



Contents

1	Rese	Research Questions 9		
2	Meth	Methodology 10		
3	Disc	Discussion 11		
		plications for practice		
3				
	3.1.1			
		Summary	13	
	3.1.2	What legislative requirements are in place regarding employers providing PPE for staff at risk of exposure to HCIDs?		
		Summary		
	3.1.3	What is the required PPE for HCIDs?		
	3.1.3	Gloves		
		Aprons		
		Scrubs		
		RPE		
		Contact HCIDs Ensembles		
		Airborne HCIDs Ensembles		
		General HCID Ensembles		
		Summary		
	3.1.4	What standards (EN) must PPE for HCID adhere to an		
	3.1.4	what design features are desirable?		
		All PPE Items		
		RPE and Surgical Masks	27	
		Eye and Face Protection	28	
		Gloves		
		Footwear	29	
		Gowns and Coveralls	29	
		Headwear	30	
		Summary	31	
	3.1.5	How should different elements of PPE be		
		integrated/interfaced and how should this be done (fo example, use of tape)?		

	Summary34
3.1.6	How should PPE be donned (put on) and doffed (taken off)?
	Location
	Donning and doffing assistance
	Donning
	Doffing
	Summary41
3.1.7	How should PPE for HCIDs be stored?41
	Summary42
3.1.8	How should single-use PPE for HCIDs be disposed of?42
	Summary44
3.1.9	How should reusable PPE for HCIDs be managed/processed?
	Summary45
3.1.10	How is 'competence'/competency' defined and measured regarding PPE for HCIDs?45
	Summary
3.1.11	What training is required for staff to be considered 'competent' in the use of PPE for HCIDs and how frequently should staff be trained to remain competent?
	Summary
3.1.12	How should staff competency be assessed?49
	Summary
3.2 lm	plications for research50
Append	ices 51
	dix 1: PRISMA 51
	dix 2: Definitions for Recommendation Grading 52
Keteren	ces 53

Key Information

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Document information

Document information	Description
Description:	This literature review examines the available
	professional literature on Personal Protective
	Equipment (PPE) for High Consequence Infectious
	Diseases (HCIDs).
Purpose:	To inform development of an HCID addendum in the
	National Infection Prevention and Control Manual
	(NIPCM) in order to facilitate the prevention and
	control of healthcare associated infections in
	NHSScotland health and care settings.
Target Audience:	All NHS staff who may be involved in the direct care
	of patients with a suspected or confirmed HCID in
	NHSScotland.
Update/review schedule:	Updated as new evidence emerges with changes
	made to recommendations as required.
	Review will be formally updated every 3 years with
	next review in 2027.
Cross reference:	National Infection Prevention and Control Manual
Update level:	Practice – Implementation of a United Kingdom
	unified HCID assessment PPE ensemble as agreed
	by healthcare bodies across the four nations and
	endorsed by the Advisory Committee on Dangerous
	Pathogens (ACDP).
	Research – Higher quality primary research is
	required to allow for the formation of evidence-based
	recommendations regarding PPE for HCID.

Contact

ARHAI Scotland Infection Control team:

Telephone: 0141 300 1175

Email: NSS.ARHAlinfectioncontrol@nhs.scot

Version history

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

Version	Date	Summary of changes
3.0	August 2025	Updated following new NIPCM methodology (2023).
		Addition of five new research questions:
		 What legislative requirements are in place regarding employers providing PPE for staff at risk of exposure to HCIDs?
		How should PPE for HCIDs be stored?
		 How should single-use PPE for HCIDs be disposed of?
		 How should reusable PPE for HCIDs be managed or processed?
		 How is 'competence' or 'competency' defined and measured regarding PPE for HCIDs?
		'IDHC' changed to 'HCID' throughout to align with UKHSA terminology.
		Updated definition of HCIDs to align with new UK agreed definition.
		PPE ensemble updated to reflect the UK unified HCID assessment PPE ensemble.
		Removed option of powered respirator hoods.
2.1	May 2018	Updated to include additional studies from the Health and Safety Laboratory in Buxton. No changes to recommendations were required.
2.0	May 2017	New recommendation 'Respirator hoods must be fluid-resistant and must offer barrier protection that is equivalent to the gown or coverall component of the PPE ensemble.'
1.0	March 2017	New literature review

Approvals

Version	Date Approved	Name
3.0	February 2025	HCID PPE ensemble operationalisation task and finish group.

1 Research Questions

The aim is to review the extant scientific literature regarding Personal Protective Equipment (PPE) for High Consequence Infectious Diseases (HCIDs) in health and care settings to inform evidence-based recommendations for practice. The specific research questions of the review are:

- **1.** What is the definition of a HCID?
- What legislative requirements are in place regarding employers providing PPE for staff at risk of exposure to HCIDs?
- 3. What is the required PPE for HCIDs?
- **4.** What standards (EN) must PPE adhere to and what design features are desirable?
- 5. How should different elements of PPE for HCIDs be integrated or interfaced for example using tape?
- 6. How should PPE for HCIDs be donned (put on) and doffed (taken off)?
- 7. How should PPE for HCIDs be stored?
- 8. How should single-use PPE for HCIDs be disposed of?
- **9.** How should reusable PPE for HCIDs be managed or processed?
- **10.** How is 'competence' or 'competency' defined and measured regarding PPE for HCIDs?
- **11.** What training is required for staff to be considered 'competent' in the use of PPE for HCIDs and how frequently should staff be trained to remain competent?
- **12.** How should staff competency be assessed?

Note: Recommendations on the use of PPE for Standard Infection Control Procedures (SICPs) and Transmission Based Precautions (TBPs) (not including HCIDs) are discussed within the corresponding PPE literature reviews within the National Infection Prevention and Control Manual.

2 Methodology

This targeted literature review was produced using a defined systematic methodology as described in the National Infection Prevention and Control Manual: Development Process. In place of the NPGE Working Group, consultation of this literature review, related documents and the NIPCM HCID addendum was provided by a dedicated task and finish group made up of topic experts from across Scotland. This included representation from infectious diseases services, maternity services, critical care services, emergency department services, National Procurement, Scottish Ambulance Service, health and safety, Infection Control Managers Network, Infection Control Doctors' Network, Senior Infection Prevention and Control Nurses Network, primary care services, NHS Education for Scotland, health protection team for remote and rural areas and a member of the team involved in the HCID PPE simulation exercise.

Due to the objectives of this literature review, the NIPCM exclusion criteria regarding effectiveness of training has been removed.

3 Discussion

3.1 Implications for practice

3.1.1 What is the definition of a HCID?

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}

Of this evidence, the systematic review with meta-analysis⁴ was graded SIGN 50 level 1+ and the remaining seven guidance documents and expert opinions were graded SIGN 50 level 4 expert opinion.^{1-3, 5-8}

There is no single accepted terminology for high consequence infectious diseases (HCIDs), indeed these infectious agents are variably referred to as 'potential pandemic pathogens', 'high consequence infections', 'highly infectious diseases', 'high consequence infectious diseases', 'infectious diseases of high consequence' across the available literature. ^{1, 3-7}

The European Centre for Disease Prevention and Control (ECDC) in 2014 defined a HCID as follows:

'Infectious diseases of high consequence (IDHC) are serious threats to human health. Patients develop severe symptoms; require a high level of care and case–fatality rates can be high. Often, there is no specific prophylaxis or treatment available. IDHC are transmissible from human to human (contagious); depending on their transmission mode (e.g. by droplets or airborne) and infectivity IDHC can generate large-scale epidemics (e.g. Ebola in West Africa 2014 or SARS in 2003) or even pandemics (e.g. the Spanish influenza pandemic in 1918).'3

UKHSA expert opinion defines a high consequence infectious disease (HCID) as the following:

- 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

HCIDs are often described as 'novel' and/or 'emerging'. The World Health Organization (WHO) defines an emerging infectious disease as 'one that has appeared in the population for the first time, or that may have existed previously but is rapidly increasing in incidence or geographical range'. The United States (US) Centers for Disease Control and Prevention (CDC) defines emerging infectious diseases as:

- new infections resulting from changes in or evolution of existing organisms
- known infections spreading to new geographical areas or populations
- previously unrecognised infections appearing in areas undergoing ecological transformation
- old infections re-emerging as a result of antibiotic resistance in known agents or breakdown in public health measures.⁸

The UK Advisory Committee on Dangerous Pathogens (ACDP) produces 'The Approved List of Biological Agents' on behalf of the HSE to act as 'approved classification' of biological agents required to make informed risk assessment per the mandatory The Control of Substances Hazardous to Health Regulations 2002 (COSHH). Infectious agents on The Approved List of Dangerous Pathogens are placed into hazard groups based on the risk of infection they pose to humans, transmission risk, and availability of prophylaxis or treatment.² Infectious agents or diseases that have been identified as HCIDs by national or international public health

organisations typically fall into hazard group 3 or 4 and are capable of human-to-human transmission.² Hazard group 3 agents "can cause severe human disease and may be a serious hazard to employees; they may spread to the community, but there is usually effective prophylaxis or treatment available". Hazard group 4 agents "cause severe human disease and are a serious hazard to employees; they are likely to spread to the community and there is usually no effective prophylaxis or treatment available".²

In the UK, an <u>agreed list of HCIDs</u> is kept under review by the UK four nations public health agencies.

Summary

While there is some variation in the definition of a HCID across the available literature, there is overall consistency that an HCID is an acute infectious disease that typically has a high case-fatality rate, may not have prophylaxis or treatment, often is difficult to detect rapidly, has the ability to spread within the community, health and care settings, and requires enhanced response across the public health system to ensure effective, efficient, and safe management.

