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A systematic risk-based strategy to select personal protective equipment for infectious diseases



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Key Words: Job hazard analysis High-consequence infections Intubation Infection prevention Exposure Industrial hygiene **Background:** Personal protective equipment (PPE) is a primary strategy to protect health care personnel (HCP) from infectious diseases. When transmission-based PPE ensembles are not appropriate, HCP must recognize the transmission pathway of the disease and anticipate the exposures to select PPE. Because guidance for this process is extremely limited, we proposed a systematic, risk-based approach to the selection and evaluation of PPE ensembles to protect HCP against infectious diseases.

Methods: The approach used in this study included the following 4 steps: (1) job hazard analysis, (2) infectious disease hazard analysis, (3) selection of PPE, and (4) evaluation of selected PPE. Selected PPE should protect HCP from exposure, be usable by HCP, and fit for purpose.

Results: The approach was demonstrated for the activity of intubation of a patient with methicillin-resistant Staphylococcus aureus or Severe Acute Respiratory Syndrome coronavirus. As expected, the approach led to the selection of different ensembles of PPE for these 2 pathogens.

Discussion: A systematic risk-based approach to the selection of PPE will help health care facilities and HCP select PPE when transmission-based precautions are not appropriate. Owing to the complexity of PPE ensemble selection and evaluation, a team with expertise in infectious diseases, occupational health, the health care activity, and related disciplines, such as human factors, should be engaged.

Conclusions: Participation, documentation, and transparency are necessary to ensure the decisions can be communicated, critiqued, and understood by HCP.

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In the context of routine patient care, personal protective equipment (PPE) is selected through standard precautions or based on the route of disease transmission identified for the infectious disease (eg, airborne, contact, or droplet precautions).¹ Standard precautions require health care personnel (HCP) to recognize the transmission pathway of an infectious disease and to anticipate the exposures that will occur during patient care to select PPE.² However, HCP consistently fail to select appropriate PPE in this context, citing time, difficulty, and lack of perceived risk as reasons for noncompliance.^{3,4} During the 2014-2015 Ebola Virus Disease (EVD) outbreak, we found that many acute care hospitals used the standard precautions framework to select PPE,⁵ but that this process was challenging in part

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E-mail address: rachael.jones@utah.edu (R.M. Jones). Conflicts of interest: None to report. because HCP lack both the knowledge and information about how, and how well, the pieces of PPE and PPE ensemble protected HCP.

The National Institute for Occupational Safety and Health has begun to address the lack of knowledge and information about PPE through the creation of the PPE-Info database,⁶ which includes descriptions of test methods, regulations, and consensus standards governing PPE performance for a variety of workplace hazards. Future plans include a database of PPE pieces that manufacturers claim meet specific regulations and standards, which would enhance the ability of health care facilities to identify specific models of PPE that meet desired performance requirements, if the necessary performance requirements can be identified.

We propose a systematic risk-based approach for the selection of PPE against infectious agents–endemic or emerging–in health care settings. This approach builds on strategies from occupational health⁷ and complements requirements in the Infectious Diseases Standard proposed by the Occupational Safety and Health Administration

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(OSHA).⁸ The approach that we propose includes the following 4 steps: (1) job hazard analysis (JHA), (2) infectious disease hazard analysis, (3) selection of PPE, and (4) evaluation of selected PPE. After describing the steps, we illustrate an application to the health care activity of intubation for methicillin-resistant *Staphylococcus aureus* (MRSA) and Severe Acute Respiratory Syndrome coronavirus (SARS-CoV).

METHODS

Step 1: Job Hazard Analysis

JHA is a technique used to describe work activities and anticipate health and safety hazards.⁹ The general approach is to break a work activity down into routine and nonroutine tasks, and for each task anticipate the hazards. This can be accomplished based on professional expertise, direct observation, photography, video recording, or drawing the activity. JHA should involve the workers who perform the activity because they have experience with how the work activity is performed, and their participation can increase their personal hazard awareness and concurrence with the outcome.⁹ Human factors engineers are trained to disaggregate work activities into discrete tasks and motions and should be included if possible.⁷ Related paradigims, such as failure mode and effect analysis, which focus on opportunities for deviation from standard work practices, may also be helpful.

