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# Respiratory Protective Equipment (RPE) Literature Review

**Version 5.0**

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**Antimicrobial Resistance & Healthcare Associated Infection (ARHAI) Scotland**
**An NHS Scotland Assure Service, part of Public Services Delivery Scotland**

# Key Information

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# Document information

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| **Description** | This literature review examines the available professional literature on Respiratory Protective Equipment (RPE) in the healthcare setting. |
| **Purpose** | To inform the recommendations for RPE in the National Infection Prevention and Control Manual in order to facilitate the prevention and control of healthcare associated infections in NHS Scotland health and care settings. |
| **Target Audience** | All staff involved in the prevention and control of infection in NHS Scotland. |
| **Update/review schedule** | Updated as new evidence emerges with changes made to recommendations as required.<br><br>Review will be formally updated every 3 years with next review in 2029. |
| **Cross reference** | National Infection Prevention and Control Manual:<br><br>• Literature Review on Transmission Based Precaution Definitions<br>• Literature Review on the use of Surgical Face Masks (SFM)<br>• Literature Reviews on Hand Hygiene<br>• Literature Review on the Safe Disposal of Waste |

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# Version history

This literature review will be updated in real time if any significant changes are found in the professional literature or from national guidance/policy.

| Version | Date | Summary of changes |
|---|---|---|
| 5.0 | 3 August 2026 | Scheduled update (includes evidence published from 2019 – 2024).<br><br>Revision of research questions to assess evidence on all types of respiratory protective equipment, rather than limiting the evidence to filtering facepiece (FFP) respirators.<br><br>Nine research questions (RQs) were removed and consolidated with other RQs to aid with readability.<br><br>RQ 8 ‘When should RPE be worn by health and care staff?’ was added to assess indications for wearing RPE for infection prevention and control purposes.<br><br>RQ 21 ‘How should RPE be disposed?’ was also added in relation to reusable RPE. |
| 4.0 | August 2020 | Updated using two-person systematic review methodology.<br><br>New questions added regarding fit testing, valved respirators, respirator standards, powered respirators and respirator storage. |
| 3.1 | November 2019 | Sections defining the list of AGPs have been removed as these are now published separately. |
| 3.0 | July 2017 | Additional research questions added for donning, doffing and decontamination of powered respirators. Fit testing added to recommendations, air changes table added as appendix 1, power respirator/FFP3 change/removal separated into 2 questions. ‘Fit test’ distinguished from ‘fit check’. |
| 2.0 | July 2015 | Addition of AGPs recommendations |

# Approvals

| Version | Date Approved | Name |
|---|---|---|
| 5.0 | August 2026 | National Policies Evidence and Guidance (NPGE) Working Group, Care Home Infection Prevention and Control Group (CHIPC), Extraordinary Transmission-based Precautions (TBP) Definitions Working Group (research question 8 only). |
| 4.0 | August 2020 | NIPC Steering and Consensus Group |
| 3.0 | October 2017 | NPGO Steering Group |
| 2.0 | July 2015 | Steering (Expert Advisory) Group for SICPs and TBPs |
| 1.0 | June 2014 | Steering (Expert Advisory) Group for SICPs and TBPs |

# Contents

# 1 Objectives

The aim is to review the extant scientific literature regarding the use of respiratory protective equipment (RPE) in health and care settings to inform evidence-based recommendations for practice. The specific objectives of the review are to determine:

1. What is respiratory protective equipment (RPE)?
2. Are there any legislative requirements for the use of RPE for infection control purposes and what standards (BS/EN) should RPE adhere to?
3. What design features of powered respirators are desirable?
4. What design features of disposable respirators are desirable?
5. What are respirator 'fit tests' and 'fit checks' and how are they performed?
6. When should a 'fit test' and a 'fit check' be performed?
7. What if a fit test or fit check is unsuccessful?
8. When should RPE be worn by health and care staff?
9. When should valved versus unvalved respirators be worn?
10. When should a patient wear RPE?
11. When should a visitor wear RPE?
12. Where and how should disposable respirators be donned?
13. Where and how should disposable respirators be doffed?
14. When should RPE be changed or removed?
15. When should a powered respirator be worn?
16. Where and how should powered respirators be donned?
17. Where and how should powered respirators be doffed?
18. How should reusable respirators be maintained?
19. How should reusable respirators be decontaminated?
20. How should RPE be stored?
21. How should RPE be disposed?

# 2 Methodology

This targeted literature review was produced using a defined systematic methodology as described in the National Infection Prevention and Control Manual: Development Process.

A search was conducted in July 2022 to identify evidence published between October 2019 and June 2022. An additional top up search was conducted to identify evidence from 2022 to September 2024. This review therefore captures relevant evidence published between October 2019 and September 2024. The search strategies are detailed in Appendix 1. The search results are detailed in a PRISMA diagram in Appendix 2, adapted from Moher et al (2009).[1]

Definitions for grades of evidence are provided in Appendix 3.

Additional exclusion criteria were applied, in addition to those listed within the development process. Studies were excluded if they:

- used predictive modelling
- focussed on method validation
- focussed on compliance
- focussed on PPE for high consequence infectious diseases (HCIDs), including air-supplying RPE
- focussed on occupational health factors relating to RPE use, for example, discomfort, headaches, dermatologic reactions
- focussed on novel RPE configurations
- did not reliably confirm infection, for example, diagnosis based on symptoms or self-reported questionnaires
- focussed on reuse of RPE following decontamination, including sterilisation and disinfection
- provided recommendations regarding the use of RPE during stock shortages

Consultation of research question eight and its associated draft recommendations and good practice points was undertaken via the Extraordinary transmission-based

precautions (TBP) definitions Working Group during development of the TBP Definitions literature review. All other research questions underwent consultation via the National Policies Guidance and Evidence (NPGE) Working Group and the Care Home Infection Prevention and Control Group (CHIPC).

# 3 Discussion

## 3.1 Implications for practice

### 3.1.1 What is respiratory protective equipment (RPE)?

In total, 31 pieces of evidence were included to answer this research question. Eight were identified in previous version(s) of this literature review,[2-9] where two of these have since been updated.[3, 9] Twenty-three additional pieces of evidence were included during this update.[10-32] One guideline published by the World Health Organization (WHO) was graded AGREE: 'Recommend with provisos' due to limitations regarding the systematic review methodology used to underpin the recommendations.[16] Twenty-seven guidance documents were graded SIGN 50 level 4 expert opinion, due to a lack of supporting evidence and lack of systematic methodology to support their development. Thirteen of the expert opinion documents were published in the UK,[2-4, 7, 8, 21-28] one in the Republic of Ireland (ROI),[30] 11 in the United States of America (USA),[5, 6, 9, 11-15, 29, 31, 32] one in Australia,[10] one in New Zealand,[20] three were published by the European Centres for Disease Prevention and Control (ECDC), therefore applicable to the European Union (EU)/European Economic Area (EAA)[17, 18, 31] and one was published by WHO, therefore applicable internationally.[16] Four of the guidance documents published in the UK were produced by the Health and Safety Executive (HSE) as part of a series.[24-27]

Sixteen guidance (all SIGN 50 level 4 expert opinion) are not specific to health or care settings.[2, 3, 5, 7, 8, 12, 14, 15, 21-28, 31] Given the scope of this research question, it is reasonable to assume that relevant definitions found in guidance aimed for the general population and/or non-health and care settings can be generalised to Scottish health and care settings. Descriptions of RPE used in environments of immediate danger to life and health, such as high-consequence infectious disease (HCID) and firefighting, have been excluded. See the NIPCM review on PPE for HCIDs.

Eight expert opinion guidance documents provide a definition for RPE used for the provision of health and care. Definitions were consistent in stating that RPE is a category of personal protective equipment worn to protect the wearer from hazardous substances found in the atmosphere.[2, 19, 22, 23, 30-33]

## Categories of RPE

There are two categories of RPE: air-supplying respirators and air-filtering respirators.[2, 5, 8, 12, 14, 22, 34] Air-supplying respirators have been excluded from further discussion in this literature review as they are typically recommended for hazards that constitute an immediate danger to life and therefore not commonly used in health and care settings. Air-filtering respirators contain a particle filter which captures hazardous particles as air passes through it, before reaching the wearer's respiratory tract.[2, 4-8, 10, 12, 19-23] Filters effective against gases or vapours have been excluded as this is outside the scope of this review

Several types of air filtering respirators are described in the evidence base. In the context of health and care settings, the term 'respirator' typically refers to disposable filtering half face piece (FFP) respirators, which form a tight seal between the edge of the respirator and the wearer's face, covering the nose and mouth.[2, 4, 5, 8, 10, 12, 13, 15, 19, 21, 22, 31] Quarter FFP respirators, which do not cover the chin, were also referenced in the evidence base, but to a lesser extent.[8, 21, 22]

FFP respirators may be valved.[4, 8, 12, 21, 31] The valve is located on the filter of the respirator to aid with breathability when the wearer exhales, and to reduce humidity.[4, 5, 12, 31] The exhaled air is released directly into the atmosphere via the valve.[7, 8, 21, 31]

## Types of RPE

### Filtering Facepiece Respirators (FFP)

Several models of FFP half face mask respirators are available for use and meet different international standards.[10, 31, 33] N95 respirators were most widely cited across the literature and are approved for use in US health and care settings.[4, 5, 9-12, 16, 19, 20, 32] As well as N95 half face mask FFP respirators, other FFP respirators discussed in literature include P2, KN95, FFP1, FFP2 and FFP3s. P2 and KN95 respirators provide equivalent protection to N95 respirators; KN95 respirators are approved for use in China, and P2 respirators are approved for use in New Zealand and Australia.[10, 20] FFP1, FFP2 and FFP3 respirators are typically used in Europe, and are categorised according to their filtration efficiencies.[2, 4, 7, 16, 18, 30, 33] FFP2

respirators provide equivalent protection to N95 respirators in terms of the protection that they provide the wearer.

### Reusable RPE

Reusable respirators are termed elastomeric respirators.[5, 12, 14, 31, 34] Unlike disposable respirators, elastomeric respirators are made of materials that can withstand cleaning and decontamination. Elastomeric half mask respirators (EHMRs) cover the nose, mouth and chin. Elastomeric full face mask respirators cover the eyes, nose, mouth and chin. Elastomeric quarter facepiece respirators cover the nose and mouth.[5, 12, 14, 34] As with disposable FFP respirators, elastomeric respirators form a tight seal around the face.[5, 14, 34] The filter cartridges of elastomeric respirators are interchangeable so that the appropriate filter is used to protect against a hazard; filtration capacity therefore varies.[2, 5, 14, 29, 34]

### Powered respirators

Air-filtering respirators may also be powered. Rather than relying on inhalation of air by the wearer, contaminated air is pulled through the filters using a battery-powered blower before delivering clean air to the wearer.[2, 5, 6, 8, 12, 34] Powered air-purifying respirators (PAPRs) may be tight fitting (half or full face mask respirators), or loose fitting (hoods and helmets) that cover the whole head.[2, 12, 14]

## Filtration efficiency

FFP respirators are classified according to their filtration efficiency, meaning their capacity to filter particles, and filtration efficiency is related to filter leakage.[16] However, the evidence base is inconsistent in the terms used when referring to the hazardous particles that respirators are capable of filtering. Some cite exact particle sizes that specific types are capable of filtering,[9-11, 16, 19, 29, 33] whereas others state that respirators are capable of filtering, for example, ‘large particles’, ‘airborne contaminants (small and large particle droplets)’, ‘aerosols’, ‘droplets’, ‘airborne particles’, ‘finely divided particles’, ‘infectious agents’ and/or ‘respiratory droplets’, without further clarity regarding particle size.[2, 4, 5, 8, 12, 13, 18, 20, 23, 30, 32] The ECDC state that FFP respirators are classed according to their ability to filter 0.3 micrometre (µM) particles.[18]

FFP2 respirators, which are equivalent to N95 and P2 respirators in terms of the protection they provide, must be able to filter at least 94% of 0.3µM particles (maximum 8% leakage).[4, 16, 18] FFP3 respirators (roughly equivalent to N99 respirators in terms of the protection they provide) must have a filter capacity of at least 99% of 0.3 µM particles (maximum 2% leakage), therefore are designed to offer the highest level of protection.[12, 16, 18]

### Summary

RPE used in health and care settings are typically air-filtering respirators, which are categorised according to their ability to filter particles from the air before inhaling. Several types of
air-filtering respirators are available. Disposable, tight-fitting respirators that may be valved or non-valved, are most typically used in health and care settings. Powered respirators and reusable respirators are also available.

## 3.1.2 Are there any legislative requirements for the use of RPE for infection control purposes and what standards should RPE adhere to?

In total, 39 documents were included to answer this research question, which was updated to include relevant standards as part of this update. Six are legislation applicable to the UK, graded SIGN 50 'mandatory'.[35-40] Thirty-three European and British standards were included, which were all graded SIGN 50 level 4 expert opinion (Appendix 3). At the time of writing, the standards are the most recent versions available. It should be noted, however, that these are subject to amendment and the list is non-exhaustive as some standards are outside the scope of this review.

There is no direct legislative requirement for health and care staff to wear a respirator when delivering care. The general wearing of PPE in a work setting is covered by The Health and Safety at Work etc. Act (1974),[35] The Control of Substances Hazardous to Health 2002 Regulations (as amended 2013) (COSHH) and The Personal Protective Equipment at Work (Amendment) Regulations (PPER).[37, 41]

In the UK, The Health and Safety at Work etc. Act 1974 (HSWA) is the primary legislation relating to occupational health at work, from which other health and safety regulations follow.[35] The HSWA outlines general employer and employee responsibilities to manage health and safety for every work activity and discusses the provision of PPE. The Management of Health and Safety at Work Regulations 1999 is more specific in the duties that employers and employees must fulfil to maintain health and safety at work.[36] These pieces of legislation do not explicitly discuss the use of PPE or RPE but are relevant to their provision in heath and care settings.

The Control of Substances Hazardous to Health (Amendment) Regulations 2002 (COSHH) describes the requirements for protecting employees from substances that are hazardous to health in the workplace and includes the use of PPE.[37] COSHH makes clear that these regulations apply to infectious agents that may cause infection.[37]

The Personal Protective Equipment at Work (Amendment) Regulations 2022 (PPER 2022) applies to employers and employees, including employees without a contract of employment.[40] This legislation covers regulations including but not limited to: suitability of PPE, compatibility of PPE, assessment of the suitability of PPE, information, instruction and training, use of PPE and storage.

The Personal Protective Equipment (Enforcement) Regulations 2018 incorporates EU Regulation 2016/425 into UK Law.[38, 39] The Personal Protective Equipment (Enforcement) Regulations 2018 describes health and safety requirements that are required before PPE products may be placed on the Great British market.[39]

### Legislation relating to health and care settings

There is no clear legislation, or guidance, regarding the required filtration efficiency of RPE used in health and care settings. According to the HSE, each class and type of RPE has an ‘assigned protection factor’ (APF), which indicates the level of protection that the item can provide the wearer if used correctly.[42] APF scores may be 4, 10, 20, 40, 200 or 2000, where for example an APF of 20 demonstrates that the RPE reduces the wearer’s exposure to the hazardous particles by 20-fold, or 1/20 of a contaminant is inhaled.[42] Other APF scores have been provided within the

evidence base, however these were taken from a US standard published by the Occupational Safety and Health Administration (OSHA) of the US Department of Labour, termed 'OSHA APF', therefore, are not applicable to Scottish health and care settings. The HSE provide APFs for RPE available for use in the UK according to their filtration efficiency and state that RPE should be chosen according to the APF required.[42] The interpretation of APFs in selecting appropriate RPE for use in health and care settings is challenging due to the lack of evidence specific to the size, movement and exposure risk associated with infectious agents in the air.

