

## **COVID-19 Rapid Evidence Profile #28**

(10 January 2022)

### **Question**

What is the filtration performance of KN95 masks compared to surgical and N95 masks, and how can their use be optimized in hospital settings?

### **What we found**

To inform guidance on KN95 masks usage and approaches to improving the fit and performance of KN95s in optimal settings in hospitals, we identified evidence, as well as experiences from four countries (Australia, South Africa, United Kingdom (U.K.), and the United States (U.S.) that are currently most affected by Omicron (see Box 1 for a description of our approach). We organized our findings using the framework below.

### **Organizing framework**

- Filtration performance of KN95 masks compared to surgical masks or N95 masks
- Factors affecting performance of KN95 masks (e.g., fit of mask)
- Approaches to improving fit and performance of KN95 masks
  - Modifications
  - Training
  - Other
- Optimal settings for use of KN95 masks in hospitals (e.g., low-risk settings within hospitals)

We identified 14 evidence documents relevant to the question, of which we deemed nine to be highly relevant. The highly relevant evidence documents include:

- one full systematic review;
- three rapid reviews; and
- five single studies that provide additional insights.

### **Box 1: Our approach**

We identified evidence addressing the question by searching the COVID-END [inventory of best evidence syntheses](#) on 7 January 2022. We identified jurisdictional experiences by searching jurisdiction-specific sources of evidence listed in the same COVID-END guide to key COVID-19 evidence sources, and by hand searching government and stakeholder websites. We selected four countries (Australia, South Africa, United States and the United Kingdom) that may have implemented additional guidance on masks to protect healthcare workers, staff and patients in hospitals during outbreaks of Omicron.

We searched for guidelines, full systematic reviews (or review-derived products such as overviews of systematic reviews), rapid reviews, protocols for systematic reviews, and titles/questions for systematic reviews or rapid reviews that have been identified as either being conducted or prioritized to be conducted. Single studies were only included if no relevant systematic reviews were identified.

We appraised the methodological quality of full systematic reviews and rapid reviews that were deemed to be highly relevant using AMSTAR. Note that quality appraisal scores for rapid reviews are often lower because of the methodological shortcuts that need to be taken to accommodate compressed timeframes. AMSTAR rates overall quality on a scale of 0 to 11, where 11/11 represents a review of the highest quality. 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 delivery, financial or governance arrangements within health systems or to broader social systems. We appraised the quality of the highly relevant guidelines using three domains in AGREE II (stakeholder involvement, rigour of development, and editorial independence) and classified guidelines as high quality if they were scored as 60% or higher on each domain.

This update of the living evidence profile was prepared in the equivalent of three days of a 'full-court press' by all involved staff.

We outline in narrative form below our key findings related to the question from highly relevant evidence documents, and based on experiences from other countries. Additional detail about experiences from other countries are provided in Table 1. A detailed summary of our methods is provided in Appendix 1, the full list of included evidence documents (including those deemed of medium and low relevance) in Appendix 2, and hyperlinks for documents excluded at the final stage of reviewing in Appendix 3.

## **Key findings from highly relevant evidence sources**

A high-quality systematic review published 1 February 2021 as a pre-print compared [the filtration performance of four different types of masks](#) (N95 respirators, surgical masks, medical masks, and non-medical masks). The review indicated that N95 or equivalent (e.g., FFP2 and KN95) masks should be the primary choice whenever possible, whether in healthcare or community settings. However, the review did not analyze findings for N95 and KN95 masks separately.

The three highly relevant rapid reviews were of low- and medium-quality and focused on filtration performance of KN95 masks compared to surgical masks or N95 masks, factors affecting the performance of KN95 masks, and/or approaches to improving the fit and performance of KN95 masks. Specifically:

- a [low-quality rapid 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; and
- a [medium-quality review](#) found a significant reduction of adequate fit of KN95 masks as the length of facial hair increased, and a [low-quality review](#) found the same and suggested adopting the use of simple resistance exercise bands as an approach to improve the fit of commonly used face masks (including N95, KF94, KN95 and procedure masks).

