers independently appraise the methodological quality of systematic reviews and rapid reviews that are deemed to be highly relevant. Disagreements are resolved by consensus with a third reviewer if needed. AMSTAR rates overall methodological quality on a scale of 0 to 11, where 11/11 represents a review of the highest quality. High-quality reviews are those with scores of eight or higher out of a possible 11, medium-quality reviews are those with scores between four and seven, and low-quality reviews are those with scores less than four. It is important to note that the AMSTAR tool was developed to assess reviews focused on clinical interventions, so not all criteria apply to systematic reviews pertaining to health-system arrangements or to economic and social responses to COVID-19. Where the denominator is not 11, an aspect of the tool was considered not relevant by the raters. In comparing ratings, it is therefore important to keep both parts of the score (i.e., the numerator and denominator) in mind. For example, a review that scores 8/8 is generally of comparable quality to a review scoring 11/11; both ratings are considered 'high scores.' A high score signals that readers of the review can have a high level of confidence in its findings. A low score, on the other hand, does not mean that the review should be discarded, merely that less confidence can be placed in its findings and that the review needs to be examined closely to identify its limitations. (Lewin S, Oxman AD, Lavis JN, Fretheim A. SUPPORT Tools for evidence-informed health Policymaking (STP): 8. Deciding how much confidence to place in a systematic review. *Health Research Policy and Systems* 2009; 7 (Suppl1):S8.

**Preparing the profile**

Each included document is hyperlinked to its original source to facilitate easy retrieval. For all included guidelines, systematic reviews, rapid reviews and single studies (when included), we prepare a small number of bullet points that provide a brief summary of the key findings, which are used to summarize key messages in the text. Protocols and titles/questions have their titles hyperlinked given that findings are not yet available. We then draft a brief summary that highlights the total number of different types of highly relevant documents identified (organized by document), as well as their key findings, date of last search (or date last updated or published), and methodological quality.

**Appendix 2: Key findings from evidence documents that address the question, organized by document type and sorted by relevance to the question and COVID-19**

| Type of document | Relevance to question | Key findings | Recency or status |
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| Guidelines | None identified | | |
| Full systematic reviews | • Filtration performance of KN95 masks compared to surgical masks or N95 masks | • This systematic review and meta-analysis compared the preventive efficacies of four different types of face masks (N95 respirators, surgical masks, medical masks, and non-medical masks) that have been routinely used as personal protective equipment (PPE) against influenza virus, SARS-CoV-1, MERS-CoV, and SARS-CoV-2<br>• The results showed that the N95 respirator or its equivalent (e.g., FFP2 and KN95) was the most effective mask type, while evidence regarding the use of medical or surgical masks showed that these masks did not show statistically significant reduction of influenza or coronavirus infections (SARS, MERS, and COVID-19)<br>• N95 or equivalent masks (e.g., FFP2 and KN95) were the most effective in providing protection against coronavirus infections in healthcare settings, however, there was insufficient data to determine the efficacy of N95 masks or equivalent in community settings<br>• The findings support that N95 or equivalent (e.g., FFP2 and KN95) masks should be the primary choice whenever possible, whether in healthcare or community settings<br>Source (10/11 AMSTAR rating) | Posted 1 February 2021 (pre-print) |
| Rapid reviews | • Filtration performance of KN95 masks compared to surgical masks or N95 masks<br>• Factors affecting performance of KN95 masks (e.g., fit of mask) | • No published or preprint studies related to the Omicron variant and masking were identified<br>• However, one study evaluated aerosol particle (<5 µm diameter) penetration and total inward leakage through re-usable fabric two-layer masks, re-useable fabric multi-layer masks, disposable | Literature last searched 13 December 2021 |

