

The role of respirators and surgical masks in mitigating the transmission of SARS-CoV-2 in healthcare settings

An overview of evidence

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Acknowledgment

Thanks to the Respiratory Evidence Panel for their contribution to earlier drafts of this report. Thanks also to colleagues within the UK Health Security Agency (UKHSA) for their support into specific aspects of this review, especially Lesley Smith, Caroline Jamieson-Leadbitter, Sean Harrison and Carole Fry.

Summary

This paper draws on review-level evidence (search up to 12 May 2022) to consider the relative effectiveness of respirators (including FFP2, FFP3 and N95 respirators) and fluid-resistant surgical face masks (FRSM) in reducing SARS-CoV-2 transmission in healthcare settings. This is a focused update of the overview of evidence conducted in 2021 for the Respiratory Evidence Panel on the role of face coverings in mitigating the transmission of SARS-CoV-2.

Five systematic or rapid reviews reporting on the effectiveness of respirators compared to surgical masks to reduce SARS-CoV-2 transmission in healthcare settings were included in this update. Overall, the primary studies assessed in the reviews were judged as being at high risk of bias and 3 reviews reported that the strength of the evidence was insufficient to draw conclusions, especially outside settings considered as higher risk such as those where aerosol generating procedures are undertaken. Evidence from the 2 other reviews, both with meta-analyses, was mixed: one review found that N95 respirators (or equivalent) may offer greater protection than surgical or medical masks against SARS-CoV-2 infections in healthcare workers and one review reported no difference between respirator and mask effectiveness in preventing SARS-CoV-2 infection in healthcare workers. Similarly, the evidence on respirators or surgical masks versus control was mixed: one review with meta-analyses found that N95 respirators (or equivalent) may be more effective in reducing SARS-CoV-2 infections in healthcare workers than no protection but that there may be no differences between surgical masks and no protection, and the other review reported that the strength of evidence was insufficient to draw conclusions.

Two of the included reviews also reported findings from other coronaviruses (and influenza, not covered in this update). Both reviews found that N95 respirators (or equivalent) may offer greater protection than surgical or medical masks against coronaviruses infections in healthcare workers. This was mainly based on low strength evidence.

Whilst the body of evidence has grown since the overview of evidence conducted in 2021, the epidemiological evidence from the coronavirus (COVID-19) pandemic remains limited due to methodological limitations, lack of precision and differences between studies. The evidence, albeit of low or very low certainty and of mixed findings, suggests that N95 respirators may offer a degree of increased protection against coronavirus infections in healthcare workers compared to surgical masks.

The panel concluded, based on the evidence assessed combined with their expert knowledge and experience, that the statement made by the Panel in 2021 remains valid:

"Epidemiological evidence (usually of low or very low certainty) from SARS-CoV-2 and other coronaviruses suggests that, in healthcare settings, N95 respirators (or equivalent*) may be more effective than surgical masks in reducing the risk of infection in the mask wearer (low confidence)."

(* Note that the evidence assessed referred to 'N95 respirators' or 'N95 respirators and equivalent', and N95 is a registered certification mark of the US Department of Health and Human Services. In the UK, if risk assessment deems that respiratory protective equipment is needed, the Health and Safety Executive (HSE) advises as a minimum, this should be a FFP3 respirator.)

More research is needed to assess the effectiveness of respirators versus surgical masks in reducing SARS-CoV-2 infections in healthcare workers in real-world settings, particularly from well-designed epidemiological studies. While this was not the focus of this review, there is a need to assess the extent of potential adverse effects of respirators use (such as self-contamination, communication issues, dehydration and facial sores) and the degree to which, if any, these play a role in clinical practice.

Purpose

This paper has been prepared for the Respiratory Evidence Panel. Its purpose is to enable access to the best available evidence on the relative effectiveness of respirators (including FFP2, FFP3 and N95 respirators) and fluid-resistant surgical face masks (FRSM) in reducing SARS-CoV-2 transmission in healthcare settings (searches to 12 May 2022). This is a focused update of the work conducted in 2021 for the Respiratory Evidence Panel (<u>1</u>).

Earlier iteration of this paper was presented to and discussed by the Respiratory Evidence Panel on 14 July 2022.

Introduction

In 2021, a Respiratory Evidence Panel was convened by Public Health England (PHE, now transitioned to the UKHSA) to critically assess the evidence behind SARS-CoV-2 transmission to inform their guidance and recommendations (<u>1</u>). The panel assessed review-level evidence (searches to 28 April 2021) in relation to the role of airborne transmission of SARS-CoV-2, the transmissibility of new SARS-CoV-2 variants, and the effectiveness of face coverings in community and healthcare settings (<u>2</u>) and produced a statement of main findings (<u>3</u>). Only one of the statements reported on the effectiveness of respirators and surgical masks in healthcare settings (<u>3</u>):

"Epidemiological evidence (usually of low or very low certainty) from SARS-CoV-2 and other respiratory viruses suggests that, in healthcare settings, N95 respirators (or equivalent) may be more effective than surgical masks in reducing the risk of infection in the mask wearer (low confidence)."

The overview of evidence also reported that mechanistical evidence from laboratory studies showed that N95 respirators had higher filtration efficiency than surgical masks, but that there was a need for more research in real-world settings, including from well-designed and powered intervention studies, to assess the effectiveness of N95 respirators (or equivalent) versus surgical masks in healthcare settings ($\underline{2}$).

The body of evidence has grown since this work was conducted and there is a need to review it. This update is focused on the effectiveness of respirators and surgical masks against SARS-CoV-2 transmission in healthcare settings as there remains uncertainty surrounding the most appropriate policy for respirators use for the prevention of SARS-CoV-2 transmission to healthcare workers.

Transmission modes of SARS-CoV-2

COVID-19 is a respiratory disease which is transmitted through respiratory particles that contain the SARS-CoV-2 virus. Person-to-person transmission primarily occurs by direct transmission (respiratory particles, also called droplets, that directly deposit on mucous membranes) and by airborne transmission (respiratory particles that remain suspended in the air for minutes to hours, also called aerosols, that can be inhaled) ($\underline{4}$, $\underline{5}$). Whilst some risk of transmission has been acknowledged via fomites whereby transmission occurs through contact with infectious virus on surfaces, the risk is thought to be lower than for other transmission routes ($\underline{4}$, $\underline{6}$).

It is now widely accepted that short-range transmission of SARS-CoV-2 can occur through both droplets and aerosols and, as the concentration of exhaled respiratory particles is higher at short-range than over a longer distance, transmission risk is considered greater at short range (less than 2 metres) (4, 5, 7). Risk of transmission at greater distance is considered to be low

outside ($\underline{8}$, $\underline{9}$). However, and as concluded by the Respiratory Evidence Panel in 2021 ($\underline{3}$), airborne transmission beyond 2 metres is possible, particularly in poorly ventilated indoor settings ($\underline{6}$, $\underline{10}$, $\underline{11}$). In healthcare settings, it is possible that aerosol generating procedures (AGPs) can result in the release of aerosols from the respiratory tract ($\underline{4}$), which could increase the risk of respiratory transmission if the patient is infected by a respiratory virus ($\underline{7}$, $\underline{12}$).

Over the course of the COVID-19 pandemic, several novel variants of SARS-CoV-2 have emerged. As of the end of June 2022, the circulating variants of concern (VOC) as defined by the World Health Organization (WHO) are the Omicron variants (BA.1, BA.2, BA.3, BA.4, BA.5 and descendent lineages, as well as recombinant BA.1/BA.2) (<u>13</u>). The evidence currently available does not suggest that the modes of transmission of VOCs have changed compared to other variants, and it is expected that the same infection prevention and control (IPC) measures are appropriate (<u>3</u>, <u>7</u>). However, as variants become more transmissible, either due to increased viral shedding, through a lower infectious dose, or through altered host-pathogen dynamics (<u>14</u>, <u>15</u>), the role of different routes of acquisition such as long distance airborne transmission may vary.

Whilst COVID-19 vaccines remains effective against severe disease and death (<u>16</u>, <u>17</u>), vaccine effectiveness against infection has been variable throughout the pandemic and influenced by the emergence of variants (<u>18</u>).

COVID-19 in healthcare settings

In April 2020, 6.2% of the NHS workforce was absent and between March 2020 and April 2021 the proportion of all days lost that was due to COVID-19 ranged from 4 to 30% (19,20). NHS absence rates remained over 5.0% between July 2021 and February 2022, with a peak of 6.7% in January 2022 (<u>21</u>). There is evidence that healthcare workers are at higher risk of COVID-19 infection than the general community, and that Black, Asian, and minority ethnic healthcare workers are disproportionately affected (<u>22</u>, <u>23</u>). Data from the UK SARS-CoV-2 immunity and reinfection evaluation (SIREN) study has found higher infection rates among healthcare workers with more frequent exposure to COVID-19 patients and working in higher risk settings (<u>24</u>).

These findings are supported by review-level evidence. For instance, the living rapid review (monthly updates; final version: search to 4 April 2022) conducted by the Scottish Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) to inform IPC practice in Scotland found that there was evidence of transmission within healthcare settings (7). One of the included studies reported that healthcare workers with patient-facing roles were at higher risk of SARS-CoV-2 infection than those without, however the review authors also highlighted evidence around the complexities in establishing direction of transmission and determining healthcare or community acquisition (7). A living review on epidemiology and risk factors for healthcare workers (update alert 10: search to 24 October 2021) by Chou and others also reported that direct contact with COVID-19 patients, as well as participating in high-risk procedures such as AGPs, were associated with increase infection risk (25, 26). However, they

found no consistent association between infection risk in healthcare workers and role, and that household or private setting exposure was a stronger risk factor than work exposure (<u>25</u>, <u>26</u>).

This epidemiological evidence is supported by environmental evidence of SARS-CoV-2 detection in healthcare settings. In particular, a systematic review by Aghalari and others (search to 1 October 2020) found that SARS-CoV-2 RNA could be detected in the air in hospital settings and that preventive measures in healthcare settings should include ventilation and air filtration (27). However, most included studies had been conducted in intensive care units and isolation rooms, and it is unclear how these results apply to healthcare settings in general. A more recent review by Ribaric and others (search to 1 June 2021) found that SARS-CoV-2, including viable virus, had been detected in the air in most hospital areas, although the highest detected rates were from patient areas (28). In addition, the review authors reported that procedures such as tracheotomy, tracheal intubation, several forms of non-invasive oxygen supplementation (including manual ventilation), cardiopulmonary resuscitation, and nebulized therapy significantly increased air and surface SARS-CoV-2 contamination whilst face mask use by patients decreased it (28).

Despite the inconsistencies and uncertainties, these results suggest that healthcare workers are likely to be at higher risk of infection not only when participating in AGPs but also more generally when having direct contact with COVID-19 patients. It should also be noted that part of the inconsistency may be due to differences in definitions of AGPs both within the literature and within different healthcare settings. In England, national guidance has changed and, as of end of June 2022, the medical procedures listed by NHS England as being considered as aerosol generating and associated with an increased risk of respiratory transmission were awake bronchoscopy, awake ear, nose and throat airway procedures that involve respiratory suctioning, awake upper gastro-intestinal endoscopy, dental procedures, respiratory tract suctioning, surgery or post-mortem procedures likely to produce aerosol from the respiratory tract or sinuses and tracheostomy procedures (29).

Infection prevention and control measures in healthcare settings

UKHSA guidance published on 27 May 2022 states that in health and care settings, non-pharmaceutical interventions (such as mask wearing and enhanced ventilation) may be used, depending on local prevalence and risk assessment, with the aim to reduce the spread of SARS-CoV-2 (<u>30</u>).

The NHS National IPC Manual for England was published on 14 April 2022 and was updated on 8 June 2022. This guidance states that FRSM should be worn for routine care of patients with suspected or confirmed COVID-19 and that an FFP3 or hood should be worn for AGPs. A clinical risk assessment should be performed using the hierarchy of controls to inform the assessment of whether Respiratory Protective Equipment (RPE) such as FFP3 respirator is required for healthcare workers when a patient is considered infectious and should include

evaluation of the ventilation in the area, operational capacity, and prevalence of infection in the local area (31).

