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Assessment of Healthcare Worker Protocol Deviations and Self-Contamination During Personal Protective Equipment Donning and Doffing

Jennie H. Kwon, DO, MSCI[1], **Carey-Ann D. Burnham, PhD**[2], **Kimberly A. Reske, MPH**[1], **Stephen Y. Liang, MD, MPHS**[1], **Tiffany Hink, BS**[1], **Meghan A. Wallace, BS**[2], **Angela Shupe, BS**[2], **Sondra Seiler, BA**[1], **Candice Cass, AA**[1], **Victoria J. Fraser, MD**[1], **Erik R. Dubberke, MSPH**[1], and **for the CDC Prevention Epicenters**

[1]Division of Infectious Diseases, Washington University School of Medicine, St. Louis, Missouri, USA

[2]Department of Pathology and Immunology, Washington University School of Medicine, St. Louis, Missouri, USA

Abstract

Objective.—To evaluate healthcare workers' (HCWs) risk of self-contamination when donning and doffing personal protective equipment (PPE) using fluorescence and MS2 bacteriophage.

Design.—Prospective pilot study.

Setting.—Tertiary care hospital.

Participants.—36 HCWs: 18 donned/doffed contact precautions (CP) PPE and 18 donned/doffed Ebola virus disease (EVD) PPE.

Interventions.—HCWs donned PPE according to standard protocols. Fluorescent liquid and MS2 bacteriophage were applied to HCWs. HCWs then doffed their PPE. After doffing, HCWs were scanned for fluorescence and swabbed for MS2. MS2 detection was performed using reverse transcriptase PCR. The donning and doffing processes were videotaped and protocol deviations were recorded.

Results.—27% of EVD PPE HCWs and 50% of CP PPE HCWs made ≥1 protocol deviation while donning. 100% of EVD PPE HCWs and 67% of CP PPE HCWs made ≥1 protocol deviation while doffing (p=0.02). The median number of doffing protocol deviations among EVD PPE HCWs was 4, vs. 1 among CP PPE HCWs. 15 EVD PPE protocol deviations were committed by doffing assistants and/or trained observers. Fluorescence was detected on 8 (44%) of EVD PPE HCWs and 5 (28%) CP PPE HCWs, most commonly on hands. MS2 was recovered from 2 (11%) EVD PPE HCWs and 3 (17%) CP PPE HCWs.

Conclusions.—Protocol deviations were common during both EVD and CP PPE doffing, and some deviations during EVD PPE doffing were committed by the HCWs' doffing assistant and/or

Corresponding author: Jennie H. Kwon, DO, MSCI, 4523 Clayton Ave, Campus Box 8051, St. Louis, MO 63110, j.kwon@wustl.edu.

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trained observer. Self-contamination was common. PPE donning/doffing are complex and deserve additional study.

Introduction

Personal protective equipment (PPE) is used in healthcare settings to protect healthcare workers (HCWs) from exposure to pathogens and to prevent the spread of pathogens to other patients. Proper use of PPE is crucial when HCWs care for patients with highly pathogenic organisms, such as the Ebola virus. To date, studies on PPE effectiveness are uncommon, small, and potentially out-of-date (i.e., evaluate PPE types no longer in use).[1] The 2014–2016 Ebola virus disease (EVD) outbreak revealed the need for better empirical data regarding best practices to safely don and doff PPE.[1–5]

Although EVD is a high visibility, high impact disease, pathogens much more likely to be encountered by HCWs on a daily basis include methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant *Enterococcus*, *Clostridium difficile*, and carbapenem-resistant *Enterobacteriaceae*. The primary form of PPE used to protect HCWs and other patients against these important hospital-associated pathogens is contact precautions (CP), which includes gown and gloves. Few data exist on whether HCWs follow guidelines for donning and doffing CP PPE and their risk of self-contamination.[6,7]