The Personal Protective Equipment at Work Amendment Regulations (2022) states that PPE used in workplace settings must be 'suitable', where suitability takes into consideration the task and the risks for which protection is required as well as other factors that relate to occupational health, such as ergonomic effects and environmental conditions.[40] This legislation is challenging to interpret and apply to health and care settings. The HSE developed expert opinion guidance to support the implementation of these regulations.[41] In response to the regulation outlined above, HSE recommend that PPE with 'maximum protection while ensuring minimum discomfort to the wearer' is worn. The 'maximum protection' recommendation has historically been interpreted to mean that RPE with 99% filtration efficiency should be used in UK health and care settings. However, the evidence behind the HSE recommendation was not provided and it can also be argued that use of an FFP3 respirator does not minimise user discomfort when compared to respirators with lower filtration efficiencies. This suggests that HSE have adopted a precautionary principle regarding RPE use.

### British and European standards

Thirty-three European and British standards were identified in relation to RPE (Appendix 3). These are all graded SIGN 50 level 4 expert opinion, due to a lack of scientific evidence used to support their development. Several of these standards specify performance requirements proposed for RPE. In particular, the methods detailed in BS EN 13274-7:2019 describe procedures to test particle filter penetration of RPE, using aerosolised sodium chloride particles as the challenge agent.[43] This approach has been employed in primary research studies to assess the efficacy of RPE in simulated care settings, and to compare them with other PPE, in particular

surgical masks. However, these methods may not accurately assess the efficacy of RPE in care settings, as biological hazards may behave differently in the air compared to sodium chloride. Moreover, these assessments are performed in very controlled experimental settings, which may not mimic the environment of a care setting. None of the standards are specific to care settings. The methods for assessing the performance of RPE do not use biological agents as a challenge agent, therefore it is possible that the current performance requirement tests may not be appropriate for RPE intended for use in care settings.

#### Summary

There are no legislative requirements regarding RPE use in health and care settings. Legislation broadly covers the use of PPE in any occupational setting, which may be applied to RPE in health and care. Similarly, there are also no specific standards for RPE in the health and care setting. The standards available are relevant to RPE provision and use in all occupational settings, therefore are often not directly applicable or relevant to RPE worn for IPC.

### 3.1.3 What design features of disposable respirators are desirable?

Only one piece of evidence published by the HSE was included for this research question, graded SIGN 50 level 4 expert opinion.[44]

The HSE published a safety notice in 2022, not specific to health and care settings, advising against the use of FFP respirators with ear loops, and those fitted with clips and ‘snuggers’ to tighten their fit. HSE advise that FFP respirators fitted with ear loops provide an insufficient seal to the face and instead recommend the use of respirators with a head harness.[44]

There is a lack of high-quality evidence regarding the desirable features of RPE relevant to IPC.

### 3.1.4 What design features of powered respirators are desirable?

There was no relevant evidence identified in relation to this research question. Valved respirators are discussed separately under Research Question 9, 'When should valved versus unvalved respirators be worn?'.

### 3.1.5 What are respirator 'fit tests' and 'fit checks' and how are they performed?

In total, 27 pieces of evidence were included that addressed what respirator fit tests or fit checks are and how they are performed. Seven evidence sources were included in the previous version(s) of this literature review.[2-4, 8, 37, 42, 45] Twenty additional pieces of evidence were identified during this update.[5, 6, 10, 12, 17, 19, 20, 22, 23, 30, 37, 46-54] One guideline graded AGREE: 'Recommend with provisos' due to limitations regarding the systematic review methodology used to underpin the recommendations,[45] three primary studies (observational) were graded SIGN 50 level 3[53-55] and 23 documents were graded SIGN 50 level 4 expert opinion.[2-6, 8, 10, 12, 17, 19, 20, 22, 23, 30, 42, 45-52]

Of the included evidence, 11 sources were published in or written for the UK,[2-4, 8, 19, 22, 23, 42, 50, 51, 56] four of which are British Standards.[8, 22, 23, 50] Whilst being directly applicable to UK settings, the membership of the technical committee(s) who contribute to British Standards is not easily accessible and information regarding how to obtain this information is unclear. Eighteen evidence sources were published in the ROI,[30] USA,[5, 6, 12, 47, 48, 52, 57] Australia,[10, 46] Canada,[19, 55] New Zealand,[20, 49] Hong Kong,[53] and internationally or for unspecified audiences.[45] One was published by the ECDC therefore applicable to the EU/EAA.[17] Eleven evidence sources are not specific to health care workers,[2, 3, 8, 22, 23, 37, 42, 47, 48, 50, 52, 56] however, this may not affect generalisability due to the nature of this research question. The process of fit testing and fit checking should apply across both health and care and non-healthcare settings, and for every person wearing them.

#### Fit testing

Fit testing is required when donning a tight-fitting respirator, which includes any respirator that forms a tight seal to the wearers face.[2, 3, 6, 8, 22, 23, 42, 47, 50] Fit tests are

a method to evaluate how well a respirator fits the wearer and therefore determine the correct model, style, and size of tight-fitting respirator suitable for an individual.[2, 3, 10, 19, 50, 56] Loose fitting devices such as powered air purifying respirators (PAPRs) with a hood, helmet, or visor, do not require a fit test.[2, 12, 42, 47, 57] Fit test results are not transferable across respirator models, sizes and styles.[10, 19, 50, 56] Literature is consistent in advising that prior to fit testing, the wearer be clean shaven, and free from items such as jewellery around the seal area to prevent interference with fit of the RPE.[2, 3, 19, 22, 50] Items of PPE, such as eye protection and RPE accessories, worn alongside RPE should be worn during the fit test to determine compatibility.[3, 4, 50]

Fit test (FT) methods are classified as quantitative (QNFT) or qualitative (QLFT).[2, 3, 6, 10, 19, 20, 22, 23, 30, 47, 49, 50]

## Quantitative fit testing

According to the HSE, QNFT methods are suitable for disposable respirators (half mask), reusable respirators (half and full mask) and powered respirators (half and full mask).[3] Specialised instruments are used during QNFTs to quantify face seal leakage into the respirator to determine a quantitative fit factor (QNFF) value that estimates fit.[2, 6, 10, 23, 47, 50] The QNFF is calculated as the ratio of two aerosol concentrations (concentration out: concentration in), taken inside and outside of the respirator.[50] The required fit factor is a numerical threshold used to determine whether a fit test is passed or failed.[23] This is dependent on the type and class of respirator device used. HSE state FFP1, 2, 3s, and half-face mask respirators all have a QNFF of 100, whereas full-face masks have a QNFF of 2000.[3]

In the BS ISO 16975-3:2017 standard, the BSI describe three QNFT procedures that have been proven for field use, these are: the generated aerosol quantitative fit test procedure, the ambient aerosol condensation nuclei-counting (CNC) instrument quantitative fit test procedure, and the controlled negative-pressure (CNP) REDON quantitative fit test procedure.[3] Further information on each of these procedures (such as operating principles and required equipment) is provided by BSI ISO16975-3:2017. Instructions on how to prepare the wearer for the ambient particle counting method and controlled negative pressure method are provided by HSE.[3]

A description of four QNFT methods are provided in BS EN 529 2005, these include the test chamber method, non-chamber methods, particle counting method and pressure method. The US OSHA state there are three approved QNFTs, the most common being 'the ambient aerosol condensation nuclei counter (CNC) test'; no other methods are named, and this has limited applicability to health and care settings due to the controlled experimental conditions in which the test is conducted, and because no references are provided.[6] The HSE provide two examples of QNFT: laboratory test chamber and portable fit test devices, such as a particle counting device.[2]

### Qualitative fit testing

QLFTs are pass or fail sensory detection tests that use agents with a distinct taste or smell, often bitter or sweet,[2, 3, 6, 8, 50] to assess leakage.[2, 3, 6, 10, 23, 47, 50] They are therefore considered subjective.[2, 3, 6, 30] QLFTs require threshold screening to determine the wearer's ability to detect the test agent at low concentration with the goal of mitigating the risk of potential leaks being undetected.[6, 8, 50] The HSE state that QLFTs are not suitable for full face masks, and suitable only for half masks, specifically half mask disposable respirators, reusable respirators, and powered respirators.[2, 3] Conversely, BS EN 529 2005 specifies that QLFTs are suitable for full-face masks, as well as half masks and filtering face pieces.[8] Other British Standards [22, 50] do not specify suitability by mask type, instead stating QLFT may be used when a required fit factor (RFF) of 100 or less is needed. The assigned protection factor (APF) for QLFTs is said to be limited to 10 by OSHA, which includes full face mask respirators.[6] Therefore, if high protection factors face masks are required, QLFTs are unlikely to be suitable.[8] BS EN 529 2005 also state respiratory devices should be fitted according to manufacturer's instructions.

Three primary studies compared QLFTs and QNFTs.[53-55] A cross-sectional study of 204 undergraduate nursing students in Hong Kong found that fit checks on two types of N95 respirators (3M 1860 S and 3M 1862) had sensitivity (ability of fit test to identify a failed quantitative fit test) of 15.2% and 23.0%, and a specificity (ability of the fit test to correctly identify a passed quantitative fit test) of 88.8% and 89.7%, respectively, when comparing against a quantitative fit test.[53] An observational study carried out on 614 health care workers across 24 residential care facilities in

Vancouver, Canada, compared the pass/fail rates of QNFTs and QLFTs using three models of N95 respirators.[55] This study demonstrated that QNFTs are more sensitive than QLFTs. A quality improvement study performed by NHS England assessed five FFP3 models that were tested according to UK HSE QFLT and QNFT fit test methods by hospital staff working in areas where FFP3 respirators were required. Secondary analysis of the data found that a QNFT was associated with lower odds of passing compared to QLFT (OR 0.71, 95% CI 0.61 – 0.82, $p < 0.05$), which further supports the conclusion that QNFTs are more sensitive than QLFTs.[54] However, in these studies inferences on true positives/true negatives cannot be made as no method to validate the pass/fail of each test method was carried out. Additionally, the studies performed in Canada and Hong Kong, respectively, may be limited in applicability to Scottish health and care settings given their geographical setting, and limited generalisability due to investigation of only one QNFT and QLFT test, respectively.[53, 54]

### Fit checking

There is consistency within extant guidance that fit checks are carried out by the wearer of tight-fitting respiratory devices as a simple and quick method to establish if the respiratory device has been correctly put on and forms a seal to the face.[6, 8, 19, 20, 23, 30, 48, 49] Three pieces of guidance state that fit checks are not substitutes for fit testing,[3, 6, 48] due to lack of sensitivity and specificity.[48] Findings from two primary studies highlight the potential inaccuracy of seal checks and support guidance recommendations that a user seal-check should not be used in place of a QNFT.[53, 55]

Manufacturer's instructions should be followed in order to establish the correct method of fit checking for individual types of respirator devices.[2, 3, 6, 10, 17, 48, 51]
Fit checks may be carried out in two ways; by positive pressure (exhaling) or by negative pressure (inhaling) once the respirator is donned (put on).[2, 4, 6, 8, 10, 30, 45, 46, 48] HSE consider the controlled negative pressure method unsuitable for disposable respirators.[3] Positive pressure fit checks are carried out by the wearer exhaling and observing for any air escaping around the face seal, which would indicate a leak and therefore an unsuccessful fit check.[4, 8, 10, 45, 46, 48, 52] Examples of indications of air leakage cited by the evidence base include: feeling air pass over the face, fogging/steaming of glasses,[48, 52] and a lack of build-up of pressure inside the

respirator device.[6, 45, 48] During negative pressure fit checks, the respirator device should then be drawn towards the face/ slightly collapse; if this is not observed, or air enters around the face seal, this is an indication of leakage and subsequently an unsuccessful fit check.[2, 4, 6, 10, 45, 46, 48]

### Summary

In conclusion, both fit tests and fit checks are required for tight-fitting respirators to ensure a tight seal has been achieved. A fit test is initially performed to determine the correct brand, model and size of respirator for the wearer. Fit tests may be quantitative or qualitative and the suitability of these tests depend on the respirator type being worn. Following confirmation of a suitable respirator using a fit test, a fit check is a simple and quick check to ensure that a respirator has been donned correctly to form a tight seal around the face. Fit tests may be performed by introducing positive or negative pressure by exhaling or inhaling, respectively. Literature was consistent that these should be performed according to manufacturer instructions. UK expert opinion guidance and standards are available for detailed procedures on how to perform fit tests. These are not specific to health and care settings.

## 3.1.6 When should a 'fit test' and a 'fit check' be performed?

Forty-six pieces of evidence were included in relation to this research question.[2-6, 8-12, 16-19, 22, 24-27, 29, 42, 45-48, 50, 52, 58-74] Twenty-seven were identified in this update,[6, 10-12, 16-19, 22, 24-27, 29, 30, 46-49, 51, 53, 60-73] and 11 were identified in the previous update(s).[2-5, 8, 9, 42, 45, 50, 58, 59] Two guidelines, one of which was published in the UK and one published for international audiences, were graded AGREE: 'Recommend with provisos' due to drawbacks relating to their systematic review methodologies.[45, 58] Five primary studies (two observational and three manikin simulations) were graded SIGN 50 level 3,[70-73, 75] and 39 guidance documents were graded SIGN 50 level 4 expert opinion.[2-6, 8-12, 16-19, 22, 24-27, 30, 46-48, 50, 51, 57-62, 64-69, 76] Of the expert opinion guidance documents included for this research question, 14 were published in the UK,[2-4, 8, 22, 24-27, 50, 51, 64, 65] one in the ROI,[30] 13 in the USA,[5, 6, 9-12, 29, 47, 48, 59, 60, 63, 76] four in Canada,[66-69] three in Australia,[46, 62] one in New Zealand,[49] three were published internationally,[16, 45, 61] and three were published by the ECDC therefore

applicable to the EU/EEA.[17, 18, 33] Four of the guidance documents published in the UK were produced by the HSE as part of a series.[24-27]

Four primary studies assessed the effectiveness of achieving a tight seal between the face and respirator by performing a fit test or fit check.[70-73] One of these studies involved human participants,[72] and three used manikins.[70, 71, 73] One study including human participants assessed the frequency of fit testing.[75]

Three simulation studies applied respirators to a manikin head using Vaseline to form a tight seal.[70, 71, 73] These studies demonstrated that respirators rely on a tight seal at the interface between the respirator edge and face for their efficacy, suggesting that fit testing and checking is necessary.[70, 71, 73] However, given the limitations of these studies, further, high-quality observational studies using human participants are necessary to verify their conclusions.

