Public Services Delivery
Scotland

NHS
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Respiratory Protective Equipment (RPE) Literature Review

Considered Judgement Forms

Version 1.0

3 August 2026

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

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 or policy.

Version	Date	Summary of changes
1.0	3 August 2026	New Document

Approvals

Version	Date Approved	Group/Individual
1.0	3 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).

Contents

Research Question 1: What is respiratory protective equipment?

A Quality of Evidence

1.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
In total, 31 pieces of evidence were included to answer this research question:[1-31] • 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.[15] • Thirty guidance documents were graded SIGN 50 Level 4 expert opinion due to a lack of rigorous scientific evidence to support their development.[1-14, 16-31] No primary research studies were included. Overall, this was considered a sufficient volume of research but of low quality.	1 x AGREE: Recommend with provisos 30 x SIGN 50 level 4 – expert opinion

1.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
There was consistency regarding definitions and features of RPE in extant guidance, as follows:

Comments

RPE definition:

A category of personal protective equipment worn to protect the wearer from hazardous substances found in the atmosphere.[1, 18, 21, 22, 29-32]

RPE categories:

Two categories of RPE were described in literature: air-supplying respirators and air-filtering respirators.[1, 4, 7, 11, 13, 21, 33] Air-supplying respirators have been excluded from this 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.[1, 3-7, 11, 18-22]

Types of air filtering respirators:

- 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 chin, nose and mouth.[1, 3, 4, 7, 9, 11, 12, 14, 18, 20, 21, 30]
- Quarter FFP respirators (do not cover the chin) were also referenced in the literature, but to a lesser extent. [7, 20, 21]

Valved respirators:

- FFP respirators may be valved.[3, 7, 11, 20, 30]
- Aid with breathability and reduce humidity.[3, 4, 11, 30]
- Exhaled air is released directly into the atmosphere via the valve.[6, 7, 20, 30]
- Note: Valved respirators are discussed in further detail under, 'When should valved versus unvalved respirators be worn?'.

Types of RPE:

- Several models of FFP half face mask respirators are available for use and meet different international standards.[9, 30, 32]
    - N95 respirators most widely cited in the included literature and are approved for use in US health and care setting.[3, 4, 8-11, 15, 18, 19, 31, 33]
    - Other FFP respirators cited include: P2, 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.[9, 19]
    - FFP1, FFP2 and FFP3 respirators are typically used in Europe (categorised according to their filtration efficiencies).[1, 3, 6, 15, 17, 29, 32]

Comments

- 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).[3, 15, 17]
- 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.[11, 15, 17]

Reusable RPE:

- Reusable respirators (can be cleaned/decontaminated for reuse) are termed elastomeric respirators.[4, 11, 13, 30, 33]
- Form a tight seal around the face.[4, 13, 33]
- The filters cartridges of elastomeric respirators are interchangeable - filtration capacity therefore varies.[1, 4, 6, 7, 11, 33, 34]

Powered respirators:

- Air-filtering respirators may also be powered (and tight or loose-fitting) - contaminated air is pulled through the filters using a battery-powered blower before delivering clean air to the wearer.[1, 4, 6, 11, 28, 33]

There was lack of consistency in the evidence-base regarding the definition of RPE filtration efficiency:

- According to the World Health Organization (WHO), FFP respirators are classified according to their filtration efficiency, meaning their capacity to filter particles. Filtration efficiency is related to filter leakage.[15]
- Some evidence sources (n = 7) cite exact particle sizes that specific types are capable of filtering,[8-10, 15, 18, 28, 32] others (n = 12) state that respirators are capable of filtering, for example, ‘very small particles’, ‘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.[1, 3, 4, 7, 11, 12, 17, 19, 22, 29, 31] The ECDC state that FFP respirators are classed according to their ability to filter 0.3 micrometre (µM) particles.[17]

1.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments
The country or countries where the guidance was published, or to which the guidance applies are as follows: • UK (n = 16)[4, 5, 8, 10-14, 23-26, 28, 30, 31] • Republic of Ireland (ROI),[29] • USA (n = 9)[4, 5, 8, 10-14, 28] • Australia (n = 1)[9] • New Zealand (n = 1)[19] • European Union (EU)/European Economic Area (EAA) (n = 2)[16, 17] • International (n = 1)[15] Four of the guidance documents published in the UK were produced by the Health and Safety Executive (HSE) as part of a series.[23-26] One document was published by the World Health Organization (WHO), therefore applicable internationally. [15] two were published by the European Centres for Disease Prevention and Control (ECDC), therefore applicable to the EU/EAA. [16, 17] Overall, the included guidance documents are produced by internationally recognised associations and are generally relevant to Scottish health and care settings. RPE definitions provided are directly applicable to any health and care setting, including those in Scotland. Sixteen pieces of guidance were not specific to health or care settings.[1, 2, 4, 6, 7, 11, 13, 14, 20-27, 30] Given the scope of this research question, it is reasonable to assume that relevant guidance aimed for the general population and/or non-health and care settings can be applied to the target setting.

1.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Not applicable as no primary research studies were included.

1.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
Definitions for RPE are well established, and therefore publication bias is not a concern.

B Evidence to Decision

1.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **“must”** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **“should”** implies that the health and care setting “should” implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **“should consider”** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
This research aimed to outline how RPE suitable for health and care settings is currently described within the literature. A respirator is a device which covers the nose and mouth and is designed to protect the wearer against inhalation of hazardous substances. It contains a particle filter which captures hazardous particles as air passes through it, before reaching the wearer’s respiratory tract.	Not applicable

1.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
Not applicable.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/ Good Practice Point were followed. Be explicit, clear about cons.

Risks/Harms
Not applicable.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/ staff/ visitor perspective, the societal perspective, or both. Recommendations/ Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
Not applicable.

1.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
Not applicable.

1.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
Not applicable.

1.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
Not applicable.

1.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
Not applicable.

1.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
Not applicable.

1.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
Not applicable.

Research Question 2: Are there any legislative requirements for the use of RPE for infection control purposes and what standards (BS/EN) should RPE adhere to?

A Quality of Evidence

2.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Thirty-nine evidence sources were included for this research question: • Thirty-three standards all graded SIGN 50 level 4 expert opinion due to a lack of rigorous scientific evidence to support their development. • Six pieces of (mandatory) legislation.[35-40] No primary research studies were included. Several of the 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.[41] Use of sodium chloride as a challenge agent may not reflect how infectious agents behave. This evidence was considered sufficient to answer the research question.	33 x SIGN 50 level 4 – expert opinion 6 x Mandatory

2.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, the group formed a judgement as to the overall direction of the evidence.

Comments
Due to the nature of the evidence, consistency amongst the legislation identified for this research question could not be evaluated. Legislation relevant to RPE identified includes: The Health and Safety at Work etc. Act 1974[35] • The primary legislation relating to occupational health at work, outlining general employer and employee duties to manage health and safety for every work activity. The Management of Health and Safety at Work Regulations 1999[36] • More specific in the duties that employers and employees must fulfil to maintain health and safety at work. The Control of Substances Hazardous to Health (Amendment) Regulations 2002[37] • The requirements for protecting employees from substances that are hazardous to health in the workplace. The Personal Protective Equipment at Work (Amendment) Regulations 2022 (PPER 2022)[40] • Applies to employers and employees, including employees without a contract of employment. 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[39] • Incorporates EU Regulation 2016/425[38] into UK Law. • Describes health and safety requirements that are required before PPE products may be placed on the Great British market. The consistency of British/European/International Standards has not been assessed due to the nature of this evidence.

2.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments
Legislation included is directly applicable to Scotland, however no legislation identified is specific to health and care settings. Standards identified are directly applicable to Scotland, however no standards specific to health and care settings were identified. The identified standards which relate to RPE are general and apply to all PPE worn in a working environment.

2.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Not applicable as no primary research studies were identified.

2.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
Risk of publication bias is not applicable due to the type of evidence identified for this research question.

B Evidence to Decision

2.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
R2.1 Employers must provide RPE which affords adequate protection against the risks associated with the task being undertaken as per Health and Safety at Work Act (1974), Control of Substances Hazardous to Health (2002 as amended) regulations and Personal Protective Equipment at Work Regulations 1992 (as amended).	Recommendation
R2.2 Employers must provide clear instruction and information on how to use provided RPE.	Recommendation
R2.3 Health and care staff must ensure that suitable RPE is worn correctly and in line with manufacturer's instructions for the task being undertaken.	Recommendation
GPP2.1 RPE intended for use in health and care settings should meet the relevant standards as detailed in Appendix 3 of the literature review.	Good Practice Point

2.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
R2.1, R2.2, R2.3, Adherence to current legislation and regulations ensures compliance with associated corporate and social governance responsibilities, including the legal requirements of the applicable health and safety management policy. R2.2 Providing clear instructions allows the proper use of the provided RPE helping ensure adequate wearer protection. R2.3 HCWs adherence ensures their safety when undertaking tasks requiring RPE. GPP2.1 Adhering to industry standards provides assurance of the quality of RPE. GPP2.1 Adhering to industry standards may result in increased user confidence in RPE.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about cons.

Harms
R2.1, R2.2, R2.3, GPP 2.1 No harms anticipated.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
R2.1, R2.2, R2.3, GPP.2.1 Only benefits identified.

2.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Resource use
R2.1, R2.2, R2.3 and GPP2.1 No additional resources or feasibility issues are expected as a result of adhering to relevant legislation and standards. However, there may be financial implications if current stock of RPE protection is non-compliant with industry standards and repurchasing is required.

2.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
R2.1 The evidence underpinning this recommendation is mandatory legislation and is therefore sufficient. No expert opinion to note. R2.1, R.2.2, R2.3 The evidence underpinning these recommendations are mandatory legislation and is therefore sufficient. No expert opinion to note. GPP2.1 Despite their low quality (SIGN 50 level 4, expert opinion) British, European and International standards are considered best practice in UK industry settings, therefore ARHAI Scotland and the Working Group agree that RPE should be worn when indicated.

2.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves

value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
None.

2.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/religious reasons.

Intentional vagueness
None.

2.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
None.

2.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
There are no specific standards for RPE worn in health and care settings. The expansion of standards pertaining to RPE against infectious particles would be beneficial.

Research Question 3: What design features of disposable respirators are desirable?

A Quality of Evidence

3.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
One HSE publication was included, graded SIGN 50 Level 4 expert opinion, as it was not underpinned by a systematic evidence base.[42] No primary research studies were included.	1 x SIGN 50 Level 4 – expert opinion.

3.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Due to the insufficient quantity of evidence, consistency cannot be evaluated. The UK Health and Safety Executive (HSE) published a safety notice, not specific to health and care settings, advising against using FFP2 respirators with ear loops, and those fitted with clips and ‘snuggers’ to tighten their fit.[42]

3.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments
The document produced by the UK HSE is specific to FFP2 respirators. As FFP3 respirators are recommended for use for Scottish health and care settings and do not have ear loops, the guidance is not applicable.[42]

3.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Not applicable as no primary research studies were included.

3.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
No primary evidence was identified for this research question therefore, risk of publication bias is not applicable.

B Evidence to Decision

3.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
GPP3.1 RPE with design features that support achieving a tight seal, for example adjustable straps, should be used in health and care settings.	Good Practice Point

3.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
GPP3.1 RPE with design features that support achieving a tight seal will improve effective wearing and therefore protection provided by RPE.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about cons.

Harms
GPP3.1 No harms anticipated.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP3.1 Procuring RPE with design features that support achieving a tight seal increases the likelihood of wearers passing a fit test and fit check.

3.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
GPP3.1 A wide range of RPE will require to be provided that have all design features to allow a tight seal to be found for the range of face sizes and shapes within the health and care setting. GPP3.1 Healthcare workers may have to be fit tested with a variety of masks before achieving an appropriate seal which will have time and cost implications.

3.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert

opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP3.1 It is the expert opinion of ARHAI Scotland and its working group that respirators should be designed to provide adequate fit and consideration of comfort.

3.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
GPP3.1 None.

3.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
GPP3.1 and GPP3.2 None.

3.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
GPP3.1 None.

3.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
Primary research comparing design features that improve fit for all users, in-line with RPE manufacturer instructions, would be beneficial.

Research Question 4: What design features of powered respirators are desirable?

A Quality of Evidence

4.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
There was no 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?'.	Not applicable

4.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Not applicable.

4.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments
Not applicable.

4.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Not applicable.

4.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
Not applicable.

B Evidence to Decision

4.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
There are no recommendations or good practice points proposed for this research question.	Not applicable

4.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
Not applicable.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/ Good Practice Point were followed. Be explicit, clear about cons.

Harms
Not applicable.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
Not applicable.

4.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
Not applicable.

4.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
Not applicable.

4.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
Not applicable.

4.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/religious reasons.

Intentional vagueness
Not applicable.

4.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
Not applicable.

4.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
Research on powered RPE that designed to be effectively decontaminated for use in health and care settings would be beneficial.

Research Question 5: What are respirator 'fit tests' and 'fit checks' and how are they performed?

A Quality of Evidence

5.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
In total, 27 pieces of evidence were included that addressed what respirator fit tests or fit checks are and how they are performed. • One guideline graded AGREE: 'Recommend with provisos' due to limitations regarding the systematic review methodology used to underpin the recommendations,[43] • Three primary studies (observational) graded SIGN 50 Level 3.[44-46] • Twenty-three guidance documents graded SIGN 50 Level 4 expert opinion, due to a lack of systematic evidence to support their findings.[1-5, 7, 9, 11, 16, 18, 19, 21, 22, 29, 43, 47-54]	1 x AGREE 'Recommend' with provisos 3 x SIGN 50 Level 3 23 x SIGN 50 Level 4 – expert opinion

5.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
There was consistency in the evidence base regarding the following aspects of fit testing:

Comments

- 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 (n = 5 SIGN 50 level 4).[1, 2, 9, 51, 55]
- Loose fitting devices such as powered air purifying respirators (PAPRs) with a hood, helmet, or visor, do not require a fit test (n = 5 SIGN 50 level 4)).[1, 11, 48, 54, 56]
- Fit test results are not transferable across respirator models, sizes and styles (n = 4 SIGN 50 level 4)).[9, 18, 51, 55]
- Prior to fit testing, the wearer should be clean shaven, and free from items such as jewellery around the seal area to prevent interference with fit of the RPE (n = 5 SIGN 50 level 4)).[1, 2, 18, 51, 55]
- Other items of PPE, such as eye protection and RPE accessories, worn alongside RPE should be worn during the fit test to determine compatibility (n = 3 SIGN 50 level 4)). [2, 51, 56]
- BS EN 529 2005 states that respiratory devices should be fitted according to manufacturer's instructions.[7]

Quantitative fit testing

- Specialised instruments are used to quantify face seal leakage into the respirator to determine a quantitative fit factor (QNFF) value to estimate fit (n = 6 SIGN 50 level 4).[1, 5, 9, 22, 48, 51]

Qualitative fit testing

- Qualitative fit tests (QLFTs) are pass or fail sensory detection tests that use agents with a distinct taste or smell, often bitter or sweet,[1, 2, 5, 7] to assess leakage.[1, 2, 5, 9, 22, 48, 51] They are therefore considered subjective.[1, 2, 5, 29]
- Three observational studies (SIGN 50 level 3), using FFP3s and N95s respectively, found that QNFTs were more sensitive than QLFTs. [44-46]

There was lack of consistency regarding the following aspects of qualitative fit testing:

- The HSE states QLFTs are not suitable for full face masks, and suitable only for half masks, specifically, half mask disposable respirators, reusable respirators, and powered respirators.[1] [2] Conversely, BS EN 529:2005 specifies that this test method is suitable for full-face masks, as well as half masks and filtering face pieces.[7] Other British Standards[21, 51] 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.

