





# **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
V1.0	25 August 2025	First version to accompany version 3.0 of the literature review.

# Introduction

All studies which are critically appraised as part of the literature review are assigned a grade of evidence based on the SIGN 50 methodology grading system (SIGN, 2019), which allows scientific studies to be assessed for quality using a number of reviewing forms (available from the SIGN website).

The main conclusions from the studies are summarized along with a brief description of the study quality in an Evidence Table. Studies, which have sufficient quality and specifically answer a defined research question are grouped together to enable formation of a "considered judgment" based on this information. This "considered judgment" is then used as the basis for formulation of recommendations. Guidelines are appraised and graded using the AGREE II grading system (details available from the <u>AGREE website</u>).

Main conclusions from evidence sources (studies and guidance) are summarised along with a brief description of the methods and limitations within evidence table entries. Evidence sources with sufficient quality, which specifically answer a defined research question, are grouped together to enable the formation of an overall assessment regarding the evidence base.

# **Evidence grading**

The following grades were given to the papers included in this evidence table:

Grade	Description
1++	High quality meta analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High quality systematic reviews of case-control or cohort studies. High quality case-control or cohort studies with a very low risk of

Grade	Description
	confounding, bias, or chance and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies, for example case reports, case series
4	Expert opinion

Grade	Description
AGREE 'Recommend'	This indicates that the guideline is of high overall quality and can be considered for use in practice without modifications.
AGREE 'Recommend with modifications'	This indicates that the guideline is of moderate overall quality. This could be due to insufficient or lacking information in the guideline for some items. If modifications are made, the guideline could still be considered for use in practice when no other guidelines on the same topic are available.
AGREE 'Do not Recommend'	This indicates that the guideline is of low overall quality and has serious shortcomings. Therefore, it should not be recommended for use in practice.

# Research questions for evidence tables

Question 1: What is the definition of a HCID?

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

Question 3: What is the required PPE for HCIDs?

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

Question 5: Should different elements if PPE for HCID be integrated/interfaced and how should this be done i.e. use of tape?

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

Question 7: How should PPE for HCID be stored?

Question 8: How should single-use PPE be disposed of?

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

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

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?

Question 12: How should staff competency be assessed?

# Question 1: What is the definition of a HCID?

# Evidence added to Literature Review V3.0:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government/ UKHSA	Expert opinion	Level 4			
Guidance: High consequence infectious diseases (HCID)					
Accessed: June 2023					

## **Assessment of evidence**

Country: United Kingdom

Target audience: Applicable generally to all healthcare workers and healthcare settings.

**Methods:** Development methods are not reported however it is noted that the UK HCID list is agreed by the 4 nations public health bodies, with input from advisory committees where necessary.

#### Relevant content:

According to The UK Health and Security Agency (UKHSA) the agreed definition of HCID in the UK is a pathogen that meets the following criteria:

· "Acute infectious disease

- Typically has a high case-fatality rate
- May not have effective prophylaxis or treatment
- Often difficult to recognise and detect rapidly
- 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"

UKHSA classifies **HCIDs** as contact or airborne based on transmission.

#### Limitations:

- The methods used to determine the UK HCID list are not clear.
- Responsible persons in the 4 nations public health bodies are not named.
- Advisory committees involved in this process are not named.
- Possible conflicts of interest are not addressed.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization Emerging Diseases Accessed: June 2023	Expert Opinion	Level 4			

## **Assessment of evidence**

**Country:** International

Target audience: Applicable generally to all healthcare workers and healthcare settings.

#### Relevant content:

The World Health Organization defines emerging diseases as those that "appear in a population for the first time, or that may have existed previously but are rapidly increasing in incidence or geographic range."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease Control and Prevention  EID Journal Background and Goals	Expert Opinion	Level 4			
Emerging Infectious Diseases Accessed: June 2023					

# Assessment of evidence

Country: United States of America

**Target audience:** Applicable generally to all healthcare workers and healthcare settings.

#### Relevant content:

The CDC states that emerging infectious diseases are those whose incidence in humans has increased in the past two decades or threatens to increase in the near future.

"These diseases, which respect no national boundaries, include:

- New infections resulting from changes or evolution of existing organisms
- Known infections spreading to new geographic areas or populations
- Previously unrecognised infections appearing in areas undergoing ecologic transformation
- Old infections reemerging as a result of antimicrobial resistance in known agents or breakdowns in public health measures."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive/Advisory Committee on Dangerous Pathogens (ACDP)	Expert opinion	Level 4			
The approved list of biological agents 2023					

**Country:** United Kingdom

**Target audience:** Applicable to those who work with biological agents, including working with humans known or suspected to be infected with such an agent.

**Methods:** The ACDP considered evidence that indicated the likelihood that an agent can cause disease in humans, how likely infection would be to spread in the community, and availability of prophylaxis or treatment when determining where biological agents would sit on the approved list.

#### **Relevant Content:**

The ACDP provides a system of categorisation for organisms which reflect the risk to humans and informs the precautions (bio containment etc) that should be used by persons who deliberately handle these organisms in labs etc. or who care for persons or animals that may be infected with them.

#### **Definitions:**

"Group 1: Unlikely to cause human disease

Group 2: Can cause human disease and may be a hazard to employees; it is unlikely to spread to communities and there is usually effective treatment or prophylaxis available.

Group 3: Can cause severe human disease and may be a serious hazard to employees; it may spread in the community, but there is usually effective treatment or prophylaxis available.

Group 4: Causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment available."

Hazard group 4 pathogens include Filovirus (Ebola and Marburg), arenavirus (Lassa), Crimean Congo haemorrhagic fever.

Hazard group 3 pathogens include MERS-CoV and SARS.

Influenza was considered a group 2 pathogen; however, it was outlined that strains which have been lethal in birds or have pandemic potential should be classified (by risk assessment) as at least group 3 pathogens.

All of the pathogens that have been identified as 'high-consequence' by other guidance/organisations fall into category 3 or 4, with the exception of influenza which is considered as group 2 unless it is a strain that is lethal in birds or has the potential to be a pandemic strain, it is highlighted that this reclassification should be guided by risk assessment and would typically result in a group 3 classification until evidence to downgrade became available.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Verbeek J.H., Rajamaki B., Ijaz S., et al.	Systematic Review and Meta-analysis	Level 1+			
Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff					
Cochrane Database of Systematic					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Reviews 4, 2020 DOI: 10.1002/14651858.C					
D011621.pub4					

**Country:** International

**Aim:** This systematic review aimed to investigate PPE ensemble, and donning and doffing methods, that are reported to have the lowest risk of HCW contamination, along with the training methods that increase compliance.

**Methods:** Systematic literature review was conducted on CENTRAL, MEDLINE, Embase and CINAHL, with a date limit up to March 2020. All controlled studies that assessed the effect of PPE used by HCWs exposed to highly infectious diseases, risk of infection, contamination or noncompliance were included, along with studies which compared donning and doffing protocols, and the effect of training. Cochrane's assessment methodology was followed.

#### Findings:

Twenty-four studies were included in the 2020 update of this review, including 2278 participants: 14 RCTs, one quasi-RCT, and nine non-randomised trials. The certainty of evidence for this systematic review's evidence base was graded as very low or low. The included studies were published or undertaken in the USA (n=12), China and Hong Kong (n=4), Canada (n=2), the UK (n=2), Australia (n=1), Germany (n=1), Russia (n=1), with another undertaken in three countries (France, Mexico, Peru).

Verbeek et al. refer to HCID as highly infectious diseases.

## **Limitations:**

Authors graded evidence included in this review as low or very low in quality.

# **Evidence from previous update(s):**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Control and Prevention  Safe use of personal protective equipment in the treatment of infectious diseases of high consequence  Version 2  2014	Expert opinion	Level 4			

#### **Assessment of evidence**

Country: European Union

Target audience: Applicable to health and care staff working with HCID.

**Methods:** These expert opinion guidelines were developed by a group of professionals with experience in medicine, infection control, preparedness, and training. This group assessed documents released by international health bodies including the WHO, CDC and Médecins Sans Frontières (MSF). This group was supported by further experts in barrier nursing, hospital infection control, and bio risk management, where necessary.

#### Relevant content:

The following description of a high consequence infectious disease is provided

"Infectious diseases of high consequence (IDHC) are serious threats to human health. Patients develop severe symptoms, require a high level of care, and the case–fatality rates can be high. Often, there is no specific prophylaxis or treatment available. IDHC are transmissible

from human to human (contagious) and therefore require transmission precautions in HCWs. Depending on the transmission mode (e.g. by droplets or airborne) and their infectivity, they 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)."

- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References are not provided within the text, only within a bibliography.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
De laco G., Puro V.,	Cross sectional	Level 3			
Fusco F.M., et al	study				
Personal protective					
equipment					
management and					
policies: European					
network for highly					
infectious diseases					
data from 48					
isolation facilities in					
16 European					
<u>countries.</u>					
Infection Control &					
Hospital					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Epidemiology 2012 33(10): p1008-1016					

**Country:** Various European (Austria, Bulgaria, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Poland, Slovenia, Spain, United Kingdom).

Setting: Isolation facilities for the management of highly infectious diseases.

**Aim:** The aim of this paper was to understand PPE selection, use, and supply across 48 isolation facilities. This paper also aims to suggest safe and appropriate PPE protocols within this setting.

**Methods:** Data was collected from the participating isolation facilities using checklists, including questions on management of PPE items, use of fit testing, and stockpiling. Preparedness of each facility was captured using an evaluation form.

# Findings:

The paper provides definitions for Highly Infectious Diseases (HIDs) as follows.

HIDs are those that are:

- easily transmissible from person to person
- cause life threatening illness, and
- present a serious hazard in the healthcare settings and in the community, requiring specific control measures.

The following agents or diseases are outlined to be included among HIDs:

- VHF due to Marburg virus, Ebola virus, Crimean Congo haemorrhagic fever virus, Lassa virus, Lujo virus, Junin, Machupo, Sabia and Guanarito.
- Severe-acute respiratory syndrome coronavirus

- MDR and XDR Mycobacterium tuberculosis (known or suspected infection)
- Newly emerging highly pathogenic strains of influenza virus
- Smallpox and other orthopox infections (e.g. monkeypox) but excluding vaccinia virus infection
- Other emerging highly pathogenic agents, including agents of deliberate release (e.g. pneumonic plague), some of which could also be extensively antibiotic resistant.

#### Limitations:

• The definitions and examples provided are based on expert opinion, however the cross-sectional design and wide geographical sampling range provides confidence that these definitions are already widely agreed upon and used.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Advisory Committee	Expert opinion	Level 4			
on Dangerous					
Pathogens					
Management of					
Hazard Group 4 viral					
haemorrhagic fevers					
and similar human					
infectious diseases					
of high consequence					
Viral haemorrhagic					
fever: ACDP					
algorithm and					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
guidance on					
management of					
patients - GOV.UK					
November 2015					

**Country:** United Kingdom

Target audience: Applicable generally to all healthcare workers and healthcare settings.

**Methods:** The ACDP assessed the risks of transmission of VHF, however, the methods of this were not reported.

#### **Relevant Content:**

Within this guidance viral haemorrhagic fevers (VHFs) are described as infectious diseases of high consequence.

It is also stated that VHFs are severe and can be life-threatening. That spread readily within health and care settings, have high-case fatality rates, are difficult to recognise and detect rapidly, and have no effective treatment.

It is stated that this guidance also applies to similar infectious diseases (including those that are new or emerging) that have significant health impact and present serious risk to public health in the UK.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

# Question 2: What legislative requirements are in place regarding employers providing staff with PPE in relation to HCID?

# Evidence added to Literature Review V3.0:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government	Legislation	Mandatory			
The Control of Substances Hazardous to Health (COSHH) Regulations 2002					

# **Assessment of evidence**

Country: United Kingdom

#### **Relevant Content:**

COSHH states that employers have the responsibility to protect employees from hazardous substances, including biological agents ("micro-organism, cell culture, or human endoparasite, whether or not genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health"), in occupational settings. These regulations supersede some aspects of The Personal Protective Equipment at Work Regulations (with amendments) 2022.

COSHH does not include regulations specific to HCIDs.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government  Health and Safety at  Work Act 1974	Legislation	Mandatory			

Country: United Kingdom

#### **Relevant Content:**

The Health and Safety at Work Act 1974 is generic legislation for the UK, covering PPE use and risk. This legislation states the duties of both employers and employees to ensure safety while carrying out occupational responsibilities.

"It shall be the duty of every employer to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all his employees."

"It shall be the duty of every employee while at work -

- (a) To take reasonable care for the health and safety of himself and of other persons who may be affected by his acts or omissions at work; and
- (b) As regards any duty or requirement imposed on his employer or any other person by or under any of the relevant statutory provisions, to co-operate with him so far as is necessary to enable that duty or requirement to be performed or complied with."

The Health and Safety at Work Act 1974 does not include regulations specific to HCIDs.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government  Management of  Health and Safety at	Legislation	Mandatory			
Work Regulations 1999					

Country: United Kingdom

#### **Relevant Content:**

This legislation states that it is the responsibility of the employer to ensure the health, safety and welfare of their employers at work, as far as is reasonably practicable. This includes:

"Arrangements for ensuring, so far as is reasonably practicable, safety and absence of risks to health in connection with the use, handling, storage and transport of articles and substances"

"The provision of such information, instruction, training and supervision as is necessary to ensure, so far as is reasonably practicable, the health and safety at work of his employees"

Under this legislation it is also noted that employees have a duty to cooperate with their employer in order for any responsibilities of the employer to be met.

Management of Health and Safety at Work Regulations 1999 does not include regulations specific to HCIDs.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government	Legislation	Mandatory			
Personal Protective Equipment at Work Regulations 1992					

**Country:** United Kingdom

#### **Relevant Content:**

The Personal Protective Equipment at Work Regulations state that employers are required to provide employees with PPE to ensure their safety while completing occupational duties, where other control measures are not possible.

The Personal Protective Equipment at Work Regulations does not include regulations specific to HCIDs.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government Personal Protective	Legislation	Mandatory			
Equipment at Work (Amendment)					
Regulations 2022					

# **Assessment of evidence**

**Country:** United Kingdom

#### **Relevant Content:**

The Personal Protective Equipment at Work (Amendment) Regulations provide amendments to the above legislation. Duties of employers were unchanged within these amendments but extends them to also cover employees that do not come under the scope of the original legislation.

The Personal Protective Equipment at Work (Amendment) Regulations does not include regulations specific to HCIDs.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government	Legislation	Mandatory			
Regulation 2016/425 and the Personal Protective Equipment (Enforcement) Regulations 2018: Great Britain May 2023					

# **Assessment of evidence**

Country: United Kingdom

# **Relevant Content:**

The Personal Protective Equipment (Enforcement) Regulations incorporate EU Regulation 2016/425 into UK law. These regulations state the health and safety requirements which PPE products must meet prior to placement on the UK market.

The Personal Protective Equipment (Enforcement) Regulations does not include regulations specific to HCIDs.

# **Evidence from previous update(s):**

This research question was added for this update.

# Question 3: What is the required PPE for HCID?

# **Evidence added to Literature Review V3.0:**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Kamali A., Jamieson	Case Report	Level 4			
D.J., Kpaduwa J., et al.					
Pregnancy, Labor, and Delivery after Ebola Virus Disease and Implications for Infection Control in Obstetric Services,					
United States Emerging Infectious Diseases 2016 22(7)p1156-1161,					

Country: USA

**Setting:** Labour and Delivery

# Findings:

This case report detailed plans put in place to limit the risk of EVD transmission from a previously infected (4 months prior to pregnancy) mother giving birth at the facility. No EVD RNA was detected in patient samples collected during pregnancy.

No PPE was recommended for casual contact with this patient. PPE was recommended for non-casual contact with specific guidance outlined below:

- Touching patient with ruptured membranes or bedding of patient with ruptured membranes wear isolation gown and single gloves
- Administering epidural wear face mask, face shield, isolation gown, double gloves, and fluid-resistant, midcalf boot covers (to be used if membranes were ruptured)
- Performing vaginal examination wear face mask, face shield, fluid resistant or impermeable gown, single gloves, and fluidresistant, midcalf boot covers (to be used if membranes were ruptured)
- Performing obstetric procedures (including placement of foetal scalp electrode or intrauterine pressure catheter, manual removal
  of placenta, bimanual massage of uterine) wear face mask, face shield, fluid resistant or impermeable gown, single or double
  gloves, and fluid-resistant, midcalf boot covers.
- While caring for mother post-partum (before changing bedding/gown wear face mask, face shield, fluid-resistant impermeable gown, single gloves and fluid-resistant, midcalf boot covers.
- While caring for mother post-partum (after changing bedding/gown) wear face mask and face shield only if splash likely, isolation gown and single gloves.
- While caring for neonate (before bathing) wear face mask, face shield, fluid-resistant or impermeable gown (if exposure to fluids likely), single gloves and fluid-resistant midcalf boot covers.

• While caring for neonate (after bathing) - wear single gloves if exposure to fluid likely.

This case resulted in a live birth, with no laboratory evidence of EVD transmission to the neonate. Additionally, there were no EVD cases reported in any staff who came into contact with the mother or neonate.

The outcome of this case report suggests that the precautions put in place to care for this patient were sufficient to protect staff from possible EVD transmission. However, the authors of this paper do highlight that the PPE ensemble and further precautions reported are not formal recommendations and were determined based on expert opinion for this specific case.

- Pertains to a single case.
- Unclear if single or double gloving used during obstetric procedures.
- USA context may limit wider applicability.
- Patient not actively infected with EVD at the time of delivery and so findings may not be applicable to treatment of cases of active infection.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Verbeek J.H., Mischke C., Ruotsakainen J.H., et al.	Systematic Review	Level 1+			
Personal protective equipment for preventing highly infectious diseases					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
due to exposure to contaminated body fluids in healthcare staff (review)					
Cochrane Database of Systematic Reviews 2016,2019,2020. Issue 4. Art. No.: CD011621. doi: 10.1002/14651858.C D011621.pub4					

**Country:** International

**Aim:** This systematic review aimed to investigate PPE ensembles, and donning and doffing methods, that are reported to have the lowest risk of HCW contamination, along with the training methods that increase compliance.

**Methods:** Systematic literature review was conducted on CENTRAL, MEDLINE, Embase and CINAHL, with a date limit up to March 2020. All controlled studies that assessed the efficacy of PPE used by HCWs exposed to highly infectious diseases, risk of infection, contamination or noncompliance were included, along with studies which compared donning and doffing protocols, and the effect of training. Cochrane's assessment methodology was followed.

# **Findings:**

Twenty-four studies were included in the 2020 update of this review, including 2278 participants: 14 RCTs, one quasi-RCT, and nine non-randomised trials. The certainty of evidence for this systematic review's evidence base was graded as very low or low.

In their analysis of studies that assessed the protective effect of different PPE types, the authors found that Powered Air Purifying Respirators (PAPRs) paired with coveralls (defined by authors as a one-piece suit) were found to provide greater protection against contamination when compared to N95 masks paired with a gown (risk ratio (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 HCWs to don (non-compliance: RR 7.5, 95% CI 1.81 to 31.1) than an N95 mask paired with a gown.

In a separate analysis, it was found that gowns may provide greater protection against contamination of the wearers body than aprons (small patches of fluorescence (≤1cm²): mean difference (MD) −10.28, 95% CI −14.77 to −5.79) This review also covered modified PPE, however, modification of PPE would not be recommended in NHS Scotland.

#### Limitations:

- Multiple interventions at once (PAPR and coverall vs N95 and gown) mean that assessment of individual PPE elements was not
  possible.
- p-values were not reported.
- Authors graded evidence included in this review as low or very low in quality.

#### **Conclusions:**

This systematic literature review suggests that when providing healthcare, gowns provide more protection from contamination with bodily fluids than aprons. It also suggests that PAPRs with coveralls may provide greater protection when compared to N95 masks paired with a gown.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Wadman M.C.,	Expert Opinion	Level 4			
Schwedhelm S.S.,					
Watson S., et al.					
<u>Emergency</u>					
Department Process					
for the Evaluation					
and Management of					
Persons Under					
Investigation for					
Ebola Virus Disease					
Annals of					
Emergency Medicine					
2015 66(3): p306-					
314.					

Country: USA

Target audience: Applicable to all health and care staff who may for patients with suspected or confirmed HCIDs.

**Methods:** These guidelines were developed through "expert review and consensus of health care workers and administrators at an active Ebola treatment center" who had experience with managing patients with Ebola virus disease, in biocontainment units and emergency departments.

# Findings:

This guidance states that when a patient meets the criteria for epidemiological risk, signs or symptoms of EVD, mask and gloves should be worn by both patient and medical personnel.

- Authors outline that when EVD is confirmed, all personnel in contact with the patient should wear "full" personal protective equipment.
- When EVD patients are in isolation PPE necessary for contact with EVD patients is outlined to be as follows: surgical gown, head and neck covers, face shield, N-95 mask, standard patient gloves, long cuff Kimberly-Clark (KC) 500 purple nitrile gloves, boot covers, duct tape, and doffing pad or large fluid-repellent drape.

It is outlined that this ensemble is deemed to be sufficient to prevent contamination of the face and neck by aerosolised fluids

To prevent inhalation, powered air-purifying respirators (PAPR) (consisting of full head and neck hood with face shield and battery powered blower) are recommended to d be used during all airway interventions.

#### It is advised that

- Fully enclosed suits and PAPR should be worn when there is a high risk of splash or aerosolised fluids.
- When risk is lower, PAPRs are not required but should be available to personnel on their request.
- That a plastic apron is worn over PPE to further limit risk of exposure to patient blood and body fluids. when chest compressions are undertaken during cardiopulmonary arrest, PAPR and plastic aprons are donned. when transporting patients under investigation, patients should be within an isolation unit or wear PPE. Specific PPE is not mentioned.

- US setting may limit applicability.
- Consulted experts were not named.
- Information regarding conflicts of interest were not outlined for consulted experts.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Park H.C., Lee Y.K., Lee S.H., et al.	Expert opinion	Level 4			
Middle East respiratory syndrome clinical practice guideline for hemodialysis facilities					
Kidney Research and Clinical Practice 2017 36 p111-116					

Country: South Korea

**Target Audience:** Applicable to health and care staff working in haemodialysis facilities caring for suspected or confirmed cases of MERS.

**Methods:** A committee was formed including members from the Korean Centers for Disease Control & Prevention (KCDC), the Korean Society of Nephrology, and the Korean Society of Dialysis Therapy, which developed these guidelines.

#### **Relevant Content:**

This expert opinion guidance states that HCWs that are involved in dialysis therapy for MERS-CoV patients should don appropriate PPE which includes gloves, goggles or face shield, gown (level D), and a highly efficient face mask.

#### Limitations:

Members of the guidance development committee were not named.

Information regarding conflicts of interest were not outlined.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
InterAgency Board	Expert Opinion	Level 4			
for Equipment					
Standardization and					
Interoperability (IAB)					
Recommendations					
on Selection and					
Use of Personal					
<u>Protective</u>					
Equipment for First					
Responders against					
Ebola Exposure					
<u>Hazards</u>					
V1.5, 2014					

# **Assessment of evidence**

Country: USA

Target Audience: Applicable to first responder staff who may care for patients with suspected or confirmed EVD.