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| | | procedure/surgical masks, KN95 masks, and fit-tested and seal-checked N95 FFR masks (the findings from this study are included in the single studies section of this table)<br>• Respirators are designed to closely fit or seal to the face, but even though fit-testing is not required for use in the community, N95s without fit-testing and KN95s cannot be assumed to filter all of the air inhaled<br>• The review concluded that given the high transmissibility of the Omicron variant and the potential increased contribution of aerosol transmission, it is important to select a mask that optimizes fit and filtration<br>Source (3/9 AMSTAR rating) | |
| | • Factors affecting performance of KN95 masks (e.g., fit of mask)<br>• Approaches to improving fit and performance of KN95 masks<br>▪ Modifications | • The fitted filtration efficiency of KN95 masks (alongside KF94 masks) was compromised by increasing beard length; however, they were still better options than procedure and cotton face masks<br>• One study on five bearded volunteers found a simple resistance exercise band improved the fitted filtration efficiency of commonly used face masks (including N95, KF94, KN95 and procedure masks) by bearded men during the COVID-19 pandemic<br>Source (1/9 AMSTAR rating) | Last updated 11 June 2021 |
| | • Factors affecting performance of KN95 masks (e.g., fit of mask) | • This rapid review looked at the clinical evidence and recommendations regarding facial hair and filtering respirator devices, such as N95 masks<br>• Two studies were identified and reported that as the length of facial hair (e.g., beards) increased, the adequacy of respiratory fit decreased significantly<br>• No recommendations were identified regarding facial hair and filtering respiratory devices<br>Source (4/9 rating) | Last updated 11 February 2021 |
| | • Filtration performance of KN95 masks compared to surgical masks or N95 masks | • The review explored the effectiveness of qualitative and quantitative fit testing methods for testing the | Published 11 June 2011 |

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| | • Factors affecting performance of KN95 masks (e.g., fit of mask)<br>• Approaches to improving fit and performance of KN95 masks<br>  ▪ Training | protection of a respirator and the factors that influence the outcomes of fit testing<br>• Qualitative fit testing uses the wearer's sense of smell or taste to detect respirator leakage while quantitative fit testing uses a generated aerosol, ambient aerosol, or controlled negative pressure to measure the amount of leakage into the respirator facepiece<br>• In terms of the qualitative fit testing method, one study found that N95 respirator users had half the rate of infection compared to medical mask users, and that there was no significant difference in infection rate between the qualitatively fit-tested respirator groups compared to the non-fit-tested groups<br>• Four studies evaluating the quantitative fit-testing method found that the fit factor may decrease when respirator users performed simulated medical procedures, but other studies concluded that in general, passing the quantitative fit test resulted in increased rates of simulated protection in the workplace<br>• Studies also found that the training of healthcare workers on the correct use of respirators affected both the qualitative and quantitative fit-testing results<br>Source | |
| | • Filtration performance of KN95 masks compared to surgical masks or N95 masks | • This rapid review was developed to provide information on N95 equivalents as an alternative to N95 respirators in a healthcare setting during the COVID-19 pandemic<br>• No research studies were identified to compare the equivalence of N95 respirators from international jurisdictions to those used in healthcare settings in Canada and the United States (National Institute for Occupational Safety and Health [NIOSH] certified)<br>• The US Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for | Published 7 April 2020 |

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| | | importing non-NIOSH– approved N95 respirators from Australia, Brazil, Europe, Japan, Korea and Mexico, which had similar standards to NIOSH<br>• The FDA issued a new EUA for non-NIOSH–approved N95 respirators made in China, which made KN95 respirators eligible for authorization if certain criteria were met, including evidence demonstrating that the respirator was authentic<br>• Health Canada accepted the NIOSH certification as an appropriate quality standard for N95 masks used by healthcare providers, and also accepted the equivalent alternate standards (although these standards were not specified)<br>• When NIOSH became aware of counterfeit respirators or those misrepresenting NIOSH approval on the market, the U.S. CDC would post them to alert users, purchasers and manufacturers<br>Source | |
| Protocols for reviews that are already underway | None identified | | |
| Titles and questions for reviews being planned | None identified | | |
| Single studies | • Filtration performance of KN95 masks compared to surgical masks or N95 masks | • This study evaluated aerosol particle (<5 μm diameter) penetration and total inward leakage through re-usable fabric two-layer masks, re-useable fabric multi-layer masks, disposable procedure/surgical masks, KN95 masks, and fit-tested and seal-checked N95 FFR masks<br>○ Overall penetration of particles was highest for two-layer masks (56%), followed by multi-layer (28%), procedure masks (10%), N95 FFR (1.4%) and KN95 (0.7%)<br>○ Based on modelling a viral concentration of 0.01% and particle size of 0.3 μm, the percent reduction in viral penetration, compared to a two-layer mask, was 99.2% for N95 FFRs, 96% | Published 6 October 2021 |