The five highly relevant single studies focused on filtration performance of KN95 masks compared to surgical masks or N95 masks, and factors affecting the performance of KN95 masks. These studies specifically focus on:

- [evaluating aerosol particle penetration and total inward leakage](#) through different types of masks (including 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 masks), and concluded that N95 masks are the best option to protect individuals from aerosols in high-risk settings;
- how [different sterilization processes result in different effects on filtration efficiencies of masks](#) (including N95s, KN95s, and surgical masks), with fewer negative effects associated with H<sub>2</sub>O<sub>2</sub> sterilization than with chlorine dioxide solution;
- the [level of proper fit for various types of masks](#) (including N95s, KN95s, surgical masks and fabric masks), and that fit checks may not be accurate, especially for those without prior mask-fit education;
- the [impact of multiple mild-steam decontaminations](#) on the performance of disposable KN95 filtering facepiece respirators; and
- the [filtration efficiency, fibre integrity, and charge density of N95 and KN95 masks](#) before and after various decontamination methods, with the conclusion that the filtration efficiency and fit factor of the N95 mask is higher than the KN95 mask.

## Key findings from the jurisdictional scan

We reviewed the experiences of Australia, South Africa, the U.K., and the U.S. [The Australian Department of Health](#) recommended on 9 December 2021 that fit checks must be completed by a wearer every time they put on a respirator, and that respirators including the P2, N95, KN95, and FFP2, need to be tested for particulate filtration to ensure that they filter out a minimum of 94% or 95% solid and liquid aerosols that do not contain oil. In September 2020, when P2 and N95 masks were the only particulate filter respirators (PFRs) in compliance with Australian standards, [the Infection Control Expert Group](#) in Australia recommended that single-use PFRs can be used for a single session of care lasting up to four hours, and that they should be discarded as soon as they are removed, and not stored or decontaminated for reuse. They also recommended that users be instructed in the correct method of fitting, removing and fit-checking PFRs, as training can improve facial seal achieved.

It is unclear whether KN95 masks are being used in hospitals in South Africa or the U.K., and which measures are being taken to improve their fit and performance. However, the [Health Protection Surveillance Centre](#) in the U.K. and the [U.S. FDA](#) recommend that if respirator masks (FFP2s or N95s) are not fluid repellent, additional protection, such as a visor, be used in situations where there is a splash risk. Both also recommend fit testing for all staff and prioritization of healthcare workers who are most likely to be involved in performing aerosol-generating procedures. Moreover, based on the RAG (red, amber, green) rating of wards, the [Royal College of Physicians of Edinburgh](#) recommends that in green zones (non-COVID-19 area), surgical masks must be worn when within two metres of a patient or in isolation rooms, in amber zones (COVID-19 cases without aerosol-generating procedures being performed), surgical masks must be worn at all times, and in red zones (COVID-19 cases with aerosol-generating procedures being performed), FFP3 respirators must be worn at all times.

In the U.S., the Food and Drug Administration's (FDA) [Emergency Use Authorization \(EUA\)](#) authorizing the use of certain respirator models approved by National Institute for Occupational Safety and Health (NIOSH) in healthcare settings, included findings from NIOSH research suggesting that all NIOSH-approved filtering facepiece respirators with exhalation valves, even without covering the valve, performed the same or better than surgical masks, procedure masks, cloth masks, or fabric. In addition, according to the [FDA](#), some N95 respirators are intended for use in a healthcare setting, specifically single-use, disposable respiratory protective devices used and worn by healthcare personnel during procedures to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The NIOSH Certified Equipment List identifies that the elastomeric respirators (equipped with a replaceable particulate filter) without exhalation valves or with filtered exhalation valves may be used in surgical settings. Other powered air-purifying respirators (PAPRs) approved by NIOSH should not be used in surgical settings due to concerns that the blower exhaust and exhaled air may contaminate the sterile field. Lastly, in an [update](#) to address NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency, the U.S. FDA indicated that facilities using elastomeric respirators and PAPRs should have up-to-date cleaning and disinfection procedures, which are an essential part of use for protection against infectious agents.