**Methods:** Development methods were not reported; however, it is stated that the InterAgency Board for Equipment Standardization and Interoperability is a voluntary collaborative panel with representatives from a broad range of professional disciplines within government and public safety, with experience in emergency preparedness and response.

#### **Relevant Content:**

High-risk exposure was classified as contact with patients with known or suspected exposure to EVD and are experiencing fever, vomiting, diarrhoea, or otherwise producing blood and body fluids. Low-risk exposure is classified as contact with patients with known or suspected exposure to EVD and are asymptomatic or present only with fever OR patients with possible exposure to EVD presenting with only fever or with fever, vomiting, diarrhoea, or otherwise producing blood and body fluids.

Within this expert opinion the following ensemble is recommended for high-risk exposure to EVD patients:

- Full-body garment (coverall) made of durable viral penetration resistant material with sealable cover flap over closure coverall with integrated hood when worn with full facepiece respirator OR coverall without hood when worn with hood-based or helmet-based PAPR where sufficient overlap between hood and coverall is provided.
- Inner single use nitrile rubber examination gloves (worn under coverall sleeve).
- Outer gloves with extended cuff 11 mil or thicker unsupported nitrile, neoprene, or other rubber without interior fabric (worn over coverall sleeve and taped in place when not integrated with coverall suit).
- Full facepiece air-purifying with P11 filters OR PAPR with P100 filters with full face shield, helmet, or hood (alternatives include open-circuit self-contained breathing apparatus and any CBRN respirator).
- Rubber boots that extend to at least lower calf OR footwear that incorporates viral-penetration barrier layer OR standard footwear with durable wear surface worn with footwear cover that extends beyond height of footwear constructed of viral penetration resistant footwear.

The following ensemble is recommended for low-risk exposure to EVD patients:

- Full body garment (coverall) constructed of disposable or more durable viral penetration resistant material with sealable cover flap over closure coverall with integrated hood OR coverall with separate hood also constructed or viral penetration resistant material and seams.
- Inner single use nitrile rubber examination gloves (worn under coverall sleeve).

- Outer gloves (single use) with extended cuff made of nitrile rubber (worn over coverall sleeve and taped in place if not integrated with coverall suit)
- Fluid resistant N95 or greater filtering facepiece respirator worn with splash-rated, non-vented or indirect-vented goggles and splash-rated full-face shield
- Footwear that incorporates viral-penetration barrier layer OR standard footwear that incorporates viral-penetration barrier layer OR standard footwear with durable wear surface worn with footwear cover that extends beyond height of footwear constructed of viral penetration resistant footwear

- Members of the guidance development panel were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Suen L.K.P., Guo Y.P., Tong D.W.K, et al. Self-contamination during doffing of personal protective equipment by healthcare workers	Cross-over study	Level 3	Use of two PPE ensembles (PPE 1 and PPE 2) for protection against Ebola virus disease	Use of a third PPE ensemble (PPE 3) for protection against Ebola virus disease	Deviations from protocol during donning and doffing. Contamination of participants bodies during doffing using a fluorescent tracer as substitute for EVD.

Antimicrobial Resistance and Infection Control  recorded by size − small (≤1cm²), medium (1cm² to	Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
17(13/1, 2010)	transmission Antimicrobial Resistance and Infection Control 7(157), 2018					contamination were recorded by size – small (≤1cm²), medium (1cm² to <3cm²), large (≥3cm² to 5cm²), extra-large

Country: Hong Kong

Aim: This study aimed to compare the efficacy of three different PPE ensembles for use during the care of patients with EVD.

# Methods:

59 HCWs participated in this study. All participants were trained and assessed in donning and doffing all three PPE ensembles in a random order as decided by a computer-generated software.

This study took place in Hong Kong and included 59 HCWs. All participants were trained and assessed in donning and doffing all three PPE ensembles in a random order as decided by a computer-generated software.

PPE 1 (Hospital Authority Standard Ebola PPE set): Neck-to-ankle outfit, N95 respirator, hood, disposable face shield, MICROCOOL Breathable High Performance surgical gown without zipper (bow is tied at the lateral side of the waist), boots, double long nitrate gloves.

PPE 2 (DuPont Tyvek, Model 1422A): Head-to-ankle coverall, N95 respirator, hood with elasticated facial opening, disposable face shield, Tyvek apparel with elasticated wrists and ankles with zipper along the centre front, plastic apron (to cover zipper), boots, double long nitrate gloves.

PPE 3 (Hospital Authority isolation gown for routine patient care and performing aerosol-generating procedures): Neck-to-ankle outfit, N95 respirator, disposable face shield, water resistant isolation gown without zipper (bow is tied at the lateral side of the waist), shoes, single latex gloves.

PPE was donned in the "clean zone" before participants moved to the "preparation zone" where fluorescent tracer solution was sprayed onto the face shield, upper limbs, gloves, and anterior surfaces of gowns. Following preparation with fluorescent tracer, participants moved to the "degown and test zone" where they doffed PPE while being recorded for evaluation. Immediately after doffing, participants and the doffing environment were assessed for presence of fluorescent tracer using an ultraviolet lamp. Areas of contamination were recorded by size − small (≤1cm²), medium (1cm² to <3cm²), large (≥3cm² to 5cm²), extra-large (≥5cm²).

# Findings:

There was significantly less contamination of the HCWs clothes by small (≤1cm2) and large (≥3cm2 to 5cm2) patches during removal of PPE1 compared to PPE2 and PPE3; median: 5.00 versus 7.00 versus 7.00, p < 0.05) and median: 1.00 versus 1.00 versus 2.00, p < 0.05), respectively (p<0.001). There was no significant difference in the number of medium (1cm2 to <3cm2) or extra-large patches (≥5cm2).

Contamination of the environment was reported when doffing PPE 1, PPE 2, and PPE 3 on the rubbish bin cover (small patches; median: 2.00 versus 7.00 versus 2.50, p=0.254. Extra-large patches; 20.00 versus 14.00 versus 23.00, p=0.737), chair (small patches; median: 3.00 versus 6.50 versus 2.00, p=0.053. Extra-large patches; 0.00 versus 36.00 versus 0.00, p=N/A), faucet (small patches; median: 2.00 versus 2.00 versus 1.50, p=0.659. Extra-large patches; 0.00 versus 16.00 versus 14.00, p=N/A), sink (small patches; median: 12.50 versus 14.00 versus 10.00, p=0.072. Extra-large patches; 75.50 versus 66.50 versus 44.00, p=0.649). No significant differences were reported in environmental contamination across the three PPE ensembles assessed.

- Fluorescent tracer used rather than surrogate of EVD.
- Participants did not have equal training or experience using PPE.
- Participants had previous experience with PPE ensembles 1 and 3 but not PPE ensemble 2.

#### **Conclusions:**

This cross-over trial suggests that doffing the ensemble, denoted in this study as PPE 1, may lead to less bodily contamination, however, as participants had previous experience with the PPE1 ensemble this creates bias and definitive conclusions cannot be drawn.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Rizzi E.B., Puro V., Schinina V., et al.	Expert Opinion	Level 4			
Radiographic imaging in Ebola Virus Disease: protocol to acquire chest radiographs					
European Radiology. 2015. 25: p3368- 3371 doi: 10.1007/s00330- 015-3748-6					

#### Assessment of evidence

**Country:** Italy

Target Audience: Applicable to all radiographic staff who may care for patients with suspected or confirmed EVD.

#### **Relevant Content:**

In this expert opinion it is stated that radiologic technologists should wear the following when caring for EVD patients:

- an impervious gown
- gloves
- goggles

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Levy B., Rao C.Y., Miller L., et al.	Expert Opinion	Level 4			
Ebola infection control in Sierra Leonean health clinics: A large cross- agency cooperative project					
American Journal of Infection Control 2015 42: p752-755					

Country: Sierra Leone

**Target Audience:** Applicable to all health and care workers who may care for patients with suspected or confirmed EVD.

#### **Relevant Content:**

In this expert opinion guidance, it is recommended that personnel screening patients for EVD in Sierra Leonean settings wear:

- gloves
- eye and face protection for example face shield, goggles, face mask

HCWs attending to suspected EVD patients are advised to wear the above, along with:

- a second pair of gloves
- gown
- boots

Cleaners are advised to wear:

- gloves
- eye and face protection
- apron
- thick rubber boots

### Limitations:

• References on PPE selection are not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Services	Expert Opinion	Level 4			
Scotland  Viral Haemorrhagic Fever (VHF) Infection Prevention and Control Precautions Summary for the Hospital Setting (Version 3.1) 2016					

Country: Scotland

**Target Audience:** Applicable to all health and care workers who may care for or be exposed to suspected or confirmed VHF patients.

#### **Relevant Content:**

Within this expert opinion guidance, it is stated that PPE worn to protect against VHF must create a full barrier against contact with contaminated surfaces, splash, spray, bulk fluids, and aerosol particles.

NSS state that where there is low possibility of VHF the PPE ensemble should include – disposable plastic apron worn over uniform, a disposable full-face visor OR half-face visor with integral fluid repellent face mask OR goggles and a fluid repellent surgical face mask, non-sterile nitril/latex gloves OR neoprene single-use gloves. It is advised that FFP3 respirators and compatible eye protection should be worn during AGPs.

NSS state that where there is a high possibility of, or confirmed, VHF the PPE ensemble should include – scrubs rather than normal uniform, disposable fluid repellent coverall (with hood), high-grade disposable plastic apron, wellington style boots with disposable over

boots, FFP3 respirator and compatible full-face visor/face shield, double gloving using disposable surgical gloves. It is advised that this ensemble should be used for any VHF patient care, including AGPs.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Crook B., Bailey C., Sykes A., et al.  Validation of personal protective equipment ensembles, incorporating powered air-purifying respirators protected from contamination, for the care of patients with high-	Observational	Level 3	PPE ensemble 1 (PPE1) which included PAPR system with power pack on waist belt, fluid resistant hood with integrated visor, fluid resistant coverall with front zipper, surgical clogs worn under coverall, shoe covers worn over coverall, three	PPE ensemble 2 (PPE2) which included PAPR system with integrated power pack, fluid resistant hood with integrated visor, fluid resistant coverall with rear zipper, wellington boots worn outside coverall with gaiters covering the top of	Presence of fluorochrome contamination on participants bodies after doffing.
			pairs of gloves with	boots, three pairs of	

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
consequence			middle pair taped to	gloves with middle	
infectious diseases.			sleeves of coverall,	pair taped to sleeves	
Journal of Hospital			long-sleeved plastic	of coverall,	
Infection 134: 71-79,			apron.	sleeveless plastic	
2023				apron.	

**Country:** United Kingdom

**Aim:** The aim of this study was to compare the ease of doffing of two PPE ensembles (including PAPR) to be used when caring for HCID patients.

#### Methods:

20 members of experienced medical staff, with training and practical experience in use of HCID PPE, participated in this study. Participants were allowed to become familiar with the PPE ensembles before following a six-step study protocol.

- Step 1 supervised donning of PAPR and PPE ensemble
- Step 2 application of fluorochrome
- Step 3 complete three physical tests that mimic movements common to patient care and a manual dexterity test
- Step 4 supervised doffing of PAPR and PPE ensemble
- Step 5 examination using UV light to identify cross contamination
- Step 6 post-test questionnaire

This protocol was repeated by each participant one for each PPE ensemble.

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.

Based on these findings and feedback gained from the post-test questionnaire the recommended PPE ensemble included the following:

- PAPR hood system with headset (powerpack attached to belt around the wearer's waist), covered by a plastic hood that covers
  the head and neck.
- Fluid-resistant coverall with front zipper (string attached to zipper to aid in donning/doffing).
- Wellington boots.
- Triple gloving inner pair of nitrile gloves worn under cuff of coverall, middle pair of thick long-cuffed gloves taped to coverall sleeves with 3 vertical strips of duct tape, outer pair of nitrile gloves.
- Apron worn over coverall and PAPR hood.

#### Limitations:

- Small sample size.
- Donning and doffing protocols were not reported.

## **Conclusions:**

This observational study suggests that PPE ensemble 1 (PAPR system with power pack on waist belt, fluid resistant hood with integrated visor, fluid resistant coverall with front zipper, surgical clogs worn under coverall, shoe covers worn over coverall, three pairs of gloves with middle pair taped to sleeves of coverall, long-sleeved plastic apron) is preferable to PPE ensemble 2 when considering contamination that occurs during doffing.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease Control and	Expert Opinion	Level 4			
Prevention					
Guidance on					
Personal Protective Equipment (PPE) To					
Be Used By Healthcare Workers					
during Management					
of Patients with Confirmed Ebola or					
Persons under					
Investigation (PUIs) for Ebola who are					
Clinically Unstable or					
Have Bleeding, Vomiting, or Diarrhea					
in U.S. Healthcare Settings, Including					
Procedures for					
Donning and Doffing PPE					
2022					

Country: USA

Target Audience: Applicable to all health and care staff caring for patients with suspected or confirmed EVD who are clinically unstable.

Methods: Development methods were not reported.

#### **Relevant Content:**

Within this expert opinion guidance it is recommend that the PPE ensemble worn during the care of patients with confirmed Ebola or an unstable person under investigation (PUI) includes:

- single-use disposable impermeable gown (extends to mid-calf) OR single-use disposable impermeable coverall (without integrated hood is preferred, thumb hooks should be considered)
- RPE should be a PAPR system with full face shield, helmet or headpiece or disposable N95 respirator
- single-use disposable gloves with extended cuffs two pairs should be worn, and the outer glove should be removed and replaced when soiled
- single-use disposable boot covers (shoe covers should only be used if a coverall with integrated socks is also worn)
- single-use disposable apron

It is also outlined that trained observers for donning and doffing should wear the following.

- single-use disposable fluid-resistant gowns (which extend to mid-calf) OR single-use disposable fluid-resistant coveralls (without integrated hoods)
- single-use disposable full-face shields
- single-use disposable surgical masks
- single-use disposable gloves with extended cuffs. Two pairs of gloves should be worn, with the outer glove having extended cuffs at a minimum.
- single-use disposable ankle-high shoe covers

#### Limitations:

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Public Health Agency of Canada  Prevention and Control of Influenza during a Pandemic for All Healthcare Settings  May 2011	Expert Opinion	Level 4			

# **Assessment of evidence**

Country: Canada

Target Audience: All health and care staff working who may contact influenza.

**Methods:** This document was developed by the Public Health Agency of Canada's Infection Prevention and Control Program, with support from an expert working group.

## **Relevant Content:**

In this expert opinion guidance, it is noted that:

- engineering and administrative controls should be in place and deemed insufficient for protection, before PPE should be required
- a point of care risk assessment be completed prior to patient interaction to determine the level of PPE and RPE is required
- when working within 2 metres of a patient with influenza, HCWs should wear a surgical mask, face and eye protection, gloves, long-sleeved gown.
- respirators are recommended when AGPs are being undertaken, the patient is forcibly coughing, or the patient is unable or unwilling to comply with respiratory hygiene (wearing a mask, coughing and sneezing into tissues, etc).
- source control using surgical masks may play a role in prevention of influenza transmission.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA)	Expert Opinion	Level 4			
OSHA Fact Sheet: PPE Selection Matrix					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
for Occupational					
Exposure to Ebola					
<u>Virus</u>					
2014					

Country: USA

**Target Audience:** Applicable to all health and care staff who may care for suspected or confirmed EVD patients.

#### **Relevant Content:**

OSHA states that when providing medical care to suspected Ebola patients without bleeding, vomiting, or diarrhea, HCWs should don double nitrile gloves, surgical face mask, face and eye protection (goggles, shield, etc) and a fluid resistant coverall or gown. When risk is deemed to be high, it is advised that HCWs should also don a fluid resistant apron, disposable N95 respirator or Elastomeric respirator or PAPR.

OSHA states that when providing medical care to suspected Ebola patients with bleeding, vomiting, or diarrhea, or those with confirmed Ebola infection, HCWs should don double nitrile gloves, face and eye protection (goggles, face shield, etc), impermeable head/neck cover (e.g. surgical hood), fluid-resistant gowns or coveralls, impermeable aprons, impermeable boot covers that extend to cover the lower leg and respirators (disposable N95, elastomeric, PAPR). It is outlined that the same ensemble should be used when undertaking AGPs on, or when transporting, suspected or confirmed Ebola patients.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.

• References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization	Expert Opinion	Level 4			
Personal protective equipment in the context of filovirus disease outbreak response 2014					

### Assessment of evidence

**Country:** International

Target Audience: Applicable to all health and care staff who may care for patients with suspected or confirmed filovirus.

### **Relevant Content:**

In this expert opinion the WHO recommend that the PPE ensemble worn during care of patients with filovirus disease, should include:

- goggles
- face shield
- fluid-resistant medical/surgical mask OR particulate respirator
- gloves

- disposable gowns OR disposable coverall
- waterproof apron OR heavy-duty apron
- hood OR headcover

They advise that PPE should be worn over surgical scrubs.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease	Expert Opinion	Level 4			
Control and					
Prevention					
For U.S. Healthcare					
Settings: Donning					
and Doffing Personal					
<u>Protective</u>					
Equipment (PPE) for					
<b>Evaluating Persons</b>					
<b>Under Investigation</b>					
(PUIs) for Ebola Who					
Are Clinically Stable					
and Do Not Have					
Bleeding, Vomiting,					
or Diarrhea					
2022					

Country: USA

Target Audience: Applicable to all health and care staff working with patients with suspected or confirmed EVD who are clinically stable.

Methods: Development methods were not reported.

## **Relevant Content:**

This expert opinion recommends that the PPE ensemble worn during care of persons under investigation (PUIs) for Ebola who are clinically stable should include:

- Single-use, fluid-resistant gown that extends to at least the mid-calf OR single-use fluid-resistant coveralls without integrated hood
- Single-use full face shield
- Single-use facemask
- Two pairs of single-use gloves. At least the outer pair should have extended cuffs.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References are not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease	Expert Opinion	Level 4			
Control and					
Prevention					
Interim Guidance for					
Emergency Medical					
Services (EMS)					
Systems and 9-1-1					
Emergency					
Communications					
Centres/Public					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Safety Answering Points (ECC/PSAPs) for Management of Patients Under Investigation (PUIs) for Ebola Virus					
Disease (EVD) in the United States 2022					

Country: USA

Target Audience: Applicable to all emergency services staff who may care for patients with suspected or confirmed with EVD.

## **Relevant Content:**

In this expert opinion guidance, it is stated that emergency medical services should wear the same PPE ensembles as recommended for health and care settings when caring for patients with suspected or confirmed Ebola (with or without symptoms).

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References are not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease	Expert Opinion	Level 4			
Control and					
Prevention					
Considerations for					
Selecting Protective					
Clothing used in					
Healthcare for					
Protection against					
Microorganisms in					
Blood and Body					
<u>Fluids</u>					
2020					

Country: USA

**Target Audience:** Applicable to all health and care staff in all settings.

# Relevant content:

This CDC guidance states that all employers should conduct a risk assessment first to identify potential exposures to blood and body fluids, that this may vary depending on stage of disease and/or severity of symptoms and that the selection of PPE will be guided by the route of transmission i.e. contact, droplet or airborne.

The CDC state that employers should:

consider the barrier properties of protective clothing.

- be mindful of the terminology that is used to describe PPE such as 'impermeable' or 'fluid resistant' as these are used inconsistently, instead refer to test standards
- consider clothing properties such as seams, as it is essential that all seams/closures provide similar barrier protection to the fabric itself e.g. welded or double taped seams. 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. It is outlined that the interfaces will determine the user's overall protection
- the characteristics of the work environment and tasks to be undertaken should also be considered

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References are not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Public Health England  Plague: interim guidance for clinicians in England managing suspected cases	Expert opinion	Level 4			

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
November 2017					

Country: United Kingdom

**Target Audience:** All health and care staff that may may be involved in the care or management of patients with suspected or confirmed Plague.

**Methods:** No development methods were reported; however, authors and contributors are named.

#### **Relevant Content:**

In this expert opinion guidance, it is recommended that HCWs wear "standard airborne PPE/RPE" when caring for patients suspected or confirmed to be infected with Plague. This ensemble includes:

- FFP3 mask, fit tested to the wearer
- Eye and Face protection (goggles or face shield)
- Fluid-repellent gown
- Single-use gloves

- Developmental methods were not reported.
- Information regarding conflicts of interest were not outlined.
- References are not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UKHSA Guidance	Expert opinion	Level 4			
Nipah virus: epidemiology, outbreaks and guidance January 2019					

**Country:** United Kingdom

**Target Audience:** All health and care staff that may may be involved in management or care of patients with suspected or confirmed Nipah virus infection.

### **Relevant Content:**

In this expert opinion guidance, UKHSA recommend that the IPC measures recommended for MERS should also be implemented when caring for patients infected with Nipah virus.

The recommended PPE ensemble includes:

- Long sleeved, fluid repellent disposable gown wearing scrubs underneath negates potential issues with laundering of uniforms and other clothing
- Non-sterile surgical gloves (double gloving required when there is a need to disinfect items from the room prior to their removal)
- FFP3 respirator conforming to EN149:2009. Fit testing required.
- Eye protection (single use and disposed of as clinical waste)

# Limitations:

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References are not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UKHSA	Expert opinion	Level 4			
Investigation and					
initial clinical					
management of					
possible human					
cases of avian					
influenza with					
potential to cause					
severe human					
<u>disease</u>					
November 2021					

# **Assessment of evidence**

Country: United Kingdom

Target Audience: All health and care staff that may may be involved in management of patients infected with Avian Influenza.

# **Relevant Content:**

In this expert opinion guidance, UKHSA recommend wearing an FFP3 respirator, gown, gloves, and eye protection as a minimum when caring for patients with possible avian influenza.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- · References are not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive/Advisory Committee on Dangerous Pathogens	Expert opinion	Level 4			
The approved list of biological agents  The Approved List of biological agents - HSE  2023					

Country: United Kingdom

**Target audience:** Applicable to those who work with biological agents, including working with humans known or suspected to be infected with such an agent.

**Methods:** The ACDP considered evidence that indicated the likelihood that an agent can cause disease in humans, how likely infection would be to spread in the community, and availability of prophylaxis or treatment when determining where biological agents would sit on the approved list.

#### Relevant Content:

This ACDP guidance outlines that the PPE/RPE combination has to establish a barrier against contact with contaminated surfaces, splash, spray, bulk fluids and aerosol particles as follows:

- Should provide adequate coverage of all exposed skin, with sufficient integrity to prevent ingress or seepage of bulk liquids or airborne particles, under foreseeable conditions of usage.
- The materials from which the PPE is made should resist penetration of relevant liquids/suspensions and aerosols.
- The various components (body clothing, footwear, gloves, respiratory/face/eye protection) should be designed to interface sufficiently well to maintain a barrier, e.g. sleeves long enough to be adequately overlapped by glove cuffs.

The ACDP states that there is no circumstantial or epidemiological evidence of airborne transmission risk from VHF patients, however, as a precautionary measure, it is considered appropriate to wear RPE to a high level Assigned Protection Factor when managing a confirmed case of VHF. It is outlined that this will usually be provided by a powered hood type respirator in specialist centres but that the use of a disposable filtering face-piece (FFP) respirator type EN 149 FFP3, certified as PPE under the European Directive 89/686/EEC can be considered as an alternative.