3.1.2 What legislative requirements are in place regarding employers providing PPE for staff at risk of exposure to HCIDs?

Six pieces of legislation were included that are applicable to the UK and relevant to this research question.⁹⁻¹⁴ All are graded 'mandatory'.

Wearing of PPE in health and care settings to protect against HCIDs specifically is not covered by any available legislation. The identified legislation does however cover health and safety within occupational settings, the use of PPE in occupational settings, and the use of PPE to protect against infectious agents.

The Health and Safety at Work etc. Act (1974) is the primary legislation regarding occupational health at work and specifies the duties of both employers and employees regarding health and safety while carrying out work activities. ¹⁰ The

Management of Health and Safety at Work Regulations 1999 further outline the requirements of employers and responsibilities of employees to maintain health and safety within occupational settings.¹¹ While these pieces of legislation do not cover PPE explicitly, they outline standards for employers and employees to protect health and safety in occupational settings as far as reasonably practicable. They are supplemented by more recent legislation regarding PPE: The Personal Protective Equipment at Work (Amendment) Regulations 2022 and The Personal Protective Equipment (Enforcement) Regulations 2018.^{13, 14}

The Personal Protective Equipment at Work Regulations 1992 and the 2022 amendments outline the legal requirement for employers to provide employees with PPE required to complete their work tasks safely, where other control measures are insufficient or not possible. 12, 13 This legislation presents regulations on the suitability and capability of PPE, as well as PPE training and storage requirements. These regulations provide general guidance on PPE but are not specific to PPE for HCIDs. Parts of these regulations are superseded by The Control of Substances Hazardous to Health (COSHH) 2002 Regulations (as amended 2013). The COSHH 2002 Regulations provides the requirements for employers to protect employees from substances that are hazardous to health in occupational settings. These requirements include the use of PPE and apply to protection against infectious agents.

The Personal Protective Equipment (Enforcement) Regulations 2018 incorporates EU Regulation 2016/425 into UK Law.¹⁴ These regulations describe health and safety requirements applied to PPE products before they may be placed on the market within Great Britain.

Summary

While there is no legislation that directly relates to wearing PPE for protection against HCIDs within health and care settings, legislation that applies to occupational settings are applicable and detail the requirements of both employers and employees to ensure the protection of staff.

3.1.3 What is the required PPE for HCIDs?

In total, 34 pieces of evidence were included for this research question. Fourteen pieces of evidence were identified within previous versions of this review^{2, 3 4, 5, 15-22} including two that were excluded from this update and five that were updated.^{2, 4, 17, 18} Twenty-three additional pieces of evidence were included during this update.^{14, 23-44}

This evidence includes one systematic literature review graded SIGN 50 1+,⁴ and five observational studies graded SIGN 50 level 3.^{22, 30, 31, 33, 39} One consensus document, from Poller et al (2018) that outlines the UK unified HCID assessment PPE ensemble was graded SIGN 50 level 4 expert opinion.³² The remaining 27 pieces of evidence were graded SIGN 50 level 4 expert opinion.^{2, 3, 5, 15-21, 23-29, 34-38, 40-44}

Three guidance documents (SIGN 50 level 4 expert opinion) state that PPE ensembles should create a complete barrier at a sufficient level to protect against the risk of contamination by and transmission of infectious agents. ^{2, 5, 40} It is noted by the Public Health Agency of Canada (PHAC) that PPE should be implemented when engineering and administrative controls will not provide sufficient protection, as per the hierarchy of controls. ⁴¹ Four pieces of literature (three expert opinion and one mandatory guidance) recommend that a variety of factors should be considered within a risk assessment before a PPE ensemble is decided upon. ^{5, 17, 18, 41} These factors should include route of transmission, risk of infection, and tasks personnel are expected to undertake. ^{5, 17, 18}

Six pieces of literature (three observational studies graded SIGN 50 level 3^{22, 30, 39}, one consensus document graded SIGN50 level 4³², and two expert opinions graded SIGN 50 level 4^{3, 20}) were identified that outline PPE ensembles or items that are recommended for protection against HCIDs generally. It is consistently recommended across this literature that PPE ensembles include:

- gloves (latex, nitrile or neoprene)^{3, 20, 22, 32, 39};
- disposable, fluid-resistant long-sleeved gown (surgical gown) or coverall³, 20, 32, 39
- respirator^{3, 20, 32}

- head and neck protection^{3, 20, 32, 39}
- eye and face protection (face shield or goggles)^{3, 20, 32}
- boots^{3, 39} or boot covers²⁰

Gloves

Single, double, and triple gloving is recommended across this general ensemble literature. ^{3, 20, 22, 32, 39} Within their systematic review and meta-analysis, Verbeek et al (2020) included two papers (one RCT and one non-randomised control study with cross-over design) that analysed the difference in glove contamination when double and single-gloving.⁴ Both of these studies used artificial contamination with harmless bacteria or virus and demonstrated a lower risk of contamination across all analysed parts of the body to be lesser when double-gloving was employed (RR 0.34, 95% CI 0.17-0.66).4 The CDC suggest that wearing more than two pairs of gloves may make it difficult to perform patient care. 18 Three pieces of literature, (one cross-over study (SIGN 50 level 3), one consensus document, and one expert opinion (both SIGN 50 level 4)) recommend the use of a third layer of disposable gloves. 21, 32, 39 The cross-over study by Crook et al (2023) did not provide analysis specific to the use of three pairs of gloves as the glove requirement of the two ensembles compared did not differ. All state that a third outer pair of gloves should be worn to allow changes to be made during patient care when visible contamination is present. 21, 32, 39 However, evidence supporting the choice to add a third layer of gloves is not presented within the literature that recommends this.

Aprons

Aprons in addition to coveralls are recommended in three pieces of literature. ²⁰ ³², ³⁹ This includes one cross-over study ³⁹, graded as SIGN 50 level 3, and two documents graded SIGN 50 level 4; one expert opinion ²⁰ and one consensus document. ³² The cross-over study compared an ensemble including a long-sleeved plastic apron to one including a sleeveless plastic apron using simulation exercises and fluorochrome application. Ease of removal of the long-sleeved apron was found to be higher than for the sleeveless apron. ³⁹ Further details on design features of

PPE for HCID is mentioned within the research question What standards (EN) must PPE for HCID adhere to and what design features are desirable?

Scrubs

Five pieces of literature (all graded SIGN 50 level 4) recommend that scrubs are worn under PPE ensembles rather than regular work uniforms^{3, 16, 19, 25, 40}, with two pieces of literature stating that this removed risks or issues associated with the laundering of uniforms and to absorb sweat while wearing PPE for protection against HCIDs.^{3, 19} However, neither include references to evidence that supports this claim.

RPE

One observational study (graded SIGN 50 level 3) assessed PPE ensembles that included powered air purifying respirators (PAPRs).³⁹ Crook et al (2023) evaluated two PPE ensembles that both included PAPR systems comprising of a headset unit with integrated air mover, worn under a fluid resistant hood with integrated visor. One also incorporated its powered pack (PPE ensemble 2), while this was attached to a waist belt for the other (PPE ensemble 1).39 Ensembles were donned by volunteers trained and experienced in use of HCID PPE ensembles under supervision of buddies. Fluorochrome was applied to the outer surface of already donned PPE ensembles and volunteers undertook standardised physical and manual dexterity exercises, before doffing PPE (without hand hygiene steps) under supervision and examination under UV light to evaluate fluorochrome crosscontamination.³⁹ One instance of cross-contamination was recorded for PPE ensemble 1 and five instances were recorded for PPE ensemble 2. Of these six instances, four were due to deviations in PPE doffing protocol and the remaining two could not be attributed to an observed event.³⁹ Findings of this study suggest that PAPR systems covered by a fluid resistant hood with integrated visor could be a potential alternative for respiratory, head and neck protection against HCIDs.³⁹

Contact HCIDs Ensembles

Fourteen pieces of evidence (one observational study (graded SIGN 50 level 3)³³, and 13 pieces of expert opinion (graded SIGN 50 level4).⁵ ^{16, 18, 25, 27, 28, 34-37, 40, 42, 43}) provide information specific to HCIDs that are included in the UK HCID list under "Contact HCIDs".¹ These include Ebola virus disease (EVD), Marburg virus disease (MVD) and other haemorrhagic fevers such as Argentine (Junin virus), Bolivian (Machupo virus) and Crimean Congo Fever (CCHF).¹ Evidence identified by this literature review covered Ebola virus disease and more generally, viral haemorrhagic fevers (VHF) or filoviruses.¹

The ACDP states that for VHF and other similar HCIDs the PPE or RPE combination worn must establish a barrier against contact with contaminated surfaces, splash, spray, bulk fluids and aerosol particles by providing adequate coverage of all exposed skin. PPE should also be made from materials that are resistant to penetration of relevant liquids or suspensions and aerosols.⁵

In three pieces of expert opinion (graded SIGN 50 level 4), the ensemble to be donned when a patient is suspected to be infected with EVD is presented as a surgical mask, gloves, and eye and face protection. ^{35, 36, 42} The US Occupational Safety and Health Administration (OSHA) also recommend that a gown or coverall is donned when a patient is suspected to be infected with EVD. ⁴² When risk of contamination or transmission from suspected EVD patients is deemed as high, HCWs should don a disposable respirator or PAPR. ⁴² When suspected patients present with bleeding, vomiting or diarrhoea HCWs should don double nitrile gloves, face and eye protection (goggles, face shield, etc), impermeable head or neck cover (for example surgical hood), fluid-resistant gown or coverall, impermeable apron, impermeable boot covers that extend to cover the lower leg, and respirator (disposable N95, elastomeric, PAPR). ⁴²