One of the primary challenges when designing studies to evaluate PPE or donning/doffing procedures is determining how to model pathogen transmission. The most commonly used surrogate marker for the presence of pathogens is fluorescence, which can be delivered in a variety of forms (powder, liquid, lotion, etc.).[7–14] Fluorescent markers are inexpensive, easy to use, and, as the read-out is visual, can provide immediate feedback to HCWs; however, fluorescence may not be an appropriate surrogate for contamination with infectious viral particles.[10] An alternate marker for viral infection is the MS2 bacteriophage, a single-strand RNA bacteriophage that is a biosafety level 1 agent and non-pathogenic to humans. MS2 has been used previously in several studies of PPE transmission and/or disinfection,[10,11,15,16] in a long-term care facility,[17] a hotel,[18] and an office.[19] Commercial preparations of MS2 are expensive and require significant laboratory expertise to use, but may be a more accurate surrogate marker for how pathogens spread in the environment than fluorescence.[3,10]

The purpose of this study was to evaluate HCWs' risk of self-contamination when donning and doffing EVD PPE and CP PPE using MS2 bacteriophage and a fluorescent marker as surrogates for pathogen transmission. The frequencies and types of protocol deviations that occurred were documented, and associations between HCW self-contamination post-doffing and particular doffing protocol deviations or HCW characteristics were determined.

Methods

This prospective pilot study was performed at Barnes-Jewish Hospital (BJH), a 1250-bed, tertiary care hospital in St. Louis, Missouri. The study was approved by the Washington University Human Research Protection Office, and all participants provided written, informed consent. During the study period, EVD PPE consisted of: inner and outer gloves (Esteem XP, Cardinal Health), boot covers (Convertors FullGuard High Top Shoe Covers,

Cardinal Health), impervious gown with Velcro on the back of the neck (Convertors SmartSleeve, Cardinal Health), a powered air purifying respirator (PAPR) and hood with face shield (Versaflo, 3M), and an outer apron (Tyvek apron, Uline). CP PPE consisted of gloves and a gown (Cardinal Health).

HCW characteristics:

Two sets of HCWs were enrolled. EVD PPE HCWs were enrolled during EVD PPE practice sessions, and included respiratory therapists, nurses, infection control preventionists, and critical care physicians. CP PPE HCWs were recruited from BJH hospital wards during their normal shifts, and included nurses, patient care technicians, and physicians. HCWs were interviewed regarding demographics and years of service, previous PPE training; HCWs' height and weight were measured and BMI calculated.

PPE donning and doffing and contamination procedures:

During EVD PPE training sessions, the donning and doffing processes were aided by a donning/doffing assistant and a trained observer who instructed HCWs step-by-step as per CDC guidelines.[20] HCWs using CP PPE were not given donning or doffing instructions; they were encouraged to proceed according to their usual practices.

After consent, participants were scanned for baseline fluorescence using an UV-A light. Any areas of fluorescence detected were cleaned and noted. Next, HCWs were instructed to don the PPE. Upon completion, HCWs were instructed to close their eyes and the MS2 bacteriophage and fluorescent marker were applied to HCWs' palms, abdomen, and ankles (EVD PPE HCWs) or palms and abdomen (CP PPE HCWs). Dummy applications of molecular grade water were applied to HCWs' shoulders. After donning, EVD PPE HCWs practiced various EVD patient care activities before doffing. CP PPE HCWs proceeded directly to doffing. The order and technique used to don and doff the PPE were videotaped and recorded. Immediately after doffing, the participant was scanned for fluorescence. Any areas of fluorescence detected were photographed and sampled utilizing a flocked swab in universal transport medium (Quidel, San Diego, CA). HCWs' hands (one swab for both hands), coat sleeves or wrist, and peri-orbital/nasal/oral areas were swabbed regardless of fluorescence.