Specific PPE combinations are not presented by this guidance, instead the characteristics, function and ISO standards are given, this allows flexibility for different PPE options.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Hall S., Poller B., Bailey C., et al.  Use of ultraviolet- fluorescence-based simulation in evaluation of personal protective equipment and care of a patient with suspected high- consequence infectious disease.  Journal of Hospital Infection 99: 218- 228, 2018	Observational	Level 3	HCID PPE ensembles from Sheffield infectious diseases unit, London royal free hospital, Newcastle, Liverpool and Glasgow surge centres.	"Basic level" PPE ensemble.	Contamination of the PPE surfaces/HCW before and after removal of PPE, in addition staff were surveyed on their comfort, preferences etc.

**Country:** United Kingdom

**Aim:** The aim of this study was to assess the efficacy of HCID PPE ensembles from five different UK Ebola surge centres.

#### Methods:

37 volunteers from Sheffield infectious diseases unit, London royal free hospital, Newcastle, Liverpool, and Glasgow surge centres. All participants were familiar with using the PPE ensemble of their unit and were required to prove competency with other ensembles before taking part in the study. HCWs provided care to 'Viral VIOLET', a mannequin rigged to excrete simulated bodily fluids containing fluorescent tracers, HCWs wore one of five different PPE ensembles from UK Ebola surge/specialist centres.

Basic PPE: surgical mask, standard length apron, single short gloves.

Royal Free Hospital: surgical cap (under mask), visor, FFP3, gown, long length endoscopy-grade apron, short first pair of gloves under gown, long second pair of gloves over gown (taped lengthways x4), short third pair of gloves donned for dirty procedures, wellington boots, scrubs, alcohol gel hand hygiene steps in doffing, buddy supervising from a distance.

Sheffield Teaching Hospitals NHS Trust: surgical cap (over mask), visor, FFP3, gown, long length endoscopy-grade apron, short first pair of gloves under gown, long second pair of gloves taped lengthways x4, short third pair of gloves, boot covers, scrubs, buddy supervising from a distance.

Newcastle upon Tyne Hospitals: theatre hood, visor, FFP3 (over hood), gown (longer length, trimmed if needed), long length endoscopy-grade apron with strings ripped and tied at the neck for high fit, long first pair of gloves worn over the gown (taped lengthwise and around the cuff x3, second short pair of gloves, wellington boots, scrubs, alcohol gel hand hygiene steps in doffing, buddy supervising from a distance.

Royal Liverpool Hospital: hood with a tightly gathered face shape with surgical cap underneath, visor, FFP3 mask, coverall with a back zip, long length endoscopy-grade apron with cuts to sides and back of neck for ripping and strings looped for high fit, long first pair of purple gloves worn under coverall, long second pair of white gloves worn over the coverall and taped lengthwise x2, long third pair of purple gloves, wellington boots worn under coverall legs, scrubs, alcohol gel hand hygiene steps during doffing, buddy assisting during doffing.

Queen Elizabeth University Hospital, Glasgow: coverall hood, visor, FFP3, coverall with a front zip, long length endoscopy-grade apron, long first pair of surgical gloves worn under the coverall, long second pair of surgical gloves worn over the coverall, wellington boots worn under coverall legs with boot covers over, scrubs, alcohol gel hand hygiene steps in doffing, buddy assisting during doffing.

Volunteers wore one of six PPE ensembles (one basic and five enhanced ensembles for suspected EVD cases), it is not clear if each participant wore all six ensembles. Volunteers were screened for background fluorescence or contamination prior to donning PPE, after donning PPE, following simulated patient care exercises, and finally after doffing PPE. There were 35 body/PPE areas for analysis. Qualitative feedback was also collected from participants following doffing.

## Findings:

Number of potential contamination events differ for each area of the body due to differing PPE ensembles.

For the basic level PPE ensemble, 31 post-doffing contamination events were observed across four simulation scenarios.

For the enhanced PPE ensembles (all five analysed together) contamination events were categorised into area contaminated.

Head, face, and neck

- Out of 730 possible contamination events, 3 post-doffing contamination events were reported.
- Feedback from participants included concerns about exposure of neck when using cap ensembles, concerns about doffing of hood using bare hands, and confusion over correct positioning for mask straps.

Upper body, shoulders, and upper arms

- Out of 1460 possible contamination events, no post-doffing contamination events were reported.
- Feedback from participants highlighted familiarity and ease of unassisted doffing of gowns. Limited sizes and need for assisted
  doffing were mentioned in relation to coveralls. Modifications to aprons that aided in doffing were reported to sometimes be
  confusing.

#### Forearms and hands

- Out of 1168 possible contamination events, one post-doffing contamination event were reported.
- The single event of post-doffing contamination was determined to be due to cough fluid penetrating the surgical gown after the
  arm of the participant being centimetres from the patient's mouth. Further testing was undertaken (methodology not reported)
  and it was reported that the cough fluid used in this study could penetrate the standard fluid repellent surgical gown that met EN
  13795 Standard Performance; AAMI Level 2, but could not penetrate the reinforced sleeve of a high-performance gown that met
  EN 1395 High Performance; AAMI Level 3.
- Donning instructions across the enhanced ensembles varied greatly and it was highlighted in participant feedback that taping
  gloves to the gown was preferred and that taping circumferentially was considered more secure.
- It was also noted that participants often forgot to don a third pair of gloves before performing "dirty" procedure leading to contamination on second pair of gloves that were taped to the gown and difficult to doff.

# Lower body, legs, and feet

- Out of 1752 possible contamination events, 8 post-doffing contamination events were reported
- Feedback was received from one participant that they felt simulated vomit drip from their apron into their boots.
- Contamination on the legs was due to contaminated gloves, scissors, apron, gown, or boot covers touched the legs, or boot covers slipped down exposing the participant's leg.

- HCID PPE ensembles differ but are bundled in analysis.
- Small sample size.
- Not clear if all participants assessed all ensembles.
- Some conclusions within this paper were based on observations by individual participants or single contamination events.

Definitive conclusions on most efficient PPE ensemble cannot be drawn due to the findings of multiple ensembles being bundled for this analysis. Given the limitations of this study, further research on individual items of PPE is required.

Findings from this study were used to support the creation of the UK unified PPE ensemble for protection against HCIDs.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Poller B., Tunbridge A., Hall S., et al.	Expert opinion	Level 4			
A unified personal protective equipment ensemble for clinical response to possible high consequence infectious diseases: A consensus document on behalf of the HCID programme.  Journal of Infection 2018 77: p496-502					

# Assessment of evidence

Country: United Kingdom

Target Audience: Applicable to all health and care staff who may care for patients with suspected or confirmed HCIDs.

**Methods:** In order to determine a unified PPE ensemble a simulation exercise was developed and is described within a different paper. The results of this exercise were discussed with an expert group with representatives from infectious disease units across the UK.

#### **Relevant Content:**

No contamination was found on any of the participants after removal of the PPE ensemble during 20 doffing events. The agreed ensemble consists of:

- Disposable filtering face piece respirators (FFP3)
- 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 bodily fluid episodes
- Surgical wellington boots
  - Must be long enough to be overlapped by gown.

This ensemble was agreed upon by a group of experts and by the SHPN HCID subgroup.

This ensemble had already been agreed by the Scottish Health Protection Network (SHPN) High Consequence Infectious Disease (HCID) subgroup for use in Scotland.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Poller B., Hall S., Bailey C., et al.  'VIOLET': a fluorescence-based simulation exercise for training healthcare workers in the use of personal protective equipment  Journal of Hospital Infection 99 (2): 229- 235, 2018	Observational study	Level 3	HCWs provided care to 'Viral VIOLET', a mannequin rigged to excrete simulated bodily fluids containing fluorescent tracers; HCWs wore a test PPE ensemble intended as a new National unified ensemble.		Contamination of the PPE surfaces following simulated care exercises

Country: United Kingdom

**Aims:** This study aims to develop a practical tool that includes simulated exposure to bodily fluids to allow assessment of level of contamination on PPE and self-contamination during doffing.

# Methods:

The study team created VIOLET (Visualising Infection with Optimised Light for Education and Training) – a female healthcare mannequin equipped to simulate vomit, diarrhoea, sweat, and cough, in line with common HCID symptoms. Each simulated body fluid contained a distinct UV tracer to identify contamination on participants.

In order to test the VIOLET system, a simulated care environment was created including a single-bed isolation ward with manikin present, a demarcated doffing area, and cameras to provide real-time monitoring.

Healthcare staff participants, with experience of using PPE, donned a PPE ensemble (items and specification not reported) and undertook simulated patient assessment which included noting temperature and blood pressure and providing further patient care. Throughout this scenario, participants were exposed to all simulated body fluids. Two participants took part in each simulated care scenario.

After leaving the patient care area, participants were scanned for contamination using a fluorochrome visualisation system before doffing and repeated scanning.

# Findings:

Nineteen simulated care exercises were undertaken, with two participants involved in each. Visualisation showed significant contamination on the outer surfaces of PPE from all simulated body fluids. Further results on contamination following doffing are presented by Hall et al (2018).

#### Limitations:

- Small sample size.
- Not clear how many participants were involved.
- No participant characteristics reported.
- UV tracer rather than surrogate bacteria or virus.

#### **Conclusions:**

This study presented the use of the 'VIOLET manikin' as a method to simulate patient care in the event of HCID infection in order to evaluate efficacy of IPC protocols, particularly PPE. The methods set out in this study supported creation of the UK unified PPE ensemble.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Servies Scotland (NSS)	Expert opinion	Level 4			
Infection Control Advice: Severe Respiratory Illness from novel or emerging pathogens e.g. Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and Avian influenza (e.g. A/H7N9, A/H5N1) Version 7.2 June 2015					

Country: Scotland

Target Audience: Applicable to all health and care staff caring for patients with suspected or confirmed HCID.

# **Relevant Content:**

This expert opinion states that all staff and visitors entering the room of a patient infected with severe respiratory illness should don:

• Long-sleeved, fluid-resistant disposable gown

- Non-sterile gloves
- An FFP3 respirator that conforms to EN149:2001
- Eye protection that is compatible with the FFP3 respirator

It is noted that fit testing of FFP3 respirator should be carried out and fit checking should be undertaken every time the FFP3 respirator is donned.

It is noted that prescription glasses do not provide adequate eye protection.

# **Evidence from previous update(s):**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Ortega R., Bhadelia N., Obanor O., et al	Expert Opinion	Level 4			
Videos in Clinical Medicine. Putting on and removing personal protective equipment					
New England Journal of Medicine 2015 372(12)					

County: USA

**Target Audience:** applicable to all health and care workers who may care for patients with suspected or confirmed EVD.

#### **Relevant Content:**

It is outlined that no skin should be exposed, and the following PPE should be worn.

- Gloves (with extended cuffs)
- Disposable boot coverings that cover up to the mid-calf
- Disposable fluid resistant or impermeable gowns or coveralls that cover the body from the neck to at least the mid-calf
- Fit tested and checked disposable respirators (N95 or PAPR)
- Disposable hoods
- Disposable fluid resistant aprons if patient has diarrhoea or vomiting
- Disposable full-face shields

This is low level expert opinion-based guidance and is based on CDC recommendations.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control	Expert opinion	Level 4			
Safe use of personal protective equipment in the treatment of infectious diseases of high consequence 2014					

Country: European Union

**Target Audience:** Applicable to all health and care staff who may care for patients with suspected or confirmed HCIDs.

**Methods:** This expert opinion guidance was developed by a group of professionals with experience in medicine, infection control, preparedness, and training. This group assessed documents released by international health bodies including the WHO, CDC and Médecins Sans Frontières (MSF). This group was supported by further experts in barrier nursing, hospital infection control, and bio risk management, where necessary.

### **Relevant Content:**

The ECDC state that:

- scrubs should be worn under PPE
- coveralls must have a protective covering for the zipper and an integrated hood
- foot protection (ideally rubber boots but clogs may also be acceptable)

- boot covers
- double gloves
- respiratory protection (either a Type IIR surgical mask or unvalved FFP2/3 respirator)
- eye protection (unvented goggles or full-face shield) with an anti-fog coating

- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References are not provided within the text, only within a bibliography.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive/Advisory Committee for Dangerous Pathogens  Management of Hazard Group 4 viral haemorrhagic fevers and similar human infectious diseases of high consequence	Expert opinion	Level 4			

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
2015					

Country: United Kingdom

Target Audience: Applicable to all health and care staff.

Methods: The ACDP state that the risks of transmission of VHF were assessed, however, the methods of this were not reported.

# **Relevant Content:**

"When selecting PPE, the infection risk, the tasks to be undertaken, the environment in which the PPE is being used and the person using the PPE must be considered."

"It is important to consider ergonomic factors to give maximum protection while ensuring minimum discomfort to the wearer. Uncomfortable equipment is unlikely to be worn properly. More than one type or size of PPE may be needed and should be tested to fit the wearer. Some types of RPE e.g. disposable respirators and half- masks, are not suitable for staff with beards or facial hair as they will not seal to the wearer's face, and achieving a good face fit can be a particular problem for a person with a small face (see also below)."

It is outlined that the PPE/RPE combination has to establish a barrier against contact with contaminated surfaces, splash, spray, bulk fluids and aerosol particles as follows:

- It should provide adequate coverage of all exposed skin, with sufficient integrity to prevent ingress or seepage of bulk liquids or airborne particles, under foreseeable conditions of usage.
- The materials from which the PPE is made should resist penetration of relevant liquids/suspensions and aerosols.
- The various components (body clothing, footwear, gloves, respiratory/face/eye protection) should be designed to interface sufficiently well to maintain a barrier, e.g. sleeves long enough to be adequately overlapped by glove cuffs.

## Limitations:

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Public Health England	Expert opinion	Level 4			
Middle East Respiratory Syndrome (MERS-CoV) Infection Prevention and Control Guidance 2016					

# **Assessment of evidence**

Country: United Kingdom

Target Audience: Applicable to all health and care staff who may care for patients with suspected or confirmed MERS-CoV.

**Relevant Content:** 

According to this expert opinion guidance all persons that enter the room of a suspected or confirmed case of MERS-CoV should wear:

- long sleeved, fluid repellent disposable gown wearing scrubs underneath obviates problems with laundering of uniforms and other clothing
- non-sterile surgical gloves (double gloving required when there is a need to disinfect items from the room prior to their removal)
- FFP3 respirator conforming to EN149:2009. Fit testing required
- eye protection (single use and disposed of as clinical waste)

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References are not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Casanova L.M., Rutala W.A., Weber W.A., et al.  Effect of single- versus double- gloving on virus transfer to health care workers' skin and clothing during	Cross-over trial	Level 3	Use of a PPE ensemble including a single pair of gloves.  Contact isolation gown, N95 respirator, eye protection, single pair of gloves (regular size).	Use of a PPE ensemble including two pairs of gloves. Contact isolation gown, N95 respirator, eye protection, first pair of gloves (regular size), second pair of	Transfer of simulated virus during doffing to participant gloves, hands, face and clothing following simulated patient care. For each site the percentage of PPE or bodily sites

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
removal of personal protective equipment				gloves (1 size larger).	contaminated was presented (%)
American Journal of Infection Control 2012 40(4) p369-374					

Country: USA

**Aim:** This study aims to compare the frequency of contamination on participants gloves, hands, face and clothing when using two different PPE ensembles; one using single gloving, the other using double gloving.

#### Methods:

Eighteen volunteer participants with previous experience using PPE, including having N95 respirator fit testing, were involved in this study. Prior to donning any PPE, participants were shown posters of CDC doffing protocol and allowed to ask questions. All participants donned the double gloving PPE ensemble first and then the front shoulder of the gown, right side of N95 respirator, upper right of eye protection, and the palm of the dominant hand were contaminated with bacteriophage MS2. While wearing contaminated PPE participants undertook a simulated care activity (assessing neck and wrist pulses on a mannequin). Following this, doffing was undertaken following the CDC protocol with verbal assistance from a trained observer who also noted any deviations.

Following doffing, the participants hands were sampled using the glove juice method, and swab samples were collected from the participants face. Clothing and inner gloves were collected for sampling.

The same methods were followed for the single gloving PPE ensemble.

# Findings:

Viral transfer was reported in 78% of hand samples when single gloving was used and 23% of samples when double gloving was employed. This difference was found to statistically significant (p=0.007). A single instance of contamination was reported on a participants face when double gloving was used, no contamination on the face was reported when using single gloving.

Viral transfer was reported on 89% of scrub tops when single gloving was used and 94% when double gloving was used. For scrub trousers, 61% were positive for contamination when single gloving was used and 56% when double gloving was used. Viral transfer on scrub tops and trousers was found to be statistically comparable for both PPE ensembles (p=1.00 for both).

#### Limitations:

Small sample size

The findings of this study suggest that self-contamination of the hands may be less frequent in PPE ensembles that include double gloving.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Beam E.L.,	Expert opinion	Level 4			
Schwedhelm S.,					
Boulter K., et al.					
Personal protective					
equipment					
processes and					
rationale for the					
<u>Nebraska</u>					
Biocontainment Unit					
during the 2014					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
activations for Ebola virus disease					
American Journal of Infection Control 2016 44(3)p340-342					

Country: USA

Target Audience: Applicable to all health and care workers who may care for patients with suspected or confirmed EVD

## **Relevant Content:**

The following two ensembles are recommended based on whether it includes use of an N95 respirator or PAPR:

## 'N95 Ebola PPE'

• Boot covers, hood, gown, N95 respirator, face shield, exam gloves, long-cuff gloves (using duct tape to attach to sleeves of gown), third layer of gloves. An apron can also be donned for patient care

#### 'PAPR Ebola PPE'

• Protective suit, boot liners (under suit, over footwear), boot covers (over suit), exam gloves (worn under suit cuffs), long-cuff gloves (taped to suit sleeves), third layer of gloves, PAPR hood. An apron can also be donned for patient care.

These ensembles are cited to be based on CDC recommendations.

- Development methods were not reported.
- The report does not indicate when one ensemble should be worn instead of the other.

• A 'patient care mask' is mentioned in doffing for both levels however this is not included in donning instructions for either ensemble so it is unclear what this is or when it should be donned.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health	Expert Opinion	Level 4			
Organization					
Interim Infection					
Prevention and					
Control Guidance for					
Care of Patients with					
Suspected or					
Confirmed Filovirus					
Haemorrhagic Fever					
in Health-Care					
Settings, with Focus					
on Ebola					
December 2014					

# **Assessment of evidence**

**Country:** International

**Target Audience:** Applicable to all health and care staff who may care for patients with suspected or confirmed filovirus haemorrhagic fever.

# **Relevant Content:**

This expert opinion guidance recommends that the following PPE ensemble should be worn when caring for patients with filovirus haemorrhagic fever:

- double non-sterile gloves, preferably nitrile. Outer glove should have long cuff extending past the wrist, ideally to mid-forearm
- disposable fluid-resistant gown or coverall
- disposable waterproof apron
- fluid-resistant surgical mask. Structured design is preferred
- goggles or face shield
- waterproof boots
- respirator should be worn when AGPs are performed

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- · References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control	Expert Opinion	Level 4			
Interim ECDC public health guidance on case and contact management for the new influenza A(H1N1) virus infection					
Version 3, 2009					

Country: European Union

Target Audience: All health and care staff involved in care of patients with suspected or confirmed influenza A virus infection.

## **Relevant Content:**

This expert opinion guidance outlines that the PPE ensemble to be worn when caring for patients with influenza A(H1N1) should include:

- a surgical mask whenever entering the patient's room
- a gown or plastic apron, disposable non-sterile gloves, protective eyewear when splash or spray is anticipated

It is outlined that when undertaking high-risk care activities, FFP2 (or higher) mask, disposable non-sterile gloves, gown or plastic apron, protective eyewear should be worn.

## Limitations:

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

# Question 4: What standards (EN) must be adhered to and what design features are desirable?

# **Evidence added to Literature Review V3.0:**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government	Legislation	Mandatory			
Guidance: CE  Marking					
Published: 2012					
Last Update August 2023					

# Assessment of evidence

Country: United Kingdom

# **Relevant Content:**

Within this legislative document it is noted that the UK Government has extended the recognition of CE marking, indefinitely, beyond December 2024.

CE marking indicates that manufacturers have ensured that products meet EU health, safety, or environmental requirements and other EU legislation.

Personal protective equipment falls under one of the product categories on which CE marking is required.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease	Expert opinion	Level 4			
Control and					
Prevention					
Considerations for					
Selecting Protective					
Clothing used in					
Healthcare for					
Protection against					
Microorganisms in					
Blood and Body					
<u>Fluids</u>					
2020					

Country: USA

Target Audience: Applicable to all health and care staff in all settings.

## Relevant content:

The CDC state that choice of protective clothing includes a number of considerations:

- physical and chemical properties of the fabric including factors such as thickness, pore size, and repellence
- shape, size, and other characteristics of microorganisms including factors such as morphology, motility, and adaptation to environmental extremes
- characteristics of the carriers includes factors such as surface tension, volume, and viscosity
- external factors including factors such as physical, chemical, and thermal stresses

- USA context may limit wider applicability.
- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Poller B., Tunbridge A., Hall S., et al.	Expert opinion	Level 4			
A unified personal protective equipment ensemble for clinical response to possible high consequence infectious diseases: A consensus document on behalf of the HCID programme  Journal of Infection 2018 77 p496-502					

Country: United Kingdom

**Target Audience:** Applicable to all health and care staff who may come into contact with HCIDs.

**Methods:** In order to determine a unified PPE ensemble a simulation exercise was developed and is described within a different paper. The results of this exercise were discussed with an expert group with representatives from infectious disease units across the UK.

# **Relevant Content:**

This expert opinion document outlines the desirable features of different PPE items. The Hall et al (2018) simulation study that assesses five different UK Ebola surge centre PPE ensembles using the VIOLET simulation methods is referenced across this consensus document.

Maximal skin coverage is preferred for most items of PPE. Head protection – Two sizes of hood should be available to accommodate as many members of staff as possible. The fastening on the front of the hood should be adjustable. Full-face visor should have a wide strap to aid in removal and should extend a minimum of 2cm below the chin. HSE guidance on RPE is referenced.

Body protection – Surgical gown should be rear fastening to account for splash, particularly from VHF patients. Surgical gown should be fluid-resistant, not fully waterproof, and should be long enough to achieve a 10-15cm overlap with top of boots. Aprons should be wide and extra-long, made from medium thickness plastic. A higher fit was desired but a commercially available apron meeting this requirement was not produced and so modifications were made to achieve this fit (tearing neck loop to allow tying and higher coverage).

Hand Protection – three layers of gloves were recommended within this ensemble with short non-sterile gloves recommended for inner and outer gloves and long cuffed glove for the middle layer to allow for overlapping with gown sleeve and taping. HSE guidance for donning and doffing gloves is referenced.

Leg and Foot Protection - boots should be long enough to be overlapped by apron and surgical gown. Boots should be oversized to allow for step-out removal technique but not large enough to increase risk of trips.

- Limited references were provided throughout the recommendations in this paper.
- Members of the High Consequence Infectious Diseases Project Working Group were not named.
- While author conflicts of interest were reported, those of the working group members were not.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization	Expert Opinion	Level 4			
Personal protective equipment in the context of filovirus disease outbreak response 2014					

**Country:** International

Target Audience: Applicable to all health and care staff who may work with patients infected with filovirus.