## Fit testing

### Indications for fit testing

Overall, the indications for fit testing proposed by expert opinion guidance align with relevant national standards and/or legislation and are generally consistent.[2, 3, 10, 12, 30, 47, 62] There was consistency in 20 SIGN 50 level 4 expert opinion guidance that staff who use tight-fitting RPE should be fit tested before use.[2, 5, 9-11, 16-19, 22, 29, 30, 46, 49, 61, 62, 64, 67-69] Three of these documents further specify that fit testing should be performed at the commencement of employment if RPE use is anticipated.[10, 16, 30]

Two guidance documents, published by the CDC and ROI Department of Health respectively, state that fit testing is not always required.[9, 30] The CDC states it may not be required for RPE models that have good fit characteristics, defined as providing an APF of ≥ 10 for at least 95% of wearers.[9] However, this premise is based on two low-quality studies.[9] The ROI Department of Health (2023) states, in line with recommendations from the Health and Safety Authority, that tight-fitting RPE should be fit tested before use, but also advise that where fit testing is not reasonably practicable, it should be prioritised for HCWs that perform aerosol generating procedures (AGPs), highlighting endotracheal intubation in particular, and HCWs exposed to airborne infection frequently or for long periods of time.[30]

One primary study (SIGN 50 level 3) conducted in Taiwan using human participants (SIGN 50 level 3) demonstrated that fit tests increase the protection provided by RPE.[72] This study investigated the filtering efficiency of FFP respirators (supplied by two manufacturers) and surgical face masks (from three manufacturers) against nebulised sodium chloride (NaCl) in controlled conditions.[72] There was a weak, statistically significant positive correlation between fit factor scores and protection factor scores ($r = 0.378$, $p < 0.05$). A significant decrease in protection factors (PFs) score was seen when a fit test had been carried out ($p < 0.05$); this association was no longer significant when only considering those who passed a fit test ($p > 0.05$).[72] This study therefore provides weak evidence that fit testing RPE before use is beneficial to increase the protection offered. The findings should be interpreted with caution given limitations including a small sample size and testing of a small number of respirator types/models. Given that facial characteristics may vary according to ethnicity and the participants were university students, the findings may also have limited generalisability and applicability to Scottish health and care settings.[72]

**Repeat fit testing**

Repeat fit testing is consistently recommended for changes in the brand, model or size of respirator used,[2, 9, 19, 46, 49, 50, 65] and following reported or observed changes to the wearer's facial shape due to factors such as scarring, dental work, cosmetic surgery, piercings or weight change.[2, 3, 5, 6, 47, 49, 50, 65] Other indications for fit testing recommended by the HSE and BSI, respectively, are the new use of, or change in the use of other head or facial PPE,[3] and discomfort reported by the wearer.[50]

There is a lack of consistency regarding how often repeat fit testing should be performed outside of these indications. Three SIGN 50 level 4 expert opinion guidance published by the WHO, HSE and The Public Health Agency of Canada (PHAC), highlight the importance of repeat fit-testing but do not provide explicit recommendations.[2, 3, 19, 61] Nine SIGN 50 level 4 expert opinion guidance recommend repeat fit-testing at least annually.[6, 10, 12, 17, 22, 50, 62, 76] Conversely, one NHS England document states that according to guidance by the British Safety Industry Foundation, who offer an accredited fit-testing service, fit testing every two years is adequate.[65] A two-year interval is also in-line with expert opinion guidance

by the Ontario Agency for Health Protection and Promotion Provincial Infectious Diseases Advisory Committee (PIDAC).[66]

One primary study performed in the USA assessed the probability of fit test failure following three and five years after passing a QLFT of the same N95 respirator model.[75] In total, 15,757 HCWs with at least one fit test result were identified. Survival analysis including 12,065 HCWs, representing 31,270 person mask-years for follow-up was performed. At three years, probability of survival free from fit-test failure was 99.45% (95% CI 99.2 – 99.6%) and 99.4% (95% CI 99.2 – 99.6%) following five years.[75] Limitations of this study were related to generalisability as it focussed on QLFTs and was a single-study site. Additionally, analysis was performed using electronic records, where some inaccuracies of these records were noted by the study authors, potentially limiting internal validity of the findings.[75] This study provides evidence to suggest that fit test results may be valid for up to five years, but does not provide sufficient evidence to inform the frequency of fit testing in a health and care setting.

The Society for Healthcare Epidemiology of America (SHEA) recommend that visitors who are required to wear RPE should be fit tested.[59]

### Fit checking

Extant guidance (one AGREE: Recommend with provisos and 20 SIGN 50 level 4 expert opinion) is consistent in advising that a fit check should be performed every time tight-fitting RPE is donned.[8-12, 16, 19, 24-27, 29, 45, 46, 48, 49, 51, 60, 62-64]

As discussed, there is consensus that a fit check should not substitute a fit test. Therefore only one document, published by the Australian Government recommends that when visitors are required to wear a respirator but have not performed a fit test, a fit check may be appropriate.[62] This recommendation was not made for staff. [62]

Only one guidance document explicitly discusses fit checking by visitors. The PHAC recommend that visitors perform a fit test before use.[19]

### Summary

In summary, despite being low-quality, the primary evidence suggests that it may be beneficial to perform a fit check every time a tight-fitting respirator is donned to ensure a facial seal is formed between the face and respirator. This conclusion is in-line with expert opinion guidance that advises a fit check to be performed every time a tight-fitting respirator is donned. Literature was consistent in advising that a fit test should be performed before a tight-fitting respirator is worn for the first time and should be repeated when it is suspected that a wearer's facial shape has changed. There was, however, variation regarding how often a fit test should be repeated outside of these indications. There was also lack of evidence regarding the fit testing and fit checking of visitors and patients if respirator use is indicated.

## 3.1.7 What if a fit test or fit check is unsuccessful?

Twenty-seven pieces of evidence were included for this research question. Seventeen were identified during this update.[10, 12, 16, 18, 22, 24-27, 30, 46, 52, 54, 56, 65, 77-81] Seven were identified during previous update(s).[2-5, 8, 45, 50] Five cohort studies were graded SIGN 50 level 3.[54, 77-80] One guideline, published by the WHO, was graded AGREE: 'Recommend with provisos' due to limitations regarding the systematic review methodology used to underpin the recommendations.[45] Twenty-one evidence sources were graded SIGN 50 level 4 expert opinion.[2-5, 8, 10, 16, 18, 22, 24-27, 30, 46, 47, 50, 52, 56, 65, 81] Of the SIGN 50 level 4 expert opinion guidance documents included for this research question, 12 were published in the UK,[2-4, 8, 22, 24-27, 50, 56, 65] one in the ROI,[30] four in the USA,[5, 47, 52, 81] two in Australia,[10, 46] one was published by the ECDC therefore applicable to the EU/EEA,[18] and one was published internationally.[45] Four of the guidance documents published in the UK were produced by the HSE as part of a series.[24-27]

Seven documents (one AGREE: Recommend with provisos and six SIGN 50 level 4) provide recommendations specific to health and care settings.[4, 10, 18, 45, 46, 65, 81] The recommendations posed in these guidance documents are directly applicable to Scottish heath and care settings. Thirteen documents provide recommendations non-specific to health and care settings but are still considered applicable due to the nature of the research question.[2, 3, 5, 8, 22, 24-27, 34, 47, 50, 52]

Five cohort studies assessed factors associated with fit test failure amongst healthcare workers.[54, 77-80] The following factors that may affect fit were identified: sex, where females were more likely to fail,[54, 77, 79] age,[77] facial hair,[78] low body mass index (BMI),[54] and ethnicity.[54, 79] Overall, sample sizes were sufficient in the primary studies; however, methods for sample selection were often unclear, a limitation that may impact generalisability, for example if participation was voluntary. The OSHA fit testing protocol and N95/P2 respirators were used in all five studies, which limits generalisability to NHS Scotland, where fit testing in-line with the BS ISO 16975-3 standard is currently in place (Appendix 1). SIGN 50 level 4 guidance documents also highlight facial hair,[2, 22, 24-27, 30, 34, 45, 47, 52] jewellery,[50, 52] spectacles,[2, 50, 52] and facial characteristics such as scarring and moles[2, 45, 50] as factors that may prevent a tight facial seal.

Ten expert opinion guidance documents recommend measures that may be taken if a tight seal cannot be achieved.

- Repeat fit testing with the same respirator after adjusting the straps and face seal.[2, 4, 8, 10, 30, 45-47, 50]
- Repeat fit testing with a different respirator size or model.[3, 16, 30, 50, 52, 65] The number of alternative sizes/models that should be available was only discussed in two documents. The BSI recommend considering number of wearers and wearer acceptance.[50] The WHO recommend a range of sizes be available to accommodate different facial characteristics.[16]
- Wearing alternative loose-fitting RPE,[2, 3, 10, 22, 30, 45, 50, 65] with specific examples including PAPRs,[10, 46, 81] elastomeric respirators that do not require fit testing,[46] hoods,[3] and helmets.[3]
- Use of spectacle frames (if required for vision) supplied by RPE manufacturer that are compatible with their RPE.[2] This measure was only referenced by the HSE.

### Summary

In summary, a tight facial seal is not always possible due to person-dependent factors that can affect the facial characteristics of the wearer, and due to other factors, such as eyewear and additional PPE. Regardless of the country of

publication, expert opinion guidance is consistent in advising that fit testing should be repeated if unsuccessful. Following repeat fit test failure of the same model, other measures are consistently recommended, including trying a different respirator brand/model/size and wearing alternative loose-fitting RPE if a facial seal cannot be achieved.

### 3.1.8 When should RPE be worn by health and care staff?

In total, 47 pieces of evidence were included to answer this research question. Ten were included in previous version(s) of this review.[2, 4, 5, 8, 9, 30, 45, 58, 82-84] Thirty-seven were included in this update. [9, 12, 15-19, 29, 31, 45, 59-61, 63, 66-72, 75, 80, 84-10] Three documents, two of which were published in the UK and one by the WHO, were graded AGREE: 'Recommend with provisos' due to limitations regarding the systematic review methodology used to underpin the recommendations.[45, 58, 84] Seven simulation studies were graded SIGN 50 level 3,[70-73, 85-88] and 35 guidance were graded SIGN 50 level 4 expert opinion.[2, 4, 5, 8-11, 13, 16-20, 30, 32, 46, 60-62, 64, 67-69, 76, 81-83, 89-97]

Of the SIGN 50 level 4 expert opinion guidance documents included for this research question, eight were published in the UK, [1, 3, 7, 63, 82, 83, 85, 90, 100] one in the ROI,[30] three in Australia,[10, 46, 62] two were published in New Zealand,[20, 94] eight in the USA,[5, 9, 13, 60, 76, 81, 82, 93, 98] five in Canada,[19, 67-69, 96] five were published by the ECDC, therefore applicable to the EU/EEA,[17, 18, 92, 99, 100] and two were published internationally or for unspecified audiences.[16, 61] Four of the guidance documents published in the UK were produced by the HSE as part of a series.[24-27]

#### Effectiveness of RPE in providing protection to the wearer

Thirty evidence sources provide relevant evidence regarding use of RPE to protect the wearer. This includes 23 guidance, 20 of which were graded SIGN 50 level 4 expert opinion[4, 9, 10, 17-19, 30, 33, 60, 62, 76, 82, 84, 90, 92, 95, 97-101] and two guidelines graded AGREE: 'Recommend' with provisos due to limitations regarding the systematic review methodology used to underpin the recommendation.[45, 84] Eight SIGN 50 level 3 simulation studies were also included. [70-73, 85-88]

## Primary research

There is a distinct lack of high-quality epidemiological evidence available for the assessment of the effectiveness of RPE at providing protection to the wearer in health and care settings. Eight experimental simulation studies compared the efficacy of N95 respirators and surgical masks.[70-73, 85-88] Three studies included human participants in their simulation,[72, 87, 88] and five used manikins.[70, 71, 73, 85, 86] Five used sodium chloride particles as the proxy challenge agent to represent biological particles.[72, 85-88] Three studies used radiolabelled saline.[70, 71, 73] As discussed under the research question, 'Are there any legislative requirements for the use of RPE for infection control purposes and what standards (BS/EN) must RPE adhere to?', the use of sodium chloride, as well as radiolabelled saline, may not be a valid proxy for infectious particles that staff may encounter in health and care settings.

One study with human participants compared the filtration capacity of FFP1, FFP2 and FFP3 respirators from two manufacturers, and surgical masks from three manufacturers, against 1.5g/100mL nebulised sodium chloride.[72] Participants donned a respirator or surgical mask and performed various exercises for two minutes each such as normal breathing, heavy breathing and talking, following a user seal check. For particle sizes 0.093 – 1.61 $\mu$m, there was no significant difference in the efficacy of FFP1, FFP2 and FFP3 respirators, despite differences in their filtration class ($p > 0.05$).[72] As expected, the FFP1, FFP2 and FFP3 respirators performed significantly better than the surgical mask in terms of filtration capacity. Two additional studies using human participants used nebulised sodium chloride to assess filtration capacity of respirators and surgical masks. One study included N95 respirators and surgical masks[87] and a second assessed KN95, KF94 and surgical masks.[88] These studies found that N95s were superior to all of the comparators.[87, 88]

The superior performance of respirators was reported in two simulation experiments which used manikins to compare the filtration capacity of RPE and surgical masks using nebulised sodium chloride.[85, 86] Conversely, one experimental study using two manikins and nebulised technretium-99 labelled 0.9% saline found no significant difference in the filtration of N95 respirators and surgical masks.[70]

Five manikin studies assessed the inward leakage of RPE and surgical masks.[70, 71, 73, 85, 86] Two of these studies did not specify how they sealed respirators to manikin heads, [85, 86] and three used Vaseline.[70, 71, 73] One study assessed surgical mask and N95 respirator efficiency at 0, 6 and 12 air changes per hour (ACH) to represent environments with no ambient airflow, a typical hospital room and a typical negative pressure room, respectively.[73] There was a significant reduction in exposure to particles, when compared to maximum exposure (no mask worn on source or receiver) when the source was wearing a respirator in all three airflow conditions; reduction in exposure compared to surgical masks was not performed.[73] Two studies found no statistically significant difference in protection when surgical masks or N95 respirators were applied to the manikin head, until the N95 respirator was subsequently sealed using Vaseline.[70, 71] Two studies that used sodium chloride particles as the challenge agent found that surgical masks had higher inward leakage when compared to N95 respirators.[85, 86]

Inward leakage of surgical masks versus N95 respirators was also assessed in the studies using human participants as they used fit test results as a proxy for PPE efficacy.[72, 87, 88] In these studies, respirators consistently performed better than surgical masks in terms of penetration of particles and inward leakage, providing evidence that N95 respirators are more effective than surgical masks at blocking challenge particles.[72, 87, 88] These findings also suggest that N95 respirators require a face-seal to maximise efficacy.

Two manikin studies assessed the impact of breathing frequency and particle size on the performance of N95 respirators and fluid-resistant surgical masks, using sodium chloride particles.[85, 86] Irrespective of inspiratory flow rate and breathing frequency there was a significantly higher filter penetration with the surgical masks compared to N95 respirators.[85, 86] These studies also found that the efficacy of N95 respirators may be negatively affected by inspiratory flow rate and breathing frequency; however, these findings have limited generalisability as these parameters are not typically monitored during real life use nor can they be altered.[85, 86]

Overall, evidence from experimental studies indicates that respirators performed better than surgical masks in terms of having less inward leakage of particles as well as greater filtration efficiency. Only one study compared respirators according to

their APF and found no significant differences in their efficacy. However, all these studies have limited power: sample sizes were small and sampling periods were short. They were also performed in controlled environments using proxy challenge agents, whereas factors such as humidity, ventilation and room size may play a significant role in particle size and behaviour in real-life settings.

### Extant guidance

As previously discussed under the research question, 'What is RPE?', RPE is designed to protect the wearer from breathing in particles in the air. The definitions of transmission modes and analysis of particle size are outside the scope of this literature review and are covered in depth in the NIPCM literature review, 'Transmission-based Based Precautions (TBPs) definitions', which is currently being updated. The following discussion cites terms used in extant guidance. In all guidance, the evidence base behind the transmission routes and definitions cited were based on expert opinion and/or low-quality evidence.