The ACDP state that although there is no evidence of airborne transmission of VHF, as a precautionary measure it is considered appropriate to wear RPE when managing a confirmed case.⁵

Further literature presents differing ensembles depending on level of protection deemed appropriate based on risk of transmission. In situations where there is low risk of EVD transmission two pieces of expert opinion guidance (one from the UK and one from the US) recommend that ensembles include:

- coverall⁴³
- gloves (outer gloves with extended cuff if worn)^{40, 43}
- N95/FFP respirator^{40, 43}
- eye and face protection (goggles, face shield)^{40, 43}
- boot/shoe cover⁴³
- apron⁴⁰

Where risk of transmission is high or patients have confirmed EVD infection, recommendations were provided by eight pieces of evidence including one observational study (graded SIGN 50 level 3)³³ and seven pieces of expert opinion guidance (graded SIGN 50 level 4).^{16, 25, 35-37, 40, 43} PPE ensembles for this risk level are recommended to include:

- surgical gown or coverall^{16, 25, 33, 35-37, 40, 43}
- head and neck cover, both as standalone items and integrated with coverall^{25, 33, 35, 43}
- eye and face protection such as goggles and a face shield 16, 25, 33, 35-37, 40
- N95/FFP respirator^{25, 33, 35, 43} (or surgical mask)⁴⁰,
- standard gloves^{16, 25, 35-37, 43}
- long cuff gloves^{16, 33, 35, 43}
- boot covers^{16, 35, 40, 43}
- boots^{33, 36, 40, 43}
- apron^{16, 25, 40}

An observational study by Suen et al (2018) (graded SIGN 50 level 3) compared three differing PPE ensembles to be worn when caring for patients with EVD and found that ensembles including a gown rather than a coverall resulted in fewer doffing (taking off) protocol deviations and lower rates of self-contamination.³³

Two sources provide differing RPE recommendations for protection against VHFs. The WHO, in their interim expert opinion guidance (graded SIGN level 4) for IPC during care of suspected or confirmed VHF patients, recommend donning a surgical mask prior to entering the patient's room. ¹⁶ In SIGN 50 level 4 guidance published by the WHO, surgical masks are presented as an alternative to particulate respirators when caring for EVD patients however, specific care tasks where this would be appropriate were not presented. ²⁵ In contrast, the InterAgency Board for Equipment Standardization and Interoperability (IAB) from the United States recommend either a FFP respirator or PAPR when treating patients with confirmed EVD. However, they do not provide guidance on which situations call for use of the PAPR instead of the FFP respirator. ⁴³

Upgrading from surgical mask to respirator and respirator to PAPR during high-risk procedures was recommended in two SIGN 50 level 4 guidance documents. 16, 35 High risk procedures are defined by both of these documents as those that have the potential to produce aerosols, including performing post mortems. 25, 35

In addition to the above, the CDC produced a package of guidance in 2022 (graded SIGN 50 level 4) that provides PPE recommendations for the care of suspected or confirmed EVD patients, with differences between ensembles based on symptoms presented. When patients are clinically stable the recommended PPE ensemble includes single-use fluid-resistant gown that extends to at least the mid-calf or single-use fluid-resistant coveralls without integrated hood, single-use face shield, single-use facemask, two pairs of single-use gloves (outer pair should have extended cuff).²⁷ When patients are clinically unstable the recommended PPE ensemble includes single-use impermeable gown that extends to at least the mid-calf or single-use fluid-resistant coveralls without integrated hood, PAPR or N95 respirator, two pairs of single-use gloves (outer pair should have extended cuff), single-use boot covers, single-use apron.¹⁸

The CDC recommend that emergency medical services (such as ambulance services) wear the same PPE ensemble as that recommended for health and care settings.²⁸ This recommendation is echoed by OSHA.⁴² The CDC also provide recommendations for PPE ensembles that donning and doffing buddies should wear while assisting HCWs. This ensemble includes single-use fluid-resistant gown that

extends to at least the mid-calf or single-use fluid-resistant coveralls without integrated hood, single-use face shield, single-use facemask, two pairs of single-use gloves (outer pair should have extended cuff), single-use ankle-high shoe covers.¹⁸

A case report from a US hospital outlined the plan put in place in order to care for a pregnant patient during delivery who had EVD in their recent medical history (4 months prior to delivery). PPE ensembles were provided for a wide variety of care situations, ranging from donning gloves when caring for the neonate after bathing, to wearing a face mask, face shield, fluid-resistant or impermeable gown, single or double gloves, and fluid-resistant, midcalf boot covers during obstetric procedures. In this case, delivery was successful and no transmission to staff was reported, however, it should be noted that all PCR samples collected 1 week before delivery, at delivery, and 1 day after delivery were negative for Ebola virus. IgG antibodies were detected from maternal blood 1 week before delivery, and from cord blood and amniotic fluid at delivery.

Airborne HCIDs Ensembles

Ten pieces of evidence provide information specific to HCIDs that are included in the UK HCIDs list under "Airborne HCIDs". One consensus document³², and nine pieces of expert opinion (graded SIGN level 4).^{15, 19, 23, 24, 26, 29, 38, 41, 44} These include Avian Influenza, Middle East Respiratory Syndrome (MERS), and Mpox (Clade I).¹

Four pieces of expert opinion were identified that provided PPE recommendations for ensembles to be worn when caring for patients with Avian Influenza. Across this literature it was recommended that ensembles include:

- fluid-resistant gown^{15, 24, 44}
- gloves^{15, 24, 44}
- FFP3 respirator^{24, 44}
- eye protection^{15, 24, 41, 44}
- surgical mask^{15, 41}

The ECDC also state that a fluid-resistant apron could be used as an alternative to a gown.¹⁵ Additionally, the PHAC recommend that a respirator be worn instead of a surgical mask when high-risk procedures or AGPs are being undertaken.⁴¹

For respiratory HCIDs, guidance differs on whether respiratory protective equipment (RPE) is required¹⁹ or if a fluid-resistant surgical mask (FRSM) is sufficient (except during AGPs).¹⁵ Current NHSScotland guidance (published in 2015) for severe respiratory illness caused by novel or emerging infectious agents recommends that a fit-tested, fit-checked FFP3 respirator is worn for all patient care activities.⁴⁴

Four guidance documents (graded SIGN 50 level 4 expert opinion) provide PPE recommendations for ensembles to be worn when caring for patients with MERS. Expert opinion from NSS recommends that the same PPE ensemble that is recommended for protection against Avian Influenza be worn for protection against MERS.⁴⁴ PHE guidance adds further support for this ensemble including a fluid-repellent disposable gown, non-sterile gloves, FFP3 respirator that adheres to relevant standards, disposable eye protection.¹⁹ This ensemble is also presented in other UKHSA (formally PHE) guidance for Nipah virus and plague.^{23, 29} As previously mentioned, the ensemble presented within this UKHSA guidance is not aligned with the UK unified HCID assessment PPE ensemble presented by Poller et al (2018).³²

Expert opinion from members of The Korean Society of Nephrology recommends that HCWs that are involved in dialysis therapy for MERS-CoV patients should don appropriate PPE which includes gloves, goggles or face shield, gown, and a 'highly efficient face mask'.³⁸

Guidance from the CDC (graded SIGN 50 level 4 expert opinion) provides recommendations on the PPE ensemble that should be donned while caring for patients with Mpox. This ensemble includes a gown, gloves, eye protection, and N95 (or higher rated) respirator.²⁶

It was concluded in the NIPCM RPE literature review that valved respirators should not be worn when source control is required, as expelled air is unfiltered. Further information on valved and unvalved respirators can be found within the NIPCM RPE literature review.

General HCID Ensembles

A Cochrane systematic review with meta-analysis by Verbeek et al (2020) analysed the protective effect offered by different types of PPE as assessed in 4 simulation studies (one randomised control trial, three cross-over studies).⁴ PAPRs paired with coveralls were found to provide greater protection against contamination when compared to an N95 mask paired with a gown (RR 0.27, 95% CI 0.17 to 0.43). It should be noted however, that PAPR paired with coveralls were reported to be more difficult for healthcare workers (HCWs) to don (put on), leading to issues with compliance. ⁴ It was also found that gowns may provide greater protection against contamination than aprons. It should be noted that the Verbeek et al (2020) Cochrane review graded the certainty of evidence included in the review as low or very low.⁴

A study undertaken using simulated body fluids to test five different PPE ensembles from UK health and care centres identified key features which may be important for an effective PPE ensemble for HCIDs.