# **Relevant Content:**

This document recommends that, when caring for patients with filovirus disease

- Goggles should create a good seal with the skin of the face, cover the eyes and surrounding area with space to accommodate
  prescription glasses. Securing band should be adjustable but remain in place during patient care. Goggles should be fog and
  scratch resistant and may include indirect venting.
- Goggles should be compliant with EU standard directive 86/686/EEC, EN 166/2002, ANSI/ISEA Z87.1-2010, or equivalent.
- Face shield should be made of materials that ensure good visibility without fogging, should completely cover the length and width of the face including the sides. Securing band should be adjustable but remain in place during patient care.
- Face shield should be compliant with EU standard directive 86/696/EEC, EN 166/2002, ASNI/ISEA Z87.1-2010, or equivalent.
- Surgical masks with a structured design, that doesn't collapse against the mouth, should be used.

- Masks should be fluid resistant if used in an ensemble with goggles, but fluid resistance is not required when used with a face shield.
- Masks should be compliant with EN 14683 Type IIR performance, ASTM F2100 level 2 or level 3 or equivalent.
- Outer gloves should have a long cuff (ideally to the mid-forearm), and the inner gloves should be worn under the cuff of the gown.
- Nitrile gloves are preferred over latex gloves due to protective effect and risk of latex allergy. Non-powdered gloves are also preferred over powdered gloves.
- Gloves should be compliant with EU standard directive 93/42/EEC Class I, EN 455, EU standard directive 89/686/EEC Category
   III, EN 374, ANSI/ISEA 105-2011, ASTM D6319-10, or equivalent.
- Fabric of gowns/coveralls should be tested for protection against penetration by blood, body fluids or blood-borne pathogens.
- Protective body wear should be fluid resistant.
- Disposable gowns should be compliant with EN 13795 high performance level, AAMI level 3 performance, AAMI PB 70 level 4 performance, or equivalent.
- Disposable coveralls should be compliant with ISO 16603 class 3 exposure pressure, ISO class 2 exposure pressure, or equivalent.
- Footwear should be slip-on without laces and cover the entire foot and ankle.

Various sizes of PPE should be available to accommodate as many members of staff as possible.

- References were not provided.
- Developmental methods were not reported.
- Individuals involved with guidance development were not named.

Information regarding conflicts of interest were not outlined.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE)	Expert opinion	Level 4			
Personal protective equipment at work. The Personal Protective Equipment at Work Regulations 1992 (as amended). Guidance on Regulations. Fourth edition 2022					

# Assessment of evidence

Country: United Kingdom.

Target audience: Applicable to all health and care staff in all settings.

# **Relevant Content:**

Items of PPE should be compatible to work together while protecting the wearer effectively against risk. An example is provided stating that if a half-mask respirator is provided, it should be compatible with goggles or other eye protection intended to be worn at the same time.

It is also stated in this guidance that risk assessment regarding PPE selection should include considerations on compatibility of items to be worn together.

Parts of these regulations are superseded by COSHH and have not been outlined in this evidence table entry.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Reidy P., Fletcher T., Shieber C., et al.	Expert Opinion	Level 4			
Personal protective equipment solution for UK military medical personnel working in an Ebola virus disease treatment unit in Sierra Leone					
Journal of Hospital Infection 2017 96 p42-48					

# Assessment of evidence

Country: Sierra Leone/United Kingdom

Target Audience: Applicable to all health and care staff working with EVD.

**Methods:** A group of specialists from Public Health England, the National Ambulance Resilience Unit and the Ministry of Defence (MoD) was convened to identify a suitable PPE ensemble, along with donning and doffing protocols, for staff working in EVD treatment units in Sierra Leone.

#### Relevant content:

Authors outline the following PPE requirements:

All PPE should meet relevant standards.

Boots – rubber and seamless to aid in decontamination. Flexible and comfortable for wearers. Light or bright colours preferred so that visible contamination can be more easily identified. Should be made from a material that is resistant to cuts and punctures.

Coveralls – Preferred as a single suit that covers head, torso, arms and legs. Should be made of a material the is breathable and seams should be taped to reduce possible penetration by liquid contamination. Finger-loops to anchor sleeves.

Aprons – Should be long enough to sit below the knee and made of a lightweight fluid repellent material. Should be adjustable so it covers the required area.

Gloves – powder-free nitrile gloves were recommended to provide protection and avoid allergic reaction. Long gloves preferred for additional arm coverage. First pair of gloves worn under the cuff of the coverall, outer gloves should be extended over the coverall sleeves.

Visor – replaceable acetate screens that provide sufficient visual range. Adjustable head band to ensure fit for as many HCWs as possible.

Headwear – coverage for the front of the head, worn over the upper edge of the visor. Fluid repellent headwear preferred.

- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.

References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease	Expert Opinion	Level 4			
Control and Prevention (CDC)					
Guidance on					
Personal Protective Equipment (PPE) to					
be used by					
healthcare workers during management					
of patients with confirmed Ebola or					
persons under					
investigation (PUIs) for Ebola who are					
clinically unstable or have bleeding.					
vomiting, or diarrhea					
in U.S. hospitals, including procedures					
for donning and					
doffing PPE.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
2022					

Country: USA

Target Audience: Applicable to all health and care staff working with patients with EVD who are clinically unstable.

Methods: Development methods were not reported.

# **Relevant Content:**

The CDC suggest 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.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Crook B., Bailey C.,	Experimental study	Level 3	PPE ensemble 1	PPE ensemble 2	Presence of
Sykes A., et al.	(crossover trial)		(PPE1) which	(PPE2) which	fluorochrome
Validation of			included PAPR	included PAPR	contamination on
personal protective			system with power	system with	
personal protective			pack on waist belt,	integrated power	

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
equipment ensembles, incorporating powered air-purifying respirators protected from contamination, for the care of patients with high- consequence infectious diseases.  Journal of Hospital Infection 2023 134 p71-79	Study Type	Evidence Level	fluid resistant hood with integrated visor, fluid resistant coverall with front zipper, surgical clogs worn under coverall, shoe covers worn over coverall, three pairs of gloves with middle pair taped to sleeves of coverall, long-sleeved plastic apron.	pack, fluid resistant hood with integrated visor, fluid resistant coverall with rear zipper, wellington boots worn outside coverall with gaiters covering the top of boots, three pairs of gloves with middle pair taped to sleeves of coverall, sleeveless plastic	participants bodies after doffing.
				apron.	

**Country:** United Kingdom

#### Aim:

This observational study aimed to compare two PPE (PPE1 and PPE2) ensembles and their propensity to contaminate individuals during the doffing process.

# Methods:

Twenty members of experienced medical staff, with training and practical experience in use of HCID PPE, participated in this study. Participants were allowed to become familiar with the PPE ensembles before following a six-step study protocol.

Step 1 – Supervised donning of ensemble

- Step 2 application of fluorochrome
- Step 3 –three physical tests that mimic movements common to patient care and a manual dexterity test
- Step 4 supervised doffing of ensemble
- Step 5 examination using UV light to identify contamination
- Step 6 post-test questionnaire

This protocol was repeated by each participant once for each PPE ensemble; however, the order each ensemble was worn by participants was not reported.

#### Results:

One instance of 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.

It was noted by the participants that removal of the long-sleeved apron used in PPE 1 was easier than the sleeveless apron used in PPE 2.

- Multiple differences between the two ensembles mean that no single aspect can be attributed to a change in contamination levels.
- Subjects could not be blinded to the intervention.
- it is not clear if individuals who assessed contamination were not blinded to the PPE ensemble which had been doffed.
- Experienced staff members specifically involved which may limit applicability.
- Small subject cohort.

#### Conclusions:

This observational study suggests that the features of PPE in PPE ensemble 1 (PAPR system with power pack on waist belt, fluid resistant hood with integrated visor, fluid resistant coverall with front zipper, surgical clogs worn under coverall, shoe covers worn over coverall, three pairs of gloves with middle pair taped to sleeves of coverall, long-sleeved plastic apron) are preferable to those in PPE ensemble 2 when considering contamination that occurs during doffing.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government	Legislation	Mandatory			
The Personal Protective Equipment (PPE) at Work Regulations 2022					

#### Assessment of evidence

**Country:** United Kingdom

#### **Relevant Content:**

This legislation states that when more than one item of PPE is worn, they must be compatible with each other and, when used together, should adequately control risk. The wearer should be able to undertake their regular job roles without impediment.

All items of PPE should also be free of rough or sharp edges, or other features, that may cause excessive irritation or injury. When the wearers body will be enclosed by PPE, PPE should be sufficiently ventilated to minimise perspiration, or made to absorb perspiration, which may impact protective effect or fit of PPE. Where necessary, PPE should also be water resistant.

When latex gloves are required to be worn, these should be non-powdered in order to limit risk of irritation or allergic reaction.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government	Legislation	Mandatory			
Regulation 2016/425 and the Personal Protective Equipment (Enforcement) Regulations 2018: Great Britain May 2023					

Country: United Kingdom

# **Relevant Content:**

The Personal Protective Equipment (Enforcement) Regulations incorporate EU Regulation 2016/425 into UK law. These regulations state the health and safety requirements PPE products must meet prior to placement on the UK market.

The Personal Protective Equipment (Enforcement) Regulations do not include regulations specific to HCIDs.

# **Evidence from previous update(s):**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety	Expert opinion	Level 4			
Executive/Advisory					
Committee on					
Dangerous					
Pathogens					
Management of					
Hazard Group 4 Viral					
<u>Haemorrhagic</u>					
Fevers and Similar					
Human Infectious					
Diseases of High					
Consequence					
November 2015					

# **Assessment of evidence**

**Country:** United Kingdom

Target audience: Applicable generally to all healthcare workers and healthcare settings.

**Methods:** The ACDP assessed the risks of transmission of VHF, however, the methods of this were not reported.

# **Relevant Content:**

PPE must bear a "CE" mark that signifies compliance with the Personal Protective Equipment Regulations 2002. This implements the European PPE Directive concerning design and manufacture and demonstrates conformance with European (EN) or International (ISO) standards.

# Limitations:

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention	Expert Opinion	Level 4			
Considerations for U.S. Healthcare Facilities to Ensure Adequate Supplies of Personal					
Protective Equipment (PPE) for Ebola Preparedness 2016					

# **Assessment of evidence**

Country: USA

Target audience: All health and care staff in all healthcare settings in the USA

#### **Relevant Content:**

The CDC guidelines state that when selecting PPE consideration must also be given to garment properties such as seams, it is essential that all seams/closures provide similar barrier protection to the fabric itself e.g. welded or double taped seams.

#### Limitations:

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE)  Respiratory Protective Equipment at Work: A practical guide. 2013	Guidance	Level 4			

# **Assessment of evidence**

Country: United Kingdom

Target audience: Applicable generally to all healthcare workers and healthcare settings.

#### **Relevant Content:**

This document highlights that RPE should be adequate and suitable to protect the wearer during their required tasks.

- "Adequate: it is right for the hazard and reduces exposure to the level required to protect the wearer's health
- Suitable: it is right for the wearer, task and environment, such that the wearer can work freely and without additional risks due to the RPE."

Choice of filter should be appropriate for the risk faced during work tasks.

RPE should be suitable to the wearer, task, and work environment.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institute	British Standard	Level 4			
BS EN 14126:2003 Protective clothing against infective agents 2003					

# Assessment of evidence

Country: United Kingdom

Target audience: All involved with providing personal protective equipment.

#### **Relevant Content:**

This standard outlines the protective effect required by personal protective clothing, with differences depending on what substances the clothing is worn to protect the wearer from.

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. 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.

# Question 5: Should different elements of PPE for HCID be integrated/interfaced and how should this be done i.e. use of tape?

# **Evidence added to Literature Review V3.0:**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
InterAgency Board for Equipment Standardization and	Expert Opinion	Level 4			
Interoperability (IAB)  Recommendations on Selection and Use of Personal					
Protective Equipment for First Responders against					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Ebola Exposure Hazards					
V1.5, 2014					

Country: USA

**Target Audience:** Applicable to first responder staff working with EVD.

**Methods:** Development methods were not reported; however, it is stated that the InterAgency Board for Equipment Standardization and Interoperability is a voluntary collaborative panel with representatives from a broad range of professional disciplines within government and public safety, with experience in emergency preparedness and response.

#### **Relevant Content:**

It is noted within this expert opinion that interfacing of different items of the PPE ensemble impacts upon the donning procedure.

Within the ensemble recommended for both high and low risk interactions with EVD patients it is stated that:

- Where outer gloves are not manufactured as integrated into coveralls, the cuff of these should be extended over the coverall and taped in place.
- Hoods integrated with coveralls are also recommended for both high and low risk interactions with EVD patients when helmet PAPR are not used.
- Tape can be used to seal hood around face protection. It is noted that the respirator should not be taped to the hood.
- When footwear does not have sock-like extensions, coverall leg openings should be taped over boots/foot covers.

A warning is included that states it is important to use a tape that will not degrade protection of PPE.

- Members of the guidance development panel were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Hall S., Poller B., Bailey C., et al.  Use of ultraviolet- fluorescence-based simulation in evaluation of personal protective equipment and care of a patient with suspected high- consequence infectious disease.  Journal of Hospital Infection 2018 99 p218-228	Observational study	Level 3	HCID PPE ensembles from Sheffield infectious diseases unit, London royal free hospital, Newcastle, Liverpool and Glasgow surge centres.	"Basic level" PPE ensemble.	Contamination of the PPE surfaces/HCW before and after removal of PPE, in addition staff were surveyed on their comfort, preferences etc.

**Country:** United Kingdom

**Participants:** 37 volunteers from Sheffield infectious diseases unit, London royal free hospital, Newcastle, Liverpool, and Glasgow surge centres. All participants were familiar with using the PPE ensemble of their unit and were required to prove competency with other ensembles before taking part in the study. HCWs provided care to 'Viral VIOLET', a mannequin rigged to excrete simulated bodily fluids containing fluorescent tracers, HCWs wore five different PPE ensembles from UK Ebola surge/specialist centres.

# Findings:

- One participant reported feeling simulated vomit dripping from the apron into boots and thus the authors concluded that aprons should cover the tops of boots to avoid this.
- Hands and forearms were the most frequently contaminated areas
- Taping of gloves to sleeves of gown was felt to prevent slipping and assisted doffing, however, thinner gloves did rip on a number of occasions during doffing and circumferential taping can easily be done too tightly, preventing removal of the sleeve.

#### Limitations:

- HCID PPE ensembles differ but are bundled in analysis.
- Small sample size.
- Not clear if all participants assessed all ensembles.

#### **Conclusions:**

This study indicates design features of items within PPE ensembles that would be preferential when considering contamination of the wearer. For example, apron length extending over the top of boots to prevent contamination within the boots. However, given the limitations of this study, further research on individual items of PPE is required.

Findings from this study were used during creation of the UK unified PPE ensemble for protection against HCIDs.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Poller B., Tunbridge A., Hall S., et al.	Expert opinion	Level 4			
A unified personal protective equipment ensemble for clinical response to possible high consequence infectious diseases: A consensus document on behalf of the HCID programme.  Journal of Infection 2018 77 p496-502					

Country: United Kingdom

Target Audience: Applicable to all health and care staff who may come into contact with HCIDs.

**Methods:** In order to determine a unified PPE ensemble a simulation exercise was developed and is described within a different paper. The results of this exercise were discussed with an expert group with representatives from infectious disease units across the UK.

# **Relevant Content:**

This document outlines that the middle pair of the three pairs of worn gloves should be taped lengthwise to the sleeves of the gown using micropore tape.

- Limited references were provided throughout the recommendations in this paper.
- Members of the High Consequence Infectious Diseases Project Working Group were not named.
- While author conflicts of interest were reported, those of the working group members were not.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease	Expert opinion	Level 4			
Control and					
Prevention					
Considerations for					
Selecting Protective					
Clothing used in					
Healthcare for					
Protection against					
Microorganisms in					
Blood and Body					
<u>Fluids</u>					
Considerations for					
Selecting Protective					
Clothing   NPPTL					
NIOSH   CDC					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Last Updated: April 2020					

Country: USA

Target Audience: Applicable to all health and care staff in all settings.

#### Relevant content:

The CDC highlight the importance of the interface between gloves and coverall sleeves, as well as between face/eye or respiratory protection and hoods of coveralls. It is stated that "these interfaces are essential to the individual's overall protection, because the overall ensemble of PPE provides their protection."

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government	Legislation	Mandatory			
Personal Protective Equipment at Work (Amendment) Regulations 2022					

Country: United Kingdom

# **Relevant Content:**

This legislation states that when more than one item of PPE is worn, they must be compatible with each other and, when used together, should adequately control risk.

# **Evidence from previous update(s):**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety	Expert opinion	Level 4			
Executive/Advisory					
Committee on					
Dangerous					
Pathogens					
Management of					
Hazard Group 4 viral					
haemorrhagic fevers					
and similar human					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
infectious diseases of high consequence					
2015					

**Country:** United Kingdom

Target audience: Applicable generally to all healthcare workers and healthcare settings.

**Methods:** The ACDP assessed the risks of transmission of VHF, however, the methods of this were not reported.

#### **Relevant Content:**

This expert opinion guidance states that the PPE/RPE combination has to establish a barrier against contact with contaminated surfaces, splash, spray, bulk fluids and aerosol particles as follows:

- through providing adequate coverage of all exposed skin, with sufficient integrity to prevent ingress or seepage of bulk liquids or airborne particles, under foreseeable conditions of usage
- through the materials from which the PPE is made resisting penetration of relevant liquids/suspensions and aerosols
- through the various components (body clothing, footwear, gloves, respiratory/face/eye protection) being designed to interface sufficiently well to maintain a barrier, e.g. sleeves long enough to be adequately overlapped by glove cuffs

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health	Expert opinion	Level 4			
Organization					
Interim infection					
prevention and					
control guidance for					
care of patients with					
suspected or					
confirmed filovirus					
haemorrhagic fever					
<u>in healthcare</u>					
settings, with focus					
on Ebola					
2014					

**Country:** International

Target audience: Applicable to all health and care workers involved in the management of patients infected with Ebola

Methods: No development methods reported

# Findings:

This expert opinion guidance states that adhesive tape should not be used to attach gloves to coveralls. It states that if the inner gloves or the coverall sleeves are not long enough, a thumb (or middle finger) hole should be made in the coverall sleeve to ensure that the forearm is not exposed when making wide movements. Authors outline that some coverall models have finger loops attached to sleeves.

#### Limitations:

- Development methods were not reported.
- individuals involved with guidance development were not named.
- information regarding conflicts of interest were not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control	Expert opinion	Level 4			
Safe use of personal protective equipment in the treatment of infectious diseases of high consequence 2014					

# **Assessment of evidence**

Country: European Union

Target audience: Applicable to health and care staff working with HCID.

**Methods:** These expert opinion guidelines were developed by a group of professionals with experience in medicine, infection control, preparedness, and training. This group assessed documents released by international health bodies including the WHO, CDC and

Médecins Sans Frontières (MSF). This group was supported by further experts in barrier nursing, hospital infection control, and bio risk management, where necessary.

#### Relevant content:

The ECDC recommends the use of tape (parcel tape rather than textile based or duct tape) to secure inner gloves to the coveralls, that coveralls should be adjusted to size (hoods) and that small gaps where PPE interfaces around the face, gloves and boots should be sealed. The authors acknowledge that there are drawbacks and potential safety issues as well as benefits, for example over-taping near the respirator can make breathing difficult, taping too tightly or using too much tape can complicate the doffing process and removing tape can delaminate the surface of protective coveralls reducing their resistance to fluids/organisms.

"Most PPE manufacturers explicitly state in the product manuals, that taping compromises the integrity and functionality of PPE components."

In addition, the authors acknowledge that joining goggles and respirators with tape can cause both items to lose their seal fit.

- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided within the text, only within a bibliography.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Cummings K.J., Choi M.J., Esswein E.J., et al.	Case report/ Expert opinion	Level 4			
Addressing infection prevention and					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
control in the first U.S. community hospital to care for patients with Ebola virus disease: context for National recommendations and future planning Annals of Internal Medicine 2016 165 p41-49					

Country: USA

Setting: Community hospital

This case report describes the protocols and processes in place for managing Ebola virus disease (EVD) patients in a specific U.S. community hospital. This hospital cared for the first imported EVD case in the U.S. and two nurses who cared for the patient were infected and contracted EVD. This prompted a review of all protocols including PPE.

# Findings:

It was noted that HCWs used tape between the outer gloves and sleeves to prevent them riding up, however, silk tape was too adhesive and risked tearing the gloves on removal whilst paper tape often tore creating issues during the doffing process.

# **Conclusions:**

This report provides anecdotal evidence that using tape to attach sleeves to gloves can cause breaches in PPE and/or difficulties in the doffing process.

# Question 6: How should PPE for HCID be donned and doffed?

# **Evidence added to Literature Review V3.0:**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Casanova L.M., Erukunnakpor K., Kraft C.S., et al. Assessing Viral Transfer During Doffing of Ebola- Level Personal Protective Equipment in a Biocontainment Unit Clinical Infectious Diseases. 2018 66(6): p945-949 doi: 10.1093/cid/cix956	Observational study	Level 3	Doffing of PPE artificially contaminated with two surrogate viruses: MS2 (a surrogate for nonenveloped human viruses) and bacteriophage \$\phi6\$ (a surrogate for enveloped viruses such as Ebola).	N/A	Plaque-forming units (PFUs) of surrogate viruses present on used PPE or skin (hands and face) of participants, and high touch surfaces.  Presence of fluorescent tracer on high touch surfaces.

Country: USA

Aim: This study aimed to investigate self-contamination of skin, inner gloves, and scrubs that can occur during doffing of PPE used when caring for Ebola virus disease (EVD), using MS2 and bacteriophage \$\displays 6\$ as surrogates for nonenveloped and enveloped human viruses.

#### Methods:

Ten participants were verbally guided through donning and doffing protocols Following donning, MS2 and \$6\$ suspended in phosphate-buffered saline containing fluorescent tracer was applied to four areas (palm of dominant hand, shoulder of gown opposite dominant hand, top side of the PAPR opposite hand, toe of shoe cover opposite dominant hand). Participants then undertook simulated care tasks including entering a patient room, emptying a urinary catheter bag, and cleaning the patient room. Doffing was then undertaken with verbal and visual support from a trained observer.

Following doffing, PPE, and participants skin (hands, face) were examined under UV light and where fluorescence tracer was present, sampled to assess the presence of bacteriophage. High touch surfaces were examined under UV light and where fluorescent tracer was present, sampled for presence of bacteriophage. Presence of bacteriophage was measured in plaque-forming units (PFUs).

# Findings:

Transfer of bacteriophage \$6\$ was detected on the scrubs of one participant (~140 PFU), MS2 transfer was detected on gloves of 7 participants (SD= 2.72 x 10<sup>6</sup>) and on the scrubs of 2 participants (SD= 4.18 x 10<sup>3</sup>). One participant (who had detectable contamination on their gloves) also had detectable transfer on both their dominant and nondominant hands (PFU 96 and 144, respectively). 21 high touch sites were sampled following visible presence of fluorescent tracer, no bacteriophage was detected from these samples.

Doffing Steps (beginning in patient room, verbal guide throughout)

- Remove apron
- Remove 1 bootie, then step onto chemical mat
- Remove other bootie, then step onto chemical mat
- Sanitise gloves

- · Remove outer gloves using the beaking method
- Sanitise inner gloves
- Remove tape
- Sanitise inner gloves
- Remove biohazard coverall
- Sanitise inner gloves
- Leave patient room, enter anteroom
- Remove PAPR hood
- Sanitise inner gloves
- Remove inner gloves using the beaking method
- Wash hands with soap and water
- Remove belt, battery, and motor (for PAPR)

#### **Conclusions:**

The findings of this study indicate that self-contamination occurred when using the presented doffing protocol, further study with a greater number of participants and comparison to other methods would be required to confirm if this doffing protocol prevents self-contamination.

