NHS National Services Scotland

Personal Protective Equipment for High Consequence Infectious Diseases Literature Review

Considered Judgement Forms

Version 1.0

25 August 2025

ARHAI Scotland

Antimicrobial Resistance and Healthcare Associated Infection

Version history

Version	Date	Summary of changes
1.0	25 August 2025	New document.

Definitions

Term used	Description	Evidence
Recommendation	'Recommendations' should be supported by high- to moderate-quality evidence (SIGN 50 level 1++, 1+, 2++, 2+, AGREE II recommend). 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 50 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 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

* A Recommendation cannot be developed when there is only SIGN50 level 4 evidence available.

Contents

Research question 1: What is the definition of a HCID?

Part A: Quality of evidence

1.1. How reliable is 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, eight pieces of evidence were included for this research question. Six pieces of evidence (3 guidance documents,[1-3] 1 systematic review with meta-analysis,[4] 2 expert opinions[5, 6]) were identified within previous versions of this review including one that was excluded from this update and three that were updated.[1, 2, 4] Two further pieces of expert opinion were included during this update.[7, 8] • One systematic review graded SIGN 50 level 1+.[4] • Seven expert opinion pieces graded SIGN 50 level 4.[1-3, 5-8] Two of these were published by international health organisations (European Centre for Disease Prevention and Control[3], World Health Organization[7]). The SIGN 50 level 1+ evidence is considered to be a well conducted systematic literature review with meta-analysis with low risk of bias. SIGN 50 level 4 evidence is considered to be of low quality as a potential risk of bias exists with this class of evidence because of a lack of supporting evidence and	1x SIGN 50 level 1+ 7x SIGN 50 level 4

Comments	Evidence level
the unclear methodology with which these documents are formulated. No primary research studies were included.	

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 or outputs, indicate how the group formed a judgment as to the overall direction of the evidence.

Comments
Six pieces of evidence (1 systematic literature review graded SIGN 50 1+ [4], 5 guidance documents graded SIGN 50 level 4 expert opinion[1, 3-7] provided terminology to describe high consequence infectious diseases. Evidence was inconsistent with infectious agents referred to as 'potential pandemic pathogens', 'high consequence infectious', 'highly infectious diseases', high consequence infectious diseases', and 'infectious diseases of high consequence' across the literature. Five guidance documents (graded SIGN 50 level 4 expert opinion)[1 3, 5-8] provided definitions of high consequence infectious disease[1, 3, 5, 7, 9] Across this evidence there was consistency that HCIDs pose a threat to human health, have the possibility of high case fatality rates, have limited or no specific treatment available, and can spread quickly. These statements are non-specific within the literature so definitions of each are not provided.

1.3. Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The countries in which the included literature was published and/or applies to are as follows: • UK (n=3) [1, 2, 5] • USA (n=1) [8] • Europe/EU/EAA (n=2) [3, 6] • International (n=2) [4, 7] The definition of HCID in the available relevant literature is applicable to health and care settings in Scotland. There are no differing definitions of HCIDs between evidence published within and outside of the UK.

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 or group of interest? Generalisability is only relevant to primary research studies.

Comments
No primary research was identified therefore generalisability does not apply.

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
The definition of a HCID is well-established within the field and so there is no concern regarding publication bias for evidence included for this research question.

Part B: Evidence to decision

1.6. Recommendations

What Recommendation(s) or Good Practice Point(s) does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"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
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach
- **"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

Recommendation	Grading
This research question aimed to outline how high consequence infectious diseases are currently defined within the literature. The UK definition of a HCID is provided by the UK Health Security Agency (UKHSA) and is as follows: • an acute infectious disease • typically has high case-fatality rate • may not have effective prophylaxis or treatment • is often difficult to recognise and detect rapidly • has the ability to spread in the community and within healthcare settings • requires an enhanced individual, population and system response to ensure it is managed effectively, efficiently and safely [1]	Not applicable as no recommendation

1.7. Balancing benefits and harms

Comment here on the potential impact of the Recommendation or 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 or Good Practice Point were followed. Be explicit, clear about pros.

Benefits
N/A

Risks and harms

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

Risks/Harms
N/A

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 or staff or visitor perspective, the societal perspective, or both. Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-harm assessment
N/A

1.8. Feasibility

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

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

Feasibility
N/A

1.9. Expert opinion

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

Expert opinion
NHSScotland adopt the UKHSA definition of an HCID recognising that agreement across the four nations to include infectious agents on the HCID list is facilitated by the UKHSA definition.

1.10. Value Judgements

Summarise value judgements used in creating the Recommendation or 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
N/A

1.11. Intentional vagueness

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

Intentional vagueness
N/A

1.12. Exceptions

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

Exceptions
N/A

1.13. Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
N/A

Research question 2: What legislative requirements are in place regarding employers providing PPE for staff at risk of exposure to HCIDs?

Part A: Quality of evidence

2.1 How reliable is 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
Six pieces of legislation were identified as applicable to the UK and relevant to this research question.[10-15] All UK legislation is considered mandatory within health and care settings in Scotland.	6x Mandatory Legislation

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 or outputs, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments

There was no legislation identified that was directly related to PPE for HCID within health and care settings. The identified legislation is relevant to all PPE, regardless of the infectious agent it is being used to protect against.

There was consistency across the following UK legislation that employers are responsible to ensure PPE is available and both employers and employees are responsible for ensuring PPE is used correctly to ensure safety of all staff at work:

- The Health and Safety at Work etc. Act (1974)[13]
- The Management of Health and Safety at Work Regulations 1999[14]
- The Personal Protective Equipment at Work (Amendment) Regulations 2022[11] and The Personal Protective Equipment (Enforcement) Regulations 2018[10]
- The Control of Substances Hazardous to Health Regulations 2002[15]

Regulation 2016/425 and the Personal Protective Equipment (enforcement) Regulations 2018: Great Britain[12] do not add to this consistency as these regulations instead mandate that manufacturers comply with health and safety requirements to ensure PPE standards are met.

2.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
All identified legislation is applicable to the United Kingdom and thus is applicable to Scottish health and care settings.[10-15] While no legislation was identified that was written directly for health and care settings, these are occupational settings therefore legislation for workplaces is applicable.

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 or group of interest? Generalisability is only relevant to primary research studies.

Comments
No primary research was identified as relevant to this research question therefore generalisability is not applicable.

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
Not applicable to this research question.

Part B: Evidence to decision

2.6 Recommendation(s)

What Recommendation(s) or Good Practice Point(s) does the Working Group agree 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 (i.e. NHSScotland) must provide PPE in line with the Health and Safety at Work Act (1974), the Control of Substances Hazardous to Health (2002 as amended) regulations, and the Personal Protection Equipment at Work Regulations 1992 (as amended).	Recommendation
R2.2 Employers (i.e. NHSScotland) must provide training and information on how to use and store said PPE, in line with the Health and Safety at Work Act (1974), the Control of Substances Hazardous to Health (2002 as amended) regulations, and the Personal Protection Equipment at Work Regulations 1992 (as amended).	Recommendation
R2.3 Employees must comply with said legislation by ensuring that suitable PPE is worn correctly for the task being carried out in line with the Health and Safety at Work Act (1974), the Control of Substances	Recommendation

Recommendation	Grading
Hazardous to Health (2002 as amended) regulations, and the Personal Protection Equipment at Work Regulations 1992 (as amended).	

2.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or 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 or Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
R2.1 Adherence to current legislation and regulations facilitates compliance with associated corporate and social governance responsibilities, including the legal requirements of the applicable health and safety management. R2.2 Staff training will ensure staff are aware of correct use and storage of PPE for HCID which ensures staff safety when using PPE and that PPE is stored in a way that does not degrade its protective effect. R2.3 Adherence by employees to current legislation ensures safety of staff against possible HCID contamination and potential transmission, while undertaking occupational responsibilities.

Risks and harms

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

Risks and harms
R2.1 None to note.
R2.2 None to note.
R2.3 None to note.

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 or staff or visitor perspective, the societal perspective, or both. Recommendations or 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 Only benefits identified.
R2.2 Only benefits identified.
R2.3 Only benefits identified.

2.8 Feasibility

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

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

Feasibility
R2.1, R2.1, R2.3 Organisations need to provide staff training for PPE use and provision to remain in adherence with UK legislation which may incur financial costs and require staff resource and time.

2.9 Expert Opinion

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

Expert opinion
No expert opinion was necessary for R2.1, R2.2 or R2.4 as there is a legal requirement to comply with the legislation and regulations specified within these recommendations.

2.10 Value judgements

Summarise value judgements used in creating the Recommendation or 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
R2.1, R2.2, R2.3 – None to note.

2.11 Intentional vagueness

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

Intentional vagueness
None

2.12 Exceptions

List situations or circumstances in which the Recommendation or 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
N/A

Research question 3: What is the required PPE for HCIDs?

Part A: Quality of evidence

3.1 How reliable is 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, 34 pieces of evidence were included for this research question. Fourteen pieces of evidence were identified within previous version(s) of this review [2-5, 16-23] including two that were excluded from this update and five that were updated.[2, 4, 18, 19] Twenty-three additional pieces of evidence were included during this update.[12, 24-45] • one systematic literature review with meta-analysis graded SIGN 50 level 1+[4] • five observational studies graded SIGN 50 level 3.[23, 31, 32, 34, 40] • 28 guidance graded SIGN 50 level 4 expert opinion. [2, 3, 5, 16-22, 24-30, 33, 35-39, 41-45]	1 x SIGN Level 1+ 5 x SIGN 50 level 3 28 x SIGN 50 level 4

Comments	Evidence level
The SIGN 50 level 1+ evidence is considered to be a well conducted systematic literature review with meta-analysis with low risk of bias. SIGN 50 level 3 evidence generally is limited by lower quality and lack of robust study design (observational studies). SIGN 50 level 4 evidence is considered to be of low quality as a potential risk of bias exists with this class of evidence because of a lack of supporting evidence and the unclear methodology with which these documents are formulated.	

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/outputs, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
• Three SIGN 50 level 4 guidance are consistent in advising that PPE ensembles, donned to protect against HCIDs, should provide a complete barrier at a sufficient level to protect against the risk of contamination with, and the transmission of, the infectious agent.[2, 5, 41] • There is consistency across five pieces of evidence (2 observational studies[33, 40] and 1 cross-over study[40] graded SIGN 50 level 3, and 2 guidance documents[3, 21] graded SIGN 50 level 4 expert opinion) that PPE ensembles donned for protection against HCIDs include respirator, disposable fluid-resistant long-sleeved gown or coverall, eye and face protection (face shield or goggles), head and neck protection, boots or boot covers, and gloves (latex, nitrile or neoprene).[3, 21, 33, 40, 46]

Comments

- The included literature is consistent in advising that either boots (3 observational studies [33, 34, 40] graded SIGN 50 level 3, 4 guidance documents[3, 37, 41, 44] graded SIGN 50 level 4 expert opinion) [3, 33, 34, 37, 40, 41, 44] or boot covers (5 guidance documents [17, 21 36, 41, 44] graded SIGN 50 level 4 expert opinion) [17, 21, 36, 41, 44] should be donned as part of PPE ensembles for protection against HCIDs.
- The included evidence is inconsistent in its recommendations with regards to how many layers of gloves should be worn; single (1 case report graded SIGN 50 level 4) [35], double (2 observational studies [31, 34] graded SIGN 50 level 3, 1 case report[35] and 11 guidance documents [3, 17, 20, 27 21, 28, 29, 36,37, 43, 44] graded SIGN 50 level 4 expert opinion) [3, 17, 19-21, 28, 29, 31, 34-37, 43, 44], or triple (1 brief report[22], 2 observational studies [31, 33, 46], and 1 cross over study[40] graded SIGN 50 level 3) .[22, 31, 33, 40, 46]
    - It is noted by one expert opinion piece that wearing more than two layers of gloves may impede HCWs ability to perform patient care.[47]
    - Across the included studies that support triple gloving, evidence supporting this is not provided. [22, 31, 33, 40, 46]
- Six guidance documents (graded SIGN 50 level 4 expert opinion) advise upgrading respiratory protective equipment from respirators to PAPR during the care of HCID patients. .[3, 17, 36, 41-43]
- The use of risk assessment to decide PPE ensembles for protection against HCIDs is consistently recommended across four guidance documents (graded SIGN 50 level 4 expert opinion).[5, 18, 19, 42] However, 29 pieces of evidence (four observational studies graded SIGN 50 level 3[23, 31, 40], one consensus document graded SIGN 50 level 4[33], and 24 expert opinions graded SIGN 50 level 4[3, 5, 16, 17, 19-21, 24-30, 35-39, 41-45]) provide specific recommended PPE ensembles. These include ensembles to be worn while caring for patients with any HCID (including the UK unified HCID assessment PPE ensemble) (three observational studies graded SIGN 50 level 3[23, 31, 40], one consensus document graded