- Head and neck protection in the form of a fluid-resistant hood was more effective than ensembles using a cap.
- Aprons should be worn to provide additional protection to critical areas.
- Aprons should cover the tops of boots.
- Boot covers should not be worn alone and their removal when worn over boots has been associated with contamination events.³⁰

In 2018, a unified HCID assessment PPE ensemble was agreed across the UK based on studies carried out on the different UK HCID surge centre ensembles devised during the 2014-15 Ebola crisis.³⁰⁻³² The agreed ensemble consists of:

- an FFP3 respirator
- Anti-infection Transfer (AIT) hood
- disposable longer-length full face visor with wide band
- rear fastening reinforced surgical gown of fluid-resistant material, long enough to overlap boots

- wide, extra-long medium thickness plastic apron (such as worn for endoscopy)
- three layers of gloves:
- inner personal protection glove (standard short non-sterile glove)
- middle glove (long-cuffed glove), taped to gown
- outer glove comprising either standard short non-sterile gloves for basic
 care, or heavier duty gloves for cleaning up of extreme body fluid episodes
- Wellington boots (must be long enough to be overlapped by gown.)³²

In their consensus document outlining the UK unified HCID assessment PPE ensemble, Poller et al (2018) present the process of gaining consensus on a single ensemble of PPE for HCIDs. This included administering a questionnaire to Infection Control Leads of NHS boards and trusts across the UK, which resulted in 29 responses and 28 unique PPE protocols for patients suspected or confirmed to be infected with a HCID.³² Since there was such a wide range of protocols, five were chosen for further simulation testing by Hall et al (2018): four from designated Ebola surge capacity centres and one from a unit with significant experience in assessing suspected (then later confirmed) Ebola patients.³⁰ Consensus from the findings of Hall et al (2018) was confirmed across an expert group made up of NHS doctors and nurses with experience working with confirmed VHF patients (representing infectious diseases, microbiology, virology, and IPC teams), HSE laboratory representatives, HSE specialist microbiologists, and PPE experts. Meetings of this expert group were chaired by the Deputy Head of the Emergency Response Department at Public Health England (PHE).³² This ensemble is presented as suitable for use in protection against all HCIDs, unrelated to mode of transmission.

It should be noted that at the time of writing, some infectious agent specific UKHSA guidance contains PPE content which is currently not in line with this 2018 unified HCID assessment PPE ensemble. In UK expert opinion guidance (graded SIGN 50 level 4) relating to MERS, Nipah virus, plague, and avian influenza it is recommended that HCWs don an ensemble including a fluid repellent disposable gown, non-sterile gloves (single pair unless items are to be disinfected prior to

removal from the patients room), FFP3 respirator that adheres to relevant standards, and disposable eye protection. 19, 23, 24, 29

Summary

The majority of available evidence relevant to this research question was SIGN level 4 expert opinion guidance from UK, and international sources. This limits the ability to make evidence-based recommendations.

However, the available literature is consistent that PPE ensembles donned when providing care to a patient who is suspected or confirmed to be infected with a HCID should create a complete barrier and should be decided upon based on risk assessment. While infectious agent specific guidance on PPE ensembles differs, the following items are recommended for use during HCID patient care, regardless of the infectious agent: gloves, gown or coverall, respirator, eye and face protection.

Beyond this there are varying additional items that could be added to an ensemble depending on infectious agent or severity of patient illness. This includes boots, boot covers, aprons, and head and neck protection for contact HCIDs, and upgrading RPE to PAPR systems in the event of AGPs. There is variation in the literature regarding the number of pairs of gloves to be worn, and insufficient evidence available to assess this. The 2018 UK unified HCID assessment PPE ensemble provides a PPE ensemble that is presented as offering personal protection against HCIDs by including gloves, respirator, gown, hood, full-face visor, apron, triple gloving, and boots.

3.1.4 What standards (EN) must PPE for HCID adhere to and what design features are desirable?

In total, 17 pieces of evidence were included for this research question. Nine pieces of evidence were identified within previous versions of this review^{3, 5, 14, 18, 45-48}, including one that was excluded during this update and three that were updated. ^{14, 18, 45} Eight additional pieces of evidence were identified during this update. ^{17, 25, 32, 43, 49, 50} Of the included evidence three are mandatory UK legislation ^{13, 14, 50}, and one cross-over study graded SIGN 50 level 3. ³⁹ One consensus document, from

Poller et al (2018) that outlines the UK unified HCID assessment PPE ensemble was graded SIGN 50 level 4 expert opinion.³² Eight guidance documents graded SIGN 50 level 4 expert opinion.^{5, 17, 18, 25, 43, 45, 46, 48, 49 51}

All PPE Items

As per The Personal Protective Equipment at Work (amendment) Regulations 2022 and UK Government guidance on CE marking, all PPE must bear a 'CE' mark that signifies compliance with the Personal Protective Equipment (Enforcement) Regulations 2018.^{14, 45, 50} This demonstrates conformance with the relevant European (EN) or International (ISO) standards. ^{14, 45, 50}

No standards were identified that specifically covered PPE for the use in HCID ensembles at the time of writing. Standards relating to individual items of PPE can be found in relevant **NIPCM literature reviews**.

WHO guidance (SIGN 50 level 4) and Poller et al (2018) (SIGN 50 level 3) advise that a variety of sizes of all PPE items should be available to accommodate as many members of staff as possible without impeding on the protective effect of PPE ensembles.^{25, 32} According to mandatory UK government legislation and expert opinion from the HSE (SIGN 50 level 4), in order to be worn together without compromising protective effect, different PPE items should be compatible. 13, 45 The ACDP adds that components of a PPE ensemble (for example full-body clothing, gloves, footwear, face and eye protection, respiratory protection) should be designed in a way that maintains barrier protection when interfaced. For example, coverall or gown sleeves should be long enough to be overlapped by glove cuffs. 5 Any fit adjustment systems included as part of PPE must be designed in a way that ensures they cannot be adjusted incorrectly without the knowledge of the wearer. Mandatory UK Government legislation, and expert opinion from HSE and Reidy et al (2017) (SIGN 50 level 4) state that areas of PPE that are in direct contact with the user must be free of rough or sharp edges, and free of any other features which may cause excessive irritation or injuries. 13, 45, 49 Furthermore, mandatory UK government legislation and HSE expert opinion (SIGN 50 level 4) notes that any items of PPE that enclose areas of the body to provide appropriate protection must be sufficiently

ventilated to avoid user perspiration, and where this is not possible, items should be able to absorb perspiration. 13, 45

The mandatory PPE at Work Regulations 1992 (as amended) (2022) state that PPE must provide adequate protection for all possible risks and be designed in a way that allows the wearer to perform their role normally without compromising protection. ^{13, 45} Any impediment to movement, posture, vision, or other sensory perception must be minimised as far as possible. ^{13, 45} It should be noted that the PPE at Work Regulations 1992 (as amended) do not cover respiratory protective equipment (RPE), apart from the need for compatibility with different items of PPE. ^{13, 45} Instead, RPE is covered by SIGN 50 level 4 graded guidelines from HSE titled 'Respiratory Protective Equipment at Work: A Practical Guide'. ⁴⁶ Similarly to the PPE at Work Regulations, this document states that RPE should provide adequate protection for the risks present and be suitable to the wearer, task, and work environment. ⁴⁶

RPE and surgical Masks

Evidence regarding the relevant standards and design specifications of RPE and surgical masks generally are covered within the relevant NIPCM PPE literature reviews.

WHO expert opinion states that particulate respirators used during the care of patients with filovirus disease (for example EVD) should be breathable and fluid resistant (minimum 80 mmHg). It is also stated that particulate respirators should use a structured design that will not collapse easily.²⁵

Expert opinion from the WHO recommends that, similar to RPE, surgical masks worn for the care of patients with filovirus infection should have a structured design so masks do not collapse against the wearers mouth.²⁵ These should also have good breathability and be fluid-resistant, particularly when paired in an ensemble with goggles. It is noted that fluid resistance is not required when a surgical mask is being paired with a full-face shield.²⁵

Eye and Face Protection

According to the UK unified HCID assessment PPE ensemble, a full-face visor should have a wide strap to aid in removal and should extend a minimum of 2cm below the chin.³² Face shields should be made from clear plastic to not impede vision and have an adjustable head band.^{32, 49} The WHO also state that fog-resistant face shields are preferrable.²⁵ Face shields should extend long enough to cover the length of the face and wide enough to cover the sides of the face.²⁵

The WHO further state in their expert opinion guidance regarding PPE to be used during filovirus outbreaks, that if goggles are being used these should be flexible enough to fit and provide good seal to the face of any wearer and have an adjustable but secure head band.²⁵ Goggles should accommodate prescription glasses while not compromising protective effect.²⁵

Gloves

As part of the UK unified HCID assessment PPE ensemble, it is recommended that for gloves, inner and outer layers are regular short cuffed non-sterile gloves however, the middle layer should be a long-cuffed glove to allow for overlap with gown sleeves and taping.³² While three layers of gloves are not recommended by the WHO in their expert opinion for caring for patients with filovirus infection, the second (outer) glove should have a longer cuff to allow for overlap with gown sleeves.²⁵ Within this expert opinion it is also recommended that nitrile non-powdered gloves are used over latex or powdered gloves both for protective effect and to avoid risk of HCW allergy.²⁵ The WHO recommendations on gloves are echoed by Reidy et al (2018) in their expert opinion paper outlining suitable PPE ensemble for treatment of patients with EVD.⁴⁹ The UK PPE and Work Regulations 1992 (as amended) state that glove materials should be chosen with wearer allergies in mind. Where latex gloves are chosen, these should be non-powdered to limit risk or allergic reaction.^{13, 45}

Further information on glove materials is available within the <u>NIPCM Gloves</u> <u>Literature Review</u>.