Twenty-nine SIGN 50 level 4 expert opinion guidance documents, and two guidelines graded AGREE: 'Recommend with provisos',[45, 58] 31 provide clear recommendations that RPE should be worn if a patient has a confirmed or suspected infection with a pathogen transmitted by the 'airborne route'.[4, 5, 9-11, 13, 16-19, 30, 33, 45, 49, 58, 60, 62, 64, 67-69, 76, 82, 84, 90, 92, 95, 96, 98, 99, 101] One of the guidelines was published by the WHO and focusses on the control of epidemic and pandemic-prone respiratory infections in health settings.[45] The second guideline was published in the UK and provides recommendations to prevent healthcare associated infection in NHS England hospitals, therefore the recommendations made are directly applicable to acute settings in NHS Scotland.[58] [45]

Twenty-seven documents provide examples of infectious diseases or infectious agents that are considered to be 'airborne': rubeola virus [measles],[19, 60, 82] chickenpox [varicella-zoster virus],[60, 82] disseminated herpes zoster (Shingles) [varicella-zoster virus],[19, 60] tuberculosis [*Mycobacterium tuberculosis*],[9, 19, 45, 60, 82, 84, 98] smallpox [variola virus],[9, 19, 82, 90, 99] and mpox.[95, 100] 19 pieces of evidence graded SIGN 50 level 4 (expert opinion) advise the use of RPE to protect wearers from acquiring respiratory infection,[5, 9, 10, 33, 49, 90, 99] specifically SARS-CoV-2,[13, 16-18, 33, 49,

[62, 67-69, 92, 96, 101] avian influenza,[90, 99] and severe acute respiratory syndrome (SARS).[9, 76]

Although extant guidance is consistent in advising that RPE should be worn for 'airborne precautions', there is variation as to the specific situations that require these precautions. These include during general patient care, for specific clinical procedures, sessionally for cohort and/or pandemic situations, and based on risk assessment. These are discussed in more detail below.

### General patient care

Seven expert opinion documents recommend that RPE is worn when in the same room or care area as a patient that requires 'airborne precautions',[4, 9, 10, 19, 30, 60, 82] or when providing general patient care until a patient is no longer considered infectious.[4, 9, 10, 19, 60, 82] Example pathogens cited within these guidance documents include rubeola virus [measles],[4, 19, 60, 82] tuberculosis [*Mycobacterium tuberculosis*],[4, 9, 19, 60, 82] SARS [SARS-CoV-1],[4] smallpox [variola virus][9, 82] pandemic influenza,[10] chickenpox [varicella-zoster virus] [4, 60, 82] and shingles [disseminated herpes zoster].[60]

The US Occupational Safety and Health Administration (OSHA) recommend an N95 respirator or higher rated respirator when within six feet (1.8 metres) of patients that have confirmed or suspected pandemic influenza infection.[5]

Nine documents make recommendations specific to COVID-19, stating that staff should wear RPE when providing direct care to patients with suspected or known COVID-19 infection.[17, 18, 33, 52, 62, 76, 92, 96, 101] Three documents published by the Government of Canada state that RPE is necessary when in the same room or within two metres of a patient or resident with suspected or confirmed COVID-19 infection.[67-69]

The CDC explicitly state that they cannot make a recommendation with regards to the use of a surgical mask or RPE for HCWs that have contact with patients with suspected and confirmed measles, chickenpox or disseminated herpes zoster due to a lack of evidence regarding the benefits of RPE use.[9] Conversely, six expert opinion documents published by different organisations internationally (Canada,

Australia and USA) recommended that RPE is worn when in the same room or care area for these infections (measles, chickenpox and disseminated herpes zoster), however what constitutes a care area was not well defined.[4, 9, 10, 19, 60, 82] However, the Public Health Agency of Canada (PHAC) state that this is only necessary if patients have varicella or measles and the WHO state this is only necessary for patients with 'obligate or preferential airborne infection'.[19, 45]

Ten documents recommend RPE with ≥ 95% efficiency, specifically P2 and N95 respirators, for general patient care;[9, 11, 30, 49, 60, 62, 67, 82, 96, 101] five documents, all published in the UK, recommend RPE with ≥ 99% efficiency, specifically an FFP3 respirator;[4, 58, 64, 84, 95] two documents, published by PHAC and the National Institute for Health and Care Excellence (NICE), do not specify the respirator type or filtration capacity.[19, 83] The ECDC, Health Care Infection Control Practices Advisory Committee (HICPAC) and WHO do not distinguish between the use of RPE with 95% or 99% filtration capacity for general COVID-19 patient or resident care.[9, 17, 18, 92]

There is consistency that RPE should be worn for airborne precautions, but lack of clarity around when RPE should be donned when these precautions are required. Some guidance recommend RPE when providing direct care, whereas others recommend RPE use when in close proximity to these patients, even when not providing care.

### Clinical procedures

Twenty-three expert opinion guidance documents published globally state that RPE should be worn when performing AGPs on a patient that has suspected or confirmed respiratory infection or any other infection spread in the air,[4, 9, 10, 13, 16-18, 30, 33, 45, 58, 60, 61, 67-69, 76, 81, 91-93, 96-98, 101] such as SARS, avian influenza, pandemic influenza, tuberculosis, *C. difficile* and SARS-CoV-2.[4, 9, 60, 61, 67-69, 76, 81, 92, 93, 96-99, 101] Eight documents recommend that RPE is worn for all AGPs, irrespective of patient symptoms, in the context of the COVID-19 pandemic.[13, 16-18, 81, 92, 96, 101] Five state that RPE should be worn in clinical areas where high-risk procedures, including AGPs, are performed, particularly in pandemic COVID-19 settings.[9, 16, 60, 68, 69]

There is a lack of consistency regarding the recommended filtering capacity of RPE needed for high-risk clinical procedures. Fourteen guidance from 12 organisations (WHO, CDC, ASA, Ministry of Health New Zealand, Government of Canada, Infectious Disease Society of America, AORN, NHMRC, APIC, NIOSH, and the Republic of Ireland Department of Health) recommend a respirator with ≥ 95% filtration capacity, for example, P2, N95 respirator or FFP2 respirator [10, 13, 16, 30, 60, 61, 67-69, 76, 81, 92, 93, 96-98, 101] and three (all UK based) recommend a respirator with ≥ 99% filtration capacity.[4, 58, 91] There is variation in ECDC guidance where FFP3 respirators are recommended in two guidance documents (99% filtration capacity), and an FFP2/3 respirator in guidance specifically for primary care settings.[17, 18, 92] The WHO IPC guidance for epidemic-and pandemic prone acute respiratory infection recommends a particulate respirator with the 'highest level of protection' for AGPs that are associated with increased transmission of acute respiratory infection. This contradicts with a later statement within this document, which recommends the use of a N95 or FFP2 respirator, rather than an N99 or FFP3 respirator for this indication (i.e. 95% versus 99% filtration capacity).[45] The WHO also do not distinguish between the use of RPE according to filtration capacity.[45, 61] Overall, the recommendations made regarding the filtration capacity in extant guidance are not based on rigorous scientific evidence, which likely accounts for the variability in recommendations across guidance documents.

Overall, extant guidance recommends RPE for staff involved in procedures (AGPs) that may produce infectious particles. However, there is a lack of consistency in the filtration capacity of the RPE recommended and it is difficult to reliably conclude if RPE is required for those working in close proximity to where AGPs are performed.

### Sessional use

Sessional use of RPE involves the wearing of RPE by healthcare workers continuously until no longer required, or until an indication to change or remove a respirator occurs. Note that although terms such as 'continuous use' and 'extended use' have been used across the evidence base, this review will use the term 'sessional use' for consistency.

PHAC recommend the sessional use of respirators when treating successive cohorted patients, in all health and care settings.[19] The WHO also recommend that sessional use of RPE may be applied when staff are treating cohorted patients with suspected or confirmed infections transmitted by the 'airborne route', providing pulmonary tuberculosis as an example of such infection.[45] This document also stipulates that although a single respirator may be worn, it may not be touched or removed at any time.[45] Similarly, CDC guidance on isolation precautions states that respirators may be re-used by the same healthcare worker when treating patients with *Mycobacterium tuberculosis* infection, so long as the respirator is not contaminated or misshapen, providing the caveat that the length of time that a respirator may be reused is not known.[9] However, removal and reapplication of disposable RPE in this manner is against manufacturer recommendations.[9] In generic guidance on preparing workplaces for influenza pandemics, the US OSHA also advise against re-use of respirators due to potential risk of cross-contamination.[5] In relation to COVID-19, the CDC's National Personal Protective Technology Library states that extended use may occur if staff are trained appropriately, but should not be worn for consecutive patients if worn in a room where an AGP was performed, or once treating a potentially infectious patient.[32]

Eight documents provided recommendations regarding sessional use in the context of the COVID-19 pandemic.[13, 20, 46, 67-69, 96] In their COVID-19 IPC guidance, the CDC recommend that a respirator is removed following a 'patient encounter'; the definition of this term is not provided, however it suggests that a respirator should not be used for successive patients. In interim COVID-19 IPC guidance for long-term care, acute settings and ambulatory settings published by the Canadian Government, sessional RPE use is also not recommended.[67-69] However, their supplementary guidance produced in response to the SARS-CoV-2 Omicron variant supports the use of either a surgical mask or KN95 for sessional use by staff and visitors, according to community transmission rates.[96] The Infection Prevention and Control Group of the Australian Government stated that the sessional use of RPE may be considered when staff are working in dedicated COVID-19 wards, where RPE should be changed when moving to a non-COVID-19 clinical care area.[46] The New Zealand Ministry of Health recommended sessional use of respirators.[20]

In guidance non-specific to health and care settings, the HSE recommend that continuous wear time of RPE should be one hour or less.[2, 24-27] This recommendation has limited applicability to Scottish health and care settings in terms of IPC.

### Risk assessment

Fifteen documents (13 SIGN 50 level 4 expert opinion guidance and two guidelines graded AGREE: 'Recommend with provisos' [45, 58]) advise that a risk assessment should be performed to determine whether RPE should be donned.[4, 13, 19, 45, 58, 62, 64, 67, 69, 83, 89, 92, 96] There is consistency that this risk assessment should consider factors relating to the patient, including their infectious status;[4, 9, 10, 13, 19, 45, 58, 62, 83, 96] the nature of the patient interaction, for example, proximity to patient, duration of interaction and the care activity being undertaken,[4, 19, 45, 58, 64, 67, 69, 83, 89, 92, 96] and factors relating to the environment, such as ventilation and crowding, including room/area occupancy.[16, 58, 64, 69, 89, 96] Six of the documents provide risk assessment recommendations in the context of the COVID-19 pandemic, such as taking consideration of the community prevalence of SARS-CoV-2, where the factors are considered generalisable outside of a pandemic setting.[13, 62, 67, 69, 92, 96] Three of these documents recommend consideration of SARS-CoV-2 community prevalence as a factor that may be considered, which is not applicable when surveillance is not in place.[62, 92, 96]

Of the 15 documents that recommend a risk assessment for RPE selection, 10 provide factors to consider but did not explicitly recommend when RPE versus surgical masks should be worn by health and care staff.[19, 58, 62, 64, 67, 69, 83, 89, 92, 96] Seven of the 15 documents provide recommendations regarding specific factors that would indicate a requirement for RPE.[4, 13, 45, 58, 67, 69, 96] These indications include wearing RPE for AGPs when patients have known or suspected infection with an infectious agent spread by the droplet or airborne route,[4, 45, 58, 67, 89] and general patient care if a patient has a suspected or confirmed infection caused by infectious agents spread by the airborne route.[45] Other factors include wearing RPE in areas with poor ventilation,[13, 45] when patients cannot wear a surgical mask for source control,[13, 69] or are coughing, shouting and heavy breathing [96] and for newly emerging infectious agents until the transmission route is confirmed.[45]

One SIGN 50 level 4 document published by the US CDC highlights that a staff member may choose to wear a mask or respirator based on their personal choice, which is informed by the potential for developing severe disease if exposed to SARS-CoV-2 as well as a risk assessment.[13] The Scottish Government published a Directorate Letter (DL) in 2022 that advised that health and care staff may choose to wear an FFP3 respirator based on personal preference without the need to perform risk assessment.[102] Scientific evidence was not used to support this recommendation. It was proposed to take into account factors including staff physical and psychological wellbeing and concerns around transmission risk in the context of working in a setting transitioning away from working in a COVID-19 pandemic environment.[102] This recommendation therefore has limited applicability outside of a COVID-19 pandemic setting.

There is a lack of consistency regarding the filtration capacity of RPE recommended for the above risk assessment. Ten documents recommend RPE with ≥95% filtration capacity, for example, N95 and/or P2 respirators.[9, 10, 13, 16, 30, 62, 67-69, 96] One expert opinion published in 2013 recommends RPE with ≥99% filtration efficiency.[4] Six do not distinguish between RPE according to filtration capacity.[19, 45, 64, 83, 89, 92] One document states that the filtration capacity of the respirator (FFP2 versus FFP3) may be incorporated as part of the risk assessment.[58]

### Source control

Six experimental simulation studies, all graded SIGN 50 level 3, compared the efficacy of RPE with that of surgical face masks when worn as a form of source control.[70, 71, 73, 103-105] Four studies used two manikins in their simulation to mimic the interaction between an infectious host and a recipient spaced three-feet (0.9 metres) apart.[70, 71, 73, 103] Two studies included human participants.[104, 105]

The four manikin studies used different variables to assess source control.[70, 71, 73, 103] Using 0.9% saline labelled with technetium-99m as the challenge agent, the first study found that an N95 respirator sealed to the manikin head using petroleum jelly resulted in greater average filtration capacity (35.7%, 95% CI 27.7 – 43.7) when compared to a tightly fitted surgical mask (14.8%, 95% CI 10.1 – 19.6) and loosely fitted surgical mask (6.07%, 95% CI 5.43 – 6.72).[70] In the second simulation, 14%

sodium chloride and 0.4% fluorescein solution was nebulised to simulate coughing;[103] an N95 respirator applied to the manikin head resulted in a reduction in mean particle mass compared to no PPE and compared to a procedure mask ($p < 0.0001$).[103] A third simulation study reported that capture efficiency, defined as the percentage of aerosol exhaled during tidal breathing, was ~100% when a sealed respirator was applied at the source and performed significantly better than an unsealed respirator and surgical masks during simulated tidal breathing ($p < 0.05$).[73] The findings were not significantly different for simulated coughing, where the differences in capture efficiency between surgical masks, sealed N95s and unsealed N95s were not significantly different.[73] Finally, simulation of an N95 sealed to a source manikin with petroleum jelly resulted in significant reduction in exposure to the other manikin in the simulation; however statistical significance was not observed when petroleum jelly was not used.[71]

Two additional simulations assessed the efficacy of N95 respirators, KN95 respirators and surgical masks as source control using human participants.[104, 105] Simulated staff/patient interaction using healthy participants found surgical masks and KN95 respirators significantly reduced outward emission of particles when talking and breathing through the mouth ($p < 0.05$).[104] When coughing, use of a non-vented KN95 respirator did not significantly reduce the outward emission particle rate, whereas use of surgical masks did achieve a significant reduction in number of particles per second.[104] Vented N95 respirators were also investigated using two participants and were not effective as a form of source control.[104] The second study compared the efficacy of KN95 respirators, N95 respirators, surgical masks and cloth masks using paired samples from 44 participants who were positive for SARS-CoV-2.[105] Controlling for number of coughs, age, sex, BMI and SARS-CoV-2 variant, viral load decreased by 98% (95% CI 97 – 99%) with use of N95 respirators.[105] This percentage decrease in viral load was observed in decreasing order with cloth masks (87% (95% CI 77 – 92)), surgical masks (74% (95% CI 65 – 81), and KN95 respirators (71% (95% CI 59 – 79%), which increased to 76% (95% CI 64 – 84%) after excluding unknown KN95 respirator brands). The non-overlapping 95% CIs suggest these findings are statistically significant.[105] Limitations including sampling being performed when different variants of SARS-CoV-2 were circulating, lack of clarity regarding the design of KN95s supplied by participants, and unclear

performance of fit testing and fit checking of RPE by participants mean the clinical significance of these findings is unclear.[105]

Use of valved versus non-valved respirators as source control is discussed under 'When should valved versus unvalved respirators be worn?'.