We also found that the Public Health Agency of Canada offers [advice for the use of COVID-9 medical masks and respirators](#), specifically that N95 respirators achieve a minimum particulate filtration efficiency of 95% and that when worn properly, the edges of the mask form a seal around the nose and mouth. Moreover, Health Canada accepts the U.S. NIOSH certification as an appropriate quality standard for N95 respirators, and all certified N95 respirators must have an

approval number stamped on the mask, represented as TC-84A-####n. An expired respirator can still be effective at protecting healthcare providers if it can be fit-tested, the straps are intact, and there are no visible signs of damage. In addition, Health Canada has asked [manufacturers and importers to stop the sale](#) of any products that do not meet the filtration criteria of 95% and re-label them as non-medical use face masks, as they could be used in settings where 95% filtration is not needed.

**Table 1: Experiences in other countries for uses of KN95 masks in hospitals compared to N95 masks, and approaches to improving fit and performance of KN95s**

Country	Summary of experiences
Australia	<ul style="list-style-type: none"> <li>• <a href="#">The Australian Department of Health</a> recommended on 9 December 2021 that respirators including the P2, N95, KN95 and FFP2 need to be tested for particulate filtration to ensure that they filter out a minimum of 94% or 95% of solid and liquid aerosols that do not contain oil <ul style="list-style-type: none"> <li>○ They also need to be fit tested to ensure proper facial seal to the wearer</li> <li>○ Fit checks must be completed by a wearer every time they put on a respirator, ensuring that the respirator is sealed over the bridge of the nose and mouth and that there are no gaps between the respirator and face</li> </ul> </li> <li>• <a href="#">The Infection Control Expert Group</a> recommended in September 2020 that particulate filter respirators (PFRs) such as the P2 (most common in Australia), N95 or equivalent should be used when caring for patients with suspected, probable or confirmed COVID-19 <ul style="list-style-type: none"> <li>○ Single-use PFRs should be discarded as soon as they are removed, and not stored or decontaminated for reuse</li> <li>○ PFRs can be used for a single session of care lasting up to four hours</li> <li>○ Users should be instructed in the correct method of fitting, removing and fit-checking PFRs, as training can improve facial seal achieved</li> </ul> </li> <li>• <a href="#">Queensland Health</a> recommends that fit checking be done each time a PFR is put on as follows: perform hand hygiene, select correctly fitting PFR, slightly bend nosepiece to form gentle curve, separate headbands and position PFR under chin with nosepiece up, pull headbands over the head ensuring top strap is at back of head and bottom is below ears, use fingertips to mold nosepiece to ensure good facial fit, complete a positive seal check by exhaling sharply (positive pressure inside PFR = no leakage), and complete a negative seal check by inhaling deeply (negative pressure = no leakage, which will make the PFR cling to face) <ul style="list-style-type: none"> <li>○ Additional instructions include: avoid touching the PFR while it is being worn, reapply the PFR after it is removed or leave the PFR dangling around the neck, change the PFR when it becomes moist, wash hands after touching the PFR, leave the patient room before removing the PFR, and dispose of the used PFR in a closed receptacle</li> </ul> </li> <li>• In September 2020, Australia's <a href="#">Department of Health and Human Services (DHHS)</a> withdrew KN95 masks from supply pending results of a review by the Therapeutic Goods Administration to ensure that they met standards for COVID-19 prevention <ul style="list-style-type: none"> <li>○ Any service providers that used KN95 masks were advised to remove them from use and supply</li> <li>○ Only P2 or N95 masks comply with Australian standards</li> <li>○ P2/N95 masks were recommended for disability workers when providing direct contact care for a client with COVID-19 risk factors</li> </ul> </li> </ul>
South Africa	<ul style="list-style-type: none"> <li>• The <a href="#">Department of Health of South Africa</a> does not provide guidance or recommendations for KN95 masks</li> <li>• Although the South African Medical Association provides <a href="#">guidance on PPE for critical-care providers</a> during the COVID-19 pandemic that references the use of N95 respirators, there is no specific guidance on respirator usage and fit</li> </ul>
United Kingdom	<ul style="list-style-type: none"> <li>• The <a href="#">Health Protection Surveillance Centre</a> recommends that FFP2 respirator masks and eye protection are worn by all healthcare workers when in contact with possible or confirmed COVID-19 cases and COVID-19 contacts</li> </ul>