Donning and doffing videos were reviewed and protocol deviations were recorded. Randomly selected videos were reviewed by second reviewer to ensure accuracy. Protocol deviations were grouped into categories based on site and the donning/doffing procedural step during which they occurred (i.e., glove removal and hand hygiene; PAPR and hood removal). Proper CP PPE and EVD PPE removal sequence were based on recommendations from the CDC[6,20] and written protocols used by the BJH infection prevention team.

MS2 and fluorescent marker:

A commercially available preparation of MS2 (Zeptometrix, Buffalo, NY), supplied as a stock solution of 1.0×10^9 PFU/mL, was utilized as a surrogate for viral transmission. This was diluted to a 1:10 solution in viral transport medium for a working solution of 1.0×10^8 PFU/mL. GloGerm Mist liquid was selected as the fluorescent marker (GloGerm, Moab,

Utah). A mixture of 100 uL of GloGerm Mist liquid with 0.5 mL of working solution MS2 was applied for each contamination site. This combination was tested and there was no negative effect on MS2 recovery and detection. The mixture of GloGerm liquid and MS2 was drawn into a 3 mL syringe with a needleless, Luer-lock tip (BD, Franklin Lakes, NJ). The syringe was attached to a pediatric intranasal mucosal atomization device (LMA MAD Nasal, Teleflex, Westmeath, Ireland). Syringes were not reused.

MS2 RNA was extracted utilizing QIAamp viral RNA mini kit (Qiagen, Valencia, CA). MS2 detection was by reverse transcriptase PCR using previously described primers[21] and the Cepheid Smart Cycler with QuantiTect® Probe RT-PCR Kit (Qiagen, Valencia, CA). A positive control with MS2 RNA and a negative control of PCR water was included in each run. The cycle threshold for all positive results was recorded.

Statistical Analyses:

The primary outcome of interest was the presence and frequency of MS2 and/or fluorescent contamination on the HCW after removal of PPE. The secondary endpoints were correlation of the presence of contamination with the number of lapses in PPE doffing techniques, years of experience, type of PPE, and BMI. Univariate analyses were performed, and $p \leq 0.05$ was considered significant. Chi-square or univariate logistic regression was used for categorical variables, and Mann-Whitney U was used for continuous variables. Analyses were performed with SPSS version 24 (IBM Corp, Armonk, NY).

Results

Thirty-six HCWs were enrolled in the study: 18 with EVD PPE and 18 with CP PPE. The majority of HCWs were nurses (78% of EVD PPE HCWs; 61% of CP PPE HCWs) (Table 1). EVD PPE HCWs were significantly older than CP PPE HCWs (median=38 vs. 28.5 years; p=0.02), and there was a trend towards greater years of service among the EVD PPE HCWs (median=8.5 years vs. 5.25; p=0.10).

Donning and doffing protocol deviations

Donning videos were available for review for 15 EVD PPE HCWs (Table 2). Donning videos for the remaining 3 HCWs were unavailable because the HCW was donning simultaneously while another HCW was being recorded. Overall, 27% of EVD PPE HCWs made at least one donning protocol deviation, compared with 50% of CP PPE HCWs (p=0.28). Protocol deviations occurred most often in the gloves and hand hygiene steps (20% of EVD PPE HCWs and 33% of CP PPE HCWs).

All EVD PPE HCWs had at least 1 doffing protocol deviation, versus 67% of CP PPE HCWs (p=0.02) (Table 2). The median number of doffing protocol deviations was greater among EVD PPE HCWs (median=4 vs. 1 among CP PPE HCWs). Fifteen protocol deviations during EVD PPE doffing were committed by the doffing assistant or trained observer, including 6 during gown or apron removal, 2 involving hand hygiene, 2 during hood removal, 2 during boot cover removal, 1 during PAPR removal, and 2 miscellaneous deviations. Among EVD PPE HCWs, the unique doffing step with the greatest number of protocol deviations was boot cover removal: 78% of HCWs made at least 1 protocol

deviation doffing boot covers. The doffing step category with the greatest number of HCWs that committed at least 1 protocol deviation (in both PPE types) was gown/apron removal (83% of EVD PPE HCWs; 50% of CP PPE HCWs), followed by glove removal/hand hygiene (67% of EVD PPE HCWs; 39% of CP PPE HCWs).