Overall, the discussed simulation studies have limitations that mean robust conclusions cannot be drawn. This review did not identify any epidemiological studies or trials for the assessment of RPE as source control therefore there is a lack of evidence regarding the effectiveness of RPE as source control in reducing transmission risk. These simulations were performed in confined chambers. In some cases, ventilation was not appropriately considered or it was unclear if the air changes used represented real-life clinical settings.[70] All the simulations were based on a small amount of data, where the number of replicates/independent experimental repeats were small, limiting the validity of the findings. In all the manikin simulations, N95 respirators were used and in most of the experiments, were sealed to manikin heads using Vaseline, limiting generalisability to other RPE and to real-life settings.

Five expert opinion guidance documents refer to RPE as source control.[13, 33, 60, 68, 99] The Association of PeriOperative Nurses (AORN) state that in addition to protecting the wearer, RPE worn by staff during surgical procedures on patients with suspected infectious tuberculosis also protect the sterile field.[60] The CDC and Government of Canada state that source control using RPE or surgical masks may be considered to prevent transmission from staff to patients.[13, 68] The ECDC recommend a respirator for staff returning to work for five days after symptom onset if RT-PCR testing is not available.[33] The CDC recommend RPE or surgical masks as source control by all those working in a facility during high levels of community SARS-CoV-2 transmission.[13] These recommendations were made in the context of the COVID-19 pandemic, where presymptomatic and asymptomatic transmission was anticipated, and may not apply to other pandemic settings or non-pandemic settings.

Outside of COVID-19 pandemic settings, the CDC expand their recommendations to other respiratory infections, recommending source control in a unit/area with an outbreak until the outbreak is over.[13] Avian influenza guidance published by the

ECDC recommends that an FFP2 respirator should be worn when contacting other individuals 10-14 days after exposure to a confirmed patient.[99]

There was minimal guidance on RPE as source control, likely given the fact that the primary function of respirators is to protect the wearer, rather than filter exhaled breath to provide protection to others.

#### Conclusion

The evidence base for this research question consists primarily of low-quality expert opinion guidance and simulation studies. Overall, there is consistency in the evidence base that RPE should be worn to protect staff from patients that have infections that may be transmitted by particles in the air. However, there is variation in guidance as to which clinical situations require RPE. In some guidance, RPE is recommended for all close contact with patients who have suspected or confirmed respiratory infection, in others, RPE is recommended based on symptoms, or for specific high-risk clinical procedures or for the duration of the shift if working in high-risk areas. The use of risk assessment to guide decision-making for RPE use was advocated in some guidance.

The sessional use of RPE is discussed by several guidance documents, however there is lack of consistency regarding the indications for implementing this measure.

There was a lack of consistency in the filtration capacity of the RPE recommended where RPE is advised for use. It is also important to note the preponderance of guidance specific to a COVID-19 pandemic response setting, which may lack generalisability to non-pandemic settings and to other infectious agents. There is minimal guidance and primary evidence on RPE as source control, likely given the fact that the primary function of respirators is to provide protection to the wearer, rather than to protect others.

### 3.1.9 When should valved versus unvalved respirators be worn?

Five pieces of evidence were included for this research question. One was identified in the previous version(s) of this review [5] and four were identified during this update.[31, 33, 106, 107] One primary study was included, graded SIGN 50 level 3,[106] and five guidance documents were graded as expert opinion, SIGN 50 level 4.[5, 31, 33, 98,

[107] Of the expert opinion guidance documents included for this research question, three were published in the USA [5, 15, 98] and one was published by the ECDC, therefore applicable to the EU/EEA.[33, 107]

One guidance document published by the CDC highlights that valved respirators are generally worn to improve comfort for the wearer.[15] None of the included evidence considered efficacy of valved versus non-valved RPE in providing protection to the wearer. This is likely because non-powered RPE (both valved and non-valved) should meet the same standards for efficacy in providing protection to the wearer.

The remainder of the guidance (n = 4 SIGN 50 level 4) discusses the use of valved versus non-valved respirators as source control. There was consistency that RPE (powered, non-powered or reusable) with exhalation valves are not appropriate as source control or when a sterile field is required as unfiltered air from the wearer is released to the environment.[5, 31, 33, 98]

A simulation study (SIGN 50 level 3) compared the use of valved versus non-valved N95 respirators as source control.[106] In this study, active air sampling was performed to measure bacterial contamination levels following simulated patient care in an enclosed 4.11 m x 4.11 m room with an air exchange rate (AER) of 24 per hour. Colony forming units (CFU)/$m^3$ were higher for an N95 with an exhalation valve when compared to an N95 without an exhalation valve (mean difference of post-hoc comparison of mean CFU/m3: -2.7; Bonferroni significance: 0.03).[106] Although this study had several limitations, including the use of only two N95 models, a small sample size (18 participants) and an unclear number of independent repeats, this study supports expert opinion recommendations that respirators with exhalation valves should not be used as source control.[106]

### Summary

In conclusion, RPE with valves are generally worn for comfort to the wearer. Although they can provide adequate protection to the wearer, the evidence base is consistent that they are not suitable for source control as unfiltered air is directly expelled into the surrounding environment.

### 3.1.10 When should a patient wear RPE?

Ten pieces of evidence were included for this research question. One guidance document, graded SIGN 50 level 4, was included in the previous version(s) of this review.[9] Nine pieces of evidence were identified in this update. Four of these were graded SIGN 50 level 4, expert opinion,[10, 11, 13, 19] and six were simulation studies graded SIGN 50 level 3.[70, 71, 73, 103-105] Of the expert opinion guidance documents included for this research question, three were published in the USA ,[9, 11, 13] one in Australia[10] and one in Canada.[19]

Overall, the guidance documents do not provide clear recommendations regarding when patients should wear RPE. The Australian Government provide clinical contraindications for patients wearing RPE, but their guidance lacks specific indications for use.[10] The Association for Professionals in Infection Control and Epidemiology (APIC) state that patients must be fit tested before wearing an N95 respirator but again, do not provide recommendations regarding when they should be worn.[11] The CDC state that clinically vulnerable people should wear the most protective form of source control that is tolerable.[13] In another document, the CDC recommend RPE for immunocompromised patients when there is risk of the presence of spores due to construction work, to prevent fungal infection.[9] Lastly, PHAC state that patients requiring airborne precautions do not require a respirator outside their isolation room; this recommendation is unclear as it may suggest they are therefore required to wear it in their isolation rooms, or they are not required to wear one at all.[19]

As previously discussed, six simulation studies, all graded SIGN Level 3, compared the efficacy of RPE to the use of surgical face masks as a form of source control. [70, 71, 73, 103-105] Refer to the research question, 'When should RPE be worn by health and care staff?' for a critical analysis of their findings. Four studies used two manikins in their simulation to mimic the interaction between an infectious host and a recipient spaced three-feet (0.9 metres) apart.[70, 71, 73, 103] Two studies included human participants.[104, 105] Briefly, three of the four manikin studies found that RPE sealed to manikin heads using petroleum jelly were more effective than surgical masks as source control. [70, 71, 103] One study found that there was no significant difference between surgical masks and RPE as source control when coughing was simulated.[73]

The studies using human participants compared vented N95s, KN95s and surgical masks. [104, 105] One study found that surgical masks were more effective than vented N95 respirators and KN95s.[104] The second study found that N95 respirators were more effective than KN95s and surgical masks.[105]

### Summary

In summary, there was a lack of high-quality evidence, both in terms of guidance and primary research for the use of RPE by patients. The guidance documents did not provide clear indications for use and did not discuss logistical issues surrounding fit testing of patients. The simulation studies had inconsistent conclusions and lacked generalisability, highlighting the need to perform additional, high-quality research in this area.

## 3.1.11 When should a visitor wear RPE?

Twelve pieces of evidence were included for this research question. One piece of evidence, graded SIGN 50 level 4 (expert opinion) was identified during the previous update(s).[11] Ten were identified during this update. Six pieces of evidence were graded SIGN 50 level 4 due to a lack of high-quality evidence to support their recommendations.[9-11, 19, 68, 96] and six experimental simulation studies were graded SIGN 50 level 3.[70, 71, 73, 103-105] Of the expert opinion guidance included for this research question, one was published in Australia,[10] three in Canada [19, 68, 96] and two in the USA.[9, 11]

Two expert opinion guidance documents published by the Government of Canada state that a surgical mask or KN95 respirator may be worn by visitors as source control and to provide protection to the wearer.[68, 96] This recommendation is broadly in-line with guidance from the CDC, which states that visitors should wear a surgical mask when visiting patients that require airborne precautions, or alternatively an N95 respirator. The CDC also state that airborne precautions may not be necessary for visitors as they may be immune or already infected.[9] Potential immunity or prior exposure of visitors was also acknowledged by PHAC. Nevertheless, PHAC recommend that visitors should have access to the same PPE as staff, particularly if visiting several patients.[19] The CDC further state that visitors can only wear an N95 respirator if fit tested, which is consistent with guidance from APIC.[11]

As previously discussed, six simulation studies, all graded SIGN Level 3, compared the efficacy of RPE to the use of surgical face masks as a form of source control.[70, 71, 73, 103-105] Refer to the research question, 'When should RPE be worn by health and care staff?' for a critical analysis of their findings. Four studies used two manikins in their simulation to mimic the interaction between an infectious host and a recipient spaced three-feet (0.9 metres) apart.[70, 71, 73, 103] Two studies included human participants.[104, 105] Briefly, three of the four manikin studies found that RPE sealed to manikin heads using petroleum jelly were more effective than surgical masks as source control. [70, 71, 103] One study found that there was no significant difference between surgical masks and RPE as source control when coughing was simulated.[73] The studies using human participants compared vented N95s, KN95s and surgical masks. [104, 105] One study found that surgical masks were more effective than vented N95 respirators and KN95s.[104] The second study found that N95 respirators were more effective than KN95s and surgical masks.[105] The limited quality of these studies and lack of generalisability of the findings does not provide sufficient evidence that respirators are required by visitors as source control.

#### Summary

In summary, there is a lack of evidence to inform RPE use by visitors. There is minimal extant guidance, where the recommendations available indicate that respirator use by visitors is not considered necessary. The primary evidence is also unclear regarding whether RPE is beneficial for use by visitors as a form of source control.

### 3.1.12 Where and how should disposable respirators be donned?

Twenty-one pieces of evidence were included for this research question. Four were included in the previous version(s) of this review,[2, 4, 18, 37, 40] where one of these documents has since been updated.[18] Sixteen pieces of evidence were identified during this update.[10, 11, 16, 19, 30, 41, 42, 46, 50-52, 60, 63, 68, 94, 96] Aside from two mandatory legislation,[37, 40] and one guideline published by the WHO graded AGREE: 'Recommend with provisos' due to limitations regarding the systematic review methodology used to underpin the recommendations,[45] the evidence base consists of guidance documents (n = 17) with little to no reference base, therefore graded SIGN 50 level 4 expert opinion. Eight pieces of evidence were published in the UK.[2,

[4, 36, 37, 41, 42, 50, 51] two were published in Canada,[19, 96] three in the USA,[11, 51, 60, 63] one in the ROI,[30] one in New Zealand.[94] one in Australia.[10] One was published by the ECDC therefore applicable to the EU and EAA.[18] and one by the WHO therefore applicable internationally.[16] Depending on the location, different respirator types are discussed, for example P2 respirators in Australian guidance and N95 respirators in USA guidance. However, given that the design of tight-fitting respirators is relatively similar, the recommendations are considered widely applicable. Additionally, this evidence base is also considered applicable to powered respirators given that RPE, powered or non-powered, is donned when required to provide respiratory protection.

### Location

Four organisations provide recommendations regarding where respirators should be donned.[10, 51, 60, 94] Expert opinion guidance was consistent in advising that RPE should be donned before entering a patient room/care area where 'airborne precautions' are required, or when a patient has an infection transmitted by the 'airborne route'.[10, 51, 60, 94] In their COVID-19 guidance, the WHO recommend that RPE should be donned before entering an area where there is a patient with suspected COVID-19 infection.[16]

### Donning method

Eight SIGN 50 level 4 expert opinion guidance provide recommendations on the sequence for donning RPE. Following hand hygiene,[9, 18, 19, 46, 51, 52, 63, 96] guidance is consistent in advising that PPE should be donned in the following order: apron/gown; respirator; eye/face protection then gloves.[9, 18, 19, 46, 51, 63] Guidance published by the Australian Government highlights that if headwear and/or spectacles are already being worn, these should be removed before donning RPE.[10] This document is the only one to state that the order for donning PPE may differ according to setting, for example in a dental or surgical setting, RPE should be donned before performing hand hygiene.[10] Performing a respirator 'fit check' is discussed as part of the donning sequence in the evidence identified. Refer to the research question, 'When should a 'fit test' and a 'fit check' be performed?' for further information.

The COSHH legislates that, “Every employer who provides any control measure, other thing or facility in accordance with these Regulations shall take all reasonable steps to ensure that it is properly used or applied as the case may be”.[37] In SIGN 50 level 4 guidance published by HSE to support the implementation of COSHH legislation, this is interpreted to mean that the technique used to don RPE should adhere to manufacturer instructions.[2, 42] This is supported in guidance published by AORN, APIC, the UK Health Security Agency (UKHSA) and the BSI.[11, 50, 51, 60] Manufacturer instructions are not mentioned in the remainder of the evidence base. Several documents provide specific instructions for donning a disposable respirator in order to achieve a tight seal: one provides techniques for P2 respirators;[10] three for N95 respirators,[11, 19, 52] one for cup-shaped respirators[30] and four do not specify the type.[2, 4, 9, 46, 74] Despite lack of consistency in the respirators mentioned, the techniques are generally similar. They can be summarised as follows:

- inspect the respirator for any defects and do not use if issues are identified[46, 52]
- align top of the respirator with nose bridge and bottom of the respirator under the chin to ensure that the nose and mouth are covered[11, 19, 46, 52]
- press down firmly using fingertips to mould the respirator to the nose bridge[11, 9, 19, 46]
- press the edge of the respirator around face[4, 9, 11, 46]
- use all the straps available, ensuring they are positioned appropriately.[2, 9, 30, 46] For example, the CDC highlight that N95 straps should be laid flat and not crossed over, and UKHSA state that the upper strap of a respirator should be positioned at the crown of the head above the ears and the lower strap at the nape of the neck[51, 52]

The Scientific Development Committee of the Healthcare Infection Society (UK) provide further detail on how to don FFP3 respirators.[4] Referencing guidance that has since been archived on how to don FFP3s, developed by the Department of Health[4] and the Healthcare Infection Society, it is advised that one hand should be used to hold the FFP3 respirator and the other should be used to open it by separating the edges.[4] The metal bridge of the FFP3 respirator should then be bent and the headbands should be separated using the thumb and index finger, before

placing the respirator over the nose and mouth as described above.[4] Although the guidance document states this is the 'correct' way to don an FFP3, it is unclear if following this sequence follows manufacturer instructions and is necessary to minimise contamination.[4] The ROI Department of Health also provide specific instructions on how to don a cup-billed respirator.[30]

Seven documents provide recommendations regarding how to wear a respirator once it is donned.[4, 10, 11, 19, 30, 45, 46] Six documents (5 SIGN 50 level 4, 1 AGREE 'recommend with provisos') state that the front of the respirator should not be touched whilst being worn,[4, 10, 11, 30, 45, 46] and four documents state that respirators should not be left hanging around the neck when not in use.[10, 11, 19, 30]

### Compatibility

The HSE guidance document published to support compliance with COSHH and PPER legislation, state where two or more items of PPE are worn, the items must be compatible with each other.[37, 40, 41] HSE provide the following example, where a half-mask respirator may not be compatible with a pair of goggles.[41]

In summary, expert opinion guidance is consistent in advising that RPE should be donned according to manufacturer instructions and that hand hygiene should be performed before RPE is donned. There is lack of clarity regarding where RPE should be donned. Where 'airborne precautions' are indicated, a small body of evidence states that RPE should be donned before entering the care area. It is unclear where RPE should be donned when 'airborne precautions' are not explicitly indicated.