In the context of pathogen exposures among HCP, we recommend that the following 3 questions be considered in the JHA to identify infectious hazards: (1) How does the HCP contact the patient's body? (2) How does the HCP contact the environment? and (3) Which bodily fluids are present where?

Step 2: Infectious disease hazard analysis

Several characteristics of an infectious disease influence the hazard to HCP, including: (1) source of the pathogen (ie, the body fluid[s] or environmental reservoir that contain[s] the pathogens); (2) source strength (ie, the number of pathogens present or rate of shedding into the environment); (3) pathogen infectivity (ie, the dose that must be received before infection is likely); (4) severity of disease (ie, the potential for severe outcomes of infection); and (5) transmission route (ie, the pathway by which the pathogen reaches a susceptible host). The airborne, contract, and droplet transmission routes combine concepts of the exposure pathway and exposure route. We suggest it may be more helpful in the selection of PPE to focus on the exposure surface where the pathogen enters a susceptible host to initiate infection.¹⁰ The exposure surface may be internal (eg, the respiratory tract) or external (eg, exposed mucous membrane surface). However, PPE should prevent the pathogen from reaching the exposure surface, regardless of the source, pathway through the environment, or exposure route.

Sources of information about infectious disease hazards include peer-reviewed clinical literature, general or disease-specific infection control guidelines,¹ and biosafety risk group classifications.¹¹ However, guidelines and classifications are infrequently updated relative to the peer-reviewed literature, and more recent research may challenge some classifications based on fundamental principles or for specific diseases.¹² Further challenges include incomplete knowledge about emerging pathogens and atypical transmission routes specific to health care activities,¹³ suggesting the value of applying the precautionary principle when making infection control decisions. Once identified, the exposure surfaces should be compared with potential exposures identified in the JHA to determine which potential exposures are relevant to infection risk.

Step 3: Selection of PPE

Selected PPE must prevent pathogens from reaching exposure surfaces, with a level of effectiveness appropriate for the severity of infection. Infectious diseases with high-disease severity require PPE (pieces and ensembles) with very low probability of penetration. Ensembles can diminish the performance of individual pieces of PPE because 1 piece of PPE can interfere with another piece of PPE, particularly at junctions.^{7,14} For each major category of PPE, we highlight issues to consider in PPE selection.

Eye and face protection should prevent the impact of pathogencontaining bodily fluids, such as those that occur with splashes, splatters, and sprays. The most relevant performance test for this hazard is class D3 of the American National Standards Institute and the International Safety Equipment Association Z78, 1-2015 standard.¹⁵ Class D3 devices feature indirect ventilation to prevent penetration of projected liquids. Eye and face protection are distinguished by the extent of facial coverage, potential for projected liquids to by-pass the equipment, and potential for workers to reach under or around the equipment and touch (self-contaminate) their face or eyes. For example, goggles with solid side shields (class D3 devices) have a tight seal to the face, cannot be penetrated by spray, and are difficult to circumvent by the wearer; however, they cover only the eyes. In contrast, full face shields cover the whole face; however, they are not tight-fitting, and allow projected liquids and HCP to reach the face. If the severity of disease is such that no exposure can be tolerated, a hood or a shroud with an integrated visor that covers the face and head should be selected, as these devices can be made of fluid-impermeable textile. Eye and face protection should be selected with consideration for corrective eyewear.

Respirators prevent the inhalation of pathogens suspended in air, which deposit in the respiratory tract. The level of protection provided by respirators is defined by the assigned protection factor (ie, the ratio of the contaminant concentration outside the respirator to the concentration inside the respirator) and varies substantially between respirator designs. The relative performance of different types of respirators has not been widely considered in health care. This is indicated by recommendations that call for an N95 filtering facepiece respirator (FFR) or a powered air-purifying respirator (PAPR), with a loose-fitting hood for use with the same infectious disease in the same setting. The protection offered by the PAPR, however, is 2.5-fold greater than that offered by the N95 FFR, and would offer substantially more protection to HCP.^{16,17} In general, if there is concern about eye and face protection, a full facepiece respirator or a PAPR with a loose-fitting hood or helmet may be preferred, as goggles can adversely affect the fit of N95 FFRs and face shields are susceptible to being by-passed by splash or touch. Facial hair interferes with the seal of tight-fitting respirators; therefore, if enforcement of facial hair policies is not feasible or undesirable, a PAPR with a loosefitting hood should be considered.