Comments
SIGN 50 level 4[33], and 2 expert opinions graded SIGN 50 level 4[3, 21]), ensembles for use while caring for patients with contact HCIDs (one observational study (graded SIGN 50 level 3)[34], and 13 pieces of expert opinion (graded SIGN 50 level4).[5 17, 19, 26, 28, 29, 35-38, 41, 43, 44]), and those for use while caring for patients with airborne HCIDs (one consensus document[33], and nine pieces of expert opinion (graded SIGN level 4).[16, 20, 24, 25, 27, 30, 39, 42, 45]). • Although not regarded as PPE, five pieces of literature (all graded SIGN 50 level 4) recommend the wearing of scrubs under HCID PPE ensembles rather than regular uniforms.[3, 17, 20, 26, 41] Two pieces of literature state that this removes risks or issues associated with the laundering of uniforms and absorbs sweat while wearing PPE for protection against HCIDs.[3, 20] However, neither include references to evidence that supports this claim.

3.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
Of the included evidence 13 (3x Mandatory, 3x SIGN 50 level 3, 7x SIGN 50 level 4)[2, 5, 12, 20, 24, 25, 30-33, 40, 41, 45] were written for UK health and care settings, making them directly applicable to Scottish health and care settings. Guidance from European (ECDC) [3, 16] and International (WHO) [17, 26] health organisations and evidence written for unspecified audiences[4] is also represented within the evidence base and is generally applicable to Scottish health and care settings. Non-UK evidence sources were written for: • United States (n=11)[18, 19, 22, 27-29, 35, 36, 43, 44, 47]

Comments

- Canada (n=2)[42, 46]
- Hong Kong (n=2)[34, 48]
- Singapore (n=1)[49]
- Sierra Leone (n=1)[37]
- Italy (n=1)[38]
- South Korea (n=1)[39]

This evidence may be less applicable to Scottish health and care settings due to differing health and care systems and varying travel situations in international settings. However, the PPE recommendations within these sources should be applicable when used in combination with UK legislation and expert opinion.

Primary studies included for this research question were undertaken in a variety of settings including:

- SARS isolation facility or hospital ward[48, 49]
- controlled “clean zone”/experimental settings[31, 34, 40]
- no setting reported[46]

The findings from these studies may not be applicable outside of the specific experimental settings.

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 or group of interest? Generalisability is only relevant to primary research studies.

Comments
Two of the infectious agents that feature on the UK HCID list are represented specifically within the included primary evidence. These are: • Ebola Virus Disease (n=1)[34] • SARS (n=2)[48, 49] Recommendations made based on this evidence may not be generalisable to other infectious agents. Other primary evidence considered HCIDs generally.

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
A formal assessment of publication bias was not conducted. The literature identified for this research question may be subject to some publication bias, but this cannot be quantified due to the nature of the literature.

Part B: Evidence to decision

3.6 Recommendations

What Recommendations or Good Practice Points does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"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
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach
- **"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

Recommendation	Grading
GPP3.1 For all HCIDs the recommended PPE ensemble for Scottish health and care settings should include: • Fit-tested and fit-checked filtering face piece 3 (FFP3) respirator • hood • full-face visor • long rear-fastening fluid-resistant surgical gown tied to the side • wide, extra-long medium thickness plastic apron (such as worn for endoscopy) • inner gloves	Good Practice Point

Recommendation	Grading
• middle gloves taped to the gown with microporous tape • outer gloves • wellington boots (a half- or one-size larger than wearer's usual size)	
GPP3.2 PPE worn for the care of patients with suspected or confirmed HCID should create a complete protective barrier to protect against contamination with, and infection transmission of, the infectious agent.	Good Practice Point

3.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or 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 or Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
GPP3.1 This ensemble provides consistency across all Scottish health and care settings meaning staff knowledge will be applicable in all areas. GPP3.1 The majority of items included in this ensemble are readily available within NHSScotland health and care facilities as part of routine PPE. GPP3.1 This ensemble should provide the wearer with a complete protective barrier if donned, used, and doffed correctly. GPP3.1 FFP3 respirators reduce the risk of airborne transmission of HCIDs when used correctly.

Benefits
GPP3.1 Donning a hood reduces the risk of contamination on the wearer's head and neck. GPP3.1 Donning a full-face visor provides eye protection against splash and spray of body fluids. GPP3.1 Surgical gowns allow for fluid resistant protection of the torso, arms and legs. Along with taping of middle pair of gloves and ensuring an overlap with wellington boots of 10-15cm, complete barrier protection can be achieved. GPP3.1 Donning an apron provides an additional layer of fluid resistance, ensuring further protection from body fluid splash and spray. GPP3.1 Donning three pairs of gloves was found to provide the greatest protection while maintaining wearers dexterity in simulation studies. GPP3.1 Taping gloves horizontally ensures that gaps between gowns or coveralls and gloves are avoided and complete barrier protection is maintained. GPP3.1 Wellington boots provide entire foot coverage and with the recommended gown overlap, can ensure complete barrier protection. GPP3.2 A complete protective barrier created by PPE ensures the highest level of protection possible and provides staff with assurance of this protection.

Risks and harms

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

Risks and harms
GPP3.1 Use of a respirator (FFP3) and longer-length visor may impede wearers communication with patients and other staff. GPP3.1 As this ensemble includes multiple layers of PPE, there is a risk that wearers may overheat and/or become dehydrated.

Risks and harms
GPP3.1 Triple layered gloves may impact on staff dexterity or sensation impacting upon their ability to undertake job roles safely. Additional cross contamination risk may be present when using multiple layers of gloves. GPP3.1 Extended use of some PPE items (for example FFP3, gloves) may cause discomfort and/or skin irritation. GPP3.1 It was noted in the literature that taping can introduce risk of tearing gloves or gown, particularly during doffing, which could introduce risk of contamination. GPP3.1 Selecting a larger size of boot than normally worn introduces a risk of trips while donned. GPP3.2 No risks or harms identified.

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 or staff or visitor perspective, the societal perspective, or both. Recommendations or 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 There were risks identified associated with PPE wearer comfort (multiple layers worn, skin irritation, etc.) however, the benefit of complete barrier protection outweighs this risk. GPP3.1 Risks were identified associated with ability to communicate while wearing facial protection, however the benefits in protection offered by these items outweigh this risk. GPP3.1 Risk of impeded dexterity was identified associated with donning three pairs of gloves, however, the benefits highlighted by simulation studies (added protection, balance between dexterity and protection) outweigh this risk.

Benefit-harm assessment
GPP3.1 The risk of gloves tearing when taped to gowns was highlighted however, the benefit of added security and complete barrier protection created when attaching gloves to gown outweigh this risk. GPP3.1 Risks of trips and falls are heightened by selecting boot sizes larger than those normally worn, however, the benefit of being able to don and doff boots without use of hands outweighs this risk. With training and ensuring that boots are no more than one size larger than wearers normal size, the risk should be minimised. GPP3.2 Only benefits identified.

3.8 Feasibility

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

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

Feasibility
GPP3.1 Procuring specific PPE items for protection against HCIDs (for example hoods and extra-long gowns) will have financial implications for the organisation. GPP3.1 A size range of PPE items, including RPE, will be required to accommodate all trained members of staff. This may incur financial costs for the organisation. GPP3.1 Additional storage space may be required to accommodate a full stock of varying PPE items. GPP3.1 In order to facilitate the use of a PPE ensemble that provides a complete protective barrier, staff training will be required which will involve resource and financial implications for the organisation.

Feasibility
GPP3.2 Procuring specific PPE items for protection against HCIDs (for example hoods and extra-long gowns) to create a complete protective barrier will have financial implications for the organisation.

3.9 Expert Opinion

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

Expert opinion
GPP3.1 This ensemble was created in 2018 based on expert opinion from the UK HCID Network and was agreed in 2019 by the UK Health and Safety Executive (HSE), the Advisory Committee on Dangerous Pathogens (ACDP), NHS England, UK Health Security Agency (UKHSA), Health Protection Scotland (now Public Health Scotland and ARHAI Scotland), Public Health Wales, and Public Health Agency Northern Ireland. GPP3.1 Three pieces of literature (1 cross-over study[40] graded SIGN 50 level 3, 1 consensus document[33] and 1 guidance document[22] graded SIGN 50 level 4) recommend three pairs of gloves be worn. These evidence sources state that a third pair of gloves facilitates the removal of the outer pair when these are contaminated during patient care before donning new gloves. This is insufficient evidence to support a recommendation. Expert opinion from the dedicated HCID task and finish group indicated that while there is the risk of reduced dexterity with adding a third pair of gloves, training should build familiarity and minimise this risk. Additionally, it was noted that the risk of self-contamination during doffing of gloves should be reduced by the addition of a third pair of gloves. The group considered that the benefits of wearing triple gloves outweighed the potential harms. This expert opinion supports development of this good practice point.

Expert opinion
Taping of the middle layer of gloves and wearing boots of a larger size than the wearer's normal size as part of the UK unified HCID assessment PPE ensemble is supported by one consensus document (graded SIGN 50 level 4 expert opinion) and are covered fully under research question 5. GPP3.2 This good practice point was informed by three guidance documents (graded SIGN 50 level 4)[2, 5, 41] and is supported by the expert opinion of the HCID Task and Finish group.

3.10 Value judgements

Summarise value judgements used in creating the Recommendation or 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, GPP3.2 - None to note.

3.11 Intentional vagueness

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

Intentional vagueness
GPP3.1 This good practice point does not include specifications of PPE items that should be included in ensembles for protection against HCIDs. Supplementary

Intentional vagueness
recommendations and good practice points are available on the relevant standards and desirable design features under research question 4. GPP3.2 – No intentional vagueness to note.

3.12 Exceptions

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

Exceptions
GPP3.1, GPP3.2 - None to note.

3.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
High quality primary research is required for all items of PPE included in ensemble for protection against HCID, particularly for triple gloving, aprons, footwear, boot covers, and PAPR. Due to the risk posed by HCIDs this primary research will likely be simulated. The 'VIOLET' study[32] provides a possible protocol that can be followed to undertake research involving simulated patient body fluids. Other protocols may also be available.

Research question 4: What standards (EN) must PPE adhere to and what design features are desirable?

Part A: Quality of evidence

4.1 How reliable is 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, 13 pieces of evidence were included for this research question. Eight pieces of evidence were identified within previous version(s) of this review[5, 15, 19, 47, 50-52], including two that were excluded during this update and three that were updated.[15, 19, 50] Eight additional pieces of evidence were included during this update.[9, 11, 26, 33, 40, 44, 53, 54] • three mandatory UK legislation[11, 12, 54] • one crossover study graded SIGN 50 level 3 [40] • one consensus document, from Poller et al (2018) that outlines the UK unified HCID assessment PPE ensemble, graded SIGN 50 level 4 [33] • nine guidance documents graded SIGN 50 level 4 expert opinion. [5, 9, 19, 26, 44, 47, 50, 52, 53] SIGN 50 level 3 evidence is generally limited by lower quality and less robust design. The majority of the evidence identified as relevant to this research questions was graded SIGN 50 level 4. SIGN 50	3 x Mandatory Legislation 10 x SIGN 50 level 4

Comments	Evidence level
level 4 evidence is considered to be of low quality and lacks sufficiently detailed reporting of rigour in development of evidence-base and recommendations, and thus, can only be considered expert opinion.	

