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A unified personal protective equipment ensemble for clinical response to possible high consequence infectious diseases: A consensus document on behalf of the HCID programme

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ARTICLE INFO

Article history:

Accepted 29 August 2018

Available online 31 August 2018

Keywords:

Personal Protective Equipment (PPE)
Healthcare
Fluorescence visualisation
Infection control
Simulation
Training
Ebola
High Consequence Infectious Diseases (HCID)

SUMMARY

The importance of appropriate personal protective equipment (PPE) as a component of healthcare worker (HCW) protection was highlighted during the Ebola virus disease (EVD) outbreak in West Africa. The large number of HCW deaths in Africa was in part due to lack of resources or prior training in PPE usage. As part of the Ebola legacy, the High Consequence Infectious Disease (HCID) programme was initiated by NHS England and Public Health England (PHE) to improve preparedness for Ebola and other infections that not only endanger the life of the patient, but also pose particular dangers to HCWs. A systematic review identified national standardisation of PPE protocols as a priority, but recognised that a lack of safety data limited the ability to mandate any one protocol.

A simulation-based exercise was developed to assess the safety of PPE ensembles in use in the UK during first assessment of a patient with a possible HCID. A mannequin was adapted to expose volunteer HCWs to synthetic bodily fluids (vomit, sweat, diarrhoea and cough), each with a different coloured fluorescent tracer, invisible other than under ultraviolet (UV) light. After exposure, HCWs were examined under UV lights to locate fluorescent contamination, and were screened again after removing PPE (doffing) to detect any personal contamination. The exercise was videoed, allowing retrospective analysis of contamination events and user errors.

The simulation testing identified significant HCW contamination events after doffing, related to protocol failure or complications in PPE doffing, providing conclusive evidence that improvements could be

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<https://doi.org/10.1016/j.jinf.2018.08.016>

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made. At a workshop with an expert stakeholder group, the data were examined and a unified PPE ensemble agreed. This ensemble was then tested in the same simulation exercise and no evidence of any HCW contamination was seen after doffing. Following further review by the working group, a consensus agreement has been reached and a unified 'HCID assessment PPE' ensemble, with accompanying donning and doffing protocols, is presented here.

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Introduction

During the early stages of the Ebola virus disease (EVD) outbreak in West Africa in 2013–2016, a large number of healthcare worker (HCW) deaths occurred.¹ This clearly demonstrated the importance of both adequate personal protective equipment (PPE) and the training required to use it appropriately. The UK's response to the outbreak was overseen by the Department of Health, with expertise from Public Health England (PHE), the national Advisory Committee for Dangerous Pathogens (ACDP) and the Health and Safety Executive (HSE). It was anticipated that the NHS could encounter a small number of UK HCWs infected with Ebola virus from overseas deployment, or infected travellers entering the UK.² Therefore, all acute receiving medical units were advised to plan for safe assessment of individuals returning from West Africa with a febrile illness.³ There was considerable concern about what constituted the safest combination of PPE for healthcare staff to wear when assessing anyone with a possible diagnosis of EVD. Previous guidance issued by ACDP was based on expert opinion rather than a clear evidence base and did not define the specific ensemble to be used. The urgency for units to establish PPE protocols for front-line HCWs resulted in significant variance in PPE ensembles around the UK, based on local preferences and PPE availability. This issue was also identified in other countries, with variation encountered and differing guidance from bodies such as the Centre for Disease Control and Prevention and World Health Organisation.⁴

As part of the legacy of the outbreak and to aid future preparedness, NHS England and PHE launched the High Consequence Infectious Disease (HCID) programme. One of its remits was to develop a unified, national PPE ensemble and donning/doffing protocol, for use when assessing patients with a possible HCID. ACDP Hazard Group 4 pathogens, such as EVD or another transmissible viral haemorrhagic fever (VHF), currently have a more stringent level of PPE advised than airborne pathogens such as Middle Eastern Respiratory Syndrome Coronavirus (MERS-CoV) or avian influenza.^{5,6} However, the consequence of transmission of all are high, therefore our aim is to have a simple standardised PPE ensemble for all HCIDs. This novel approach will reduce variability in practice, aiming to reduce risk for all HCWs involved in the care of such patients.