Comments
There was consistency in the evidence base regarding the following aspects of fit checking: • 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 (n = 8 SIGN 50 level 4).[5, 7, 18, 19, 22, 29, 49, 50] • Three pieces of guidance stated that fit checks are not substitutes for fit testing,[2, 5, 49] due to lack of sensitivity and specificity.[49] • Two primary studies (SIGN 50 level 3) highlighted the potential inaccuracy of seal checks and support guidance recommendations that a user seal-check should not be used in place of a QNFT.[44, 46] • Manufacturer's instructions should be followed to establish the correct method of fit checking for individual types of respirator devices (n = 6 SIGN 50 level 4).[1, 2, 5, 9, 49, 52] Fit checks may be carried out in two ways; by positive pressure (exhaling) or by negative pressure (inhaling) (n = 8 SIGN 50 level 4).[1, 3, 5, 7, 9, 43, 47, 49] • 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 (n = 6 SIGN 50 level 4).[3, 7, 9, 43, 49, 53] • Examples of indications of air leakage cited by the evidence-base included: feeling air pass over the face, fogging/steaming of glasses,[49, 53] and a lack of build-up of pressure inside the respiratory device. [5, 43, 49] • During negative pressure fit checks, the respiratory device should be drawn towards the face/ slightly collapse; if this is not observed, or air enters around the face seal, this is indication of leakage and subsequently an unsuccessful fit check (n = 7 SIGN 50 level 4).[3, 7, 9, 43, 47, 49, 53]

5.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments
The country or countries in which the guidance/research was conducted and/or applies to are as follows:

Comments
• UK (n = 11) [1-3, 7, 18, 21, 22, 51, 52, 54, 55] four of which were British Standards.[7, 21, 22, 51] • ROI (n = 1)[29] • USA (n= 7)[4, 5, 11, 48, 49, 53, 56] • Australia (n = 1)[9, 47] • Canada (n = 2)[18, 46] • New Zealand (n = 2)[19, 50] • Hong Kong (n = 1),[44] • International or for unspecified audiences (n = 1)[43] • EU/EAA.[16] One guidance document was published by the ECDC therefore is applicable to the EU/EAA.[16] Another was published by the WHO and therefore applies internationally.[43] Performing fit tests/checks are consistent across all occupational settings. The recommendations made in the extant guidance were therefore considered relevant to Scottish health and care settings. Twelve pieces of evidence were not specific to health care workers,[1, 2, 7, 21, 22, 37, 48, 49, 51, 53-55] however, this may not affect applicability 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.

5.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Three primary studies (SIGN 50 Level 3) may have limited generalisability.[44-46] One study recruited undergraduate nursing students; thus the findings may not be generalisable as the participants likely have less experience in fit testing and fit checking when compared to experienced healthcare staff.[44] The second study recruited healthcare staff working in residential facilities, therefore the findings may not be generalisable to staff working in acute healthcare settings where RPE are worn on a regular basis.[46] Conversely, the final study is considered applicable as it was performed in England using FFP3s and included NHS staff working in

Comments
hospitals, therefore is considered applicable, though to staff working in non-hospital settings to a lesser extent.[45]

5.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
The primary evidence identified is particularly at risk of publication bias. Studies that found no significant difference in sensitivity/specificity of fit test methods may not have been published, which may bias the conclusions drawn.

B Evidence to Decision

5.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
GPP5.1 A fit test ensures that an FFP respirator can properly fit the wearers face shape, with no gaps between mask and face for unfiltered air to pass, and should be conducted by a competent fit test operator. British and International Standard BS ISO 16975-3: 2017 outlines the requirements for RPE fit testing.	Good Practice Point
GPP5.2 The wearer should be clean shaven where the respirator forms a seal to the wearers face and free of any jewellery or piercings to support effective fit testing by ensuring a smooth surface area for a seal.	Good Practice Point
GPP5.3 A record of fit testing including the style, model and size needed for each individual, or if unable to be fitted to any available RPE, should be held.	Good Practice Point
GPP5.4 Fit testing results should not be transferred across respirator styles, models and sizes.	Good Practice Point
GPP5.5 A fit check is a method to establish whether RPE has been correctly put on to form a tight seal to the wearer's face. A fit check should follow manufacturer instructions,	Good Practice Point

Recommendation	Grading
which can recommend a positive or negative pressure fit check.	
GPP5.6 A fit check should not replace or be a substitute for fit testing.	Good Practice Point

5.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
GPP5.1, GPP5.2, GPP5.3, GPP5.4, GPP5.5 and GPP5.6 Following fit checking and fit testing manufacturer instructions ensures an adequate seal is achieved when tight-fitting RPE is worn, potentially reducing the risk of acquisition of infectious agents and subsequent nosocomial infection. GPP5.1 and GPP5.5 Fit testing/fit checking encourages staff confidence regarding the effectiveness of RPE. GPP5.2 Ensuring the wearer is clean shaven and free from any jewellery/piercings increases the likelihood of forming an adequate seal and subsequently passing a fit test. GPP5.3 Recording of fit test results ensures that the correct model of RPE is selected by the wearer when required for use. GPP5.3 Recording of fit test results may support stock management. GPP5.4 Not transferring fit testing results across respirator styles, models and sizes, will prevent use of respirators that do not fit the wearer. GPP5.6 A fit test will ensure that the respirator fits the wearer properly and will ensure full protection when worn.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about cons.

Harms
GPP5.1. GPP5.2, GPP5.3, GPP5.4, GPP5.5, GPP5.6 No harms anticipated.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP5.1. GPP5.2, GPP5.3, GPP5.4, GPP5.5, GPP5.6 Only benefits identified.

5.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
GPP5.1 Performing fit testing will have financial implications, in addition to additional material and human resource requirements, including time away from clinical areas to undertake fit testing. These resource requirements would be increased for quantitative fit testing compared to qualitative fit testing. GPP5.1 and GPP5.4 Fit testing will require staff experienced in the protocols to conduct training and fit testing. GPP5.2 None to note. GPP5.3 Implementing and maintaining a system to maintain fit testing records may be resource intensive in terms of time and training. GPP5.4 There will be resource implications from repeating fit testing due to changes, face fit failures or availability of RPE brand, model, style or size.

5.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often

involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP5.1 ARHAI Scotland and the Working Group supports extant expert opinion that fit testing should be performed by a trained operator (6 SIGN 50 level 4). [1, 2, 5, 9, 48,] ARHAI Scotland working group supports protocols for fit testing in line with manufacturer instructions and aligned with BS ISO 16975-3:2017. GPP5.2 ARHAI Scotland and the Working Group supports extant expert opinion (5 SIGN50 level 4)[1, 2, 18, 51, 55] that the wearer should be clean shaven where the respirator forms a seal to the wearers face and free from items that interfere with a tight fit. GPP5.3 There is insufficient evidence in relation to if and how fit test results should be recorded. It is the expert opinion of ARHAI Scotland, the Working Group and the short life working group convened by ARHAI Scotland to advise the Scottish Government on aspects relating to RPE fit testing that fit testing results, including the compatible model and size of RPE, should be recorded for every individual to allow for future reference. GPP5.4 This good practice point is informed by four guidance documents graded SIGN 50 level 4 expert opinion, that state that fit test results are not transferable across respirator models, sizes and styles.[9, 18, 51, 55] This is because the results are specific to that particular respirator that has been tested. No additional expert opinion to note. GPP5.5 There is insufficient evidence to support one single method for fit checking. ARHAI Scotland and the Working Group support six SIGN 50 level 4 expert onion that fit checking should follow manufacturer instructions.[1, 2, 5, 9, 49, 52] GPP5.5 This good practice point is informed by three guidance graded SIGN 50 level 4 expert opinion that state that fit checks are not substitutes for fit testing, due to lack of sensitivity and specificity.[2, 5, 49] No additional expert opinion to note. GPP5.6 This GPP is supported by five SIGN50 level 4 expert opinion documents.[1, 2, 5, 9, 49, 52] ARHAI Scotland and the Working Group support expert opinion that fit checking methods should follow manufacturer instructions for specific RPE models. GPP5.7 This good practice point is informed by three guidance graded SIGN 50 level 4 expert opinion that state that fit checks are not substitutes for fit testing, due to lack of sensitivity and specificity.[2, 5, 49] No additional expert opinion to note.

5.10. Value judgements

Summarise value judgements in creating the Recommendation/ Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
None.

5.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
None.

5.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
GPP5.2 This GPP does not apply to individuals who are unable to wear tight fitting RPE for religious or cultural reasons, for example due to the presence of facial hair or headscarves.

5.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None.

Research Question 6: When should a ‘fit test’ and a ‘fit check’ be performed?

A Quality of Evidence

6.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Forty-five pieces of evidence were included in relation to this research question:[1-5, 7-11, 15-18, 21, 23-26, 28, 43, 47-49, 51, 53, 54, 57-73]	
• Two guidelines, one of which was published in the UK and one was published for international audiences, were graded AGREE: ‘Recommend with provisos’ due to limitations regarding the systematic review methodologies used to underpin the recommendations.[43, 57]	2 x AGREE: Recommend with provisos
• Five primary research studies, graded SIGN 50 Level 3. [69-72, 74] Two of these studies included human participants,[45, 71] and three were simulation studies that used manikins.[69, 70, 72]	5 x SIGN 50 level 3
• 38 guidance documents graded SIGN 50 level 4 expert opinion.[1-5, 7-11, 15-18, 21, 23-26, 29, 47-49, 51, 52, 56-61, 63-68, 75]	38 x SIGN 50 level 4 – expert opinion
This was considered a high volume of evidence, that was of overall low-quality.	

6.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments

Consistencies across simulation studies:

Three simulation studies applied respirators to a manikin head using Vaseline to form a tight seal.[69, 70, 72] These studies demonstrate 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.[69, 70, 72] Fit testing consistencies:

- The indications for fit testing proposed by expert opinion guidance align with relevant national standards and/or legislation and are generally consistent (n = 7). [1, 2, 9, 11, 29, 48, 61]
- Staff who use tight-fitting RPE should be fit tested before use (n = 20).[1, 4, 8-10, 15-18, 21, 28, 29, 47, 50, 60, 61, 63, 66-68]
- Repeat fit testing is consistently recommended for changes in the brand, model or size of respirator used (n = 7),[1, 8, 18, 47, 50, 51, 64] 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 (n = 8).[1, 2, 4, 5, 48, 50, 51, 64]

Fit testing inconsistencies:

- Two guidance documents, published by the CDC and ROI Department of Health respectively, state that fit testing is not always required when RPE is donned.[8, 29]
- Fit testing of visitors was only mentioned by one document (The Society for Healthcare Epidemiology of America (SHEA)).[20]
- Only two documents further specify that fit testing should be performed at the commencement of employment if RPE use is anticipated.[9,15]

Regular repeat fit testing – inconsistencies:

- One primary study performed in the USA assessed the probability of fit test failure at three and five years after passing a fit test of the same N95 respirator model.[74] At three years, probability of survival free from fit-test failure was 99.45% (95% CI 99.2 – 99.6%) after three years and 99.4% (95% CI 99.2 – 99.6%) after five years.[74] This study provides evidence to

Comments

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.

- Four documents published by the WHO, HSE and the Public Health Agency of Canada (PHAC), highlight the importance of regular repeat fit testing but do not provide explicit recommendations.[1, 2, 18, 60] Nine expert opinion guidance documents recommend repeat fit-testing at least annually.[5, 9, 11, 16, 21, 51, 61, 75]
- Two SIGN 50 level 4 expert opinion documents suggest a two-year interval for fit testing is adequate.[64, 65]

Fit checking consistencies:

- Twenty-one extant expert opinion guidance advise that a fit check should be performed every time tight-fitting RPE is donned.[7-11, 15, 18, 23-26, 28, 43, 47, 49, 50, 52, 59, 61-63]

Generally, guidance did not discuss the use of a fit test instead of a fit check therefore consistency was not assessed.

6.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments

The country or countries in which the guidance/research was conducted and/or applies to are as follows:

- UK (n = 13)[1-3, 7, 21, 23-26, 51, 52, 63, 64] Four were produced by the HSE as part of a series.[23-26]
- ROI (n = 1)[29]
- USA (n = 15)[4, 5, 8-11, 28, 48, 49, 58, 59, 62, 69, 70, 75]
- Canada (n = 4)[65-68]
- Australia (n = 3)[47, 61]
- New Zealand (n = 1)[50]
- international (n = 3)[15, 43, 60]

Comments
• EU/EAA (n = 3) [16, 17, 32] • Hong Kong (n = 1)[44] • Taiwan (n = 1)[71] Guidance published by the ECDC (n = 3) applies to the EU/EAA and is directly applicable to Scottish health and care settings.[16, 17, 32] Guidance published by the World Health Organization (WHO) applies internationally.[15, 43, 60]

6.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
The simulation studies have limited generalisability outside of their controlled settings: in most cases manikins were used instead of human subjects, thus the findings may lack validity outside of the experimental setting.[45, 76-79] The studies that did use human subjects had very small sample numbers and only included adults, limiting generalisability to all adults as it is likely the participants did not represent all facial shapes or sizes.

6.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
The primary evidence identified is particularly at risk of publication bias. Studies that found non-significant differences in the use of fit tests versus fit checks may not have been published.

B Evidence to Decision

6.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
R6.1 Tight-fitting RPE, for example an FFP3 respirator, should be fit tested prior to first use.	Recommendation
GPP6.1 Fit testing should be performed if changing the brand, model or size of respirator used.	Good Practice Point
GPP6.2 Fit testing should be repeated on a regular basis.	Good Practice Point
GPP6.3 In addition to routine fit testing on a regular basis, fit testing should be repeated following reported or observed changes to the wearer's face that could impair the face seal with the mask (for example as a result of weight gain/loss, dental or cosmetic work, piercing, surgery, or scarring).	Good Practice Point
GPP6.4 A fit check should be performed every time RPE is donned (put on).	Good Practice Point

6.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
R6,1, GPP6.1, GPP6.2, GPP6.3 and GPP6.4 Ensuring tight-fitting RPE forms a seal with the wearer's face will provide adequate protection.
R6.1, GPP6.1, GPP6.2, GPP6.3 and GPP6.4 Confirming the correct brand/model/size remains suitable for a wearer provides assurance of the tight-fit and efficacy of RPE.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about cons.

Harms
R6.1, GPP6.1, GPP6.2, GPP6.3 None identified.
GPP6.4 Fit checking as part of donning increases the time to don which may delay delivery of patient care.

Benefit-Harm assessment

Classify as "benefit outweighs harm" (or vice versa) or a "balance of benefit and harm." Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
R6.1, GPP6.1, GPP6.2, GPP6.3 Only benefits identified.
GPP6.2 Benefit outweighs the harm as fit testing regularly ensures that staff can continue to select appropriate RPE to achieve a tight fit.
GPP6.4 Fit checking as part of donning increases the time to don which may delay delivery of patient care, however the provision of a proper fit (and reduction of transmission risk) outweighs this potential harm.

6.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
R6.1, GPP6.1, GPP6.2, GPP6.3, GPP6.4, GPP6.5 Implementing a fit testing programme to capture all indications for fit testing has financial implications and is resource intensive, as it requires the purchase of equipment and training of staff to lead and participate in fit testing programmes. R6.1, GPP6.1, GPP6.2, GPP6.3 Fit testing may be challenging for patients or visitors required to wear RPE. GPP6.4 Fit checking may be challenging for patients or visitors required to wear RPE.