MS2 and Fluorescence

Overall, fluorescence was detected on 8 (44%) of EVD PPE HCWs and 5 (28%) of CP PPE HCWs (p=0.49). Twenty-one unique HCW sites fluoresced. The most common site of fluorescence was HCWs' hands (6 among EVD PPE HCWs and 5 among CP PPE HCWs) (Table 3). Of the 125 samples tested for MS2, 5 were positive (4%). MS2 was recovered from 2 (11%) EVD PPE HCWs and 3 (17%) CP PPE HCWs. The two EVD PPE HCW sites from which MS2 was recovered were from an alcohol foam pump in the doffing area and a HCWs' hands (Table 3). The 3 CP PPE HCW sites from which MS2 was recovered were from a HCWs' face and HCWs' sleeves/wrist (2). Among the 5 sites positive for MS2, 2 (40%) also fluoresced. The association between fluorescence and doffing protocol deviations is given in Table 4. There were no significant differences in detection of any fluorescence by protocol deviation type, although there was a trend toward significance with boot cover removal (100% of EVD PPE HCWs with fluorescence detected had a boot cover protocol deviation, versus 60% of EVD PPE HCWs without fluorescence; p=0.09).

HCW characteristics and donning/doffing protocol deviations

Among EVD PPE HCWs, there was no significant difference in the median number of donning or doffing protocol deviations by years of service (data not shown). There were no significant differences in fluorescence and/or MS2 detection between BMI categories (normal, overweight, or obese) (data not shown). There also were no significant differences in the frequencies of types of donning or doffing protocol deviations by BMI (data not shown).

Discussion

Proper use of PPE is essential to protecting patients and HCWs from infectious diseases. However, our results indicate that protocol deviations were common in both donning and doffing. Notably, we found that 100% of EVD PPE HCWs committed at least 1 protocol deviation during doffing, and 27% while donning. This is not surprising, given the complexity of EVD PPE, and is consistent with previous studies.[8,14,22] In a study involving 120 students, Casalino et al found that EVD PPE doffing errors occurred even after a three-phase training program.[22] While protocol deviations while doffing are a major focus for HCW self-contamination, donning deviations, such as an improperly tied gown (a deviation we observed) may increase the future risk of self-contamination while doffing. Further, we demonstrated that not all protocol deviations were committed by the donning and doffing HCW. For example, several doffing assistants touched the inside of HCWs' gowns when undoing the neck Velcro, and trained observers occasionally failed to instruct HCWs to perform hand hygiene. While previous studies have evaluated HCWs' own protocol deviations while doffing PPE, few have evaluated the role of other HCWs in the doffing process. This is an important area for future investigation.

Boot cover removal was particularly problematic. HCWs received varied instructions on the specifics of the boot cover removal process. HCWs struggled to balance their legs in the air or rest their legs on their scrubs without contaminating themselves, and left-handed HCWs struggled to use right-handed scissors. All 3 left-handed EVD PPE HCWs made ≥1 protocol deviation during boot cover removal. Many HCWs touched their scrubs with their shoes or gown, both potentially contaminated, during boot cover removal and shoe disinfection. Herlihey et al. also reported difficulties with shoe cover removal.[23] HCWs caring for EVD patients may be exposed to large amounts of environmental contamination;[3] thus this component of EVD PPE removal may benefit from process improvement. Of note, the recommendations for boot cover removal have changed since this study was performed. At BJH, the revised process doffs gowns before boot covers, eliminates the use of scissors, and allows HCWs to keep their feet on the ground. We hypothesize that these changes will decrease protocol deviations, but more studies are needed to confirm this.