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| | | for disposable procedure/surgical masks, and 59% for multi-layer masks<br>○ It was concluded that N95 FFRs were the only masks evaluated that provided both high fabric protection factor and total inward leakage protection factor, and that N95 FFRs are the best option to protect individuals from exposure to aerosols in high-risk settings<br>○ Mask fit with an effective face seal was also found to be more important to increasing total inward leakage protection factor than the mask material<br>Source | |
| | • Factors affecting performance of KN95 masks (e.g., fit of mask) | • This study assessed the impact of multiple mild-steam decontaminations with 121°C/2000 mbar/20 min on the protection performance of disposable KN95 filtering facepiece respirators (FFRs)<br>• It was found that after up to 10 cycles, only minor degradation was observed in the filter efficiency and breathing resistance, and there was no apparent degradation observed in the material structure, suggesting a potential for multiple decontamination cycles to be performed without significantly affecting the protective properties of KN95 FFRs<br>• The study also found that depending on the KN95 FFR, secondary components like elastic bands or bonding of the nose clip occasionally started to degrade the respirator starting from five cycles on, which may limit the number of decontamination cycles<br>Source | Published June 2021 |
| | • Factors affecting performance of KN95 masks (e.g., fit of mask) | • This study evaluated the level of fit of various types of masks, and assessed the accuracy of implementing fit checks from the U.K. National Health Service guidelines by comparing fit-check results<br>• The findings showed that KN95 respirators had poor fits across all (seven) participants | Published 22 January 2021 |

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| | | • While KN95 masks have high filtration efficiencies, the lack of an adequate seal fails to offer increased protection<br>• Findings also showed that "fit checks" or self-assessments of the fit of masks might not be accurate, especially in those without prior mask-fit education<br>Source | |
| | • Filtration performance of KN95 masks compared to surgical masks or N95 masks | • The CDC has listed KN95 masks as a suitable alternative when N95s are not available<br>• Mean filtration efficiencies (SD) of untreated masks are above 95% for N95s, at 97.3% (0.4%), 96.7% (1.0%) for KN95s, and 95.1% (1.6%) for surgical face masks<br>• While surgical face masks' efficiency was reduced to 91.6% (1.0%) with $H_2O_2$ sterilization, both the N95s and KN95s retained at least 95% efficiency, at 96.6% (1.0%) and 97.1% (2.4%), respectively<br>• There was a marked reduction in filtration efficiency to under 80% with the chlorine dioxide solution sterilization treatment in the KN95s and surgical face masks. The efficiency of N95s remained high at 95.1% (1.6%)<br>• All masks' pressure drop changes with sterilization were acceptable<br>• Sterilization processes have different effects on different masks' filtration efficiencies, with fewer negative effects associated with $H_2O_2$ sterilization than with chlorine dioxide solution; filter material should be investigated as it may degrade further after multiple cycles of sterilization<br>• The filtration efficiencies by aerosol size were more than 95% for all untreated masks<br>  ○ With chlorine dioxide sterilization, N95s' mean (SD) filtration efficiency for particles of approximately 300 nm decreased to | Published 15 June 2020 |