6.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
R6.1 [Tight-fitting RPE should be fit tested prior to first use.] ARHAI Scotland and the Working Group support extant primary research findings (3 SIGN 50 level 3) and expert opinion (23 SIGN 50 level 4) that RPE should be fit tested prior to first use according to manufacturer instructions.[1, 4, 8-10, 15-18, 21, 28, 29, 47, 50, 60, 61, 63, 66-70, 72] GPP6.1 [Fit testing should be repeated if changing the brand, model or size of respirator used] ARHAI Scotland and the Working Group support extant expert opinion (7 SIGN 50 level 4) that RPE fit testing should be repeated for changes in the brand, model or size of respirator used.[1, 8, 18, 47, 50, 51, 64] GPP6.3 The extant evidence is inconclusive regarding an appropriate time period for repeat fit testing across all occupational settings. Noting current feasibility issues associated with fit testing a large workforce on an annual basis, Scottish Government have commissioned ARHAI Scotland to consider potential options for

Expert opinion
fit testing frequency in NHS Scotland. Scottish Government will then consider these. GPP6.4 In addition to routine fit testing, fit testing should be repeated following reported or observed changes to the wearer's face that could impair the face seal with the mask (for example as a result of weight gain/loss, dental or cosmetic work, piercing, surgery, or scarring). ARHAI Scotland and the Working Group support extant expert opinion (8 SIGN 50 level 4) that fit testing should be repeated after potential; changes to the wearer's facial shape due to factors such as scarring, dental work, cosmetic surgery, weight change or piercings.[1, 2, 4, 5, 48, 50, 51, 64] GPP6.5 A fit check should be performed every time RPE is donned (put on)] ARHAI Scotland and the Working Group support extant expert opinion (21 SIGN 50 level 4) that a fit check should be performed every time RPE is donned.[7-11, 15, 18, 23-26, 28, 43, 47, 49, 50, 52, 59, 61-63]

6.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state "none". Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
GPP6.2 The extant evidence is inconclusive regarding an appropriate time period for repeat fit testing across all occupational settings. Noting the feasibility issues associated with fit testing a large workforce on an annual basis, Scottish Government have commissioned ARHAI Scotland to consider potential options for fit testing frequency in NHS Scotland. Scottish Government will then consider these.

6.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state "none". Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality,

anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/religious reasons.

Intentional vagueness
GPP6.3 Noting feasibility issues associated with fit testing a large workforce on an annual basis, Scottish Government have commissioned ARHAI Scotland to consider potential options for fit testing frequency in NHS Scotland. This work is currently underway.

6.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
GPP6.3 does not apply to patients and visitors. GPP6.1, GPP6.2, GPP6.3, GPP6.4 Fit testing of FFP respirators is not required for those whose religious or cultural beliefs would predict that a test would fail. For example, if part of an individual's religion requires them to keep their facial hair, there should not be an organisational expectation that this group should be asked to shave in order to be face fit tested for RPE. This is where alternative RPE that does not require a fit test or fit check would be considered.

6.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
GPP6.3 Further research regarding the frequency of repeat fit testing would be beneficial as it is resource intensive. Primary research may include a cohort study assessing risk of fit test failure over time, to ascertain whether repeat fit testing could occur at longer time intervals, such as every three years or every five years.

Research Question 7: What if a fit test or fit check is unsuccessful?

A Quality of Evidence

7.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Twenty-seven pieces of evidence were included in relation to this research question:[9, 11, 15, 17, 21, 23-26, 29, 45, 47, 53, 55, 64, 76-80]	
• Five cohort studies, graded SIGN 50 Level 3.[45, 76-79]	5 x SIGN 50 level 3
• One guideline, published by the WHO, graded AGREE: 'Recommend with provisos' due to limitations regarding the systematic review methodology used to underpin the recommendations.[43]	1 x AGREE: Recommend
• Twenty-one guidance documents, graded SIGN 50 Level 4 expert opinion due to a lack of rigorous scientific evidence to support their recommendations.[1-4, 7, 9, 15, 17, 21, 23-26, 29, 47, 48, 51, 53, 55, 64, 80]	21 x SIGN 50 level 4 – expert opinion
This was considered a moderate volume of evidence that was of overall low quality.	

7.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments

Factors that impact fit

- Five cohort studies assessed factors associated with fit test failure amongst healthcare workers.[45, 76-79] The following factors that may affect fit were identified: sex, where females were more likely to fail,[45, 76, 78] age,[76] facial hair,[77] low body mass index (BMI),[45] and ethnicity.[45, 78]
- SIGN 50 Level 4 expert opinion guidance was consistent in highlighting facial hair (n = 11),[1, 21, 23-26, 29, 33, 43, 48, 53] jewellery (n = 2),[51, 53] spectacles (n = 3),[1, 51, 53] and facial characteristics, such as scarring and moles (n = 3),[1, 43, 51] as factors that may prevent a tight facial seal.

Measures to improve fit

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 (n = 9).[1, 3, 7, 9, 29, 43, 47, 48, 51]
- Repeat fit testing with a different respirator size or model (n = 6).[2, 15, 29, 51, 53, 64] The number of alternative sizes/models that should be available was only discussed in two documents. [51] The BSI recommend considering number of wearers and wearer acceptance.[51] The WHO recommend a range of sizes be available to accommodate different facial characteristics.[15]
- Wearing alternative loose-fitting RPE (n = 9),[1, 2, 9, 21, 29, 43, 47, 51, 64, 80] with specific examples including PAPRs,[9, 47, 80] elastomeric respirators that do not require fit testing,[47] hoods,[2] and helmets.[2]

7.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments

The country or countries in which the guidance/research was conducted and/or applies to are as follows:

- UK (n = 14)[1-3, 7, 21, 23-26, 45, 51, 55, 64, 78] Four were produced by the HSE as part of a series.[23-26]
- ROI (n = 1)[29]

Comments
• USA (n = 4)[4, 48, 53, 80] • Australia (n = 5)[9, 47, 76, 77, 79] • EU/EEA, [17] • International.[43] One guidance document was published by the ECDC therefore applicable to the EU/EAA.[17] Another was published by the WHO therefore applicable internationally.[43] The US Occupational Safety and Health Administration (OSHA) fit testing protocol and N95/P2 respirators were used in the primary studies,[76, 77, 79] which limits applicability to NHS Scotland, as FFP3 respirators and the BS EN fit testing protocol standard is currently in place. Seven documents provide recommendations specific to health and care settings.[3, 9, 17, 43, 47, 64, 80] The recommendations posed in these guidance documents are applicable to Scottish heath and care settings. Thirteen documents provided recommendations non-specific to health and care settings but are still considered applicable due to the nature of the research question.[1, 2, 4, 7, 21, 23-26, 33, 48, 51, 53]

7.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
The primary studies included for this research question included cohorts of health and/or care staff. 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.

7.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
The primary evidence identified is particularly at risk of publication bias, where primary research that did not find significant risk factors did not reach publication.

B Evidence to Decision

7.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
GPP7.1 If a fit test/check is unsuccessful, the following should be considered, in this order: 1. Adjust the straps and face seal and repeat fit test/check. 2. Repeat fit test with a different size or model of tight-fitting respirator (note: this is not applicable for fit checks) 3. If a tight seal cannot be achieved with an FFP respirator, other types of RPE that offer equivalent protection (for example a powered respirator with a hood or helmet) may be considered	Good Practice Point
GPP7.2 A task that requires respiratory protection should not be undertaken by a staff member that has failed a fit test or where fit check has failed and alternative RPE is unavailable.	Good Practice Point

7.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
GPP7.1 This good practice point increases the likelihood of a successful fit test/check so that the user can wear respiratory protection. It also provides a means for respiratory protection if a fit test cannot be passed with any FFP model, by wearing loose-fitting RPE, such as a powered hood or helmet (if available). GPP7.2 This good practice point prevents exposure of a healthcare worker to respiratory hazards by ensuring they do not undertake a task without respiratory protection, where risk assessment has determined that RPE is necessary.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about cons.

Harms
GPP 7.1 Use of alternative RPE types (e.g. powered hoods or helmets) may reduce the ability to communicate, reduce visibility, and require more time to don and doff, which may delay or negatively impact delivery of patient care. GPP7.2 If a healthcare worker is unable to undertake a task due to not having sufficiently fitting RPE, and no other healthcare worker (with sufficiently fitted RPE) is available to assist, there may be a delay to patient care or an inability to provide patient care

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/ Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP7.1 The benefits outweighs the harm as this GPP increases the likelihood of staff having the ability to provide patient care when RPE is required. GPP7.2 The benefit outweighs the harm to prevent nosocomial transmission of infectious agents from patients to staff.

7.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
GPP7.1 and GPP7.2 There is a need to procure sufficient stock of different models/sizes of FFP masks and loose-fitting RPE which will require determination at local level. This requires financial investment, staff time and resource to manage and adequate storage space. GPP7.1 and GPP7.2 There is a need to maintain a record of staff fit test results for auditing purposes, and to inform appropriate procurement and maintenance of RPE stock. GPP7.1 and GPP7.2 Staff training is required to ensure compliance with steps to be taken when fit tests are not successful. GPP7.1 and GPP7.2 Health and care settings also need to consider adequate provision of tight-fitting RPE of various styles and sizes, which may have financial implications and the consideration of storage solutions and waste generation during frequent fit testing.

7.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP7.1 ARHAI Scotland and the Working Group are in agreement with nine SIGN 50 level 4 expert opinion documents that are consistent in advising that straps and face seal should be adjusted when a face seal cannot be achieved.[1, 3, 7, 9, 29, 43, 47, 48, 51] ARHAI Scotland note that a facial seal is required for a fit test and fit check, where this GPP is applicable to both. GPP7.1 ARHAI Scotland and the Working Group support six SIGN 50 level 4 expert opinion documents that recommend repeat a fit test with a different size or model of RPE if a tight seal cannot be achieved with an FFP respirator [2, 15, 29, 51, 53, 64] GPP7.1 ARHAI Scotland and the Working Group support nine SIGN 50 level 4 expert opinion documents that loose-fitting RPE with equivalent protection as FFP3s should be worn if a tight seal cannot be achieved.[1, 2, 9, 21, 29, 43, 47, 51, 64, 80] GPP7.2 It is the expert opinion off ARHAI Scotland and the Working Group that a clinical task that requires RPE should not be undertaken if alternative loose-fitting RPE is unavailable following an unsuccessful fit test or fit check following the measures suggested in GPP7.1.

7.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
GPP7.1 and GPP7.2 Where fit testing failure is due to maintenance of facial hair (or other features) for religious or cultural reasons, provision of powered hoods and helmets supports equality/diversity by allowing individuals to practice their religious/cultural norms whilst undertaking their workplace tasks.

7.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality,

anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
GPP 7.1 and 7.2 The GPPs have not been specific regarding the range of sizes and models of tight-fitting RPE that should be available for use. Health and care settings should consider staff numbers and relevant demographics that may affect fit.

7.12. Exceptions

List situations or circumstances in which the Recommendation/ Good Practice Point should not be applied.

Exceptions
None.

7.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
Studies that assess the protection offered by non-fit tested RPE compared to fit-tested RPE to assess the risk associated with RPE that has not been fit tested would be beneficial for scenarios where staff may require PPE but not yet be fit tested, and for pandemic preparedness.

Research Question 8: When should RPE be worn by health and care staff?

A Quality of Evidence

8.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
In total, 47 pieces of evidence were included to answer this research question. [1-5, 7-12, 15-19, 21, 23-26, 28, 31, 43, 47-49, 51, 53, 54, 57-73, 80-93]	
• Three guidelines two of which were published in the UK and one by the WHO, graded AGREE: 'Recommend with provisos' due to limitations regarding the systematic review methodology used to underpin the recommendations.[43, 57, 83]	3 x AGREE: Recommend with provisos
• Eight experimental simulation studies graded SIGN 50 Level 3. [69-72, 92-95]	8 x SIGN 50 Level 3
• Thirty-six guidance documents were graded SIGN 50 Level 4 expert opinion. [1, 3, 4, 7-10, 12, 15-19, 29, 31, 47, 59-61, 63, 66-68, 75, 80-82, 84-89, 96-99]	36 x SIGN 50 Level 4 – expert opinion
This was considered a high volume of evidence that was overall low quality.	

8.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments

Protection to wearer (primary research):

Three simulation studies included human participants in their simulation,[71, 94, 95] and five studies used manikins.[69, 70, 72, 92, 93] Of these, five used sodium chloride particles as the proxy challenge agent to represent biological particles.[71, 92-95] Three studies used radiolabelled saline.[69, 70, 72]

- Filtration capacity:
    - The three human studies found that RPE had greater filtration capacity when compared to surgical masks.[71, 94, 95]
    - 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.[92, 93]
    - One 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.[69]
    - One study additionally compared the filtration capacity of FFP1, FFP2 and FFP3 respirators and found no significant difference in their efficacy.[71]
- Inward leakage: Five manikin studies assessed the inward leakage of RPE and surgical masks. [69, 70, 72, 92, 93] Two studies did not specify how they sealed respirators to manikin heads,[92, 93] and three used Vaseline.[69, 70, 72]
    - One study found 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 but did not compare to surgical masks.[72]
    - Two studies found no statistically significant difference in protection when surgical masks or N95 respirators were applied to a manikin head, until the N95 respirator was subsequently sealed using Vaseline.[69, 70]
    - Two studies found that surgical masks had higher inward leakage when compared to N95 respirators.[92, 93] In three human studies, respirators consistently performed better than surgical masks in terms of penetration of particles and inward leakage.[71, 94, 95]
- Breathing frequency and particle size: Irrespective of inspiratory flow rate and breathing frequency, surgical masks had significantly higher filter penetration when compared to N95 respirators.[92, 93] Two studies also found that the efficacy of N95 respirators may be affected by inspiratory flow rate and breathing frequency; however, these findings have limited

Comments

generalisability as these parameters are not typically monitored during real life use.[92, 93]

Protection to wearer, consistencies in extant guidance:

- Twenty-nine expert opinion documents, and two guidelines graded AGREE: 'Recommend with provisos'[43, 57] provide clear recommendations regarding the requirement for RPE if a patient has confirmed/suspected infection with a pathogen spread by the 'airborne route'.[3, 4, 8-10, 12, 15-18, 29, 32, 43, 50, 59, 61, 63, 66-68, 75, 81, 83, 85, 88, 89, 97, 100-102] Twenty-seven documents provided examples of such pathogens.[8, 10, 18, 43, 59, 81, 83, 88, 97, 100, 102, 103]

The specific instances that RPE should be worn for 'airborne precautions' are inconsistent, as follows:

- General patient care: Six expert opinion documents recommend that RPE is worn when in the same room or care area as a patient that requires 'airborne precautions' (n = 7).[3, 8, 9, 18, 29, 59, 81] or when providing general patient care until a patient is no longer considered infectious (n = 6).[3, 8, 9, 18, 59, 81] Example pathogens cited within these guidance documents include rubeola virus [measles],[3, 18, 59, 81] tuberculosis [*Mycobacterium tuberculosis*],[3, 8, 18, 59, 81] SARS [SARS-CoV-1],[3] smallpox [variola virus][8, 81] pandemic influenza,[9] chickenpox [varicella-zoster virus][3, 59, 81] and shingles [disseminated herpes zoster][59]
- COVID-19: Nine documents make recommendations specific to COVID-19, stating that staff should wear RPE when providing direct care to patients with suspected or confirmed COVID-19 infection.[16, 17, 32, 53, 61, 75, 85, 89, 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.[66-68]
- 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 as a patient with measles, chickenpox or disseminated herpes zoster, however what constituted a care area was not well defined.[3, 8, 9, 18, 59, 81] Conversely the CDC stated that a recommendation could not be made regarding when RPE was required instead of a surgical mask for these infectious agents due to a lack of evidence regarding the benefits of RPE use in preventing transmission.[8]
- Clinical procedures: Twenty-three expert opinion guidance documents published globally state that RPE should be worn when performing aerosol generating procedures (AGPs) on a patient that has suspected or confirmed respiratory infection, or any other infection spread in the air (n = 25).[3, 8, 9, 12, 15-17, 29, 32, 43, 57, 59, 60, 66-68, 75, 80, 84-86, 89, 98, 100, 101] Eight documents recommend

Comments

that RPE is worn for all AGPs, regardless of patient symptoms, in the context of the COVID-19 pandemic.[12, 15-17, 80, 85, 89, 101] Others state that RPE should be worn in clinical areas where high-risk procedures, including AGPs, are performed, particularly in pandemic COVID-19 settings (n = 5).[8, 15, 59, 67, 68]

Sessional use – inconsistencies in extant guidance:

- Sessional use of RPE was not recommended in five documents not specific to the COVID-19 pandemic.[3, 9, 28, 43] PHAC and the WHO recommended sessional use for cohorted patients.[18, 43] The CDC The National Personal Protective Technology Library state 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 after treating a potentially infectious patient.[31]
- Eight documents provided recommendations regarding sessional use in the context of the COVID-19 pandemic.[12, 19, 47, 66-68, 89] Overall, sessional use was not recommended, where the Canadian Government Omicron guidance supports the use of either a surgical mask or KN95 for sessional use by staff and visitors, according to community transmission rates.[89] Australian Government and New Zealand Ministry of Health recommend sessional use of RPE in COVID-19 care areas.[47]
- HSE recommend that RPE are disposed after one use, continuous wear time should be one hour or less, however this recommendation was not specific to health and care settings.[1, 23-26] Conversely, in generic guidance on preparing workplaces for influenza pandemics, the US OSHA advise against re-use of respirators due to potential risk of cross-contamination.[4] The lack of consistency in these recommendations from HSE and US OSHA are likely because US OSHA guidance is focussed on viral contamination, however the guidance by HSE considers the use of RPE for non-biological hazards. These recommendations have limited applicability to Scottish health and care settings.
- Risk assessment: 13 expert opinion documents and two guidelines graded AGREE: 'Recommend with provisos', [43, 57] recommend a risk assessment .[3, 8, 9, 12, 18, 43, 57, 61, 63, 82, 85, 89, 96] Inconsistencies as to what the risk assessment should consider: including infectious status (n = 10),[3, 8, 9, 12, 18, 43, 57, 61, 82, 89]the nature of the patient interaction (for example, proximity to patient, duration of interaction and the care activity being undertaken (n = 11),[3, 18, 43, 57, 63, 66, 68, 82, 85, 89, 96] and factors relating to the environment (such as ventilation and crowding, including room/area occupancy (n = 5).[15, 57, 68, 89, 96] The level of community SARS-CoV-2 transmission is included as part of this risk assessment in three guidance documents.[61, 85, 89] Patient

Comments
behaviour, including heavy breathing, shouting and ability to wear a mask, was mentioned by one guidance document.[89] **Personal Preference** • Two documents stated that staff may make a personal choice to wear RPE, without performing an individual risk assessment.[12, 99] • 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.[12] • 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.[99] Scientific evidence was not used to support this recommendation. **Protection to others - 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.[69, 70, 72, 90, 91, 104] Two studies included human participants.[91, 104] 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. [69, 70, 90] One study found that there was no significant difference between surgical masks and RPE as source control when coughing was simulated.[72] The studies using human participants compared vented N95s, KN95s and surgical masks.[91, 104] One study found that surgical masks were more effective than vented N95 respirators and KN95s.[91] The second study found that vented N95 respirators were more effective than KN95s and surgical masks.[104] • Five expert opinion guidance documents referred to RPE as source control. [12, 32, 59, 67, 102] The documents stated that RPE may be considered as source control, but there was an overall lack of guidance on RPE as source control, likely given the fact that respirators are primarily designed to provide protection to the wearer, rather than protection to others. **Filtration efficiency of RPE:** • There was lack of consistency regarding the required filtration efficiency of RPE depending on the country in which guidance was published or primary research was conducted, and the potential risk of transmission from patients to staff.

Comments

- General patient care: Ten documents recommend RPE with ≥ 95% efficiency, specifically P2 and N95 respirators, for general patient care;[8, 10, 29, 50, 59, 61, 66, 81, 89, 101] five documents, all published in the UK, recommend RPE with ≥ 99% efficiency, specifically an FFP3 respirator;[3, 57, 63, 83, 88] two documents, published by Public Health Agency of Canada (PHAC) and the National Institute for Health and Care Excellence (NICE), do not specify the respirator type or filtration capacity.[18, 82] The European Centre for Disease Prevention and Control (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.[8, 16, 17, 85]
- Clinical procedures: Fourteen guidance from 12 organisations (WHO, the US Centres Centers for Disease Control and Prevention (CDC), American Society of Anesthesiologists (ASA), Ministry of Health New Zealand, Government of Canada, Infectious Disease Society of America, Association of periOperative Registered Nurses (AORN), National Health and Medical Research Council (NHMRC), Association for Professionals in Infection Control and Epidemiology (APIC), National Institute for Occupational Safety and Health (NIOSH), and the Republic of Ireland Department of Health) recommend a respirator with ≥ 95% filtration capacity, for example, P2, N95 respirator or FFP2 respirator [9, 12, 15, 29, 59, 60, 66-68, 75, 80, 85, 86, 89, 98, 100, 101] and three (all UK based) recommend a respirator with ≥ 99% filtration capacity.[3, 57, 84] 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.[16, 17, 85] 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).[43] The WHO also do not distinguish between the use of RPE according to filtration capacity.[43, 60]

8.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments

The country or countries in which the guidance/research was conducted and/or applies to are as follows:

- UK (n = 14)[1-3, 7, 21, 23-26, 51, 52, 63, 64, 99]
- USA (n = 21)[4, 5, 8-11, 28, 31, 48, 49, 58, 59, 62, 69, 70, 72, 90-94, 104]
- Canada (n = 4)[65-68]
- Australia (n = 2)[47, 61]
- International (n =3)[15, 43, 60]
- EU/EEA (n = 2)[16, 17]
- Taiwan (n = 1)[71]
- Japan (n = 1)[95]

Two guidance documents were published by the ECDC therefore applicable to the EU/EEA.[16, 17] Three guidance documents were published by the WHO therefore applicable internationally.[15, 43, 60]Overall, the included extant expert opinion guidance are applicable to Scottish health and care settings.

Some guidance was specific to certain healthcare settings or groups of infectious agents, including care facilities,[60, 63, 66, 84] surgical settings,[80, 81] ambulatory care,[75] acute care settings, [68] acute respiratory infections,[4, 12, 15, 17, 32, 47, 66-68, 83, 85, 86, 88, 89, 96, 97, 100, 102, 103] or other infectious agents.[98] Where appropriate, findings in relation to these documents have been connected, in text, to their respective infectious agent or setting specific guidance.

The level of community SARS-CoV-2 transmission is included as part of risk assessment for wearing RPE in three guidance documents[61, 85, 89, 96] however, this recommendation has limited applicability in settings where community surveillance is not being undertaken and outside of the COVID-19 pandemic. A small number of sources (n = 8) state that the risk assessment may include personal preference and perceived level of protection by the wearer. [9, 12, 15, 61, 66, 68, 85, 89] Again, this recommendation was made in the context of the COVID-19 pandemic.

The Scottish Government DL on regarding staff use of RPE based on personal preference has limited generalisability outside of a COVID-19 pandemic setting.[99] 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.[99]

8.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
The simulation studies have limited generalisability outside of their controlled parameters: in most cases manikins were used,[69, 70, 72, 90] rather than human subjects.[91, 104] All the simulations were based on a small amount of data, where the number of replicates/independent experimental repeats were small. One of the studies included participants who had paired SARS-CoV-2 samples, where participants were recruited from one university in the USA and the surrounding community, which may limit generalisability of the findings.[44, 69-71, 104] The use of sodium chloride and saline in the manikin studies may not be a valid proxy for infectious particles that staff may encounter in health and care settings.

8.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
The primary evidence identified is particularly at risk of publication bias. Studies that found non-significant differences in the use of surgical masks versus respirators for example, may not have reached publication which would bias the conclusions drawn in this review. A formal assessment of publication bias was not carried out.

B Evidence to Decision

8.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
GPP8.1 When indicated for use, RPE with at least 99% filtration efficiency (FFP3 respirator or equivalent) should be selected.	Good Practice Point
GPP8.2 RPE should be worn by all staff providing care for a service user with a suspected or confirmed infection caused by a category R2 or R3 respiratory infectious agent (as defined in the TBP Definitions literature review).	Good Practice Point
GPP8.3 Health and care staff should wear RPE during provision of care for a patient with a suspected or confirmed infection caused by a category R1 respiratory infectious agent (as defined in the TBP Definitions literature review) if advised by occupational health, a GP or another medical practitioner.	Good Practice Point
GPP8.4 Where a surgical mask is indicated during provision of care for a service user with a suspected or confirmed infection with a category R1 respiratory infectious agent (as defined in the TBP Definitions literature review), health and care staff may choose to wear RPE as an alternative to a surgical mask. This decision can be based on personal choice. This personal choice may be informed by high-risk	Good Practice Point

Recommendation	Grading
exposures that are discussed in the TBP Definitions literature review and will be made clear in final guidance regarding RPE use.	

8.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
GPP8.1 When compared to FFP respirators with lower filtration efficiency, the use of FFP respirators with at least 99% filtration efficiency ensures that employees are provided with the maximum level of respiratory protection available. It is anticipated that this will provide the greatest reduction in risk of respiratory transmission respirators are required to be worn. GPP8.2 The design of RPE is considered mechanistically superior to surgical masks against the inhalation of respiratory infectious agents. GPP8.2 Use of RPE during the care of service users with suspected or confirmed infection caused by a category R2 or R3 respiratory infectious agents provides protection against infectious agents which are considered to present the highest risk in terms of severity of infection outcome. GPP8.3 Use of RPE, if advised by occupational health, a GP or other medical practitioner, when caring for patients with suspected or confirmed R1 respiratory infection may reduce the risk of occupational exposure. GPP8.4 Selection of RPE where surgical masks are indicated for care of service users with suspected or confirmed R1 respiratory infection on the basis of personal choice facilitates autonomy by the wearer and may reduce staff concerns associated with the risk of occupational exposure.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/ Good Practice Point were followed. Be explicit, clear about cons.

Harms
GPP8.1 Wearing RPE with higher filtration capacity (i.e. 99% filtration efficiency versus 95%) may result in discomfort to the wearer due to higher breathing resistance over time. GPP8.2 Prolonged and frequent use of RPE may result in skin damage and/or general discomfort to the wearer. GPP8.3 None anticipated. GPP8.4 Selection of RPE instead of surgical masks based on personal choice may result in skin damage and/or general discomfort during wear, potential for poor compliance with safe donning and doffing, more touching of the face or RPE whilst worn, and could result in the perception that RPE will reduce the risk of transmission without the need for other IPC mitigations. GPP8.4 Selection of RPE versus surgical masks based on personal choice for category R1 respiratory infectious agents may cause confusion and concern around sufficient protection.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/ Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP8.1 and GPP8.2 The anticipated benefit of providing the maximum protection available where FFP respirators are required to be worn, is considered to outweigh the discomfort created by breathing resistance. This benefit is increased for R2 and R3 respiratory infectious agents, as the infection acquisition has an increased risk of poor health outcomes. GPP8.3 Only benefits identified. GPP8.4 As personal choice supports staff autonomy and decision making, the benefits are considered to outweigh the harms where guidance that includes appropriate supporting information and education.

8.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context? Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be

associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
GPP8.2, GPP8.3, GPP8.4 There may initially be an increased use of RPE. This will have an impact financially, in procuring the additional RPE, waste generation may increase and additional needs for training staff as well as increase in providing fit testing. GPP8.2, GPP8.3, GPP8.4 The environmental impact of potentially increased RPE use should be assessed or monitored to evaluate opportunities for improvement. GPP8.2, GPP8.3 GPP 8.4 There is a requirement to monitor and anticipate appropriate RPE stock levels. GPP8.2, GPP8.3 GPP 8.4 There may be a need to provide additional storage for RPE.

8.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP8.1 There is inconsistent evidence regarding the filtration efficiency of RPE worn by health and care staff for general patient care and when performing clinical procedures according to the countries(s) in which guidance is published and applicable to. Generally, guidance published outside of the UK, including the EU/EAA, Canada, the USA, recommends RPE with 95% filtration efficiency, including P2, N95 and FFP2 respirators.[8-10, 12, 15, 29, 50, 59-61, 66-68, 75, 80, 81, 85, 86, 89, 98, 100, 101] Guidance published for the UK recommend the use of FFP3 respirators.[3, 57, 63, 83, 84, 88] COSHH legislates that employers provide employees with PPE, including RPE, that provides ‘adequate’ protection (SIGN 50 Mandatory), which ARHAI Scotland note is not a quantified or well-defined term.[37] The Health and Safety Executive interpret COSHH legislation to mean that employers should provide staff with RPE that offers “maximum” protection available (SIGN 50 Level 4). ARHAI Scotland and the Extraordinary Working Group support extant UK HSE expert opinion (SIGN 50 level 4) that PPE with maximum protection should be worn (i.e. FFP respirator with ≥99% filtration efficiency) to ensure that COSHH legislation is met.[1]

Expert opinion

GPP8.2, GPP8.3, GPP8.4 The GPPs within this research question have relied heavily on the expert opinion of the Extraordinary Working Group convened for the TBP definitions review. Much of the wording and structure of these GPPs in relation to the R1-R3 respiratory TBP categories were informed by decisions made in this forum.

In light of the insufficient epidemiological evidence regarding real-world effectiveness of RPE (in comparison to surgical masks) the Extraordinary Working Group considered the application of a precautionary principle for RPE use, where RPE would be used for all suspected and confirmed respiratory infections, regardless of the causative infectious agent. This is in acknowledgement that respiratory particles of respirable size are produced by all individuals, regardless of their infectious status.

The Extraordinary Working Group considered the anticipated benefits, harms and feasibility of this approach (use of RPE for all transmissible respiratory infections), which is summarised below.

- Anticipated benefits: use of 'mechanistically superior' RPE will provide the greatest protection against inhalation of respiratory infectious agents; simplicity of mask choice (surgical masks only for splash/ spray, RPE for respiratory protection); pandemic preparedness would be supported as RPE would be the default (unless HCID PPE were required)
- Anticipated harms: significant increase in total staff numbers required to use RPE as well as a significant increase in the total time each individual would require to wear RPE would be anticipated. This would result in discomfort during wear, potential for poor compliance with appropriate donning; potentially more touching of mask/face; and the risk of the perception that RPE is providing protection over and above other IPC mitigations.
- Anticipated feasibility: all employees would require to be fit tested resulting in increased cost due to use of RPE instead of surgical masks (RPE is more expensive per unit) and increased time out of clinical practice to facilitate fit testing. There would also be increased cost and time resource associated with staff training and education to support effective donning and wear and compliance with indications

The Extraordinary Working Group agreed that whilst there is a lack of data to support this, transmission events are generally rare where surgical masks are currently worn for non-AGP care of patients with respiratory infections (for R1 infectious agents). Some group members stated that transmission events from patients to health and care staff during individual care and outbreaks where patient case numbers are high have not been observed and they would expect to see this if surgical masks were ineffective. The group agreed that the harms currently

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outweigh the benefits for use of RPE at all times for care of patients with R1 respiratory infectious agents.

The group agreed that for R2 and R3 respiratory infectious agents, the risk and consequence of onwards transmission is accepted to be higher; the specific reasons for this are unknown however it may in part be due to an ability to remain infectious for longer when in the air.

A proportionate approach to risk is therefore preferred by the Extraordinary Working Group with regards to RPE selection and the group are in favour of using the R1-R3 categorisation system as defined in the TBP Definitions review to support mask selection. Consequently, the group agreed that that RPE should be worn for R2 and R3 infectious agents at all times due to the increased risk of severity of health outcome.

The R1-R3 categorisation of respiratory infectious agents and the associated risk assessment for RPE selection was reviewed by the UK Health and Safety Executive, who highlighted this approach is pragmatic and practical.

GPP8.3 It is the expert opinion of ARHAI Scotland and the Extraordinary Working Group that RPE should be worn by health and care staff, if advised by occupational health, a GP or other medical practitioner, when caring for R1 patients. In line with the Equality Act, which states that it may be necessary to provide reasonable adjustments to staff, this is to account for personal risk factors that the health and care staff may have, that can increase the risk of serious health outcomes if R1 infection is acquired (for example, underlying health issues, pregnancy, unvaccinated). For most people, the risk of severe health outcomes associated with R1 infectious agents is anticipated to be low and therefore FRSM is considered sufficient. The use of RPE is a precautionary measure to account for vulnerability in this staff cohort.