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 or outputs, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Consistency across the evidence included for this research question was limited since most identified pieces provided evidence or recommendations for desirable features of only one type of PPE. • There is consistency across the included evidence(2 mandatory legislations[12, 54], 1 guidance document graded SIGN 50 level 4 expert opinion[50]) stating that PPE should be CE marked.[12, 50, 54] • It is consistently recommended across the included evidence (1 mandatory legislation[11], 1 consensus document[33] and 6 guidance documents graded SIGN 50 level 4 expert opinion[5, 26, 47, 50, 52, 53] that items of PPE be made in a way that does not impede the wearer's ability to work effectively or cause discomfort, including fit, compatibility, and comfort.[11, 26, 33, 50, 53] • A single piece of expert opinion from the WHO (graded SIGN 50 level 4) provides advice on RPE. It states that respirators should be of a structured design to allow good breathability and that, if goggles are to be worn, RPE should be fluid resistant.[26] • There is consistency in the included evidence (1 consensus document [33] and 2 guidance documents graded SIGN 50 level 4 expert opinion[26, 50])

Comments

that eye and face protection (for example goggles or face shield) should have an adjustable but secure headband. They also should not impede vision and accommodate for prescription glasses if required.

- The included evidence (1 consensus document[33] and 2 guidance documents graded SIGN 50 level 4 expert opinion[26, 50] is inconsistent in the number and type of gloves that should be worn as part of a HCID PPE ensemble. However, there is consistency in the included evidence (1 mandatory legislation[11], 3 guidance documents graded SIGN 50 level 4 expert opinion[26, 46, 50]) that glove materials should be chosen with possible allergies in mind.
- Where footwear recommendations are included in the evidence (1 consensus document[33] and 3 guidance documents graded SIGN 50 level 4 expert opinion[19, 26, 50]) it is consistently stated that footwear should cover the entire foot and ankle of the wearer, be large enough to facilitate easy donning and doffing, and made of a material that is resistant to puncture.[19, 26, 33, 53]
- It is consistently recommended across the included evidence (1 consensus document[33] and 3 guidance documents[5, 19, 26] graded SIGN 50 level 4 expert opinion) that gowns and coveralls are made from fluid resistant material.
- Three pieces of evidence (3 guidance documents graded SIGN 50 level 4 expert opinion) [19, 26, 50] advise that the sleeves of coveralls have integrated thumb hooks to ensure sleeves do not move up and expose the forearm during patient care.
- Limited evidence providing recommendations on headwear were included so consistency cannot be commented on, however two guidance documents (graded SIGN 50 level 4[26, 50]) advised that headwear should extend to the top of the gown or coverall worn.

4.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The majority of included evidence (n=11) relevant to this research question was written for UK health and care settings. Of those which were not written for UK settings, three were published for health and care settings within the United States of America by recognised governmental organisations (CDC and InterAgency Board for Equipment Standardization and Interoperability (IAB)). An additional piece of expert opinion written outside of the UK was published by the World Health Organization and is applicable internationally. All of the included evidence is either directly applicable or can be assumed to be applicable to PPE for HCID in Scottish health and care settings.

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 or group of interest? Generalisability is only relevant to primary research studies.

Comments
No primary research was identified as relevant to this research question.

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
A formal assessment of publication bias was not conducted. The literature identified for this research question may be subject to some publication bias, but this cannot be quantified due to the nature of the literature.

Part B: Evidence to decision

4.6 Recommendations

What Recommendations or Good Practice Point does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"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.
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach.
- **"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.

Recommendation	Grading
R4.1 All PPE intended for use in Scottish health and care settings must bear a CE mark that signifies compliance with the Personal Protective Equipment Regulations 2002.	Recommendation

Recommendation	Grading
R4.2 Any design characteristics of PPE worn to protect against HCIDs should not impact upon the protective effect or the ability of the wearer to perform tasks/duties associated with their job role.	Recommendation
GPP4.1 All PPE worn for protection against HCIDs should adhere to the relevant International and British Standards.	Good Practice Point
GPP4.2 Stock of PPE worn for protection against HCID should include a range of sizes.	Good Practice Point
GPP4.3 PPE worn to protect against HCIDs should be made of material that is resistant or impermeable to infectious agents and is compliant with relevant legislation and standards (as per R4.1 and GPP4.1).	Good Practice Point
GPP4.4 Of the three layers of gloves worn in HCID PPE ensembles, the middle layer should have a longer length cuff.	Good Practice Point
GPP4.5 To aid in doffing, boots worn for protection against HCIDs should be a half- to one-size larger than the wearer's usual shoe size.	Good Practice Point

4.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or 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 or Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
R4.1 Ensuring all PPE is CE marked provides the organisation and user with assurance that PPE items comply with the Personal Protective Equipment Regulations 2002. R4.2 Ensuring that the design of PPE does not impede on the protective effect or the ability of the wearer to perform their job role, provides the user with assurance that PPE is fit for purpose. GPP4.1 Adhering to International and British standards provides assurance to both the organisation and the wearer on quality of PPE used within health and care settings for protection against infectious agents. GPP4.2 Ensuring that a wide range of PPE sizes are available for use allows for all staff to be protected and to undertake their job role safely. GPP4.3 Providing PPE made from materials that are resistant or impermeable to infectious agents ensures protection of the wearer. GPP4.4 Longer cuffed middle gloves allow for increased coverage of the arm and can ensure that the sleeves of the gown are held in place. GPP4.5 Providing boots that are slightly larger than wearer's usual size ensure that doffing can be undertaken without touching the possibly contaminated outer surface of boots.

Risks and harms

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

Risks and harms
R4.1 No harms to note. R4.2 None to note. GPP4.1 No harms to note. GPP4.2 None to note

Risks and harms
GPP4.3 Materials that are resistant or impermeable to infectious agents could create barrier protection that is less comfortable for the wearer. GPP4.4 None to note. GPP4.5 Using boots of a larger size than wearer's usual may introduce risk of tripping.

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 or staff or visitor perspective, the societal perspective, or both. Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-harm assessment
R4.1 Only benefits identified. R4.2 Only benefits identified. GPP4.1 Only benefits identified. GPP4.2 Only benefits identified. GPP4.3 While there is a risk of discomfort of the wearer due to PPE materials it is anticipated that the benefits provided by these materials in barrier protection will outweigh risk. GPP4.4 Only benefits identified. GPP4.5 While there is risk that using boots of a larger size than the wearer normally would, can cause a trip hazard it is anticipated that the benefit of being able to don and doff without touching the boots will outweigh this risk.

4.8 Feasibility

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

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

Feasibility
R4.2 In order to ensure that design characteristics of PPE do not impede upon tasks/duties of all staff, purchase and testing of multiple items of PPE may be required which will have associated costs and staff resource required to procure. GPP4.1 PPE procured for the protection against HCIDs should adhere to the relevant International and British Standards, which may have financial implications. GPP4.2 In order to provide a wide range of sizes of PPE, a larger volume may need to be procured which will have associated costs. Holding a stockpile of various sizes may also require a large or alternative area for storage. GPP4.2 Human resource will be required to ensure safe storage of stock, maintaining stock rotation, and monitoring stock levels. GPP4.3 Providing PPE made from materials that are resistant or impermeable to infectious agents will have associated costs.

4.9 Expert opinion

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

Expert opinion
R4.1 [All PPE intended for use in Scottish health and care settings must bear a CE mark that signifies compliance with the Personal Protective Equipment Regulations

Expert opinion

2002] there is no expert opinion to note for this recommendation as it is informed by mandatory legislation.

R4.2 This recommendation is based on 1 piece of mandatory legislation[11], 1 consensus document[33] (SIGN 50 level 4) and 5 pieces of published expert opinion[5, 26, 47, 50, 52] (SIGN 50 level 4). This was deemed sufficient evidence to create a recommendation.

GPP4.1 [All PPE worn for protection against HCIDs should adhere to the relevant International and British Standards.] This good practice point is informed by the expert opinion of the HCID Task and Finish group.

GPP4.2 [Stock of PPE worn for protection against HCID should include a range of sizes]. This good practice point is informed by 1 SIGN 50 level 4 guidance document published by WHO[26], and 1 SIGN 50 level 4 consensus document published by Poller et al (2018)[33] which outlines the UK ensemble. This evidence is insufficient in quantity and quality for the development of a recommendation. The expert opinion of the HCID Task and Finish group is that a range of sizes will increase the ability to provide PPE to a wider staff group which would provide greater resilience in an HCID situation.

GPP4.3 [PPE worn to protect against HCIDs should be made of material that is resistant or impermeable to infectious agents and is compliant with relevant legislation and standards (as per R4.1 and GPP4.1).] This good practice point is informed by one consensus document[33] three guidance documents[5, 19, 26] (all graded SIGN 50 level 4); this evidence is insufficient in quantity and quality for the development of a recommendation but sufficient to support a good practice point combined with the expert opinion of the HCID Task and Finish group.

GPP4.4 [Of the three layers of gloves worn in HCID PPE ensembles, the middle layer should have a longer length cuff.] This good practice point is informed by 1 SIGN 50 level 4 guidance document published by WHO[26], and 1 SIGN 50 level 4 consensus document published by Poller et al 2018)[33] which outlines the UK ensemble. This evidence is insufficient in quantity and quality for the development of a recommendation. The expert opinion of the HCID Task and Finish group is that a longer cuff on the middle pair (of three) will reduce the risk of a gap forming

Expert opinion
between the glove and gown sleeve, thus reducing the risk of HCW contamination during patient care activities. GPP4.5 [To aid in doffing, boots worn for protection against HCIDs should be a half- to one-size larger than the wearer's usual shoe size.] This good practice point is based on advice found in 1 consensus document[33] and 3 expert opinion guidance documents[19, 26, 50] (all graded SIGN 50 level 4) and is supported by the expert opinion of the HCID Task and Finish group.

4.10 Value judgements

Summarise value judgements used in creating the Recommendation or 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
R4.1 – R4.2 None to note. GPP4.1 – GPP4.5 – None to note.

4.11 Intentional vagueness

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

Intentional vagueness
R4.2 This good practice point remains vague in not specifying specific design features, this is to allow organisations to independently identify any possible design

Intentional vagueness
characteristics that could impede upon protective effect or ability to perform job role. GPP4.1 Specific British and International standards have not been detailed as these are subject to updates and amendments which may come into force prior to ARHAI Scotland updating this review.

4.12 Exceptions

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

Exceptions
None to note.

4.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
Further primary evidence on design characteristics of PPE is needed. It is understood that this evidence would require to be simulated or retrospective so as to protect research subjects which would have an impact on the quality of evidence.

Research question 5: How should different elements of PPE for HCID be integrated or interfaced and how should this be done (for example, use of tape)?

Part A: Quality of evidence

5.1 How reliable is 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, nine pieces of evidence were included for this research question. Six pieces of evidence were identified within previous version(s) of this review[3, 5, 9, 11, 17, 55], including two that have been updated.[9, 11] Three additional pieces of evidence were included during this update.[31, 33, 44] • one mandatory UK legislation [11] • one observational study graded SIGN 50 level 3 [31] • one consensus document, from Poller et al (2018) that outlines the UK unified HCID assessment PPE ensemble, graded SIGN 50 level 4 [33] • seven guidance graded SIGN 50 level 4 expert opinion[3, 5, 9, 17, 44, 55] SIGN 50 level 3 evidence generally is limited by lower quality and lack of robust study design. SIGN 50 level 4 evidence is considered to be of low quality as a potential risk of bias exists with this class of	1 x Mandatory 1 x SIGN level 3 7 x SIGN 50 level 4

Comments	Evidence level
evidence because of a lack of supporting evidence and the unclear methodology with which these documents are formulated.	