Footwear

PPE at Work Regulations 1992 (as amended) state that comfort of the wearer should be taken into account when choosing footwear. Footwear should be flexible to aid in donning and doffing, along with having the ability to absorb perspiration to ensure comfort. Protective footwear should be water resistant. ^{13, 45}

Expert opinion guidance from the WHO, CDC and Reidy et al (2017) on PPE to be worn to protect against filoviruses states that protective footwear should cover the entire foot and ankle of the wearer and the material of protective footwear should be resistant to cuts and punctures. ^{18, 25, 49} In the UK unified HCID assessment PPE ensemble it is recommended that boots be tall enough to achieve an overlap with gown and apron. ³² Boots or protective footwear should be large enough to facilitate slip-on/step-out donning and doffing but not large enough to increase the risk of trips. ^{25, 32, 49} It is also noted that visible contamination is easier to identify on footwear that is a light or bright colour. ⁴⁹

Gowns and Coveralls

The ACDP state that the materials from which PPE for VHF is made should resist penetration of relevant liquids or suspensions and aerosols.⁵ Disposable, fluid-resistant gowns should be resistant to liquid penetration and should have achieved a hydrostatic pressure test result of ≥20cm; this is equivalent to a "standard performance" surgical gown that is compliant with EN 14126.⁵² Coveralls suitable for protection against HCIDs typically achieve the highest classification for protection against biological agents in accordance with EN 14126:2003; this is usually described in the manufacturer's technical notes as type 3-B, 4/5/6.⁵² The WHO also recommend that gowns or coveralls are made from fluid-resistant materials and should be tested for protection against penetration by blood and body fluids.²⁵

In addition to providing sufficient barrier protection, gowns for managing cases of HCIDs should be back-fastening with a high neckline and be of sufficient length to achieve a 10-15cm overlap of the gown with the wellington boots.³² The WHO provide expert opinion on gowns, coveralls, and aprons to be used while caring for patients with filovirus disease. All of these items should be tested to the levels of relevant standards for fluid penetration or resistance to penetration by blood-borne

infectious agents.²⁵ The WHO also suggest that light colours may be preferrable in order to visually detect contamination more efficiently.²⁵

In their expert opinion guidance (SIGN 50 level 4) on PPE for protection against Ebola, the CDC recommends that gown and coverall cuffs, zips, storm flaps and similar items should be constructed of the same material as the rest of the garment or have an equivalent resistance to penetration by fluid or biological materials. ¹⁸ Expert opinion (SIGN 50 level 4) from the CDC, the WHO and Reidy et al (2017) on filoviruses notes that coveralls with integrated thumb hooks or finger loops should be considered, these prevent sleeves from riding up and exposing the bare forearm during patient care. ^{18, 25, 49} Consideration must also be given to garment properties such as seams. Expert opinion (SIGN 50 level 4) from the CDC and Reidy et al (2017) state that it is essential that all seams or closures provide similar barrier protection to the fabric itself, using for example welded or double taped seams. ^{48, 49} Placement of the blower unit of a powered respirator (self-contained or externally belt-mounted) will determine the order of donning and doffing, and the required decontamination. ¹⁸

A cross-over study by Crook et al (2023) (graded SIGN 50 level 3) compared an ensemble including a long-sleeved plastic apron to one including a sleeveless plastic apron using simulation exercises and fluorochrome application.³⁹ Ease of removal of the long-sleeved apron was found to be higher than for the sleeveless apron.³⁹ Sleeve length was not mentioned within other evidence that recommended aprons (one consensus document³² and one expert opinion document⁴⁹, both graded SIGN 50 level 4), however the consensus document did note that aprons should be wide, extra-long, and of medium thickness, similar to those worn for endoscopy procedures.³² The expert opinion only recommends a fluid-resistant apron.⁴⁹

Headwear

WHO expert opinion (SIGN 50 level 4) on PPE for protection against Ebola recommends that protective head coverings are fluid resistant and adjustable while remaining in place during care tasks. Expert opinion (SIGN 50 level 4) from WHO and Reidy et al (2017) states that headwear should extend to the top of the gown or coverall that is also worn as part of the PPE ensemble.^{25, 49} According to the UK

unified HCID assessment PPE ensemble, the hood used for head protection should be adjustable and fasten at the front.³²

Summary

The majority of evidence relevant to this research question was mandatory (legislation or guidance) or expert opinion. A single piece of primary evidence was identified as relevant to this research question (one cross-over study graded SIGN 50 level 3), meaning evidence-based recommendations for design specifications desirable or required specifically for PPE for HCIDs are not possible.

The majority of expert opinion discussed as part of this research question was relevant to Ebola or Filoviruses more generally. Within this evidence, it is noted that:

- RPE and face masks should be breathable and fluid-resistant with a structured design
- full-face visors should have a wide strap and extend 2cm below the chin and be wide enough to cover the sides of the face. The WHO also recommend that these are fog-resistant
- goggles should be flexible, provide a good fit and seal to the face. Their headband should be adjustable but secure. If required, goggles should accommodate for prescription glasses without compromising protective effect
- inner and outer gloves should be regular short-cuffed gloves, however,
 middle pair of gloves should be long-cuffed to allow for overlap with gown sleeves and taping
- boots should be tall enough to achieve overlap with the apron and should be large enough to facilitate step-in donning and step-out doffing
- coveralls or gowns should be made from materials resistant to penetration
 of liquids and aerosols as per relevant standards. They should be back
 fastening, have a high neckline and be of sufficient length to achieve a
 10-15cm overlap with wellington boots.

 headwear should also be made from materials resistant to penetration of liquids and aerosols. They should be adjustable and fasten at the front

As per mandatory UK guidance, all PPE chosen to be used within UK health and care settings must bear the 'CE' mark and adhere to relevant British (BS), European (EN) or International (ISO) standards. There is little consensus across the literature on design features that are preferable when selecting PPE for ensembles protecting against HCIDs, with a number of design characteristics presented. However, the literature is consistent in stating the following:

- any design characteristics should not impact upon protective effect and must allow the wearer to perform their role normally
- health and care facilities should provide PPE in a range of sizes to accommodate as many members of staff as possible
- any systems to adjust PPE fit must be incorporated in a way that ensures they cannot be adjusted without the knowledge of the wearer and in a way that does not impact on protective effect

3.1.5 How should different elements of PPE be integrated/interfaced and how should this be done (for example, use of tape)?

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, 13, 17, 25, 53}, including two that have been updated.^{13, 17} Three additional pieces of evidence were included during this update.^{30, 32, 43}

Of the included evidence, one is mandatory legislation¹³, one is an observational experimental study graded SIGN 50 level 3 evidence.³⁰ Seven documents were graded SIGN 50 level 4 expert opinion and included one case report, one consensus document, two pieces of expert opinion and three expert opinion guidance documents.^{3, 5, 17, 25, 32, 43, 53} The majority of evidence included was graded SIGN 50 level 4 and consisted of expert opinion guidance from UK, US, and international sources. This evidence has inherent limitations in its guality and presentation.

The mandatory Personal Protective Equipment (PPE) at Work Regulations 1992 state "Every employer shall ensure that where the presence of more than one risk to health or safety makes it necessary for their employee to wear or use simultaneously more than one item of personal protective equipment, such equipment is compatible and continues to be effective against the risk or risks in question." The CDC advises that employers and HCWs should consider how the garment will interface with other elements of PPE such as gloves with the sleeves of the gown, or respiratory protection with the hood. The interfaces will determine the users overall protection. 48

There is variation in extant guidance regarding the use of tape to secure the interface between PPE for HCID. The WHO (SIGN 50 level 4) state that adhesive tape should not be used to attach gloves to the sleeves of coveralls, if the inner gloves or coverall sleeve are too short they recommend making a thumb hole (or utilise thumb or finger loops if available) to ensure forearms are not exposed when making wide movements.²⁵ The ECDC recommends the extensive use of parcel tape to secure inner gloves to coveralls, adjust coverall size (hoods) and to seal small gaps and interfaces around the face, gloves and boots.3 However, the ECDC acknowledge that there are potential safety issues with the use of tape. 'Over-taping' near the respirator can make breathing difficult or cause the respirator to lose its seal. Taping too tightly or using too much tape can complicate the doffing process. and removing tape can delaminate the surface of protective clothing potentially reducing its barrier function.³ Guidance from IAB in the US (graded SIGN 50 level 4 expert opinion) recommends taping outer gloves into place over coverall sleeves in ensembles for both high and low risk interactions with EVD patients. Additionally, they suggest that the legs of coveralls should be taped over boots or foot covers when sock like extensions are not present on selected footwear. They also recommend taping the hood or coveralls to face protection but highlight that tape should not be used to secure respirators. Hoods should be integrated with coveralls unless a PAPR is being used.⁴³ The UK unified HCID assessment PPE ensemble recommends taping the middle pair of (three) gloves to the gown sleeves using four pieces of micropore tape placed lengthwise (from wrist towards elbow) across cuff of glove and forearm of the gown to enable doffing of both items in a single step.³²

Following admission of the first imported case of EVD to the US and subsequent transmission to two HCWs the hospital involved reviewed its PPE protocols. The case report (SIGN 50 level 4) details that the tapes being used were either too adhesive and would tear gloves on removal, or the tape itself would tear creating doffing issues. PPE protocols were altered to utilise thumb holes rather than tape.⁵³

In a simulation exercise to test different ensembles from UK HCID 'surge' centres, users (HCWs) felt that taped gloves were more secure and led to easier doffing but the study also reported tearing of gloves and that circumferential taping (around the wearers wrist or forearm) could risk making sleeve removal difficult if taped too tightly.³⁰

Summary

There is a lack of primary research available for the assessment of methods and approaches to integrating PPE for HCID. The available literature (1 simulation study, 1 case report, 4 extant guidance) highlights both the intended benefits (secure interface) and the potential risks (PPE tearing and damage) of using tape to secure the PPE interface.