GPP8.4 Staff choice to wear a respirator instead of a surgical mask without performing a risk assessment was supported by one expert opinion document and a DL published by the Scottish Government.[12, 99] This DL, published in 2022 is specific to COVID-19, highlighting that staff working in non-respiratory pathways may have concerns about COVID-19 exposure.[99] ARHAI Scotland and the Extraordinary Working Group support the Scottish Government DL that HCWs may choose to wear RPE based on personal choice.

The TBP Definitions literature review has developed a good practice point (GPP4.1) that identifies coughing (both natural and procedurally induced on awake patients) as presenting a higher-risk exposure compared to most other natural respiratory activities. It also identifies use of high-speed devices on tissues within the respiratory tract (and extra-pulmonary TB sites) in surgery/ post-mortem and dentistry, as presenting a high-risk exposure (GPP4.2). Exposure risk associated

Expert opinion

with both of these increases with proximity to the infectious patient. However, how exposure risk relates to transmission risk, remains unknown.

The Extraordinary Working Group acknowledged that respiratory transmission can occur without requiring coughing symptoms and in the absence of high-speed device use and will depend on multiple factors. The Extraordinary Working Group considered whether RPE should be worn for all coughing respiratory infection patients (natural and procedurally induced) and during use of high-speed devices on respiratory infection patients. This would be a precautionary approach to account for exposure risk, in the absence of evidence regarding transmission risk. Because GPP8.2 provides for RPE at all times when caring for R2 and R3 respiratory patients (accounting for the most hazardous infectious agents), the precautionary approach for RPE would be applicable to care of R1 respiratory patients only.

The Extraordinary Working Group agreed that surgical face masks are sufficient for care of R1 respiratory patients, as per GPP5.5 of the surgical face masks review, and as detailed in the expert opinion section for GPP8.3 of this RPE review. However, the Extraordinary Working Group agreed that healthcare workers should be permitted to choose to wear RPE in place of a surgical face mask when caring for R1 respiratory patients if they prefer. This would be a personal choice, acknowledging that some HCWs may perceive the exposure risk associated with some elements of R1 care as warranting a higher-grade mask (RPE). GPP8.4 of this RPE review provides for RPE use based on vulnerability of the healthcare worker (personal risk factors that the HCW may have, that can increase the risk of serious health outcomes if R1 infection is acquired (for example, underlying health issues, pregnancy, being unvaccinated)). The addition of personal choice, as a separate good practice point, is to account for any additional concerns regarding exposure risk associated with R1 patient care. The Extraordinary Working Group agreed that information regarding exposure risks should be provided in final guidance to support personal choice.

The TBP Definitions literature review has informed good practice points within that review that identify certain scenarios to be high-risk in terms of exposure risk. These include coughing and induced coughing, and use of highspeed devices on tissues within the respiratory tract (and extrapulmonary sites on TB patients). The appropriate actions required to mitigate these exposures are associated with:

1. the need to provide protection to healthcare workers working at proximity to the source where they will be exposure to the full spectrum of respiratory particles sizes (respirable and non-respirable), and,
2. protection against respirable particles at further afield where particles may remain suspended in the air for some time after leaving the source.

Expert opinion
As per the TBP Definitions literature review, R2 and R3 infectious agents are considered to present a greater hazard if exposed. However, exposure risk is higher if high-risk exposures are present and risk increases with increasing proximity to the source. To mitigate exposure risk, the Extraordinary Working Group agreed that RPE may be considered by staff, rather than a surgical mask, when caring for service user who have suspected or confirmed respiratory infection by an R1 infectious agent. Exposure risk increases with: providing care at close range to a service user (within one metre or three feet); close proximity to service users who are actively coughing, as they produce the most respiratory particles; medical procedures that induce coughing, and medical procedures that use high-speed devices on tissues within the respiratory tract (and extra-pulmonary tuberculosis sites) during surgery/post-mortem and dentistry produce more particles and, therefore, increase exposure risk. The transmission risk associated with these factors remain unknown.

8.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
GPP8.1 None. GPP8.2 None. GPP8.3 This GPP has been developed as ARHAI Scotland recognise and support that staff may choose to wear RPE based on personal choice. GPP8.4 None.

8.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality,

anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
GPP8.1, GPP8.2, GPP8.3, GPP8.4. None.

8.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
GPP8.1, GPP8.2, GPP8.3, GPP8.4. None.

8.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None.

Research Question 9: When should valved versus unvalved respirators be worn?

A Quality of Evidence

9.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Five pieces of evidence were included in relation to this research question: • One simulation study, graded SIGN 50 Level 3.[105] • Four guidance documents graded SIGN 50 Level 4 expert opinion.[4, 30, 100, 106] As well as being low in quantity, the evidence is low quality.	1 x SIGN 50 Level 3 4 x SIGN 50 Level 4 – expert opinion

9.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Extant guidance (n = 4) is generally consistent in advising that RPE (powered, non-powered or reusable) with exhalation valves are not appropriate when a sterile field is required as unfiltered air from the wearer is released to the environment.[4, 14, 30, 100] **Primary research:** • Consistency was not assessed as only one primary study that compared the use of valved versus non-valved RPE was included in this review.[105]

Comments
• This study simulated patient care in an enclosed chamber to assess the use of an N95 with an exhalation valve as source control, using bacterial contamination of the sterile field as a proxy measure. Colony forming units (CFU)/m^3 in the air were higher when an N95 with an exhalation valve was used 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).[105]

9.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments
The country or countries in which the guidance was conducted and/or applies to are as follows: • USA (n = 4)[4, 14, 30, 105] • EU/EAA (n = 1)[106] One document was published by the ECDC therefore applicable to the EU/EAA.[106] Though non-UK guidance considered RPE not currently used in Scotland, the recommendations are generally applicable due to the nature of the research question, which focusses on exhalation valves.

9.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Only one primary study was identified in relation to this research question.[105] This study had limited generalisability due to the use of a manikin to simulate a patient and small volume of data produced.[105]

9.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
Only one primary study was deemed relevant to this research question, suggesting publication bias may be a concern in this area of research. A formal assessment of publication bias was not carried out.

B Evidence to Decision

9.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
GPP9.1 Respirators with unshrouded valves are not considered to be fluid resistant. Where there is a risk of contamination with blood or body fluids additional PPE should be worn, such as full face shield/visor.	Good Practice Point
GPP9.2 Valved respirators should not be worn when a sterile field is required.	Good Practice Point

9.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
GPP9.1 Use of a visor of face shield to provide fluid resistance when wearing respirators with unshrouded valves prevents exposure to potentially infectious blood and body fluids. GPP9.1 This good practice point ensures that a sterile field is maintained as it advises against the use of valved respirators which release unfiltered air from the wearer.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/ Good Practice Point were followed. Be explicit, clear about cons.

Harms
GPP9.1 and GPP9.2 No harms anticipated.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP9.1 and 9.2 Only benefits identified.

9.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
GPP9.1 Training is required to ensure that staff are aware that valved RPE should not be worn when a sterile field is required. GPP9.1 and GPP9.2 There will be resource implications related to the procurement of valved and non-valved RPE.

9.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP 9.1 There was no evidence or extant guidance regarding unshrouded or shrouded valved respirators. In the opinion of ARHAI Scotland, unshrouded valved respirators should not be worn when spraying or splashing is anticipated as they are not fluid resistant. GPP9.2 Four SIGN 50 level 4 guidance documents and one primary study graded SIGN 50 level 3[105] support this good practice point in regards that valved RPE should not be worn where a sterile field is required.[4, 14, 30, 100] It is the expert opinion of ARHAI Scotland and the Working Group that valved respirators should not be worn when a sterile field is required. As unfiltered air is expelled from valved respirators, it is therefore not safe for patients and others that may be exposed if worn when source control is needed.

9.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
None.

9.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality,

anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/religious reasons.

Intentional vagueness
None.

9.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
None.

9.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None.

Research question 10: When should a patient wear RPE?

A Quality of Evidence

10.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Ten evidence sources were included: • Four guidance documents, graded SIGN 50 level 4 expert opinion.[8-10, 18] • Six experimental simulation studies graded SIGN 50 level 3.[69-72, 90, 91] The evidence identified for this research question was both of low quality and low quantity.	4 x SIGN 50 level 4 – expert opinion 6 x SIGN 50 level 3

10.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Extant guidance documents do not provide clear recommendations regarding when patients should wear RPE, therefore consistency could not be assessed: • The Australian Government, PHAC, The Association for Professionals in Infection Control and Epidemiology (APIC) and the CDC refer to the use of RPE as source control – but overall the recommendations/statements lacked clarity around specific indications for use compared to the use of surgical masks, or the benefit of using RPE as source control.[9, 10, 12]

Comments

Primary research:

- 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.[69, 70, 72, 90, 91, 104] 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. [69, 70, 72, 90, 104] Two used human participants.[91, 104]
    - 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. [69, 70, 90]
    - One study found that surgical masks were more effective than vented N95 respirators and KN95s.[91]
    - The second study found that N95 respirators were more effective than KN95s and surgical masks.[104]

10.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments

The country or countries in which the guidance/research was conducted and/or applies to are as follows:

- USA (n = 6)[8, 10, 69, 70, 72, 90, 91, 104]
- Australia (n = 1)[9]
- Canada (n = 1)[18]

The guidance recommendations are generally applicable to Scottish health and care settings due to the nature of the research question. Recommendations made in the context of the COVID-19 pandemic may not be applicable to non-pandemic settings.

One document was specific to non-surgical settings,[9] however the recommendations were applicable to all patients given the nature of the recommendations posed.

10.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
The simulation studies have limited generalisability outside of their controlled settings: in most cases manikins were used instead of human subjects, thus the findings may lack validity outside of the experimental setting.[69, 70, 72, 90, 91, 104] The studies that did use human subjects had very small sample numbers and only included adults, limiting generalisability to all adults due to differences in facial shapes/sizes, and to children.

10.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
The primary evidence identified is particularly at risk of publication bias. Studies that found non-significant differences in the use of surgical masks versus respirators for example, may not have reached publication which would bias the conclusions drawn in this review.

B Evidence to Decision

10.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
There are no recommendations or good practice points proposed in relation to this research question.	N/A

10.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
Not applicable.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about cons.

Harms
Not applicable.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
Not applicable.

10.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
Not applicable.

10.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
Not applicable.

10.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
Not applicable.

10.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/religious reasons.

Intentional vagueness
Not applicable.

10.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
Not applicable.

10.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None.

Research Question 11: When should a visitor wear RPE?

A Quality of Evidence

11.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
12 evidence sources were included for this research question: • Six guidance graded SIGN 50 Level 4 expert opinion.[8-10, 18, 67, 89] • Six experimental simulation studies graded SIGN 50 Level 3.[69, 70, 72, 90, 91, 104] A low volume of low-quality evidence was included in relation to this research question.	6 x SIGN 50 level 4 – expert opinion 6 x SIGN 50 level 3

11.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
There was a low quantity of guidance identified which limited the ability to assess consistency: • There were no clear recommendations in extant expert opinion guidance for the use of RPE by visitors. [8-10, 18, 67, 89] • If airborne precautions were required by staff, four SIGN 50 level 4 guidance recommend RPE as an option alongside the use of surgical masks.[8, 18, 67, 89]

Comments

- Only one document published by the US Association for Professionals in Infection Control and Epidemiology (APIC) and specific to non-surgical settings states that RPE may only be worn if fit tested prior.[10]

Primary research:

- 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.[69, 70, 72, 90, 91, 104] Three 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, 72, 104] Two used human participants.[91, 104] 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.[69, 70, 90] One study found that surgical masks were more effective than vented N95 respirators and KN95s.[91] The second study found that N95 respirators were more effective than KN95s and surgical masks.[104]
- The review did not include any evidence that assessed the effectiveness of RPE use in visitors in real-life settings for source control or use for respiratory protection.

11.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments

The country or countries where the research was conducted, or to which the guidance applies are as follows:

- USA (n = 7).[8, 10, 69, 70, 72, 90, 91]
- Australia (n = 1)[9]
- Canada (n = 3)[18, 67, 89]

Four documents are considered directly applicable as they are general to all health and care settings. [8, 9, 18, 89] One document was specific to non-surgical settings[10], one document was specific to visitors in outpatient/ambulatory care settings, therefore the recommendations made may not be directly applicable in other health and care settings.[71] One document is specific to the COVID-19 pandemic,

Comments
which means the recommendations made may not apply to non-pandemic settings.[90]

11.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
The simulation studies have limited generalisability outside of their controlled settings: in most cases manikins were used instead of human subjects, thus the findings may lack validity outside of the experimental setting.[69, 70, 72, 90, 91, 104] The studies that did use human subjects had very small sample numbers and only included adults, limiting generalisability to all adults due to differences in facial shapes/sizes, and to children.

11.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
The primary evidence identified is particularly at risk of publication bias. Studies that found non-significant regarding the use of RPE as source control may not have reached publication which would bias the conclusions drawn in this review.

B Evidence to Decision

11.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
GPP11.1 Consideration should be given to providing visitors with RPE visiting a patient with a suspected or confirmed infection caused by a category R2 or R3[1] respiratory infectious agent.	Good Practice Point

[1] Transmission descriptors are being developed separately by ARHAI Scotland and the Extraordinary TBP Definitions Working Group (a sub-group of the NPGE Working Group). R2 respiratory infectious agents can cause severe human disease and may be a serious hazard to employees; they may spread to the community; but there is usually effective prophylaxis or treatment available. R3 respiratory infectious agents cause severe human disease and are a serious hazard to employees; they are likely to spread to the community; and there is usually no effective prophylaxis or treatment available. Respiratory infectious agents included in R2 and R3 categories are typically those which current guidance would consider as airborne and/or HCID.

11.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
GPP11.1 Onward transmission of infections agents from patients to visitors is minimised.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/ Good Practice Point were followed. Be explicit, clear about cons.

Harms
GPP11.1 As visitors are likely not to be practiced in fit testing or checking, and removing RPE, and not familiar with the risks associated with loosening or removing RPE, there is a risk that RPE may not be worn or removed correctly and therefore not provide the intended protection. GPP11.1 There will be concern from staff that visitors have not had adequate training to wear RPE and where their responsibility lies with this.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/ staff/ visitor perspective, the societal perspective, or both. Recommendations/ Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP11.1 The harms outweigh benefits. However, individual circumstances must be taken into account and a local decision can be made in conjunction with the infection prevention and control team (IPCT) and clinical teams.

11.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context? Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
GPP11.1 There is cost and general increased resource required to support fit testing of RPE by visitors, in terms of fit testing available, additional supply of RPE and training of visitors on RPE use11.1 GPP11.1 Increase in waste generation as a result of increased RPE use in health and care settings.

11.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP11.1 There was insufficient evidence regarding the use of RPE by visitors. ARHAI Scotland and the Working Group are in agreement that RPE may be considered for visitor use when visiting a patient with a suspected or confirmed infection caused by a category R2 or R3 infectious agent.

11.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
None.

11.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/religious reasons.

Intentional vagueness
None.

11.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
None.

11.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None.

Research Question 12: Where and how should disposable respirators be donned?

