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## Commentary

## Examining health care personal protective equipment use through a human factors engineering and product design lens

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Health care–associated infections continue to cause significant morbidity and mortality and increase costs. Although investigators have devoted considerable attention to examining the clinical, microbiological, and epidemiologic determinants of infection, recent epidemics of highly transmissible pathogens, such as Ebola virus, have increased interest in assessing the design and use of personal protective equipment (PPE) to prevent the spread of infectious agents. This work has highlighted important limitations in PPE design, which can render PPE ineffective in actual practice settings.

We are conducting a study funded by the Centers for Disease Control and Prevention (CDC) to assess factors that increase the risk of health care workers contaminating themselves when they doff PPE. In particular, we are assessing whether health care workers contaminate themselves when they doff gowns, masks, and gloves with different designs during simulated donning and doffing sessions. We have also conducted pilot sessions with health care workers who train others to don and doff or who have experience with infection prevention. The insights reported in this article come from our collective observations during these sessions, as well as from ongoing discussions within our team of human factors engineers and infection prevention specialists and with other health care professionals in hospitals. In addition, we have reviewed the literature to identify issues recognized by other investigators and guidelines or statements from other agencies regarding PPE design and use.

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Based on our experience and literature review, we identified 2 major limitations or issues with PPE design and use: (1) PPE items often fit health care workers poorly and (2) health care workers' donning and doffing processes vary, suggesting that these processes have not been standardized, possibly in part because of variations in PPE design and lack of homogenized training. In addition, we identified 13 specific PPE design opportunities. In this article, we first discuss the 2 limitations and then present our insights on the 13 design opportunities.

## PPE DESIGN LIMITATIONS

PPE that does not fit well cannot provide adequate protection. The Occupational Safety and Health Administration and the European Centre for Disease Prevention and Control<sup>1,2</sup> provide guidance on PPE size and fit. They highlight that a “one size fits all” approach to PPE design is ineffective. In practice, poorly fitting PPE continues to be common. Winter et al,<sup>3</sup> for instance, found that 3 different test respirators fit only a quarter of their study participants, and none of these respirators fit individual health care workers perfectly.<sup>3</sup> Our own experience confirms reports<sup>4,5</sup> that some hospitals still provide only universal sizes for different PPE items. PPE designs are also not inclusive. Almost 80% of health care workers are women, but PPE is often designed to fit men.<sup>6-9</sup>

Health care workers vary in their PPE donning and doffing practices, and some of these variations may reduce PPE effectiveness. Researchers have found that health care workers find donning and doffing PPE to be difficult, which may cause them to take unsafe shortcuts, particularly if they have limited time in which to do their required work. Notable problems include premature removal of individual PPE items from a PPE ensemble.<sup>10-14</sup> In addition, health care workers rarely follow recommended practices while donning and doffing PPE, and they may not follow the same process each time

they put on or take off specific items.<sup>10,15–20</sup> To help health care workers don and doff PPE properly, the CDC developed illustrated instructions for different items and ensembles.<sup>21</sup> Many hospitals, research groups (including ours through a CDC-funded project), and agencies (eg, the World Health Organization) have also developed recommendations and training materials for donning and doffing PPE. However, the recommendations and training materials have not been standardized, which may in part account for practice variations.

Other agencies, including the US Food and Drug Administration (FDA), Occupational Safety and Health Administration, American National Standards Institute, ASTM International, and Association for the Advancement of Medical Instrumentation, have developed standards and guidelines regarding the design and manufacture of PPE. However, these agencies provide only broad guidance. Furthermore, their standards and guidelines focus primarily on how the material properties of the PPE affect the wearer's safety.<sup>22,23</sup> For example, the FDA considers PPE items to be medical devices and classifies them as class I or II based on the "risk the device poses to the patient and/or the user."<sup>24</sup> The FDA requires that companies provide premarket notification for some items to demonstrate that the product is "at least as safe and effective" as an existing product, whereas premarket notification is not required for others. FDA guidelines advise manufacturers to follow recognized voluntary consensus standards but also acknowledge that manufacturers can opt to follow other comparable approaches to address safety concerns. The voluntary nature of the standards increases the likelihood that companies will not follow them and that the manner in which PPE items are designed and used will vary.

Additionally, the standards focus on ensuring that engineering specifications are robust and not on use scenarios or the unintended consequences of inappropriate or faulty use of PPE items in practice. For instance, ASTM International acknowledged that 1 of its standard specifications for a rubber examination glove is "intended as a reference to the performance and safety of natural rubber examination gloves, and that the safe and proper use of natural rubber examination gloves is beyond the scope of this specification."<sup>25</sup>

In summary, federal agencies have created broad guidelines on functionality, usability, comfort and wearability, durability, maintenance, reuse, aesthetics, and cost of PPE items. Moreover, the CDC has established a design and engineering process for PPE that includes specific activities, such as gathering user requirements, translating user needs into design specifications, and performing field evaluations to improve the design and use of PPE.<sup>26</sup> Nevertheless, manufacturers vary in their adherence to the standards and recommendations, and hospitals vary in their interpretation and application of the guidelines when they make PPE purchasing decisions.