PPE for protection of the body (eg, torso, arms, and legs) is highly variable with respect to body coverage, design, and performance. Kilinic-Balci^{18,19} provides a comprehensive review of textiles, design, and testing requirements used in health care settings. Generally, performance is measured by fluid resistance, such as defined by the American National Standards Institute and the Association for the Advancement of Medical Instrumentation PB70 criteria. Body coverings, however, are also marketed as offering bloodborne pathogen protection and frequently tested using the American Standard Test Method F1670 or F1671. Beyond performance, body protection should be selected with consideration for sizing and range of motion.

The priority of head protection in health care settings is to contain hair or protect the head and hair from contamination, rather than to protect the head from falling objects.²⁰ Devices may be made from fluid-impermeable textiles and include: head bands, bouffant caps,

surgical head coverings (hood with open face), and surgical helmets or hoods. Surgical helmets were used outside the operating room by health care workers during the 2014-2015 EVD outbreak, apparently for the first time.²¹ Surgical helmets worn with loose-fitting hoods may look and feel like PAPRs to the wearer, but surgical helmets are not respirators as they do not filter the air prior to its introduction into the face or head covering, ummarized

Gloves are the primary hand protection devices in health care, and serve as barriers to pathogens and pathogen-containing bodily fluids, while preserving appropriate levels of dexterity and tactility. The American Standard Test Method D7103-06²² summarizes medical glove standards as follows: the material is assumed to act as a barrier unless the integrity of the material is damaged or degraded owing to the stress of use. Glove performance depends on the materials used. For example, gloves with greater elongation percentages are more likely to stretch than tear when pulled, and gloves with increased tensile strength are stiffer.²³⁻²⁵ Wearing 2 pairs of gloves (doubling gloving) can have advantages with respect to needle punctures and doffing procedures. Long gloves may help to ensure skin coverage at the wrist, where gaps can form between short gloves and arm coverings, or gloves may also be integrated with body coverings to eliminate the junction between gloves and arm coverings.

In health care setings, foot protection (eg, footwear and footwear coverings) is typically selected to protect against bodily fluids and slips, rather than to protect the foot from injury. Footwear may be disposable or reusable if they can be cleaned and decontaminated. Footwear coverings are typically chosen to be fluid-resistant, and should have elastic around the top to prevent fluids from dripping into the shoe or boot.

Step 4: Evaluation of PPE

The pieces of PPE selected for a potential pathogen exposure in the context of a work activity must be evaluated individually for performance and as an ensemble. The 3 broad categories of PPE performance that must be considered include: (1) donning, doffing, and changing; (2) usability, and (3) fit for purpose. Table 1 shows the types of questions that should be considered in each of these categories. HCP who will use the PPE ensembles must be involved in the evaluation, such as through practice and simulation of care activities, with the selected PPE ensemble.

Table 1

Questions to consider in evaluation of PPE ensembles to protect health care workers from infectious diseases