- Small sample size.
- No control group.
- No significance testing.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Casanova L.M., Teal L.J., Sickbert-Bennett E.E., et al. Assessment of Self-Contamination During Removal of Personal Protective Equipment for Ebola Patient Care Infection Control & Hospital Epidemiology 37(10):1156-1161, 2016 doi: 10.1017/ice.2016.16	Observational study	Level 3	PPE artificially contaminated with two surrogate viruses: MS2 (a surrogate for nonenveloped human viruses) and bacteriophage \$\phi6\$ (a surrogate for enveloped viruses such as Ebola).	N/A	Plaque-forming units (PFUs) of surrogate viruses present on used PPE or skin (hands and face) of participants, and high touch surfaces.

Country: USA

**Aim:** This study aimed to investigate self-contamination of skin, inner gloves, and scrubs that can occur during doffing of PPE used when caring for Ebola virus disease (EVD), using MS2 and bacteriophage \$\phi\$6 as surrogates for nonenveloped and enveloped human viruses.

# Methods:

In this study, fifteen participants were verbally guided through donning and doffing protocol and performed simulated patient care activities. Following donning, MS2 and 66 suspended in phosphate-buffered saline containing fluorescent tracer was applied to four areas

(palm of dominant hand, shoulder of gown opposite dominant hand, top side of face shield on the same side as the dominant hand, toe of shoe cover opposite dominant hand). During doffing, ten participants cleaned gloved hands using ABHR and five used hypochlorite solution (HOCI).

Following doffing, scrubs and inner gloves were collected for sampling and participant's hands and face were sampled for contamination with bacteriophage. Presence of bacteriophage was measured in plaque-forming units (PFUs).

# Findings:

No contamination with bacteriophage \$6\$ was reported on any sampled site/item. Contamination with MS2 was reported on the inner gloves of eight participants who cleaned gloved hands with ABHR with one of these participants having contamination of their scrub top. No contamination of inner gloves was reported for participants that cleaned gloved hands with HOCl but one of these participants was positive for contamination on both their hands and another had contamination on their scrub top.

Doffing protocol performed with trained monitor:

- Wash gloved hands with water and chlorhexidine
- Step into chlorine bath, remain in bath for 1 minute contact time before stepping onto absorbent pad
- Check integrity of PPE
- Remove first set of gloves, check integrity of inner glove
- Clean gloved hands with ABHR (70% ethanol gel) or liquid hypochlorite (1850ppm)
- Remove impervious gown by grabbing at the shoulder and pulling forward
- Clean gloved hands with ABHR (70% ethanol gel) or liquid hypochlorite (1850ppm)
- Remove Tyvek suit
- Clean gloved hands with ABHR (70% ethanol gel) or liquid hypochlorite (1850ppm)
- Remove hood, mask, and face shield

- Clean gloved hands with ABHR (70% ethanol gel) or liquid hypochlorite (1850ppm)
- Remove inner gloves using aseptic technique
- Clean hands with ABHR
- Step into chlorine bath, remain in bath for 1 minute contact time before stepping onto absorbent pad
- Remove boots keeping boots in "hot zone"
- Clean hands with ABHR

#### **Conclusions:**

The findings of this study may suggest that self-contamination with non-enveloped viruses is limited when using this PPE doffing protocol and that risk of self-contamination may be higher with enveloped viruses. However, due to the small sample sizes and lack of statistical analysis definitive conclusions cannot be drawn and further research is needed.

- small sample size
- differing hand hygiene methods used for cleaning gloved hands across sample.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Xi H., Cao J., Liu J., et al.	Time Series study	Level 3	Implementing real- time monitoring and	N/A	Error rate (%) of doffing when
Improving health care workers' protection against infection of Ebola			communication with HCWs doffing PPE via video surveillance in observation and		assessed using WHO guidelines on Ebola level PPE

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
hemorrhagic fever through video surveillance American Journal of Infection Control 2016. 44 p922-924, doi: 10.1016/j.ajic.2016.0 2.015			treatment wards of an Ebola treatment unit.		doffing by trained supervisors.  Error rate = % of errors occurring across all doffing events.

Country: China/Liberia

**Aim:** The aim of this study was to assess the impact of introducing a supervisory role during doffing of PPE used for the care of Ebola patients through the use of video surveillance viewed by a trained observer.

#### Methods:

This study took place in the observation and treatment wards of the China Ebola treatment unit in Liberia between 26<sup>th</sup> January – 4<sup>th</sup> March 2015.

Fifty surveillance cameras were installed throughout the two studied wards, allowing for observation when staff left these wards and doffed PPE. Observation was undertaken via monitor by supervisors who were able to provide reminders and guidance verbally. Supervisors would also record any mistakes made to provide feedback to staff. Doffing was undertaken following WHO Ebola guidance and evaluation was based on a checklist of doffing protocol.

# Findings:

Over the study period (5 weeks) 63 HCWs entered the study wards, resulting in 1680 doffing events and 1797 errors.

Error rate was calculated each week:

- Week 1 = 0.60% 50.60%
- Week 2 = 0% 19.05%
- Week 3 = 0% 0.89%
- Week 4 = 0% 1.19%
- Week 5 = 0% 0.89%

Significant reductions in error rate were reported between week 1 and 2 (p<0.01). No significant difference in error rate was found for the rest of the study period. Overall, there was a significant reduction in error rate across the study period (p<0.01).

#### **Conclusions:**

The findings of this study suggest that implementing real time monitoring and communication during doffing may reduce the rate of errors during the process.

- Small sample size.
- Single centre study.
- No analysis of contamination during doffing undertaken.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Wadman M.C., Schwedhelm S.S., Watson S., et al.	Expert Opinion	Level 4			

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Emergency					
Department Process					
for the Evaluation					
and Management of					
Persons Under					
Investigation for					
Ebola Virus Disease					
Annals of					
Emergency Medicine					
2015 66(3)p306-314					

Country: USA

Target Audience: Applicable to health and care staff caring for patients with suspected or confirmed EVD.

**Methodology:** These guidelines were developed through "expert review and consensus of health care workers and administrators at an active Ebola treatment center" who had experience with managing patients with Ebola virus disease, in biocontainment units and emergency departments.

#### **Relevant Content:**

This expert opinion guidance states that:

- When a patient meets the criteria for epidemiological risk, signs or symptoms of EVD, mask and gloves should be worn by both
  patient and medical personnel. PPE should be donned under the supervision of a lead nurse, who is fully trained in donning and
  doffing procedures.
- There must be a low-traffic area which should be designated for the donning, doffing, and waste management of HCID PPE.

- Regarding doffing, a location for personnel involved in transporting patients under investigation should be agreed with receiving unit prior to patient arrival and a plan for disposal of PPE waste should also be pre-arranged.
- In the setting described by this paper, when EVD patients are in isolation staff will collect three packets, one of which contains necessary for showering and personal hygiene after doffing.

- US setting may limit wider applicability.
- Experts that were consulted were not named.
- No conflicts of interest were declared for consulted experts.
- No references were provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Park H.C., Lee Y.K., Lee S.H., et al.	Expert opinion	Level 4			
Middle East respiratory syndrome clinical practice guideline for hemodialysis facilities					
Kidney Research and Clinical Practice 2017 36: p111-116					

Country: South Korea

**Target Audience:** Applicable to health and care staff working in haemodialysis facilities and caring for suspected or confirmed MERS patients.

**Methods:** A committee was formed including members from the Korean Centers for Disease Control & Prevention (KCDC), the Korean Society of Nephrology, and the Korean Society of Dialysis Therapy, which developed these guidelines.

#### **Relevant Content:**

While this expert opinion document does not present a protocol for donning or doffing PPE, it does note that hand hygiene should be performed before and after donning and doffing PPE.

- Members of the guidance development committee are not named.
- No conflicts of interest were declared for consulted experts.
- No references were provided.
- South Korean context may limit wider applicability.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
InterAgency Board	Expert Opinion	Level 4			
for Equipment					
Standardization and					
Interoperability (IAB)					
Recommendations					
on Selection and					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Use of Personal					
<u>Protective</u>					
<b>Equipment for First</b>					
Responders against					
Ebola Exposure					
Hazards					
V1.5 2014					

**Country:** USA

**Target Audience:** Applicable to first responder staff caring for suspected or confirmed EVD patients.

**Methods:** Development methods were not reported; however, it is stated that the InterAgency Board for Equipment Standardization and Interoperability is a voluntary collaborative panel with representatives from a broad range of professional disciplines within government and public safety, with experience in emergency preparedness and response.

# **Relevant Content:**

No specific donning or doffing protocol is recommended in this expert opinion guidance; however, it is noted that:

- the procedure for donning is impacted by selection of PPE and how each item interfaces
- PPE should be donned following an established protocol, under supervision, and with support as required
- When doffing, removing face/eye protection and inner gloves last is recommended
- doffing should occur in a sequence that prevents/limits risk of transfer of contamination to the PPE wearer or others
- doffing should occur under supervision and with support as required

- gloved hands should be rinsed with appropriate decontamination solution (that does not degrade material of gloves) after any contact with a potentially contaminated surface
- cutting PPE to aid in doffing is outlined, however it is stated this should be accounted for in the garment's design

- Members of the guidance development panel were not named.
- Information regarding conflicts of interest was not outlined.
- No references were provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Suen L.K.P., Guo Y.P., Tong D.W.K, et al.  Self-contamination during doffing of personal protective equipment by healthcare workers to prevent Ebola transmission  Antimicrobial Resistance and Infection Control	Cross-over study	Level 3	Use of two PPE ensembles (PPE 1 and PPE 2) for protection against Ebola virus disease	Use of a third PPE ensemble (PPE 3) for protection against Ebola virus disease	Deviations from protocol during donning and doffing.  Contamination of participants bodies during doffing using a fluorescent tracer as substitute for EVD.  Areas of contamination were recorded by size − small (≤1cm²),

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
2018 7(157) doi: 10.1186/s13756- 018-0433-y					medium (1cm² to <3cm²), large (≥3cm² to 5cm²), extra-large (≥5cm²).

Country: Hong Kong

Aim: This study aimed to compare the efficacy of three different PPE ensembles for use during the care of patients with EVD.

#### Methods:

59 HCWs participated in this study. All participants were trained and assessed in donning and doffing all three PPE ensembles in a random order as decided by a computer-generated software.

PPE 1 (Hospital Authority Standard Ebola PPE set): Neck-to-ankle outfit, N95 respirator, hood, disposable face shield, MICROCOOL Breathable High Performance surgical gown without zipper (bow is tied at the lateral side of the waist), boots, double long nitrate gloves.

- Donning protocol: Visually inspect PPE, perform HH, don N95 respirator and perform fit test, perform HH, don hood, don face shield, don gown, perform HH, don boots, perform HH, don gloves.
- Doffing protocol: Doff gloves, perform HH, doff gown, perform HH, put clogs on floor, doff boots and don clogs, perform HH, doff full face shield, perform HH, doff hood, perform HH, doff N95 respirator, perform HH.

PPE 2 (DuPont Tyvek, Model 1422A): Head-to-ankle coverall, N95 respirator, hood with elasticated facial opening, disposable face shield, Tyvek apparel with elasticated wrists and ankles with zipper along the centre front, plastic apron (to cover zipper), boots, double long nitrate gloves.

• Donning: Visually inspect PPE, perform HH, don inner gloves, don coverall and inspect for integrity, don boots, don N95 respirator and perform fit test, don face shield, don hood, don outer apron, don outer gloves.

• Doffing: Disinfect outer gloves, doff apron, disinfect outer gloves, doff hood, disinfect outer gloves, doff coverall and outer gloves in one step, disinfect inner gloves, doff face shield, disinfect inner gloves, doff N95 respirator, disinfect inner gloves, put clogs on floor, doff boots and don clogs, disinfect inner gloves, doff inner gloves, perform HH.

PPE 3 (Hospital Authority isolation gown for routine patient care and performing aerosol-generating procedures): Neck-to-ankle outfit, N95 respirator, disposable face shield, water resistant isolation gown without zipper (bow is tied at the lateral side of the waist), shoes, single latex gloves.

- Donning: Visually inspect PPE, perform HH, don N95 respirator and perform fit test, perform HH, don cap, don full-face shield, don gown, perform HH, don gloves.
- Doffing: Doff gloves, perform HH, doff gown, perform HH, doff full-face shield, doff cap, perform HH, doff N95 respirator, perform HH.

PPE was donned in the 'clean zone' before participants moved to the 'preparation zone' where fluorescent tracer solution was sprayed onto the face shield, upper limbs, gloves, and anterior surfaces of gowns. Participants then moved to the 'degown and test zone' where they doffed PPE while being recorded for evaluation. Immediately after doffing, participants and the doffing environment were assessed for presence of fluorescent tracer using an ultraviolet lamp.

# Findings:

There was significantly less contamination of the HCWs clothes by small ( $\leq 1 \text{cm}^2$ ) and large ( $\geq 3 \text{cm}^2$  to  $5 \text{cm}^2$ ) patches during removal of PPE1 compared to PPE2 and PPE3; (median: 5.00 versus 7.00 versus 7.00, p=<0.05 and median: 1.00 versus 1.00 versus 2.00, p=<0.05), respectively (p=<0.001)). There was no significant difference in the number of medium ( $1 \text{cm}^2$  to  $< 3 \text{cm}^2$ ) or extra-large patches ( $\geq 5 \text{cm}^2$ ).

Contamination of the environment was reported when doffing PPE 1, PPE 2, and PPE 3 on the rubbish bin cover (small patches; median: 2.00 versus 7.00 versus 2.50, p=0.254. Extra-large patches; 20.00 versus 14.00 versus 23.00, p=0.737), chair (small patches; median: 3.00 versus 6.50 versus 2.00, p=0.053. Extra-large patches; 0.00 versus 36.00 versus 0.00, p=N/A), faucet (small patches; median: 2.00 versus 2.00 versus 1.50, p=0.659. Extra-large patches; 0.00 versus 16.00 versus 14.00, p=N/A), sink (small patches; median: 12.50

versus 14.00 versus 10.00, p=0.072. Extra-large patches; 75.50 versus 66.50 versus 44.00, p=0.649). No significant differences were reported in environmental contamination across the three PPE ensembles assessed.

#### Limitations:

- Fluorescent tracer used rather than surrogate of EVD.
- Participants did not have equal training or experience using PPE.
- Participants had previous experience with PPE ensembles 1 and 3 but not PPE ensemble 2.

#### Conclusions:

This cross-over trial suggests that doffing the ensemble, denoted in this study as PPE 1, may lead to less bodily contamination, however, as participants had previous experience with the PPE1 ensemble this creates bias and definitive conclusions cannot be drawn.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Reidy P., Fletcher T., Shieber C., et al.	Expert opinion	Level 4			
Personal protective equipment solution for UK military medical personnel working in an Ebola virus disease					
treatment unit in Sierra Leone					

Study Type	Evidence Level	Intervention	Comparison	Outcome measure
	Study Type	Study Type Evidence Level	Study Type Evidence Level Intervention	Study Type Evidence Level Intervention Comparison

Country: Sierra Leone/United Kingdom

Target Audience: Applicable to all health and care staff caring for patients with suspected or confirmed EVD.

**Methods:** A group of specialists from Public Health England, the National Ambulance Resilience Unit and the Ministry of Defence (MoD) was convened to identify a suitable PPE ensemble, along with donning and doffing protocols, for staff working in EVD treatment units in Sierra Leone.

#### Relevant content:

In this expert opinion guidance, it is recommended that donning should take place in the following order:

- Coverall
- Apron
- Surgical hat
- Face mask
- Visor
- Pull up hood of coverall
- Inner gloves
- · Place loop on coverall sleeve over middle finger
- Outer gloves

Buddy check of PPE

It is recommended that doffing should be undertaken as follows, with the help of a buddy:

- Step onto a disinfection mat and scrape the soles of boots
- Step into chlorine bath and agitate before stepping out
- Wash gloved hands with 0.5% chlorine
- Remove apron avoid touching the front of the apron or other PPE while doing this
- Wash gloved hands with 0.5% chlorine
- Remove outer gloves
- Wash gloved hands with 0.5% chlorine
- Buddy assists in removing coverall hood, rolling it inside out
- HCW and buddy both wash gloved hands with 0.5% chlorine
- Remove coverall from torso with assistance of buddy
- HCW and buddy both wash gloved hands with 0.5% chlorine
- Remove lower half of coverall
- Wash gloved hands with 0.5% chlorine
- Remove surgical cap
- Wash gloved hands with 0.5% chlorine
- Remove inner gloves
- Wash hands with 0.05% chlorine

Step onto rubber disinfection mat and scrape boot soles before stepping into chlorine bath

# Limitations:

- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest was not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Rizzi E.B., Puro V., Schinina V., et al.	Expert opinion	Level 4			
Radiographic imaging in Ebola Virus Disease: protocol to acquire chest radiographs					
European Radiology 201525: p3368- 3371, doi: 10.1007/s00330- 015-3748-6					

# **Assessment of evidence**

**Country:** Italy

Target Audience: Applicable to all radiographic staff who may come into contact with EVD.

#### **Relevant Content:**

In this expert opinion guidance, it is stated that personnel undertaking chest radiology procedures should don PPE in a clean area out with the patient's room. Doffing should be undertaken in a separate area also out with the patient's room and assistance should be provided for disinfection.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Servies	Expert opinion	Level 4			
Scotland (NSS)					
Infection Control					
Advice: Severe					
Respiratory Illness					
from novel or					
emerging pathogens e.g. Middle East					
Respiratory					
Syndrome Syndrome					
Coronavirus (MERS-					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
CoV) and Avian					
influenza (e.g.					
A/H7N9, A/H5N1)					
Version 7.2					
June 2015					

Country: Scotland

Target Audience: Applicable to all health and care staff caring for patients with suspected or confirmed HCID.

#### **Relevant Content:**

This expert opinion guidance states that PPE should be donned before entering patient's room and that PPE should be donned in the following order:

- Gown
- FFP3 respirator
- Eye protection (goggles or full-face visor)
- Disposable gloves

It is stated that PPE should be doffed before leaving a patient's room and in the following order (which authors state minimises the potential for cross-contamination):

- Gloves
- Gown
- Eye protection

- Leave patient room
- FFP3 respirator

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Crook B., Bailey C.,	Cross-over study	Level 3	PPE ensemble 1	PPE ensemble 2	Presence of
Sykes A., et al.			(PPE1) which	(PPE2) which	fluorochrome
Validation of			included PAPR	included PAPR	contamination on
personal protective			system with power	system with	participants bodies
equipment			pack on waist belt,	integrated power	after doffing.
ensembles,			fluid resistant hood	pack, fluid resistant	
incorporating			with integrated visor,	hood with integrated	
powered air-purifying			fluid resistant	visor, fluid resistant	
respirators protected			coverall with front	coverall with rear	
			zipper, surgical clogs	zipper, wellington	
from contamination,			worn under coverall,	boots worn outside	
for the care of			shoe covers worn	coverall with gaiters	
patients with high-			over coverall, three	covering the top of	
			pairs of gloves with	boots, three pairs of	

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
consequence infectious diseases.  Journal of Hospital Infection 134: 71-79, 2023			middle pair taped to sleeves of coverall, long-sleeved plastic apron.	gloves with middle pair taped to sleeves of coverall, sleeveless plastic apron.	

**Country:** United Kingdom

**Aim:** The aim of this study was to compare the ease of doffing of two PPE ensembles (including PAPR) to be used when caring for HCID patients.

# Methods:

20 members of experienced medical staff, with training and practical experience in use of HCID PPE, participated in this study. Participants were allowed to become familiar with the PPE ensembles before following a six-step study protocol.

- Step 1 Supervised donning of PAPR and PPE ensemble
- Step 2 application of fluorochrome,
- Step 3 complete three physical tests that mimic movements common to patient care and a manual dexterity test,
- Step 4 supervised doffing of PAPR and PPE ensemble,
- Step 5 examination using UV light to identify cross contamination,
- Step 6 post-test questionnaire.

This protocol was repeated by each participant one for each PPE ensemble.

# Findings:

One instance of cross-contamination was recorded for PPE ensemble 1 (on a participant's finger from removing the hood and failure to follow protocol of performing hand hygiene) and five instances were recorded for PPE ensemble 2 (one instance on the face, chest and neck from deviation from doffing protocol, two instances of contamination on hands and upper arms due to unreported human error, and two instances that could not be linked to an observed event).

Based on these findings and feedback gained from the post-test questionnaire the recommended PPE ensemble included the following:

- PAPR hood system with headset (powerpack attached to belt around the wearer's waist), covered by a plastic hood that covers
  the head and neck
- Fluid-resistant coverall with front zipper (string attached to zipper to aid in donning/doffing)
- Wellington boots
- Triple gloving inner pair of nitril gloves worn under cuff of coverall, middle pair of thick long-cuffed gloves taped to coverall sleeves with 3 vertical strips of duct tape, outer pair of nitrile gloves
- Apron worn over coverall and PAPR hood

In this observational study PPE was donned and doffed by known (but not reported) protocols that included supervision.

#### **Limitations:**

- Small sample size.
- Donning and doffing protocols were not reported.

#### **Conclusions:**

This observational study suggests that PPE ensemble 1 (PAPR system with power pack on waist belt, fluid resistant hood with integrated visor, fluid resistant coverall with front zipper, surgical clogs worn under coverall, shoe covers worn over coverall, three pairs of gloves with

middle pair taped to sleeves of coverall, long-sleeved plastic apron) is preferable to PPE ensemble 2 when considering contamination that occurs during doffing.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Public Health Agency of Canada	Expert opinion	Level 4			
Prevention and Control of Influenza during a Pandemic for All Healthcare Settings May 2011					

# **Assessment of evidence**

Country: Canada

Target Audience: All health and care staff caring for patients with suspected or confirmed influenza.

**Methods:** This document was developed by the Public Health Agency of Canada's Infection Prevention and Control Program, with support from an expert working group.

# **Relevant Content:**

Within an appendix of this expert opinion guidance a diagram outlining donning and doffing steps is presented.

# **Donning**

Perform hand hygiene

- Put on gown
- Put on mask/N95 respirator
- Put on protective eye wear
- Put on gloves

# **Doffing**

- Remove gloves
- Remove gown
- Perform hand hygiene
- Remove eye protection
- Remove mask/N95 respirator
- Perform hand hygiene

It is outlined that additional hand hygiene may be performed after doffing gloves and after doffing eye protection. It is also noted that hand hygiene can be performed before leaving the care area, however the timing of this is not presented in this appendix.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease	Expert Opinion	Level 4			
Control and					
Prevention					
For U.S. Healthcare					
Settings: Donning					
and Doffing Personal					
<u>Protective</u>					
Equipment (PPE) for					
<b>Evaluation Persons</b>					
<u>Under Investigation</u>					
(PUIs) for Ebola Who					
Are Clinically Stable					
and Do Not Have					
Bleeding, Vomiting,					
or Diarrhea					
2022					

Country: USA

Target Audience: Applicable to all health and care staff caring for patients with suspected or confirmed EVD who are clinically stable.