## PPE DESIGN OPPORTUNITIES

The design characteristics of PPE items directly influence how they can be used in practice. The ways in which different PPE styles and ensembles interact during routine donning and doffing practice are still poorly understood. Further, guidelines and standards provide directions based on an item's intended use, but health care workers often use PPE in an unintended manner, which may jeopardize their safety. For example, health care workers may feel protected from contamination because their gowns are tied when they care for patients. They might, therefore, ignore the contamination risk associated with doffing and either pay little attention while untying the gown or tear the gown rather than untie it. The designer intended that health care workers untie the tie and may not have expected that, in reality, health care workers doff gowns in unintended and perhaps unsafe ways.

The PPE life cycle and conditions under which PPE items are used, including uses or actions for which the items were intended and those for which they were not, can reveal design gaps and opportunities for resolving these gaps. In the following paragraphs, we will discuss—from human factors engineering and product design viewpoints based on product design theory—the 13 PPE design opportunities we identified when addressing these gaps.<sup>27–29</sup>

We present the gaps as design opportunities because we hope researchers and PPE designers will be challenged to think creatively about potential solutions that will "design out" impediments to the proper use of PPE:

1. *Health care workers' anthropometry*: Health care workers' ability to use PPE effectively is affected by how well the PPE items fit and how comfortable the workers feel when wearing PPE. Loose-fitting PPE may limit health care workers' dexterity and can be difficult to doff properly, whereas tight-fitting PPE may break or tear during use. Further, health care workers (male and female) vary in anthropometry and strength. Thus, PPE items should be available in different sizes or should be adjustable to accommodate these variations and facilitate appropriate body movement during both patient care and PPE donning and doffing. Designers consider proper fit to be an evidence-based requirement for PPE. However, the large range of variations in anthropometry and the movements and postures workers use when donning PPE, caring for patients while wearing PPE, or doffing PPE introduces significant field-based constraints on fit and comfort.
2. *Color and texture of contaminated PPE surfaces*: Color and texture are important but neglected PPE design considerations. The outer surface of a PPE item becomes contaminated during use. To doff PPE items safely, health care workers must touch only the clean inner surfaces. However, the inner and outer PPE surfaces are the same color and texture, which does not help health care workers distinguish clean and dirty surfaces while doffing. The design and manufacturing cost may limit color and texture choices, but field studies that include cost-benefit analyses could help us determine if adding such features merely improves PPE aesthetics or if these features decrease the likelihood that health care workers will contaminate themselves while using or doffing PPE.
3. *Weight distribution of PPE ensembles*: The weight of a PPE item affects comfort, particularly when PPE is worn for longer periods of time. Most PPE items are worn in combination with other items, adding to the total weight. In addition, PPE items, particularly those used when caring for patients with Ebola virus infection or other highly transmissible pathogens, may be worn in layers. In these situations, the weight of each item interacts with the weight of every other item. At present, we know little about this interaction and how the weight of the individual items and entire ensemble affects health care workers' overall comfort and their ability to care for patients. Thus, assessing PPE weight is an important research and design opportunity.
4. *PPE volume and compactness*: PPE volume and compactness determine whether the PPE item remains close to the worker's body and does not billow out and obstruct patient care actions. Volume and compactness also affect health care workers' ability to dispose of PPE safely. For example, if PPE items do not compact well, health care workers or housekeeping staff may press them down into the wastebasket, likely increasing their chances for contamination and infection.
5. *Ease of PPE handling*: Health care workers' ability to don, doff, and use PPE properly is affected by the ease with which they can handle each item. Characteristics such as size, thickness, slipperiness, and volume can substantially affect a worker's ability to don PPE correctly and to remove it safely. For

example, we found that health care workers, particularly those with arthritis in their fingers, have difficulty grasping and tying long, narrow gown ties and thus may not fasten the gowns. Handling characteristics also may affect the complexity of PPE donning and doffing. For instance, handling characteristics can affect workers' ability to easily grasp and manipulate the PPE item while donning or doffing.