## 3.1.13 Where and how should disposable respirators be doffed?

Twenty-one pieces of evidence were included in relation to this research question. Five pieces of evidence were included in the previous version(s) of this literature review.[4, 5, 9, 37, 58] Sixteen additional pieces of evidence were included during this update.[10, 13, 18, 19, 22, 30, 46, 52, 63, 64, 74, 92, 96, 98, 108, 109] One legislation (COSHH) was graded 'Mandatory',[37] one UK guideline was graded AGREE: 'Recommend with provisos' due to limitations regarding the systematic review methodology used to underpin the recommendations,[58] and 19 guidance documents were graded SIGN 50

level 4 expert opinion. Of the expert opinion guidance documents included for this research question, five were published in the UK,[4, 22, 58, 64, 74] one in the ROI,[30] eight in the USA,[5, 9, 13, 52, 63, 98, 108, 109] two were published in Australia,[10, 46] two in Canada,[19, 96] and two were published by the ECDC therefore applicable to the EU/EEA.[18, 92]

### Where should doffing take place?

One mandatory legislation and seven SIGN 50 level 4 expert opinion guidance provide information regarding the doffing of PPE or RPE.[4, 10, 30, 37, 60, 64, 7438] The COSHH legislates that contaminated PPE should be doffed "on leaving the work area".[38] In line with COSHH legislation, this BSI recommendation states that RPE should not be removed in the same area where RPE is required. The remainder of the guidance is consistent in recommending that RPE is doffed outside of the patient care area upon leaving the room, or in an anteroom, where applicable.[4, 10, 30, 60, 64] AORN specifies that the door of the patient room should be closed before doffing RPE.[60] UKHSA highlight that removing RPE outside the patient room, anteroom or lobby may not be feasible and in such circumstances, they recommend removing RPE in a 'safe area'. However, only one example of a safe area was provided (outside of an isolation room).[74] Finally, the Australian Government recommend that respirators are removed outside a patient room or over one metre away if in the same room and the patient is symptomatic.[10] The rationale behind this recommendation is unclear.

Only one document, published by the UK Government Department of Health and Social Care, provides recommendations on where to remove RPE when delivering care in a patient's home.[64] It is recommended that RPE is doffed outside of a room in which an aerosol generating procedure (AGP) is to be performed, and if this procedure is performed at home, the RPE should be doffed outside the home.[64]

### The doffing sequence

Seven documents (one AGREE: Recommend with provisos and six SIGN 50 level 4) provide recommendations on a PPE doffing sequence to minimise cross-contamination.[4, 9, 10, 18, 19, 58, 60] All seven advise that RPE should be doffed last when worn with other items of PPE, as follows: gloves, gown, eye or face protection, then

respirator.[4, 9, 10, 18, 19, 58, 60] Twelve documents (one AGREE: Recommend with provisos and 11 SIGN 50 level 4) advise that hand hygiene should be performed as the last step of the doffing sequence, immediately after touching and disposing of used RPE.[4, 9-11, 13, 18, 19, 58, 74, 92, 96, 109] In the PD ISO/TS 169701:2016 standard, the BSI does not specify an order for doffing, but made clear that the order of doffing should ensure that respirator protection is maintained when required.[22] Indications for hand hygiene are outside the scope of this literature review. Refer to the NIPCM literature review on indications and techniques for hand hygiene for further information.

### Doffing technique

The technique used to remove RPE is discussed by 13 SIGN 50 level 4 documents.[4, 5, 9-11, 19, 30, 52, 60, 63, 74, 98] Although various RPE models, including FFP2/3, N95 and P2, are discussed, the recommendations provided are generally consistent. The techniques described aim to minimise the risk of cross contamination from the used respirator to the wearer, by removing the respirator by pulling the straps on the back of the head and not touching the front of the respirator.[5, 9-11, 19, 30, 52, 60, 63, 98] Six of these documents specify that the bottom strap should be pulled first, followed by the top strap.[4, 9, 11, 19, 63, 74] The ECDC specify that a finger and thumb should be used to pull straps by placing them under the straps.[18] More specifically, APIC state that the head should be tilted forward whilst doffing an N95 respirator, pulling the bottom strap over the head first, and then the second strap, whilst keeping the straps tight.[11] This is consistent with guidance from UKHSA, who also specify that the wearer should let the FFP3 respirator fall from the face once the straps have been pulled over the head.[74] APIC state that the straps should not be allowed to snap back onto the head in case of contamination.[11]

Lastly, UKHSA also recommend that doffing following an aerosol-generating procedure should be supervised by another staff member standing two metres away to reduce the risk of accidental cross contamination.[74] Use of a buddy to assist doffing was not discussed in any other evidence sources, which may be because this document was initially published early in the COVID-19 pandemic, when SARS-CoV-2 was considered a high-consequence infectious disease. Despite

reclassification of SARS-CoV-2, the document was since updated in 2022 and the doffing recommendations remain extant.[74]

In summary, expert opinion guidance is consistent with mandatory COSHH legislation which specifies that RPE should be removed immediately upon leaving the patient care area, in a location where respiratory protection is no longer required. Techniques for removing RPE should minimise possible cross-contamination where possible, and hand hygiene is recommended once doffing is complete.

### 3.1.14 When should RPE be changed or removed?

Twenty-two pieces of evidence were included in relation to this research question. Five were identified in previous version(s) of this review.[2, 4, 5, 9, 45] Eighteen were identified during this update.[10, 11, 13, 19, 20, 24-27, 29, 30, 46, 52, 67-69, 93] One guideline published by the WHO was graded AGREE: 'Recommend with provisos' due to limitations regarding the systematic review methodology used to underpin the recommendations.[45] Twenty-one documents were graded SIGN 50 level 4 expert opinion, due to the lack of a high-quality systematic review to support their recommendations. [2, 4, 5, 9-11, 13, 19, 20, 24-27, 29, 30, 46, 52, 67-69, 93] Six were published in the UK,[2, 4, 24-27] one in the ROI,[30] seven were published in the USA,[5, 9, 11, 13, 29] two in Australia,[10, 46] one in New Zealand,[20] five in Canada,[19, 67-69, 96] and one was published for international audiences.[45] Four of the guidance documents published in the UK were produced by the HSE as part of a series.[24-27]

Irrespective of setting, RPE type, clinical speciality or procedure, extant guidance is consistent regarding when RPE should be changed or removed. In addition to being removed when no longer required as they are considered single-use,[2, 4, 5, 10, 11, 24-27, 29, 30] indications can be summarised as follows:

- when they become moist[10, 19, 29, 30, 45, 46, 52, 60, 68, 69]
- when they become visibly soiled[5, 9, 13, 19, 20, 29, 45, 46, 60, 68, 69]
- when they become damaged[13, 29] [4, 5, 9, 30, 68, 69]
- when there is suspected or confirmed contamination by body fluids [4, 9, 29, 30, 67, 68]

Other indications that were highlighted less frequently across the evidence base are:

- when breathing becomes difficult[4, 13, 19, 30]
- when the face seal is compromised (where applicable)[5, 9, 29]
- when there has been direct contact between the respirator and a patient or resident[67-69]

### Summary

Overall, the guidance is consistent in recommending that RPE is single use therefore should be removed when not required and in addition if they become moist, soiled or damaged. RPE should also be changed when contamination may not be visible but is suspected.

## 3.1.15 When should a powered respirator be worn?

Seven pieces of evidence were included in relation to this research question and all were guidance graded SIGN 50 level 4 expert opinion due to a lack of high-quality evidence to support their recommendations.[2, 5, 10, 32, 46, 81] Three pieces of evidence were included in previous version(s) of this literature review.[2, 5, 57] Four additional pieces of evidence were identified during this update.[10, 32, 46, 81] Of the expert opinion guidance documents included for this research question, one was published in the UK,[2] two in Australia,[10, 46] and four in the USA.[5, 32, 57, 81]

Three of six expert opinion documents recommend the use of loose-fitted powered respirators if the wearer cannot achieve an adequate seal with tight-fitting respirators.[10, 32, 81] Three documents also recommend their use for extended periods of time to aid with non-IPC factors including comfort, breathability, and communication.[2, 57, 81 57] In HSE guidance, it is recommended to use one piece of PPE that can offer different forms of PPE protection, for example, integrated PPE, providing the use of a powered helmet respirator to protect the eyes, face and head.[2]

In terms of use of PAPRs for IPC, the American Society of Anaesthesiologists (ASA) also highlight that PAPRs may be worn for aerosol-generating procedures in the context of the COVID-19 pandemic.[57, 81] ASA do not state that PAPRs offer greater protection when compared to a tight-fitting respirator thus do not make this recommendation.[81] In their guidance on preparing workplaces for pandemic

influenza, OSHA recommend the use of PAPRs for high-risk medical or dental procedures when treating confirmed or suspected infected patients, where it is anticipated that bioaerosols will be generated; examples of such procedures were not provided.[5] OSHA also recommend the use of supplied-air powered respirators in an influenza pandemic setting where there is close contact with infected patients, however, supplied-air respirators were deemed outside the scope of this literature review as they are typically required for 'life or death' environments outside the health and care setting.[5]

One document, published by the Infection Prevention and Control Group of the Australian Government, highlights that a PAPR may not offer additional protection when compared to a tight-fitting respirator.[46] It is assumed this is because the protection afforded by PAPRs depends on factors including their design specification and filtration capability. This document is the only one to highlight that PAPRs may be used for sterile procedures.

In summary, powered respirators are recommended when a tight face seal cannot be achieved for particulate respirators, or for occupational health reasons when a long RPE wear-time is anticipated. A small number of guidance documents recommend their use in pandemic settings, however, the rationale for this was unclear as an evidence base was not referenced by these documents. Moreover, powered respirators do not necessarily afford better protection to wearers, as their filtration capacity depends on the filters chosen.

### 3.1.16 Where and how should powered respirators be donned?

One document, graded SIGN 50 level 4 expert opinion was included for this research question.[2] The HSE has developed expert opinion guidance on the use of PPE at work.[2] This is the only source that provides specific instructions for donning powered respirators but is not specific to health and care settings.[2] There was no evidence identified regarding the preferred location for donning powered respirators. The HSE advise that a powered respirator should be checked for any defects prior to donning: all straps provided should be used, positioned and adjusted according to manufacturer instructions, sufficient airflow for the task should be chosen and the same filters used if the respirator has multiple filters.[2] Finally, HSE also state that

other PPE items worn should be compatible with powered respirators when donned as an ensemble, however further information on factors such as the sequence for donning was not provided.[2]

Discussion of the general recommendations regarding where RPE should be donned, and the sequence for donning PPE when wearing RPE is also applicable to powered respirators and can be found under, 'Where and how should disposable respirators be donned?'.

In summary, there is a lack of specific evidence on where and how powered respirators should be donned. One resource published by HSE was identified, however the recommendations proposed are not specific to use of powered respirators in health and care settings.

### 3.1.17 Where and how should powered respirators be doffed?

There was no evidence identified in relation to this research question. General recommendations regarding where and how RPE should be doffed can be found under, 'Where and how should disposable respirators be doffed?'.

### 3.1.18 How should reusable respirators be maintained?

Twelve pieces of evidence were included in relation to this research question. Two pieces of evidence were included in the previous version(s) of this review.[2, 37] Nine additional pieces of evidence were identified in this update.[22, 24-27, 40, 41, 46, 50] Two UK legislation were graded 'Mandatory',[37, 40] and 10 guidance documents were graded SIGN 50 level 4 expert opinion due to a lack of high-quality evidence to support their recommendations.[2, 5, 22, 24-27, 37, 41, 46, 50] Eight were published in the UK,[2, 22, 24-27, 37, 50] one in the USA,[5] and one in Australia.[46] Four of the expert opinion documents were published by HSE as part of a series.[24-27]

Nine documents (seven SIGN 50 level 4, two mandatory legislation) provide recommendations on general PPE or RPE maintenance without specifying RPE type;[2, 8, 22, 24-27, 37, 50] three SIGN 50 level 4 documents provide recommendations on PAPR maintenance,[2, 5, 46] and one SIGN 50 level 4 document provides recommendations on elastomeric half mask respirator (EHMR) maintenance.[5]

The COSHH legislates that wearers of PPE should report any damage or loss of PPE to employers so they can be maintained appropriately.[37] This is in line with other guidance published in the UK,[22, 42] and The Personal Protective Equipment at Work (Amendment) Regulations 2022.[40]

There is a lack of consistency regarding the frequency of RPE maintenance in UK guidance, as follows: The PD ISO/TS 16975-1:2016 standard, which is not specific to health and care settings, states that general maintenance should be carried out on at least a monthly basis, or in line with local or national regulations.[22] In guidance produced by HSE to help employers align with COSHH legislation, it is stated that RPE should be maintained at least once every three months;[24-27] another document produced by HSE does not specify a timeframe but states RPE should be maintained and checked regularly, and that prior to donning, powered respirators should be checked to ensure they are in good working order.[2] COSHH legislation is unclear, stating that RPE should be checked at suitable intervals.[37]

The methods for RPE maintenance were not discussed in depth. Extant guidance is consistent in advising that maintenance procedures should follow manufacturer instructions.[2, 5, 8, 22, 24-27, 50] Further recommendations are not provided. PD ISO/TS 16975-1:2016 describes RPE selection, use and maintenance. It states that maintenance involves the following processes:

- inspection
- decontamination
- cleaning and/or disinfection
- routine maintenance, which may involve checking RPE performance, repair, and disposal[22]

This standard, however, is based on expert opinion from a technical committee whose area of expertise may not be relevant to health and care settings.

Six SIGN 50 level 4 guidance documents, including five published by the HSE and only one specific to health and care settings, specify the steps involved during inspection, which include: checking for damage; the condition of valves, seals, harnesses, filters, straps; checking battery charge and flow rate (if powered) and

checking expiry dates, where applicable.[2, 8, 22, 24-27] The BSI and HSE highlight that defective parts should be replaced using components made by the RPE manufacturer.[2, 22] The BSI recommend that the wearer should inspect the condition of RPE parts prior to use.[8, 22]

Refer to 'How should reusable RPE be decontaminated?' and 'How should RPE be disposed?' for discussion regarding these aspects of maintenance.