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 or outputs, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Within the limited amount of evidence (n=9) included for this research question, there is little consistency. • Three sources (2 SIGN 50 level 4[5, 11, 47], 1 mandatory legislation[11]) are consistent in advising that any items of PPE that are worn together should be compatible and one item should not impede on the protective effect of another. • The literature is inconsistent in recommendations regarding the use of adhesives to integrate different items of a PPE ensemble. With this recommended in 3 pieces of evidence (1 observational study[31] graded SIGN 50 level 3, 1 consensus document[33] and 1 expert opinion[3] graded SIGN 50 level 4 expert opinion), but recommendations against this practice featuring in 2 pieces of evidence (2 SIGN 50 level 4 expert opinion).[26, 55] Within one paper that recommends use of adhesive tape it is noted that this practice may have potential safety issues, including taping too tightly impacting upon safe doffing, and overuse of tape near respirators degrading respirator seal. [3] • Two guidance documents (graded SIGN 50 level 4 expert opinion) recommend that gowns or coveralls with integrated thumb holes are used as an alternative to taping glove cuffs to sleeves.[26, 55]

5.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments

Four pieces of literature identified as relevant to this research question were written in the UK or for UK health and care settings[5, 11, 31, 33], making them directly applicable to Scottish health and care settings.

The remaining evidence included for this research question was written for:

- United States (n=3)[9, 44, 55]
- Europe (n=1)[3]
- International (n=1)[17]

One guidance document published by the ECDC (graded SIGN 50 level 4)[3] applies to the EU and EEA and is directly applicable to Scottish health and care settings.

One guidance document published by the WHO (graded SIGN 50 level 4) [17] applies internationally. While this is applicable to Scottish health and care settings to a lesser extent, it can be applied more generally.

The three guidance documents published in the USA were all published by recognised governmental organisations (CDC[9, 55] and IAB[44]) (all graded SIGN 50 level 4)[9, 44, 55] and so, while this is applicable to Scottish health and care settings to a lesser extent, it can be applied more generally.

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 or group of interest? Generalisability is only relevant to primary research studies.

Comments
A single piece of primary evidence was included for this research question.[31] Within this observational study, 11 HCW volunteers donned 5 different HCID PPE ensembles before undertaking simulated patient care activities. While HCWs are the general target audience of PPE for HCID recommendations, this small sample included only doctors and nurses that had previous experience using HCID level PPE.[31] This may not be generalisable to HCWs with less frequent opportunity to care for HCID patients. This study was undertaken within a controlled experimental environment and so it's findings may not be generalisable to HCWs working in settings outside of this.[31]

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
A formal assessment of publication bias was not conducted. The literature identified for this research question may be subject to some publication bias, but this cannot be quantified due to the nature of the literature.

Part B: Evidence to decision

5.6 Recommendations

What Recommendation(s) or Good Practice Point(s) does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"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
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach
- **"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

Recommendation	Grading
R5.1 When it is necessary to wear more than one item of PPE for protection against HCID, these should be compatible and retain protective effect when worn together.	Recommendation
GPP5.1 When taping the middle pair of gloves to the gown (as is required in the UK unified HCID assessment PPE ensemble), micropore tape should be used. Four pieces of tape should be placed lengthwise (from wrist to elbow).	Good Practice point

5.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or 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 or Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
R 5.1 PPE ensembles being compatible and maintaining a barrier when worn together ensures the expected level of protection provided by the ensemble is maintained. GPP5.1 Taping the middle pair of gloves to the sleeves of coverall or gown using micropore tape ensures that they do not slip out of place while caring for HCID patients. It also allows for doffing of gown or coverall and gloves in one motion. Use of specifically micropore tape (instead of more adhesive tapes such as parcel tape) reduces the risk of tearing of the gloves and apron sleeves. GPP5.1 During simulation testing users felt that taping gloves to gown or coverall sleeves using this method felt more secure and made doffing easier.

Risks and harms

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

Risks and harms
R 5.1 Maintaining a complete barrier of PPE may introduce some staff discomfort, for example overheating. GPP5.1 There is risk of tape tearing items of PPE raising risk of contamination during patient care. This could also occur during doffing further raising the risk of contamination during this activity. The use of micropore tape may reduce the risk of tearing (in place of more adhesive tape types such as parcel tape).

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 users or staff or visitor perspective, the societal perspective, or both. Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-harm assessment
R 5.1 Benefits outweigh identified risk if all donning protocols are correctly followed. Overheating may be reduced by taking regular breaks. GPP5.1 Benefits outweigh identified risk if taping protocol is followed correctly. Training will support this.

5.8 Feasibility

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

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

Feasibility
R 5.1 In order to ensure all items of PPE are compatible with each other, staff resource will be required to check that items are compatible. Purchasing of alternative or additional PPE items may be required which will have associated costs. R 5.1 In order to ensure all PPE items are correctly donned to maintain barrier protection staff training will be required. GPP5.1 Taping gloves to coveralls or gowns is not routinely recommended in NHS Scotland so staff will require training in this practice. This may have financial, resource and time implications for the organisation. A sufficient supply of micropore tape will be required which will have incur financial costs.

5.9 Expert opinion

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

Expert opinion
R5.1 This recommendation is informed by mandatory legislation[11] which states that PPE worn together must be compatible and continue to be effective against the risk or risks in question. No additional expert opinion is required. GPP5.1 This good practice point is informed by one consensus document (graded SIGN 50 level 4)[33] and is supported by the expert opinion of the HCID Task and Finish group. Taping using differing techniques, for example extensive taping with parcel tape[3] and taping outer gloves to coverall sleeves, is supported by two guidance documents (graded SIGN 50 level 4)[3, 44]

5.10 Value judgements

Summarise value judgements used in creating the Recommendation or 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
R5.1 None to note. GPP5.1 None to note.

5.11 Intentional vagueness

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

Intentional vagueness
R5.1, GPP5.1 - None to note.

5.12 Exceptions

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

Exceptions
R5.1 None to note. GPP5.1 None to note.

5.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
Further primary research assessing the integration/interfacing of PPE is required to provide greater rigour to recommendations. However, it is likely that studies pertaining to HCIDs will have to be simulated in order to control any risk posed to participants.

Research question 6: How should PPE for HCID be donned and doffed?

Part A: Quality of evidence

6.1 How reliable is 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-one pieces of evidence were included for this research question. Nine pieces of evidence were identified within previous version(s) of this review[3-6, 17, 19, 21, 22, 56] including updates of one systematic review[4] and one piece of expert opinion.[19] Twenty-two additional pieces of evidence were included within this update.[20, 28, 29, 33, 34, 36, 38-40, 42, 44, 45, 53, 57-65] • one systematic review graded SIGN 50 level 1+ [4] • eleven studies graded SIGN 50 level 3 (1x cross-sectional study[6], 1x brief report [22], 1x time-series analysis[60], 1x non-randomised trial[66], 1x case report[62], 6 x observational studies).[34, 40, 56-59] • one consensus document, from Poller et al (2018) that outlines the UK unified HCID assessment PPE ensemble, graded SIGN 50 level 4 [33] • eighteen guidance documents graded SIGN 50 level 4 expert opinion, of which two were	1 x Mandatory 1 x SIGN level 2++ 11 x SIGN 50 level 3 18 x SIGN 50 level 4

Comments	Evidence level
posters providing donning and doffing protocols in picture form.[3, 5, 17, 19-21, 28, 29, 33, 36, 38, 39, 42, 44, 45, 53, 63-65] The SIGN 50 level 1+ evidence is considered to be a well conducted systematic literature review with meta-analysis with low risk of bias. SIGN 50 Level 3 evidence generally is limited by lower quality and lack of robust study design (observational and non-randomised studies) SIGN 50 level 4 evidence is considered to be of low quality as a potential risk of bias exists with this class of evidence because of a lack of supporting evidence and the unclear methodology with which these documents are formulated.	

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 or outputs, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Location There is a lack of consistency across the literature included in this research question on the location where doffing should take place. • 4 pieces of evidence (graded SIGN 50 level 4) state that all steps should be done away from the patient care area.[21, 36, 38, 63] • 3 pieces of evidence (1 observational study graded SIGN 50 level 3[59], 2 guidance documents graded SIGN 50 level 4[20, 45, 58]) state that doffing

Comments

should be completed up to a designated point within the patient care area before moving to a second location.

- 5 pieces of evidence (1 observational study[57] graded SIGN 50 level 3, 4 guidance documents ([21, 36, 38, 63] are consistent in recommending that doffing should take place in an area outside of the patient care area. However, three guidance documents (graded SIGN 50 level 4) [20, 45, 58] are consistent in recommending that doffing should partially take place within the patient care area before moving outside of patient care area to complete the protocol.

Donning and doffing assistance

- It is consistently recommended across the literature (1 brief report [22] and 1 observational study[40], 9 guidance document graded SIGN 50 level 4 [3, 19, 21, 26, 33, 36, 38, 44, 53] that a trained observer or buddy is present during donning and doffing. [3, 21, 22, 26, 29, 33, 36, 38, 40, 44, 53]
- Literature (1 systematic literature review graded SIGN 50 level 1+ [4], 1 time-series analysis[60] graded SIGN 50 level 3, 1 guidance document[19] graded SIGN 50 level 4) (quantity, quality) was consistent in advising on how the individual providing assistance should be involved in the process, stating that verbal communication should be used.

Donning protocol

- It is consistently recommended (2 observational studies graded SIGN 50 level 3 [57, 58], 6 guidance documents graded SIGN 50 level 4 expert opinion[3, 19, 21, 26, 28, 39]) that scrubs are donned, jewellery is removed, and hand hygiene is performed before donning begins. [3, 19, 21, 26, 28, 39, 58, 59]

Doffing protocol

- It is consistently recommended (1 observational study graded SIGN 50 level 3[34], 5 guidance documents graded SIGN 50 level [43, 19, 21, 26, 29]) that PPE should be inspected for damage/contamination before removal and removed using disinfectant wipes before proceeding with doffing.[3, 19, 21, 26, 28, 34]

Comments

- There is inconsistency in recommendations for performing hand hygiene or changing gloves during doffing. Three pieces of evidence (3 guidance documents graded SIGN 50 level 4) recommend that hands or gloves should be disinfected using hand rub between doffing steps[19, 26, 42], while three pieces of evidence (1 brief report graded SIGN 50 level 3[22], 2 guidance documents graded SIGN 50 level 4[3, 19]) recommend that outer gloves are changed between doffing steps. [3, 19, 22]
- It is consistently recommended (4 guidance documents graded SIGN 50 level 4) that care is taken to avoid touching potentially contaminated areas of PPE, such as the outside of coveralls/gowns or front-facing areas of eye and face protection. [19, 21, 26, 53]
- The evidence is consistent (1 brief report[22] graded SIGN 50 level 3, 6 guidance documents[3, 19-22, 26, 53] graded SIGN 50 level 4) in recommending that gowns/coveralls should be doffed by rolling away from the body, only touching the inside of the item and that eye and face protection should only be handled using ties or straps.
- The evidence is inconsistent in recommendations regarding the use of scissors or other sharps during doffing. Two pieces of expert opinion (graded SIGN 50 level 4) suggest that scissors can be used to cut PPE while doffing[3, 44], while one piece of expert opinion (graded SIGN 50 level 4) recommends that scissors are not used during doffing to protect the integrity of items of PPE still to be doffed. [19]

6.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments

Eight pieces of evidence were written for UK health and care settings. [5, 20, 33, 40, 45, 57, 64, 65] These are directly applicable to Scottish health and care settings.

A further five pieces of evidence were written for European[3, 6, 38] or international[4, 17] settings, meaning that these are likely to be applicable to Scottish health and care settings. The additional 11 pieces of evidence from North America[19, 21, 22, 28, 29, 36, 44, 56, 58, 59, 67] can also be considered as likely to be applicable to Scottish health and care settings.