6. *Use scenarios*: Use scenarios help designers identify variations in the way health care workers don, use, and doff PPE items and ensembles. Thus, use scenarios may help designers identify design constraints and create products that are easy to use safely.
7. *Health care workers' doffing actions*: Doffing may be more important than donning because health care workers can contaminate themselves while removing their PPE. The doffing actions that health care workers employ may provide clues as to how to design PPE for safe doffing. For instance, if workers must do specific actions while doffing gowns to ensure that the outside of the gown does not float toward their bodies, increasing their risk of self-contamination, designers would know that they need to create a gown that does not float in this manner. Similarly, if routine PPE doffing actions cause PPE items to tear or break at unintended sites, designers would know that the gown should be redesigned to prevent tearing or breaking. Ideally, PPE should be designed such that health care workers do not need physical capabilities beyond those required for donning to doff PPE easily and safely. Moreover, PPE designs that can be doffed safely by more than 1 method could accommodate a wider range of health care workers. For example, we found that petite health care workers and those with limited thoracic spinal mobility may find gowns with breakaway backs difficult to doff if the back can be broken only by flexing the thoracic spine and pulling the gown forward at the waist. These health care workers may be able to remove such gowns safely if the gowns can be doffed by crossing their arms over their chests and pulling the gowns downward. Thus, designers should work with users to identify sequences of actions that are equally safe to use when doffing the products they design.
8. *PPE fasteners and securement devices*: The types of fasteners (eg, ties, Velcro, sticky tabs) and securement devices (eg, elastic bands) and the locations of these features affect whether PPE items will stay in place while health care workers are caring for patients and whether workers can don and doff safely. For example, gowns with ties or sticky tab fasteners on the back of the neck cannot be removed properly without first undoing the fasteners. Thus, workers must move their hands behind their necks to undo the fasteners, and in doing so they may contaminate themselves with their dirty gloves. Gowns with breakaway backs do not have fasteners at the neck and thus do not require this risky practice.
9. *PPE packaging*: The manner in which PPE items are packaged affects their use and disposal. For example, a gown that is folded several times will have permanent creases and folds when it is donned. These folds may prevent the gown from hanging properly and could allow static electricity to accumulate in the gown during use.
10. *PPE usability*: Usability encompasses several aspects that enhance or detract from a worker's interaction with PPE, including the ease of learning how to use it and the ease of use in the field. Truly usable PPE would be designed such that the sequence of actions needed to don and doff items is obvious and intuitive and health care workers do not require extensive training to use products effectively. Design affordances, constraints, and usability conventions<sup>30</sup> (eg, in fasteners, access points needed for donning and doffing) can help health care workers use the specific technique the designer intended them to use. For example, when users see a clothing fastener made with Velcro, they notice the sticky sides and intuitively understand how to use it to secure the clothing.

The Velcro strip allows users to secure the clothing item in only 1 way, and users know what to do with Velcro based on convention. Similarly, a usable PPE design would allow health care workers who are not familiar with a specific model to don the item properly and doff it safely with little to no training and without stopping to think about how to do these processes properly.

11. *Visual and physical access control points*: Health care workers must touch specific places (ie, access control points) on PPE items when donning and doffing. To do so efficiently and safely, health care workers need to both see and reach these locations. For instance, as noted in the discussion of fasteners and securements, the risk of self-contamination is higher if workers must reach behind their necks to remove their gowns. If fasteners and securements are placed where workers can see and reach them, their donning and doffing techniques might improve, allowing them to doff without contaminating themselves. However, designers should ensure that placing access control points in an easy to reach location does not increase the likelihood that these control points will be activated accidentally.
12. *Adequate clearances*: Clearances are important when designers are determining PPE dimensions. For example, gowns with adequate clearances for the neck and wrists would allow workers to move comfortably, without chafing or major restrictions. This would enable them to do their work without hindrance and to reach the control points, allowing them to doff the gown easily and safely.
13. *Optimal strength requirements*: The strength health care workers must exert when donning and doffing PPE becomes an important determinant of whether the PPE is put on correctly and removed safely so that workers do not hurt or contaminate themselves in the process. A health care worker's strength exertion capability depends on the worker's traits (eg, age, sex, physical limitations), the donning and doffing task (eg, postural requirements and reach distances required to do the task), the effort required to care for the patient, and the PPE item (eg, the type of item, the type of fastener used to secure the item, the material properties of the item, the techniques needed to don and doff the item). If the PPE item requires workers to use considerable force and strength while donning or doffing, workers are unlikely to use these items or are likely to use them improperly. For example, if workers have difficulty breaking a gown's breakaway back, they may not put the gown over their heads when donning, which may increase their risk of contamination while caring for patients.

## CONCLUSIONS

We have described design opportunities we identified from our literature review and while observing health care workers don and doff PPE. As a research community with a stake in preventing infections, our challenge is to provide the evidence that will encourage designers and manufacturers to create PPE items that facilitate proper PPE use and decrease the risk of self-contamination during patient care and doffing. Administrative solutions such as compliance mandates alone will not prevent health care workers from contaminating themselves if the PPE provides poor protection or encourages them to use the items improperly. In contrast, well-designed PPE will encourage proper use, protect the worker, and increase organizational compliance.

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