Ventilation in healthcare settings

Ventilation is part of the hierarchy of controls of clinical risk assessments (31) and there is comprehensive advice and guidance for estates teams aimed at improving ventilation for healthcare buildings (32). However, there is still no specific recommendation for ventilation in healthcare settings when treating COVID-19 patients. In addition, large parts of the NHS estate have challenges with adequate ventilation. In 2021, the Respiratory Evidence Panel concluded based on their expertise that effective ventilation as part of the implementation of the hierarchy of risk controls should be used to reduce airborne exposures beyond 2 metres (high confidence) (3).

More recently, a systematic review on ventilation and coronaviruses by Thornton and others (search to January 2021; preprint) found that increased ventilation was associated with decreased transmission risk. In particular, the review reported that increased ventilation rate was associated with decreased transmission risk for longer exposure times, but that ventilation may not be an effective measure to reduce airborne transmission risk at short range. The results of this review are not specific to healthcare settings, although the authors noted that 15 out of the 32 included studies had been conducted in healthcare settings which tend to have higher indoor air quality than other settings, and that efforts should therefore be made to improve high-risk sites. Overall, the review authors highlighted the importance of ventilation to reduce the risk of transmission of SARS-CoV-2 but noted that specific quantification of ventilation parameters remained a significant research gap (<u>33</u>).

Masks and respirators in healthcare settings

Masks can prevent transmission by reducing the burden of particles produced by the wearer ('source control') and by protecting the wearer from particles produced by others ('wearer protection'). Among the most common types of masks used in the NHS are fluid-resistant surgical face masks (Type IIR FRSM) and filtering facepiece (FFP3) respirators. FRSM provide source control and protect the wearer from splashes and ballistic drops but provide limited protection against inhalation of aerosols.

Respirators such as FFP3 provide wearer protection by minimising the risk of inhaling aerosols and are therefore an example of RPE. They are designed to meet certain standards and are, by definition, superior to surgical masks for filtering out small aerosols. However, real-world conditions of respirator use may impact their effectiveness. There is limited data on potential problems associated with respirator use. Some respirators can be uncomfortable to wear and may interfere with communication and vision, which can affect compliance. There is also a risk of self-contamination due to inadequate donning and doffing procedures, adjustments, respirator or face touches, under-the-respirator touches, and eye touches (<u>34</u>). When respirators are not worn in accordance with the manufacturer's instructions, they may give a

false sense of protection. Estimating the level of risk of aerosol transmission and the degree of real-world benefit of different strategies of respirator use in healthcare settings presents many methodological challenges and there remains limited high-quality studies on the benefit of RPE for wearer protection.

There is nonetheless broad consensus on the recommendation for RPE when performing AGPs (<u>35</u>). Recommendations for RPE are generally less prescriptive outside of these specific procedures both in the UK and internationally, incorporating for example the presence of additional risk factors for transmission (such as the ventilation in the area, the ability of the patient to wear face masks, the vaccination status of the patient, the local prevalence of infection) (<u>31</u>, <u>36</u>, <u>37</u>). Respirators can be used for a single patient interaction or for a period of time when the healthcare worker is undertaking clinical duties in a specific clinical area (sessional use).

International guidance has evolved several times throughout the COVID-19 pandemic, initially recommending widespread use of FFP3 then reserving FFP3 for AGPs only. For instance, a review and guidance article jointly produced by the British Infection Association (BIA), Healthcare Infection Society (HIS), Infection Prevention Society (IPS) and Royal College of Pathologists (RCPath) recommended that FFP3 should be used when performing AGPs regardless of the COVID-19 status of the patient, and that FRSM should be used when caring for patients with suspected or confirmed SARS-CoV-2 infection (<u>12</u>). RPE guidance must balance the protective benefits of RPE with potential negative consequences, however little evidence is available on the unintended consequences of FFP3 respirators use in the UK. In the context of a pandemic, mask supply may be limited so prioritisation may be required. Current NHS guidance states that FRSM should be worn for routine care of patients with suspected or confirmed COVID-19 and that an FFP3 or hood should be worn for AGPs (<u>31</u>).

However, there remains uncertainty in the most appropriate policy for RPE use for the prevention of SARS-CoV-2 occupational transmission to health and care workers and there is a pressing need to improve the evidence base to best protect health and wellbeing of front-line healthcare workers.

Note that the evidence often refers to 'N95 respirators' or 'N95 respirators and equivalent' whilst in the UK, if risk assessment deems that respiratory protective equipment is needed, this should be a FFP3 respirator. Similarly, the evidence usually refers to medical or surgical masks rather than to FRSM. A glossary of the terms used in this paper is provided in <u>Annexe A</u>.

Methods

Full details on the methodology are provided in Annexe B.

Database searches were completed on 12 May 2022 to identify any existing systematic or rapid reviews related to the comparative effectiveness of respirators and surgical masks in healthcare settings. Ovid Medline, Ovid Embase, medRxiv, Research Square and the WHO COVID-19 database were searched for reviews published since 28 April 2021, which was the search date for the overview of evidence conducted for the Respiratory Evidence Panel in 2021 (2). Results were screened on title and abstract in duplicate by 2 reviewers for 10% of the eligible studies, and the remainder was completed by one reviewer. Full-text screening was completed by one reviewer and checked by a second. Disagreements were resolved by discussion.

Additionally, several COVID-19 review repositories (list provided in <u>Annexe C</u>) were searched on 18 May 2022. Results were first screened by an information scientist. Potentially relevant reviews were screened by a reviewer on full text and checked by a second. Disagreements were resolved by discussion.

All systematic and rapid reviews meeting the inclusion criteria were further assessed and final decision for inclusion in this overview of evidence was based on recency of searches, overlap of relevant primary studies between reviews, and review quality (AMSTAR 2). This is to avoid including reviews which would have assessed a similar body of evidence.

Whilst there is a larger body of evidence from other respiratory viruses on effectiveness of RPE and surgical masks, only reviews focusing on evidence from the COVID-19 pandemic were considered for this paper. Some of the included reviews considered wider evidence from other coronaviruses and relevant results were reported, but this was not part of the search strategy which was focused on COVID-19 evidence.

A narrative summary is provided and summaries of each included review are presented in evidence tables at the end of this document. Conclusions were drawn based on the evidence presented and informed by discussions and expertise of the Respiratory Evidence Panel. Knowledge gaps were identified and summarised.

Evidence identified

Search results

A total of 901 records were identified by database searches. After removal of duplicates, 737 records were screened by title and abstract. Of these, 64 articles were screened on full text for eligibility. An additional 27 records identified from searching COVID-19 review repositories were screened on full text. In total, 8 reviews met the inclusion criteria: 4 systematic reviews with meta-analyses (<u>38 to 41</u>), 2 living rapid systematic reviews (<u>25, 42</u>) and 2 rapid reviews (<u>7, 43</u>).

Of the 4 systematic reviews with meta-analyses, 2 included a limited number of studies conducted in healthcare settings during the COVID-19 pandemic (one study in one review (41) and 3 in the other review (40)) and did not conduct meta-analyses or sub-group analyses for SARS-CoV-2 only (SARS-CoV-2 results pooled with other coronaviruses studies). These were therefore excluded from this overview of evidence.

The 2 living rapid systematic reviews were both from Chou and others, one reporting on effectiveness of masks against respiratory virus infections, including SARS-CoV-2, in both healthcare and community settings (last update: update 7, search to 2 December 2021) (<u>42</u>, <u>44</u>) and one on epidemiology of and risk factors for coronavirus infection in healthcare workers (last update: update: update 10, search to 24 October 2021) (<u>25</u>, <u>26</u>). As the living review on mask effectiveness had the most recent search and the review on healthcare workers had no unique relevant studies, it was agreed to only consider the living review on masks.

The 2 rapid reviews ($\underline{7}$, $\underline{43}$), not peer-reviewed, were both conducted to inform guidance. They were considered relevant and sufficiently unique for inclusion.

In total, 5 reviews were extracted into an evidence table and summarised ($\underline{7}$, $\underline{38}$, $\underline{39}$, $\underline{43}$, $\underline{44}$). Note that the quality of the reviews was not taken into account when deciding on which reviews to include as the overlap of primary studies and relevance of the analyses conducted (for the reviews with meta-analyses) provided clear arguments for which review to include.

The flow chart outlining the review selection process is represented in Figure 1, below.

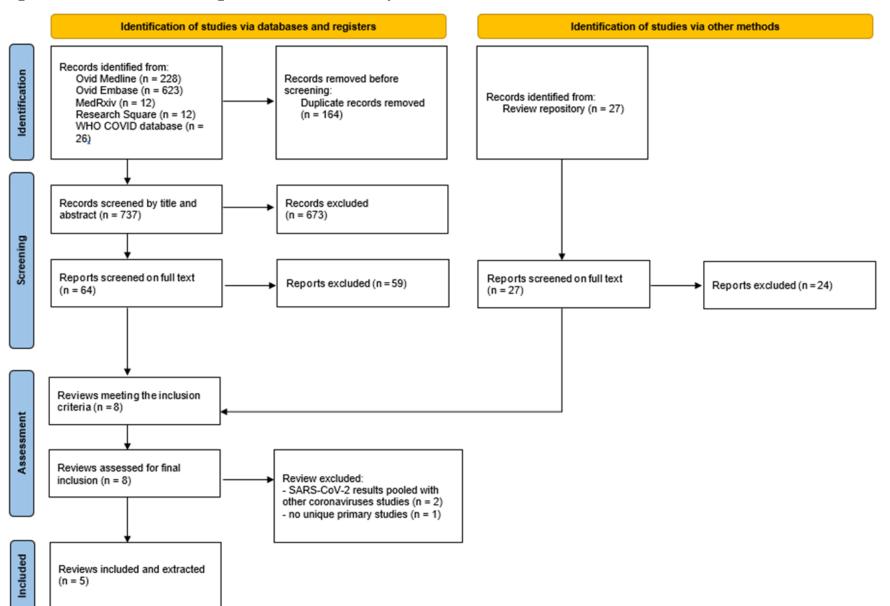


Figure 1. Flow chart outlining the review selection process

Accessible text version of Figure 1

A flow chart showing the flow of studies through this review, 5 studies identified from databases and registers and 3 studies identified via other methods.

From identification of studies via databases and registers, records identified from databases:

- Ovid Medline (n=228)
- Ovid Embase (n=623)
- medRxiv (n=12)
- Research Square (n=12)
- WHO COVID database (n=26)

From these, records removed before screening:

• duplicate records removed (n=164)

n=737 records screened, of which n=673 were excluded.

n=64 reports screened on full text, of which n=59 were excluded.

n=27 records identified from identification of studies via other methods:

• review repository (n=27)

n=27 reports screened on full text, of which n=24 were excluded

In total, n=8 reviews met the inclusion criteria, and all were assessed for final inclusion. Of these, 3 were excluded:

- SARS-CoV-2 results pooled with other coronaviruses studies (n=2)
- No unique primary studies (n=1)

n=5 reviews included and extracted in this review.

Included reviews

The systematic review with meta-analysis with the most recent search date (up to 14 June 2021) was conducted by Kunstler and others (<u>39</u>) and rated low for quality (downgraded due to the presence of multiple non-critical weaknesses). The objective of this review was to assess the comparative effectiveness of respirators and surgical masks in preventing SARS-CoV-2 infections in healthcare workers, as well as the likelihood of experiencing adverse events, considering peer-reviewed and preprint evidence from comparative epidemiological studies (experimental and observational). Pairwise meta-analysis was conducted (random effects model using the Mantel-Haenszel method) to calculate odds ratios (OR) but the certainty of the overall body of evidence was not reported. Twenty-one studies were included, of which one was a randomised control trial (RCT).