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| | | approximately 86.2% (6.8%), although the overall efficiency was still ~95%<br>○ Caution should be exercised under this condition<br>○ The mean filtration efficiencies decreased significantly for KN95s and 47.1% for surgical face masks for particles of approximately 300 nm<br>• To better protect personnel in hospitals, measuring the respirator's filtration efficiency by aerosol size is recommended instead of just measuring the overall filtration efficiency<br>Source | |
| | • Filtration performance of KN95 masks compared to surgical masks or N95 masks<br>• Factors affecting performance of KN95 masks (e.g., fit of mask) | • The filtration efficiency and fit factor of the N95 mask is much higher than the KN95 even after heat treatments<br>○ The KN95 has four major layers (outer, filter, middle and inner layers) while the N95 has three (outer, filter and inner)<br>○ The thickness of the filter layer in the N95 is eight-fold thicker than KN95, and the KN95 uses a single thick layer of spun-bond PP fabric for the inner layer, while the N95 uses multiple thin layers of fabric, explaining the higher filtration efficiency of the N95 (97.03%) compared to the KN95 (87.76%) in pristine conditions<br>○ Since 70°C inactivates SARS-CoV-2 with no damage on fibre integrity of the masks, contaminated N95 and KN95 masks were heat-treated in the oven, and filtration efficiencies of the N95 after each cycle of 70°C treatment was 97.16%, while the KN95 was 83.64% due to the greater thickness of the filter layer in the N95<br>○ When heated to 150°C, fibre deformation occurred at the inner layer of the N95 and KN95, and the spun-bound PP of KN95 began | Published 9 July 2020 (pre-print) |

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| | | to break their bonds, showing lower thermal durability compared to the N95<br>○ The fit factor of the N95 was 55 and the KN95 was 2.7, meaning that the N95 was tighter fitting to the face; even under heat treatment, the fit factor of the N95 was 10-fold higher than the KN95<br>Source | |
| | • Filtration performance of KN95 masks compared to surgical masks or N95 masks | • This study evaluated three kinds of masks (disposable medical masks, surgical masks, KN95-grade masks) treated by a hot water decontamination and charge-regeneration approach for their filtration qualities<br>• The hot water decontamination involved soaking used masks in hot water at a temperature greater than 56°C for 30 minutes (based on recommendations by the National Health Commission of the People's Republic of China), then dried using a hair dryer to recharge the masks with electrostatic charge<br>• The findings showed that the filtration qualities of the regenerated masks were almost maintained<br>• All the regenerated masks (disposable medical masks, surgical masks, KN95-grade masks) retained similar waterproof property, microstructure, and filterability in comparison with the respective new masks<br>• The authors found that the KN95-grade masks retained a particle filtration efficiency (PFE) greater than 95% after being treated in pressurized steam at 121°C for 30 minutes<br>Source | Published 1 October 2020 |
| | • Filtration performance of KN95 masks compared to surgical masks or N95 masks | • Expired N95s and sterilized, used N95s can be used when new N95s are not available<br>○ Expired N95 masks which had been subjected to ethylene oxide and hydrogen peroxide sterilization had unchanged fitted filtration efficiencies (FFEs) of >95%, while the | Published 11 August 2020 |

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| | | performance of N95 masks in the wrong size resulted in decreased FFEs of 90-95%<br>○ Surgical and procedure masks had lower FFEs relative to N95 masks (98.5% overall FFE)<br>○ Masks secured with elastic ear loops had the lowest FFEs (38.1% overall FFE)<br>Source | |
| | • Factors affecting performance of KN95 masks (e.g., fit of mask) | • In this study, heat and ultraviolet (UV) disinfection methods for N95 masks were investigated by fit testing masks using a quantitative respirator fit-test system<br>• The disinfection methods used in the study were dry heat (75˚C, 30 minutes) and UV germicidal irradiation (UVGI) (UVGI 254 nm, 8W, 30 minutes), and five models of N95 masks were used<br>• Results of the study showed that five cycles of dry heat treatment did not degrade the fit of the test N95 masks (-0.56% change), while applying UVGI over 10 cycles had significantly degraded respirator fit (-90% change)<br>• Outcomes of the study suggest that UVGI methods of decontamination cause significant degradation of the fit of N95 masks<br>Source | Published 17 April 2020 (pre-print) |