The remainder of the evidence base (n = 8 SIGN 50 level 4) focusses on the maintenance of RPE filters.[2, 5, 8, 22, 24-27, 57] Six of these documents are not specific to health and care settings. Therefore, the guidance may not appropriately consider the risk of re-using filters that have been used to protect the wearer from inhaling biological hazards from ambient air. The BSI states that although RPE filters should not be shared between wearers, there is no simple recommendation for how they should be maintained as they are affected by factors such as how they are stored, temperature, humidity, the type of hazardous substance, air flow and breathing rate.[8] OSHA recommended filters should be used until they are unsuitable for further use, however it is unclear what parameters make them unsuitable, particularly in health and care settings.[5]

Other documents state that filters should be replaced when they become clogged from use, therefore reducing air flow and making breathing difficult.[2, 5, 8, 22, 57] Three documents published by the HSE, and OSHA state that filters should be replaced if they are visibly contaminated,[2, 5, 57] and four documents state they should be replaced if visibly damaged.[2, 5, 8, 57]

The HSE recommend that filters should be changed according to manufacturer instructions and that they should be used within their expiry date.[2, 22, 24-27] Similarly, the BSI standard on RPE maintenance recommends the correct filter(s) are used, filters are fitted correctly, not damaged and that the expiry date is written on the filter.[8, 22]

In summary, relevant legislation and extant guidance states that it is the responsibility of an RPE wearer to report any defects, loss or damage to employers to allow for subsequent maintenance. RPE should be inspected prior to each use, and overall, the evidence is consistent that maintenance should be performed

according to manufacturer instructions. There was lack of consistency in extant guidance in relation to the maintenance of RPE filters, this is likely because the guidance documents included were not specific to health and care settings.

### 3.1.19 How should reusable respirators be decontaminated?

Thirteen pieces of evidence were included in relation to this research question. Six pieces of evidence were included in the previous version(s) of this review.[2, 4, 5, 7, 37, 42] Seven additional pieces of evidence were identified in this update.[12, 22, 29, 41, 46, 50, 57] One piece of mandatory legislation was identified,[37] and 12 guidance documents were graded SIGN 50 level 4 expert opinion.[2, 4, 5, 7, 12, 22, 29, 41, 42, 46, 50, 57]

Of the expert opinion guidance, four documents were published in the USA[5, 12, 29, 32, 57] and seven were published in the UK.[2, 4, 7, 22, 37, 42, 50] Two of the documents in the UK provide guidance on the implementation of international standards.[22, 50]

The guidance documents provide recommendations for the decontamination of powered respirators and their components, or recommendations in relation to elastomeric half face mask respirators. The documents generally refer to cleaning and disinfection when discussing decontamination. The recommendations, regardless of respirator type, are broad and can be applied to any reusable respirator.

#### How decontamination is performed

Like evidence on general RPE maintenance, the guidance and legislation identified focusses on how decontamination should be performed, and how often it should be performed. The COSHH mandates that it is the employer responsibility to specify decontamination and disinfection protocols.[37] Overall, SIGN 50 level 4 guidance is consistent in advising that manufacturer's instructions regarding decontamination, including the materials used for cleaning and disinfection, should be followed.[2, 4, 5, 7, 12, 22, 41, 42, 46, 50, 57] The PD ISO/TS 16975-1:2016 standard guidance states that the reusable components should be disassembled prior to decontamination.[22]

Few documents discussed the decontamination of filters and filter cartridges. As discussed under, 'How should reusable respirators be maintained?', this is likely because filters are designed to be single use.[12, 50]

### Where decontamination should be performed

Two SIGN 50 level 4 documents discuss where RPE should be decontaminated.[41, 57] The HSE state that decontamination should occur in a clean area, however this recommendation was not specific to health and care settings.[41] The CDC suggest cleaning at the point of use, then centralising where disinfection is performed.[57]

### Frequency of decontamination

There is some inconsistency regarding the frequency of decontamination. The UK Healthcare Infection Society Working Group on Respiratory and Facial Protection state that decontamination protocols should be followed between each use, but it is unclear if 'between use' refers to between each patient interaction, or between wearers, given that reusable respirators may be shared between wearers.[4] The CDC are more specific and recommend that elastomeric half face mask respirators should be cleaned/disinfected between each patient interaction immediately after they have been doffed, and that ideally PAPRs should be cleaned after each use, or as often as required so that they remain clean;[29, 57] it is unclear if these recommendations apply when caring for cohorted patients. The PD ISO/TS 16975-1:2016 recommends different intervals depending on the scenario: as often as necessary to be kept in a sanitary condition if used by one individual, between use by different individuals, or after each fit test if used for training or fit test.[22] These recommendations are further supported in another British standard (BS ISO 16975-3:2017) and guidance by HSE to adhere to COSHH legislation, which both advise that RPE are cleaned and disinfected between use when used by different individuals.[42, 50] COSHH legislation, however, does not provide clear recommendations regarding when cleaning should be performed. The HSE advises that PPE decontamination is performed prior to storage.[41]

Irrespective of RPE type, there is consistency across the evidence base that decontamination should follow manufacturer instructions, decontamination should be performed in a clean area, and that filters are considered single-use items, thus do

not require decontamination. There is lack of consistency amongst extant guidance regarding how often decontamination of non-reusable parts should be performed.

### 3.1.20 How should RPE be stored?

Thirteen pieces of evidence were included for this research question. Two pieces of evidence were included in the previous version(s) of this review.[2, 37] Eleven additional pieces of evidence were found during this update.[8, 22, 24-27, 29, 41, 67-69] One mandatory legislation was relevant to this research question,[37] and 13 guidance documents were graded SIGN 50 level 4 expert opinion.[2, 8, 22-27, 29, 67-69] Three guidance documents were published in Canada,[67-69] one in the USA,[29] and eight were published in the UK.[2, 8, 22, 24-27] Four of the guidance documents published in the UK were produced by the HSE as part of a series.[24-27]

#### General PPE storage

Extant guidance regarding storage is relatively consistent. Available guidance focusses on two aspects of respirator or PPE storage, namely optimising accessibility and maintaining product integrity. COSHH legislation is relatively vague and specifies that PPE must be 'properly stored in a well-defined place' and 'kept apart from uncontaminated clothing and equipment' if contaminated following use; further detail is not provided.[37] To adhere to this legislative requirement, the HSE recommends that employers should provide storage for PPE that protects from contamination, loss, and/or damage, citing potential sources of damage being hazardous substances, sunlight/heat and damp.[24-27] It is unclear if hazardous substances may refer to environmental contamination, which is an IPC risk for PPE items stored in health and care settings.

#### RPE storage

The Government of Canada, BSI and the CDC provide recommendations for the storage of RPE specifically rather than PPE in general.[8, 22, 29, 67-69] The BSI states that employers are responsible for providing appropriate storage for RPE, including facilities to separate clean and dirty items.[8, 22] The Government of Canada recommend that PPE, including RPE, are stored in a location easily accessed by staff at the point-of-care, as well as visitors if required.[67-69] Two expert opinion

guidance advise that RPE should be stored away from contaminated items.[67, 68] However, it was unclear whether the location of storage should be a room or a designated clean area.[67, 68] The CDC also recommend that reusable RPE should be stored between use, ensuring that RPE is decontaminated, dried thoroughly, and stored, in a manner that does not distort the facepiece or straps.[29]

In summary, there was a small volume of evidence found in relation to this research question; guidance was vague and applicable to a range of workplace settings, not specific to healthcare. Conclusions regarding the storage of RPE specifically cannot be drawn due to lack of evidence. However, the evidence is consistent that PPE should be stored in a dedicated space and in a manner that reduces the risk of damage and potential contamination.

### 3.1.21 How should RPE be disposed?

In total, 10 pieces of evidence were included for this research question. Five pieces of evidence were identified in the previous version(s) of this literature review.[2, 4, 8, 18, 37] One of these documents has since been updated.[18] Five additional pieces of evidence were included during this update.[10, 11, 19, 22, 29] One legislation was graded mandatory ,[37] and nine guidance documents were graded SIGN 50 level 4 expert opinion.[2, 4, 8, 10, 18, 19, 22, 29, 30] Of the expert opinion guidance documents included for this research question, four were published in the UK,[2, 4, 8, 22] one in the ROI,[30] one in Australia,[10] one in the USA,[29] one in Canada[19] and one published by the ECDC therefore applicable to the EU/EEA.[18]

Four SIGN 50 level 4 guidance were consistent in advising that RPE should be disposed of immediately after use as part of the doffing procedure.[18, 19, 29, 74]
The National Health and Medical Research Council of the Australian Government and ROI Department of Health recommend that RPE should be disposed of outside of the patient care area.[10, 30]

Five SIGN 50 level 4 guidance and one mandatory legislation were consistent in advising that RPE should be disposed of using the appropriate waste stream, in adherence with local policies and legislation.[4, 18, 19, 22, 29, 37] The waste stream referenced is inconsistent. The Healthcare Infection Society Working Group on Respiratory and Facial Protection, state they should be disposed of as ‘healthcare

waste',[4] whereas the HSE state that respirators may be considered as 'hazardous waste' depending on their use.[2]

Two documents discussed the specification of the waste containers used for disposal.[10, 19] This is considered outside the scope of this literature review, refer to the NIPCM review on the safe disposal of waste.

Overall, there is a lack of evidence found in relation to the disposal of RPE. There is consensus that RPE should be disposed of immediately after use. Guidance generally referred to adherence with local policies when referring to appropriate waste streams.

## 3.2 Implications for research

There is a lack of high-quality evidence in relation to the use of RPE in health and care settings. The expert opinion guidance included as SIGN 50 level 4 evidence is not underpinned by high quality evidence and instead reflects historical practice. This therefore highlights the need for additional high-quality research relating to the use of RPE in the context of infection prevention and control. Moreover, the majority of expert opinion guidance was developed in the context of the COVID-19 pandemic. These guidance documents were often developed at speed, without input from expert groups.

There is consistency in the evidence base that RPE should be worn to protect wearers from particles in the air. In health and care settings, this would relate to potentially infectious particles from patients. However, as evidenced by this review, there is a distinct lack of high-quality epidemiological research that provides evidence to support that RPE is effective in reducing infectious agent transmission. Where research was considered suitable for inclusion, it was of low-quality (SIGN 50 level 3) and simulated staff and patient interactions in controlled experimental set-ups, rather than situations reflective of practice. This body of evidence lacked power due to small sample sizes and a small number, or no, replicates or independent repeats. The environmental conditions (such as humidity and air flow) were controlled and may not be generalisable to Scottish health and care settings. Moreover, it was unclear if simulated manikin cyclic breathing rates accurately mimic the breathing patterns of humans, and it was unclear if simulated particles accurately

reflected the behaviour of biological hazards. Although these experimental studies demonstrate the mechanistic superiority of RPE when compared to surgical masks, the findings cannot be generalised outside their fixed conditions.

There is a lack of high-quality clinical trials that demonstrate the effectiveness of different types of RPE, and RPE in general, in practice. Of note, there were four randomised controlled trials,[110-113] and seven systematic reviews with meta-analyses that included these RCTs,[114-120] which compared the use of a respirator, typically an N95, to the use of masks, by staff who were working in health and care settings. RCTs did not demonstrate a superior effect of RPE when compared to surgical masks. However, these RCTs were deemed insufficient quality for inclusion in this review following critical appraisal. They had several methodological limitations that meant conclusions regarding PPE efficacy could not be reliably drawn. Some of these limitations include compliance with RPE use and the inability to control for possible acquisition of infection outside of the work setting. These RCTs, despite being low quality, were included in the aforementioned meta-analyses.[114-120] Although it can be argued that these meta-analyses were produced using robust methods, their conclusions cannot be considered rigorous due to the limitations of the underlying data. The only conclusion that can reliably be drawn from this evidence base is that alternative study designs may be required to assess the effectiveness of RPE in health and care settings.

There is a lack of evidence regarding the desirable features of respirators for use in health and care settings. Desirable design features may increase the likelihood of a successful fit test or check or minimise self and cross-contamination when donning or doffing. This is therefore an important area of research that may benefit health and care settings by improving the effectiveness of RPE and decreasing the likelihood of non-compliance with the use of RPE. The lack of research in this area may be because RPE is used in a range of workplace settings, for example construction, where issues such as cross-contamination whilst doffing is not always a concern.

Finally, a large body of evidence was identified in relation to the occupational health impacts of RPE use. Although outside the scope of this literature review, this is an important aspect to consider given that issues such as dermatological reactions and

headaches, which often arise from wearing RPE for prolonged periods of time, can affect compliance and occupational health. It is therefore important that IPC recommendations proposed in relation to RPE consider these factors.

In conclusion, there are several areas of research that would benefit from a more robust primary evidence base. This would support the development of evidence-based recommendations for the use of RPE in health and care settings.

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# Appendices

## Appendix 1: Search Strategy

Date searches conducted – 6 July 2022 and 22 October 2024

### Medline and Embase

| | |
|---|---|
| 1 | exp Respiratory Protective Devices/ |
| 2 | ("respiratory protective device*" or "respiratory protective equipment" or respirator or respirators).ti,ab,kf. |
| 3 | (FFP1 or FFP2 or FFP3 or N95 or KN95 or P1 or P2 or P3 or "filtering face?piece").ti,ab,kf. |
| 4 | 1 or 2 or 3 |
| 5 | exp infection control/ |
| 6 | exp cross infection/ |
| 7 | exp disease transmission, infectious/ |
| 8 | exp decontamination/ |
| 9 | exp equipment contamination/ |
| 10 | exp aerosols/ |
| 11 | ("infection control" or infection* or contaminat* or sterili#e or "decontaminat*or cross infect* or aerosol*").ti,ab,kf. |
| 12 | ((contact or airborne or droplet) adj2 (infection* or precaution*)).ti,ab,kf. |
| 13 | 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 |
| 14 | 4 and 13 |
| 15 | limit 14 to english language |
| 16 | limit 15 to 2019 - current |

## Cinahl

S13 Limiters – 2019 - current; Language: English

S12 S4 AND S11

Search modes - Boolean/Phrase

S11 S5 OR S6 OR S7 OR S8 OR S9 OR S10

S10 TI ( "infection control" or infection* or contaminat* or sterili#e or decontaminat*or “cross infect*” or aerosol* ) OR AB ( "infection control" or infection* or contaminat* or sterili#e or decontaminat*or “cross infect*” or aerosol* ) OR ( DE "infection control" or infection* or contaminat* or sterili#e or decontaminat*or “cross infect*” or aerosol* )

S9 (MH "Aerosols")

S8 MH "Equipment Contamination"

S7 MH "Disease Transmission+"

S6 MH "Cross Infection+"

S5 MH "Infection Control+"