The second systematic review with meta-analysis was conducted by Kim and others (search to 5 February 2021) (<u>38</u>) and rated moderate for quality (due to the presence of more than one non-critical weakness). The objective of this review was to compare the effectiveness of N95 respirators, surgical masks, face coverings and personal protective equipment against respiratory virus infections, considering evidence from both healthcare and community settings and focusing on the use of mask as PPE, that is, as wearer protection. RCTs, cluster RCTs, cohort studies, case control studies and cross-sectional studies were considered for inclusion, whether they were peer-reviewed or preprints. Network and pairwise meta-analyses were conducted (random effects model using the inverse variance method) and OR were calculated, and the certainty of the evidence was assessed using the GRADE framework.

For the network meta-analyses, the hierarchy of mask type was ranked using the surface under the cumulative ranking curve value (SUCRA). In total, 35 studies were included in the metaanalyses (27 from healthcare settings), of which 10 were studies conducted during the COVID-19 pandemic (8 in healthcare settings). A number of comparisons and sub-group analyses were conducted, including for SARS-CoV-2 only. However, the results for the comparisons respirators versus surgical masks were only reported in the supplementary material, and less information was provided for these comparisons than for the ones comparing each type of mask versus control which were discussed in the main text (authors were contacted for more information but did not respond). Note that this review had been identified as a preprint (<u>45</u>) in the overview of evidence conducted for the respiratory evidence panel in 2021 (<u>2</u>), but had not been formally included due to missing information (supplementary material was not available). The version included here is the peer-reviewed version, which includes the information that was previously missing, and an updated search.

The living rapid review by Chou and others (<u>42</u>, <u>44</u>, <u>46 to 51</u>) aimed at assessing the effectiveness of face coverings (N95 respirators, surgical masks and non-medical masks) for preventing respiratory virus infection, including SARS-CoV-2. The search for the last update (update 7) was conducted on 2 December 2021. This review, rated moderate for quality due to the presence of more than one non-critical weakness, assessed evidence from both healthcare

and community settings from peer-reviewed and preprint evidence from randomised trials and observational studies (cohort, case-control and cross-sectional). Twenty-one studies from the COVID-19 pandemic were included, of which 11 were from healthcare settings. The strength of the evidence was graded as high, moderate, low and insufficient. Note that this living review was included in the overview of evidence conducted for the respiratory evidence panel in 2021 ($\underline{2}$), although the most recent update at that time was update 5 (search to 2 February 2021).

A rapid review conducted by Alberta Health Service in Canada to inform masking guidance for healthcare workers was identified (search to 29 June 2021) (<u>43</u>). This rapid review was rated critically low for quality, due to the lack of risk of bias assessment of the included studies and further downgraded due to multiple non-critical weaknesses. Seventeen studies from the COVID-19 pandemic were included, although only 10 were primary studies (the remaining were mainly review-level evidence).

A living rapid review of the literature conducted by ARHAI Scotland to inform IPC guidance for prevention and management of COVID-19 in healthcare settings was included (search to 4 April 2022) (7). This rapid review was rated critically low for quality due to the lack of risk of bias assessment of the included studies and further downgraded due to multiple non-critical weaknesses. This review lacks systematic methods (search strategy provided, but no information on number of studies included and no risk of bias assessment), although it was deemed relevant for this overview as it included evidence published until the 4 April 2022.

A summary of the findings is presented in <u>Table 1</u>, below, and full data extraction in <u>Table 2</u> and <u>Table 3</u> at the end of this document. The overlap of primary studies between included reviews as well as the main characteristics of the primary studies (objective, setting, study design and study period) can be found in <u>Annexe D</u>.

Results

Evidence from the overview of evidence conducted in 2021

The conclusion from the previous overview of evidence (search to 28 April 2021) was that all type of face coverings were, to some extent, effective in reducing transmission of SARS-CoV-2 in both healthcare and community settings. However, the evidence available on effectiveness of respirators and surgical masks to reduce SARS-CoV-2 infection in healthcare settings was limited. Due to this lack of evidence, Chou and others (50) and Kim and others (preprint version) (45) had assessed the evidence on SARS-CoV-2 together with the evidence from other coronaviruses outbreaks. Tian and others (52) did conduct sub-group analyses for SARS-CoV-2 only, but only 3 studies were included for the comparison of N95 respirators versus no N95 respirator (OR 0.08; 95% CI 0.01 to 0.65) and only one study for surgical masks versus no surgical masks (OR 0.02; 95% CI 0.00 to 0.37).

The conclusion from the 2021 overview of evidence was that N95 respirators may be more effective than surgical masks in reducing infection risk in healthcare settings, but that this was mainly based on epidemiological results from respiratory viruses other than SARS-CoV-2, usually of low or very low certainty, and was accordingly rated as low confidence by the Panel.

The only available randomised-controlled trial evidence with a high GRADE rating were studies on influenza, which showed no difference in transmission risk by mask type ($\underline{2}$, $\underline{3}$). However, due to differences in transmission dynamics between influenza and SARS-CoV-2 ($\underline{53}$) but also to potential differences in adherence between pandemic settings and seasonal influenza, it was agreed by the Panel that influenza results would not be considered in this update.

New evidence: systematic reviews with metaanalyses (Table 2)

The systematic review with meta-analyses conducted by Kunstler and others (search to 14 June 2021) identified 12 studies reporting on SARS-CoV-2 infection rates in healthcare workers wearing respirators compared with those wearing surgical masks (39). Infection rates were similar between healthcare workers wearing respirators (9.0%) and those wearing surgical masks (9.5%) and the odd ratio comparing respirators and surgical masks was not statistically significant:

respirators versus surgical masks: OR 0.85; 95% CI 0.72 to 1.01, p = 0.08: l² = 60% (12 studies; SARS-CoV-2)

The included studies were deemed to be at high risk of bias and, in the absence of large, randomised trials, the review authors concluded that the evidence was insufficient to draw a firm conclusion ($\underline{39}$).

Kunstler and others also found that healthcare workers reported more headaches, respiratory distress or shortness of breath, facial itching irritation and pressure-related injuries when wearing respirators compared to surgical masks, but that there were no differences for sweating, attention deficit or disorders, or erythema, see results in <u>Table 2</u> (<u>39</u>). However, potential impact of these adverse events on compliance and on effectiveness of respirators was not assessed.

The systematic review with meta-analysis conducted by Kim and others (search to 5 February 2021) (<u>38</u>) found that N95 respirators or equivalent were likely to be more effective than surgical or medical masks in reducing SARS-CoV-2 infections:

N95 respirators (or equivalent) versus surgical or medical masks: OR 0.43; 95% CI 0.24 to 0.77 (number of comparisons not reported; SARS-CoV-2)

Whilst this comparison aimed to include evidence from both healthcare and community settings, in practice the 2 studies with direct comparisons were both from healthcare settings. The total number of direct and indirect comparisons and which studies were used was not reported, although 75% of the comparisons were direct and, based on our assessment, it is likely that the 2 studies used for direct comparisons were included in the meta-analysis conducted by Kunstler and others reported above. These 2 studies were rated as being at moderate risk of bias by Kim and others but at high risk of bias by Kunstler and others. However, as Kunstler and others conducted pairwise meta-analyses, they would not have included the indirect comparisons considered by Kim and others.

Subgroup analyses specific to healthcare settings were also conducted, although it included evidence from all coronavirus outbreaks (SARS, MERS and SARS-CoV-2) (<u>38</u>). The results were similar, suggesting that N95 respirators may offer better protection against infections than surgical masks:

N95 respirators (or equivalent) versus surgical or medical masks: OR 0.42; 95% CI 0.27 to 0.65 (number of comparisons not reported; SARS, MERS, SARS-CoV-2)

For the sub-group analyses conducted for all coronaviruses in healthcare settings, Kim and others specified that they used 'usual care' data (that is, not when doing AGPs) when studies had reported results for 'usual care' and AGPs separately (<u>38</u>). However, the proportion of data from 'usual care' was not provided. Separated sub-group analyses were conducted for AGPs, showing that the difference between N95 respirators and surgical masks was not statistically significant although the value of the odds ratio (0.40) combined with the large confidence interval suggests it may be due to a lack of statistical power rather than a lack of effect:

N95 respirators (or equivalent) versus surgical or medical masks: OR 0.40; 95% CI 0.13 to 1.22 (number of comparisons not reported; SARS, MERS, SARS-CoV-2; AGPs)

These comparisons (respirators versus surgical masks) were only reported in the supplementary material and corresponding grading of the certainty of the results were not provided. However, all results based on SARS-CoV-2 only as well as those based on all coronavirus infections were deemed to be at risk of publication bias and had been graded as being of low or very low certainty. It is therefore expected that similar grading would have been achieved for these comparisons. In addition, it should be noted that whilst risk of bias in the included studies was overall considered to be low or moderate, the risk of bias in the SARS-CoV-2 studies was judged as being moderate to serious.

In all 3 sets of comparisons (community and healthcare settings for SARS-CoV-2 only, usual care in healthcare settings for all coronaviruses infections, AGPs in healthcare settings for all coronaviruses infections), N95 respirators or equivalent were found to offer greater protection against infections than control whilst surgical masks may not be more effective against infection than control – see results in <u>Table 1</u>. 'Control' corresponds to no mask or very low frequency of use (mask type not specified). For all 3 sets of comparisons, the hierarchy of mask type based on the SUCRA ranking order was N95 respirators (or equivalent) first, followed by surgical or medical masks (<u>38</u>).

The results reported here are based on a network meta-analysis; results obtained by pairwise meta-analysis were similar (see <u>Table 2</u>) (<u>38</u>).

New evidence: rapid reviews with narrative synthesis (Table 3)

Chou and others (search to 2 December 2021) identified 5 observational studies reporting on effectiveness of N95 respirators versus surgical masks in healthcare settings (all from moderate to high risk settings) but concluded that the strength of the evidence available was insufficient to draw conclusions due to limitations in methodology, inconsistency across studies and lack of precision (44). Similarly, the strength of evidence on N95 respirators versus no masks as well as on surgical masks versus no masks was insufficient to draw conclusions.

Considering evidence from other respiratory viruses, Chou and others concluded that in healthcare settings N95 respirators may be more effective than surgical masks in reducing infection risks for SARS and MERS (5 observational studies; low strength of evidence). N95 respirators or equivalent were found to offer greater protection than no masks against SARS or MERS infections (4 observational studies, low strength of evidence). For surgical masks versus no mask, Chou and others found that the strength of evidence was insufficient to draw conclusions (6 observational studies on SARS and MERS) (<u>44</u>).

The rapid review conducted by Alberta Health Service (search to 29 June 2021) found that the peer-reviewed evidence available was insufficient to determine whether N95 respirators offer better protection than surgical masks against SARS-CoV-2 infection for healthcare workers outside of AGPs (43). This result was deemed as being very uncertain by the review authors and based on low to very low study quality. For healthcare workers with prolonged continuous contact with COVID-19 patients, evidence from self-reported surveys suggested that N95 may offer better protection than surgical masks, although other factors such as non-healthcare exposures and behaviours may have impacted the results. Overall, the body of evidence was judged as being of low quality by the review authors, including due to lack of assessment of other factors such as community incidence, PPE supply or mask fit. A lack of consistency in methodology between studies was also noted.

The rapid review by ARHAI Scotland (search to 4 April 2022) provides a narrative summary from a range of study designs on SARS-CoV-2 and other respiratory viruses to assess the evidence on respirators and surgical masks as source control and as wearer protection. No epidemiological evidence was identified on source control (mainly experiments looking at efficacy) and the evidence included only reported on surgical masks. The body of evidence identified on wearer protection was larger and included epidemiological evidence.