Question	Rationale
Donning, doffing, and changing	
1. How long does it take to don the PPE ensemble?	Doffing duration affects the response time, which can affect the usability of the ensemble in an emergency scenario. ²⁹
2. How long does it take to doff the PPE ensemble?	In the event of gross contamination, PPE failure, or high anxiety, HCP should be able to doff the PPE and remove themselves to a safe environment for rapid evaluation of risk or disinfection. Doffing speed is not a priority in all care scenarios.
3. How easy is it to don the PPE correctly?	PPE should be easy to don correctly, difficult to don incorrectly, and/or should have a clear indicator of incorrect donning so as to minimize risk of PPE failure.
4. Can pieces of PPE be removed or changed without contaminating the wearer or other pieces of PPE in the ensemble?	HCP should be able to remove or change a piece of the ensemble without contaminating their body or respiratory tract, and without contaminating other pieces of PPE in the ensemble. In the con- text of doffing, this helps to minimize risk associated with doffing other pieces of PPE.
5. Can a piece of PPE be replaced without affecting performance of the other pieces of PPE in the ensemble? <i>Usability</i>	HCP should be able to replace pieces of PPE that are contaminated or fail without doffing completely and egressing to a safe environment.
1. Is the piece of PPE correctly sized for the wearer?	PPE that is too large or too small may limit usability. For example, fabric may bunch at the wrist when gowns are too large, whereas gowns that are too small may not cover the wrists or may limit arm motions. ¹⁴
2. Can the wearer move in the PPE ensemble?	PPE should be designed to allow for full range of motion.
3. Does the PPE allow for necessary dexterity and tactility?	Although dexterity and tactility are most closely associated with hands, it is more broadly relevant as health care requires HCP to use all parts of their bodies.
4. Does the PPE ensemble allow for unobstructed vision?	Eye, face, and/or head coverings should not distort or limit the field of view.
5. Does the PPE ensemble allow for the use of corrective eyewear?	Many HCP wear corrective eyewear (eye glasses) that must fit under or adjacent to pieces of PPE.
6. Can the wearer hear people and equipment while wearing the PPE ensemble?	HCP need to be able to hear the patient, other HCP, and equipment during care activities. Some pieces of PPE, such as PAPRs, make noise that can impact hearing.
Can people understand verbal communication from the wearer of the PPE ensemble?	HCP need to be understood by the patient and other HCP. Sounds made by the HCP need to pene- trate the PPE ensemble.
8. Can the wearer breathe comfortably while wearing the PPE?	Resistance to breathing can cause discomfort and anxiety.
9. How long can the PPE ensemble be worn without the wearer experiencing physiological or psychological stress?	HCP must be able to wear the PPE ensemble for a longer period of time than the care activity requires. Physiological and psychological stress is known to occur with PPE, ³⁰ and should be evaluated as part of ensemble testing.
10. How long do the pieces of PPE and the PPE ensemble maintain their integrity and functionality during use?	PPE should not tear, move on the body, or degrade during the planned duration of use. Frequent
11. Does the PPE ensemble prevent by-pass by the wearer?	It should be difficult or impossible for HCP to reach under or around the PPE, such as to shift the respirator to scratch her/his face.
12. Is the PPE disposable?	PPE that is not disposable requires a plan for cleaning and disinfection. Disposable PPE requires a plan for waste management, and a robust supply.
Fit for purpose	
1. Is the PPE sterile?	Some contexts require the use of sterile pieces of PPE.
2. Does the PPE ensemble have junctions between pieces of PPE	There may be gaps between pieces of PPE that may need to be closed through the use of tape or
through which pathogens may penetrate?	adjustments. Consider, is there an alternative piece of PPE that would eliminate that junction? Critical junctions may occur at the wrist, forehead, or neck, for example. ^{14,31}
3. Does the PPE ensemble block the anticipated disease transmission pathway?	Revisit the hazard analysis to ensure that the PPE ensemble covers the necessary body parts-the exposure surfaces, otherwise effectiveness will be reduced.
4. Does the PPE offer the necessary level of protection?	Some pieces of PPE allow penetration of some fraction of pathogens by design, others may fail, resulting in exposure. High hazard infectious diseases should lead to the selection of PPE with low penetration and low likelihood of failure

HCP, health care personnel; PAPRs, powered air-purifying respirators; PPE, personal protective equipment.

Evaluation of a PPE ensemble can be staged. First, visual inspection can evaluate fit and identify gaps at junctions between pieces of PPE. Second, tracers can be used to evaluate penetration during care activities and contamination during doffing. Finally, user evaluation can determine ease of PPE use, impact on job performance, and physiological and psychological impact. In experimental settings, a variety of tracers have been used. Unlike bacteriophage tracers, fluorescent materials can be readily visualized in training and simulation settings.²⁶ Lower-tech options include colored liquid (Kool-Aid; The Kraft-Heinz Co, Glenview, IL) or chocolate syrup. User evaluation may include self-report or survey, observation, and biological measures of physiological parameters.^{27,28}

RESULTS

In this section, the proposed approach is illustrated using the task of intubation. Table 2 illustrates a JHA for the work activity of intubation developed from standard medical texts and through discussion among the research team, which included members who have performed or observed the procedure and members with expertise in infectious diseases and industrial hygiene. Experimental simulation of intubation using fluorescent-simulated body fluid in the respiratory tract of a task trainer demonstrated contamination of the air in the breathing zone of participants and on the gloves, gowns (torso

Table 2

JHA for the work activity of intubation

and cuffs), and face shields of participants,³¹ which affirms the sites of body contamination identified by the JHA.