In order to generate data to inform the choice of national PPE ensemble, a simulation-based exercise was developed to test efficacy of protection afforded to HCWs by various PPE protocols in current use. These results were shared with an expert stakeholder group, which agreed a new, consensus PPE protocol to be further evaluated in the simulation exercise. Development of the final consensus PPE protocol and its performance characteristics in the simulation exercise are described here.

Methodology of the consensus process

Selection of PPE protocols for initial testing

A simple questionnaire was designed to obtain details of PPE protocols in use for assessment of patients with a possible HCID;

this was disseminated via the British Infection Association and Healthcare Infection Society networks to Infection Prevention and Control leads at acute trusts in the UK. Of 29 responses, 28 had different PPE protocols. It was not feasible to test fully every PPE protocol in use in the UK in the simulation exercise. Therefore five different protocols were chosen for testing: four from the units designated as the UK's Ebola surge capacity centres (Royal Free London, Sheffield, Liverpool and Newcastle) in response to the West Africa outbreak, and one from a unit with significant previous experience of assessing patients subsequently confirmed to have a VHF (Glasgow).

Simulation-based testing of PPE protocols

A novel simulation-based exercise was developed to assess the safety of the selected PPE protocols during first assessment of a patient with any possible HCID, including airborne pathogens. The development of the mannequin and simulation exercise built on work by the UK Army medical corps when training personnel going out to work in Ebola treatment centres in W Africa.⁷ In brief, a mannequin was adapted to expose volunteer HCWs to synthetic bodily fluids (vomit, sweat, diarrhoea and cough), each with a different coloured fluorescent tracer, invisible unless under UV light. HCWs were trained in each PPE ensemble by repeated donning and doffing up to ten times until assessed as competent by a staff PPE trainer ahead of the simulation. During the exercise, they used PPE according to the protocol being tested, and undertook a variety of simulated clinical tasks (such as obtaining routine clinical observations). After exposure, HCWs were examined under UV lights to locate fluorescent contamination, recorded on a 35-grid bodymap and photographed, and were screened again after removing PPE (doffing) to detect any personal contamination. The exercise was videoed, allowing retrospective analysis of contamination events and user errors. This is described in detail elsewhere.⁸

Results summary from initial testing phase

The five PPE ensembles were tested by staff a total of 37 times. A contamination event was defined as the presence of fluorescent tracer on the skin or PPE in a single 'body-map' area (e.g. forearm, hand, neck, and face), which was individually assessed for all four bodily fluids. Multiple contamination events were seen on all volunteers immediately after the exercise. Participants were instructed through the process of doffing by a PPE trainer to prevent deviation from guidelines. After doffing, fluorescence could still be observed in twelve body-map areas, affecting the face, neck, forearm and lower legs. A root cause analysis (RCA) was performed for each event; recorded contemporaneous observations, film footage and photographs were retrospectively reviewed by the same three researchers to determine the mechanisms of contamination. Breaches were identified as being related either to protocol failure, such as contamination of exposed skin, or complications in PPE doffing such as when removing boot covers. Results of this study are fully described elsewhere.⁹

Analysis of results, development and testing of consensus PPE

Results from the first testing phase were presented by the VIOLET research group to the High Consequence Infectious Diseases Project Working Group, brought together at a full day meeting. This group comprised twelve NHS doctors and ten nurses from the Ebola surge capacity centres and those with experience in caring for confirmed VHF cases, with representation from Infectious Diseases, Microbiology, Virology and Infection Prevention and Control. Six representatives from HSE's laboratory including members of the project delivery team and PPE experts provided safety and technical expertise. In order to ensure oversight from a body independent of the NHS, two HSE specialist microbiologists contributed to the process, and the meetings were chaired by the Deputy Head of PHE's Emergency Response Department.

As well as the test results and RCA findings, the expert group heard qualitative judgments gathered from participant feedback about ease of PPE use and comfort, both of which were considered important safety factors to improve users' compliance with protocols.

In addition, the aim was for items selected to be available within the NHS supply chain, to allow access to all UK users, since bulk-buying of non-core items such as coverall suits resulted in procurement issues during the EVD outbreak. Ideally, items should not need modification, also donning and doffing protocols were to be developed to reduce user variability.