However, the evidence identified on SARS-CoV-2 was deemed to be at high risk of bias by the review authors who noted that other factors not considered by the study authors may have impacted the results, including exposure outside healthcare settings, lack of information on other factors that may have impacted on transmission risk (including infectiousness of the patient and lack of compliance), confounding resulting from PPE provision, variations in testing protocol, other IPC measures in place, and so on. As a result, the review authors concluded that there was no clear evidence from epidemiological studies that respirators offered more protection against coronavirus infection than surgical masks and recommended that FFP3 respirators should be used when performing AGPs or when risk of transmission was deemed unacceptable after application of mitigation measures and risk assessment (7). Otherwise, it is recommended that healthcare workers should wear type IIR FRSM.

Review	Respirators versus surgical masks	Respirators versus no masks or control	Surgical masks versus no masks or control	Ad
Alberta Health Services (<u>43</u>) (Search: 29 June 2021; AMSTAR 2: critically low)	 insufficient evidence to determine outside AGPs; low to very low study quality 			
ARHAI Scotland (7) (Search: 4 April 2022; AMSTAR 2: critically low)	 no clear evidence that respirators offer more protection against coronaviruses; evidence on SARS-CoV-2 at high risk of bias 			• 0 0 5
Chou and others Living review (8 versions): the original (<u>42</u>) and 7 updates (<u>44</u> , <u>46 to 51</u>) (Most recent search: 2 December 2021; AMSTAR 2: moderate)	 SARS-CoV-2: strength of evidence insufficient to draw conclusions (5 observational studies) SARS and MERS: N95 may offer greater protection than surgical mask (5 observational studies, low strength of evidence) 	 SARS-CoV-2: strength of evidence insufficient to draw conclusion (2 observational studies) SARS and MERS: N95 may offer greater protection than no masks (4 observational studies, low strength of evidence) 	 SARS-CoV-2: strength of evidence insufficient to draw conclusion (3 observational studies) SARS and MERS: strength of evidence insufficient to draw conclusion (6 observational studies) 	• e ł (
Kim and others (<u>38</u>) (Search: 5 February 2021; AMSTAR 2: moderate) (Only results from network meta-analysis reported)	 SARS-CoV-2: OR 0.43; 95% CI 0.24 to 0.77 (2 studies [B]; community and healthcare settings) coronaviruses: OR 0.42; 95% CI 0.27 to 0.65 (6 studies [B]; healthcare settings) coronaviruses: OR 0.40; 95% CI 0.13 to 1.22 (2 studies [B]; AGPs) 	 SARS-CoV-2: OR 0.30; 95% CI 0.17 to 0.55; p <0.001; GRADE: low, not serious risk of bias (4 studies – 6 comparisons; community and healthcare settings) coronaviruses: OR 0.29; 95% CI 0.19 to 0.44; p <0.001; GRADE: low, not serious risk of bias (8 studies – 14 comparisons; healthcare settings; usual care) coronaviruses: OR 0.36; 95% CI 0.15 to 0.86 (3 studies [B]; AGPs) 	 SARS-CoV-2: OR 0.71; 95% CI 0.44 to 1.14; p =0.156); GRADE: very low, serious risk of bias (5 studies – 7 comparisons; community and healthcare settings) coronaviruses: OR 0.69; 95% CI 0.44 to 1.07; p =0.097; GRADE: very low, serious risk of bias (6 studies – 12 comparisons; healthcare settings; usual care) coronaviruses: OR 0.88; 95% CI 0.27 to 2.84 (2 studies [B]; AGPs) 	•
Kunstler and others (<u>39</u>) (Search: 14 June 2021; AMSTAR 2: low)	 OR 0.85; 95% CI 0.72 to 1.01 (12 studies; healthcare settings; SARS- CoV-2, most studies at high risk of bias) 			• ł r t

Table 1. Summary table – effectiveness c	of respirators and surgical masks against SA	ARS-CoV-2 in healthcare settings [A]
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Notes

[A] Blank cells: no information available; risk of bias and certainty of evidence reported when available; meta-analyses results: p-value, and number of studies and of comparisons reported when available

[B] Results only discussed in the supplementary material and numbers of comparisons (direct and indirect) and GRADE assessment not reported; the number of studies with direct comparison was estimated from data reported in the forest plot figures and the estimate is more uncertain for comparisons between masks than for those with controls, as the type of mask being compared is not specified (that is, surgical or non-medical mask).

dditional considerations
conclusions focused on guidelines for respirators and surgical mask use in healthcare settings
evidence was from moderate or high-risk healthcare settings (inpatients)
publication bias for coronavirus infections was considered serious results exhibited global inconsistency
healthcare workers wearing respirators might be more likely to experience more adverse effects than with surgical masks

Conclusions

Five systematic or rapid reviews reporting on the effectiveness of respirators compared to surgical masks to reduce SARS-CoV-2 transmission in healthcare settings were included in this overview of evidence. Overall, the studies assessed in the reviews were judged as being at high risk of bias and 3 reviews with narrative synthesis found that the strength of the evidence was insufficient to draw conclusions, especially outside settings considered as higher risk such as those where AGPs are undertaken. Evidence from one review with meta-analysis of 12 studies (mostly at high risk of bias) found no statistical differences between respirators and surgical masks. Another review with network meta-analysis found that respirators were more effective than surgical masks in reducing SARS-CoV-2 infections in healthcare workers, but this was based on a smaller number of studies (2 studies with direct comparison, number of indirect comparisons not reported; low or very low certainty). Evidence from SARS-CoV-2 combined with other coronaviruses (MERS and SARS) suggests that respirators may offer better protection against coronavirus infections in healthcare workers than surgical masks (2 reviews; low or very low strength of evidence). Note that the focus of this overview was on evidence from the COVID-19 pandemic and that whilst some of the included reviews considered wider evidence from other coronaviruses, this was not part of the search strategy.

Two of the included reviews also reported on the effectiveness of respirators versus no respirators and surgical masks versus no masks in reducing infection in healthcare workers. The evidence from the COVID-19 pandemic was deemed to be at serious risk of bias and one review reported that the strength of evidence was insufficient to draw conclusions. The second review, with network meta-analyses, found that respirators such as N95 respirators may offer greater protection against SARS-CoV-2 infection compared with no respirators (low strength of evidence), but that there may be no difference between surgical masks versus no masks (very low strength of evidence). Evidence from SARS-CoV-2 combined with other coronaviruses (MERS and SARS) suggests that respirators are more effective than no respirators to protect against coronavirus infections (2 reviews, low strength of evidence). The evidence for surgical mask versus control was not conclusive (due to lack of statistical significance or to insufficient strength of evidence). Note that the focus of this overview was on evidence from the COVID-19 pandemic and that whilst some of the included reviews considered wider evidence from other coronaviruses, this was not part of the search strategy.

Most of the COVID-19 evidence on healthcare settings is from acute hospital settings, which limit the applicability of these results to outpatient settings. In addition, the available evidence does not allow comparison of the effectiveness of respirators and surgical masks for different healthcare worker roles or situations, for example AGPs versus no AGPs (note that AGPs definition may vary between studies and was not always specified).

Whilst the body of evidence has grown since the overview of evidence conducted in 2021, the epidemiological evidence from the COVID-19 pandemic remains limited due to methodological limitations, lack of precision and differences between studies. Many primary studies did not take

into account in their analyses factors that may have impacted the results, including whether participants may have been infected in other settings (such as household or social), whether masks or respirators were correctly worn (including fit and consistency of use) and differences in IPC practice. As a result, these factors were not taken into account in the meta-analyses. Some reviews considered the strength of evidence to be insufficient to draw conclusions whilst other reviews conducted meta-analyses using a similar body of evidence; results from the meta-analyses should therefore be taken with caution. The evidence, albeit of low or very low certainty and of mixed findings, suggests that N95 respirators may offer a degree of increased protection against coronavirus infections in healthcare workers compared to surgical masks, but highlights the need for well-designed epidemiological studies to assess the effectiveness of respirators versus surgical masks in healthcare settings remains.

The Panel concluded, based on the evidence assessed, combined with their expert knowledge and experience, that the following statement, made by the Panel in 2021, including its confidence rating, remains valid:

"Epidemiological evidence (usually of low or very low certainty) from SARS-CoV-2 and other coronaviruses suggests that, in healthcare settings, N95 respirators (or equivalent) may be more effective than surgical masks in reducing the risk of infection in the mask wearer (low confidence)."

Limitations

As this overview of the evidence is based on review-level evidence, it is dependent on the quality and reporting of those reviews. Only 3 out of the 5 reviews had used a satisfactory technique to assess risk of bias in included studies, and only 2 had assessed the certainty of the overall body of evidence. It should however be noted that these reviews were conducted with the aim to provide timely evidence in the context of a pandemic caused by a novel pathogen. In particular, 2 of the 5 reviews were non-peer-reviewed rapid reviews conducted at pace to inform guidance and their methodological shortcuts were fully acknowledged by the review authors.

Some of the primary studies were preprinted manuscripts. Preprints have not been peer reviewed nor subject to publishing standards and may be subject to change.

The evidence was heterogeneous in terms of methods, settings and study designs. Additionally, there was often not enough information provided in relation to settings (such as inpatient or emergency department versus outpatients, or AGPs versus no AGP), healthcare professional role (such as patient-facing role or not) and type of respirator or surgical mask used. The evidence assessed referred to 'N95 respirators' or 'N95 respirators and equivalent' whilst in the UK, if risk assessment deems that respiratory protective equipment is needed, this should be a FFP3 respirator.

Most of the primary studies included in the reviews were at risk of bias due to study design considerations (observational studies) and lack of adjustment for potential confounding factors.

This paper mainly relies on evidence from the COVID-19 pandemic and whilst some of the included reviews considered wider evidence from other coronaviruses, this was not part of the search strategy.

Knowledge gaps

More research is needed to assess the effectiveness of respirators versus surgical masks in reducing SARS-CoV-2 infections in healthcare workers in real-world settings, particularly from well-designed epidemiological studies. This knowledge gap was already identified in 2021 and remains a priority.

In particular, there is a need to assess the relative effectiveness of respirators and surgical masks in healthcare settings others than acute hospital settings. More research is needed to understand infection risks and effectiveness of respirators versus surgical masks in function of roles and settings, including:

- patient facing versus not patient facing role
- AGPs versus no AGPs
- inpatient or emergency department versus outpatient areas

There is also a need to assess mask and respirator effectiveness as source control as, whilst PPE have been designed for wearer protection, they have been increasingly used as source control during the COVID-19 pandemic.

Studies reporting on SARS-CoV-2 remain at high risk of bias and provide low or very low certainty evidence. There is a need for higher quality, larger and better conducted epidemiological studies. For example, researchers conducting observational studies should consider whether factors other than the intervention may impact the results, for example differences in wider IPC practice, and should take them into account in their analyses. In the context of healthcare settings, information on healthcare worker roles and types of settings should be reported to allow for more detailed assessment of effectiveness of respirators or surgical masks by role and settings. Behavioural factors and aspects such as mask fit should also be reported.

While this was not the focus of this review, there is a need to assess the extent of potential adverse effects of RPE use (such as self-contamination, communication issues, dehydration and facial sores) in order to understand their potential impact on effectiveness of RPE in real-world settings, and the degree to which, if any, these play a role in clinical practice.

