

Contextual data

KQ6. Should health workers providing direct care or indirect care to patients with Ebola or Marburg disease and using eye protection (goggles/face shield) wear them **under versus over** the *head and neck covering*?

We conducted a rapid review for KQ6, especially updating the Hersi et al. 2015 rapid review and the Verbeek et al. 2020 systematic review with respect to protocols, procedures and order for donning and doffing of eye protection PPEs and head/neck protection PPEs. [1] [2] We found very limited data to support the choice of whether HWs should wear the PPE for eye protection **under** or **over** the PPE to protect head/neck skin.

Table 1 summarizes PPE recommendations related to the order on how to don and doff PPEs for eye and head/neck protection by the WHO, US CDC and European CDC. According to the European CDC, there are different ways of putting on and removing the PPEs but there is no gold standard on how to do this. The European CDC suggests it is more important to understand the rationale behind the chosen approach for donning and doffing. The most critical aspects in the process are how to avoid secondary disease transmission to HWs involved in patient care and avoid self-contamination while doffing. [3]

The WHO recommends that PPEs to protect mucosae should be taken off as late as possible during the PPE removal process, preferably at the end, to prevent inadvertent exposure of the mucous membranes (Table 1). If a hood is used, it should be put on after eye, nose and mouth protection PPEs so that mucosal protection is maintained after taking off the hood. As such, the WHO recommends wearing a PPE for eye protection **under** a PPE for head/neck skin protection. [4]

In the procedures for donning PPE with a N95 respirator option, the US CDC recommends putting on a hood before putting on a face shield, wearing a PPE for eye protection **over** a PPE for head/neck skin protection (Table 1). [5]

In the suggested steps for donning PPEs, the European CDC recommends putting on the hood (step 7) then putting on eye protection (step 10), wearing a PPE for eye protection **over** a PPE for head/neck skin protection (Table 1). [3]

With respect to the extraction of contextual data, the key findings are as follows (Table 2).

- Chughtai et al. 2018 conducted a simulation study in which they tested 10 different PPE donning and doffing protocols recommended by various health organizations for Ebola. Ten participants were recruited for this study and each was randomly assigned to use three different PPE protocols. After donning of PPE, fluorescent lotion and spray were applied on the external surface of the PPE to simulate contamination, and ultraviolet light was used to count fluorescent patches on the skin after doffing.
 - Two PPE protocols were tested in which the eye-protection PPEs were worn **under** the head/neck protection PPEs, with 1 protocol (WHO, coverall and N95) was observed with 4 large patches (Table 3). There were no small patches observed with these two protocols.
 - Eight PPE protocols were tested in which the eye-protection PPEs were worn **over** the head/neck protection (Table 3). One protocol (North Carolina, coverall and N95) was observed with 1 large patch on a front forehead and 1 large patch on a front right forearm. Two PPE protocols were observed with small patches, including the “CDC, coverall and N95” with 1 small patch on the back of a right hand and the “Health Canada, gown and N95” with 1 small patch on a front forehead and 1 large patch on a front right forearm.

- Suen et al. 2018 conducted an experimental study with one group using multiple comparisons. In total, 59 participants randomly performed PPE donning and doffing (Table 2). The trial consisted of PPE donning, applying fluorescent solution on the PPE surface, PPE doffing of participants, and estimation of the degree of contamination as indicated by the number of fluorescent stains on the working clothes and environment. PPE1 consisted of a neck-to-ankle outfit, N95 respirator, hood, disposable face shield, surgical gown, boots and double gloves. PPE2 consisted of a head-to-ankle coverall, N95 respirator, hood, disposable face shield, boots and double gloves. PPE3 consisted of neck-to-ankle outfit, N95 respirator, no hood, disposable face shield, isolation gown, shoes and single latex gloves. The results relevant to KQ 6 are displayed in Figure 1.
 - With PPE1, the face shield was worn **over** the head cover (Figure 1). One contamination with a small patch was observed on the face with PPE1.
 - With PPE2, the face shield was worn **under** the hood of the coverall (Figure 1). Four contaminations with small patches were observed on the face with PPE2.
 - Neither PPE1 nor PPE2 was observed with large patches on the face (Figure 1).
- Poller et al. 2018 conducted a simulation study and consensus panel to identify a unified PPE ensemble for clinical response to possible high consequence infectious diseases (HCID) in the United Kingdom (Table 2). 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, diarrhea and cough), each with a different colored 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 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. The consensus PPE ensemble were also tested in the study; it attained no contamination events. In the ensemble, a disposable full-face visor was worn **over** the hood.