The remaining evidence was written for:

- Korea (n=2)[39, 62]
- China (n=1)[60]
- Canada (n=1)[42]
- Hong Kong (n=1)[34]
- Sierra Leone (from the perspective of the UK military) (n=1)[53]

While these settings may not be directly comparable to Scottish health and care settings, the topic of this literature review calls for evidence from these settings that have experience in dealing with HCIDs.

Primary studies included for this research question were undertaken in a variety of settings including:

- pathogen specific isolation/treatment unit[6, 57, 60,58]
- controlled “clean zone”/experimental settings[59, 33, 40]

The findings from these studies may not be applicable outside of the specific experimental settings.

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 or group of interest? Generalisability is only relevant to primary research studies.

Comments
Three of the infectious agents that feature on the UK HCID list are represented specifically within the included primary evidence. These are: • Ebola Virus Disease (n=4)[34, 58-60] • MERS (n=1)[62] • Mpox (Clade 1) (n=1)[68] Recommendations made based on this evidence may not be generalisable to other infectious agents. Other primary evidence considered HCIDs generally.

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
A formal assessment of publication bias was not conducted. The literature identified for this research question may be subject to some publication bias, but this cannot be quantified due to the nature of the literature.

Part B: Evidence to decision

6.6 Recommendations

What Recommendation(s) or Good Practice Point(s) does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"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
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach
- **"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

Recommendation	Grading
GPP6.1 Before commencing the donning protocol HCWs should put on scrubs, and perform a personal risk assessment to ensure they: • are hydrated and fed • have been to the toilet • feel well enough to enter the patient's room • have removed extraneous items (i.e. jewellery, name badge, pens) • have performed hand hygiene	Good Practice Point
GPP6.2 A detailed and pre-defined sequence for donning and doffing should be adopted, implemented and monitored by Scottish health and care settings.	Good Practice Point
GPP6.3 The following donning sequence should be followed, taking time to ensure each item is fitted	Good Practice Point

Recommendation	Grading
correctly, adjusted to obtain a good fit and interfaces well with the other items of PPE: 1. wellington boots (a half- or one-size larger than wearer's usual size) 2. FFP3 respirator 3. Anti-infection hood 4. first pair of gloves (standard nitrile) 5. gown – Do not use the inside tie, secure the Velcro fastening at the back of the neck, tie at the sides and ensure the gown cuffs fully overlap the bottom pair of gloves 6. check for sufficient overlap of the gown over wellington boots (10-15cm) 7. second pair of gloves (long cuffed), these should fully overlap the cuff of the gown 8. tape the second pair of gloves to the gown using four strips of microporous tape placed lengthways 9. high grade, long length plastic apron. Tie ensuring a 'high fit' i.e. with the apron high up over the chest area 10. visor. Ensure the band of the visor overlaps with the hood, showing no skin. Visors should wrap around the face and extend below the chin 11. third pair of gloves (task specific)	
GPP6.4 A trained observer or 'buddy' should run through each step to ensure each item of PPE is donned correctly; once all checks are complete the	Good Practice Point

Recommendation	Grading
'buddy' should record the time of HCW entering patient area.	
GPP6.5 The following doffing sequence should be followed: 1. remove apron. Pull forward from the front of the apron to break the neck tie. Fold apron down on itself, hold at edges of apron and pull to break waist tie. Roll the apron in on itself taking care to touch the inside only 2. outermost gloves (third pair) 3. gown. Unfasten the side tie of the gown, remove by grabbing the shoulder areas with the opposite hands, pull away from the body folding inside out. The second pair of gloves (taped to sleeves of gown) should come off with the gown 4. visor. Stand straight, reach for the band at the back of the head and lift upwards and over the head (do not lean forward) 5. Anti-infection hood – touching only the outer surface, slowly pull apart the Velcro tabs at the side of the hood and keep them in your vision, bend forward at the waist and lift the hood up and over the head 6. inner gloves 7. perform hand hygiene with ABHR (dispensed by a buddy) 8. FFP3 mask. Standing up straight, slide fingers under the bottom strap and move up to the top strap, lift these to the top of the head. Lift the	Good Practice Point

Recommendation	Grading
straps over the top of the head and allow the mask to fall away 9. wellington boots 10. perform hand hygiene.	
GPP6.6 A trained observer or 'buddy' should inspect the HCW PPE before doffing to check for damage or contamination, following a hands-off approach. They should assist the HCW with verbal prompts to ensure the correct doffing sequence is followed.	Good Practice Point
GPP6.7 Where contact with the HCW providing care is required during doffing by a trained observer or 'buddy' they should wear: • Fluid resistant gown • Type II fluid resistant surgical face mask • full-face visor • long-cuffed gloves • Wellington Boots Where there is risk of aerosolization of an infectious agent the surgical face mask should be substituted for a fit-tested FFP3 respirator.	Good Practice Point
GPP6.8 Sharp instruments should not be used to assist in the removal of PPE.	Good Practice Point
GPP6.9 Removal of PPE should take place in a designated area, agreed locally (for example an amber zone), out with the patient care area (red zone) and that can be easily decontaminated.	Good Practice Point

6.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or 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 or Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
GPP6.1 Donning scrubs before PPE ensemble ensures HCW own clothes are not at risk of contamination when doffing. GPP6.1 Removing extraneous items before donning PPE reduces the risk of contamination of these items and subsequent contamination of those handling said items. GPP6.1 Ensuring staff are hydrated, well-fed, have been to the toilet and feel well enough to enter the patient's room maximises their comfort for the duration of time they are required to wear PPE. GPP6.1 Performing hand hygiene prior to donning PPE ensures that clean PPE is not contaminated during the donning process. GPP6.2 Having a detailed and pre-defined sequence for donning and doffing ensures that staff can be trained in a consistent manner that allows for repetition to assist in commitment to memory, thus ensuring the highest level of safety possible. GPP6.2 Having a detailed and pre-defined sequence for donning and doffing reduces the margin for error while staff are undertaking these tasks. GPP6.3 This donning sequence was created during simulation and consensus studies that led to the creation of the UK unified HCID assessment PPE ensemble. Therefore, it has been created as the donning protocol most suited to this ensemble.

Benefits
GPP6.4 Having a buddy present during donning ensures the correct procedure is followed and provides support for HCW donning PPE. GPP6.5 This doffing sequence was created during simulation and consensus studies that led to the creation of the UK unified HCID assessment PPE ensemble. Therefore, it has been created as the doffing protocol most suited to this ensemble. GPP6.6 Having a buddy present during doffing ensures the correct procedure is followed, that there is visual confirmation of any damage or contamination and that the HCW doffing can receive verbal prompts as assistance when required. GPP6.7 Trained observers or 'buddies' donning a PPE ensemble while assisting in donning and doffing will manage the risk of contamination between HCWs wearing PPE and the trained observer or 'buddy'. GPP6.8 Avoiding use of sharp instruments when doffing ensures the integrity of PPE remains thus ensuring protection from contamination of the HCW removing the PPE. GPP6.9 Having a designated area for doffing that is away from the patient care area and is able to be easily decontaminated ensures that risk of contamination to HCW is reduced.

Risks and harms

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

Risks and harms
GPP6.1 None to note. GPP6.2 None to note. GPP6.3 None to note. GPP6.4 None to note.

Risks and harms
GPP6.5 None to note. GPP6.6 Having a trained observer or 'buddy' present during doffing may present risk of infection for this member of staff due to possible close contact with contaminated PPE items. GPP6.7 None to note. GPP6.8 None to note. GPP6.9 Leaving the patient care area to doff PPE may introduce opportunities to self-contaminate or contaminated the surrounding area.

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 or staff or visitor perspective, the societal perspective, or both. Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-harm assessment
GPP6.1 Only benefits identified. GPP6.2 Only benefits identified. GPP6.3 Only benefits identified. GPP6.4 Only benefits identified. GPP6.5 Only benefits identified. GPP6.6 The benefit of having doffing assistance outweighs the possible risk of infection to the trained observer or 'buddy' since this second member of staff should be wearing appropriate PPE and should not come into contact with potentially contaminated PPE. GPP6.7 Only benefits identified. GPP6.8 Only benefits identified.

Benefit-harm assessment
GPP6.9 The benefit of having a designated area, outwith the patient care area to doff PPE outweighs the possible risk of contaminating the surroundings when leaving the patient care area. Risk of onward contamination should the surroundings become contaminated is reduced by ensuring the area can be easily decontaminated.

6.8 Feasibility

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

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

Feasibility
GPP6.1 Ensuring that staff follow instructions and perform a personal risk assessment prior to donning PPE will require training which may have financial, resource, and time implications for the organisation. GPP6.2 Adopting, implementing and monitoring of a detailed and pre-defined donning and doffing protocol will involve time, resource, and financial investment by the organisation. GPP6.3 Implementing this donning sequence will require staff training which will incur financial, resource, and time implications for the organisation. GPP6.4 Facilitating the presence of trained observers for donning will require staff training which will incur financial, resource, and time implications for the organisation. GPP6.5 Implementing this donning sequence will require staff training which will incur financial, resource, and time implications for the organisation.

Feasibility
GPP6.6 Facilitating the presence of trained observers for doffing will require staff training which will incur financial, resource, and time implications for the organisation. GPP6.7 Implementing a PPE ensemble for the trained observer or 'buddy' will require training which may incur financial, resource, and time implications for the organisation. GPP6.8 None to note. GPP6.9 Providing a designated space for doffing out with the patient care area requires space within facilities which may not always be easily available in areas near the patient care areas of the standard required to care for suspected or confirmed HCID cases.

6.9 Expert opinion

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

Expert opinion
GPP6.1 [Before commencing the donning protocol HCWs should put on scrubs, perform a personal risk assessment to ensure they: • are hydrated and fed • have been to the toilet • feel well enough to enter the patient's room • have removed extraneous items (i.e. jewellery, name badge, pens) have performed hand hygiene] This good practice point is informed by 2 observational studies graded SIGN 50 level 3 [57, 58] and 6 guidance documents

Expert opinion

graded SIGN 50 level 4 expert opinion[3, 19, 21, 26, 28, 39] and is also supported by the expert opinion of the HCID Task and Finish group.

GPP6.2 [A detailed and pre-defined sequence for donning and doffing should be adopted, implemented and monitored by Scottish health and care settings.] This good practice point is informed by 1 systematic literature review with meta-analysis [4] and 1 observational study[56] and is supported by the expert opinion of the HCID Task and Finish group.

GPP6.3 and GPP6.5 These donning and doffing sequences were developed in 2018 by the research group (Poller et al[33]) that developed the UK ensemble. Although there is an absence of evidence cited by Poller regarding the sequences, they were informed by simulation experiments[31-33] (SIGN 50 level 3) that assessed PPE use and contamination. As per GPP3.1, this ensemble has been adopted for use by NHSScotland and aligned with training materials developed by the UK HCID network.

GPP6.4 [A trained observer or 'buddy' should run through each step to ensure each item of PPE is donned correctly; once all checks are complete the 'buddy' should record the time of HCW entering patient area.] This good practice point was informed by 1 systematic literature review [4] graded SIGN 50 level 1+, 1 time-series analysis [19], 1 brief report[22], 1 observational study[40] (graded SIGN 50 level 3), and 10 guidance documents graded SIGN 50 level 4[3, 21, 26, 29, 33, 36, 38, 44, 53, 60]. It was also supported by the expert opinion of the HCID task and finish group.

GPP6.4 The HCID task and finish group discussed HSE guidance[52] that advises FFP3 respirators should be worn for tasks lasting up to 1 hour in duration, this is due to human factors, not a limitation of the filters. For this reason, the group support SIGN 50 level 4 guidance by Poller et al that advises writing the time of donning on the wearers shoulder, so that FFP3 wear time (and HCW comfort) can be monitored.