We considered 2 infectious agents, MRSA and SARS-CoV, which were selected because epidemiologic evidence indicates that they pose different hazards for HCP (Table 3). Intubation of patients with SARS-CoV has been associated with occupationally acquired SARS-CoV infections.³² MRSA colonization of the nares of HCP is relatively common, however, occupationally acquired MRSA infection typically affects HCP with injuries (eg, cuts), and to our knowledge has not been associated with performing intubation.³³ Therefore, the risk-based selection of PPE ensembles should yield different recommendations for HCP performing intubation on patients with SARS-CoV or MRSA.

The exposure surface for SARS-CoV is the respiratory tract since cellular receptors for the virus are located in the bronchi and alveoli.³⁶ The JHA indicates potential for respiratory tract exposure associated with inhalation and inspiration of aerosols (steps 2 and 7, Table 2) and exposure of the nose and mouth mucous membranes via aerosol deposition and self-contact with hands contaminated during the procedure, respectively. Therefore, the potential exists for the virus to reach the exposure surface (the respiratory tract), and PPE should be selected to protect the respiratory tract.

Surgical masks protect HCP from relatively large aerosols that project onto the face and exposed facial mucous membranes, but do not protect against inhalation of aerosols. These devices are also loose

		Hazards			Anticipated HCP
Task	Description	Patient's body	Environment	Patient's bodily fluids	exposure surface
1. Preparation	HCP obtains and opens the intu- bation kit	None	HCP may go back and forth between patient area and kit storage area	None	Hands
2. Pre-Oxygenation	HCP uses an ambu-bag to venti- late the patient	HCP may need to position the patient's head; HCP's hands touch the patient's head	HCP handles the ambu-bag	Ventilation may generate respiratory aerosols	Hands and respiratory tract
3. Pretreatment	HCP administers sedative through IV access*	HCP may touch patient near IV access point	None	None	None
4. Paralysis induction	HCP administers paralytic drug through IV access	HCP may touch patient near IV access point	None	None	None
5. Protection	HCP inserts tooth protector into patient's mouth	HCP' hands touch patient's face and mouth		HCP may touch respiratory secretions in patient's mouth	Hands
6. Positioning	HCP adjusts the position of the patient's head	HCP' hands touch patient's head	None	None	None
7. Placement and proof	HCP inserts the endotracheal tube and checks its placement in the respiratory tract	HCP may hold patient's head in place with torso and arms; HCP may lean close to the patient's face	None	Insertion may induce cough and vomiting, generating aerosols	Torso, arms, and respiratory tract
8. Post-Intubation management	HCP secures the intubation tube by taping it to the patient's face, and connects tube to the ventilator machine	HCP may touch patient's face	HCP touches ventilator machine and tubing	Respiratory secretions may be on the tube or patient's face	Hands

HCP, health care personnel; JHA, job hazard analysis.

*Assume that intravenous access has already been established, otherwise use of a syringe has potential for blood exposure.

Table 3

Infectious disease hazard analysis for methicillin-resistant Staphylococcus aureus (MRSA) and Severe Acute Respiratory Syndrome coronavirus (SARS-CoV) in health care settings

Hazard information	MRSA	SARS-CoV
Source Source strength	Present on skin and at site of colonization or infection, including nares Shed from skin and site of colonization, high bacterial concentrations in fluids at site of infection	Respiratory secretions, blood, and stool High viral concentrations in fluids; aerosols emitted in cough and through aerosol-generating medical procedures involving the respiratory tract
Infectivity	Generally considered to have low infectivity ³⁴	Moderate infectivity ³⁵
Transmission route(s)	Contact transmission ¹	Contact and droplet; opportunistic airborne ¹
Exposure surface	Colonization or infection occurs in the nares, skin, or breaks in the skin	Infection initiated in the respiratory tract ³⁶
Disease severity	Severe for people with risk factors, such as invasive devices and compromised immune systems	Severe acute respiratory infection