A Quality of Evidence

12.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Nineteen pieces of evidence were included for this research question which was considered a sufficient volume of evidence, however it is of low quality: • two pieces of mandatory legislation,[37, 40] • one guideline published by the WHO graded AGREE: 'Recommend with provisos' due to limitations regarding the systematic review methodology used to underpin the recommendations, [43] • 16 guidance graded SIGN 50 Level 4.[1, 3, 9, 10, 15, 17, 18, 29, 37, 51, 52, 54, 59, 62, 87, 89] No primary research studies were included.	2 x Mandatory legislation 1 x AGREE: Recommend 16 x SIGN 50 Level 4 – expert opinion

12.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Location Four organisations provide recommendations regarding where respirators should be donned.[9, 52, 59, 87]

Comments

- Consistency 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'.[9, 52, 59, 87]

Donning technique

Eight expert opinion guidance provide recommendations on the sequence for donning RPE:

- Following hand hygiene,[8, 17, 18, 47, 52, 53, 62, 89] extant guidance (n = 7) is consistent in advising that PPE should be donned in the following order: apron/gown; respirator; eye/face protection then gloves .[8, 17, 18, 47, 52, 62]
- Guidance published by the Australian Government highlights that if headwear and/or spectacles are already being worn, these should be removed before donning RPE.[9] 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.[9]

There was inconsistency regarding the technique that should be followed to don RPE:

- Six guidance documents highlight that manufacturer instructions should be followed when donning RPE.[1, 10, 51, 52, 54, 59]
- Eight documents provided specific instructions for donning a disposable respirator with the focus of achieving a tight seal.[1, 3, 9, 10, 18, 47, 53, 73]
- The Scientific Development Committee of the Healthcare Infection Society (UK) provide further detail on how to don FFP3 respirators with a focus to minimise contamination.[3] The ROI Department of Health also provide specific instructions on how to don a cup-billed respirator.[29]
- Six documents state that the front of the respirator should not be touched whilst being worn.[3, 9, 10, 29, 43, 47]

Wearing RPE

- UK HSE guidance 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, 107]
- Four documents state that respirators should not be left hanging around the neck when not in use.[9, 10, 18, 29]

12.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments
The country or countries in which the guidance/research was conducted and/or applies to are as follows: • UK (n = 8)[1, 3, 36, 37, 51, 52, 54, 107] • Canada (n = 2)[18, 89] • USA (n = 4)[10, 52, 59, 62] • New Zealand (n = 1)[87] • Australia (n = 1)[9] • EU/EAA (n = 1)[17] • International[15] One document was published by the WHO, therefore applicable internationally.[15] One was published by the ECDC therefore applicable to the EU/EAA.[17] Depending on the setting, different respirator types are discussed, for example P2 respirators in Australian guidance and N95 respirators in USA guidance. However, given the design of tight-fitting respirators are relatively similar, the guidance is applicable to Scottish health and care settings. The order of donning PPE is also applicable to Scottish health and care settings. Five guidance documents were specific to certain healthcare settings or groups of infectious agents for example care homes or acute respiratory infections.[3, 10, 16, 18, 52] Where appropriate, findings in relation to these documents have been connected, in text, to their respective infectious agent or setting specific guidance.

12.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Not applicable as no primary research studies were included.

12.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
No primary evidence was identified for this research question therefore, risk of publication bias is not applicable.

B Evidence to Decision

12.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
R12.1 Where two or more items of PPE are worn, these must be compatible with one another.	Recommendation
GPP12.1 RPE should be donned (put on) outside of the service user's room/care area, or within an ante room.	Good Practice Point
GPP12.2 RPE should be worn in accordance with manufacturer's instructions, including use within expiration dates.	Good Practice Point
GPP12.3 Hand hygiene should be performed before donning RPE, or all PPE when worn as part of an ensemble.	Good Practice Point
GPP12.4 RPE should be checked for any damage or defects prior to donning (putting on).	Good Practice Point
GPP12.5 When part of a PPE ensemble, RPE should be donned after aprons/gowns, and before eye/face protection. If eye/face protection is already being worn, these should be removed before donning RPE.	Good Practice Point
GPP12.6 Once donned (put on) the front of RPE should not be touched.	Good Practice Point

12.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
R12.1 Wearing PPE items that are compatible with each other ensures the level of protection offered is not compromised. GPP12.1 Donning (putting on) RPE outside of a service user's room, care area, or within an ante room will ensure that far-field protection is in place on entry to the room/space allowing the HCW to commence care immediately. GPP12.2 Donning tight-fitting RPE according to manufacturer instructions, including within its expiration date, ensures the item is being worn as intended and the full protection offered is provided, reducing the risk of transmission. GPP12.3 Performing hand hygiene before donning (putting on) RPE minimises risk of cross transmission of infectious agents from the wearer's hands. GPP12.4 Inspecting RPE for any defects or damage ensures the full protection offered is provided. GPP12.5 Donning sequence for PPE, is a pragmatic approach and in the context of RPE, may reduce risk of dislodging seal when donning an apron/gown after the RPE. GPP12.6 Not touching RPE when worn reduces the potential of cross transmission of infectious agents.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/ Good Practice Point were followed. Be explicit, clear about cons.

Harms
R12.1, GPP 12.1, GPP12.2, GPP12.3, GPP 12.4, GPP 12.5, GPP12.6 No harms anticipated.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP12.1, GPP12.2, GPP12.3, GPP 12.4, GPP 12.5, GPP12.6 Only benefits identified.

12.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
R12.1 None. GPP12.1 There may not be clearly defined areas for donning (putting on) RPE in all Scottish health and care settings. Local factors may impact this (space availability, location of storage of RPE, ergonomics, room layout) which will require local decision-making. Staff resource may be required to support this. GPP12.2 and GPP12.6 There will be resource implications related to staff education and training regarding wearing RPE in accordance with manufacturer’s instructions. Particularly if more than one type/style of RPE is available.

12.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
R12.1 Two pieces of mandatory legislation, COSHH and PPER, and one piece of SIGN50 level 4 expert opinion by HSE underpin this recommendation. Therefore, the evidence is sufficient, no expert opinion to note.[37, 40, 107] GPP12.1 This good practice point on donning (putting on) RPE outside of the service user's room/care area, or within an ante room, is informed by four SIGN50 Level 4 expert opinion guidance pieces.[9, 52, 59, 87] This evidence was considered insufficient for a recommendation due to limitations of SIGN50 Level 4 evidence, therefore a good practice point was developed. GP12.2 ARHAI Scotland and the Working Group support extant expert opinion that RPE should be worn in accordance with manufacturer's instructions to ensure each type/style of RPE is worn correctly.[1, 10, 51, 52, 54, 59] It is the expert opinion of ARHAI Scotland and the Working Group that RPE should be worn within the item's expiration date. GPP12.3 ARHAI Scotland and the Working Group support seven SIGN50 level 4 expert opinion pieces that hand hygiene should be performed prior to donning (putting on) RPE, or all PPE when worn as part of an ensemble. [8, 17, 18, 47, 52, 53, 62, 89] GPP12.4 It is the expert opinion of ARHAI Scotland and the Working Group that RPE should be visually inspected to ensure no damage or defects are present prior to donning (putting on) this item of PPE. GPP12.5 ARHAI Scotland and the Working Group support extant expert opinion guidance that RPE should be donned (put on) after donning an apron/gown and before donning eye/face protection.[8, 17, 18, 47, 52, 62] GPP12.6 ARHAI Scotland and the Working Group support extant expert opinion guidance that the front of RPE should not be touched once donned (put on) to reduce the risk of cross contamination of potentially infectious agents. [3, 9, 10, 29, 43, 47]

12.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state "none". Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
None.

12.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
None.

12.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
None.

12.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None.

Research Question 13: Where and how should disposable respirators be doffed?

A Quality of Evidence

13.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Twenty-one pieces of evidence were included in relation to this research question: • One legislation, graded 'Mandatory'.[37] • One UK guideline graded AGREE: 'Recommend with provisos' due to limitations regarding the systematic review methodology used to underpin the recommendations.[57] • Nineteen guidance documents graded SIGN 50 level 4 expert opinion. [3, 4, 8, 9, 12, 17-19, 21, 23-26, 28, 29, 47, 53, 57, 62, 63, 66-68, 73, 85, 86, 89, 100, 108, 109]	1 x 'Mandatory' 1 x AGREE: Recommend 19 x SIGN 50 Level 4

13.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
• One mandatory legislation and seven SIGN 50 level 4 expert opinion guidance provide information regarding the doffing of PPE or RPE.[3, 9, 29, 37, 59, 63, 7338] UK guidance was consistent with COSHH legislation: • The COSHH legislates that contaminated PPE should be doffed "on leaving the work area".[37] 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

Comments

ensure that respirator protection is maintained when required.[21] In line with COSHH legislation, BSI 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 (n = 5). [3, 9, 29, 59, 63] One document (SIGN 50 level 4) published by AORN specifies that the door of the patient room should be closed before doffing RPE.[59]

- The Australian Government (SIGN 50 level 4) recommends that respirators are removed outside a patient room or over one metre away if in the same room and the patient is symptomatic.[9]
- One document (SIGN 50 level 4), 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.[63] 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.[63]

Seven documents (one AGREE: Recommend with provisos and six SIGN 50 level 4) provide recommendations on a PPE doffing sequence to minimises cross-contamination: [3, 8, 9, 17, 18, 57, 59]

- All advise that RPE should be doffed last when worn with other items of PPE, as follows: gloves, gown, eye or face protection, then respirator.[3, 8, 9, 17, 18, 57, 59]
- Twelve documents (one AGREE: Recommend with provisos and 11 SIGN 50 level 4)) referenced hand hygiene as part of this PPE doffing sequence. At a minimum, there is consistency that hand hygiene should be performed as the last step of the doffing sequence, immediately after touching and disposing of used RPE.[3, 8-10, 12, 17, 18, 57, 73, 85, 89, 109]

The technique used to remove RPE is discussed by 13 SIGN 50 level 4 documents. Although various RPE models, including FFP2/3, N95 and P2, are discussed, the recommendations provided are generally consistent:

- The techniques described aimed 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.[4, 8-10, 18, 29, 53, 59, 62, 100]Six of these documents specify that the bottom strap should be pulled first, followed by the top strap.[3, 8, 10, 18, 62, 73]
- The ECDC and APIC (SIGN 50 level 4) provide additional information on the technique used to remove RPE straps.[10, 17]

Comments
• UKHSA (SIGN 50 level 4) 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.[73]

13.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments
The country or countries in which the guidance applies to are as follows: • UK (n = 5) [3, 21, 57, 63, 73] • ROI (n = 1)[29] • USA (n = 8)[4, 8, 12, 53, 62, 100, 108, 109] • Australia (n = 2)[9, 47] • Canada (n = 2)[18, 89] • EU/EEA (n = 2)[17, 85] Two documents were published by the ECDC therefore applicable to the EU/EAA.[17, 85] Depending on the setting, different respirator types are discussed, for example P2 respirators in Australian guidance and N95 respirators in USA guidance. This is not relevant to the doffing sequence therefore recommendations were applicable irrespective of respirator type. All included guidance that advises on the order of doffing PPE is also applicable to Scottish health and care settings. UKHSA 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.[73] Use of a buddy to assist doffing was not discussed in any other evidence sources. This may be because the document published by UKHSA 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 made remain extant.[73]

Comments
The remainder of the evidence-base was considered applicable to the target population.

13.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Not applicable as no primary research studies were identified.

13.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
No primary evidence was identified for this research question therefore, risk of publication bias is not applicable.

B Evidence to Decision

13.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
R13.1 RPE must be doffed (removed) after exiting the area in which the RPE was required.	Mandatory
GPP13.1 When RPE is worn as part of a PPE ensemble, RPE should be doffed (removed) last.	Good Practice Point
GPP13.2 RPE should be doffed in a manner that minimises contact with the front of the mask, using only the straps.	Good Practice Point
GPP13.3 Hand hygiene should be performed before and after doffing (removing) RPE.	Good Practice Point

13.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
R13.1 Doffing (removing) RPE after exiting the area in which the RPE was required area minimises the risk of exposure to infectious particles. GPP13.1 Removing PPE, including RPE, in the correct sequence minimises the risk of self-contamination. This may increase staff safety by reducing the transmission of infectious agents. GPP13.2 Not touching the front of RPE limits transmission of infectious agents. GPP13.3 Performing hand hygiene after removing and disposing of RPE minimises self-contamination. This may increase staff safety by reducing the transmission of infectious agents.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/ Good Practice Point were followed. Be explicit, clear about cons.

Harms
R13.1, GPP13.1, GPP13.2, GPP13.3 No harms anticipated.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
R13.1, GPP13.1, GPP13.2, GPP13.3, GPP13.4 Only benefits identified.

13.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be

associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
R13.1 There may not be clearly designated areas for doffing (taking off) RPE in all Scottish health and care settings. Local factors may impact this (space availability, ergonomics, and room layout) which will require local decision making. Staff resource may be required to support this.

13.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
R13.1 The evidence around whether RPE should be doffed after leaving the work area was inconclusive. The mandatory COSHH legislation allows for either, and therefore it is the expert opinion of ARHAI Scotland and the Working Group that RPE should be removed outside the care area (bay, room) to minimise the risk of transmission to the person once the RPE is doffed. GPP13.1 ARHAI Scotland support extant six SIGN 50 level 4 expert opinion documents (UK and international) that RPE should be removed last if worn as part of a PPE ensemble.[3, 9, 17, 18, 57, 59] GPP13.2 ARHAI Scotland support seven SIGN 50 level 4 expert opinion documents (UK and international) that RPE should be removed by handling the straps and not touching the front of the respirator to minimise self-contamination.[4, 9, 10, 18, 53, 59, 62] GPP13.3 ARHAI Scotland support 11 SIGN 50 level 4 expert opinion documents (UK and international) that hand hygiene should be performed immediately after doffing and disposal of RPE.[3, 9, 10, 12, 17, 18, 57, 73, 85, 89, 109]

13.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other

beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
None.

13.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
None.

13.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
None.

13.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None.

Research Question 14: When should RPE be changed or removed?

A Quality of Evidence

14.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Twenty-two pieces of evidence were included in relation to this research question: • One guideline published by the WHO, graded AGREE: 'Recommend with provisos' due to limitations regarding the systematic review methodology used to underpin the recommendations.[43] • Twenty-one guidance documents graded SIGN 50 Level 4 expert opinion, due to the lack of a high-quality systematic review to support their recommendations.[1, 3, 4, 8-10, 12, 18, 19, 23-26, 28, 29, 47, 53, 66-68, 86] Overall, the evidence base was low quality but of sufficient volume. There were no primary scientific studies included for this research question.	1 x AGREE: Recommend with provisos 21 x SIGN 50 Level 4

14.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Irrespective of setting, RPE type, clinical speciality or procedure, the SIGN 50 level 4 expert opinion guidance and one guideline graded AGREE: Recommend with provisos 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,[1, 3, 4, 9, 10, 23-26, 28, 29] indications can be summarised as follows: • When they become moist (n = 10), [9, 18, 28, 29, 43, 47, 53, 59, 67, 68] • When they become visibly soiled (n = 10),[4, 8, 12, 18, 19, 28, 43, 47, 59, 67, 68] • When they become damaged (n = 8),[3, 4, 8, 12, 28, 29, 67, 68] • When there is suspected or confirmed contamination by body fluids from spraying or splashing (n = 6).[3, 8, 28, 29, 66, 67] Other indications that were highlighted less frequently across the evidence-base are: • When breathing becomes difficult (n = 4),3, 12, 18, 29 • When the face seal is compromised (where applicable) (n = 3),4, 8, 28 • When there has been direct contact between the respirator and a patient or resident (n = 3).[66-68]

14.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments
The country or countries in which the guidance applies are as follows: • UK (n = 6),[1, 3, 23-26] • ROI (n = 1)[29] • USA (n = 7) [4, 8, 10, 12, 28] • Australia (n = 2)[9, 47] • New Zealand (n = 2)[19] • Canada (n = 5)[18, 66-68, 89] • International (n = 1)[43]

Comments
One document was published by the WHO, therefore applicable internationally. [43] Four of the guidance documents published in the UK were produced by the HSE as part of a series.[23-26] Given the nature of the question, the recommendations regarding when a respirator should be changed or removed are applicable to all Scottish health and care settings.

14.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Not applicable as no primary research studies were included.

14.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
No primary evidence was identified for this research question therefore, risk of publication bias is not applicable.