Real-world studies to generate evidence in support of the choice of whether HWs should wear the PPE for eye protection **under** or **over** the PPE to protect head/neck skin are challenging to conduct since these studies will need to test protocols involving multiple steps, generally under highly stressful conditions for study participants. Simulation studies offer alternative designs, particularly suitable for testing these protocols. For example, see the methods section of Drew et al. 2019 for the planning and Poller et al. 2018 for a simulation platform for such studies. [6, 7]

Table 1: Summary of PPE recommendations regarding protocols, procedures and order for donning and doffing of goggles, face shield and head cover by the WHO, US and European CDC

Source	Procedures and order for donning and doffing of goggles, face shield and head cover
WHO [4]	2014
Recommendation 1	<p>All health workers should have the mucous membranes of their eyes, mouth and nose completely covered by PPE while providing clinical care for patients with filovirus disease in order to prevent virus exposure.</p> <p><i>Strong recommendation. High quality evidence for protecting mucous membranes compared to no protection.</i></p>
Recommendation 2	<p>All health workers should use either a face shield or goggles while providing clinical care for patients with filovirus disease in order to prevent virus exposure.</p> <p><i>Strong recommendation. Very low quality evidence for the comparative effectiveness of face shields and goggles for the prevention of filovirus transmission to health workers.</i></p> <p>Rationale and remarks Protection of the mucous membranes of the eyes, nose and mouth is an integral part of standard and contact precautions. Contamination of mucous membranes is probably the most important mode for filovirus transmission. Hence, PPE to protect mucosae is essential. <i>These devices should be taken off as late as possible during the PPE removal process, preferably at the end, to prevent inadvertent exposure of the mucous membranes.</i></p> <p>There is currently no scientific evidence comparing the effectiveness of face shields and goggles, worn with an appropriate head cover (see recommendations 11 and 12), for the prevention of filovirus transmission to health workers. Their effectiveness was considered equal and either device could be used as determined by other factors, including the personal preference of the health worker and local availability of good quality items. Face shields and goggles, however, should not to be used together.</p>
Recommendation 11	<p>All health workers should wear a head cover that covers the head and neck while providing clinical care for patients with filovirus disease in order to prevent virus exposure.</p> <p><i>Conditional recommendation. Low quality evidence for effectiveness of head cover in preventing transmission</i></p>
Recommendation 12	<p>The head cover is suggested to be separate from the gown or coverall, so that these may be removed separately.</p> <p><i>Conditional recommendation. Low quality evidence comparing different types of head covers.</i></p> <p>Rationale and remarks: The purpose of head covers is to protect the head and neck skin and hair from virus contamination and the possibility of subsequent unrecognized transmission to the mucosae of the eyes, nose or mouth. Hair and hair extensions need to fit inside the head cover.</p> <p>Recommendation 11 is conditional since there is no evidence to support use of a head cover over a hood (covering the shoulders) or hair cap for preventing transmission of infection. The need for covering all skin surfaces including the back</p>

	<p>of the neck was discussed in detail during the GDG meeting. There was no consensus among the GDG: nine experts were of the opinion that all skin surfaces should be covered, three disagreed and one was absent during voting.</p> <p>Recommendation 12 is conditional since there was no comparative evidence of effectiveness in preventing transmission between a separate head cover and a head cover that is integrated in the coverall. When a separate head cover is not available, a coverall with hood can be worn if <i>the hood is put on after eye, nose and mouth protection so that mucosal protection is maintained after taking off the hooded coverall.</i></p>
<p>US CDC [5]</p>	<p>Section 9B. Donning PPE, N95 Respirator Option Donning PPE, N95 Respirator Option – This donning procedure assumes the facility has elected to use N95 respirators.</p> <ol style="list-style-type: none"> 1. Engage Trained Observer 2. Remove Personal Clothing and Items 3. Inspect PPE Before Donning 4. Put on Boot Covers 5. Put on Inner Gloves 6. Put on Gown or Coverall 7. Put on N95 Respirator: Put on N95 respirator. Complete a user seal check. 8. Put on Surgical Hood: <i>Over the N95 respirator, place a surgical hood that covers all of the hair and the ears, and extends past the neck to the shoulders. Ensure that hood completely covers the ears and neck.</i> 9. Put on Outer Apron (if used) 10. Put on Outer Gloves 11. Put on Face Shield: <i>Put on full-face shield over the N95 respirator and surgical hood to protect the eyes, as well as front and sides of the face.</i> 12. Verify
<p>European CDC [3]</p>	<p>Suggested steps for donning</p> <ol style="list-style-type: none"> 1 Putting on scrubs and hair cover 2 Perform hand hygiene 3 Putting on the coverall 4 Putting on foot protection 5 Perform hand protection 6 Wear respiratory protection and perform orientation fit test 7 Putting on the hood 8 Close the zipper 9 Close adhesive flaps 10 Put on eye protection 11-14 ...