Evidence tables

Table 2. Systematic reviews with meta-analysis

Reference	Review question	Methods and evidence identified	Main findings
Kim and others, 2022 (<u>38</u>) 'Comparative effectiveness of N95, surgical or medical, and non-medical facemasks in protection against respiratory virus infection: A systematic review and network meta- analysis' AMSTAR 2 rating: moderate (due to the presence of more than one non-critical weakness)	Review question: what is the comparative effectiveness of N95 respirators, surgical or medical masks and non- medical masks used as PPE to prevent respiratory infections? Settings: healthcare and community settings Viruses: influenza, SARS, MERS and SARS-CoV-2 Mask types: N95 respirators or equivalent, surgical masks, medical masks (such as cloth or cotton)	 Search dates: inception up to 5 February 2021 Data sources: PubMed, Google Scholar and medRxiv databases; manual search of references from review articles Inclusion criteria study design: RCTs, cluster RCTs, prospective and retrospective cohort studies, case control studies and crosssectional studies intervention: adhered to face mask wearing (must have specified mask type) comparator: no or little mask wearing outcome: reduction in the risk of respiratory virus infection (must have presented outcomes individually for mask types) Studies included: total: 35 studies included in the final meta-analyses by settings: 8 studies in non-healthcare and 27 in healthcare settings by study design: 12 RCTs or cluster RCTs ad 23 observational studies 10 studies on SARS-CoV-2 (8 in healthcare settings; 1 RCT) Meta-analysis: network (NMA) and pairwise meta-analysis presenting odd ratios (ORs) and 95% confidence intervals (95% CI) using a frequentist framework and random effects model consistency between direct and indirect comparisons assessed (p-values < 0.05 represents lack of consistency), and neat heat plot done to visualise inconsistency matrix heterogeneity) and publication bias (funnel plots and Egger's test) also assessed hierarchy of mask type ranked using the surface under the cumulative ranking curve value (SUCRA) subgroup analysis for virus types, clinical settings and study design post-hoc analysis for usual healthcare setting versus aerosol-generating procedure (AGP) information on adjustment for potential confounders not reported 	 Wearing masks, regardless of type, as infection (community and healthcare s [OR (95% CI)] overall respiratory viral infection: 0 I² = 42%; 22 comparisons (GRADE bias) SARS-CoV-2: 0.49 (0.31 to 0.78), comparisons (GRADE: low, not se SARS and MERS: 0.30 (0.14 to 0. comparisons (GRADE: low, seriou) influenza: 0.71 (0.42 to 1.21), p = 0 (GRADE: moderate, not serious ris COVID-19 infections (community and Network meta-analysis: N95 versus surgical: 0.43 (0.24 to comparisons but total number of comparisons (GRADE: low, risk of surgical versus control: 0.71 (0.44 comparisons (GRADE: low, risk of surgical versus control: 0.71 (0.44 comparisons (GRADE: very low, riserious) non-medical versus control: 0.73 (2 comparisons (GRADE: very low, riserious) non-medical versus control: 0.73 (2 comparisons (GRADE: very low, riserious) non-medical versus control: 0.73 (2 comparisons (GRADE: very low, riserious) non-medical versus control: 0.73 (0.24 to comparisons (GRADE: very low, riserious) non-medical versus control: 0.73 (0.25 to non-medical versus control: 0.73 (0.26 to 0.95 versus surgical: 0.48 (0.25 to 0.95 versus surgical: 0.48 (0.25 to 0.95 versus control: 0.73 (0.43 to 0.75 versus control: 0.73 (0.45 to 0.75 versus control: 0.

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associated with reduced risk of
settings, pairwise meta-analysis)
0.50 (0.37 to 0.68), p <0.001,
DE: low, not serious risk of
 p = 0.003, l<sup>2</sup> = 48%; 8
erious risk of bias)
 0.63), p = 0.001, l<sup>2</sup> = 35%; 6
us risk of bias)
 0.208, I<sup>2</sup>= 30%; 8 comparisons
risk of bias)
nd healthcare settings) [OR (95% CI)]
o 0.77) (2 studies and ~75% direct
comparisons not reported [B])
0.55), p <0.001; 4 studies, 6
of bias and imprecision: not serious)
4 to 1.14), p = 0.156; 5 studies, 7
risk of bias and imprecision:
8 (0.25 to 2.14), p = 0.566; 2 studies,
v, risk of bias: not serious,
l indirect comparison: Q = 7.64, p-
 44.9%
RAs: N95, surgical, non-medical and
o 0.94) (2 studies)
0.66) (4 studies)
3 to 1.17) (5 studies)
8 (0.25 to 2.14) (2 studies)
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Reference Review question	Methods and evidence identified	Main findings
	 Risk of bias assessment: RoB2 for RCTs and ROBINS-I for observational studies in general, risk of bias considered low to moderate, except for the 10 SARS-CoV-2 studies (3 at serious risk of bias, moderate for 5, and could not be assessed for 2) Grading of evidence: certainty of evidence classified as high, moderate, low or very low using the GRADE approach inconsistency and imprecision were considered as not serious for all comparisons 'type of mask' versus control; publication bias was considered serious for all coronavirus infections (overall, MERS and SERS only, SARS-CoV-2 only), except overall community settings GRADE was assessed as being low or very low for all coronavirus infections Overlap between reviews [A]: 3 of the 8 studies conducted in healthcare settings during COVID-19 are unique to this review Notes on results: 'control' = no mask or very low frequencies; 'surgical masks' = medical or surgical masks; N95 = N95 respirators or equivalent; non-medical = non-medical masks studies = number of studies with direct comparisons 	 Coronavirus infections (SARS, MERS, usual care [OR (95% CI)] Network meta-analysis: N95 versus surgical: 0.42 (0.27 to 0 comparisons but total number of co N95 versus control: 0.29 (0.19 to 0. comparisons (GRADE: low, risk of I surgical versus control: 0.69 (0.44 t comparisons (GRADE: very low, riss serious) inconsistency between direct and ir value = 0.0061, heterogeneity: I² = Rank hierarchy according to SUCR Pairwise meta-analysis: N95 versus surgical: 0.46 (0.28 to 0 N95 versus control: 0.31 (0.20 to 0. surgical versus control: 0.73 (0.45 t Coronavirus infections (SARS, MERS, (healthcare settings) [OR (95% CI)] Network meta-analysis: N95 versus surgical: 0.40 (0.13 to 1 comparisons but total number of co N95 versus control: 0.36 (0.15 to 0. comparisons but total number of co N95 versus control: 0.36 (0.15 to 0. comparisons [B]) surgical versus control: 0.88 (0.27 t direct comparisons but total numbe no evidence of inconsistency betwee comparisons: Q = 0; p-value = 0.97 heterogeneity: I² = 53.7%; net heat number of studies available rank hierarchy according to SUCRA Pairwise meta-analysis: N95 versus surgical: 0.37 (0.12 to 1 N95 versus surgical: 0.37 (0.12 to 1 N95 versus control: 0.38 (0.16 to 0. surgical versus control: 0.85 (0.24 to 1

, COVID-19) in healthcare settings, 0.65) (6 studies and ~80% direct comparisons not reported [B]) 0.44), p <0.001; 8 studies, 14 f bias and imprecision: not serious) to 1.07), p = 0.097; 6 studies, 12 isk of bias and imprecision: indirect comparison: Q = 12.41; p-20.2% RAs: N95, surgical and control 0.76) (6 studies) 0.50) (8 studies) 5 to 1.18) (6 studies) 6, COVID-19) during AGPs 1.22) (2 studies and ~90% direct comparisons not reported [B]) 0.86) (3 studies, 100% direct ' to 2.84) (2 studies and ~80% per of comparisons not reported [B]) veen direct and indirect 9791; moderate to high at plot not done due to small RAs: N95, surgical and control 1.19) (2 studies)

0.92) (3 studies) 4 to 3.03) (2 studies)

e settings, [OR (95% CI)]

Reference	Review question	Methods and evidence identified	Main findings
			 surgical versus N95: 0.89 (0.75 to 1.06) (7 studies and ~100% direct comparisons but total number of comparisons not reported [B]) N95 versus control: 0.72 (0.31 to 1.69), p = 0.451; 2 studies, 9 comparisons (GRADE: moderate, risk of bias: not serious, imprecision: serious) surgical versus control: 0.65 (0.28 to 1.49), p = 0.309; 3 studies, 10 comparisons (GRADE: moderate, risk of bias: not serious, imprecision: serious) non-medical versus control: 1.29 (0.24 to 6.94, p= 0.767 (1 study, 1 comparison). GRADE: very low, risk of bias: not serious, imprecision: very serious no evidence of inconsistency between direct and indirect comparison: Q = 3.84; p-value = 0.1466, heterogeneity: I² = 0% rank hierarchy according to SUCRAs: surgical, N95, control and non-medical masks
Kunstler and others, 2022 (39) 'P2/N95 respirators and surgical masks to prevent SARS-CoV-2 infection: effectiveness and adverse effects' AMSTAR 2 rating: low (downgraded due to the presence of multiple non- critical weaknesses)	Review question: what are the differences in likelihood of SARS-CoV- 2 infection and adverse events (AEs) between health care workers using respirators and surgical masks? Settings: healthcare settings Viruses: SARS-CoV-2 Mask types: respirators and surgical masks	 Search dates: inception up to 14 June 2021 Data sources: PubMed, Cochrane COVID-19 Study Register, Europe PMC, Research Square and medRxiv. SARS-CoV-2 studies published before December 2020 identified in the living systematic review by Chou and others New South Wales Health COVID-19 Critical Intelligence Unit Daily Evidence Digest used as additional source Inclusion criteria: study design: comparative epidemiological studies (preprint or peer-reviewed) intervention: respirators (FFP2, N95, KN95, KF94, P2 or equivalent) comparator: surgical masks outcome: SARS-CoV-2 infection or AEs Studies included: 21 (1 RCT) in different countries (8 from the US) comparing surgical masks with N95 (16), KF94 or KF95 (1), FFP2 (3 – all reporting on AEs) or various (1) respirators in healthcare workers (HCWs) Meta-analysis: Pairwise meta-analysis; data (extracted as event counts, therefore not adjusted for confounding) pooled using the Mantel-Haenszel method and random effects to calculate ORs (95% CI). Erythema data pooled using SMD (SD) 	SARS-CoV-2 infection – respirators versus surgical masks (12 studies) • similar rate of infection in HCWs wearing respirators (1,398 out of 15,598 = 8.96%) and those wearing surgical masks (1,698 out of 17,947 = 9.46%) • respirators versus surgical masks: OR 0.85; 95% CI 0.72 to 1.01; p = 0.08 • heterogeneity l ² = 60% Adverse events (AEs) – respirators versus surgical masks (8 studies) • de novo headaches: respirator = 99 out of 159 (62.3%), surgical mask = 156 out of 314 (49.7%); OR 2.62; 95% CI 1.18 to 5.81; p = 0.02, l ² = 67% (3 studies) • respiratory distress or shortness of breath: respirator = 83 out of 148 (56.1%), surgical mask = 52 out of 217 (24.0%); OR 4.21; 95% CI 1.46 to 12.13; p = 0.01, l ² = 78% (3 studies) • facial itching or irritation: respirator = 66 out of 256 (25.8%), surgical mask = 51 out of 256 (19.9%); OR 1.80; 95% CI 1.03 to 3.14; p = 0.04, l ² = 0% (3 studies) • sweating: respirator = 1,263 out of 1,485 (85.1%), surgical mask = 93 out of 494 (18.8%); OR 6.80; 95% CI 0.55 to 84.68; p = 0.14, l ² = 98% (3 studies) • pressure-related injuries: respirator = 878 out of 1,523 (57.6%), surgical mask = 94 out of 532 (17.7%); OR 4.39; 95% CI 2.37 to 8.15; p < 0.001, l ² = 52% (3 studies) • attention deficit or disorders: respirator = 33 out of 76 (43.4%), surgical mask = 40 out of 145 (27.6%); OR 2.59; 95% CI 0.62 to 10.87; p = 0.19, l ² = 77% (2 studies)

Reference R	Review question	Methods and evidence identified	Main findings
		 12 studies included for rate of infection; 8 for AEs Risk of bias assessment: ROBINS-I for non-randomised studies, RoB-2 for randomised studies 18 out of 21 studies at high risk of bias Grading of evidence: not reported Overlap between reviews [A]: 6 of the 12 studies conducted in healthcare settings during COVID-19 and included in the meta-analysis are unique to this review 	 degree of erythema: SMD -0.29; 9 studies)

Notes

[A] Overlap between studies was done considering only the studies conducted in healthcare settings during the COVID-19 pandemic; laboratory studies, studies conducted in community settings and evidence from viruses other than SARS-CoV-2 were not included (See <u>Annexe D</u>).

[B] Results were only discussed in the supplementary material and numbers of comparisons (direct and indirect) and GRADE assessment were not reported. The number of studies (with direct comparisons) included was estimated from data reported in the forest plot figures and the estimate is more uncertain for comparisons between masks than for those with controls, as the type of mask being compared is not specified.