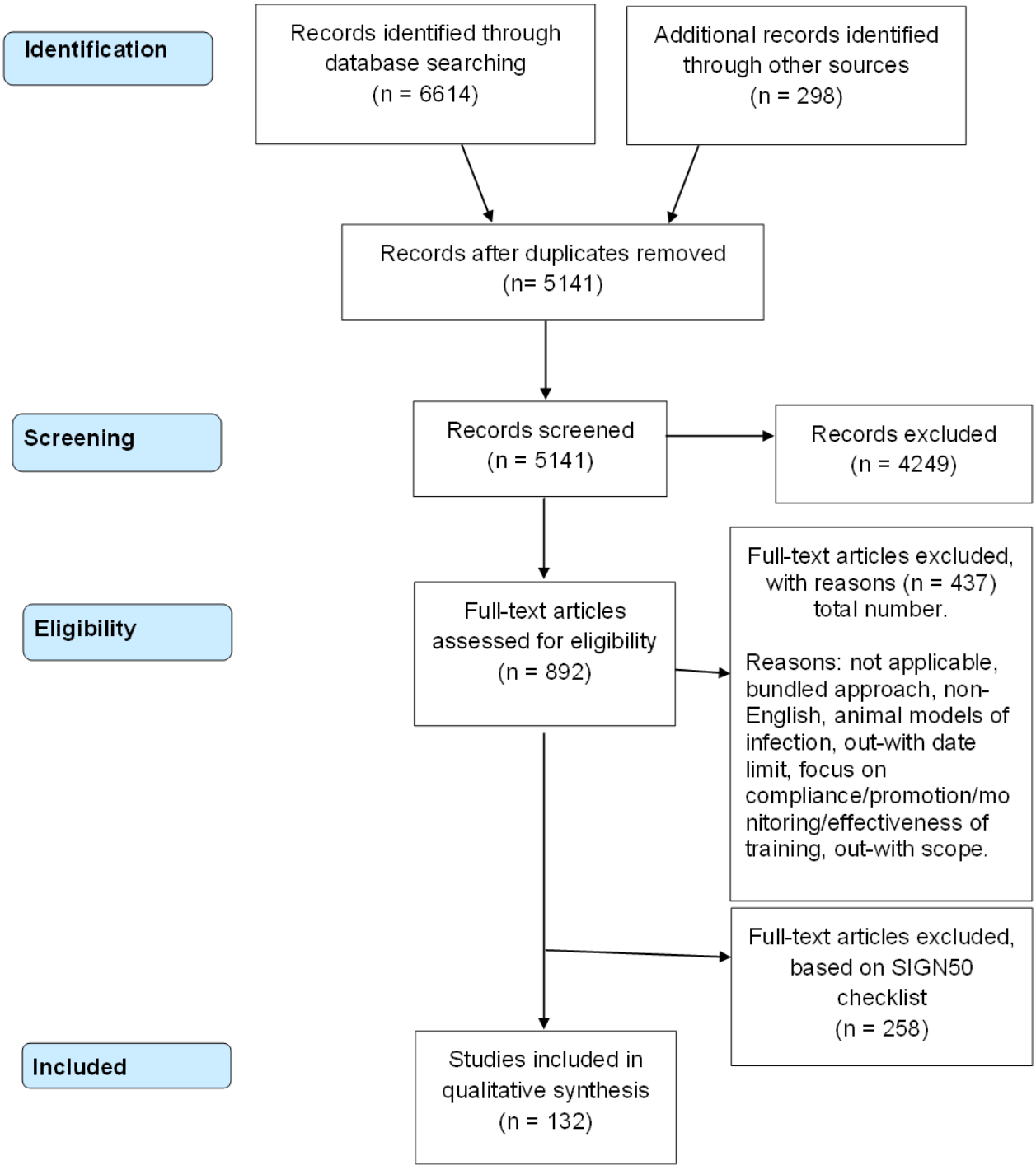
S4 S1 OR S2 OR S3

S3 TI (FFP1 or FFP2 or FFP3 or N95 or KN95 or "filtering face#piece") OR AB (FFP1 or FFP2 or FFP3 or N95 or KN95 or P1 or P2 or P3 or "filtering face#piece") OR DE (FFP1 or FFP2 or FFP3 or N95 or KN95 or P1 or P2 or P3 or "filtering face?piece")

S2 TI (respirator OR respirators) OR AB (respirator OR respirators) OR (DE respirator OR respirators)

S1 MH "Respiratory Protective Devices"

# Appendix 2: PRISMA Flow Diagram



# Appendix 3: Evidence Levels

## SIGN 50 Evidence Levels

| Grade | Description |
|---|---|
| **1++** | High quality meta analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias |
| **1+** | Well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias |
| **1-** | Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias |
| **2++** | High quality systematic reviews of case-control or cohort studies. High quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal |
| **2+** | Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal |
| **2-** | Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal |
| **3** | Non-analytic studies, for example case reports, case series |
| **4** | Expert opinion |

# Appendix 4: Standards pertaining to RPE that are applicable to health and care settings

This appendix provides a non-exhaustive list of standards pertaining to RPE. The standards listed represent the most recent versions available at the time of publication. Please note, however, standards are subject to amendments, and the most recent versions should always be sourced and used in practice.

| Standard | Title | Description | Publication Date |
|---|---|---|---|
| BS EN 13921:2007 | Personal protective equipment. Ergonomic principles | Provides guidance on the generic ergonomic characteristics related to personal protective equipment (PPE) – it does not however cover the requirements which relate to specific hazards that PPE may be designed. | September 2007 |
| BS EN 136:1998 | Respiratory protective devices. Full face masks. Requirements, testing, marking | Provides minimum requirements for full face masks for RPE. Laboratory and practical performance tests for compliance with requirements are also described. | June 1998 |
| BS EN 14387:2004 +A1:2008 | Respiratory protective devices. Gas filter(s) and combined filter(s). Requirements, testing, marking | Provides requirements on the testing and marking of gas filters and combined filters used as replaceable components in unassisted RPE. Laboratory and practical performance | March 2021 |

| Standard | Title | Description | Publication Date |
|---|---|---|---|
| | | tests for compliance with requirements are also described. | |
| BS EN 134:1998 | Respiratory protective devices. Nomenclature of components | Provides nomenclature for RPE components. | May 1998 |
| EN 135:1999 | Respiratory protective devices. List of equivalent terms | Provides a list of common terms related to RPE in English, French and German languages for consistency of terms used relating to RPE. | April 1999 |
| BS EN 140:1999 | Respiratory protective devices. Half masks and quarter masks. Requirements, testing, marking | Provides minimum requirements for half masks and quarter masks used as RPE. Laboratory and practical performance tests for compliance with requirements are also described. | April 1999 |
| BS EN 143:2021 | Respiratory protective devices – Particle filters – Requirements, testing, marking | Provides minimum requirements for particle filters as replaceable components. Therefore, filtering facepiece respirators are outside the scope of this standard. Laboratory and practical performance tests for compliance with requirements are also described. | March 2021 |

| Standard | Title | Description | Publication Date |
|---|---|---|---|
| BS EN 148-1:2018 | Respiratory protective devices - Threads for facepieces. Standard thread connection. | Provides specification for threads of RPE, a description of test devices required for the assessment to meet some of these requirements. | January 2019 |
| BS ISO 17420-4:2021 | Respiratory protective devices. Performance requirements - Requirements for supplied breathable gas RPD | Provides the requirements for the performance and testing of supplied breathable gas RPE and their components according to their classification and for use in the workplace to protect the wearer. | January 2021 |
| BS ISO 17420-2:2021 | Respiratory protective devices. Performance requirements - Requirements for filtering RPD | Provides requirements for the performance and testing of filtering RPE according to their classification and for use in the workplace to protect the wearer. | January 2021 |
| PD ISO/TS 17420-9:2021 | Respiratory protective devices — Performance requirements — Part 9: Special application chemical, biological, radiological and nuclear (CBRN) supplied breathable RPD | Provides requirements for RPE used in response to incidents involving biological materials used to cause harm or released accidentally, as well as other hazardous materials outside the scope of this literature review. Potential wearers include emergency medical personnel. | November 2021 |

| Standard | Title | Description | Publication Date |
|---|---|---|---|
| BS EN 13274-1:2001 | Respiratory protective devices. Methods of test Determination of inward leakage and total inward leakage | Describes two procedures to determine inward leakage of RPE using sodium chloride aerosol or sulphur hexafluoride, respectively. Information on how to prepare the device, selection of test subjects, test procedure and the method to calculate leakage is also described. | March 2001 |
| BS EN 13274-2:2019 | Respiratory protective devices. Methods of test - Practical performance tests | Describes practical performance tests for RPE to assess the properties and function of the item when worn by test subjects who are simulating practical use. | September 2019 |
| EN 13274-3:2001 | Respiratory protective devices – Methods of test – Part 3: Determination of breathing resistance | Describes the methods to measure breathing resistance of filters for RPE. | November 2001 |
| BS EN 13274-7:2008 | Respiratory protective devices. Methods of test - Determination of particle filter penetration | Describes procedures to test particle filter penetration of RPE. | August 2019 |
| BS ISO 16900-1:2019 | Respiratory protective devices — Methods of test and test equipment — Part 1: | Describes test methods to determine inward leakage of respiratory interfaces, and total inward leakage of | August 2019 |

| Standard | Title | Description | Publication Date |
|---|---|---|---|
| | Determination of inward leakage | RPE using specific test agents and body movements at specified metabolic work rates. The test results are not indicative of the performance of RPE during actual use. | |
| ISO 16900-2:2017 | Respiratory protective devices — Methods of test and test equipment — Part 2: Determination of breathing resistance | Describes test methods to determine breathing resistance for RPE, filters for RPE, and respiratory interfaces. | February 2018 |
| BS ISO 16900-3:2012 | Respiratory protective devices — Methods of test and test equipment — Part 3: Determination of particle filter penetration | Describes test methods to determine particle filter penetration. | April 2013 |
| BS ISO 16900-7:2020 | Respiratory protective devices. Methods of test and test equipment - Practical performance test methods | Describes performance test methods for RPE. | May 2020 |
| PD ISO/TS 16975-2: 2016 | Respiratory protective devices: selection, use and maintenance condensed guidance to establishing and | Provides brief guidance on establishing and implementing a RPE programme that meets relevant performance requirements. | March 2017 |

| Standard | Title | Description | Publication Date |
|---|---|---|---|
| | implementing a respiratory protective device programme | | |
| BS EN ISO 16972:2020 | Respiratory protective devices – Vocabulary and graphical symbols | Defines terms and provides units of measurements for RPE, and information on graphical symbols required on RPE, RPE parts or instruction manuals. | March 2020 |
| PD ISO/TS 20141:2022 | Personal safety – Personal protective equipment – Guidelines on compatibility testing of PPE | Describes compatibility of PPE ensembles, i.e. wearing more than one piece of PPE at the same time. The principles of this document also apply to interactions between non-PPE items and PPE. | October 2022 |
| BS EN 1827:1999+A1:2009 | Respiratory protective devices. Half masks without inhalation valves and with separable filters to protect against gases or gases and particles or particles only. Requirements, testing, marking | Describes marking requirements and performance requirements for re-usable half masks used against gases, or gases and particles. Laboratory and practical performance tests for compliance with requirements are also described. | June 1999 |
| BS EN 405:2001+A1:2009 | Respiratory protective devices. Valved filtering half masks to protect against | Describes marking requirements and performance requirements for valved filtering half masks with gas or | February 2002 |

| Standard | Title | Description | Publication Date |
|---|---|---|---|
| | gases or gases and particles. Requirements, testing, marking | combined filters as RPE. Laboratory and practical performance tests for compliance with requirements are also described. | |
| BS EN 149:2001+A1:2009 | Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking | Describes requirements of filtering half masks so that they protect against particles. Laboratory and practical performance tests for compliance with requirements are also described. | June 2001 |
| BS EN 12942:1998+A2:2008 | Respiratory protective devices – Power assisted filtering devices incorporating full face masks, half masks, half masks or quarter masks – Requirements, testing, marking | Describes minimum requirements of RPE with a full-face mask, half mask or quarter mask with gas, particle or combined filter(s). Laboratory and practical performance tests for compliance with requirements are also described. | April 1999 |
| BS EN 529:2005 | Respiratory protective devices — Recommendations for selection, use, care and maintenance. Guidance document | Provides guidance on establishing and implementing a respiratory protective device programme, including information on how to select, use, care and maintain RPE. | November 2005 |
| BS EN 12942: 1998+A2:2008 | Respiratory protective devices. Power assisted filtering devices incorporating | Provides minimum requirements for powered RPE that incorporate a full-face mask, half mask or quarter mask | April 1999 |

| Standard | Title | Description | Publication Date |
|---|---|---|---|
| | full face masks, half masks or quarter masks. Requirements, testing, marking | with a gas, particle or combined filter(s). Laboratory and practical performance tests for compliance with requirements are also described. | |
| BS EN 12941:1998+A2:2008 | Respiratory protective devices – Powered filtering devices incorporating a helmet or a hood – Requirements, testing, marking | Provides minimum requirements for powered respirators with a helmet or hood, and with particle or combined filter(s). Laboratory and practical performance tests for compliance with requirements are also described. | April 1999 |
| PD ISO/TS 16975-1:2016 | Respiratory protective devices: selection, use and maintenance establishing and implementing a respiratory protective device programme | Describes the selection use and maintenance of RPE and guidance on implementing a respiratory protective device programme that meets performance requirements and relevant standards. | March 2017 |
| BS ISO 16975-3:2017 | Respiratory protective devices - Selection, use and maintenance<br>Part 3: Fit-testing procedures | Provides guidance on how to perform a fit test for RPE that are tight-fitting to determine if there is an effective seal between the wearer's face and the respiratory interface. | October 2017 |
| BS EN 137:2006 | Respiratory protective devices. Self-contained open-circuit compressed air | Provides minimum performance requirements for self-contained open-circuit compressed air breathing | November 2006 |

| Standard | Title | Description | Publication Date |
|---|---|---|---|
| | breathing apparatus with full face mask. Requirements, testing, marking | apparatus with full face mask. Guidance is applicable to settings where risk of hot environmental conditions are low. | |
| BS EN 138:1994 | Respiratory protective devices. Specification for fresh air hose breathing apparatus for use with full face mask, half mask or mouthpiece assembly | Provides minimum requirements for fresh hose breathing apparatus used with a full-face mask, or a mouthpiece assembly, as RPE. Laboratory and practical performance tests for compliance with requirements are also described. | December 1994 |

# Appendix 4: Excluded studies

The following primary studies were excluded during critical appraisal based on their limitations:

- Asadi S, Cappa CD, Barreda S, et al. Efficacy of masks and face coverings in controlling outward aerosol particle emission from expiratory activities. Scientific reports 2020; 10: 15665.

- Barros AJ, Sifri CD, Bell TD, Eby JC, Enfield KB. Effectiveness of Elastomeric Half-Mask Respirators vs N95 Filtering Facepiece Respirators During Simulated Resuscitation: A Nonrandomized Controlled Trial. JAMA Netw Open. 2021 Mar 1;4(3):e211564. doi: 10.1001/jamanetworkopen.2021.1564. PMID: 33724389; PMCID: PMC7967080.

- Cassini A, Mo Y, Simniceanu A, et al. COVID-19 in Health Workers Collaborative Group. Infection prevention and control risk factors for SARS-CoV-2 infection in health workers: a global, multi-centre, case-control study. J Hosp Infect. 2025 Jan;155:40-50.

- Chakladar A, Jones CG, Siu J, et al. Microbial contamination of powered air purifying respirators (PAPR) used by healthcare staff during the COVID-19 pandemic: an in situ microbiological study. American Journal of Infection Control 2021; 49: 707-712.

- Checchi V, Montevecchi M and Checchi L. Variation of Efficacy of Filtering Face Pieces Respirators over Time in a Dental Setting: A Pilot Study. Dentistry journal 2021; 9.

- Chen X, Chughtai AA, MacIntyre CR. Herd protection effect of N95 respirators in healthcare workers. J Int Med Res. 2017 Dec;45(6):1760-1767. doi: 10.1177/0300060516665491. Epub 2016 Oct 26. PMID: 27789807; PMCID: PMC5805185.

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