fitting and easy for HCP to by-pass. Respirators protect HCP from inhaling aerosols and from projected droplets. Tight-fitting respirators and respirators with loose-fitting hoods can limit self-contact by HCP. Elastomeric full-facepiece respirators and respirators with loose-fitting hoods offer better respiratory protection and more facial coverage against splash than FFRs. Given the severity of SARS-CoV infection, the higher level of protection afforded by a PAPR with a loose-fitting hood may be warranted. The JHA also indicated that contamination of the torso, arms, and hands is likely. Body and hand coverings should be used because, although SARS-CoV does not infect through the dermis, contaminated clothing and skin may serve as an environmental reservoir. Given the relatively short duration and limited fluid volume produced during intubation of SARS patients, fluidimpermeable gowns may not be required, particularly if HCP are able to rapidly doff soiled body coverings and perform hand hygiene.

The exposure surface for MRSA is the dermis and the nares. Although infection typically requires a wound, colonization can occur at many locations on the body (Table 3). During intubation HCPs may be exposed to respiratory secretions and vomitus, which are unlikely to contain MRSA unless the patient is colonized in the nares or throat, or has an active MRSA pneumonia. Aerosols formed during intubation may be inhaled by an HCP into the nares, or transferred to the nares during self-contact with hands contaminated during the procedure; the torso and arms may be contaminated with respiratory secretions (Table 2). Unless the HCP has an open wound or indwelling device, there is low risk of developing infection from exposures associated with intubation. PPE is necessary to prevent contamination of HCP clothing and skin, which could serve as an environmental reservoir for future transmission. Colonization of HCP rarely leads to overt symptoms; however, protection of the nares with a mask or respirator could decrease the risk of colonization or further transmission. Selection of PPE for intubation of a MRSA patient, however, should consider the likelihood of undiagnosed colonization or infection by another microorganism.

DISCUSSION

PPE is one of the several strategies for protecting HCP from occupationally acquired infectious diseases. From the perspective of occupational health, PPE should be used only when engineering and administrative controls are insufficient to adequately reduce exposures. However, PPE is the default strategy in health care, as reflected in the standard and transmission-based infection control precautions.¹ This makes it particularly important that the PPE be chosen with caution and reason. The rationale for PPE selection is not always transparent, which means that decision making will be neither reproducible nor convincing to HCP. This issue was apparent in the changing guidelines for PPE during the 2014-2015 EVD.⁵ The risk-based approach we propose in this study enables transparent decisionmaking, even in the face of uncertainty or disagreement, because each step of the approach can be documented, allowing review (and critique) by others.

OSHA has been working for several years on the development of the Infectious Diseases Standard, a programmatic standard to protect HCP from occupationally acquired infectious diseases.⁸ This standard will require employers to identify and assess the potential exposures of employees to pathogens, and when the exposure is deemed unacceptable, to select and implement control strategies consistent with commonly accepted practices. Under this standard, compliance with the selected control strategies would be enforceable by OSHA. The JHA and risk-based approach to the selection of PPE ensembles described in this study could be used as part of a program required by the Infectious Diseases Standard.

The level of protection offered by PPE used in health care settings has not been evaluated in depth. Product evaluation tests typically involve only components of the PPE (eg, the penetration of fluid through the textile, not the seams in the garment or performance in the field),^{18,19} and federal agency representiatives and others have been called on to test the permeability of textiles to specific infectious agents.³⁷ Although there is room to improve the realism of this type of product testing, it is equally important to evaluate how PPE ensembles perform in the field, where human behavior and individual pieces of PPE influence protection. The 2014-2015 EVD outbreak motivated substantial research about the potential for self-contamination associated with doffing complex PPE ensembles,²⁶ and more work about ensemble performance during care activities. Hall et al³⁸ evaluated 5 PPE ensembles intended for use with suspected EVD patients, using a complex health care activity simulation with fluorescent simulated body fluids, and found contamination under the PPE and other flaws with all ensembles tested. Herlihey et al¹⁴ evaluated 7 PPE ensembles designed for use with highly infectious diseases, using a human factors lens, and found problems with protection, comfort, and function of all ensembles testing during simulated care activities or doffing. This research highlights that existing pieces of PPE are imperfect and should be evaluated for performance before implementation. Although sophisticated, formal research methods can be used, a lot of information can be gained with fewer resources. For example, in the Chicago area, HCP used visual inspection and colored liquids (eg, Kool-Aid [The Kraft-Heinz Co]) to evaluate dermal coverage and fluid impermeability of PPE, respectively, to increase confidence in PPE selection decisions during EVD preparations.⁵