**Appendix 3: Documents excluded at the final stages of reviewing**

| Type of document | Hyperlinked title |
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| Guidelines | Care of critically ill adult patients with COVID-19<br><br>WHO recommendations on mask use by health workers, in light of the Omicron variant of concern: WHO interim guidelines, 22 December 2021<br><br>Mask use in the context of COVID-19<br><br>COVID-19 medical masks and respirators: Information for health professionals<br><br>Advice on the use of masks in the community, during home care and in health care settings in the context of the novel coronavirus (2019-nCoV) outbreak<br><br>Update alert: Use of N95, surgical, or cloth masks to prevent COVID-19 in health care and community settings: Living practice points from the American College of Physicians (Version 1) |
| Full systematic reviews | Protecting healthcare workers from pandemic influenza: N95 or surgical masks?<br><br>N95 respirator and surgical mask effectiveness against respiratory viral illnesses in the healthcare setting: A systematic review and meta-analysis<br><br>Medical masks vs N95 respirators for preventing COVID-19 in healthcare workers: A systematic review and meta-analysis of randomized trials<br><br>Use of powered air-purifying respirator (PAPR) by healthcare workers for preventing highly infectious viral diseases - A systematic review of evidence<br><br>Exploring options for reprocessing of N95 Filtering Facepiece Respirators (N95-FFRs) amidst COVID-19 pandemic: A systematic review<br><br>Decontamination and reuse of surgical masks and N95 filtering facepiece respirators during the COVID-19 pandemic: A systematic review<br><br>Decontaminating N95/FFP2 masks for reuse during the COVID-19 epidemic: A systematic review<br><br>Filtering facepiece respirator (N95 Respirator) reprocessing: A systematic review |

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| | Efficacy and safety of disinfectants for decontamination of N95 and SN95 filtering facepiece respirators: A systematic review (pre-print)<br><br>Decontaminating N95 masks with Ultraviolet Germicidal Irradiation (UVGI) does not impair mask efficacy and safety: A systematic review<br><br>Personal protective equipment for reducing the risk of COVID-19 infection among health care workers involved in emergency trauma surgery during the pandemic: An umbrella review<br><br>Protecting healthcare workers from pandemic influenza: N95 or surgical masks? |
| Rapid reviews | The need of health policy perspective to protect Healthcare Workers during COVID-19 pandemic. A GRADE rapid review on the N95 respirators effectiveness<br><br>Interim IPAC recommendations for use of personal protective equipment for care of individuals with suspect or confirmed COVID-19<br><br>What is the efficacy of standard face masks compared to respirator masks in preventing COVID-type respiratory illnesses in primary care staff?<br><br>Mask decontamination methods (model N95) for respiratory protection: A rapid review<br><br>Safety of extended use and reuse of N95 respirators<br><br>The need of health policy perspective to protect healthcare workers during COVID-19 pandemic. A GRADE rapid review on the N95 respirators effectiveness |
| Protocols for reviews that are already underway | Will decontamination of N95 filtering facepiece respirators result in compromised performance? A living systematic review |
| Titles and questions for reviews being planned | None identified |
| Single studies | None identified |

Al-Khateeb S, Bain T, Bhuiya A, Mansilla C, Mehta V, Sood T, Wang Q, Soueidan S, Rintjema J, Wang A, Lavis JN, Wilson MG. Appendices for COVID-19 rapid evidence profile #28: What is the filtration performance of KN95 masks compared to surgical and N95 masks, and how can their use be optimized in hospital settings? Hamilton: McMaster Health Forum, 10 January 2022.

The COVID-19 Evidence Network to support Decision-making (COVID-END) is supported by an investment from the Government of Canada through the Canadian Institutes of Health Research (CIHR). To help Canadian decision-makers as they respond to unprecedented challenges related to the COVID-19 pandemic, COVID-END in Canada is preparing rapid evidence responses like this one. The opinions, results, and conclusions are those of the evidence-synthesis team that prepared the rapid response, and are independent of the Government of Canada and CIHR. No endorsement by the Government of Canada or CIHR is intended or should be inferred.


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