95% CI -0.82 to 0.25; I² = 0% (2

Table 3. Systematic or rapid reviews without meta-analysis

Reference	Review question	Methods and evidence identified	Main findings
Alberta Health Services, 2021 (43) 'COVID-19 Scientific Advisory Group Rapid Evidence Report; Interim Update: Masking Guidance for Healthcare Workers' AMSTAR 2 rating: critically low (due to lack of satisfactory technique to assess risk of bias in included studies and downgraded further due to multiple non-critical weaknesses)	Review questions: 1. Is there a clinically important difference in occupational infection with SARS-CoV-2 in healthcare workers using particulate respirators versus surgical masks, based on published or local data? 2. Is there evidence that guidance for respiratory protection should be different for variants of concern, particularly Delta? 3. Have any jurisdictions changed their guidance around PPE use for healthcare workers as a result of increasing rates of variants of concern? (Evidence relating to research question 3 not extracted here) Settings: healthcare Viruses: SARS-CoV-2 Mask types: N95 and surgical masks	 Search dates: 2020 up to 29 June 2021 Database sources: Ovid Medline, Embase, Australian National COVID-19 Clinical Evidence Taskforce Living Guidelines, WHO Publications, WHO COVID-19 database, CADTH, CPG Infobase, US Centers for Disease Control and Prevention (CDC), COVID-19 Primer, medRxiv, bioRxiv, National Collaborating Centre for Methods and Tools (NCCMT), NICE, Penn Medicine COVID-19 Guidance Summaries, Public Health England COVID-19 Rapid Reviews, Google and Google Scholar Inclusion criteria study design: systematic reviews, RCTs, observational studies, and case series were included. Descriptive articles, in vitro, nonhuman, narrative reviews, commentaries, editorials and case reports were excluded exposure: article must specifically describe PPE used and PPE includes masks outcome: COVID-19 infection or positivity; non-epidemiological outcomes were excluded comparator: study must be comparative quality: article must be from a credible source, have a clear research question, and present data appropriate to address the research question Studies included: 27 studies included, of which 17 addressed research questions 1 and 2: one umbrella review one systematic review and metaanalysis 2 rapid reviews and 1 rapid scoping review one cohort one cohort one case-control 5 cross-sectional 	 Research question 1: peer-reviewed evidence is insufficient respirators offer better protection that against SARS-CoV-2 infection in heaperforming AGPs (very uncertain; low) there is some evidence from self-represpirators may be more protective for prolonged continuous contact with C exposures and behaviours are not fueling in donning and doffin SARS-CoV-2 infection but mask type quality) body of evidence is of low quality: lint factors such as community incidence lack of consistency in methodology to intensity of exposure and assessment Research question 2: clinical evidence is extremely limited no published evidence on the Deltage grey literature recommending chang clinical or epidemiological evidence, filtration efficiency and precautions of there is no evidence that current PPE not mandated) are not sufficient to produce that the review used interchangeal medical, surgical and procedural material and procedural procedural procedural procedural procedural procedural procedural procedural procedural pro

ient to determine that N95 han medical or surgical masks nealthcare workers who are not low to very low study quality) eported survey data that N95 e for healthcare workers with COVID-19 patients (but other fully assessed by these studies) fing of PPE may be associated with vpe may not be (one study; low

limited assessment of external nce, PPE supply or mask fit. y between studies, particularly in nent methods

ed

a variant was identified nges to PPE policy is not based on e, but on expert opinion around s due to uncertainty in the evidence PE requirements (N95 respirators protect healthcare workers in

eably: nasks

Reference	Review question	Methods and evidence identified	Main findings
ARHAI Scotland, 2022 (<u>7</u>)	Review question: to examine the	 3 case series one briefing note one jurisdictional scan Overlap between reviews [A]: 8 of the 11 primary studies conducted in healthcare settings during COVID-19 were unique to this review Search dates: 2000 up to 4 April 2022 	Evidence assessed on source control:
 'Rapid review of the literature: Assessing the infection prevention and control measures for the prevention and management of COVID-19 in health and care settings' Living review: 25 versions published (version 25 is the final version) AMSTAR 2 rating: critically low (due to lack of satisfactory technique to assess risk of bias in included studies and downgraded further to multiple non-critical weaknesses) 	transmission routes of COVID-19 as well as the personal protective equipment requirements to inform the infection prevention and control measures required for the prevention and management of COVID-19 in health and care settings Settings: healthcare Viruses: mainly SARS-CoV-2, but evidence from other respiratory viruses also discussed Mask types: N95 and surgical masks (type IIR FRSM and standard types I and II)	 Databa sources: Medline, Embase, medRxiv, grey literature searching Inclusion criteria: inclusion criteria kept broad study design: any study design (including reviews), animal studies excluded Studies included: information not available (no PRISMA) Overlap between reviews [A]: based on the references cited in the narrative summary: 3 of the 5 primary studies conducted in healthcare settings during COVID-19 were unique to this review 	 no epidemiological evidence, mainly the proportion of respiratory particles suggest that surgical masks reduced particles released but that leak throug in efficiency only one study from the COVID-19 pasampling showing no virus detected wearing surgical masks) no studies reporting on efficacy or efficacy or efficacion and that respirators with exhalation valve control and that respirators in genera air (wearer protection) rather than extended that respirators or encoded that there was no offer more protection than surgical masks of bias and are insuffir respirators offer better protection that authors highlighted that factors not ta studies may have impacted the resul (information usually not provided), pothealthcare settings, lack of information impacted on transmission risk (include confounding resulting from PPE provand other IPC measures in place, an not reported here – results from review guidance

ly based on experiments measuring es passing through a mask; results ed the quantity of respiratory ough sides could led to a reduction

pandemic included (environmental d around 2 hospitalised patients

efficiency of N95 respirators or included, although the authors noted ves should not be used as source eral are designed to filter incoming expelled air (source control) ion:

ource control, and includes mainly observational), but the no clear evidence that respirators masks against coronaviruses ary studies show that these studies ufficient to conclude whether nan surgical masks; the review taken into account in the primary sults, including lack of compliance possibility of exposure outside of ation on other factors that may have uding infectiousness of the patient), ovision, variations in testing protocol and so on

views and discussion of existing

Reference	Review question	Methods and evidence identified	Main findings
			 type IIR FRSM mask should be worn blood, body fluids, secretions or exc the nose or mouth healthcare workers across all pathw throughout their shift non-medical staff and healthcare wo clinical areas should wear a type IIR apart in certain circumstances (such inpatients across all pathways shoul time if it does not compromise care at FFP3 respirators are required for AC pathway use of FFP3 respirators across the u clinical areas used for the respirator risk of transmission despite IPC meat a non-valved as opposed to valved u situations where sterility is required sterile site where there are shortages of FFP3 u respirators should be considered patients and their visitors entering he face covering visitors entering care homes should resident's rooms, mask wearing can visiting guidance
Chou and others, 2022 Living review (8 versions): the original (42) and 7 updates (44, 46 to 51) 'Masks for Prevention of Respiratory Virus Infections, Including SARS-CoV-2, in Health Care and Community Settings: A Living Rapid Review' AMSTAR 2 rating: moderate (due to the presence of more than one non-critical weakness)	Review question: to examine the effectiveness of N95, surgical, and cloth masks in community and health care settings for preventing respiratory virus infections, and effects of reuse or extended use of N95 Settings: healthcare and community. In healthcare settings the review reported mainly in healthcare workers Viruses: SARS-CoV-2, SARS, MERS, influenza, influenza-like illness, and other viral respiratory infections	 Search dates: 2003 up to 2 December 2021 (update 7) Data sources: Medline, Embase, the WHO COVID-19 database and medRxiv preprint server; reference lists of relevant articles Inclusion criteria: study design: randomised trials, cohort, case-control and cross-sectional studies; for update 7, inclusion restricted to randomised trials and observational studies that controlled for confounders preprints included in the original review but not in the updates, unless they were based on data collected after February 2021 for update 7 	 Main findings – SARS-CoV-2 Healthcare settings: N95 versus surgical mask: insufficient conclusion due to limitations in meth studies and lack of precision (5 obset) any mask versus no mask: insufficient conclusion (2 observational studies) N95 versus no mask: insufficient stress conclusion (3 observational studies) surgical mask versus no mask: insufficient stress conclusion (3 observational studies) surgical mask versus no mask: insufficient stress conclusion (3 observational studies) surgical mask versus no mask: insufficient stress conclusion (3 observational studies) all studies from moderate or higher r Community settings:

orn during procedures with a risk of cretions splashing or spraying onto ways should wear a type IIR FRSM vorkers who are not on duty in IR FRSM at all time whilst at work, ch as when working alone) uld wear a type IIR FRSM all the and they can be tolerated AGPs on patients in the respiratory unit should be considered in bry pathway where there is a high easures in place respirator should be worn in d directly over a surgical field or 3 respirators, the use of FFP2 healthcare settings should wear a d wear a type IIR FRSM. Inside an be relaxed according to current ient strength of evidence to draw thodology, inconsistency across servational studies) cient strength of evidence to draw s) trength of evidence to draw s) sufficient strength of evidence to studies) insufficient strength of evidence to studies) risk settings (inpatients)

Reference	Review question	Methods and evidence identified	Main findings
	Mask types: all types included (N95, surgical and cloth masks) N95 and equivalent respirators: fitted devices tested to achieve very efficient filtration of small airborne particles, including aerosols Surgical masks: surgical or medical masks that are loose-fitting, fluid resistant, block large particles and create a physical barrier Cloth masks: nonmedical face coverings. Filtration and fluid resistance vary depending on material, number of layers and fit	 outcome: infection with any of the included viruses and harms of mask usage Studies included: 39 studies in the original review: 18 RCTs 10 cohorts 11 case-control studies only 2 from the COVID-19 pandemic in following updates, 19 additional studies identified, all COVID-19 in total, 21 studies from the COVID-19 pandemic, of which 11 from healthcare settings: 6 cohorts 2 case-control 3 cross-sectional Quality assessment: randomised trials assessed using criteria adapted from the US Preventive Services Task Force for observational studies, key limitations noted (potential recall, selection, participation bias or issues related to outcome evaluation, analytical method and confounding) Grading of evidence: strength of evidence graded as high, moderate, low or insufficient based on study design, risk of bias, inconsistency, indirectness and imprecision Overlap between reviews [A]: 4 of the 11 included primary studies conducted in healthcare settings during COVID-19 were unique to this review 	 N95 respirators versus surgical mask surgical mask versus no mask in ho settings: decreased risk of infection; and one observational study) Main findings: respiratory viruses other settings Moderate or higher risk settings (inpatie N95 versus surgical mask: SARS and MERS – decreased ris evidence (5 observational studies influenza – similar effects or no dif evidence (3 RCTs) N95 versus no mask: SARS and MERS – decreased ris evidence (4 observational studies influenza – no studies Surgical mask versus no mask: SARS and MERS – insufficient str conclusion (6 observational studies influenza – no studies Lower risk setting (outpatient): one study (RCT, influenza), showing difference for N95 versus surgical m evidence) Harms: reporting of harms suboptimal; wher different types of masks), most com discomfort, breathing difficulties and no serious harms reported

Note

[A] Overlap between studies was done considering only the studies conducted in healthcare settings during the COVID-19 pandemic. Laboratory studies, studies conducted in community settings and evidence from viruses others than SARS-CoV-2 were not included (see <u>Annexe D</u>).