All items apart from a hood were already available in the NHS supply chain. No hood currently in use fulfilled all necessary requirements: to be water repellent, covering the head and neck, easy to remove and not to compromise the function of the wearer's FFP3 respirator mask. Consequently, working with a bespoke PPE designer/manufacture (KIT Design, Sheffield), a hood to fulfil the above requirements was developed using standard water-repellent surgical gown material. Reinforced gown material was not used as the head area had a low contamination rate in first phase testing.⁹ Additionally, the thinner standard fabric would be cooler to wear, improving comfort.

Taking all the information together, the expert group proposed a unified, consensus PPE ensemble to undergo testing: the 'HCID assessment PPE'.

Validation of the 'HCID assessment PPE' ensemble

Further validation of the HCID assessment PPE was undertaken to provide evidence that the PPE and revised doffing procedures consistently and repeatedly prevented cross-contamination. Ten pairs of volunteer healthcare staff underwent the same 'VIOLET' simulation exercise,⁸ replicating the standard of practice of the original phase of testing. Thirteen of the seventeen participants were new to 'VIOLET' to minimise user bias as much as was possible with available resources. Subjective feedback was again contemporaneously obtained on user-friendliness and ease of training. Volunteers had previous experience of using 'suspected case' PPE, but as all were new to this ensemble they all underwent training prior to the exercise, practising until deemed competent.

As before, data were captured for UV fluorescent contamination on PPE both after the simulation and after doffing PPE. The new ensemble was tested 20 times. Multiple contamination events were again noted on the outside of the PPE after the simulation exercise and were comparable to those observed in the initial phase, with vomit and sweat again most frequently observed. However, after doffing the new PPE ensemble, no residual contamination was seen on any volunteer.

Following testing, the same expert working group convened again for a further full day meeting to review these data and refine the protocols for use of the unified PPE.

Crucial safety improvements and refinements of protocol

Head protection

- FFP3 mask to be selected according to prior fit-testing for the wearer, with strap positioning consistent with suppliers' recommendations, to provide respiratory protection; the mask must also be fit-checked.¹⁰
- Hood for head and neck protection. Maximal skin coverage was essential, as use of a surgical cap during initial testing resulted in direct skin contamination.⁹ The latest iteration of the hood was reviewed, and further refined to ensure good fit for all users. It was agreed that 2 sizes of hood, small and large, would be sufficient given the hood's adjustable closure. The final design of this AIT (Anti-Infection Transfer) Hood can be seen in Fig. 1.
- Disposable full-face visor, with wide strap to aid removal. It was agreed that longer length visors (minimum of 2 cm below the chin) should be used, which cover the jaw fully as well as the face, offering additional splash protection. One participant was noted to have 'vomit' on their mask, believed to be the result of a splash entering underneath a shorter visor.

Body protection

- Rear-fastening reinforced surgical gown. This ensemble was designed considering that even patients with confirmed VHF infections in the UK have presented early in their course of illness. Therefore, fluid-resistant rather than fully waterproof fabric was considered to be sufficiently protective. In addition, fully waterproof fabric items are less readily available. Although seepage of fluid through the sleeve of a standard surgical gown was noted in the 1st phase, this was not seen when using a reinforced surgical gown during the 2nd phase, testing the consensus PPE.
- The length of the gown must be sufficient to achieve a 10–15 cm overlap of the gown with the top of the boot. This mitigates against dripping of fluid from the gown into the boot as seen in initial testing.⁹ However, longer length gowns can be a potential trip hazard for smaller staff as well as trailing material being a contamination risk (see Fig. 2); long sleeves and excess material around the body can also compromise safety when doffing (see Fig. 3). Gowns should therefore be available in a range of sizes and widths to reduce this risk. Longer length gowns could be trimmed with scissors if necessary for shorter staff. Taller staff who are unable to achieve sufficient overlap with the longest available gown cannot be considered safe to proceed to provide patient care.
- Wide, extra-long medium thickness plastic apron (such as worn for endoscopy): although agreed that ideally PPE items should not be modified, a higher fit to protect the upper chest was desired and no such apron existed. Tearing the neck loop in the middle so both the neck and waist areas were tied was deemed an acceptable and simple modification, which significantly improved protection.

Hand protection

Three layers of gloves:

- Inner personal protection glove (standard short non-sterile glove), with surgical gown sleeve overlapping;
- Middle glove (long cuffed glove) overlapping and taped lengthwise to the gown sleeve with 4 pieces of Micropore™ tape. Taping allows gloves to be secured and they will come off simultaneously with the gown. Lengthwise tape is preferred over circumferential since the latter can prevent removal of the glove/gown combination if taping is too tight.
- Outer glove comprising either standard short non-sterile gloves for basic care, or heavier duty gloves for cleaning up of extreme

Table 1
Summary of agreed HCID assessment PPE.