	<ul style="list-style-type: none"> <li>○ FFP2 respirator masks are equivalent to N95 face masks</li> <li>○ If respirator masks are not fluid repellent, additional protection, such as a visor, is recommended in situations where there is a splash risk</li> <li>● The <a href="#">Health Protection Surveillance Centre</a> recommends fit testing for all staff and prioritization of healthcare workers who are most likely to be involved in performing aerosol-generating procedures, and healthcare workers who are most likely to have the most prolonged exposure to COVID-19 in settings where aerosol-generating procedures are performed</li> <li>● The <a href="#">Royal College of Physicians of Edinburgh</a> offers the following recommendations for PPE based on the RAG (red, amber, green) rating of wards <ul style="list-style-type: none"> <li>○ NHS hospitals are organized into green (non-COVID-19 area), amber (COVID-19 cases without aerosol-generating procedures being performed) and red (COVID-19 cases with aerosol-generating procedures being performed) wards, and PPE recommendations differ based on the rating of the wards</li> <li>○ In green zones, surgical masks must be worn when within two metres of a patient or in isolation rooms, in amber zones, surgical masks must be worn at all times, and in red zones, FFP3 respirators must be worn at all times</li> </ul> </li> <li>● In June 2020, the <a href="#">Health and Safety Executive (HSE)</a> advised that KN95 masks should not be used unless assessments have been undertaken by HSE as the Market Surveillance Authority <ul style="list-style-type: none"> <li>○ It is unclear whether KN95 masks are being used in hospitals in the U.K. and which measures are being taken to improve their fit and performance</li> </ul> </li> </ul>
United States	<ul style="list-style-type: none"> <li>● The <a href="#">CDC</a> has authorized the use of KN95 masks as a suitable alternative to N95 masks for its response to COVID-19 and the new Omicron variant</li> <li>● According to the <a href="#">FDA</a>, some N95 respirators are intended for use in a healthcare setting, specifically single-use, disposable respiratory protective devices used and worn by healthcare personnel during procedures to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material</li> <li>● On <a href="#">2 March 2020</a>, the FDA issued an Emergency Use Authorization (EUA) authorizing the use of certain NIOSH-approved respirator models in healthcare settings <ul style="list-style-type: none"> <li>○ NIOSH-approved alternatives to N95 respirators should be used where feasible, including other classes of filtering facepiece respirators, elastomeric half-mask and full facepiece air-purifying respirators, and powered air-purifying respirators (PAPRs)</li> <li>○ Every other NIOSH-approved filtering facepiece respirator is at least as protective as the N95, including N99, N100, P95, P99, P100, R95, R99, and R100 (with or without an exhalation valve)</li> <li>○ 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</li> <li>○ The NIOSH Certified Equipment List identifies that the elastomeric respirators (equipped with a replaceable particulate filter) without exhalation valves or with filtered exhalation valves may be used in surgical settings</li> <li>○ NIOSH maintains a searchable, online version of the certified equipment list identifying all NIOSH-approved respirators</li> </ul> </li> <li>● The FDA recommends that if there is a risk that a worker may be exposed to splashes, sprays, or splatters of blood or body fluids, then a face shield or surgical face mask should be worn over the standard N95 respirator <ul style="list-style-type: none"> <li>○ Care should be taken not to compromise the fit of the respirator if a face shield is placed over the respirator</li> </ul> </li> </ul>

	<ul style="list-style-type: none"><li>• Other PAPRs approved by NIOSH should not be used in surgical settings due to concerns that the blower exhaust and exhaled air may contaminate the sterile field<ul style="list-style-type: none"><li>○ PAPRs are reusable respirators that are battery-powered and when equipped with a high-efficiency (HE) filter, provide a higher level of protection than N95 respirators (they are 99.97% efficient against 0.3 micron particles)</li></ul></li><li>• On <a href="#">March 28, 2020</a>, FDA issued an update to address NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency<ul style="list-style-type: none"><li>○ The update indicated that facilities using elastomeric respirators and PAPRs should have up-to-date cleaning and disinfection procedures, which are an essential part of use for protection against infectious agents.</li></ul></li></ul>
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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. 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.

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