Methods: Development methods were not reported.

# **Relevant Content:**

In this expert opinion guidance, the protocol for donning and doffing PPE to be worn when caring for clinically stable Ebola patients is presented.

# **Donning**

- Personal clothing or items should be removed before donning and scrubs should be worn
- PPE should be inspected before donning
- Perform hand hygiene
- Put on inner gloves
- Put on gown or coverall
- Put on facemask
- Put on outer gloves (extending cuffs over sleeves of gown or coverall)
- Put on face shield
- HCW should then verify that PPE has been donned correctly, there are no damaged items, and all areas of the body are covered before starting care tasks.

# Doffing

- Inspect PPE for visible contamination or damage
- Disinfect outer gloves with wipe or ABHR then remove
- Inspect inner gloves for damage, disinfect
- Remove face shield
- Disinfect inner gloves
- Remove gown or coverall
- Disinfect and change inner gloves
- Remove surgical mask

- Disinfect and remove inner gloves
- Perform hand hygiene
- Inspect scrubs for contamination

#### Limitations:

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References are not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Crane J., McCullough C.	Expert opinion	Level 4			
High-Consequence Infectious Disease: 10 Principles for Patient Safety					

# **Assessment of evidence**

**Country:** United States

Target Audience: Applicable to all health and care staff working with HCID.

**Methods:** This document was developed taking into account lessons learned from care of Ebola patients in the USA and included input from representatives from the CDC, the University of Nebraska, Emory University, UCLA, KSU, and the Association of Infection Control Professionals.

# **Relevant Content:**

Within this online expert opinion guidance on design of facilities for caring for HCID patients, it is outlined that PPE should be donned and doffed in areas outside of the patient care area and that donning should be undertaking in a 'clean' area separate from the doffing space.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease	Expert opinion	Level 4			
Control and					
Prevention (CDC)					
Interim Guidance for					
Emergency Medical					
Services (EMS)					
Systems and 9-1-1					
Emergency					
Communications					
Centers/Public					
Safety Answering					
Points (ECC/PSAPs)					
for Management of					
Patients Under					
Investigation (PUIs)					
for Ebola Virus					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Disease (EVD) in the United States					
2022					

Country: USA

Target Audience: Applicable to all emergency services staff who may care for patients with suspected or confirmed EVD.

#### **Relevant Content:**

In this expert opinion guidance, it is stated that emergency services personnel should don PPE before entering the scene with a patient under investigation for Ebola and not doffed until contact with the patient has ended. It is stated that PPE should be donned and doffed under the supervision of a trained observer and that the facility receiving the patient from emergency services personnel, should help to facilitate the supervised doffing of PPE.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References are not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Public Health England (PHE)	Expert opinion	Level 4			
Middle East Respiratory Syndrome (MERS-CoV) Infection Prevention and					
Control Guidance 2016					

Country: United Kingdom

Target Audience: Applicable to all health and care staff who may care for patients with suspected or confirmed MERS-CoV

**Relevant Content:** 

It is noted in this document that the order of donning is less critical than the order of doffing.

It is outlined that donning should occur in the following order:

- Gown
- FFP3 Respirator
- Eye protection (goggles or face shield)
- Disposable gloves

It is outlined that doffing should occur in the following way and order:

Peel off gloves and gown together, rolling inside out

- Perform hand hygiene
- Remove goggles
- Exit patient area
- Remove respirator
- Perform hand hygiene

- Developmental methods were not reported
- Individuals involved with guidance development were not named
- Information regarding conflicts of interest were not outlined
- · References are not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Poller B., Tunbridge A., Hall S., et al.	Expert opinion	Level 4			
A unified personal protective equipment ensemble for clinical response to possible high consequence infectious diseases:  A consensus					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
document on behalf of the HCID programme					
Journal of Infection 2018 77: p496-502					

**Country:** United Kingdom

**Target Audience:** Applicable to all health and care staff who may care for patients with suspected or confirmed HCIDs.

**Methods:** In order to determine a unified PPE ensemble a simulation exercise was developed and is described within a different paper. The results of this exercise were discussed with an expert group with representatives from infectious disease units across the UK.

### **Relevant Content:**

This ensemble has been agreed upon by a group of experts and by the SHPN HCID subgroup.

In addition to the ensemble several other practical or safety recommendations were made:

- After donning the ensemble, a 'buddy' should check for any gaps/breaks etc.
- When doffing the buddy should use a hands-off approach and verbally guide the HCW through the process
- Instructional posters should be provided in the donning/doffing areas and there should be clear demarcation of different areas

- Limited references were provided throughout the recommendations in this paper.
- Members of the High Consequence Infectious Diseases Project Working Group were not named.
- While author conflicts of interest were reported, those of the working group members were not.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Poller B., Tunbridge A., Hall S., et al.	Expert opinion	Level 4			
A unified personal protective equipment ensemble for clinical response to possible high consequence infectious diseases:  A consensus document on behalf					
of the HCID programme  Annex 1: Personal Protective Equipment for Suspected High					
Consequence Infectious Diseases: How to put on PPE (Donning) Journal of Infection 2018 77: p496-502					

Country: United Kingdom

Target Audience: Applicable to all health and care staff who may care for patients with suspected or confirmed HCIDs.

**Methods:** In order to determine a unified PPE ensemble a simulation exercise was developed and is described within a different paper. The results of this exercise were discussed with an expert group with representatives from infectious disease units across the UK.

### **Relevant Content:**

Within this document it is stated that HCWs should change into scrubs and remove and jewellery or ID badges before donning PPE.

Donning stages are outlined as follows:

- Perform hand hygiene
- Wellington boots
- FFP3 mask and check for fit
- Hood and check for fit around face and jaw, overlap with mask
- Inner gloves
- Long reinforced gown with cuffs overlapping inner gloves
- Check overlap between boots and the bottom of the gown (10-15cm)
- Middle gloves
- Tape middle gloves
- Break neck loop of plastic apron where it will sit at the back of the neck
- Apron, tying broken loop behind neck to achieve a 'high fit'
- Visor with band overlapping hood
- Ensure no skin is exposed between the hood and visor
- Outer gloves

• Buddy should check that all items have been donned correctly and that there are no gaps between items of PPE. If there are, these should be addressed before the HCW enters the patient care area.

# Limitations:

• References are not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Poller B., Tunbridge A., Hall S., et al.	Expert opinion	Level 4			
A unified personal protective equipment ensemble for clinical response to possible high consequence infectious diseases: A consensus document on behalf of the HCID programme					
Annex 2: Personal Protective Equipment for Suspected High Consequence Infectious Diseases:					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
How to remove PPE (Doffing)					
Journal of Infection 2018 77: p496-502					

**Country:** United Kingdom

Target Audience: Applicable to all health and care staff who may care for patients with suspected or confirmed HCIDs.

**Methods:** In order to determine a unified PPE ensemble a simulation exercise was developed and is described within a different paper. The results of this exercise were discussed with an expert group with representatives from infectious disease units across the UK.

#### **Relevant Content:**

It is outlined that doffing should take place in an 'amber zone' between the patient area (the 'red zone') and clean areas (the 'clean zone'). It is advised that a buddy should be present to assist in doffing, and they should be made aware of any known PPE breaches that have occurred during patient care.

Doffing stages are outlined as follows:

- Apron
- Outer gloves
- Unfasten side ties of gown
- Remove gown and middle (taped) gloves in single motion
- Visor
- Hood

- Inner gloves
- HH with ABHR
- FFP3 mask
- Wellington boots, stepping forward out of boots, towards the clean area. HCWs should not step backwards into dirty area.
- Pinch inner surface of boots to pick them up and place them into bin. They should remain here until HCID results are known. If negative, boots can be cleaned and re-worn.
- Hand hygiene should be performed with soap and water

### Limitations:

· References are not provided

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease	Expert opinion	Level 4			
Control and Prevention (CDC)					
Guidance on					
personal protective					
equipment to be					
used by healthcare					
workers during					
management of patients with					
confirmed Ebola or					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
persons under					
investigation (PUIs)					
for Ebola who are					
clinically unstable or					
have bleeding,					
vomiting, or					
diarrhoea in U.S.					
hospitals, including					
procedures for					
donning and doffing.					
2022					

Country: USA

**Target Audience:** Applicable to all health and care staff caring for patients with EVD who are clinically unstable.

**Methods:** Development methods were not reported.

## **Relevant Content:**

The CDC state that:

- PPE must be removed slowly and deliberately in the correct sequence.
- A trained observer should read aloud each step in the procedure and visually confirm and document that the HCW completes this correctly. It is noted that the trained observer must not provide physical assistance to the HCW.
- That scissors must never be used to remove tape or any other part of PPE.

The following donning process is advised if an N95 respirator is included as part of the ensemble:

- Change into surgical scrubs and remove all jewellery, pens etc. Tie hair back and secure eyeglasses if worn
- Inspect PPE
- Boot covers (will be under coverall)
- Inner gloves
- Gown or coverall, sleeves or inner gloves are tucked under gown or coverall
- N95 respirator
- Surgical hood
- Apron
- Outer gloves
- Face shield
- Trained observer should now check the integrity of the ensemble

The following doffing process is advised if an N95 respirator is included as part of the ensemble:

- Inspect PPE for contamination or damage, if contamination is present then disinfect
- Disinfect outer gloves
- Remove apron by breaking ties and rolling away from body
- Inspect PPE again
- Disinfect and remove outer gloves
- Disinfect inner gloves
- Remove face shield

- Disinfect inner gloves
- Remove surgical hood
- Disinfect inner gloves
- Remove gown or coverall, avoid touching scrubs, roll away from body turning inside out touching only the inside of the garment
- Disinfect inner gloves
- Remove boot covers
- Disinfect inner gloves
- Remove N95 respirator
- Disinfect inner gloves
- Disinfect washable shoes
- Disinfect and remove inner gloves
- Perform HH
- Final inspection of scrubs for contamination, if contamination present carefully remove and shower immediately.

The following donning process is advised if a PAPR is included as part of the ensemble

- Put on boot covers
- Inner gloves
- Gown or coverall, if a PAPR with self-contained battery and blower then belt and battery must be worn under the coverall, if an
  external belt –mounted blower is used this must be worn on the outside of the gown or coverall
- Outer gloves
- PAPR with full face shield, helmet or headpiece.

- Single use disposable hood over PAPR, ensuring hair and ears covered
- Apron

The following doffing process is advised if a (PAPR) is included as part of the ensemble (it is outlined that each PPE item should be inspected after removal):

- Disinfect outer gloves
- Remove apron by breaking ties and rolling away from the body
- Disinfect and remove outer gloves
- Remove respirator with external belt-mounted blower if using a self-contained respirator this should be removed last place all reusable parts in a designated area or container for disinfection
- Disinfect inner gloves
- Remove coverall, tilt head back and unzip completely before rolling the coverall down simultaneously turning inside out, touch
  only the inside of the coverall
- Disinfect inner gloves
- Remove boot covers
- Disinfect washable shoes using disinfectant wipe
- Disinfect inner gloves and remove

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest was not outlined.

References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Verbeek J.H., Mischke C., Ruotsakainen J.H., et al.	Systematic Review with Meta analysis	Level 1+			
Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff (review)					
Cochrane Database of Systematic Reviews 2016,2019,2020. Issue 4. Art. No.: CD011621. doi: 10.1002/14651858.C D011621.pub4					

**County:** International

**Aim:** This systematic review aimed to investigate PPE ensembles, and donning and doffing methods, that are reported to have the lowest risk of HCW contamination, along with the training methods that increase compliance.

**Methods:** Systematic literature review was conducted on CENTRAL, MEDLINE, Embase and CINAHL, with a date limit up to March 2020. All controlled studies that assessed the effect of PPE used by HCWs exposed to highly infectious diseases, risk of infection, contamination or noncompliance were included, along with studies which compared donning and doffing protocols, and the effect of training. Cochrane's assessment methodology was followed.

# Findings:

Twenty-four studies were included in the 2020 update of this review, including 2278 participants: 14 RCTs, one quasi-RCT, and nine non-randomised trials. Certainty of evidence across this evidence base was graded as very low or low.

Meta-analysis suggested that:

- using Centers for Disease Control and Prevention (CDC) recommendations for doffing may lead to less contamination compared to no guidance (small patches of fluorescence (≤1cm²): MD −5.44, 95% CI −7.43 to −3.45). (Based on 1x cross-over study)
- One-step removal of gloves and gown may lead to less bacterial contamination (RR 0.20, 95% CI 0.05 to 0.77) but not to less fluorescent contamination (RR 0.98, 95% CI 0.75 to 1.28) than separate removal. (Based on 1x RCT)
- Double-gloving may lead to less viral or bacterial contamination compared to single gloving (RR 0.34, 95% CI 0.17 to 0.66) but not to less fluorescent contamination (RR 0.98, 95% CI 0.75 to 1.28). (Based on 1x non-randomised controlled study and 1x randomised simulation study)
- Additional spoken instruction may lead to fewer errors in doffing (MD−0.9, 95% CI −1.4 to −0.4) and to fewer contamination spots (MD −5, 95% CI −8.08 to −1.92). (Based on 1x randomised simulation study and 1x before and after study)

### Limitations:

- Authors graded the evidence included in this systematic review as low or very low quality
- Statistical significance was not reported

**Conclusions:** The findings of these meta-analyses results cannot be used in isolation to inform recommendations as the included studies were considered low or very low quality, and often only a single study has informed conclusions. Further study is required to gain insight into doffing practices.

# **Evidence from previous update(s):**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Ortega R., Bhadelia N, Obanor O, et al.	Expert Opinion	Level 4			
Videos in Clinical  Medicine. Putting on and removing personal protective equipment					
New England Journal of Medicine 2015 372: e16					

## **Assessment of evidence**

Country: USA

Target Audience: applicable to all health and care workers who may care for suspected or confirmed EVD patients.

#### **Relevant Content:**

This documents states that:

- donning and doffing PPE should take place in separate and distinct areas out with the patient care area.
- a trained observed must be used for both donning and doffing PPE.

The following donning and doffing protocols are recommended within this document:

# Donning:

- Use the restroom and make sure you are hydrated
- Ensure prescription glasses (if worn) are secure
- Change into scrubs and washable shoes, secure hair and remove personal items
- Visually check integrity of PPE
- HH with ABHR
- Put on first pair of gloves
- Sit and put on shoe/boot covers
- Put on gown ensuring that inner gloves are under the sleeves, the trained observer may assist you to tie the gown at the back
- On the respirator by cupping over face and securing the ties/elastic, mould the nose strip to your nose and perform a fit check
- Place the hood over the head ensuring it overlaps the gown, extending to the shoulders and both head and neck are completely covered
- Put on apron, the trained observer may help to tie
- Put on the second pair of gloves with the cuffs extending over the sleeves of the gown.

- Place the face shield over the hood and adjust to fit
- If necessary, adjust all PPE until comfortable
- Trained observer will check the ensemble is intact.

# Doffing:

- Before leaving the patients room, removes any visible contamination with a disinfectant wipe and apply ABHR to outer gloves
- After leaving the room conduct another check for visible contamination and remove with a disinfectant wipe, if necessary
- Apply ABHR to outer gloves
- Remove apron by breaking ties behind back, then neck. Pull away from the body and roll inside out. Discard.
- Inspect for contamination
- Apply ABHR to gloves
- Sit down and remove boot covers
- Apply ABHR to gloves
- Remove outer gloves
- Apply ABHR to inner gloves
- Remove face shield, tilt head forward and remove by strap, lift above and away from head without touching shield
- Apply ABHR to gloves
- Remove hood, grasping near top and carefully pulling away
- Apply ABHR to gloves
- Remove gown, untie at back, grasp at the shoulders and peel away turning inside out and wrapping into a bundle.

- Apply ABHR to gloves
- Remove inner gloves
- Apply ABHR to hands
- Put on a new pair of gloves
- Remove N95 respirator, touching only the straps
- Apply ABHR to gloves
- Sit in designated chair and wipe all external surfaces of shoes with disinfectant wipe
- Apply ABHR to gloves
- Remove gloves
- Apply ABHR to hands

This is low level, expert opinion-based guidance. The protocol suggests using a PAPR if a proper fit cannot be achieved with an N95, however, guidance on using PAPR was out with this guidance document's scope. This protocol was developed using guidance on Ebola PPE from the CDC.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Beam E.L., Schweldhelm S., Boulter K., et al.	Expert opinion	Level 4			
Personal protective equipment process and rationale for the Nebraska Biocontainment Unit during the 2014 activations for Ebola					
virus disease  American Journal of Infection Control 2016 44 p340-342					

Country: USA

Target Audience: Applicable to all health and care workers who may care for patients with suspected or confirmed EVD.

### **Relevant Content:**

The following donning and doffing orders are recommended for level 1:

Level 1 donning order:

Boot cover, hood, gown, N95, face shield, perform HH, exam gloves, long-cuffed gloves (duct tape to gown), perform a safety check, third set of gloves (used for direct patient care)

Level 1 doffing order:

Slowly remove tape to prevent gone tearing or aerosolisation, long cuff gloves, doffing partner change gloves, gown, inner gloves, doffing partner and HCW change gloves, boot covers, doffing partner change gloves, face shield, N95 respirator, surgical hood, bleach wipe plastic footwear, hand hygiene, gloves and patient care mask, antimicrobial wipe personal eyewear (if worn), shower.

The following donning and doffing orders are recommended for level 2:

Level 2 donning:

Boot liner (inside coverall, over footwear), protective suit pulled to waist, boot covers (over suit), examination gloves (under suit cuffs), suit over upper body zipped to chest, PAPR belt with blower and tubing, turn on blower and put on hood, tuck inner collar into suit, zip suit to neck and seal flap, lay outer collar over shoulders, safety check, third layer of gloves, aprons for patient care.

Level 2 doffing:

Remove tape slowly, long cuff gloves, boot covers, PAPR belt (keep motor on), protective suit, exam gloves (replace with clean gloves), switch PAPR off, undo tubing from motor, place filter cap on air outlet, PAPR hood, boot liners, bleach wipe plastic footwear, HH, gloves and patient care mask, antimicrobial wipe personal eyewear (if worn), shower.

The PAPR hood, which provides respiratory protection, is removed last. To protect the internal components of the PAPR blower motor, the air outflow is covered with a filter cap as the PAPR blower motor is turned off, and all filters are kept in place during surface disinfection. The blower motor assembly is surface decontaminated using bleach wipes in a systematic fashion, and then recharged before reuse by another team member in full protective gear in.

This guidance is based on expert opinion and is specific to Ebola. The authors note that the ensembles are based on CDC guidance and doffing is based on The Nebraska Method.

- Development methods were not reported.
- The report does not indicate when one ensemble should be worn instead of the other.

• A 'patient care mask' is mentioned in doffing for both levels however this is not included in donning instructions for either ensemble so it is unclear what this is or when it should be donned.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety	Expert opinion	Level 4			
Executive/Advisory					
Committee on					
Dangerous					
Pathogens					
Management of					
Hazard Group 4 viral					
haemorrhagic fevers					
and similar human					
infectious diseases					
of high consequence					
Viral haemorrhagic					
fever: ACDP					
algorithm and					
guidance on					
management of					
patients - GOV.UK					
2015					

Country: United Kingdom

Target Audience: Applicable generally to all health and care staff in all healthcare settings.

Methods: The ACDP outline that the risks of transmission of VHF were assessed, however, the methods of this were not reported.

### **Relevant Content:**

The ACDP state that a detailed and pre-defined sequence for donning and doffing items should be developed, implemented and monitored.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization	Expert opinion	Level 4			
Interim infection prevention and control guidance for care of patients with suspected or confirmed filovirus					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
haemorrhagic fever					
in healthcare					
settings, with focus					
on Ebola					
2014					

**Country:** International

Target Audience: Applicable to all health and care staff who may care for patients with suspected or confirmed filovirus.

**Relevant Content:** 

The WHO state that

- PPE must be put on and removed in the proper order and must not be adjusted in the patient are area.
- That the person's name and time of entry should be written on the apron or head cover.
- That eye protection should be put on so that it is taken off as late as possible in the doffing process.

All WHO protocols begin by removing all jewellery pens etc, putting on scrubs and wellington boots and performing HH.

The WHO provide donning and doffing orders for both gown and coveralls as follows:

Donning using gowns

- Gloves
- Gown
- Mask
- Face shield/goggles

- Surgical bonnet (covering neck and sides of head) or hood
- Disposable apron
- Second pair of gloves (long cuff)

# Doffing using gowns

- HH
- Apron breaking ties and rolling away and inside out
- HH
- Outer gloves
- HH
- Head cover rolling from back to front and inside out
- HH
- Gown untie and roll away from shoulders turning inside out
- HH
- Eye protection
- HH
- Mask handle by ties
- HH
- Remove boots without touching
- HH

- Inner gloves
- HH

Donning using coverall

- HH
- Inner gloves
- Coverall
- Face mask
- Face shield or goggles
- · Surgical bonnet (covering neck and sides of head) or hood
- Disposable apron
- Second pair of gloves (long cuff)

Doffing using coverall:

- HH
- Apron breaking ties and rolling away and inside out
- HH
- Bonnet or hood
- HH
- Coverall, carefully unzip without touching scrubs, roll down from shoulder and remove outer gloves while freeing arms, carefully roll the coverall down to the top of the boots, use boots to remove coverall and step away
- HH

- Eye protection
- Mask handle by ties
- HH
- Remove boots without touching
- HH
- Inner gloves
- HH

- Development methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control	Expert opinion	Level 4			
Safe use of personal protective equipment in the treatment of					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
infectious diseases of high consequence					
2014					

Country: European Union

Target Audience: Applicable to all health and care staff who may care for patients with suspected or confirmed HCIDs.

**Methods:** These expert opinion guidelines were developed by a group of professionals with experience in medicine, infection control, preparedness, and training. This group assessed documents released by international health bodies including the WHO, CDC and Medécins Sans Frontières (MSF). This group was supported by further experts in barrier nursing, hospital infection control, and bio risk management, where necessary.

### **Relevant Content:**

The following donning and doffing stages are advised:

## Donning:

- Put on scrubs and hair cover
- HH
- Coverall, fingers loops should be used under inner gloves
- Foot protection
- HH
- FFP3/surgical mask
- Put hood up

- Close zipper and storm flaps
- Eye protection
- Disinfect inner gloves and don outer gloves
- Apron
- Check fit of PPE

## Doffing (assisted):

- Remove apron
- Assistant inspects PPE for damage and wipes with disinfectant
- HCW removes outer gloves and assistant dons new pair of outer gloves
- · Assistant removes tape from face area and goggles
- Assistant removes the hood
- Assistant rolls down the coveralls
- Assistant rolls down the sleeves and integrated gloves
- HCW steps out of the coverall
- Assistant changes outer gloves
- Assistant removes respirator
- HCW performs HH, removes hair cover, hydrates and showers.

The guidance also suggests that rather than opening the coverall by the zipper, the assistant can use scissors to cut open the coverall.

- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided within the text, only within a bibliography.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Tomas M.E., Kundrapu S., Thota P., et al.  Contamination of health care personnel during removal of personal protective equipment.  JAMA Internal Medicine 175(12): 1904-1910, 2015	Before and After study	Level 3	A 10-minute video on PPE donning and doffing followed by 20 minutes of demonstration and practice.  Gloves were artificially contaminated with fluorescent lotion and bacteriophage MS2, visualized using a black light to provide immediate feedback while emphasizing the most common errors. Trainers observed	Errors and contamination during doffing compared before and after training intervention.	Percentage of doffing instances which caused contamination. (%) Percentage reduction in instances of contamination. (%)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
			and recorded errors and contamination during doffing after training.		