Figure 1. Contamination during doffing of PPE (copy from Suen et al. 2018 without permission)[8]

Location	Small sized contaminated patches (< 1 cm ²), median				Extra large sized contaminated patches (≥ 5 cm ²), median			
	PPE1	PPE2	PPE3	p-value	PPE1	PPE2	PPE3	p-value
Hair and head	1.00	2.00	2.50	0.68	0.00	17.00	0.00	N/A
Face	1.00	4.00	2.00	0.602	0.00	0.00	8.00	N/A
Neck (anterior)	2.50	5.00	11.00	0.095	0.00	0.00	24.00	N/A
Neck (posterior)	2.00	1.00	18.50	0.824	0.00	0.00	0.00	N/A
Arms (right)	3.50	1.00	4.00	0.414	0.00	0.00	28.00	N/A
Arms (left)	2.00	2.00	1.00	0.909	0.00	0.00	49.00	N/A
Hands or wrists	1.00	1.00	6.00	0.414	8.00	61.00	0.00	N/A
Working clothes (upper)	8.50	9.00	7.00	0.997	21.00	48.50	42.00	0.690
Working clothes (lower)	2.00	2.50	6.00	0.111	12.00	46.00	17.50	0.276
Clogs	3.00	5.00	13.50	< 0.001*	121.00	55.00	133.00	0.397
Environment (rubbish bin cover)	2.00	7.00	2.50	0.254	20.00	14.00	23.00	0.737
Environment (chair)	3.00	6.50	2.00	0.053	0.00	36.00	0.00	N/A
Faucet	2.00	2.00	1.50	0.659	0.00	16.00	14.00	N/A
Sink	12.50	14.00	10.00	0.072	75.50	66.50	44.00	0.649
Overall	5.00	7.00	7.00	0.05*	39.00	43.00	47.00	< 0.001*

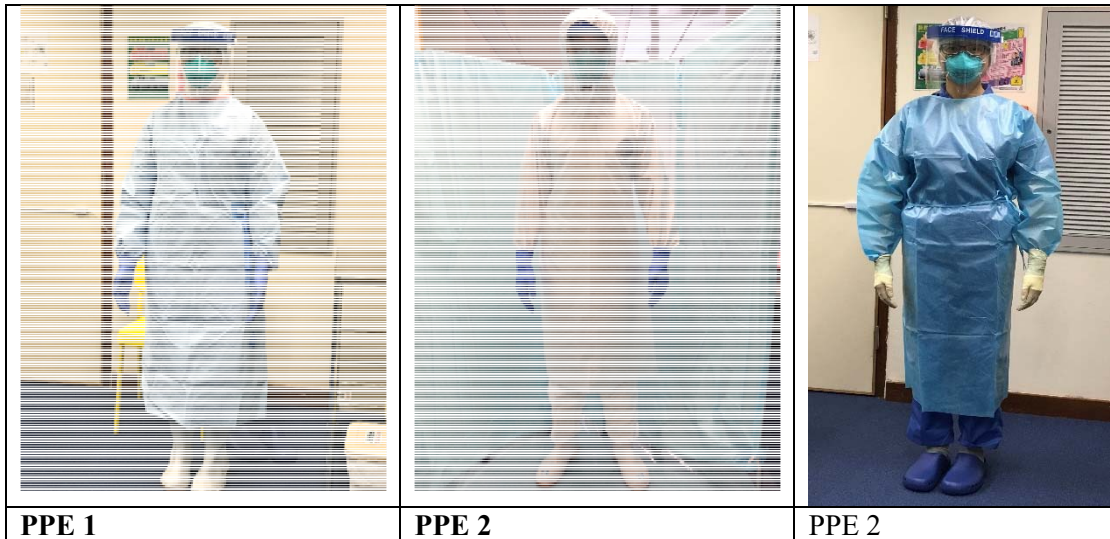
*significant p values

N/A: There are fewer than two groups for the dependent variables, so no inferential statistics are computed using ANOVA

PPE1: Hospital Authority Standard Ebola PPE set

PPE2: DuPont™ Tyvek®, Model 1422A

PPE3: Hospital Authority isolation gown for routine patient care and performing aerosol-generating procedures



