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Major Article

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

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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). 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. However, HCP consistently fail to select appropriate PPE in this context, citing time, difficulty, and lack of perceived risk as reasons for noncompliance. During the 2014-2015 Ebola Virus Disease (EVD) outbreak, we found that many acute care hospitals used the standard precautions framework to select PPE, but that this process was challenging in part 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, 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 health and complements requirements in the Infectious Diseases Standard proposed by the Occupational Safety and Health Administration.
(OSHA). 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. 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. Human factors engineers are trained to disaggregate work activities into discrete tasks and motions and should be included if possible. Related paradigms, 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. 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, and biosafety risk group classifications. 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. Further challenges include incomplete knowledge about emerging pathogens and atypical transmission routes specific to health care activities, 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. For each major category of PPE, we highlight issues to consider in PPE selection.

Eye and face protection should prevent the impact of pathogen-containing 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. 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. 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 loose-fitting 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 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. 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.23–25 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, unmarred

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 D7103-06 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 donning 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 settings, 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 |
| --- |
| **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. | 1. 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. |
| 2. How long does it take to doff the PPE ensemble? | | |
| 3. How easy is it to don the PPE correctly? | | |
| 4. Can pieces of PPE be removed or changed without contaminating the wearer or other pieces of PPE in the ensemble? | | |
| 5. Can a piece of PPE be replaced without affecting performance of the other pieces of PPE in the ensemble? | | |
| **Usability** |
| 1. Is the piece of PPE correctly sized for the wearer? | | |
| 2. Can the wearer move in the PPE ensemble? | | |
| 3. Does the PPE allow for necessary dexterity and tactility? | | |
| 4. Does the PPE ensemble allow for unobstructed vision? | | |
| 5. Does the PPE ensemble allow for the use of corrective eyewear? | | |
| 6. Can the wearer hear people and equipment while wearing the PPE ensemble? | | |
| 7. Can people understand verbal communication from the wearer of the PPE ensemble? | | |
| 8. Can the wearer breathe comfortably while wearing the PPE? | | |
| 9. How long can the PPE ensemble be worn without the wearer experiencing physiological or psychological stress? | | |
| 10. How long do the pieces of PPE and the PPE ensemble maintain their integrity and functionality during use? | | |
| 11. Does the PPE ensemble prevent by-pass by the wearer? | | |
| 12. Is the PPE disposable? | | |
| **Fit for purpose** |
| 1. Is the PPE sterile? | | |
| 2. Does the PPE ensemble have junctions between pieces of PPE through which pathogens may penetrate? | | |
| 3. Does the PPE ensemble block the anticipated disease transmission pathway? | | |
| 4. Does the PPE offer the necessary level of protection? | | |

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 dosing. 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. 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.

**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 and cuffs), and face shields of participants, 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. 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. 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. 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

| Task                      | Description                                                                 | Hazards                                                                 | Anticipated HCP exposure surface |
|---------------------------|----------------------------------------------------------------------------|------------------------------------------------------------------------|---------------------------------|
| 1. Preparation           | HCP obtains and opens the intubation kit                                   | Patient’s body                                                         | None                            |
|                           |                                                                           | Environment                                                            | HCP may go back forth between patient area and kit storage area             |
|                           |                                                                           | Patient’s bodily fluids                                                | None                            |
|                           |                                                                           | Hands                                                                  |                                 |
| 2. Pre-Oxygenation        | HCP uses an ambu-bag to ventilate the patient                              | HCP may need to position the patient’s head; HCP’s hands touch the patient’s head | HCP handles the ambu-bag            |
|                           |                                                                           | HCP handles the ambu-bag                                                | Ventilation may generate respiratory aerosols     |
|                           |                                                                           | Hands and respiratory tract                                             | Hands and respiratory tract     |
| 3. Pretreatment           | HCP administers sedative through IV access                                | HCP may touch patient near IV access point                             | None                            |
|                           |                                                                           | HCP may touch patient near IV access point                             | None                            |
|                           |                                                                           | Hands                                                                  | None                            |
| 4. Paralysis induction    | HCP administers paralytic drug through IV access                          | HCP may touch patient near IV access point                             | None                            |
|                           |                                                                           | Hands                                                                  | None                            |
| 5. Protection            | HCP inserts tooth protector into the patient’s mouth                       | HCP’s hands touch the patient’s face and mouth                         | HCP may touch respiratory secretions in patient’s mouth                      |
|                           |                                                                           | Hands                                                                  | Hands                            |
| 6. Positioning           | HCP adjusts the position of the patient’s head                            | HCP’s hands touch patient’s head                                       | None                            |
|                           |                                                                           | Hands                                                                  | 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 |
|                           |                                                                           | Hands                                                                  | Hands                            |
| 8. Post-Intubation        | 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                                           | Respiratory secretions may be on the tube or patient’s face                   |
| management                |                                                                           | HCP touches ventilator machine and tubing                              | 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.

| Hazard information                        | MRSA                                                                 | SARS-CoV                                                                        |
|-------------------------------------------|---------------------------------------------------------------------|---------------------------------------------------------------------------------|
| Source                                    | Present on skin and at site of colonization or infection, including nares | Respiratory secretions, blood, and stool                                        |
| Source strength                           | Shed from skin and site of colonization, high bacterial concentrations in fluids at site of infection | 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                        | Moderate infectivity                                                          |
| Transmission route(s)                     | Contact transmission                                                | Contact and droplet; opportunistic airborne                                    |
| Exposure surface                          | Severe for people with risk factors, such as invasive devices and compromised immune systems | Infection initiated in the respiratory tract                                     |
| Disease severity                          |                                                                     | 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 FRFs. 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, fluid-impermeable 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. 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. The risk-based approach we propose in this study enables transparent decision-making, 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. 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), and federal agency representatives and others have been called on to test the permeability of textiles to specific infectious agents. 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 donning complex PPE ensembles, and more work about ensemble performance during care activities. Hall et al 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 al 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 donning. 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.

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.

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