However, the literature (including mandatory UK legislation) is consistent in recommending that all items of PPE worn together must be compatible with each other and the wearing of one should not impact upon the protective effect of another, or that of the overall ensemble. Recommendations for the use of adhesives to attach different items of a PPE ensemble across the available literature are inconsistent.

3.1.6 How should PPE be donned (put on) and doffed (taken off)?

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, 18, 20, 21, 25, 54} including updates of one systematic review⁴ and one piece of expert opinion.¹⁸ Twenty-two additional pieces of evidence were included within this update.^{19, 27, 28, 32, 33, 35, 37-39, 41, 43, 44, 49, 54-62}

Of this included evidence, one systematic review with meta-analysis was graded level 1+ evidence⁴, and 11 pieces of evidence graded SIGN 50 level 3 (1 cross-sectional study⁶, 1 brief report²¹, 1 time-series analysis⁵⁸, 1 non-randomised trial⁶³, 1 case report⁵⁹, 6 observational studies^{33, 39, 54-56, 64}). The 19 remaining pieces of evidence were graded SIGN 50 level 4 expert opinion, of which two were posters providing donning and doffing protocols set out in the Poller et al (2018) consensus document in picture form.^{3, 5, 18-20, 25, 27, 28, 32, 35, 37, 38, 41, 43, 44, 49, 60, 61, 62}

The UK ACDP (SIGN 50 level 4) state that a detailed and pre-defined sequence for donning and doffing should be developed, implemented and monitored.⁵

A 2020 Cochrane systematic review found that using the CDC doffing protocol was associated with a reduced risk of contamination compared to doffing without following a protocol. Evidence to support the finding was from a single observational study.⁴ Tomas et al (2015) observed that contamination was less frequent when participants followed CDC doffing protocol correctly compared to those who followed the same protocol with errors.⁵⁴

Location

Eight pieces of literature (2 observational studies^{55, 57} graded SIGN 50 level 3 and 6 expert opinion^{19, 44, 20, 35, 37, 60} graded SIGN 50 level 4) provide evidence on the location in which donning or doffing should take place. Two observational studies (graded SIGN 50 level 3) assessed contamination of HCW and their surrounding environment when doffing PPE. In one, contamination was found to be present in the doffing environment which may indicate that doffing should take place in an area that can be easily decontaminated to reduce risk of transmission from the environment.⁵⁷ The second concluded that the recommended doffing protocol should include doffing PPE in the patient care area up until removal of coveralls, then moving to an anteroom to complete doffing of PPE.⁵⁵ Four pieces of expert opinion guidance (graded SIGN 50 level 4), from the US, Italy and an international source recommend that donning and doffing PPE should be undertaken in an area completely separate from the patient area.^{20, 35, 37, 60} Three expert opinion guidance state that doffing should be started in the patient area before moving to a separate space to complete doffing.^{19, 44, 55} Extant guidance published by NSS⁴⁴ and PHE¹⁹ recommend that

doffing of all PPE apart from FFP3 respirator should be done within the patient area and the respirator should be doffed outside of this area. One expert opinion notes that the doffing of PPE by personnel transporting HCIDs patients under investigation (PUIs) should be facilitated by the receiving unit and agreed upon before patient arrival.³⁵

Donning and doffing assistance

It is consistently recommended in literature (1 observational study³⁹ and 1 brief report²¹both graded SIGN 50 level 3, and 1 consensus document³² and 8 guidance documents graded SIGN 50 level 4^{3, 18, 20, 25, 35, 37, 43, 49}) that a trained observer or 'buddy' should be present for donning and doffing of PPE for HCIDs. The buddy may actively assist in the donning and doffing process and/or may serve to instruct the HCW and record adherence to the protocol.^{3, 20, 21, 25, 28, 32, 35, 37, 39, 43, 49} The CDC recommend that the buddy should not be actively involved in doffing but only provide verbal instructions.¹⁸ Verbeek et al note that spoken instruction from a trained buddy may lead to fewer doffing errors and decreased contamination.⁴ A time-series analysis (graded SIGN 50 level 3) by Xi et al (2016) found that real-time monitoring of PPE doffing (via video) and communication with HCWs when doffing errors occur can reduce doffing error rate.⁵⁸

Location of donning and doffing is closely linked with the ability to provide donning and doffing assistance. Where active assistance is recommended, donning and doffing would be required to be undertaken outside of the patient room so that the assisting HCW is not required to enter the area of a patient with suspected or confirmed HCID infection.

Donning

Before donning (putting on) PPE, expert opinion (8 guidance documents^{3, 18, 20, 25, 27, 38, 55, 56} graded SIGN 50 level 4 expert opinion) is consistent in advising that HCWs should put on clean scrubs, remove any jewellery and pens and perform hand hygiene, they should also ensure they are well hydrated.^{3, 18, 20, 25, 27, 38, 55, 56} There was limited consistency in the order for donning PPE in the identified protocols, this is largely due to the variation in the PPE combinations used.

A detailed donning guide was produced by PHE (now UKHSA) in 2018 supporting use of the national UK ensemble.³²

Before putting on PPE, PHE recommend that the HCW should:

- ensure they are hydrated, have been to the toilet and feel well to enter the patient's room
- if necessary, change into scrubs. Tie back long hair and remove any jewellery, ID badges or lanyards
- perform hand hygiene and cover any cuts or abrasions with a waterproof dressing⁶²

The sequence recommended for donning the UK unified HCID assessment PPE ensemble is:

- 1. wellington boots
- **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', that is 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 (glove choice is task specific)⁶²

The chosen glove to be donned as outer or third layer may differ depending on the task being performed. For example, standard non-sterile gloves would be worn for general patient care, while longer heavy-duty gloves may be worn to undertake cleaning of body fluids.³² Further guidance on glove choices depending on task can be found in the NIPCM literature review on **Gloves**.

A buddy or observer should run through each step to ensure each item is donned correctly, once all checks are complete the buddy should write the time on the shoulder of the HCW.⁶²

Doffing

There was limited consistency in the order for doffing PPE in the identified protocols, this is largely due to the variation in the PPE combinations used. However, it was consistently recommended that when doffing:

- PPE should be inspected for damage and/or contamination before removal, any visible contamination should be removed with disinfectant wipes before proceeding^{3, 18, 20, 25, 27, 33}
- hand hygiene (or disinfection of gloves) using hand rub must be performed after each contact with PPE,^{18, 25, 41} alternatively, some protocols recommend changing outer gloves rather than hand hygiene^{3, 18, 21}
- care must be taken to avoid touching potentially contaminated areas such as the outside of the coveralls or gowns or front-facing areas of respirators or masks and eye protection.^{18, 20, 25, 49}
- the removal of gowns or coveralls must be done carefully by peeling or rolling away from the body taking care to only touch the inside of the garment. Similarly, items of PPE such as eye or face and respiratory protection should only be handled by the ties or elastics ^{3, 18-21, 25, 49}

These findings were reflected in a survey of European isolation facilities which found that doffing sequences varied considerably but there was general consensus that contact between contaminated gloves or hands with facial and respiratory protection should be avoided, and that hand hygiene should be performed after each contact with potentially contaminated PPE. In addition, it was recommended that goggles and face shields should be removed early in the sequence as survey respondents reported that they can be cumbersome and can impair vision and therefore PPE removal.⁶

There is differing guidance on the use of sharps such as scissors as doffing aids. The ECDC suggest the use of scissors to cut away coveralls from the back while doffing, and the IAB suggest that PPE could be cut to aid in doffing.^{3, 43} In contrast, the CDC state that scissors must never be used to remove tape or any item of PPE, in order to avoid damage of other gloves and PPE still to be doffed.¹⁸

A Cochrane systematic review by Verbeek et al (2020) reported that removing gown and gloves as a single step may reduce the risk of bacterial contamination (RR 0.20, 95% CI 0.05-0.77) when compared to doffing separately. However, the same reduction was not found in studies that used fluorescence as a surrogate for bacterial contamination (RR 0.98, 95% CI 0.75-1.28).⁴

Three pieces of expert opinion guidance advise to disinfect gloves using a solution that does not degrade glove material between each doffing step rather than performing hand hygiene or changing gloves.^{20, 27, 43} In their systematic literature review, Verbeek et al noted that disinfecting gloves with quaternary ammonium or bleach may decrease presence of contamination on gloves however, the same decrease may not be seen when using hand rub.⁴

A detailed doffing guide was produced by PHE (now UKHSA) in 2018 supporting use of the national ensemble.³²

A buddy should assist (without touching) in the removal of PPE. The sequence recommended for doffing the UK unified HCID assessment PPE ensemble is:

- 1. remove apron. Pull forward from the front of the apron to break the neck and waist ties. Roll the apron in on itself taking care to touch the inside only
- 2. outermost gloves (third pair) using the 'pinch and pull' method
- **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,

- taking care to touch the inside of the gown only. The second pair of gloves 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 hand rub (dispensed by a buddy)
- **8.** FFP3 mask. Standing up straight, bring the bottom string of the respirator up to the top string and lift these to the top of the head. Lift the strings over the top of the head and allow the mask to fall away
- 9. wellington boots
- **10.** perform hand hygiene⁶¹