B Evidence to Decision

14.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
GPP14.1 RPE should be changed or removed when clinical procedure(s) or task(s) in a single care episode has been completed and/or there is no longer an exposure risk which indicates the need for RPE.	Good Practice Point
GPP14.2 RPE should be changed or removed • when they become moist • when they are visibly soiled or damaged • if contaminated by blood or body fluids	Good Practice Point

14.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
GPP14.1, GPP14.2 The change or removal of RPE prevents potential cross contamination. GPP14.2 The change or removal of RPE when moist, when soiled or physically damaged minimises the risks of RPE performance being affected.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about cons.

Harms
GPP14.1, GPP14.2 No harms anticipated.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP14.1, GPP14.2 Only benefits identified.

14.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
GPP14.1, GPP14.2, No additional financial implications are expected as a result of changing or removing RPE, however this will require sufficient stock. GPP 14.2 Staff education to support identification of indicators to change RPE may be required. GPP 14.6 Disposal of damaged RPE will involve waste management processes which may have an environmental impact depending on the recommended method of disposal.

14.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP14.1 ARHAI Scotland and the Working Group support extant expert opinion (11 SIGN 50 level 4 including four published by the UK HSE)[1, 3, 4, 9, 10, 23-26, 28, 29] that RPE should be removed when no longer required. GPP14.2 ARHAI Scotland and the Working Group support 11 SIGN 50 level 4 extant expert opinion guidance documents that RPE should be changed or removed when they become moist. [9, 18, 28, 29, 43, 47, 53, 59, 67, 68] GPP14.3 ARHAI Scotland and the Working Group support extant expert opinion guidance that RPE should be changed or removed when they become visibly soiled (11 SIGN 50 level4) [4, 8, 12, 18, 19, 28, 43, 47, 59, 67, 68] or damaged (eight SIGN 50 level 4). [3, 4, 8, 12, 28, 29, 67, 68] GPP14.4 ARHAI Scotland and the Working Group support six SIGN 50 level 4 expert opinion guidance documents that RPE should not be worn if contamination by blood or body fluids is suspected. [3, 8, 28, 29, 66, 67]

14.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other

beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
None.

14.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
None.

14.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
None.

14.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None.

Research Question 15: When should a powered respirator be worn?

A Quality of Evidence

15.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Overall, the evidence base for this research question was of low quantity and low quantity. Six pieces of guidance were included and all were graded SIGN 50 level 4 expert opinion, due to a lack of high-quality evidence to support their recommendations.[1, 4, 9, 31, 47, 80] No primary research studies were included.	6 x SIGN 50 level 4 – expert opinion

15.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Consistency could not be assessed given that only six pieces of evidence were included for this research question. The evidence can however be summarised as follows: • 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.[9, 31, 80] Three documents also recommend their use for extended periods of time to aid with non-IPC factors including comfort, breathability, and communication.[1, 56, 80]

Comments
• The US CDC and American Society of Anaesthesiologists (ASA) highlight that PAPRs may be worn for aerosol-generating procedures in the context of the COVID-19 pandemic.[56, 80] • The ASA does highlight that a PAPR may not offer additional protection when compared to a tight-fitting respirator.[80] The rationale is not provided but it is assumed this is because the protection afforded by PAPRs depends on factors including their design specification and filtration capability. • Similarly, in their guidance on preparing workplaces for pandemic influenza, the US OSHA recommend the use of PAPRs for high-risk medical or dental procedures when treating confirmed or suspected pandemic influenza cases, where it is anticipated that bioaerosols will be generated.[4]

15.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments
The country or countries where the guidance applies are as follows: • USA (n = 4)[4, 31, 56, 80] • Australia (n = 2)[9, 47] • UK (n =1)[1] Given the nature of the research question, general recommendations for health and care settings are applicable to Scottish settings.

15.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Not applicable as no primary research studies were identified.

15.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
No primary evidence was identified for this research question therefore, risk of publication bias is not applicable.

B Evidence to Decision

15.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
GPP15.1 Reusable powered RPE should be considered for use by individuals who cannot undertake or pass a fit test; where feasible, reusable components (for example, powered hoods and helmets) should be personally issued.	Good Practice Point

15.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
GPP15.1 Use of personally issued RPE, where feasible, acknowledges the challenges around the decontamination of reusable components.

Benefits
GPP15.1 Use of powered RPE would ensure essential care is provided to an individual despite their infectious status GPP15.1 Use of powered RPE would ensure that a staff member can provide patient care when RPE is indicated but they are unable to pass or undergo a fit test. GPP15.1 Use of powered RPE would ensure that patients can still receive essential visitors where fit testing for visitors is not feasible.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about cons.

Harms
GPP15.1 Use of powered reusable RPE by staff and/or visitors may cause stress to patients due to communication difficulties and their intimidating appearance.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP15.1 Benefits outweigh the harm as the provision of care irrespective of whether staff can be fit tested and is essential.

15.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
GPP15.1 There may be additional financial implications to procure powered RPE for visitor use. GPP15.1 Adequate stock will be required to be maintained at national and local levels. GPP15.1 Additional management including appropriate storage of the powered RPE will be required at a local level. GPP15.1 Additional training for visitors would be required and need to be provided at a local level. GPP15.1 Resource will be required to ensure staff are trained in the use of powered RPE for both personal use if required and as a support to those who are using it on an ad-hoc basis (i.e. visitors). GPP15.1 It is not feasible to provide visitors personally issued reusable RPE components. GPP15.1 Resource will be required to ensure staff are trained on adequate decontamination procedures for reusable components.

15.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP15.1 ARHAI Scotland and the Working Group support three SIGN 50 level expert opinion guidance that powered RPE may be worn when delivering care if a seal cannot be achieved with tight-fitting RPE.[9, 31, 80] GPP15.1 ARHAI Scotland recognise that manufacturer recommendations regarding decontamination are not specific to health and care settings (Refer to Research Question 19 in relation to the decontamination of reusable RPE). Given that manufacturers have not provided assurance that the decontamination protocols are effective against infectious agents, it is the expert opinion of ARHAI Scotland that reusable RPE components should be personally issued where feasible to limit potential staff exposure. GPP15.1 ARHAI Scotland and the Working Group advise that loose-fitting RPE may be worn by visitors where fit testing of tight-fitting RPE is not feasible.

15.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
GPP15.1 The availability of loose-fitting RPE allows those who are unable to shave facial hair for religious or cultural reasons to participant in patient care activities where RPE is indicated. This will allow patient equitable access to the right members of staff to provide care despite them having a known or suspected infection. GPP15.1 Use of alternative RPE which does not require a fit test or fit check RPE by visitors is beneficial to the patient in terms of social interaction and wellbeing.

15.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
None.

15.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
None.

15.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None.

Research Question 16: Where and how should powered respirators be donned?

A Quality of Evidence

16.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
There was insufficient evidence identified in relation to this research question. One expert opinion document published by the HSE was graded SIGN 50 level 4, expert opinion, due to an absence of supporting evidence.[1]	1 x SIGN 50 level 4 – expert opinion

16.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Unable to comment on consistency due to lack of evidence, however the extant evidence can be summarised as follows: 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 should be used if the respirator has multiple filters.[1]

16.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments
Yes, the recommendations are generic to any work setting. They are published in the UK so can be applied to Scottish health and care settings.

16.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Not applicable as no primary research studies were included.

16.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
No primary evidence was identified for this research question therefore, risk of publication bias is not applicable.

B Evidence to Decision

16.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
GPP16.1 Powered respirators should be configured according to manufacturer instructions, including correct airflow and choice of filter.	Good Practice Point
GPP16.2 Elastomeric (non-powered, reusable) RPE should be configured according to manufacturer instructions using the appropriate choice of filter.	Good Practice Point
R12.1, GPP12.1, GPP12.2, GPP12.3, GPP12.4, GPP12.5 and GPP12.6 also apply to powered and non-powered reusable (elastomeric) RPE.	Not applicable

16.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
GPP16.1 and GPP16.2 Donning powered RPE and reusable non-powered (elastomeric) RPE according to manufacturer instructions in accordance with manufacturer's instructions, including filters, ensures the item is being worn as intended and the full protection offered is provided, reducing the risk of transmission. See benefits associated with R12.1, GP12.1, GPP12.2, GPP12.3, GPP12.4, GPP12.5 and GPP12.6.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/ Good Practice Point were followed. Be explicit, clear about cons.

Harms
GPP16.1 and GPP16.2 No harms anticipated. R12.1, GPP 12.1, GPP12.2, GPP12.3, GPP 12.4, GPP 12.5, GPP12.6 No harms anticipated.

Benefit-Harm assessment

Classify as "benefit outweighs harm" (or vice versa) or a "balance of benefit and harm." Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
R12.1, GPP 12.1, GPP12.2, GPP12.3, GPP 12.4, GPP 12.5, GPP12.6 Only benefits identified.

16.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
GPP16.1 and GPP16.2 There will be resource implications related to staff education and training regarding wearing RPE in accordance with manufacturer's instructions. Particularly if more than one type/style of RPE is available.

16.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state "none". Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP16.1 ARHAI Scotland support extant expert opinion guidance (UK – HSE) that reusable RPE (powered and non-powered) should be configured and donned according to manufacturer instructions.[1] R12.1, GPP 12.1, GPP12.2, GPP12.3, GPP 12.4, GPP 12.5, GPP12.6 It is the expert opinion of ARHAI Scotland and the Working Group that the Rs and GPPs relating to single-use RPE are relevant to powered and non-powered reusable RPE.

16.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state "none". Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
None.

16.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/religious reasons.

Intentional vagueness
None.

16.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
None

16.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None.

Research Question 17: Where and how should powered respirators be doffed?

A Quality of Evidence

17.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)]

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
No evidence identified for this research question.	Not applicable

17.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Not applicable.

17.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments
Not applicable.

17.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Not applicable.

17.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
Not applicable.

B Evidence to Decision

17.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
R13.1, GPP13.1, GPP13.2 and GPP13.3 are applicable to powered RPE and reusable non-powered (elastomeric) RPE.	Not applicable

17.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
Refer to Research Question 13 for benefits associated with R13.1, GPP13.1, GPP13.2 and GPP13.3.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about cons.

Harms
R13.1, GPP13.1, GPP13.2 and GPP13.3 No harms anticipated.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
R13.1, GPP13.1, GPP13.2, GPP13.3 Only benefits identified.

17.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
Refer to Research Question 13 for feasibility considerations relating to R13.1.

17.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
Refer to Research Question 13 for expert opinion relating to R13.1, GPP13.1 GPP13.2 and GPP13.3. It is the expert opinion of ARHAI Scotland and the Working Group that the Rs and GPPs relating to single-use RPE are relevant to powered and non-powered reusable RPE.

17.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
None.

17.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
None.

17.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
None.

17.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
Refer to research question 13 for recommendations for research in relation to GPP13.2.

Research Question 18: How should reusable respirators be maintained?

A Quality of Evidence

18.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Twelve pieces of evidence were included: • Two UK legislation graded 'Mandatory',[37, 40] • 10 guidance documents graded SIGN 50 level 4 expert opinion, due to a lack of high-quality evidence to support their recommendations.[1, 21, 23-26, 40, 47, 51, 107] Overall, there was an adequate volume of research identified in relation to this research question, where the evidence base was considered low quality.	2 x 'Mandatory' 10 x SIGN 50 level 4 expert opinion

18.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Legislation and extant guidance: • 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,[21, 54] and The Personal Protective Equipment at Work (Amendment) Regulations 2022.[40]

Comments

- SIGN 50 level 4 extant guidance (n = 8) focussed on how reusable RPE should be maintained and how often maintenance should be performed.

There was lack of consistency regarding the frequency of RPE maintenance in UK sources, 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.[21]
- HSE states RPE should be maintained at least once every three months;[23-26] another document produced by HSE does not specify a timeframe but states they should be maintained and checked regularly, and that prior to donning, powered respirators should be checked to ensure they are in good working order.[1]
- COSHH legislation is unclear, stating that RPE should be checked at suitable intervals.[37]

The methods for RPE maintenance were not discussed in depth in extant guidance:

- There is consensus that maintenance procedures should follow manufacturer instructions (n = 9).[1, 4, 7, 21, 23-26, 51] Further recommendations are not provided. PD ISO/TS 16975-1:2016 describes RPE selection, use and maintenance, and provides steps for maintenance.[21]
- Six 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.[1, 7, 21, 23-26]
- The BSI and HSE highlight that defective parts should be replaced using components made by the RPE manufacturer.[1, 21]
- The BSI recommend that the wearer should inspect the condition of RPE parts prior to use.[7, 21]

Conclusions around the maintenance of filters are difficult to draw due to a lack of consistency regarding the information provided in extant guidance, as follows:

- The BSI states that although RPE filters should not be shared between wearers, there is no simple recommendation for how they should be maintained.[7]
- The US OSHA recommended filters should be used until they are unsuitable for further use, however it is unclear what parameters make them unsuitable.[4]

Comments

- Other documents (n = 5 SIGN 50 level 4) state that filters should be replaced when they become clogged from use, therefore reducing air flow and making breathing difficult.[1, 4, 7, 21, 56]
- Three documents published by the HSE, and US OSHA stated filters should be replaced if they are visibly contaminated,[1, 4, 56] and four documents stated that filters should be replaced if visibly damaged.[1, 4, 7, 56]
- The HSE recommend that filters should be changed according to manufacturer instructions and that they should be used within their expiry date.[1, 21, 23-26] 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.[7, 21]

18.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments

The country or countries in which the guidance applies are as follows:

- UK (n = 8) [1, 21, 23-26, 37, 51]
- USA (n = 1)[56]
- Australia (n = 1)[47]

Four of the expert opinion documents were published by HSE as part of a series.[23-26]

Nine documents provide recommendations on general PPE or RPE maintenance without specifying RPE type, therefore may be applicable to all RPE;[1, 7, 21, 23-26, 37, 51] three documents provide recommendations on PAPR maintenance,[1, 4, 47] and one document provides recommendations on EHMR maintenance.[4] The latter recommendations are only applicable to the RPE discussed.[1, 4, 47]

The majority of the evidence base regarding filters is not specific to health and care settings. The applicability of the recommendations made regarding filters may therefore lack applicability, as the recommendations 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.

18.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Not applicable as no primary research studies were identified.

18.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
No primary evidence was identified for this research question therefore, risk of publication bias is not applicable.

B Evidence to Decision

18.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
R18.1 Users must report any damage or loss of RPE to employers.	Mandatory
R18.2 Reusable RPE should be visually inspected for damage, cleanliness, expiry dates and integrity at suitable intervals according to frequency of use, at a minimum monthly or as determined by the manufacturer (whichever is earlier/sooner).	Mandatory
GPP18.1 RPE and its reusable components, including filters, should be maintained according to manufacturer instructions.	Good Practice Point
GPP18.2 Where visitors or service users are required to don (put on) reusable RPE, staff should perform relevant maintenance requirements on their behalf according to manufacturer instructions.	Good Practice Point
GPP18.3 RPE filters/filter cartridges should be discarded after use.	Good Practice Point
GPP18.4 RPE filters/filter cartridges should be replaced if breathing becomes difficult, if they are visibly damaged or if they become visibly contaminated.	Good Practice Point

18.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
R18.1 Adhering to current legislation allows compliance with associated corporate and social governance responsibilities, including the legal requirements of the applicable health and safety management policy.
R18.1 Reporting damage or loss of RPE to employers allows opportunity for employers to repair or replenish RPE.
R18.2, Checking RPE at suitable intervals allows compliance with associated corporate and social governance responsibilities, including the legal requirements of the applicable health and safety management policy.
R18.2, Checking reusable RPE at suitable intervals ensures the item is functional and the full protection offered is provided, reducing the risk of transmission.
GPP18.1 Maintaining RPE according to manufacturer instructions ensures the item is being maintained as intended and the full protection offered is provided, reducing the risk of transmission.
GPP18.2 Appropriate maintenance of RPE to be worn by visitors ensures that RPE is functional in order to maintain safety of visitors and patients.
GPP18.3 Discarding filters after use ensures cross transmission of infectious agents does not occur.
GPP18.4 Changing filters/filter cartridges at appropriate indications ensures user comfort and reduces risk of cross contamination, and subsequent risk of infection.
R18.2, GPP18.1, GPP18.2 Appropriate maintenance increases longevity of RPE.
R18.2, GPP18.1, GPP18.2 Appropriate maintenance reduces the risk of RPE damage.
GPP18.1, R18.2, GPP18.2Appropriate maintenance increases the likelihood that RPE last longer before being replaced, supporting sustainability goals.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about cons.