Component	Required piece of PPE
Respiratory protection	Disposable filtering face piece respirators (FFP3)
Head protection	Anti-Infection Transfer (AIT) hood
Eye protection	Disposable longer-length full face visor with wide band
Gown	Rear fastening reinforced surgical gown of fluid-resistant material, long enough to overlap boots <ul style="list-style-type: none"> • e.g. 365 Healthcare; Ref 36520405v
Apron	Wide, extra-long medium thickness plastic apron (such as worn for endoscopy)
Gloves	Three layers of gloves: <ul style="list-style-type: none"> • 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
Boots	Surgical wellington boots <ul style="list-style-type: none"> • Must be long enough to be overlapped by the gown (see above).



Fig. 1. Final hood model.

bodily fluid episodes. These outer gloves can be removed and replaced as required during patient care in accordance with infection control principles e.g. need for sterile gloves. A third glove was agreed as these are the most heavily contaminated part of PPE, and this improved safety of doffing.

- For the top and base layer one of two 'pinch and pull' methods of glove removal is advised in accordance with any previous training the HCW has undertaken.^{11,12} The mid layer glove comes off when the gown is removed.

Leg and foot protection

- Surgical wellington boots long enough to be overlapped by the apron and surgical gown. Whilst boot covers (worn without boots underneath) overcome storage issues, they were shown to be a frequent cause of cross-contamination in initial testing, and carry an unacceptable risk.⁹
- An oversize boot should be chosen to assist heel loosening and a 'step-out' removal technique, obviating the need for a 'boot-jack' boot remover, but ensuring they are not so big as to compromise movement or increase the risk of tripping.

A summary of the final ensemble is found in [Table 1](#), whilst the final donning and doffing protocols are found in annexes 1 and 2. See [Fig. 4](#) for picture of HCID PPE.

Other instructions

Buddy check and sign off: Once donning of PPE is believed to be complete, the health worker should undergo a final check by their donning assistant or 'buddy'. If gaps in PPE are identified the wearer must not proceed until this has been rectified. When the buddy is happy that the donning is complete and correct, they should write their initials and the time on the shoulder/sleeve of the gown with a marker pen.

Maximal time of use: The maximal time in which it is safe to wear this PPE will vary according to factors such as integrity of PPE, tasks undertaken, exposure to bodily fluids, comfort and tolerance of the HCW. There is a lack of evidence to stipulate time-based recommendations,¹³ and local risk assessments should be performed at the time of use. HCWs undertaking extended periods of patient care in isolation rooms should be monitored externally by staff.

Reuse of footwear: A separate bin should be provided for boots so that they can be retained safely until HCID test results are avail-



Fig. 2. Trailing gown.



Fig. 3. Inability to safely manage gown material.

able. If the patient tests negative the boots can then be cleaned and re-used, and if positive they should be sent for safe disposal as contaminated waste. Recycling of boots prior to a negative test is not advisable due to potential risk of contamination to the next person donning.

Doﬃng assistance: A ‘hands off’ doﬃng buddy is essential to support staff in safe removal of PPE and to avoid buddy contamination.⁹ The buddy should talk the HCW slowly through each step, instructing and mirroring each action face to face (see Fig. 5). This also allows the buddy to identify any slip of PPE, such as the mask or hood moving on the face, which ensures the person doﬃng avoids inadvertent contamination.

Instructions and signage: Instruction posters (donning and doﬃng cards) for the new PPE ensemble can be found in annexes 1 and 2. It is recommended that they are clearly visible in the don-

ning and doﬃng area, but should not replace the support of a ‘doﬃng buddy’ to ensure all stages are followed safely. Clear zone demarcations are recommended, and can be reinforced visually at the zone boundaries by laminated cards stating the area (e.g. ‘Red area: you are entering the dirty zone’, ‘Amber area: you are entering the doﬃng zone’, ‘Green area: you are entering a clean area’). Doﬃng areas should be sufficiently spacious to allow the HCW to move freely without touching surfaces or walls.