It is not clear how Poller et al (2018) came to these donning and doffing protocols however, both sequences are largely similar to those seen in other published literature by Suen et al (2018), Casanova et al (2018), and Casanova et al (2018).^{33, 55, 56}. However, there is a degree of consistency in the available evidence (1 brief report²¹ graded SIGN 50 level 3 and, nine guidance documents^{3, 18-20, 25, 27, 41, 44, 49} graded SIGN 50 level 4 expert opinion) that RPE should be donned later in the protocol than that recommended by Poller et al (2018), usually after donning of a gown.^{3, 18-21, 25, 27, 41, 44, 49} Protocols for ensembles that required fewer items of PPE do present more significant differences. However, this is to be expected given the 'missing' steps that would not be required for these ensembles.^{19, 25, 41, 44}

One observational study differs by removing boots at the start of the process and having HCWs stand on a "chemical mat"⁵⁵ while another recommends removing footwear after removing the gown.³³ Expert opinion written in response to the UK military medical personnel involvement in the response to EVD recommends starting

the doffing process with scraping the soles of boots before stepping into a chlorine bath.⁴⁹

Three observational studies (graded SIGN 50 level 3) recommend protocols that include decontaminating gloves or performing hand hygiene between each doffing step.^{33, 55, 56} Additionally, Suen et al (2018) also recommend performing hand hygiene between each doffing step.³³ Expert opinion guidance also suggests that hands or gloves should be decontaminated between each doffing step.^{18, 20, 25, 49}

Summary

Extant guidance is consistent in advising that a protocol for donning and doffing should be implemented and monitored for compliance within health and care settings. A trained observer or 'buddy' should be present during donning and doffing to provide support and ensure HCWs don and doff PPE correctly. Prior to donning, HCWs should remove uniform and don scrubs, perform hand hygiene, and remove any jewellery, pens, or ID badges. There is wide variation in doffing protocols across the available literature, with differences frequently being as a result of different components of PPE ensembles.

There is some variation in recommendations regarding location of doffing, however, all identified evidence recommends that PPE is either wholly or partially doffed outside of the patient care area.

3.1.7 How should PPE for HCIDs be stored?

One guidance document was included for this research question, which was added for the first time as part of this update.⁵ The guidance document was published by the Advisory Committee on Dangerous Pathogens (part of the Health and Safety Executive) and is graded as SIGN 50 level 4 expert opinion.⁵

In their guidance on management of hazard group 4 viral haemorrhagic fevers, the ACDP state that PPE should be stored in a way that protects it from damage and contamination. It should be stored off the floor in a designated, clean, and dry area.⁵

ACDP state that any PPE that is used infrequently should be subject to stock rotation to ensure there is no deterioration in protective effect when required for use.⁵ RPE equipment should be thoroughly examined, tested, and maintained at regular intervals to ensure protective effect when required for use and a record of this testing should be kept for at least 5 years. If any PPE is found to be defective it should be repaired or replaced.⁵

There was limited evidence available relevant to storage of PPE specifically needed for ensembles protecting against HCIDs. However, storage of PPE is covered by other NIPCM PPE literature reviews.

Summary

Limited evidence was available to inform recommendations regarding the storage of PPE for HCIDs. The one included guidance document stated that PPE should be stored in a clean and dry 'safe' place where it will not get damaged. Stock rotation of single-use PPE is essential to ensure that there is no degradation in protective effect.

3.1.8 How should single-use PPE for HCIDs be disposed of?

Seven pieces of evidence were included for research question. Two pieces of evidence were identified within previous version(s) of this review.^{5, 19} An additional five pieces of evidence were identified within this update.^{40, 65-68} Of the included evidence that was relevant to this research question, one is considered mandatory in the UK.⁶⁸ The remaining six pieces of evidence were graded as SIGN 50 level 4 expert opinion. ^{5, 19, 40, 65-67}

The majority of evidence identified as relevant to this research question was graded as SIGN 50 level 4 which carries with it inherent limitations. It is unclear across these documents where primary research may have been used to inform expert opinion recommendations. All of the literature identified as relevant to this research question was written for or by UK settings and all but one was published to inform practice

within health and care settings, meaning their recommendations are directly applicable to NHSScotland.

As per three pieces of SIGN 50 level 4 expert opinion UK guidance, including Scottish SHTN-03-01 waste management guidance, PPE must be disposed of into the same waste stream as other healthcare waste produced from the management of a patient with a HCID, in accordance with local waste management policy. 19, 40, 65

Four guidance documents (graded SIGN 50 level 4 expert opinion) advise that PPE used during care of a patient with a suspected or confirmed HCID should be considered infectious clinical waste, even in cases where visible contamination with infectious blood or body fluids is not present. ⁵ ^{40, 65, 66} It is prohibited, under the mandatory legislation Landfill (Scotland) Regulations 2003, to send infectious waste directly to landfill for disposal. ^{65, 68} As such, waste should be disposed of in orange or yellow infectious waste streams. ^{65, 66} Categorisation into yellow or orange waste stream is decided based on the category of waste as outlined by the UK Carriage of Dangerous Goods and Transportable Pressure Equipment Regulations 2009 (as amended). ⁶⁷ Category A waste is that which is contaminated with an infectious substance that "is capable of causing permanent disability, life-threatening or fatal disease to humans or animals." ⁶⁷ Category A waste should be disposed of in the yellow waste stream and should undergo specialist treatment for safe disposal. ^{65, 66}

Most ACDP Hazard Category 4 and some Category 3 infectious agents fall under Category A infectious agents. ⁶⁵⁻⁶⁷ However, it should be noted that only cultures of Yersinia pestis are considered Category A waste and so PPE generated from care of a patient infected with this infectious agent would be disposed of in the orange waste stream. ^{66, 67}

A number of HCIDs are considered Category B as these infectious agents are defined as those that do "not meet criteria for inclusion in Category A". ⁶⁷ Category B waste should be disposed of in the orange waste stream and should be rendered safe before final disposal. ^{65, 66}

The ACDP Approved List of biological agents is available.

The ACDP provide limited information on waste disposal within their guidance for management of viral haemorrhagic fevers however, they do state that single-use items of PPE should be used where possible and only when these provide adequate protection.⁵

For further guidance on safe disposal of waste, including PPE, see the NIPCM <u>safe</u> <u>disposal of waste</u> literature review.

Summary

There is some consistency across the identified literature that PPE for HCIDs should be disposed of in accordance with local policy. Waste generated during the care of a patient infected with a HCID, including PPE, should be considered infectious, disposed of within the clinical waste stream (yellow or orange) and undergo treatment to be rendered safe before disposal.

3.1.9 How should reusable PPE for HCIDs be managed/processed?

Four pieces of evidence were included for this research question. Three pieces of evidence were identified within previous version(s) of this review.^{5, 19, 40} An additional consensus document was identified within this update.³² All included evidence was graded SIGN 50 level 4 expert opinion. ^{5,19, 32, 40}

There was limited literature identified as relevant to this research question and all of this literature was graded as SIGN 50 level 4. This limits the ability to provide evidence-based recommendations for practice in response to this research question.

Some items of PPE used for HCIDs may be considered reusable for example PAPR, goggles, and wellington boots however, extant guidance advises that wherever possible PPE should be single-use disposable.^{5, 19, 40} If reusable items of PPE are used these must be decontaminated after each use, following the manufacturer's instructions; a protocol for decontamination must be in place and responsibility assigned.^{19, 40}

As part of their recommendations for the UK unified HCID assessment PPE ensemble, Poller et al (2018) recommend that only wellington boots should be considered reusable PPE. However Poller et al (2018) also recommend that these

should only be decontaminated and reused if used during care of a suspected HCID patient who ultimately return negative testing results. While results are unknown, wellingtons should be stored in a designated container.³²

The ACDP advise that methods of decontamination, and products used as part of these, should be validated as effective against the suspected or confirmed contaminating infectious agent and should not degrade PPE or compromise future effectiveness.⁵

Summary

It is recommended in extant guidance that, wherever possible, PPE used during the care of HCID patients should be single-use and disposable. Where reusable PPE is used, it should be decontaminated following manufacturer's instructions after each use.

3.1.10 How is 'competence'/competency' defined and measured regarding PPE for HCIDs?

Three evidence sources were included as relevant to this research question. Two guidance documents from the UK HSE were included within previous versions of this review.^{69, 70} Both were graded SIGN 50 level 4 evidence in accordance with SIGN methodology. One piece of additional evidence relevant to this research question was identified within this update from the UK National Occupational Standards (NOS).⁷¹ This was also graded SIGN 50 level 4 expert opinion.

The HSE states that 'competence can be described as the combination of training, skills, experience and knowledge that a person has and their ability to apply them to perform a task safely', as well as 'the ability to undertake responsibilities and perform activities to a recognised standard on a regular basis.' 69,70

The NOS outlines that competence/competency can be measured by ensuring staff meet knowledge and understanding, and performance criteria.⁷¹ These include:

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.⁷¹

Summary

There was limited evidence available that was relevant to this research question and that which was included was all graded SIGN 50 level 4 expert opinion.

HSE guidance is consistent in defining competency as the ability of staff to perform their responsibilities in a safe manner and to a recognised standard on a regular basis. For PPE, this is specific to being able to use all PPE according to manufacturer's instructions and local policy.

A single piece of expert opinion from NOS provided definitions for competency of 'the combination of training, skills, experience and knowledge that a person has and their ability to apply them to perform a task safely' and 'the ability to undertake responsibilities and perform activities to a recognised standard on a regular basis'. This expert opinion also stated that competency can be measured by ensuring staff meet criteria in knowledge and understanding, and performance.

3.1.11 What training is required for staff to be considered 'competent' in the use of PPE for HCIDs and how frequently should staff be trained to remain competent?