Country: USA

**Aim:** The aim of this study was to assess the efficacy of a PPE donning and doffing training programme by determining contamination on the skin and clothes of participants caused by artificially contaminated gloves during doffing before and after training.

### Methods:

Participants were employed as HCWs across four hospitals in Ohio, United States. HCWs wore gowns and gloves which were artificially contaminated with fluorescent lotion and asked to doff the PPE using their own method. Trained observers recorded any errors in doffing according to the CDC checklist and then assessed contamination on participants skin and clothing using a black light.

## Findings:

The study included 435 PPE doffing removal simulations, with contamination occurring in 200 (46%) instances. Contamination occurred more frequently when incorrect vs correct technique was observed for contaminated glove and gown removal (70.3% vs 30.0%, p < 0.001). The most common errors were removing the gown by pulling over the head, gloves not covering the wrists and touching the contaminated surface of the gloves while removing.

#### **Conclusions:**

This study provides evidence that correctly following the CDC method results in significantly reduced contamination compared to not following this protocol The study does not demonstrate superiority of the CDC method over that of any other organisation.

## Limitations:

Simulation study using fluorescent lotion so findings may not be generalisable to real-life scenarios and transmission events.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
De laco G., Puro V., Fusco F.M., et al.	Cross sectional	Level 3			
Personal protective equipment management and policies: European network for highly infectious diseases data from 48 isolation facilities in 16 European countries.					
Infection Control& Hospital Epidemiology 2012 33(10): p1008-1016					

**Country:** Various European countries (Austria, Bulgaria, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Poland, Slovenia, Spain, United Kingdom).

**Setting:** Isolation facilities for the management of highly infectious diseases.

**Aim:** The aim of this paper was to understand PPE selection, use, and supply across 48 isolation facilities. This paper also aims to suggest safe and appropriate PPE protocols within this setting.

**Methods**: Data was collected from the participating isolation facilities using checklists, including questions on management of PPE items, use of fit testing, and stockpiling. Preparedness of each facility was captured using an evaluation form.

#### Limitations:

• It is noted that the donning/doffing practices outlined by survey participants represent protocols used rather than formal expert opinion or evidence-based guidance.

### **Conclusions:**

This paper provides some guidance on removal of PPE based on answers submitted from 46 European isolation facilities. The authors state that since several proposed sequences already exist, only a few general rules are indicated, these were as follows:

- Avoiding contact of contaminated gloves or hands with facial protection (e.g. goggles, face shield and respirator).
- Goggles and face shield being removed early in the sequence (with clean hands or gloves), because they are cumbersome and can impair vision during PPE removal.
- Always washing hands after removal of gloves and after each contact with potentially contaminated PPE.

# **Question 7: How should PPE for HCID be stored?**

# **Evidence added to Literature Review V3.0:**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive/Advisory Committee on Dangerous Pathogens  Management of Hazard Group 4 viral haemorrhagic fevers and similar human	Expert opinion	Level 4			
infectious diseases of high consequence 2015					

# **Assessment of evidence**

**Country:** United Kingdom

Target audience: Applicable generally to all healthcare workers and healthcare settings.

Methods: The ACDP assessed the risks of transmission of VHF, however, the methods of this were not reported.

### **Relevant Content:**

The ACDP state that PPE should be stored in a way that protects it from damage and contamination, and that it should remain off of the floor of storage areas. Any PPE that is used infrequently should be subject to stock rotation and control procedures to ensure effective PPE is available when required. PPE that is found to be damaged or defective in any way should be repaired (if applicable) or replaced.

### Limitations:

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

# **Evidence from previous update(s):**

This question was added for this update.

# Question 8: How should single-use PPE for HCID be disposed of?

# **Evidence added to Literature Review V3.0:**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Services Scotland	Expert opinion	Level 4			
NHSScotland Assure  NHSScotland Waste  Management  Guidance Scottish  Health Technical					
Note 03-01 Version 8.0 2024					

## Assessment of evidence

Country: United Kingdom

**Target audience:** All health and care staff in all healthcare settings

**Relevant Content:** 

While this guidance does not cover HCID waste specifically it does provide guidance on NHSScotland healthcare waste streams.

This guidance states that a local waste management policy should be in place that identifies arrangements for segregation and collection.

It is noted that infectious or potentially infectious waste should be considered special (hazardous) waste, waste generated during the care of a patient with a HCID would be considered potentially infectious.

This guidance highlights that infectious waste can fall into two of the colour-coded waste streams used in NHSScotland.

Yellow stream infectious waste

- For waste that is known or suspected to be contaminated with a Category B (UN3291) pathogen as per the Carriage Regulations.
- This waste requires incineration in a licenced or permitted facility.
- When unexpected circumstances occur, infectious clinical waste known of suspected to be contaminated with a Category A (UN2814) pathogen, as per the Carriage Regulations, this may also fall into the yellow waste stream for off-site disposal.
- Wherever possible, infectious clinical waste known of suspected to be contaminated with a Category A (UN2814) pathogen should be treated (e.g. by autoclave) on site before being transported.

Orange stream infectious waste

- For waste that is known or suspected to be contaminated with a Category B (UN3291) pathogen as per the Carriage Regulations.
- Waste within this stream should be treated to be rendered safe before final disposal. This treatment should be undertaken in a licenced or permitted facility.
- Rendered safe in this context means that waste must undergo a process that reduces number of infectious organisms present to a level that no longer required additional precautions to protect human health against infection risk from the waste.

Both yellow and orange waste streams are subject to the controls of the Special Waste Regulations

It should be noted that under the Landfill Regulations, it is prohibited to send infectious waste direct to landfill for disposal.

#### Limitations:

- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided within the text, only within a bibliography.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
NHS England	Expert opinion	Level 4			
Health Technical Memorandum 07-01: Safe and sustainable management of healthcare waste					
2022					

# Assessment of evidence

**Country:** England. This guidance is applicable to NHS England. It is based on legislation and practices of England. It is noted that it may not be applicable in other UK nations. It is specifically highlighted that the colour-coded waste system used in NHSScotland differs from that used in England.

Target audience: Healthcare staff of NHS England

# **Relevant Content:**

In this document the definition of clinical waste is based on the Controlled Waste (England and Wales) Regulations 2012. These regulations state that clinical waste is "waste from a healthcare activity (including veterinary healthcare) that —

- (a) Contains viable micro-organisms or their toxins which are known or reliably believed to cause disease in humans or other living organisms
- (b) Contains or is contaminated with a medicine that contains a biologically active pharmaceutical agent, or
- (c) Is a sharp, or a body fluid or other biological material (including human and animal tissue) containing or contaminated with a dangerous substance within the meaning of Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances."

Simply, clinical waste includes any healthcare waste that presents a risk of infection and all clinical waste (other than four noted exceptions that do not apply to PPE for HCID) should be managed as hazardous waste.

NHS England outline that in order to determine if clinical waste is infectious, it should be considered whether:

- "It came from a patient being treated for an infection or from contact with a patient carrying a transmissible disease, for example PPE items that have come into contact with an infectious patient.
- It came from a patient with a history of a known infection, for example a blood-borne virus or Clostridioides difficile.
- It has been identified as infectious by a clinician.
- It is a culture, stock or sample of infectious agents from laboratory work or it has been in contact with them."

NHS England state that when waste meets any of the above criteria it should be considered infectious and should be placed in an infectious waste stream

- Orange bag authors state that this should be used when waste is infectious but does not have any other hazardous properties.
   Orange stream waste should be treated at a permitted facility or incinerated (Legal, but not recommended under waste hierarchy).
- Yellow bag authors state that this should be used when waste is infectious and contaminated with medicines or chemicals.
   Yellow stream waste requires incineration or other treatment at a permitted facility prior to disposal.

These guidelines state that staff involved in management of waste should be provided with training and clear instructions on segregation of waste.

NHS England state that facilities which became operational after this guidance was published should store infectious waste (excluding pharmaceutical, chemical, anatomical, or palletised waste) in a secure building whilst facilities that were operational before this guidance was published, are permitted to store infectious waste outside if the following conditions are met:

- "It is not technically or economically feasible to store them in a building.
- Alternative storage arrangements provide an equivalent level of environmental protection to storage in a building.
- An appropriate site-specific environmental risk assessment is carried out which includes (but is not limited to) an assessment of
  emissions to land and water (including odour), pests and flood risk.
- The waste is in containers that remain closed and locked at all times, except when waste is being loaded or unloaded from them.
- The containers are stored in a secure area of the site that has impermeable surfacing and sealed drainage."

Within this document a list of Category A pathogens is provided: Crimean-Congo haemorrhagic fever virus, Ebola virus, Hantavirus causing haemorrhagic fever with renal syndrome, Junin virus, Lassa virus, Machupo virus, Marburg virus, Monkeypox virus, Nipah virus, and cultures of Yersinia pestis fall under UN 2814.

- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided within the text, only within a bibliography.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Transport	Expert opinion	Level 4			
Transport of Infectious Substances UN2814, UN2900, UN3373					
Revision 7 2012					

**Country:** United Kingdom

Target audience: All staff involved in the management of infectious waste.

#### **Relevant Content:**

This guidance note provides information from the Carriage of Dangerous Goods and Transportable Pressure Equipment Regulations 2009 as amended.

Category A pathogens are defined as those that are "transported by any mode in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals."

Authors state that if there is doubt about the category waste falls under it should be transported as Category A.

Within this document a list of Category A pathogens is provided. Crimean-Congo haemorrhagic fever virus, Ebola virus, Hantavirus causing haemorrhagic fever with renal syndrome, Junin virus, Lassa virus, Machupo virus, Marburg virus, Monkeypox virus, Nipah virus, and cultures of Yersinia pestis fall under Category A (UN 2814).

Category B pathogens are defined as "an infectious substance that does not meet the criteria for inclusion in Category A"

# Limitations:

- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Scottish Government	Legislation	Mandatory			
The Landfill (Scotland) Regulations 2003 2003					

# **Assessment of evidence**

Country: Scotland

# **Relevant Content:**

The Landfill (Scotland) Regulations 2003 outlines that it is prohibited to send infectious waste to landfill. This legislation is referenced in Scottish Health Technical Note 03-01.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Services Scotland	Expert Opinion	Level 4			
Viral Haemorrhagic Fever (VHF) Infection Prevention and Control Precautions Summary for the Hospital Setting (Version 3.1) 2016					

Country: Scotland

Target audience: All health and care staff involved in the care of VHF patients.

#### **Relevant Content:**

National Services Scotland (NSS) state that where there is low possibility of VHF, waste should be disposed of according to SICPs using the orange waste stream (Category B waste).

They state that where there is high possibility of VHF, waste should be double bagged within the yellow waste stream (category A waste that should be autoclaved/incinerated) and that this waste should be held within the patient's room until VHF status is confirmed.

NSS state that where there is confirmed VHF, waste should be double bagged within the yellow waste stream (category A waste that should be autoclaved/incinerated).and that this waste should be held in a safe area until transport is available.

# Limitations:

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

# **Evidence from previous update(s):**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Public Health England  Middle East Respiratory Syndrome (MERS-CoV) Infection Prevention and Control Guidance 2016	Expert opinion	Level 4			

# **Assessment of evidence**

Country: England

Target audience: All health and care staff involved in the management of MERS-CoV patients.

# **Relevant Content:**

Public Health England (PHE) note that large volumes of PPE waste can be created when treating a MERS patient and that a local waste management plan should be created before any potential patients are admitted.

PHE state that all MERS PPE should be disposed of as clinical waste and handled following local policy.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References are not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive/Advisory Committee on	Expert opinion	Level 4			
Dangerous Pathogens					
Management of Hazard Group 4 viral haemorrhagic fevers					
and similar human infectious diseases of high consequence					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
2015					

Country: United Kingdom

Target audience: Applicable generally to all healthcare workers and healthcare settings.

Methods: The ACDP assessed the risks of transmission of VHF, however, the methods of this were not reported.

#### **Relevant Content:**

The ACDP states that single-use (disposable) equipment should be used when caring for VHF patients, however, reusable RPE (e.g. powered hood respirator) may be considered to ensure effective protection. They also state that users should receive clear instructions on how to dispose of used PPE and that VHFPPE should be considered contaminated after use, even if visible contamination is not present.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

# Question 9: How should reusable PPE for HCID be managed/processed?

# Evidence added to Literature Review V3.0:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Poller B., Tunbridge A., Hall S., et al.	Expert opinion	Level 4			
A unified personal protective equipment ensemble for clinical response to possible high consequence infectious diseases:  A consensus document on behalf of the HCID programme.  Journal of Infection 2018 77 p496-502					

# **Assessment of evidence**

**Country:** United Kingdom

Target Audience: Applicable to all health and care staff who may come into contact with HCIDs.

**Methods:** In order to determine a unified PPE ensemble a simulation exercise was developed and is described within a different paper.

The results of this exercise were discussed with an expert group with representatives from infectious disease units across the UK.

#### **Relevant Content:**

Within this consensus document the only reusable item of PPE recommended is wellington boots. Is outlined that after doffing these should be stored in a separate container until HCID infection status is known. If the results are negative, it is stated that boots should be cleaned in accordance with manufacturer's instructions before reuse. If the results are positive, it is stated that the boots should be sent for safe disposal in the appropriate waste stream.

#### Limitations:

- Limited references were provided throughout the recommendations in this paper.
- Members of the High Consequence Infectious Diseases Project Working Group were not named.
- While author conflicts of interest were reported, those of the working group members were not.

# **Evidence from previous update(s):**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Public Health	Expert opinion	Level 4			
England					
Middle East					
Respiratory					
Syndrome (MERS-					
CoV) Infection					
Prevention and					
Control Guidance					
2016					

Country: England

Target audience: All health and care staff involved in the management of MERS-CoV patients

# **Relevant Content:**

PHE recommend that re-usable equipment should be avoided where possible. However, if it is used it is stated that it should be decontaminated according to manufacturer's instructions.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- · References are not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Services Scotland	Expert Opinion	Level 4			
Viral Haemorrhagic Fever (VHF) Infection Prevention and Control Precautions Summary for the					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Hospital Setting					
(Version 3.1)					
2016					

Country: Scotland

Target audience: All health and care staff involved in the care of VHF patients.

# **Relevant Content:**

In this expert opinion guidance wellington style boots, full length visors and goggles are all presented as PPE that can potentially be reusable within this expert opinion.

Reusable wellington style boots are recommended to be worn when caring for confirmed or high risk of suspected VHF cases. It is advised that these should only be used by a single healthcare worker and decontaminated between use following locally agreed protocols.

It is noted that any reusable PPE must have a decontamination schedule and responsibility of this should be assigned.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety	Expert opinion	Level 4			
Executive /Advisory					
Committee on					
Dangerous					
Pathogens					
Management of					
Hazard Group 4 viral					
haemorrhagic fevers					
and similar human					
infectious diseases					
of high consequence					
2015					

Country: United Kingdom

**Target audience:** Applicable generally to all healthcare workers and healthcare settings.

**Methods:** The ACDP assessed the risks of transmission of VHF, however, the methods of this were not reported.

# **Relevant Content:**

The ACDP states that single-use (disposable) equipment should be used when caring for VHF patients, however, reusable RPE (e.g. powered hood respirator) may be considered to ensure effective protection. Where reusable PPE is unavoidable, it is stated that it should be decontaminated using an appropriate method before being safely stored. It is outlined that methods of decontamination should be validated as effective against VHF and should not degrade PPE or compromise future effectiveness.

#### Limitations:

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

# Question 10: How is 'competence'/'competency' defined regarding PPE for HCID?

# **Evidence added to Literature Review V3.0:**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK National	Expert Opinion	Level 4			
Occupational					
Standards					
Skills for Health					
Use Personal					
<u>Protective</u>					
Equipment to					
Prevent the Spread					
of Infection					
2022					

Country: UK

Target Audience: All staff involved in using PPE to prevent the spread of infection

#### **Relevant Content:**

This document outlines the performance and knowledge criteria staff should meet in order to be considered competent in the use of PPE for prevention of the spread of infectious diseases.

#### 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.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

# **Evidence from previous update(s):**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive	Expert Opinion	Level 4			
What is competence?					

## Assessment of evidence

Country: United Kingdom

Target audience: Applicable to all involved in training relevant to health and safety.

#### **Relevant Content:**

On this webpage HSE define competence as "the combination of training, skills, experience and knowledge that a person has and their ability to apply them to perform a task safely."

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive	Expert Opinion	Level 4			
Human factors: Training and Competence					

Country: United Kingdom

**Target audience:** Applicable to all involved in training relevant to health and safety.

#### **Relevant Content:**

On this webpage HSE define competence as "the ability to undertake responsibilities and perform activities to a recognised standard on a regular basis. It is a combination of skills, experience and knowledge." It is also noted that inadequate management of competence can lead to disasters, fatalities, personal injuries, and ill health.

HSE present some key principles regarding competency:

- "Competence assurance should be linked to key responsibilities, activities and tasks identified in risk assessments"
- "Competency assurance systems should aim to establish and maintain competency for all those involved in safety-related work, including managers. This is particularly important in the management and prevention of major accidents."
- "Training is an important component of establishing competency but is not sufficient on its own. For example, consolidation of knowledge and skills through practice is a key part of developing competency."
- "Competence assurance systems should take account of foreseeable work and operating conditions including infrequent and complex activities, emergency situations and upsets, maintenance etc."

- "Training and competence assessment methods should be appropriate to the hazard profile of the tasks being undertaken. For example, competency assurance systems for safety critical tasks should be more robust."
- "'On-the-job' training should be structured and linked to risk assessments and associated control measures including procedures. In safety critical environments, on-the-job training should be supported by other forms of training where appropriate e.g classroom training, simulation."
- "Training should be validated ('Did it deliver what it was supposed to?') and evaluated ('Is this the right kind of training for our needs?') and recorded."
- "There should be refresher training for infrequent, complex or safety critical tasks and this may include appropriate reassessment."
- "Vocational qualifications should include site-specific aspects and link appropriately to the hazards and risks in your workplace."
- "Aim to achieve a suitable balance between competence and supervision."
- "Careful consideration should be given to the potential consequences of outsourcing of safety-related work. Companies must take steps to ensure that contractors are competent to carry out health and safety-related work. Companies should seek to retain intelligent customer capability to ensure that they can appropriately manage and oversee the work."

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

# 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?

# Evidence added to Literature Review V3.0:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Rueda-Medina B., Aguilar-Ferrandiz M.E., Esteban- Burgos A.A., et al.  Impact of Non-Face- To-Face Teaching with Passive Training on Personal Protective Equipment Use in Health Science Students: A Randomized Controlled Trial International Journal of Environmental Research and Public Health 2022 Vol (Issues)	Randomised Control Trial	Level 1+	Face-to-face teaching of PPE protocols with active training on the donning, use, and doffing of PPE (cap, isolation gown, gloves, goggles, N95 mask).	Non-face-to-face teaching of PPE protocols with passive training consisting of watching pre-recorded videos regarding donning and doffing procedures.	Adherence (percentage number of errors, %) to donning and doffing protocols as assessed by a trained instructor using a checklist.

Country: Spain

**Participants:** 142 health science students; 36.6% male, 63.4% female, from nursing (32.4% and physiotherapy (67.6% cohorts), in their 1<sup>st</sup> (28.2%), 2<sup>nd</sup> (21.8%, and 3<sup>rd</sup> (50%) years of study.

**Methods:** Participants were randomized into one of the two study groups using the Oxford Minimization and Randomization method. Prior to training, participants were assessed on their donning and doffing of PPE by an instructor using a checklist. Through this, the total number of donning and doffing errors were calculated, along with noting the time taken for donning and doffing.

Each group underwent training following their assigned method, then undertook the same clinical scenario based on management of a COVID-19 patient. Each simulation session included a maximum of 12 participants who took part in a 15-minute simulation, followed by a 75 minute debrief session. Participants were then assessed again following the same methods as above.

#### Results:

Of all donning and doffing steps included in this study, a significant difference between the study groups was only seen for one step. A significantly higher number of errors occurred in the passive training group when participants were removing their gown compared to the active training group (percentage of errors recorded within the passive training group when doffing gown 62.8% vs percentage of errors recorded within the active training group when doffing gown 37.2%, p=0.034). The total number of errors made by participants in the passive training group was significantly higher than the active training group (SD 1.99 vs 1.78, p=0.029).

## **Limitations:**

- COVID-19 PPE ensemble used for training (not HCID).
- Participants had prior PPE training (method of training not reported) so baseline levels of knowledge may have varied.
- Participants were all health sciences students, not qualified HCWs so may not be generalizable.

**Conclusions:** This RCT suggests that there are no significant differences in the number of donning and doffing errors when comparing groups of participants who undertook face-to-face versus non-face-to-face training.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Li Y., Wang Y., Li Y., et al  Comparison of Repeated Video Displays vs Combined Video Display and Live Demonstration as Training Methods to Healthcare Providers for Donning and Doffing Personal	Randomised Control Trial	Level 1++	Intervention  Training using four ten-minute video demonstrations (Group A)	Training using two ten-minute video demonstrations and two ten-minute live demonstrations (Group B)	Score given regarding accuracy of donning and doffing procedures using a standardised checklist by trained observers.
Protective Equipment: A Randomized Controlled Trial. Risk Management and Healthcare Policy. 2022 Vol (Issue) doi: 10.2147/RMHP.S267 514					

Country: China

**Aim:** The aim of this randomised control was to assess the most effective training method to teach donning and doffing of PPE to healthcare workers.

# Participants:

48 participants were allocated to the two study groups (Group A and Group B) using a random sequence of computer-generated numbers. No participants had experience using PPE before the study began and all were employed as nurses or doctors.

#### Methods:

Following training (detailed above), staff were assessed using a checklist of key steps, with each key step being worth between 1-6 points up to a total of 100 for the entire checklist (points were not equally distributed). Checklist steps included hand hygiene, donning the correct PPE items, and checking items were suitable for wear.

#### Results:

The average score for Group B was significantly higher than that of Group A (Mean (SD) 94.92 (1.72) vs 86.63 (6.34), p<0.001).

## **Limitations:**

- COVID-19 ensemble not applicable to HCID.
- Small sample size (n=24 per study group).
- Checklist was received a day before training meaning some participants may have been able to 'revise' with potential impact on their retention of information.
- Relationships between participants and scoring physicians was not clear.

#### **Conclusions:**

This RCT suggests that the combination of video and live demonstration is a more effective method of training than video demonstration alone when training healthcare workers on the correct steps for donning and doffing PPE.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Christensen L., Rasmussen C.S., Benfield T., et al. A Randomised Trail of Instructor-Led Training Versus Video Lesson in Training Health Care Providers in Proper Donning and Doffing of Personal Protective	Randomised Control Trial	Level 1+	Video based training in donning and doffing a PPE ensemble for protection against Ebola Virus Disease	Face-to-face instructor led training for donning and doffing a PPE ensemble for protection against Ebola Virus Disease.	Score of accuracy in donning and doffing of PPE ensemble as assessed by an evaluator using a standardised checklist.
Equipment.  Disaster Medicine and Public Health Preparedness. 2020. 14 (4) p514-520 doi: 10.1017/dmp.2020.5 6					

Country: Denmark

# Participants:

Twenty-one participants were randomised into two study groups by dice roll on arrival at the study location. Group 1 = 9 participants, Group 2 = 12 participants (10 for evaluation).