Implementation of a systematic risk-based process for selection of a PPE ensemble to protect HCP from infectious diseases benefits from a team with expertise in occupational health, infectious diseases, human factors, and health care activities. The questions in Table 1 are intended to help ensure that PPE ensembles are evaluated holistically, but may not be complete. Ensemble selection and evaluation should be iterative, changing as new knowledge and perspectives are acquired through discussion and evaluation, and it is unlikely that there is a single best answer for every health care activity or health care setting. Therefore, it is important that the rationale used to select PPE ensembles be documented and transparent. Although the focus of this work has been on occupational health, we recognize that protection of patients is another important function for PPE that should be considered in PPE selection and evaluation.

In future work, we will transform this approach into a worksheet and evaluate how usable the proposed risk-based approach is for individuals involved in selecting PPE to protect HCP from occupationally acquired infections. Our goal is to make this an easy-to-use, transparent approach to enhance dissemination.

References

- Siegel JD, Rhinehart E, Jackson M, Chiarello L, Healthcare Infection Control Practices Advisory Committee. 2007 guideline for isolation precautions: preventing transmission of infectious agents in healthcare ettings. Am J Infect Control 2007;35(Suppl):65-164.
- Centers for Disease Control and Prevention. Standard precautions for all patient care. Available from: https://www.cdc.gov/infectioncontrol/basics/standard-precautions.html. Accessed April 17, 2018.
- Gammon J, Morgan-Samuel H, Gould D. A review of the evidence for suboptimal compliance of healthcare practitioners to standard/universal infection control precautions. J Clin Nurs 2008;17:157-67.
- Kinlay J, Flaherty K, Scanlon P, Mehrotra P, Potter-Bynoe G, Sandora TJ. Barriers to the use of face protection for standard precautions by health care providers. Am J Infect Control 2015;43:169-70.
- Bleasdale SC, Sikka M, Brosseau LM, Fritzen-Pedicini C, Moritz D, Stiehl E, et al. Experience of Chicagoland acute care hospitals preparing for Ebola Virus Disease, 2014-2015. J Occup Environ Hyg 2019;16:582-91.
- National Institute for Occupational Safety and Health. NIOSH personal protective equipment information (PPE-Info). Available from: https://www.cdc.gov/ppeinfo. Accessed August 17, 2018.

- Gudgin Dickson E. Personal protective equipment for chemical, biological and radiological hazards: design, evaluation, and selection. Hoboken (NJ): John Wiley & Sons;; 2013.
- Occupational Safety and Health Administration. OSHA's infectious diseases regulatory framework. Available from: https://www.osha.gov/dsg/id/tab6.pdf. Accessed August 17, 2018.
- **9.** Roughton J, Crutchfield N. Job hazard analysis: a guide for voluntary compliance and beyond. Burlington (MA): Elsevier Science & Technology; 2011.
- Zartarian V, Bahadori T, McKone T. Adoption of an official ISEA glossary. J Expo Anal Environ Epidemiol 2005;15:1-5.
- 11. Chosewood CL, Wilson DE. Biosafety in microbiological and biomedical laboratories. Atlanta (GA): US Department of Health and Human Services; 2009.
- Jones RM, Brosseau LM. Aerosol transmission of infectious disease. J Occup Environ Med 2015;57:501-8.
- Roy CJ, Milton DK. Airborne transmission of communicable infection the elusive pathway. N Engl J Med 2004;17:1710-2.
- 14. Herlihey TA, Gelmi S, Fewwelling CJ, Hall TN, Banez C, Moirta PP, et al. Personal protective equipment for infectious disease preparedness: a human factors evaluation. Infect Control Hosp Epidemiol 2016;37:1022-8.
- International Safety Equipment Association. Eye and face protection selection tool. Available from: https://safetyequipment.org/wp-content/uploads/2015/05/ISEA-EF-2016-Selection-and-Use-1.pdf. Accessed August 9, 2017.
- 16. Centers for Disease Control and 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. Hospitals, including procedures for donning and doffing PPE. Available from: https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance.html. Accessed March 24, 2017.
- Bollinger N. NIOSH respirator selection logic, 2004. Cincinnati (OH): US Department of Health and Human Services; 2004.
- Kilinc-Balci FS. Isolation gowns in health care settings: laboratory studies, regulations and standards, and potential barriers of gown selection and use. Am J Infect Control 2016;44:104-11.
- Kilinc FS. A review of isolation gowns in healthcare: fabric and gown properties. J Eng Fiber Fabr 2015;10:180-90.
- 20. Spruce L. Surgical head coverings: a literature review. AORN J 2017;106:306-16.
- Yiannakis E, Boswell T. Ebola preparedness: a personal perspective. J Hosp Infect 2015;91:8-10.
- O'Connell K, El-Masri M, Broyles J, Korniewicz D. Testing for vial penetration of non-latex surgical and examination gloves: a comparison of three methods. Clin Microbiol Infect 2004;10:322-6.
- American Standards for Testing and Materials [ASTM]. Standard specification for nitrile examination gloves for medical application: D6319-10 (reapproved 2015). West Conshohocken (PA): International ASTM; 2015.