Hand hygiene and glove removal protocol deviations were common during doffing of both EVD and CP PPE (67% and 39% of HCWs made ≥1 error, respectively). During EVD PPE doffing, common protocol deviations included touching outer gloves with inner gloved hands, and touching the outside of gloves with bare hands. Herlihey et al reported similar challenges doffing multiple pairs of gloves.[23] Casanova et al compared HCW self-contamination after doffing PPE with single gloves vs. double gloves, using MS2 as a marker, and found that while double gloves reduced viral transfer, MS2 was still recovered from the hands of 23% of HCWs post-doffing.[15] These results may not be directly comparable to our study because it is unclear whether those HCWs performed hand hygiene post-doffing. Regardless, hand hygiene and glove removal are high-risk opportunities for HCW self-contamination. For both the EVD and CP groups, we found fluorescence on HCWs' hands more often than any other site. HCWs may benefit from targeted training in the correct method for glove removal during EVD PPE doffing, and training should reinforce the fact that gloves are not a substitute for proper hand hygiene.

Measures to reduce HCW self-contamination rates include training and maintenance of training. Several previous studies have suggested that, regardless of PPE type, increased training and access to published donning/doffing guidelines improves HCWs' ability to don and doff PPE without protocol deviation.[7,12,22,24,25] All EVD PPE HCWs in our study previously had received formal EVD PPE training. By contrast, although 72% of CP PPE HCWs reported having previous training in PPE donning/doffing, often this was informal, "on the job" training from other HCWs. Similarly, Turnberg et al reported that 15%−40% of HCWs had not received PPE training during the previous 12 months,[26] and John et al found that "on the job" training was the most common method of PPE training for HCWs.[27] Despite the comparative simplicity of the CP PPE donning/doffing process, only half of the HCWs were able to don PPE without protocol deviation, and only approximately one third were able to doff PPE without protocol deviation. Common CP PPE doffing protocol deviations included touching the front of the gown with bare hands or allowing the contaminated gown to brush against scrubs while disposing. Possibly, HCWs may be unaware that specific guidelines exist for donning/doffing CP precautions.[6] Beam et al demonstrated that simple exposure to a poster showing the correct donning/doffing sequence may not be enough to improve HCW practices.[8] Tomas et al found that a training session on

CP PPE doffing techniques led to a significant decrease in HCW self-contamination.[7] Formal, targeted interventions or education programs may be needed to improve CP PPE donning/doffing practices.

We were unable to demonstrate clear superiority of either surrogate marker. Fluorescence was detected more frequently than MS2. MS2 was not detected from most sites with fluorescence, and MS2 was detected from three sites without fluorescence. Commercial preparations of MS2 are expensive; thus fluorescent markers, which are inexpensive, may be preferable. Conversely, Casanova et al found considerable MS2 transfer to HCWs' hands and scrubs in the absence of fluorescence;[10] thus fluorescence may not accurately mimic transmission of viral particles. MS2 is not visible to the naked eye, and it is possible in our study that additional areas of MS2 contamination were not detected because, outside of HCWs' hands, face, and arms, we sampled only those areas that fluoresced. Additional data are needed on the relative benefits and limitations of these surrogate markers.

This study has several limitations. It was a relatively small pilot study and as such was underpowered. The small number of HCWs may not be reflective of HCW populations at large. The methods need replication in larger studies, and our methods and results may be useful in designing these. The end of the 2014–2015 EVD outbreak may remove the impetus for healthcare facilities to continue EVD PPE training programs, potentially making future studies of HCWs using EVD PPE more challenging. Some EVD PPE doffing recommendations have been revised since this study was performed. CP PPE, however, are routinely used in healthcare facilities, and larger studies may be possible. We used PCR for MS2 detection; therefore MS2 detection may not be reflective of viable MS2.