#### Methods:

Group 1 – Control - training was conducted face-to-face by a trained instructor during a single two-to-three-hour session with one to four participants. After demonstration of donning and doffing, participants undertook these steps themselves and were provided with feedback. Each participant was required to perform these tasks sufficiently (as deemed by the instructor) before leaving the training.

Group 2 – Intervention- training was conducted by providing pre-recorded videos of donning and doffing techniques (4:42 and 6:11 minutes, respectively). Participants were required to watch the videos once immediately after randomization and then had access to watch again as many times as they wished.

Donning and doffing protocols were the same for both methods of training. Evaluation took place 1 month after training. Participants were asked to don and doff PPE as taught while being assessed by an evaluator. The evaluator used a standardized checklist for evaluation, scoring each participant on accuracy.

#### Results:

For donning, the overall mean score for group 1 was 84.8 and for group 2 it was 88.0 (95% CI: -7.7 to 9.5, p=0.54). For doffing, the overall mean score for group 1 was 79.1 and for group 2 it was 73.9 (95% CI: -7.6 to 18.0, p=0.54).

Group 1 spent between 120- and 180-minutes training while the average time spent training via videos in group 2 was 55 minutes.

# **Limitations:**

- Small sample size
- Data on participant characteristics was not reported.

# **Conclusions:**

This RCT suggests that there is no significant difference between training using face-to-face sessions with feedback and ones using video training tools that were freely accessible to the group.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Wadman M.C.,	Expert Opinion	Level 4			
Schwedhelm S.S.,					
Watson S., et al.					
Emergency					
Department Process					
for the Evaluation					
and Management of					
Persons Under					
Investigation for					
Ebola Virus Disease					
Annals of					
Emergency Medicine					
2015 66(3) p306-314					

Country: USA

Target audience: Emergency Department staff that may be involved in the management of EVD patients

## **Relevant Content:**

Within this expert opinion document, it is recommended that simulation sessions should be run in full barrier protection PPE to address any concerns of HCWs that PPE will impede their standard of patient care or ability to perform care tasks.

Proposed simulation sessions included assessing psychomotor skills involved in invasive procedures that have risk of exposure to blood/body fluids, such as central venous access, radial artery access, intubation, continuous venovenous haemodialysis and managing mechanical ventilation.

- Experts that were consulted were not named.
- Information on potential conflicts of interest was not provided for consulted experts.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease	Expert opinion	Level 4			
Control and					
Prevention (CDC)					
Guidance on					
Personal Protective					
Equipment (PPE) To					
Be Used By					
Healthcare Workers					
during Management					
of Patients with					
Confirmed Ebola or					
Persons under					
Investigation (PUIs)					
for Ebola who are					
Clinically Unstable or					
Have Bleeding,					
Vomiting, or Diarrhea					
in U.S. Healthcare					
Settings, Including					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Procedures for					
<b>Donning and Doffing</b>					
PPE					
2022					

Country: USA

**Target Audience:** Applicable to all health and care staff working with patients with EVD who are clinically unstable.

Methods: Development methods were not reported.

#### **Relevant Content:**

The CDC recommends that HCWs are trained and evaluated in all recommended PPE and protocols. Training should involve simulated patient care activities while wearing PPE and proficiency and competency should be recorded. Proficiency can only be achieved through repeated practise.

The CDC suggest the following elements for training:

- How to safely don, adjust and remove PPE
- How to conduct routine clinical care while wearing PPE
- Limitations of PPE
- What to do if there is a breach or failure of PPE
- How to dispose of PPE
- Awareness of the physical strain of wearing PPE

Regular refresher training is outlined to be essential to maintain these skills.

This guidance was developed due to the emerging Ebola crisis and was produced rapidly to assist HCW and their employers, it is based on expert opinion.

#### Limitations:

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest was not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government	Legislation	Mandatory			
The Control of Substances Hazardous to Health (COSHH) Regulations 2002					

# **Assessment of evidence**

Country: United Kingdom

# **Relevant Content:**

Under COSHH it is stated that employers should provide "suitable and sufficient information, instruction and training" to employees who undertake work that has risk of exposure to a substance hazardous to health. This training should include:

Details of substances that are hazardous to health.

- Any significant findings from risk assessment.
- Precautions and actions that should be taken by the employee.
- The results of any exposure monitoring that has taken place, including any workplace exposure limit.
- Results of any relevant health surveillance, ensuring that this is anonymous.
- If work with Hazard Group 4 biological agents is expected, written instructions should also be displayed in the workplace.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Reidy P., Fletcher T., Shieber C., et al.  Personal protective equipment solution for UK military medical personnel working in an Ebola virus disease treatment unit in Sierra Leone  Journal of Hospital Infection. 2017. 96: p42-48 doi:	Expert Opinion	Level 4			

Country: Sierra Leone/United Kingdom

**Target Audience:** Applicable to all health and care staff working with EVD.

**Methods:** A group of specialists from Public Health England, the National Ambulance Resilience Unit and the Ministry of Defence (MoD) was convened to identify a suitable PPE ensemble, along with donning and doffing protocols, for staff working in EVD treatment units in Sierra Leone.

#### Relevant content:

Within this expert opinion guidance, it is stated that training should be provided and repeated at regular intervals or at the beginning of periods of outbreaks of HCIDs.

Training during the EVD outbreak discussed in this expert opinion guidance was administered using a formal presentation followed by donning and doffing demonstration videos. HCWs were then split into small groups in order to practice donning and doffing, culminating in undertaking simulated care tasks using ultraviolet tracer dye to facilitate body-mapping of contamination after doffing.

- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Elcin M., Onan A., Odabasi O., et al.	Expert opinion	Level 4			
Developing a Simulation-Based					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Training Program for the Prehospital Professionals and Students on the Management of Middle East Respiratory Syndrome					
Simulation in Healthcare 2016. 11(6)p394-403 doi: 10.1097/SIH.000000 0000000198					

**Country:** Turkey

Target audience: Applicable to trainee and qualified emergency service providers involved in management of MERS patients.

#### **Relevant Content:**

Within this paper, the authors aimed to develop a training programme for medical professionals and students regarding managing MERS outbreak situations, which would include simulation scenarios.

Feedback from participants involved in the development of the training programme highlighted that the practical element of the proposed training programme supported their learning due to its immersive nature.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease	Expert Opinion	Level 4			
Control and					
Prevention (CDC)					
For U.S. Healthcare					
Settings: Donning					
and Doffing Personal					
<u>Protective</u>					
Equipment (PPE) for					
<b>Evaluating Persons</b>					
<u>Under Investigation</u>					
(PUIs) for Ebola Who					
Are Clinically Stable					
and Do Not Have					
Bleeding, Vomiting,					
or Diarrhea					
2022					

Country: USA

**Target Audience:** Applicable to all health and care staff caring for patients with suspected or confirmed EVD who are clinically stable.

# **Relevant Content:**

CDC expert opinion states that when combined with an established protocol, proper training facilitates compliance with PPE guidance.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References are not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease	Expert opinion	Level 4			
Control and					
Prevention (CDC)					
Interim Guidance for					
Emergency Medical					
Services (EMS)					
Systems and 9-1-1					
Emergency					
Communications					
Centers/Public					
Safety Answering					
Points (ECC/PSAPs)					
for Management of					
Patients Under					
Investigation (PUIs)					
for Ebola Virus					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Disease (EVD) in the United States					
2022					

Country: USA

**Target Audience:** Applicable to all emergency services staff who may care for patients with suspected or confirmed EVD.

# **Relevant Content:**

In this expert opinion guidance, it is stated that personnel who may respond to PUI for Ebola should be trained in the proper use of PPE. These personnel should have also demonstrated competency in proper use of PPE.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References are not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Services Scotland	Expert opinion	Level 4			
NHSScotland Assure					
NHSScotland Waste Management					
Guidance. Scottish					
Health Technical Note 03-01					
Version 8.0					
2024					

Country: United Kingdom

Target audience: All health and care staff in all healthcare settings

## **Relevant Content:**

NHSScotland Assure states that training on healthcare waste disposal should be designed for specific groups including IPC staff, all nursing staff, and facilities staff.

It is outlined that trainers should have experience teaching and have experience in managing healthcare waste.

HFS states that training programmes should:

- be written in an understandable way
- take account of differing knowledge levels
- be up-to-date

made available to all relevant staff in all areas

This expert opinion guidance refers to Management of Health and Safety at Work Regulations and COSHH.

It is stated that training records should be kept and be available to line managers to monitor level of training staff have received.

#### Limitations:

- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided within the text, only within a bibliography.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE)  Respiratory protective equipment at work. A practical guide Fourth Edition 2013	Expert opinion	Level 4			

## **Assessment of evidence**

Country: United Kingdom

Target audience: Applicable to any staff using RPE in occupational settings

#### **Relevant Content:**

The Health and Safety Executive state that RPE should only be used by those that are properly trained and supervised.

It is outlined that training should include:

- Why RPE is required and how it works
- What RPE will be provided, including fit testing requirements, and how to wear and check RPE
- Use and misuse of RPE
- Hazards, risk, and effect of exposure
- What maintenance is required and when
- Responsibilities of employer and employee and how to report problems with RPE

HSE state that training requirements should be communicated by the RPE provider and that training records should be kept.

- Development methods not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided within the text, only within a bibliography.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Verbeek J.H., Mischke C., Ruotsakainen J.H., et al.	Systematic Review with meta-analysis	Level 1+			
Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff (review)					
Cochrane Database of Systematic Reviews 2016,2019,2020. Issue 4. Art. No.: CD011621. doi: 10.1002/14651858.C D011621.pub4					

**Country:** International

**Aim:** This systematic review aimed to investigate PPE ensembles, and donning and doffing methods, that are reported to have the lowest risk of HCW contamination, along with the training methods that increase compliance.

**Methods:** Systematic literature review was conducted on CENTRAL, MEDLINE, Embase and CINAHL, with a date limit up to March 2020. All controlled studies that assessed the effect of PPE used by HCWs exposed to highly infectious diseases, risk of infection, contamination or noncompliance were included, along with studies which compared donning and doffing protocols, and the effect of training. Cochrane's assessment methodology was followed.

## Findings:

Twenty-four studies were included in the 2020 update of this review, including 2278 participants: 14 RCTs, one quasi-RCT, and nine non-randomised trials. Certainty of included evidence was graded as very low or low.

#### Authors state that:

- "The use of additional computer simulation may lead to fewer errors in doffing (MD −1.2, 95% CI −1.6 to −0.7)."
- "A video lecture on donning PPE may lead to better skills scores (MD 30.70, 95% CI 20.14 to 41.26) than a traditional lecture."
- "Face-to-face instruction may reduce noncompliance with doffing guidance more (odds ratio 0.45, 95% CI 0.21 to 0.98) than providing folders or videos only"

#### Limitations:

- Authors graded the evidence included in this systematic review was graded as low or very low quality.
- Statistical significance was not reported.

## **Conclusions:**

This systematic review meta-analysis suggests that more active training methods (simulation, face-to-face instruction) may improve competency with training for PPE donning, use and doffing.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Poller B., Tunbridge A., Hall S., et al.	Expert opinion	Level 4			
A unified personal protective equipment ensemble for clinical response to possible high consequence infectious diseases: A consensus document on behalf of the HCID programme.  Journal of Infection. 2018. 77 p496-502					

Country: United Kingdom

Target Audience: Applicable to all health and care staff who may come into contact with HCIDs.

**Methods:** In order to determine a unified PPE ensemble a simulation exercise was developed and is described within a different paper. The results of this exercise were discussed with an expert group with representatives from infectious disease units across the UK.

#### **Relevant Content:**

It is recommended by authors that staff working in high-risk areas should receive training every six months. For staff in all other areas, it is outlined that training should be provided every year.

#### Limitations:

- Limited references were provided throughout the recommendations in this paper.
- Members of the High Consequence Infectious Diseases Project Working Group were not named.
- While author conflicts of interest were reported, those of the working group members were not.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government	Legislation	Mandatory			
Personal Protective Equipment at Work (Amendment) Regulations 2022					
2022					

## **Assessment of evidence**

Country: UK

## **Relevant Content:**

The regulations state that employers must provide suitable information, instruction and training for their employees to make effective use of the PPE provided to them. Training must include how to correctly fit and wear PPE as well as the purpose and limitations of the PPE. 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.

# **Evidence from previous update(s):**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Northington W.E., Mahoney M., Hahn M.A., et al.  Training retention of level C personal protective equipment use by emergency medical services personnel  Academic Emergency Medicine 14(10) 2007, p846- 849.	Before and After Study	Level 3	Evaluation of donning and doffing skills and knowledge levels regarding HAZMAT PPE immediately after training.	Evaluation of donning and doffing skills and knowledge levels regarding HAZMAT PPE, six months post-training.	Number of participants with errors occurring during donning and doffing as reported by observer six months post training

## **Assessment of evidence**

Country: USA

**Aim:** This study aimed to assess the retention of skills and knowledge of trainee emergency services providers regarding the use of Level C PPE (coverall, gloves, boots, air-purifying respirator).

Participants: 36 trainee emergency service providers participated in the study.

#### Methods:

A 90-minute training session was provided to trainees, which included 30 minutes of verbal instruction followed by a demonstration and practical elements. Each participant then undertook supervised donning and doffing, with corrections, until these were deemed to be done 100% accurately.

## Results:

On reassessment six months post training, only three students (8.6%) were able to correctly don and doff all required PPE.

#### Limitations:

- small sample size
- participants were all trainee paramedics no other staff group was assessed
- it is unclear if participants applied training within the six months or had further experience during this time.

#### **Conclusions:**

This study demonstrates that knowledge retention of this cohort was poor six months post training. The authors do not suggest an alternative training schedule, however, in this study students were required to don and doff PPE independently. The authors suggest that a trained observer could assist in the process to minimise errors, this is current practice in NHSScotland when using enhanced PPE.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Casalino E.,	Experimental study	Level 3	Reinforced training	Conventional training	Student competency
Astocondor E.,			programme (RTP)	programme (CTP)	following three
Sanchez J.C., et al.			for both enhanced	for both enhanced	training sessions
Personal protective			(RTP-E) and basic	(CTP-E) and basic	using either
equipment for the			(RTP-B) PPE in	(CTP-B) PPE	conventional or
<u>oquipinone for the</u>			student volunteers	consisting of	

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Ebola virus disease: A comparison of 2 training programs.  American Journal of Infection Control. 2015. 43 p1281- 1287			consisting of theoretical and practical modules followed by debrief with trainer.	theoretical and practical modules without debrief.	reinforced training methods.  Percentage of students remaining error or critical error free (%).

**Country:** France/Peru/Mexico

**Aim:** The aim of this study was to compare two different strategies of training (reinforced vs conventional) nursing and medical students in the use of enhanced and basic PPE ensembles.

**Participants:** 120 students, across three countries, participated in the study, none of whom reported having experience or previous training in using PPE.

**Results:** Basic PPE groups - both conventional and reinforced training resulted in improvements over the three sessions (CTP-B p<0.0001, RTP-B p<0.001); at the third session, in the CTP-B the percentage of students free of doffing errors and critical errors were 56.7% and 66.7%, respectively. For the RTP-B group these percentages were 93.3% and 96.7%, respectively.

Enhanced PPE groups – for both conventional and reinforced training there were significantly fewer errors after completion of three training sessions (CTP-E p<0.0001, RTP-E p<0.0001). After the third training session doffing errors and critical errors were 50% and 60%, respectively, in the CTP-E group and 76.7% and 83.3%, respectively, in the RTP-E group.

- This study did not follow up on students past the third training session and so it is unknown whether either training method led to superior knowledge retention.
- P-values for changes in percentage of students doffing error free were not reported.

## **Conclusions:**

This study provides evidence that repeated training when using either conventional or reinforced training methods decreases the risk of making errors when donning and doffing PPE. It also provides evidence that 'reinforced' training where students are given verbal instruction and given context and further information following errors during training can significantly improve competency, with higher percentages of students completing donning and doffing without errors or critical errors.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Tomas M.E., Kundrapu S., Thota P., et al.  Contamination of health care personnel during removal of personal protective equipment.  JAMA Internal Medicine 175(12): 1904-1910, 2015	Before and After study	Level 3	A 10-minute video on PPE donning and doffing followed by 20 minutes of demonstration and practice.  Gloves were artificially contaminated with fluorescent lotion and bacteriophage MS2, visualized using a black light to provide immediate feedback while emphasizing the most common errors.	Errors and contamination during doffing compared before and after training intervention.	Percentage of doffing instances which caused contamination. (%) Percentage reduction in instances of contamination. (%)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
			Trainers observed		
			and recorded errors		
			and contamination		
			during doffing after		
			training.		

Country: USA

**Aim:** The aim of this study was to assess the efficacy of a PPE donning and doffing training programme by determining contamination on the skin and clothes of participants caused by artificially contaminated gloves during doffing before and after training.

#### Methods:

Participants were employed as HCWs across four hospitals in Ohio, United States. HCWs wore gowns and gloves which were artificially contaminated with fluorescent lotion and asked to doff the PPE using their own method. Trained observers recorded any errors in doffing according to the CDC checklist and then assessed contamination on participants skin and clothing using a black light.

## Findings:

The study included 435 PPE doffing removal simulations, with contamination occurring in 200 (46%) instances. Contamination occurred more frequently when incorrect vs correct technique was observed for contaminated glove and gown removal (70.3% vs 30.0%, p =< 0.001). The most common errors were removing the gown by pulling over the head, gloves not covering the wrists and touching the contaminated surface of the gloves while removing.

Contamination after glove removal alone was significantly reduced (60.0% vs 18.9%, p=< 0.001) immediately after the training intervention. The significant reduction in contamination with fluorescent lotion was sustained at one and three months after the intervention (12.0% at both time points, p=<0.001 compared with before the intervention).

## Conclusions:

This study provides evidence that training interventions with practical elements and immediate feedback on technique can significantly reduce contamination of skin and clothes during doffing and that this may be sustained up to three months after training. The authors suggest that annual refresher training should be provided and that the use of doffing assistants could further reduce contamination.

## Limitations:

• Simulation study using fluorescent lotion so findings may not be generalisable to real-life scenarios and transmission events.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive / Advisory Committee on	Expert opinion	Level 4			
Dangerous Pathogens  Management of					
Hazard Group 4 viral haemorrhagic fevers and similar human					
infectious diseases of high consequence					
2015					

Country: United Kingdom

**Target audience:** Applicable generally to all healthcare workers and healthcare settings.

Methods: The ACDP assessed the risks of transmission of VHF, however, the methods of this were not reported.

#### **Relevant Content:**

The ACDP recommend that staff involved in caring for VHF patients should be trained appropriately and regularly, including in the correct protocol for donning and doffing PPE. It is noted that training should be provided with consideration of susceptibility to human error. It also states that records of training should be kept.

The ACDP state that ambulance personnel should be trained in the transfer of VHF patients, including undertaking periodic training exercises that test their procedures and exercises with receiving units. It is noted that Ambulance Trusts should follow guidance available on transfer of VHF patients in the UK (ICHD Ambulance Service Basic Training Manual, 2008. Section 17.5 Category 4 Infections)

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest were not outlined.
- References were not provided.

# Question 12: How should staff competency be assessed?

# **Evidence added to Literature Review V3.0:**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease	Expert Opinion	Level 4			
Control and					
Prevention (CDC)					
Guidance on					
Personal Protective					
Equipment (PPE) To					
Be Used By					
Healthcare Workers					
during Management					
of Patients with					
Confirmed Ebola or					
Persons under					
Investigation (PUIs)					
for Ebola who are					
Clinically Unstable or					
Have Bleeding,					
Vomiting, or Diarrhea					
in U.S. Healthcare					
Settings, Including					
Procedures for					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Donning and Doffing PPE					
2022					

Country: USA

Target Audience: Applicable to all health and care staff working with patients with EVD who are clinically unstable.

**Methods:** Development methods were not reported.

#### **Relevant Content:**

The CDC recommends that HCWs are trained and evaluated in all recommended PPE and protocols. Assessment of proficiency and competency should involve observations of simulated patient care activities while wearing PPE and outcomes of assessment should be recorded.

The CDC states that employees should be able to demonstrate how to properly don, use, and doff the PPE they will be using during the care of Ebola patients.

This guidance was developed due to the emerging Ebola crisis and was produced rapidly to assist HCW and their employers, it is based on expert opinion.

- Developmental methods were not reported.
- Individuals involved with guidance development were not named.
- Information regarding conflicts of interest was not outlined.
- References were not provided.

# **Evidence from previous update(s):**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Williams C.K and Carnahan H.	Expert opinion	Level 4			
Development and validation of tools for assessing use of personal protective equipment in healthcare.					
American Journal of Infection Control. 2013 41 p28-32					

#### Assessment of evidence

Country: Canada

Target audience: Applicable to staff involved in training health and care staff in use of PPE

## Methods:

Using a Delphi methodology a checklist for assessing PPE competency was developed by consensus. The checklist assessed hand hygiene, PPE donning and PPE doffing. One point is awarded for each task done correctly and zero points were awarded for a task not done or done incorrectly. In addition, the donning checklist awarded five points for each correctly selected PPE item (zero points for incorrectly selected or unselected items) and both the donning and doffing checklists awarded five points for donning or doffing all required items in the correct order.

Twenty-nine participants with no or minimal training (newly trained group) underwent web-based training on hand hygiene and routine practices for a maximum of 40 minutes. Followed by a simulated clinical scenario (baseline) which included donning and doffing PPE, then received feedback from observers, before undertaking a further simulated care scenario (immediate transfer test). One week later, participants returned to undertake a further simulated care scenario (delayed transfer test).

The newly trained group were compared to the experienced group which was made up of eleven participants with moderate to extensive experience using PPE. This group had the option to review training materials for a maximum of 40 minutes before completing the baseline simulated case scenario. This group did not complete further simulated care scenarios.

Assessors were trained in assessment tools and blinded to participants' level of experience. Interobserver reliability was evaluated using interclass correlation coefficient (ICC), with an ICC >0.75 deemed acceptable.

#### Results:

- Assessors were found to provide reliably similar scores when using the checklist (ICC=0.92).
- Comparisons between groups donning and doffing scores were not analysed, however their global rating scale (including case & risk assessment, PPE handling, flow of operation, self-contamination, contamination of environment, cross-contamination) was compared between the groups.
- When analysed using an independent t-test, no significant difference was found in the global rating scores between experienced participants at baseline and newly trained participants at delayed transfer test (18.7±1.3 vs 16.2±0.5; t(13.61) = 1.89; P =.081; r = 0.46).

- Small sample size.
- Details of the checklists were not provided.
- individuals involved with consensus were not named.
- information regarding conflicts of interest was not outlined.

#### **Conclusions:**

Reliability of the expert panellist's responses was graded as high enough for the checklists to be applied in the clinical setting (Cronbach's  $\alpha > 0.9$ ).

This study describes a checklist in which all elements of PPE donning and doffing are assessed and provides a score for the PPE user. The study was able to differentiate between newly trained and experienced users, however, the authors note that as the tests were performed immediately after training the results demonstrate a training effect rather than retained learning. The study does not state a minimum score or pass mark for competency; it is assumed that staff must get full marks to be deemed competent.