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Major article

Effect of single- versus double-gloving on virus transfer to health care workers' skin and clothing during removal of personal protective equipment

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Background: The removal of personal protective equipment (PPE) after patient care may result in transfer of virus to hands and clothing of health care workers (HCWs). The risk of transfer can be modeled using harmless viruses to obtain quantitative data. To determine whether double-gloving reduces virus transfer to HCWs' hands and clothing during removal of contaminated PPE, we conducted a human challenge study using bacteriophages to compare the frequency and quantity of virus transfer to hands and clothes during PPE removal with single-gloving and double-gloving technique.

Methods: Each experiment had a double-gloving phase and a single-gloving phase. Participants donned PPE (ie, contact isolation gown, N95 respirator, eye protection, latex gloves). The gown, respirator, eye protection, and dominant glove were contaminated with bacteriophage. Participants then removed the PPE, and their hands, face, and scrubs were sampled for virus.

Results: Transfer of virus to hands during PPE removal was significantly more frequent with single-gloving than with double-gloving. Transfer to scrubs was similar during single-gloving and double-gloving. The amount of virus transfer to hands ranged from 0.15 to 2.5 $\log_{10}$ most probable number. Significantly more virus was transferred to participants' hands after single-gloving than after double-gloving.

Conclusions: Our comparison of double-gloving and single-gloving using a simulation system with MS2 and a most-probable number method suggests that double gloving can reduce the risk of viral contamination of HCWs' hands during PPE removal. If incorporated into practice when full PPE is worn, this practice may reduce the risk of viral contamination of HCWs' hands during PPE removal. The use of double gloves should be explored in larger controlled studies.

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Caring for patients with communicable diseases places health care workers (HCWs) at risk for exposure to respiratory viruses, such as severe acute respiratory syndrome coronavirus (SARS Co-V) and influenza, that spread via contact, droplets, and aerosols. Exposure during patient care activities can result in infection, illness or death, and HCWs can spread infectious agents to other HCWs, their families, or other patients. Protecting HCWs from occupationally acquired respiratory infections uses a barrier approach, with personal protective equipment (PPE) to protect HCWs from exposure to pathogens during patient care.[1] PPE may include gowns, gloves, eye protection, masks, and respirators to protect HCWs' mucous membranes, airways, skin, and clothing from contact with infectious agents.

The risks of occupationally acquired respiratory infections and the importance of PPE for HCWs was graphically illustrated by the worldwide outbreak of SARS. HCWs represented approximately 20% of cases,[2] and failure to properly and consistently use PPE was a risk factor for infection of HCWs.[2-6] As new risks from potential pandemic human and avian-derived influenza emerge, protecting HCWs from respiratory infection will be increasingly important.

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The SARS outbreak reinforced the vital role of PPE in protecting HCWs from occupationally acquired infection, but also led to the realization that the step of equipment removal was potentially a neglected source of contamination and an infection risk. PPE must be removed after each patient encounter, and transfer of organisms from contaminated PPE to hands or clothing could be a source of infection for HCWs as well as others. The Centers for Disease Control and Prevention (CDC) responded by asking experts to design a protocol to minimize contamination of the wearer's hands and clothing during PPE removal.[1]

This protocol was based on expert opinion and knowledge, but was not empirically validated when it was designed. Whether these PPE removal practices effectively protect HCWs is an empirical question that is not easily answered in real-world health care settings, especially in the context of an ongoing outbreak. Data may be affected by problems with recall and variations in PPE use among health care facilities and among HCWs within the same facility. Outbreak settings do not allow for rigorous comparisons of PPE use practices, because obviously staff cannot be assigned or randomized to practices that might expose them to infection.

Empirical data on the effectiveness of PPE removal protocols and other aspects of PPE use can be objectively improved by using model systems with human volunteers and surrogate microorganisms. Modeling viral contamination and transfer events using harmless viruses in controlled settings allow investigators to obtain quantitative data on virus transfer events and risks to HCWs without exposing participants to the risk of infection. Bacteriophages are candidate surrogates for human viral pathogens. They are nonpathogenic, posing no risk to study participants. They are structurally similar to nonenveloped human viruses, including norovirus and hepatitis A,[7,8] and because of these similarities have been previously used as surrogates to examine aspects of health care hand hygiene[9] and virus transfer[10] with human volunteers. A model system with human volunteers and the MS2 bacteriophage has been used to evaluate the CDC's PPE removal protocol. That study found that removing contaminated PPE according to the protocol still resulted in virus transfer to the wearer's hands and clothing.[11]