Harms
R18.1, R18.2 GPP18.1, GPP18.2, GPP18.3, GPP18.4. No harms anticipated.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
R18.1, R18.2, GPP18.1, GPP18.2, GPP18.3, GPP18.4, Only benefits identified.

18.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
R18.1, R18.2. GPP18.1, GPP18.2, GPP18.3, GPP18.4. Ongoing training will be required to ensure that relevant staff are aware of the protocols for RPE maintenance. This will need to be provided across all brands or makes used and supplied.

18.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
R18.1. This recommendation is underpinned by COSHH Amendment Regulations (2002) is mandatory legislation.[37] No expert opinion to note. R18.2 COSHH legislation is unclear, stating that RPE should be checked at suitable intervals.[37] The expert opinion is not consistent. 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.[21] HSE states RPE should be maintained at least once every three months;[23-26] another document produced by HSE does not specify a timeframe but states they should be maintained and checked regularly, and that prior to donning, powered respirators should be checked to ensure they are in good working order.[1] It is the expert opinion of ARHAI Scotland and the Working Group that staff should perform maintenance according to how often the item is worn, or in-line with manufacturer instructions. GPP18.2 The good practice point that RPE should be maintained according to manufacturer instructions is informed by nine SIGN50 level 4 expert opinion guidance documents, including four published by the UK HSE.[1, 4, 7, 21, 23-26, 51] No further expert opinion to note. GPP18.3 It is the expert opinion of ARHAI Scotland and the Working Group that where visitors are required to don reusable RPE, staff should perform relevant maintenance requirements on their behalf. GPP 18.4 ARHAI Scotland support nine expert opinion documents, including four published by the UK HSE that maintenance should be performed according to manufacturer instructions.[1, 4, 7, 21, 23-26, 51] GPP18.5 ARHAI Scotland and the Working Group support four expert opinion documents (UK and international) that RPE filters should be changed if breathing becomes difficult and when they become visibly contaminated.[1, 4, 7, 56]

18.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
None.

18.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
GPP18.1 This recommendation is intentionally vague as maintenance requirements advised by the manufacturer will likely differ according to brand and model of RPE.

18.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
R18.1, GPP18.1, GPP18.2, GPP18.3, GPP18.4, GPP18.5 Patients and visitors are not required to adhere to recommendations/GPPs relating to maintenance.

18.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None.

Research Question 19: How should reusable respirators be decontaminated?

A Quality of Evidence

19.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Thirteen pieces of evidence were included in relation to this research question; the quantity of evidence was sufficient but of low quality: • One piece of mandatory legislation.[37] • Thirteen guidance documents graded SIGN 50 level 4 expert opinion.[1, 3, 4, 6, 11, 21, 28, 47, 51, 54, 56, 107]	1 x 'Mandatory' 12 x SIGN 50 level 4 expert opinion

19.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
There is consistency that decontamination should follow manufacturer instructions: • The COSHH mandates that it is the employer's responsibility to specify decontamination and disinfection protocols.[37] • Expert opinion guidance highlights that manufacturer's instructions regarding decontamination, including the materials used for cleaning and disinfection, should be followed (n = 11).[1, 3, 4, 6, 11, 21, 47, 51, 54, 56, 107] • The PD ISO/TS 16975-1:2016 standard states that the reusable components should be disassembled prior to decontamination,[21]

Comments
There was insufficient evidence to assess consistency regarding where RPE should be decontaminated: • HSE state that decontamination should occur in a clean area.[107] • The CDC suggest cleaning at the point of use, then centralising where disinfection is performed.[56] There was inconsistency around 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.[3] • The CDC are more specific and recommend that elastomeric half facepiece 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.[28, 56] • 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.[21] • BS ISO 16975-3:2017 and guidance by HSE to support adherence to COSHH legislation, both advise that RPE are cleaned and disinfected between use when used by different individuals.[51, 54] • COSHH legislation, however, does not provide clear recommendations regarding when cleaning should be performed. The HSE also advise that PPE decontamination is performed prior to storage.[107]

19.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments
The country or countries in which the guidance applies are as follows: • UK (n = 7)[1, 3, 6, 21, 37, 51, 54] • USA (n = 4)[4, 11, 28, 56]

Comments
Two of the documents in the UK provide guidance on the implementation of international standards.[21, 51] UK guidance is directly applicable to Scottish health and care settings. Mandatory legislation is also directly applicable. OSHA requirements are not directly applicable to Scotland but are generally relevant and applicable. Non-healthcare guidance is considered applicable, however may not appropriately consider IPC risks of improper decontamination.

19.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Not applicable as no primary research studies were identified.

19.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
No primary evidence was identified for this research question therefore, risk of publication bias is not applicable.

B Evidence to Decision

19.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
R19.1 Employers must ensure that cleaning and/or disinfecting arrangements are in place for reusable RPE.	Mandatory
GPP19.1 Reusable RPE should be decontaminated according to manufacturer's instructions, or in line with local policy or procedure.	Good Practice Point
GPP19.2 Reusable RPE should be decontaminated following each use.	Good Practice Point
GPP19.3 Hand hygiene should be performed after decontamination of reusable RPE.	Good Practice Point

19.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
R19.1 Ensuring cleaning and/or decontamination arrangements are in place for reusable RPE will provide assurance of cleanliness to users. GPP19.1 Following local policy, procedure, or manufacturer's instructions for cleaning and/or disinfection of RPE ensures this is being carried out effectively whilst maintaining integrity of reusable RPE. GPP19.2 Cleaning and/or disinfection of RPE prior to re-use or storage prevents cross contamination and subsequent infection risk. GPP19.3. Performing hand hygiene after cleaning RPE reduces the risk of cross contamination and subsequent infection.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about cons.

Harms
R19.1, GPP19.1, GPP19.2, GPP19.3 No harms anticipated.

Benefit-Harm assessment

Classify as "benefit outweighs harm" (or vice versa) or a "balance of benefit and harm." Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
R19.1, GPP19.1, GPP19.2, GPP19.3 Only benefits identified.

19.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
R19.1, GPP19.1, GPP19.2 Designated areas may be required to facilitate cleaning and/or disinfection of reusable RPE.
R19.1, GPP19.1, GPP19.2 and GPP19.3 There may be resource implications related to staff education and training in relation to cleaning and/or disinfection protocols.
R19.1, GPP19.1 and GPP19.2 There may be financial implications whereby following manufacturer's instructions for cleaning and/or disinfection requires additional cleaning products.
GPP19.1 Manufacturer' instructions may not align with their use in a health and care setting context. Therefore, there may be resource implications to develop policy or procedure for decontamination processes.
R19.1, GPP19.1, GPP19.2, GPP19.3 Appropriate decontamination will require staff experienced in the protocols to conduct training.

19.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state "none". Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
R19.1 The COSHH mandates that it is the employer's responsibility to specify decontamination and disinfection protocols.[37] Therefore the evidence supporting this recommendation is sufficient.
GPP19.1 ARHAI Scotland and the Working Group support 11 SIGN 50 level 4 expert opinion guidance documents that decontamination should be performed in accordance to manufacturer instructions.[1, 3, 4, 6, 11, 21, 47, 51, 54, 56, 107]

Expert opinion
GPP19.2 Expert opinion guidance identified during part A were not specific to health and care settings. The indications for decontamination have been proposed by ARHAI Scotland to minimise the risk of cross transmission of infectious agents between staff and patients/service users. GPP19.3 It is the expert opinion of ARHAI Scotland and the Working Group that hand hygiene should be performed immediately after decontamination is performed.

19.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
None.

19.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/religious reasons.

Intentional vagueness
None.

19.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
None.

19.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None

Research Question 20: How should RPE be stored?

A Quality of Evidence

20.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Thirteen pieces of evidence were included for this research question. This was considered a low volume of evidence that was of low quality: • One mandatory legislation [37] • 12 guidance documents graded SIGN 50 level 4 expert opinion. [1, 7, 21, 23-26, 28, 66-68, 107]	1 x 'Mandatory' 12 x SIGN 50 level 4

20.2. Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Extant legislation, and expert opinion guidance can be summarised as follows, where consistency cannot be assessed due to a low volume of research identified: • 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,

Comments
loss, and/or damage, citing potential sources of damage being hazardous substances, sunlight/heat and damp.[23-26] The Government of Canada, BSI and the CDC provided recommendations for the storage of RPE specifically rather than PPE in general.[7, 21, 28, 66-68] Their recommendations can be summarised as follows: • The BSI states that employers are responsible for providing appropriate storage for RPE, including facilities to separate clean and dirty items.[7, 21] • 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.[66-68] • Two expert opinion guidance state that RPE should be stored away from contaminated items.[66, 67] However, it was unclear whether the location of storage should be a room or a designated clean area.[66, 67] • 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.[28]

20.3. Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments
The country or countries in which the guidance/ applies are as follows: • eight were published in the UK (n = 8)[1, 7, 21, 23-26] • Canada (n = 3)[66-68] • USA (n = 1)[28] Four of the guidance documents published in the UK were produced by the HSE as part of a series.[23-26] Overall, the included guidance documents are produced by internationally recognised national organisations and are generally relevant to Scottish health and care settings. RPE definitions provided are directly applicable to any health and care setting, including those in Scotland.

20.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Not applicable as no primary research studies were identified.

20.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
No primary evidence was identified for this research question therefore, risk of publication bias is not applicable.

B Evidence to Decision

20.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
R20.1 When not being used, RPE must be stored in a well-defined, accessible, safe storage place where it is protected from loss, contamination and damage, such as from sunlight, dust and moisture.	Recommendation
GPP20.1 RPE should be stored within their original packaging in an appropriate dedicated room or allocated space that is accessible and near to the intended point of use, outside of service user rooms/zones.	Good Practice Point

20.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
R20.1, GPP20.1 Safe storage of RPE prevents damage and loss of integrity and ensures the full protection being offered is provided.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about cons.

Harms
R20.1, GPP20.1 No harms anticipated.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
R20.1, GPP20.1 Only benefits identified.

20.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
R20.1, GPP20.1 There will be a requirement for designated storage areas to facilitate the safe storage of RPE.

20.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert

opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
R20.1 The PPER mandatory legislation[37] and 11 pieces of SIGN50 level 4 expert opinion,[1, 7, 21, 23-26, 28, 66-68, 107] including items published by the UK HSE and BSI underpins this recommendation.[1, 7, 21, 23-26] Therefore the evidence supporting this recommendation is sufficient. GPP20.1 ARHAI Scotland support three expert opinion guidance documents published by the Government of Canada that RPE should be easily accessible by users.[66-68]

20.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
None.

20.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
None.

20.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
None

20.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None.

Research Question 21: How should RPE be disposed?

A Quality of Evidence

21.1. How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Ten pieces of evidence were included for this research question. Overall, the evidence base was considered of low volume and low quality: • One legislation graded mandatory,[37] • nine guidance graded SIGN 50 Level 4 expert opinion.[1, 3, 7, 9, 17, 18, 21, 28, 29]	1 x 'Mandatory' 9 x SIGN 50 Level 4 – expert opinion.

21.2 Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results/conclusions, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
How RPE should be disposed: • Four expert opinion guidance were consistent in advising that RPE should be disposed of immediately after use as part of the doffing procedure (n = 4).[17, 18, 28, 73] • 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.[9, 29]

Comments
Waste stream: • Five SIGN 50 level 4 expert opinion 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 (n = 6).[3, 17, 18, 21, 28, 37] • The waste stream referenced is inconsistent. The Healthcare Infection Society Working Group on Respiratory and Facial Protection state respirators should be disposed of as 'healthcare waste',[3] whereas the HSE state that respirators may be considered as 'hazardous waste' depending on their use.[1]

21.3 Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators or outcomes as those common to Scottish health and care settings?

Comments
The country or countries in which the guidance applies are as follows: • UK (n = 4)[1, 3, 7, 21] • ROI (n = 1)[29] • Australia (n = 1)[9] • USA (n = 1)[28] • Canada (n =1)[18] • EU/EEA (n = 1)[17] One document published by the ECDC is applicable to the EU/EAA.[17] Guidance signposting to local legislation are directly applicable to Scottish health and care settings. Recommendations that refer to discrete patient areas may not be directly applicable to care and domiciliary settings.

21.4. Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Not applicable as no primary research studies were identified.

21.5. Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
No primary evidence was identified for this research question therefore, risk of publication bias is not applicable.

B Evidence to Decision

21.6. Recommendation(s)

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach.

Recommendation	Grading
R21.1 RPE should be disposed of as infectious waste within an appropriate waste receptacle. Please refer to the Safe Disposal of Waste Literature Review to determine the 'appropriate' disposal route for RPE.	Recommendation
GPP21.1 Single-use RPE should be disposed of immediately after use.	Good Practice Point
GPP21.2 Hand hygiene should be performed after disposing of used RPE.	Good Practice Point

21.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
R21.1 Disposal of RPE as infectious waste may reduce occupational exposure risk from potentially infectious agents, reducing the risk of cross transmission and subsequent infection. GPP21.1 Disposing of single-use RPE after use ensures the equipment is being managed in line with the manufacturer's instructions. GPP21.2 Performing hand hygiene after disposing of used RPE reduces the risk of cross contamination.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/ Good Practice Point were followed. Be explicit, clear about cons.

Harms
R21.1, GPP21.1, GPP21.2. No harms anticipated.

Benefit-Harm assessment

Classify as "benefit outweighs harm" (or vice versa) or a "balance of benefit and harm." Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
R21.1, GPP21.1, GPP21.2 Only benefits identified.

21.8. Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on resource use is lacking.

Feasibility
R21.1 Disposal of single-use RPE will involve waste management processes and may have an environmental impact depending on the recommended disposal method(s).

21.9. Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand its influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
R21.1 PPER legislation[37] and five pieces SIGN 50 level 4 expert opinion guidance documents underpin this recommendation. Therefore, the evidence is sufficient to support this recommendation, no expert opinion to note.[3, 17, 18, 21, 28, 37]
GPP21.1 ARHAI Scotland and the Working Group support four SIGN 50 level 4 extant expert opinion documents that RPE should be disposed of immediately after use. [17, 18, 28, 73]
GPP 21.2 ARHAI and the Working Group support four SIGN 50 level 4 expert opinion guidance documents that RPE should be disposed as part of the doffing procedure.[17, 18, 28, 73]

21.10. Value judgements

Summarise value judgements in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
None.

21.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if a decision to be vague is made, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/religious reasons.

Intentional vagueness
None.

21.12. Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
None.

21.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None.

Definitions

Term used	Description	Evidence
Recommendation	In general, 'Recommendations' should be supported by high- to moderate-quality evidence. In some circumstances, however, 'Recommendations' may be made based on lower quality evidence when high-quality evidence is impossible to obtain, and the anticipated benefits strongly outweigh the harms or when the Recommendation is required by Legislation or Mandatory Guidance	Sufficient evidence (SIGN level 1++, 1+, 2++, 2+, 3, 4* AGREE Recommend AGREE Recommend with Modifications) Legislation, or mandatory guidance
Good Practice Point	Insufficient evidence or a lack of evidence to make a recommendation but identified best practice based on the clinical/technical experience (expert opinion) of the Working Group, with a clear balance between benefits and harms.	Insufficient evidence + Working Group expert opinion OR No evidence + Working Group expert opinion
No Recommendation	Both a lack of pertinent evidence and an unclear balance between benefits and harms	No evidence

*Recommendation cannot be developed when there is only SIGN 50 level 4 evidence available.

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