asks: no studies identified nouseholds and other community n; low strength of evidence (2 RCTs er than SARS-CoV-2; healthcare tients) isk of infection, low strength of es) difference, moderate strength of isk of infection, low strength of es) strength of evidence to draw lies) ng similar effects or no masks (moderate strength of

en reported (clinical trials for mmon adverse effects were nd skin events

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Annexe A. Glossary

Term	Meaning
Aerosols	Respiratory particles that can remain suspended in the air for minutes to hours and can subsequently be inhaled. Aerosols can be any size between <0.1 and 100 microns but become smaller as they move from human sources due to evaporation.
Aerosol generating procedures	Any interventions or procedures that could produce aerosols capable of transmitting infectious diseases. They include awake bronchoscopy, awake airway procedures that involve respiratory suctioning, awake upper gastro-intestinal endoscopy, dental procedures, respiratory tract suctioning, surgery or post-mortem procedures likely to produce aerosol from the respiratory tract or sinuses and tracheostomy procedures (29).
Airborne transmission	The spread of infection from one person to another by airborne particles (aerosols) containing infectious agents.
Droplets	Respiratory particles larger than 100 microns which have a ballistic trajectory and normally deposit within 2 metres of an infected individual. This is the definition used in the UK and based on the work by Milton (54), but other definitions, including by the WHO, consider the threshold for droplets to be set at 5 to 10 microns (<u>55</u>).
Face coverings	Broadly defined as any type of face covering that covers the mouth and the nose (including medical masks and other types of masks).
FFP3 respirators	FFP3 respirators have a 99%+ filtration efficiency (European classification). They are the equivalent to N99 USA classified respirators.
Healthcare settings	These include any service or place where healthcare occurs, such as acute care hospitals, urgent care centres, rehabilitation centres and other long-term care facilities, specialised outpatient services and outpatient surgery centres.
Infection prevention and control	A clinical and public health specialty based on a practical and evidence- based approach to preventing patients, healthcare workers and visitors to healthcare facilities from acquiring preventable infections during healthcare provision.
N95 respirators	These have a 95% filtration efficiency. They are equivalent to FFP2 respirators. FFP2 is the European classification and N95 is the USA classification.
Respiratory particles	These include all particles produced by exhalation and carry infectious virus from infected individuals. They are often split into 2 categories (droplets and aerosols), usually based on size and behaviour in air.

Term	Meaning
Source control	Refers to protection designed to capture particles that are exhaled by the wearer and acts to reduce the amount of virus that is released into a space.
Surgical masks	 Also called 'medical masks', these are flat or pleated masks that are fixed to the head with straps that go around the ears, head or both. Designed to be worn over the mouth and nose to prevent against droplet transmission from the wearer to the surrounding environment (source control), they are constructed to a standard that specifies design, performance and testing requirements (EN 14683:2019). There are 4 types of surgical masks which are based on material properties rather than fit of the mask: types I, IR, II and IIR: type I and type IR have a BFE (bacterial filtration efficiency) of 95% and type II and type IIR face masks have a BFE of 98% type IR and type IIR, also called fluid resistant surgical masks (FRSM), have a splash-resistant layer that protect the wearer against splashes of blood and body fluid; types I and type II are not splash-resistant in the UK, the surgical masks recommended for use during contact with any patients are the FRSM type IIR
Universal masking	Universal masking is when everyone, with some exceptions (such as children under 3 years old due to safety reasons, or some patient groups who may not be able to tolerate it), is required to wear a mask.
Wearer protection	Protection conferred to an unaffected person (the wearer) through reducing their exposure to virus-containing respiratory particles.

Annexe B. Methods

This report employed a rapid review approach to address the review question: "What is the relative effectiveness of respiratory protective equipment (RPE) and fluid-resistant surgical face masks (FRSM), including FFP2, FFP3 and N95 respirators, in reducing SARS-CoV-2 transmission in healthcare settings?"

Note the following points:

- in 2021, an overview of review-level evidence (2) was conducted for the Respiratory Evidence Panel (REP) (1) which examined the evidence on the role of face coverings in mitigating SARS-CoV-2 transmission in both healthcare and community settings
- this is a focused update of this work looking only at RPE and FRSM in healthcare settings; only reviews published since 28 April 2021 (cut-off for the original REP work) were considered
- whilst there is a larger body of evidence from other respiratory viruses on effectiveness of RPE and surgical masks, only reviews focusing on evidence from the COVID-19 pandemic were considered; some of the included reviews considered wider evidence (especially from other coronaviruses) but this was not part of the search strategy which focused only on COVID-19

Protocol

A protocol was produced before the literature search began, specifying the research question and the inclusion and exclusion criteria.

Sources of evidence

Medline, Embase, medRxiv, WHO COVID-19 Research Database and selected COVID-19 review repositories (see list in <u>Annexe C</u>).

Consultation with panel members.

Search strategy

Searches were completed for reviews published between 28 April 2021 to 12 May 2022.

Search terms covered the main aspects of the review question.

Search strategy for Ovid Medline:

1. (surgical face mask* or surgical face-mask*).tw,kw.

The role of respirators and surgical masks in mitigating SARS-CoV-2 transmission in healthcare settings

- 2. surgical mask*.tw,kw.
- 3. N95 respirator*.tw,kw.
- 4. respirator mask*.tw,kw.
- 5. facepiece respirator*.tw,kw.
- 6. P100 respirator*.tw,kw.
- 7. gas mask*.tw,kw.
- 8. (full face respirator or full-face respirator*).tw,kw.
- 9. face shield*.tw,kw.
- 10. medical mask*.tw,kw.
- 11. medical face-mask*.tw,kw.
- 12. KN95 respirator*.tw,kw.
- 13. FFP.tw.
- 14. (FFP1 or FFP2 or FFP3).tw,kw.
- 15. masks/ or n95 respirators/
- 16. exp Respiratory Protective Devices/
- 17. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
- 18. exp SARS-CoV-2/
- 19. exp COVID-19/
- 20. (corona* adj1 (virus* or viral*)).tw,kw,kf.
- 21. (CoV not (Coefficien* or "co-efficien*" or covalent* or Covington* or covariant* or covarianc* or "cut-off value*" or "cutoff value*" or "cut-off volume*" or "cutoff volume*" or "combined optimi?ation value*" or "central vessel trunk*" or CoVR or CoVS)).tw,kw,kf.
- 22. (coronavirus* or 2019nCoV* or 19nCoV* or "2019 novel*" or Ncov* or "n-cov" or "SARS-CoV-2*" or "SARSCoV-2*" or SARSCoV2* or "SARS-CoV2*" or "severe acute respiratory syndrome*" or COVID*2).tw,kw,kf.
- 23. exp COVID-19 vaccines/
- 24. exp COVID-19 testing/
- 25. or/18-24
- 26. 17 and 25
- 27. limit 26 to "reviews (best balance of sensitivity and specificity)"
- 28. limit 26 to "systematic review"
- 29. 27 or 28

Inclusion and exclusion criteria

Articles eligibility criteria are summarised in the table below.

Table B.1. Inclusion and exclusion criteria

	Included	Excluded
Population	All population	
Settings	Healthcare settings	Community settings
Context	COVID-19 pandemic [A]	Other infectious disease
Intervention or exposure	 respiratory protective equipment (RPE) – includes FFP2, FFP3 and N95 respirators fluid-resistant surgical face masks (FRSM) – also called 'medical masks' or 'surgical masks' 	Any face coverings others than RPE and FRSM
Comparators	 RPE versus FRSM RPE or FRSM versus no use	
Outcomes	 COVID-19 transmission [B] COVID-19 infection [B] Example of measures: risk or odd ratios for COVID-19 infection (meta-analysis) narrative synthesis of studies reporting on COVID-19 transmission or infections 	
Language	English	
Date of publication	28 April 2021 to May 2022	
Study design	 systematic reviews with or without [C] meta-analyses rapid systematic reviews 	 non-systematic reviews primary studies modelling studies guidelines opinion pieces
Publication type	 peer-reviewed preprint publication published on non- commercial publishers 	

Notes

[A] Reviews which include evidence of SARS-CoV-2 as well as other viruses (including MERS, SARS or influenza) were considered for inclusion.

[B] Any outcomes related to transmission, whether to or from healthcare workers or to and from patients, would be considered for inclusion.

[C] Depending on the evidence identified, systematic reviews with meta-analysis may be prioritised over those without.

Screening

Results from the COVID-19 repositories were screened by an information scientist and potentially relevant reviews were screened on full text by a reviewer and checked by a second.

Results from the databases were screened on title and abstract in duplicate by 2 reviewers for 10% of the eligible studies, with the remainder completed by one reviewer. Screening on full text was undertaken by one reviewer and checked by a second. Disagreements were resolved by discussion.

All studies meeting the inclusion criteria were considered for inclusion but final decision for inclusion also included consideration of recency of searches, overlap of primary studies between review and review quality (assessed using a modified version of AMSTAR 2, see below).

Data extraction

Summary information for each review were extracted and reported in tabular form. Information included review question, types of masks included, search dates, number of studies included and study design, and main findings. This was undertaken by one reviewer and checked by a second.

Quality assessment

Quality of the included studies was assessed using the <u>AMSTAR 2 tool</u>. We slightly modified the original AMSTAR 2 tool to apply it to systematic and rapid reviews of COVID-19 evidence (as it was developed for critically appraising systemic reviews). In particular, we amended the criteria for full yes for question 4 on search strategy: the criteria for partial yes was kept the same as the original (2 databases, search strategy provided and any restrictions justified) but the criteria for full yes was simplified to require only one additional step (one additional database relevant to the research question searched, or reference lists of included or relevant studies searched; and requirement to include reference checking or contacting experts removed).

Four questions were considered as critical: Q4 on literature search, Q9 on validity of the risk of bias assessment tool, Q11 on statistics used in the meta-analysis and Q13 on consideration of bias when discussing results. Studies were rated as per the original AMSTAR 2: reviews with one critical flaw were rated as low quality and those with more than one critical flaw were rated as critically low; studies were rated as high quality if they had no or only one non-critical weakness and moderate quality if they had more than one non-critical weakness but no critical flaws; studies with multiple non-critical weaknesses can be downgraded. Note that the overview of evidence conducted in 2021 mainly included rapid review or evidence summary and reviews with 2 non-critical weaknesses were rated as high quality, but would be rated here as medium quality.

Quality was assessed in duplicate by 2 reviewers.

Annexe C. COVID-19 review repositories and prospective review registers

These included:

- <u>Cochrane Rapid Reviews</u>
- <u>COVID-19 Best Evidence Front Door</u>, University of Michigan
- <u>COVID-END</u> Evidence about public-health measures
- Emergency Care Research Institute (ECRI)
- Epistemonikos, COVID-19 L.ove
- Health Information and Quality Authority, Ireland
- McMaster Uni, National Collaborating Centre for Methods and Tools (NCCMT)
- Prospero
- SPOR Evidence Alliance
- <u>UNCOVER</u> (Usher Network for COVID-19 Evidence Reviews)
- VA Evidence Synthesis Program

Additionally, we searched for any relevant reviews available in:

- <u>COVID-19 portfolio</u> (which includes preprints)
- LitCovid
- PHE COVID-19 Evidence Systematic Review Updates (a spreadsheet and Endnote library of reviews, compiled from searches of Medline, Embase, medRxiv, SSRN and WHO COVID database, started on 19 October 2020 and updated every 2 weeks)
- <u>SAGE scientific evidence</u>

Annexe D. Mapping of primary studies

The overlap of primary studies between the 5 reviews included in this overview is presented in Table D.1. This was done by mapping the primary studies reporting on SARS-CoV-2 transmission in healthcare settings. The main characteristics of these primary studies are presented in Table D.2.