- American Standards for Testing and Materials [ASTM]. Standard specification for tubber surgical gloves: D3577-09 (reapproved 2015). West Conshohocken (PA): International ASTM; 2015.
- American Standards for Testing and Materials [ASTM]. Standard specification for rubber examination gloves: D3578-05 (reapproved 2015). West Conshohocken (PA): International ASTM; 2015.
- 26. Kwon JH, Burnham CD, Reske KA, Liang SY, Hink T, Wallace MA, et al. Assessment of healthcare worker protocol deviations and self-contamination during personal protective equipment donning and doffing. Infect Control Hosp Epidemiol 2017;38:1077-83.
- Dorman L, Havenith G. The effects of protective clothing on energy consumption during different activities. Eur J Appl Physiol 2009;105:463-70.
- **28.** Garner A, Laurence H, Lee A. Practicality of performing medical procedures in chemical protective ensembles. Emerg Med Australas 2004;16:108-12.
- 29. Koo A, Walsh R, Knutson T, Young S, McGrane K, Bothwell J, et al. Comparison of intubation using personal protective equipment and standard uniform in simulated cadaveric models. Mil Med 2018;183:216-8.
- 30. Grillet G, Marjanovic N, Diverrez JM, Tattevin P, Tadie JM, L'Her E. Intensive care medical procedures are more complicated, more stressful, and less comfortable with Ebola personal protective equipment: a simulation study. J Infect 2015;71:703-6.
- Weber R, Phan L, Fritzen-Pedicini C, Jones R. Environmental and personal protective equipment contamination during simulated healthcare activities. Ann Work Expo Health 2019;63:784-96.
- Fowler RA, Gues CB, Lapinsky SE, Sibbald WJ, Louie M, Tang P, et al. Transmission of severe acute respiratory syndrome during intubation and mechanical ventilation. Am J Respir Crit Care Med 2004;169:1198-202.
- Haamann F, Dulon M, Nienhaus A. MRSA as an occupational disease: a case series. Int Arch Occup Environ Health 2011;84:259-66.
- Jarvis WR, Jarvis AA, Chin RY. National prevalence of methicillin-resistant Staphylococcus aureus in inpatients at United States health care facilities, 2010. Am J Infect Control 2012;40:194-200.
- Chowell G, Abdirizak F, Lee S, Lee J, Jung E, Nishiura H, et al. Transmission characteristics of MERS and SARS in the healthcare setting: a comparative study. BMC Med 2015;13:210.
- **36.** Sims AC, Burkett SE, Yount B, Pickles RJ. SARS-CoV replication and pathogenesis in an in vitro model of the human conducting airway epithelium. Virus Res 2008;133:33-44.
- Sprcher AG, Caluwaerts A, Draper M, Feldmann H, Frey CP, Funk RH, et al. Personal protective equipment for filovirus epidemics: a call for better evidence. J Infect Dis 2015;212(Supplement):98-100.
- Hall S, Poller P, Bailey C, Gregory S, Clark R, Roberts P, et al. Use of ultraviolet-fluorescence-based simulation in evaluation of personal protective equipment worn for first assessment and care of a patient with suspected high-consequence infectious disease. J Hosp Infect 2018;99:218-28.