The results of the previous volunteer study indicate the need for alternative PPE removal protocols to reduce the risk of wearer contamination during removal. Using the same model system as used in that study, we can empirically test such alternatives. One such alternative is double-gloving, in which 2 pairs of gloves are worn one on top of the other. When removing PPE, the outer pair of gloves is removed first, followed by the rest of the PPE items, and the inner pair of gloves is removed last. The HCW never actually touches any contaminated PPE item with bare hands. To examine whether double-gloving reduces the probability of virus transfer to HCWs' hands and clothing during the removal of contaminated PPE, we conducted a human challenge study using the bacteriophage MS2. This study compared the frequency and quantity of virus transfer to hands and clothes during PPE removal using single-gloving and double-gloving techniques.

METHODS

The study protocol was approved by the University of North Carolina's Biomedical Institutional Review Board (Study 05-2856), and written informed consent was obtained from each participant. The study population was individuals working as health care providers. The inclusion criteria for enrollment were age >18 years, not pregnant, no latex allergy, no active skin disorders, and previous fit testing for an N95 respirator. Experiments were performed in a patient care room in the University of North Carolina Hospital Clinical and Translational Research Center. The experimental protocol is shown in Figure 1.

Each experiment comprised 2 phases: a double-gloving phase and a single-gloving phase. Before beginning, participants were shown a poster presenting of the CDC's PPE removal protocol and given an opportunity to read it and ask questions. The double-gloving phase was performed first. Participants changed into a scrub shirt and pants and donned a full set of PPE, consisting of a contact isolation gown, an N95 respirator, eye protection, and 2 pairs of latex gloves. The first (inner) pair of gloves was put on so that the wrist of the glove was under the elastic cuff at the wrist of the gown sleeve. The second (outer) pair, one size larger, was worn over the first pair so that the wrist of the glove was over the elastic cuff at the end of the gown sleeve. Although the CDC protocol calls for donning and doffing PPE at the door of the patient's room, participants carried out these activities in the center of the room, to minimize the possibility of accidental touching of room surfaces or objects.

After donning, PPE was contaminated with bacteriophage MS2 suspended in 0.01 M phosphate-buffered saline. Sites of contamination were the front shoulder of the gown, right side of the N95 respirator, upper right front of the eye protection, and palm of the dominant hand. Each site was contaminated with a total of 5 $\log_{10}$ plaque-forming units (PFU) of MS2 in 5 drops of 5 μL each to simulate droplet contamination. To simulate typical physical movement that would occur while wearing PPE, the participant then performed a routine health care task (assessing neck and wrist pulses on a mannequin).

The participant then removed the PPE according to the CDC protocol, with modifications. The participant was verbally instructed to remove the outer pair of gloves first and discard them, then remove the remaining items of PPE according to the protocol. Once the gown, eye protection, and respirator were removed according to the protocol, the inner pair of gloves was removed last. The protocol was available to the participant for reference at all times during PPE removal. During the removal process, the investigator observed the participant and noted any deviations from the CDC removal protocol on a data sheet.

After removal, the inner gloves were immediately placed in containers of eluent liquid. The participant was instructed to stand in the center of the room without touching the hair or face. Hands were sampled using the glove juice method.[12] Each hand was placed inside a bag containing 75 mL of stripping solution (0.4 g of KH_2PO_4, 10.1 g of Na_2HPO_4, and 1.0 mL of Triton-X/L of reagent water) and massaged for 60 seconds to cover all hand surfaces with solution. The nondominant hand was sampled first, followed by the dominant hand. The face was sampled by dipping a polyester-tipped swab in stripping solution and swabbing a 1-cm^2 area of each cheek where the edge of the N95 respirator had rested. The swab was immediately placed in a tube of eluent liquid. The hands were decontaminated by washing with soap and water and rubbing with 70% ethanol. The removed scrub shirt and pants were collected for sampling immediately and placed in containers of eluent liquid. The participant took a shower with full body washing and then donned a clean pair of scrubs.

The single-gloving phase was performed next. The participant donned a single glove on each hand and followed the CDC removal protocol as written. Sampling was identical to that in the double-gloving phase. The hands were decontaminated by washing with soap and water and rubbing with 70% ethanol, and the participant showered before changing back into street clothes. The removed scrubs were collected for sampling in the same manner as in the double-gloving phase. Samples were transported to the laboratory and assayed within 4 hours of collection. No more than 20 minutes elapsed between application of virus and placement of hand, face, glove, and scrub samples in eluent liquid.

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