Primary study (first author)	Kim and others (38)	Kunstler and others (39)	Chou and others (44)	ARHAI (7)	Alberta (43)	Total
Akinbami	x	x	х		х	4
Bryan		x				1
Chatterjee			х			1
Chen	X					1
Chung					х	1
Davido			х			1
Ferris				x	х	2
Fletcher		x	х			2
Guo	X					1
Haller		x	х	x	x	4
Heinzerling			х			1
Khalil	х		х			2
Khurana	x					1
Kingden-Milles					х	1
Klompas		x				1
Kumar	х	x				2
Lawton				х		1
Lentz					х	1
Loconsole					х	1
Mariani					х	1
Martischang		x				1
Mastan					х	1
Ng K		x				1
Niikura		x				1
Periyasamy		x				1

Table 4.1. Mapping of primary studies (SARS-CoV-2; healthcare settings)

The role of respirators and surgical masks in mitigating SARS-CoV-2 transmission in healthcare settings

Primary study (first author)	Kim and others (38)	Kunstler and others (39)	Chou and others (44)	ARHAI (7)	Alberta (43)	Total
Piapan			х			1
Schmitz					x	1
Shah				х		1
Sims	x	x	х			3
Staub					x	1
Su				x		1
Venugopal		x	х			2
Wang	x		х			2
Total	8	12	11	5	11	

Table D.2. Main characteristics of the primary studies included in the systematic review

The following acronyms are used: FRSM = fluid-resistant surgical mask, HCW = healthcare worker, ICU = intensive care unit, NR = not reported by study, PPE = personal protective equipment

Primary study	Objective	Setting	Country	Study design	Study period
'SARS-CoV-2 seroprevalence among healthcare, first response, and public safety personnel, Detroit Metropolitan Area, Michigan, USA, May to June 2020.' Akinbami and others	To estimate the prevalence of SARS-CoV-2 antibodies among employees and to describe associations between seroprevalence and workplace characteristics	Emergency medical service agencies and 27 hospitals across Detroit	US	Cross-sectional	May to June 2020
'Seroepidemiology among employees of New York City health and hospitals during the first wave of the SARS-CoV-2 Epidemic.' Bryan and others [A]	To estimate the seroprevalence of SARS-CoV-2 antibodies among HCWs and describe associations between seroprevalence and demographic and occupational factors	Eleven hospitals and over 70 community facilities in New York City	US	Cross-sectional	April to June 2020
'Healthcare workers and SARS-CoV-2 infection in India: A case-control investigation in the time of COVID-19.' Chatterjee and others	To identify factors associated with SARS-CoV-2 infection among HCWs in India	Healthcare settings across India	India	Case-control	May 2020
'High SARS-CoV-2 antibody prevalence among healthcare workers exposed to COVID-19 patients.' Chen and others	To estimate the seroprevalence of SARS-CoV-2 among HCWs exposed to 4 patients with laboratory-confirmed COVID-19	Hospital in Nanjing	China	Cohort	January to February 2020
'Risk of COVID-19 transmission from infected outpatients to healthcare workers in an outpatient clinic.' Chung and others	To evaluate the risk of infection among HCWs from patients with confirmed COVID-19 in the outpatient clinic setting	Tertiary care hospital in Seoul	South Korea	Cohort	January to September 2020
'The first wave of COVID-19 in hospital staff members of a tertiary care hospital in the greater Paris area: a surveillance and risk factors study.' Davido and others	To characterise exposure types and identify factors associated with SARS-CoV-2 infection among hospital staff	Tertiary care hospital in Paris	France	Cross-sectional	March to May 2020
'FFP3 respirators protect healthcare workers against infection with SARS-CoV-2.' Ferris and others	To evaluate the incidence of SARS-CoV-2 infection in HCWs before and after the transition from FRSMs to FFP3 respirators	Tertiary care hospital in Cambridge	England	Cohort	November 2020 to January 2021
'Healthcare-acquired COVID-19 is less symptomatic than community-acquired disease among healthcare workers.' Fletcher and others	To evaluate the proportion of asymptomatic spread and the symptomology of COVID-19 among HCWs with and without high-risk exposure outside healthcare settings	Community based teaching hospital in Michigan	US	Cross-sectional	August to September and December 2020
'Survey of COVID-19 disease among orthopaedic surgeons in Wuhan, People's Republic of China.' Guo and others	To evaluate SARS-CoV-2 infection levels among orthopaedic surgeons and the possible risk factors for infection	24 hospitals in Wuhan	China	Case-control	December 2019 to February 2020
'Use of respirator versus surgical masks in healthcare personnel and its impact on SARS- CoV-2 acquisition: a prospective multicentre cohort study.' Haller and others [B]	To evaluate the effectiveness of FFP2 respirators compared to surgical masks for protecting against SARS-CoV-2 among HCWs involved in patient care	7 acute care institutions, 1 rehabilitation clinic and 3 psychiatry clinics	Switzerland	Cohort	June 2020 to March 2021

Primary study	Objective	Setting	Country	Study design	Study period
'Transmission of COVID-19 to health care personnel during exposures to a hospitalized patient: Solano County, California, February 2020.' Heinzerling and others	To evaluate risk factors for SARS-CoV-2 transmission among HCWs who were exposed to a patient with confirmed COVID-19	2 hospitals in California	US	Cohort	February 2020
'Role of personal protective measures in prevention of COVID-19 spread among physicians in Bangladesh: a multicenter cross- sectional comparative study.' Khalil and others	To evaluate the role of personal protective measures in preventing the spread of COVID-19 among physicians working at health facilities	Hospitals across Bangladesh	Bangladesh	Cross-sectional	May to June 2020
'Prevalence and clinical correlates of COVID-19 outbreak among health care workers in a tertiary level hospital in Delhi.' Khurana and others [A]	To estimate the infection rate of SARS-CoV-2 among HCWs, and to evaluate factors associated with positivity	Tertiary level hospital in Delhi	India	Case-control	NR
'Prevalence of SARS-COV-2 positivity in 516 German intensive care and emergency physicians studied by seroprevalence of antibodies national covid survey.' Kingden-Milles and others	To estimate the prevalence of SARS-CoV-2 infection in intensive care and emergency physicians	Intensive care and emergency physicians across Germany	Germany	Cross-sectional	June to July 2020
'A SARS-CoV-2 cluster in an acute care hospital.' Klompas and others	To describe a cluster of SARS-CoV-2 infections in an acute care hospital with infection prevention and control policies	Teaching hospital in Boston	US	Case-control	September to October 2020
'Risk factors and outcome among COVID-19 exposed and quarantined healthcare workers.' Kumar and others	To identify the infection rate of SARS-CoV-2 among HCWs as well as risk factors and behaviours associated with infection	COVID-19 isolation or quarantine facility in New Delhi	India	Retrospective cohort	April to May 2020
'Airborne protection for staff is associated with reduced hospital-acquired COVID -19 in English NHS Trusts.' Lawton and others	To evaluate differences in rates of hospital- acquired SARS-CoV-2 infection between NHS hospital trusts using airborne respiratory protection (eg FFP3 masks) and NHS hospital trusts using mainly droplet precautions (eg surgical masks)	NHS hospital trusts across England	England	Cohort	August 2020 to September 2021
'Assessing COVID-19 transmission to healthcare personnel: the global ACT-HCP case-control study.' Lentz and others	To evaluate associations between exposures inside and outside of the medical workplace and SARS-CoV-2 infection among HCWs	Healthcare delivery settings across the world	International (mostly Europe and North America)	Case-control	April to May 2020
'Investigation of an outbreak of symptomatic SARS-CoV-2 VOC 202012/01-lineage B.1.1.7 infection in healthcare workers, Italy.' Loconsole and others	To describe an outbreak of SARS-CoV-2 B.1.1.7 among 3 HCWs in a hospital setting in Italy	Hospital	Italy	Outbreak investigation	February to March 2021
'Factors associated with risk of COVID-19 contagion for endoscopy healthcare workers: a	To evaluate the risk of SARS-CoV-2 infection and associated factors among HCWs in endoscopy centres	201 endoscopy centres across Italy	Italy	Cross-sectional	March to April 2020

Primary study	Objective	Setting	Country	Study design	Study period
survey from the Italian society of digestive endoscopy.' Mariani and others					
'Severe SARS-CoV-2 seroconversion and occupational exposure of employees at a Swiss university hospital: a large longitudinal cohort study.' Martischang and others	To evaluate trends and risk factors for SARS- CoV-2 seroconversion among hospital staff with different occupational exposures	Tertiary care centre in Geneva	Switzerland	Cohort	March to June 2020
'COVID-19 infection is related to differences in the use of personal protective equipment by orthopaedic specialist trainees caring for hip fracture patients during the second surge of COVID-19 in the North West of England.' Mastan and others	To evaluate PPE practices in 19 hospitals caring for hip fracture patients	19 hospitals caring for hip fracture patients in the North West of England	England	Cross-sectional	November 2020
'COVID-19 and the risk to health care workers: a case report.' Ng and others	To describe the clinical outcome of HCWs caring for a patient with severe pneumonia before they received a diagnosis for COVID-19	Hospital	Singapore	Case report	February 2020
'International observational survey of the effectiveness of personal protective equipment during endoscopic procedures performed in patients with COVID-19.' Niikura and others	To evaluate the cumulative incidence of SARS- CoV-2 among HCWs during endoscopic procedures	Endoscopy-related healthcare professionals across the world	International (mostly Asia)	Cohort	April to August 2020
'Aerosolized SARS-CoV-2 transmission risk: Surgical or N95 masks?' Periyasamy and others	To describe the clinical outcome of HCWs exposed during aerosol-generating procedures to a patient infected with SARS-CoV-2 before receiving a COVID-19 diagnosis	Hospital	Malaysia	Descriptive	2020 (specific study period NR)
'COVID-19 outbreak in healthcare workers in hospitals in Trieste, North-East Italy.' Piapan and others	To evaluate risk factors associated with COVID- 19 positivity among HCWs	Public hospitals in a north-eastern province	Italy	Cohort	March to April 2020
'Association between personal protective equipment and SARS-CoV-2 infection risk in emergency department healthcare workers.' Schmitz and others	To investigate the association between PPE use and SARS-CoV-2 infections among emergency department personnel	45 emergency departments in the Netherlands	Netherlands	Cross-sectional	March to May 2020
'Evaluation of healthcare personnel exposures to patients with SARS-CoV-2 associated with personal protective equipment.' Shah and others	To identity factors related to lapses in PPE use that may influence transmission of SARS-CoV-2 from patients to healthcare personnel	Tertiary-care medical centre in Minnesota	US	Retrospective Cohort	May to November 2020
'COVID-19 seropositivity and asymptomatic rates in healthcare workers are associated with job function and masking.' Sims and others	Large scale serological study to assess COVID-19 exposure associated with different job functions at Beaumont Health and to alleviate employees' fears of SARS-CoV-2	8 Beaumont Health hospitals in Detroit, Michigan	US	Cohort	April to May 2020

Primary study	Objective	Setting	Country	Study design	Study period
'Case series of 4 re-infections with a SARS- CoV-2 B.1.351 variant, Luxembourg, February 2021.' Staub and others	To describe 4 cases of re-infection with the B.1.351 variant in HCWs that have been previously infected in 2020 before the first detection of the B.1.351 variant in Europe	4 HCWs living in Moselle (France) and working in a hospital in Luxembourg	Luxembourg	Case series	December 2020 to February 2021
'Masks and closed-loop ventilators prevent environmental contamination by COVID-19 patients in negative-pressure environments.' Su and others	To examine viral contamination by SARS-CoV-2 patients on surfaces in ICUs and ordinary wards and to determine whether the use of surgical masks prevents contamination	Local surfaces around 3 patients in negative- pressure isolation room in a hospital in Tapei	Taiwan	Three case studies	March to April 2020
'SARS-CoV-2 seroprevalence among health care workers in a New York City hospital: a cross-sectional analysis during the COVID-19 pandemic.' Venugopal and others	To evaluate the seroprevalence of SARS-CoV-2 IgG antibodies among HCWs at a community hospital heavily affected by the COVID-19 pandemic	Community hospital in New York	US	Cross-sectional	March to May 2020
'Association between 2019-nCoV transmission and N95 respirator use.' Wang and others	To evaluate differences in SARS-CoV-2 infection among HCWs wearing N95 respirators and HCWs not wearing medical masks	6 departments in a hospital in Wuhan	China	Retrospective cohort	January 2020

Notes

[A] Preprint at the time of review search.

[B] Preprint in 3 reviews, peer-reviewed publication in one review.

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Published: November 2022

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