Training: In order to ensure familiarity of this PPE and sustain competency in its use, it is advised that a regular mandatory training programme be in place. For units that anticipate regular assessment of suspected HCID patients, such as infectious diseases units or emergency departments, six-monthly sessions are advised. For all other units, an annual training session should be provided.



Fig. 4. New ‘HCID assessment PPE’ ensemble, front and back.



Fig. 5. 'Mirroring' during buddy-led doffing.

Limitations

This is the first PPE protocol for HCWs assessing possible HCID patients with an evidence base for its safety in use. However, the Working Group recognises that there are limitations with this ensemble and its testing methodology. Debate continues over whether UV-fluorescent markers or various viral surrogates are best-suited for testing PPE.^{14–16} However, UV-fluorescence has advantages of both cost and the training benefit of visual reinforcement of contamination, which was a key consideration for this work. The method aimed to provide realistic exposure events in terms of quantity and means of contamination. One limitation of this was that contamination across volunteers was not standardised, however, the advantages described above were considered to outweigh this. Choice of methodology is discussed further in the original VIOLET study.⁸

Although the PPE elements have been carefully considered, the ensemble itself is only as good as the user's adherence to instructions in its use, alongside measures to reduce environmental contamination and potential for exposure. Training is therefore a fundamental part of its safety and must be provided and maintained. To aid this, the PPE components have been selected with NHS staff in mind, choosing items that HCWs should be familiar with, and can obtain mostly from local stock.

PPE that covers the face and neck and adds layers to the body can be uncomfortable to wear. Also, the incorporation of a hood precludes auscultation by standard stethoscope. Previous PPE guidance for HCID respiratory pathogens would have allowed use of one, and some may challenge this change in guidance. However, the consensus group's opinion was that auscultation is unlikely to offer clinical information that is unobtainable by other methods. While every effort has been made to balance comfort with safety, some HCWs may find that it is too claustrophobic to be able to care safely for their patient. Regular training will help HCWs to adjust to the reality of providing patient care while wearing PPE. Those identified as being unable to tolerate or wear the PPE safely can be identified in advance of a critical incident and allocated an alternative role. Knowledge gaps around issues of heat stress, impaired communication and duration of work were highlighted in a WHO document on PPE in tropical climates, but are also relevant in other environments.¹³

Summary

After demonstrating that currently used ensembles do not afford sufficient protection for use across all acute care services, a new unified model was proposed by a panel of UK expert representatives, termed the 'HCID assessment PPE' ensemble. This has now been tested successfully, with no evidence of post-doffing

contamination events. Subjective feedback on the new PPE ensemble was positive, with many users feeling more protected.

This novel approach of a unified PPE ensemble provides significant advantages. Firstly, having the same ensemble for both bodily fluid (such as Ebola) and airborne (such as MERS-CoV) transmitted pathogens removes any confusion about which is the correct PPE to be used. Secondly, unified training means that staff moving to work in different areas of the UK will not need retraining in PPE donning and doffing. This prevents errors from mixing of protocols, plus a robust PPE training assessment process will ensure standardised practice in donning and doffing can be maintained. Lastly, staff can have confidence that they are using PPE with an evidence base for its safety.

It is envisaged that PHE and NHS England will develop plans for adoption of this consensus guidance in England, with information shared with the devolved UK nations.

Funding

This work was funded by the Health and Safety Executive. Its contents, including any opinions and/or conclusions expressed, are those of the authors alone and do not necessarily reflect HSE policy.

Bozena Poller received funding through the [Healthcare Infection Society's](#) Graham Ayliffe Training Fellowship [GATF2017/02/001](#); no other project costs were funded by HIS.

Conflict of interest

Bozena Poller received salary funding through the Graham Ayliffe Training Fellowship (GATF2017/02/001) from Healthcare Infection Society.

Acknowledgements

Our grateful thanks go to all members of the High Consequence Infectious Diseases Project Working Group, and especially those who participated in the volunteer PPE trials. Thanks also to Paula Romano and Fiona Jones from KIT Design, Sheffield for their advice and support in developing a bespoke hood. We are also grateful to David Equeall, Medical Videographer at Sheffield Teaching Hospitals, for film and photography support. Special thanks to Richard Clark and the team in the simulation suite at Sheffield Teaching Hospitals, without whom none of this work would have been possible.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:[10.1016/j.jinf.2018.08.016](https://doi.org/10.1016/j.jinf.2018.08.016).

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