PPE are critical for protecting both HCWs and patients from pathogens, regardless of whether the pathogen in question is high impact like EVD or commonly encountered like *C. difficile*. Previously published data on donning and doffing EVD PPE are limited, both by the number of studies available and the types of data and analyses.[1,4] There are even fewer data on donning and doffing CP PPE. Our study highlights some potential areas for future research, including an improved boot cover removal process, improved HCW education in the correct processes for glove removal, and an overall need for better training in the use of CP PPE. Both fluorescent markers and MS2 can be used safely as surrogates for pathogen transmission, although the relative strengths of each need further evaluation. Overall, improved processes for donning/doffing PPE and improved methods for evaluated these processes will help to protect both HCWs and patients from exposure to pathogens.

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Table 1.

Healthcare Worker Demographics

Characteristic	Ebola PPE HCW (n=18) N (%) or median (range)	Contact precautions PPE HCW (n=18) N (%) or median (range)	p
Age	38 (27 – 55)	28.5 (24 – 61)	0.02
Female	15 (83)	15 (83)	1.00
Years of service	8.5 (2.5 – 30)	5.25 (<1 – 30)	0.10
Previous PPE training	17 (94)	13 (72)	0.18
HCW type			
RN, PA, or NP	14 (78)	11 (61)	Ref
MD	2 (11)	2 (11)	0.82
Other	2 (11)	5 (28)	0.21
Left handed	3 (17)	1 (6)	0.60
Body mass index			
Normal	7 (39)	6 (33)	Ref
Overweight	8 (44)	5 (28)	0.69
Obese	3 (17)	7 (39)	0.26

Table 2.

Donning and doffing protocol deviations by PPE type

Characteristic	**Ebola PPE HCW (n=18; n=15 for donning[a]) N (%) or median (range)**	**Contact precautions PPE HCW (n=18) N (%) or median (range)**
Donning		
Any[b]	4 (27)	9 (50)
Gloves / hand hygiene	3 (20)	6 (33)
Gown / apron	3 (20)	4 (22)
PAPR / hood	2 (13)	N/A
Other	1 (7)	0 (0)
Number of protocol deviations	0 (0 – 4)	0.5 (0 – 2)
Doffing		
Any[c]	18 (100)	12 (67)
Boot cover removal	14 (78)	N/A
Gloves / hand hygiene	12 (67)	7 (39)
Gown / apron	15 (83)	9 (50)
PAPR / hood	7 (39)	N/A
Shoe disinfection	8 (44)	N/A
Other	2 (11)	0 (0)
Number of protocol deviations	4 (2 – 8)	1 (0 – 2)

[a] Donning videos were available for 15 of 18 EVD PPE HCWs.

[b] p=0.28.

[c] p=0.02

Table 3.

Sites of fluorescence and/or MS2 (N=24)[a] by PPE type

Site of fluorescence and/or MS2	EVD PPE Number of detections	Contact precautions PPE Number of detections
Hands	7[b]	5
Alcohol foam pump	2[c]	0
Chest	0	2
Forearm	1	0
Knee	1	1
Sleeves / wrist	1	2[d]
Thigh	0	1
Face	0	1[e]

[a] 6 HCWs had >1 site of fluorescence (none had >1 site of MS2)

[b] 6 were fluorescent; 1 was MS2 positive

[c] 1 fluorescent only; 1 fluorescent and MS2 positive

[d] MS2 positive only

[e] Fluorescent and MS2 positive

Table 4.

Fluorescence and doffing protocol deviations

Characteristic	Any fluorescence detected n=13; n=8 among EVD PPE HCWs	Not fluorescent n=23; n=10 among EVD PPE HCWs
Doffing protocol deviation		
Any	12 (92)	18 (78)
Boot cover removal[a]	8 (100)	6 (60)
Gloves / hand hygiene	8 (62)	11 (48)
Gown / apron	10 (77)	14 (61)
PAPR / hood[a]	3 (38)	4 (40)
Shoe disinfection[a]	5 (63)	3 (30)
Other	0 (0)	2 (9)

[a]Among EVD PPE HCWs only (n=18).