GPP6.6 [A trained observer or 'buddy' should inspect the HCW PPE before doffing to check for damage or contamination. They should assist the HCW with verbal prompts to ensure the correct doffing sequence is followed.] This good practice point was informed by 1 systematic literature review [4] graded SIGN 50 level 1+, 1

Expert opinion
time-series analysis[60], 1 brief report[22], 2 observational studies[34, 40] (graded SIGN 50 level 3), and 12 guidance documents graded SIGN 50 level 4[3, 19, 21, 26, 28, 29, 33, 36, 38, 44, 53, 60]. It was also supported by the expert opinion of the HCID task and finish group. GPP6.7 This good practice point is informed by the expert opinion of the HCID Task and Finish group. The group indicated that despite a hands-off approach being recommended, the donning and doffing buddy would be required to don PPE in order to provide 'hands on' assistance if required. GPP6.8 [Sharp instruments should not be used to assist in the removal of PPE.] This good practice point is informed by one expert opinion from the CDC (graded SIGN 50 level 4)[19] and supported by the expert opinion of the HCID Task and Finish group. GPP6.9 [Removal of PPE should take place in a designated area, agreed locally (e.g. amber zone), out with the patient care area (red zone) that can be easily decontaminated.] This good practice point is informed by 4 guidance documents (graded SIGN 50 level 4)[21, 36, 38, 63] and supported by the expert opinion of the HCID Task and Finish group. The task and finish group noted that it was important to define zones for doffing which could be used to assist in local planning.

6.10 Value judgements

Summarise value judgements used in creating the Recommendation or 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
GPP6.1 – GPP6.9 None to note.

6.11 Intentional vagueness

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

Intentional vagueness
GPP6.1 – GPP6.9 None to note.

6.12 Exceptions

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

Exceptions
None to note.

6.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
GPP6.3 and GPP6.5 are based on one piece of level 3 evidence and one expert opinion piece as these are the donning and doffing sequences agreed for the UK unified HCID assessment PPE ensemble. Further high-quality research on sequences for donning and doffing would improve the reliability of these sequences. Further research on location of donning and doffing, with a focus on NHSScotland settings is required for recommendations to be formed on this topic.

Research question 7: How should PPE for HCID be stored?

Part A: Quality of evidence

7.1 How reliable is 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 guidance document was included for this research question which was published by the UK Advisory Committee on Dangerous Pathogens (part of the Health and Safety Executive) and is graded SIGN 50 level 4. [5] SIGN 50 level 4 evidence is considered to be of low quality as a potential risk of bias exists with this class of evidence because of a lack of supporting evidence and the unclear methodology with which these documents are formulated.	1 x SIGN 50 level 4

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 or outputs, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
As only one guidance document was included for this research question, consistency is not applicable. The guidance advises that PPE be stored in a designated clean and dry area, in a way that protects it from damage and

Comments
contamination. Stock rotation is also advised in order to avoid degradation and retain protective effect of PPE.

7.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The one guidance document included for this research question was written for UK health and care settings which make its findings directly applicable to Scottish health and care settings. [5]

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 or group of interest? Generalisability is only relevant to primary research studies.

Comments
No primary research was identified as relevant to this research question; therefore, generalisability is not applicable.

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
A formal assessment of publication bias was not conducted. The literature identified for this research question may be subject to some publication bias, but this cannot be quantified due to the nature of the literature.

Part B: Evidence to decision

7.6 Recommendations

What Recommendation(s) or Good Practice Point(s) does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"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.
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach.
- **"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.

Recommendation	Grading
GPP7.1 PPE for HCIDs should be stored in a clean and dry place where it can be easily accessed and not exposed to potentially damaging conditions.	Good Practice Point
GPP7.2 Rotation of HCID PPE stock should be implemented to ensure there is no deterioration in protective effect as a result of stock passing its expiry date whilst in storage.	Good Practice Point
GPP7.3 Health and care facilities should hold a stock of PPE that would be sufficient to care for a patient with a suspected or confirmed HCID for approximately 72 hours (local variation	Good Practice Point

Recommendation	Grading
and transfer times should be considered) and to provide PPE for regular staff training.	

7.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or 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 or Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
GPP 7.1 Appropriate storage of PPE items ensures that they are in good condition and accessible for use when required. GPP 7.2 Stock rotation of PPE items ensures that they are within expiration dates when required and not at risk of deterioration in protection effect due to storage past its expiry date. GPP7.3 Retaining a stock of PPE to cover 72 hours of HCID patient care and regular staff training ensures that health and care facilities are prepared to care for a HCID case should the need arise.

Risks and harms

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

Risks and harms
GPP7.1 No risks or harms to note. GPP 7.2 No risks or harms to note.

Risks and harms
GPP7.3 No risks or harms to note.

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 or staff or visitor perspective, the societal perspective, or both. Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-harm assessment
GPP 7.1 Only benefits identified. GPP 7.2 Only benefits identified. GPP7.3 Only benefits identified.

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, human factors etc., that may be associated with following a Recommendation or Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
GPP 7.1 Having a clean, dry, and safe place to store PPE requires use of a designated space within health and care settings where they are accessible when required. GPP 7.2 Rotation of stock requires time and resource to check expiration dates of items. GPP7.2 Some PPE used for protection against HCID is also used during other health and care procedures. There is the opportunity to pass items near expiration date to other areas of health and care settings to be used before expiration date.

Feasibility
GPP7.3 Holding a PPE for HCID stock sufficient to cover 72 hours of patient care may incur financial and storage issues for the organisation.

7.9 Expert Opinion

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

Expert opinion
GPP7.1 This GPP is informed by the single SIGN 50 level 4 guidance document (published by UK ACDP)[5] included for this research question– this quantity of evidence is insufficient for the development of a recommendation. No further expert opinion to note. GPP7.2 This GPP is informed by the single SIGN 50 level 4 guidance document (published by UK ACDP)[5] included for this research question – this quantity of evidence is insufficient for the development of a recommendation. Expert opinion from the dedicated HCID task and finish group indicated that health and care facilities should hold a stock that would be sufficient to care for a patient with a suspected HCID for approximately 72 hours. This is based on the estimated time to organise the transfer of a patient to an appropriate HCID treatment centre in NHS England. However, depending on location and ease of access to procure more items when required, volume of this stockpile may differ between NHS boards. The HCID task and finish group discussed that a volume of stock will also be required to ensure regular staff training can be undertaken. GPP7.3 This good practice point is informed solely by the expert opinion of the HCID Task and Finish group. It is informed by estimated procurement delivery times which should be confirmed locally and depending on this the volume of stock should be adjusted.

7.10 Value judgements

Summarise value judgements used in creating the Recommendation or 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 to note.

7.11 Intentional vagueness

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

Intentional vagueness
GPP 7.1 A specific designated place for PPE storage is not presented within this good practice point as this will differ across settings and organisations. GPP7.3 Actual volume of stock required for 72-hour care period and regular staff training are not presented as these will differ between health and care facilities and should be determined locally.

7.12 Exceptions

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

Exceptions
None to note.

7.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None

Research question 8: How should single-use PPE for HCID be disposed of?

Part A: Quality of evidence

8.1 How reliable is 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
Seven pieces of evidence were included for this research question. Two pieces of evidence were identified within previous version(s) of this review.[5, 20] An additional five pieces of evidence were identified within this update.[41, 69-72] • one mandatory UK[72] • six SIGN 50 level 4 expert opinion [5, 20, 41, 69-71] including waste management guidance for NHS health and care settings published by NHSScotland Assure (SHTN 03-01)[69] SIGN 50 level 4 evidence is considered to be of low quality as a potential risk of bias exists with this class of evidence because of a lack of supporting evidence and	1 x Mandatory 6 x SIGN 50 level 4

Comments	Evidence level
the unclear methodology with which these documents are formulated.	

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 or outputs, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
• There is consistency across the evidence (three guidance documents graded SIGN 50 level 4) that local waste management policies should be followed when disposing PPE for HCID waste.[20, 41, 69] • It is consistently stated in the identified evidence (one mandatory Scottish legislation, six guidance documents graded SIGN 50 level 4) that PPE for HCID waste should be considered infectious and disposed of in yellow or orange waste streams.[5, 20, 41, 69-72]

8.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
All evidence identified as relevant to this research question were written for or in UK contexts and so are applicable to Scottish health and care settings. [5, 20, 41, 69-71]

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
No primary research was identified as relevant to this research question.

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
A formal assessment of publication bias was not conducted. The literature identified for this research question may be subject to some publication bias, but this cannot be quantified due to the nature of the literature.

Part 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 PPE waste generated from caring for HCID patients should be disposed of as per SHTN 03-01.	Good Practice Point

8.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or 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 or Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
GPP8.1 Adherence to national guidance/legislative requirements as detailed in SHTN 03-01 for HCID PPE waste disposal reduces the risk of cross contamination and exposure to HCID pathogens.

Risks and harms

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

Risks and harms
GPP8.1 None to note.

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 or staff or visitor perspective, the societal perspective, or both. Recommendations or 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 Only benefits identified.

8.8 Feasibility

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

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

Feasibility
GPP8.1 PPE used when caring for HCID patients will generate infectious clinical waste which will require specialist disposal as per SHTN 03-01, this may have financial and sustainability implications for organisations.

8.9 Expert Opinion

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

Expert opinion
GPP8.1 This good practice point is informed by 1 mandatory legislation[72] and 6 guidance documents (graded SIGN 50 level 4 expert opinion)[5, 20, 41, 69-71] one of which is SHTN 03-01[69] which is best practice guidance for Scottish health and care settings. the HCID Task and Finish group support compliance with SHTN 03-01. SHTN 03-01 is published by NHSScotland Assure and outlines waste management guidance to be followed in NHS health and care settings in Scotland. It states that waste produced during the care of HCID patients, classified Category A waste, should be disposed of within the yellow (infectious) waste stream.

8.10 Value judgements

Summarise value judgements used in creating the Recommendation or 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 to note.

8.11 Intentional vagueness

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

Intentional vagueness
GPP8.1 None to note.

8.12 Exceptions

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

Exceptions
GPP8.1 None to note.

8.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
Research on this topic is unlikely to be undertaken as sufficient legislation and guidance is available.

Research question 9: How should reusable PPE for HCID be managed/processed?

Part A: Quality of evidence

9.1 How reliable is 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
Four pieces of evidence were included for this research question. Three pieces of evidence were identified within previous version(s) of this review.[5, 20, 33, 41] An additional piece of evidence was identified within this update.[33] • One consensus document, from Poller et al (2018) that outlines the UK unified HCID	4 x SIGN 50 level 4

Comments	Evidence level
assessment PPE ensemble, graded SIGN 50 level 4 [33] • Three guidance documents graded SIGN 50 level 4 [5, 20, 41] SIGN 50 level 4 evidence is considered to be of low quality as a potential risk of bias exists with this class of evidence because of a lack of supporting evidence and the unclear methodology with which these documents are formulated.	

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/outputs, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
While there is a limited amount of evidence included for this research question some consistencies can be noted. • It is consistently stated across the available evidence (three guidance documents graded SIGN 50 level 4) that single-use, disposable PPE should be used when caring for patients with HCID rather than reusable items.[5, 20, 41] • Where recommendations for reusable items are provided (three guidance documents graded SIGN 50 level 4), it is stated that these should be decontaminated according to manufacturer's instructions, and by a method proven to be effective against HCID that will not degrade the protective effect of PPE. [5, 20, 41] • In one consensus document (graded SIGN 50 level 4)[33] it is noted that reusable PPE should be stored in a designated space while awaiting

Comments
HCID test results and decontamination should only take place if the patient returns a negative sample. If a positive sample is returned, PPE should be disposed of following recommendations of SHTN 03-01, as indicated under Research Question 8.

9.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
All evidence identified as relevant to this research question was written for UK contexts, making them applicable to Scottish health and care settings. [5, 20, 33, 41]

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 or group of interest? Generalisability is only relevant to primary research studies.