PPE 1

PPE 2

PPE 2

Table 2. Summary of contextual data

Author	Year	Study methods	Method details, measures or findings relevant to the extraction of contextual data	Data type	Contextual data
Chughtai [9]	2018	Simulation study	We tested 10 different PPE donning and doffing protocols, recommended by various health organizations for Ebola. Ten participants were recruited for this study and randomly assigned to use 3 different PPE protocols. After donning of PPE, fluorescent lotion and spray were applied on the external surface of the PPE to simulate contamination, and ultraviolet light was used to count fluorescent patches on the skin after doffing.	Implementation	After testing 30 PPE sequences, large fluorescent patches were recorded after using “WHO coverall and 95” and “North Carolina coverall and N95” sequences, and small patches were recorded after using “CDC coverall and N95” and “Health Canada gown and N95” sequences. In the results, two PPE protocols were tested in which the eye-protection PPEs were worn under the head/neck protection, with 1 protocol (WHO, coverall and N95) was observed with 4 large patches (no small patches were observed). Eight PPE protocols were tested in which the eye-protection PPEs were worn over the head/neck protection, with 1 protocol (North Carolina, coverall and N95) was observed with 1 large patch on a front forehead and 1 large patch on a front right forearm. Two PPE protocols were observed with small patches, including the “CDC, coverall and N95” with 1 small patch on the back of a right hand and the “Health Canada, gown and N95” with 1 small patch on a front forehead and 1 large patch on a front right forearm (Table 2).
Suen [8]	2018	An experimental study of one group using multiple comparisons	A total of 59 participants randomly performed PPE donning and doffing. The trial consisted of PPE donning, applying fluorescent solution on the PPE surface, PPE doffing of participants, and estimation of the degree of contamination as indicated by the number of fluorescent stains on the working clothes and environment. Protocol deviations during PPE donning and doffing were monitored. PPE1 consists of a neck-to-ankle outfit, N95 respirator, hood, disposable face shield, surgical gown, boots and double gloves. PPE2 consists of a head-to-ankle coverall, N95 respirator, hood, disposable face shield, boots and double gloves. PPE3 consists of neck-to-ankle outfit, N95 respirator, no hood, disposable face shield, isolation gown, shoes and single latex gloves.	Usability	The results relevant to KQ 6 are displayed in Figure 1. With PPE1, the face shield was worn over the head cover. One contamination with a small patch was observed on the face with PPE1. With PPE2, the face shield was worn under the hood of the coverall. Four contaminations with small patches were observed on the face with PPE2. Neither PPE1 nor PPE2 was observed with large patches on the face.
Poller [10]	2018	Simulation study and consensus panel to identify a unified PPE ensemble for clinical response to possible high consequence infectious diseases in the United Kingdom	A simulation study and consensus panel to identify a unified PPE ensemble for clinical response to possible high consequence infectious diseases in the United Kingdom. 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 high-consequence-infectious-disease. A mannequin was adapted to expose volunteer HCWs to synthetic bodily fluids (vomit, sweat, diarrhea and cough), each with a different colored fluorescent tracer, invisible other than under ultraviolet (UV) light. After exposure, HWs were examined under UV lights to locate fluorescent contamination, and were screened again after removing PPE (doffing) to detect any	Implementation	The simulation testing identified significant HCW contamination events after doffing, related to protocol failure or complications in PPE doffing. The consensus PPE ensemble were tested in the study; it attained no contamination events. In the ensemble, a disposable full-face visor was worn over the hood.

Author	Year	Study methods	Method details, measures or findings relevant to the extraction of contextual data	Data type	Contextual data
			personal contamination. The exercise was videoed, allowing retrospective analysis of contamination events and user errors.		

Table 3. Number of participants with fluorescent patches after various PPE protocols (Sources: Chughtai et al. 2018, use without permission) [9]

Donning/Doffing Protocol	Order of wearing eye protection PPE under/over head and neck cover PPE	Total participants	# participants with small patches	# participants with large patches	Contamination details
WHO, gown and N95	Under	3	0	0	
WHO, coverall and N95	Under	3	0	1	1 large patch on back of neck, 1 large patch on back of right forearm, 2 large patches on right and left of front shoulder
CDC, coverall and PAPR	Over	3	0	0	
CDC, coverall and N95	Over	3	1	0	1 small patch on back of right hand
ECDC, coverall and N95	Over	3	0	0	
Health Canada, gown and N95 [11]	Over	3	1	0	1 small patch on front neck
North Carolina, coverall and N95 [12]	Over	3	0	1	1 large patch on front forehead and 1 large patch on front right forearm
NSW DoH CEC, gown and N95 [13]	Over	3	0	0	
NSW DoH CEC, gown and PAPR [13]	Over	3	0	0	
MSF, coverall and N95 [14]	Over	3	0	0	
Total		10	2	2	

References

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