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, 13, 18, 54, 72-74}, including updates to one piece of legislation¹³, one systematic review⁴ and one expert opinion.¹⁸ An additional 14 pieces of evidence were identified within this update.^{9, 14, 27, 28, 32, 35, 41, 46, 49, 65, 75-78}

Of the included evidence, three pieces of legislation are considered mandatory in the UK. ^{9, 13, 14} Three randomised control trials.^{75, 76, 78} and one systematic review and meta-analysis⁴ were graded SIGN 50 level 1. Three observational studies were graded SIGN 50 level 3; one experimental study⁷², two before and after studies.^{54, 73}

Twelve remaining pieces of evidence were graded SIGN 50 level 4 expert opinion.^{5,} 18, 27, 28, 32, 35, 41, 46, 49, 65, 74, 79)

The mandatory PPE at Work Regulations 1992 (as amended) and The Control of Substances Hazardous to Health (COSHH) Regulations 2002 state that employers must provide suitable information, instruction and training for their employees to make effective use of the PPE provided to them.^{9, 13, 45} Training must include how to correctly fit and wear PPE as well as the purpose and limitations of the PPE. ^{13, 45} Training should include elements of both theory and practice and should be carried out in accordance with any recommendations or instruction supplied by the manufacturer.^{13, 45}

In their guidance for managing patients with suspected or confirmed EVD, the CDC recommend that HCWs are trained in all recommended PPE and protocols; that training involve simulated care activities while wearing PPE and should include donning, doffing and disposing of PPE correctly as well as procedures to follow if there is a breach in PPE.^{18, 27, 28}

It is consistently recommended by guidance and extant literature (3 observational studies^{54, 72, 73} graded SIGN 50 level 3, and 4 guidance documents^{18, 35, 49, 79} graded SIGN 50 level 4 expert opinion) that training should include practical elements ('active training'). A 2020 Cochrane systematic review with meta-analysis (graded SIGN 50 level 1 demonstrated some evidence to support this, with an included study finding that the risk of noncompliance with PPE protocols and errors in doffing were lower when active training had taken place compared to when passive training had taken place (OR 0.63, 95% CI 0.31-1.3 and OR 0.45, 95% CI 0.21-0.98).4 In two before and after studies, correcting errors made during training and then immediately reinforcing correct technique with further education improved competency and led to better rates of knowledge retention.^{54, 72} Casalino et al (2015) found that the percentage of participants free of doffing errors after three sessions of training was between 50 and 83.3% for conventional (without reinforcement) training and between 56.7 and 96.7% for those that underwent reinforced training.⁷² Tomas et al (2015) included feedback on errors between training sessions and saw significant reduction in simulated self-contamination following glove removal however, no comparison to a study group without feedback was presented.⁵⁴

A RCT by Li et al (2020) found that training using video and live demonstration (but no active training techniques) significantly improved participants accuracy scores for donning and doffing PPE.⁷⁸ In contrast, two RCTs from Rueda-Medina et al (2022) and Christensen et al (2020) found no significant difference in donning or doffing errors or accuracy between two study groups; one using active training and the other passive.^{75, 76}

The CDC state that refresher training is essential to maintain competency but do not recommend a frequency for refresher training.¹⁸ An observational study by Northington et al (2007) demonstrated that six months following HAZMAT PPE training only 8.6% of students remained competent.⁷³

Expert opinion published regarding UK military medical personnel responding to the EVD outbreak in West Africa stated that HCIDs PPE training should be repeated at regular intervals or at the beginning of outbreak situations.⁴⁹

Four guidance documents (graded SIGN 50 level 4 expert opinion) are consistent in advising that training records should be kept and be available to monitor staff training levels.^{5, 18, 46, 65}

Summary

Legislation mandates the need for suitable training and instruction for employees in relation to PPE use. This must be made up of both theory and practice, which is supported by primary research and expert opinion guidance. Training should include donning and doffing procedures, understanding of correct PPE fit, and limitations in the protection offered by PPE.

UK and International expert opinion also recommends regular refresher training, particularly in the event of outbreak situations. Expert opinion guidance also recommends that training records are kept to monitor staff training levels.

3.1.12 How should staff competency be assessed?

Two pieces of evidence were included for this research question, both identified within previous version(s) of this review. This includes a guidance document that has been updated since the previous version of this review, graded SIGN 50 level 4 expert opinion, ¹⁸ and a consensus document, graded SIGN 50 level 4. ⁸⁰ No additional evidence relevant to this research question was identified within this update.

The CDC states that hospitals should ensure that employees can demonstrate how to properly don, use and doff the same type or model of PPE and respirators they will use when caring for a patient. A consensus document from Williams et al (2013) compiled the expert opinion of 23 IPC specialists across Canada on the key PPE skills required to create a tool to validate PPE skills. Within this document the Delphi method was used and checklists for hand hygiene, donning and doffing PPE were assessed by experts and graded on a 5-point scale. Details on the content of these assessment checklists was not presented within this paper. Reliability of the expert panellist's responses was graded as high enough for the checklists to be applied in the clinical setting (Cronbach's $\alpha > 0.9$).

It should be noted that the PPE skills to be validated by checklists created from the findings of this consensus were not specific to HCIDs, but PPE skills more generally. Additionally, the competency assessments that were identified did not provide a minimum score or pass mark for competency. Since HCWs must be able to select, don and doff all items correctly it must be assumed that a score of 100% is required to demonstrate competency.

Summary

Limited evidence was identified to inform this research question. However, the need for employees to demonstrate their knowledge in donning and doffing PPE was mentioned. Checklists were suggested as a way to assist in assessment of competency.

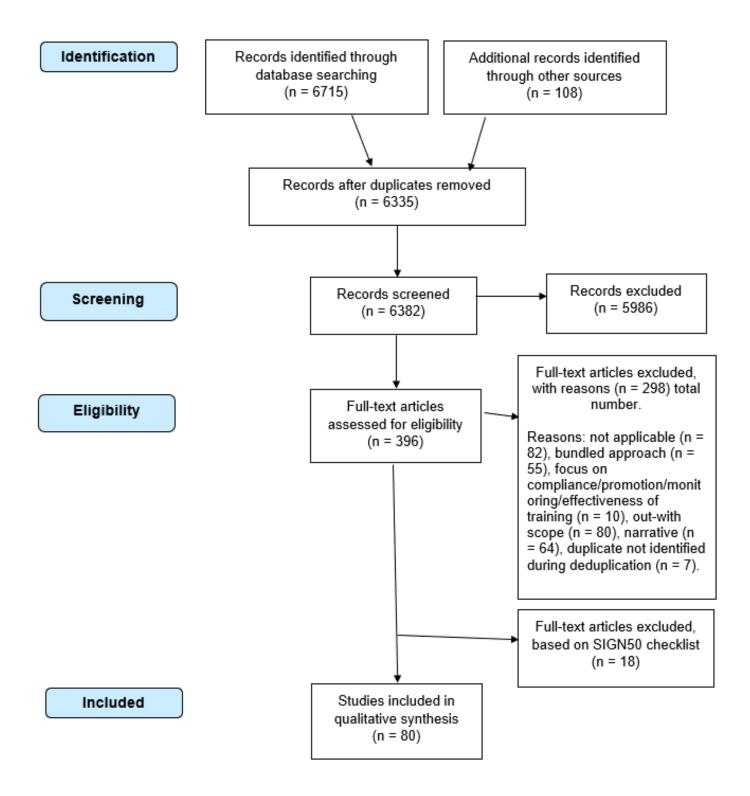
3.2 Implications for research

There continues to be a lack of high-quality studies to determine appropriate selection and use of PPE for HCIDs. No extant evidence-based guidelines were identified as part of this review. Although many guidelines on PPE for HCIDs exist, the vast majority of these are focussed on Ebola and were developed rapidly in response to the Ebola crisis in West Africa from 2014-2016 and are compiled using expert opinion rather than a robust evidence base. Lack of an evidence base at that time led to substantial variation in recommendations for PPE. There are inconsistencies in both the type of PPE recommended and the order for donning and doffing. In the event of a HCID pandemic which requires an international response, disparity between protocols puts HCWs at risk; given the increased likelihood of infection for staff, HCWs must have access to PPE and protocols that are consistent with their training.

This literature review has identified extremely limited evidence for defining and assessing HCW competency in the PPE required for HCIDs.

Appendices

Appendix 1: PRISMA



Appendix 2: Definitions for Recommendation Grading

Term used	Description	Evidence
Recommendation	'Recommendations' should be	Sufficient evidence
	supported by high- to moderate-	(SIGN50 level 1++,
	quality evidence (SIGN 50 level	1+, 2++, 2+, 3, 4*
	1++, 1+, 2++, 2+,	AGREE II
	AGREE II Recommend). In some	Recommend
	circumstances, however,	AGREE
	'Recommendations' may be made	Recommend with
	based on lower quality evidence	Modifications)
	when high-quality evidence is	
	impossible to obtain, and the	Legislation, or
	anticipated benefits strongly	mandatory guidance
	outweigh the harms, or when the	
	Recommendation is required by	
	Legislation or Mandatory Guidance.	
Good Practice Point	Insufficient evidence or a lack of	Insufficient evidence
	evidence to make a	+ Working Group
	recommendation but identified best	expert opinion
	practice based on the	OR
	clinical/technical experience of the	No evidence +
	Working Group, with a clear	Working Group
	balance between benefits and	expert opinion
	harms.	
No	Both a lack of pertinent evidence	No evidence
Recommendation	and an unclear balance between	
	benefits and harms.	

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

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