Comments
No primary research was identified as relevant to this research question.

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
A formal assessment of publication bias was not conducted. The literature identified for this research question may be subject to some publication bias, but this cannot be quantified due to the nature of the literature.

Part 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 When a patient returns a positive HCID sample, reusable PPE (wellington boots) should be disposed of as per SHTN 03-01.	Good Practice Point
GPP9.2 Any reusable PPE items (wellington boots) should have a defined disinfection protocol in place, and be correctly stored	Good Practice Point
GPP9.3 Disinfectant products should be suitable for use against the identified infectious agent, compatible with the PPE item and used in accordance with the manufacturer's instructions.	Good Practice Point

Recommendation	Grading
GPP9.4 While awaiting patient results, reusable PPE (wellington boots) should be stored in a designated container before disinfection or disposal.	Good Practice Point

9.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or 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 or Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
R9.1 Disposing of PPE when a positive HCID test result is returned ensures that risk of contamination and onward transmission of HCID is limited. GPP9.2 Having a disinfection protocol and adequate storage ensures the safety of all who use this PPE. GPP9.3 Using suitable disinfectants provides assurance that contaminating infectious agents are destroyed. GPP9.3 Using compatible disinfectants ensures maintenance of the integrity of PPE items, within manufacturers guarantee, for future use. GPP 9.4 Reusing only PPE that has been used when caring for a suspected HCID patient who returns a negative sample reduces risk to staff. GPP9.4 Having designated storage for possibly contaminated wellington boots ensures that no accidental contamination of clean PPE can occur and removes risk of wellingtons being reused before results are returned and disinfection has taken place.

Risks and harms

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

Risks and harms
GPP9.1 None identified.
GPP9.2 None identified.
GPP9.3 None identified.
GPP9.4 There is a risk of contamination during the process of storing used PPE prior to decontamination.

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 or staff or visitor perspective, the societal perspective, or both. Recommendations or 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 Only benefits identified.
GPP9.2 Only benefits identified.
GPP9.3 Only benefits identified.
GPP9.4 The benefit of storing potentially contaminated HCID PPE in a designated container prior to HCID test results outweighs the risk of contamination posed by undertaking the storage process.

9.8 Feasibility

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

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

Feasibility
GPP9.1 PPE used when caring for HCID patients will generate infectious clinical waste which will require specialist disposal as per SHTN 03-01. This may have financial and sustainability implications for the organisation. GPP9.2 Staff will require training on methods of decontamination of PPE items. This will require time, resource, and financial input from the organisation. GPP9.2 Reprocessing of PPE will require investment in correct materials in order to follow manufacturer's instructions. This may have financial implications on the organisation. GPP9.3 Staff will require training on methods of decontamination of PPE items. This will require time, resource, and financial input from the organisation. GPP9.3 Reprocessing of PPE will require investment in correct materials in order to follow manufacturer's instructions. This may have financial implications on the organisation. GPP9.4 Disposal of reusable PPE items that have been used in the care of a patient that is positive for a HCID may have financial and sustainability implications for organisations. GPP9.4 In order to store reusable PPE items before reprocessing or disposal while testing is undertaken, safe storage space may need to be made available.

9.9 Expert Opinion

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

Expert opinion
GPP9.1 [When a patient returns a positive HCID sample, reusable PPE (wellington boots) should be disposed of as per SHTN 03-01.] This good practice point is informed by one consensus document (graded SIGN 50 level 4)[33] and is also supported by the expert opinion of the HCID Task and Finish group. GPP9.2 [Any reusable items (wellington boots) should have a defined disinfection protocol in place, be correctly stored] This good practice point takes account of decontamination protocols outlined by the UK HCID network and is supported by the expert opinion of the HCID Task and Finish group. GPP9.3 [Disinfectant products should be suitable for use against the identified infectious agent, compatible with the PPE item and used in accordance with the manufacturer’s instructions.] This good practice point is informed by 3 guidance documents (graded SIGN 50 level 4)[5, 20, 41] and supported by expert opinion of the HCID Task and Finish group. GPP9.4[While awaiting patient results, reusable PPE (wellington boots) should be stored in a designated container before disinfection or disposal.] This good practice point is informed by one consensus document (graded SIGN 50 level 4)[33] and supported by expert opinion from the HCID Task and Finish group.

9.10 Value judgements

Summarise value judgements used in creating the Recommendation or 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 or Good Practice Point. If none was intended, state “none”. Recommendations or Good Practice Points should be clear and specific, but if there is a decision to be vague, acknowledging the 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 or 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
Research on this topic is unlikely to be undertaken due to the risks posed by testing decontamination methods against HCID, however, further guidance from recognised health and care organisations would add to the evidence base available to provide good practice points relating to this research question.

Research question 10: How is 'competence'/'competency' defined and measured regarding PPE for HCID?

Part A: Quality of evidence

10.1 How reliable is 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
Three evidence sources were included for this research question. Two guidance documents from the UK HSE were included within previous versions of this review.[73, 74] One piece of additional evidence from the UK National Occupational Standards (NOS)[75] was identified within this update. • Three graded SIGN 50 level 4 expert opinion [73-75] SIGN 50 level 4 evidence is considered to be of low quality as a potential risk of bias exists with this class of evidence because of a lack of supporting evidence and the unclear methodology with which these documents are formulated.	3 x SIGN 50 level 4

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/outputs, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
There is consistency across two HSE guidance documents (graded SIGN 50 level 4) that competency is defined as the ability of staff to undertake their responsibilities in a safe manner that can be assessed by a recognised standard. [73, 74] A single evidence source (graded SIGN 50 level 4 expert opinion) provides advice on methods to measure competency regarding PPE for HCID, so consistency is not applicable. This expert opinion states that competency can be measured by ensuring staff meet set knowledge and understanding, and performance criteria including: • knowing how to safely put on, remove, and dispose of PPE • using all items of PPE according to manufacturer's instructions and relevant local policy.[75]

10.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
All expert opinion included for this research question were published by recognised UK organisations (HSE and NOS) and so are applicable to Scottish health and care settings. [73-75]

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 or group of interest? Generalisability is only relevant to primary research studies.

Comments
No primary research was identified as relevant to this research question.

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
A formal assessment of publication bias was not conducted. The literature identified for this research question may be subject to some publication bias, but this cannot be quantified due to the nature of the literature.

Part B: Evidence to decision

10.6 Recommendations

What Recommendation(s) or Good Practice Point(s) does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"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.
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach.

- **"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.

Recommendation	Grading
Competence can be defined as: • 'the combination of training, skills, experience, and knowledge that a person has and their ability to apply them to perform activities safely to a recognised standard on a regular basis.'	No Recommendation
Competency can be measured by ensuring staff meet knowledge and understanding, and performance criteria including: • knowing how to safely put on, remove, and dispose of PPE • using all items of PPE according to manufacturer's instructions and local policy.	No Recommendation

10.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or 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
N/A

Risks and Harms

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

Risks/Harms
N/A

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 or staff or visitor perspective, the societal perspective, or both. Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
N/A

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, human factors etc., that may be associated with following a Recommendation or Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
N/A

10.9 Expert Opinion

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

Expert opinion
N/A

10.10 Value judgements

Summarise value judgements used in creating the Recommendation or 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
N/A

10.11 Intentional vagueness

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

Intentional vagueness
N/A

10.12 Exceptions

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

Exceptions
N/A

10.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None.

Research question 11: What training is required for staff to be considered 'competent' in the use of PPE for HCID and how frequently should staff be trained to remain competent?

Part A: Quality of evidence

11.1 How reliable is 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 for this research question. Eight pieces of evidence were identified during previous version(s) of this review[4, 5, 11, 19, 56, 76-78], including updates to one piece of legislation[11], one systematic review[4], and one expert opinion.[19] An	3 x Mandatory 4 x SIGN 50 level 1 3 x SIGN 50 level 3 12 x SIGN 50 level 4

Comments	Evidence level
additional 14 pieces of evidence were identified within this update.[12, 15, 28, 29, 33, 36, 42, 52, 53, 69, 79-82] Of the included evidence, • three mandatory UK legislation [11, 12, 15] • three randomised control trials[79, 80, 82] and one systematic review with meta-analysis [4] graded SIGN 50 level 1. • one experimental study[76], and two before and after studies [56, 77] graded SIGN 50 level 3 • twelve pieces of expert opinion graded SIGN 50 level 4.[19, 28, 29, 33, 36, 42, 52, 53, 69, 78, 83] The SIGN 50 level 1 evidence is considered to be a well conducted systematic literature review with meta-analysis or randomised control trial with low risk of bias. SIGN 50 Level 3 evidence generally is limited by lower quality and lack of robust study design (observational and non-randomised studies). SIGN 50 level 4 evidence is considered to be of low quality as a potential risk of bias exists with this class of evidence because of a lack of supporting evidence and the unclear methodology with which these documents are formulated.	

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 or outputs, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments

It is consistently recommended in the included evidence (three observational studies[56, 76, 77] graded SIGN 50 level 3, four guidance documents graded SIGN 50 level 4[19, 36, 53, 83]) that training should include practical elements ('active training').[19, 36, 53, 56, 76, 81]

There is some consistency in evidence (four guidance documents graded SIGN 50 level 4[5, 19, 52, 69]) stating that staff training records should be kept in order to monitor training levels.[5, 19, 52, 69]

The included evidence (one observational study[77] graded SIGN 50 level 3, one guidance document and one expert opinion graded SIGN 50 level 4[19, 53]) is consistent in recommending frequent refresher training, however no included evidence provides a timeframe for refresher training to occur.

11.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments

Seven pieces of evidence were written in the UK or for UK health and care settings.[5, 11, 12, 15, 33, 52, 69] These are directly applicable to Scottish health and care settings.

A further three pieces of evidence were written for European health and care settings, meaning that these could be applicable to Scottish health and care settings. [79, 80, 83]

The remaining evidence was written for:

- United States of America (n=7) [19, 28, 29, 36, 56, 77, 81]
- International (n=2) [4, 76]
- Canada (n=1) [42]

Comments
• China (n=1) [82] • Saudi Arabia (n=1)[78] • Sierra Leone (from a UK military perspective) (n=1) [53] While these settings may not be directly comparable to Scottish health and care settings, the topic of this literature review calls for evidence from these settings that have experience in dealing with HCIDs.

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 or group of interest? Generalisability is only relevant to primary research studies.

Comments
Five studies (2 randomised control trials [75, 76] (graded SIGN 50 level 1), one experimental study[72] and one observational study[77] (graded SIGN 50 level 3), and one guidance document[78] (graded SIGN 50 level 4) included participants with no previous training or experience, while a single study included participants with varying levels of previous experience in using HCID PPE meaning that their findings should be generalisable across all staff cohorts within NHSScotland.[76, 79-81, 84]

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
A formal assessment of publication bias was not conducted. The literature identified for this research question may be subject to some publication bias, but this cannot be quantified due to the nature of the literature.

Part B: Evidence to decision

11.6 Recommendations

What Recommendation(s) or Good Practice Point(s) does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"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.
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach.
- **"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.

Recommendation	Grading
R11.1 Training for both wearers and donning/doffing buddies must be formed of both theory and practice.	Recommendation
R11.2 Training for both wearers and donning/doffing buddies should include:	Recommendation

Recommendation	Grading
• how to correctly fit and wear all required PPE • the purpose and limitations of the required PPE • how to don, doff and dispose of all required PPE safely • procedures to follow if there is a breach in PPE	
R11.3 Regular refresher training for both wearers and donning/doffing buddies should be provided to ensure HCWs remain competent in the requirements specified in R11.2 for PPE required for HCID.	Recommendation
R11.4 Training should be completed before staff care for suspected or confirmed HCID patients.	Recommendation
GPP11.1 The frequency of refresher training should be determined locally, but should occur at least annually as a minimum with consideration given to increasing frequency for staff groups most likely to come into contact with HCID patients.	Good Practice Point
GPP11.2 Records of who has undertaken training and when this occurred should be kept to monitor staff training.	Good Practice Point

11.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or 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 or Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
R11.1 Training using theory ensures staff develop knowledge and understanding of each element of PPE used in ensembles for protection against HCIDs, and why each of these are important. R11.1 Training using practice provides staff with basic experience using PPE ensembles for HCIDs within a controlled environment. R11.2 Training should include all the necessary elements listed to ensure confidence of staff when using PPE items as part of ensembles for protection against HCIDs. R11.3 GPP11.1 Refreshing training on a regular basis provides the opportunity to build staff competence and confidence regarding PPE for HCIDs thus increasing compliance with correct and safe PPE use which should ensure the protection of staff. R11.4 Providing training to staff who may care for suspected or confirmed HCID patients can increase staff knowledge and competence before they are in higher risk situations. GPP11.2 Maintaining records ensures that there is evidence of staff training and can be used to avoid lapse in regular training, thus contributing to maintaining competence. Records can also be used to identify what staff members are available to be operationalised when suspected or confirmed HCID patients enter a health and care setting.

Risks and harms

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

Risks and harms
R11.1 None to note R11.2 None to note. R11.3 None to note. R11.4 None to note. GPP11.1 Level and frequency of staff training is determined at board level with consideration to feasibility (resource, financial, etc). However, lack of training could place staff and patients at risk. GPP11.2 None to note.

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 or staff or visitor perspective, the societal perspective, or both. Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-harm assessment
R11.1 Only benefits identified. R11.2 Only benefits identified, R11,3 Only benefits identified. R11.4 Only benefits identified. GPP11.1 The benefit of allowing local decision making when it comes to frequency of staff training, particularly in allowing frequency to differ between staff groups (with those more likely to come into contact with HCID patients receiving more

Benefit-harm assessment
regular training) outweighs the risk of staff not receiving training at the same frequency. GPP11.2 Only benefits identified.

11.8 Feasibility

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

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

Feasibility
R11.1 Staff training will involve resource, time, and/or financial implications for the organisation. R11.2 Staff training will involve resource, time, and/or financial implications for the organisation. R11.3 Undertaking staff training on a regular basis will involve resource, time and/or financial implications for the organisation. R11.4 Providing training prior to caring for HCID patients will require planning in advance of these situations which will require resource, time, and/or financial input from the organisation. R11.4 Requiring staff to be trained before caring for HCID patients will limit the number of staff with the level of training required when a HCID patient is admitted to a health and care facility. GPP11.1 Staff training will involve resource, time, and/or financial implications for the organisation. Frequency of training may be impacted by these factors. GPP11.2 Maintaining training records will involve time and resource implications for the organisation.

11.9 Expert opinion

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

Expert opinion
R11.1 [Training for both wearers and donning/doffing buddies must be formed of both theory and practice.] This recommendation is informed by two mandatory legislations, one before and after study and one experimental study both graded SIGN 50 level 3 [72], four guidance documents graded SIGN 50 level 4 [19, 36, 53, 77] and supported by the expert opinion of the HCID Task and Finish group. Expert opinion from the HCID Task and Finish group noted that training for PPE wearers and donning and doffing buddies would include different knowledge and skills checks. R11.2 [Training for both wearers and donning/doffing buddies should include: • how to correctly fit and wear all required PPE • the purpose and limitations of the required PPE • how to don, doff and dispose of all required PPE safely Procedures to follow if there is a breach in PPE] This recommendation is informed by two mandatory legislation and one guidance document [9, 13, 46] and supported by the expert opinion of the HCID Task and Finish group. The HCID Task and Finish group expert opinion suggested that training should also include recognition of the type of outer gloves required for certain tasks, and the size of gloves and wellington boots required. R11.3 [Regular refresher training for both wearers and donning/doffing buddies should be provided to ensure HCWs remain competent in the requirements specified in R11.2 for PPE required for HCID.] This recommendation is informed by 2 mandatory legislation [10, 15] and 2 guidance documents [46, 53] (graded SIGN 50 level 4 expert opinion) and is supported by the expert opinion of the HCID Task and Finish group.

Expert opinion
R11.4 [Training should be completed before staff care for suspected or confirmed HCID patients.] This recommendation was supported by two mandatory legislation [10, 15] and four pieces of expert opinion [19, 28, 29, 46] (graded SIGN 50 level 4) and is supported by the expert opinion of the HCID Task and Finish Group. Expert opinion from the dedicated task and finish group also highlighted the possibility of using 'just in time' style training videos for staff to boost competency if a suspected HCID patient arrival is imminent. GPP11.1 [The frequency of refresher training should be determined locally, but should occur at least annually as a minimum with consideration given to increasing frequency for staff groups most likely to come into contact with HCID patients.] This good practice point is informed by the expert opinion of the HCID Task and Finish group. It was indicated that due to training being a resource intensive activity, regular training should occur no more frequently than annually. However, it was noted that some staff groups, for example those in infectious disease departments, may require more frequent training or competency checks than staff who are less likely to come into contact with a HCID infected patient. It was also noted that regular refresher training and respirator fit testing must remain two distinct tasks. GPP11.2 [Records should be kept to monitor staff training.] This good practice point is informed by four guidance documents graded SIGN 50 level 4 ([4],[19],[51,66]) and is supported by the expert opinion of the HCID Task and Finish group.

11.10 Value judgements

Summarise value judgements used in creating the Recommendation or 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 to note.

11.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation or Good Practice Point. If none was intended, state “none”. Recommendations or Good Practice Points should be clear and specific, but if there is a decision to be vague, acknowledging the 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.

Intentional vagueness
None to note.

11.12 Exceptions

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

Exceptions
None to note.

11.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
While evidence regarding staff training is not limited, the majority of this evidence was not specific to PPE ensembles for protection against HCIDs. Further research focussed on this aspect of staff training could be useful to build upon the available evidence.

Research question 12: How should staff competency be assessed?

Part A: Quality of evidence

12.1 How reliable is 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
Two pieces of evidence were included for this research question, both identified within previous version(s) of this review. This includes a piece of expert opinion that has been updated since the previous version of this review,[19] and a consensus document.[85] • one consensus document graded SIGN 50 level 4[85] • one expert opinion graded SIGN 50 level 4. [19] SIGN 50 level 4 evidence is considered to be of low quality as a potential risk of bias exists with this class of evidence because of a lack of supporting evidence and the unclear methodology with which these documents are formulated.	2 x SIGN 50 level 4

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/outputs, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Quantity of evidence identified as relevant to this research question was limited and so consistency across the included evidence was also limited. • There is no consistency across the included evidence (one consensus document and one guidance document graded SIGN 50 level 4 expert opinion) on methods for measuring staff competency. [19, 85] • One consensus document (graded SIGN 50 level 4) states that HCWs should be able to demonstrate proper donning, doffing and use of PPE[85], while one expert opinion (graded SIGN 50 level 4) highlights that checklists can be useful tools when assessing competency.[19]

12.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
Both pieces of identified evidence were written for or within North American health and care settings. [19, 85] These settings are assumed to be similar to the standard of health and care setting found in Scottish contexts.

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 or group of interest? Generalisability is only relevant to primary research studies.

Comments
A single piece of primary literature was identified as relevant to this research question. Within this paper, consensus was found regarding checklists for the assessment of PPE skills using the Delphi method between 23 IPC experts based in Canada: 43% involved in clinical practice, 83% in education, 50% involved in policy making, and 53% in research. The generalisability of this study may be limited due to the small number of participants (n=23) and their varied backgrounds.

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
A formal assessment of publication bias was not conducted. The literature identified for this research question may be subject to some publication bias, but this cannot be quantified due to the nature of the literature.

Part B: Evidence to decision

12.6 Recommendations

What Recommendation(s) or Good Practice Point(s) does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"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.
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach.
- **"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.

Recommendation	Grading
GPP12.1 Staff should be able to correctly perform all tasks related to wearing PPE for HCID including: • donning PPE in the correct sequence • doffing PPE in the correct sequence and using the correct techniques • safely disposing of PPE	Good Practice Point
GPP12.2 Assessments should check and record correct completion of each step of PPE donning and doffing, and ensure the trainee understands the theory underpinning the process.	Good Practice Point
GPP12.3 Assessment of staff competency on donning and doffing should be supported by use of training checklists, assessment videos and other methods of knowledge and skills assessment.	Good Practice Point

Recommendation	Grading
GPP12.4 Staff should complete assessment of PPE for HCID competency, without assistance or prompting, without error.	Good Practice Point

12.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or 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 or Good Practice Point were followed correctly. Be explicit, clear about pros.

Benefits
GPP12.1 Staff being able to correctly perform all tasks relating to PPE for HCID use ensures that they are trained and capable of undertaking these tasks safely when caring for a HCID patient. GPP12.2 Assessing competency on donning and doffing of PPE and staff understanding of theory ensures that their knowledge is robust, and their training has been sufficient. GPP12.3 Checklists can provide consistency and assurance that staff can select appropriate PPE and perform all steps of donning and doffing correctly. GPP12.4 Expecting a competency score of 100% ensures that staff have sufficiently understood the training and are able to don, doff, and dispose of PPE in a way that protects them and others from contamination.

Risks and harms

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

Risks and harms
GPP12.1 None to note.
GPP12.2 None to note.
GPP12.3 None to note.
GPP12.4 None to note.

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 or staff or visitor perspective, the societal perspective, or both. Recommendations or 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 Only benefits identified.
GPP12.2 Only benefits identified.
GPP12.3 Only benefits identified.
GPP12.4 Only benefits identified.

12.8 Feasibility

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

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

Feasibility
GPP12.1 Training staff to correctly perform all tasks related to wearing PPE for HCID will involve financial, resource, and time implications for the organisation. GPP12.1 In order to ensure staff can correctly perform all tasks related to wearing PPE, stocks of PPE will be required which will have financial and sustainability implications for organisations. GPP12.2 Training of both PPE wearing staff and trainers to undertake assessment will incur financial, resource, and time implications for the organisation. GPP12.3 Organisations would need to identify a relevant checklist or develop their own which could have resource, time, or financial implications. GPP12.3 Development of a checklist requires extensive knowledge of the process being assessed to ensure safe practice. GPP12.4 Expecting a competency score of 100% could lead to higher numbers of staff failing assessment and limit the number of staff that are trained in use of PPE for HCID.

12.9 Expert opinion

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

Expert opinion

GPP12.1 [Staff must be able to correctly perform all tasks related to wearing PPE for HCID including:

- donning PPE in the correct sequence
- doffing PPE in the correct sequence and using the correct techniques

Safely disposing of PPE] This good practice point was informed by one expert opinion[19] (graded SIGN 50 level 4) and is supported by the expert opinion of the HCID Task and Finish group.

GPP12.2 [Assessments should check and record correct completion of each step of PPE donning and doffing, and ensure the trainee understands the theory underpinning the process.] This good practice point is informed by the expert opinion of the HCID Task and Finish group.

GPP12.3 [Assessment of staff competency on donning and doffing should be supported by use of training checklists, assessment videos and other methods of knowledge and skills assessment.] This good practice point is informed by one consensus document[85] (graded SIGN 50 level 4) and is supported by the expert opinion of the HCID Task and Finish group.

GPP12.4 [Staff are expected to complete assessment of PPE for HCID competency, without assistance or prompting, without error.] This good practice point is informed by the expert opinion of the HCID Task and Finish group. The group indicated that any errors in assessment of training could lead to risk of errors in practice and consideration of further training is required.

12.10 Value judgements

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

Intentional vagueness
GPP12.3 Specific checklists are not suggested for use as these were not present in the evidence base.

12.12 Exceptions

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

Exceptions
None to note.

12.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
There is currently insufficient evidence regarding assessment of staff competency in use of PPE for HCIDs. Further research is required outlining potential checklists to assist staff assessment. Research into other methods of staff assessment specific to PPE or PPE for HCIDs is also required.

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