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Major Article

Assessment of half-mask elastomeric respirator and powered air-purifying respirator reprocessing for an influenza pandemic

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Background: Health care facilities are considering the use of reusable respiratory protective devices (RPDs) to mitigate a potential N95 filtering facepiece respirator shortage caused by an influenza pandemic. US regulators are also considering stockpiling reusable RPDs for pandemic preparedness, but limited data exist on the effectiveness of cleaning and disinfection of these devices. This study defines reprocessing protocols and evaluates their effectiveness against a pandemic influenza strain in a laboratory setting.
Methods: Five half-mask elastomeric respirator models and 3 powered air-purifying respirator models were contaminated with influenza virus and artificial skin oil on multiple surfaces. RPDs were then manually treated with 1 of 2 methods: cleaned or cleaned and disinfected. Presence of viable influenza was determined via swab sampling and a median tissue culture infectious dose assay.
Results: Across 41 RPD surfaces, a mean log reduction in viable influenza of 4.54 ± 0.97 $\log_{10}$ median tissue culture infectious dose was achieved for all treated surfaces, which included both cleaned and cleaned and disinfected surfaces.
Conclusions: The methods defined as part of this study are effective for eliminating viable influenza in the presence of artificial skin oil on most of the RPD surfaces tested. Material type and RPD design should be considered when implementing RPD reprocessing protocols.

Influenza transmission in health care settings is a substantial safety concern that places patients, health care workers (HCWs), and other staff at risk for infection.[1] Given the potential severity of health consequences (ie, illness and death) associated with pandemic influenza, a comprehensive pandemic influenza preparedness plan should address airborne transmission in addition to contact and droplet transmission to ensure that HCWs are protected against all potential routes of exposure.[2] The use of a particulate respirator that is at least as protective as a National Institute of Occupational Safety and Health-approved N95 filtering facepiece respirator (FFR) is listed by the Occupational Safety and Health Administration (OSHA) as a recommendation for pandemic influenza preparedness.[2] The Centers for Disease Control and Prevention (CDC) issued guidance calling for the use of N95 respirators for HCW protection during the initial stages of the 2009 H1N1 pandemic.[3] Because HCWs are at risk of exposure to airborne infectious agents, including influenza,[2] an adequate supply of respiratory protection devices (RPDs) must be available for the HCW population. The supply of single-use N95 FFRs during an influenza pandemic or a widespread outbreak of other infectious respiratory illnesses may be inadequate,[2,4,5] which could potentially result in shortages for health care facilities, as was observed during the early part of the 2009 H1N1 pandemic.[6-9] Reusable RPDs, such as half-mask elastomeric respirators (HMERs) and powered air-purifying respirators (PAPRs), have been identified as an option to mitigate a potential FFR shortage.[4,6,10]

Even when used properly, personal protective equipment (PPE) has the potential to become fomites via handling, aerosol deposition of respiratory secretions, or other transmission route.[11,12] As opposed to single-use N95 FFRs, which are intended to be disposed of after each use, reusable RPDs require reprocessing (cleaning and disinfecting) to maintain sanitary conditions as often as

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necessary or before being used by a different individual according to OSHA[13]; manufacturer's guidance may vary. The requirement to clean and disinfect respirators necessitates the establishment of reprocessing protocols for HCWs to follow. According to CDC guidance, cleaning refers to the removal of visible soil from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Disinfection is defined as a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects usually through the use of liquid chemicals or wet pasteurization.[14]

OSHA requires reprocessing procedures to be included in an employer's respiratory protection program for all worksites where respirator use is required.[13] According to OSHA, an employer must use either the cleaning and disinfecting procedures recommended by OSHA or the procedures recommended by the respirator manufacturer, as long as the procedures are equivalent in effectiveness to the OSHA method.[13] Other disinfection or sterilization methods, such as ethylene oxide exposure or steam autoclaving, are generally not compatible with HMERs or PAPRs.[15] Ultimately, clear and specific instructions should be provided to HCWs in such a way that they can easily understand and follow to reprocess reusable RPDs in a safe and effective manner. Yet, depending on the source, guidance for cleaning and disinfecting respirators does not always provide the same type of information necessary to perform these procedures.

Currently, guidance for HMER reprocessing varies between manufacturers in regard to the level of detail provided to the user.[16-20] For example, 3M (St Paul, MN) defines the cleaning agent for their 6200/7502 HMER models as a 3M respirator wipe in addition to a warm cleaning solution not exceeding 120°F and the disinfecting agent as a 0.4% bleach solution with an undefined contact time.[16,17] Honeywell (Morris Plains, NJ) defines the cleaning agent for their North 7700 model simply as a cleaner sanitizer solution to be used according to its instructions.[20] Briefly, OSHA's cleaning guidance recommends the use of a mild detergent with water at a 110°F maximum temperature followed by rinsing and draining. For disinfection, OSHA defines 2 disinfecting agents and provides appropriate concentrations and contact times.[13] A 2015 study performed by Bessesen et al[21] evaluated reprocessing procedures provided by HMER manufacturers. As part of this study, 6 subjects tested manufacturers' instructions for use (IFUs) for cleaning and disinfecting an HMER; all participants made multiple errors during the HMER reprocessing. Out of 66 attempts, 31 errors were made using the manufacturers' IFUs. Observations made by the study's authors include that there was no mention of PPE, the difficulty of reading the IFUs due to small print, and no contact time specified for disinfecting solutions for the HMER models used in this study.[21]

PAPR reprocessing can be even more complicated due to the various PAPR components having their own separate guidance on reprocessing.[22-24] There is also variability in the level of detail provided in reprocessing guidance between manufacturers and device models from the same manufacturer. For example, to properly clean all of the components of a 3M Air-Mate PAPR system, there are at least 5 different protocols to follow: blower unit, breathing tube, belt, hood, and battery, not all of which have recommended cleaning steps provided by the manufacturer.[22] Based on the product manuals, a disinfection protocol is provided for the 3M Breathe Easy model, but not for the 3M Air-Mate or Syntech MAXAIR 78SP SeriesPAPR (Stilwell, KS) models.[22-24] To further complicate the task of establishing PAPR reprocessing protocols, OSHA's recommended practices for RPD reprocessing cannot be used with several PAPR parts due to their electrical components, leaving guidance gaps that may hinder HCWs from being able to effectively reprocess PAPRs.[13]

The US Food and Drug Administration (FDA) uses the Spaulding classification scheme of medical devices as critical, semicritical, or noncritical according to the degree of risk for infection involved in use of the items and accordingly recommends the appropriate microbicidal processes for each category.[25] Critical devices are introduced directly into the bloodstream or contact a normally sterile tissue during use and must be cleaned and sterilized after each use. Semicritical devices contact intact mucous membranes or nonintact skin and must be cleaned and either sterilized or treated with a high-level disinfection process. Noncritical devices contact intact skin only (without penetration) and must be cleaned and treated with either an intermediate- or low-level disinfection process depending on the level of contamination.

Currently, reusable RPDs are not cleared by the FDA for use in hospitals, yet there are health care institutions using the devices as part of their respiratory protection program.[21,26] The Veterans Health Administration has stockpiled 3 models of reusable HMERs as a means to meet demand for respiratory protection during an influenza or other large-scale aerosol transmissible outbreak.[21] FDA clearance would likely require data supporting the effectiveness of reprocessing protocols, but few studies assessing the effectiveness of cleaning and disinfection protocols for HMERs and PAPRs have been published. In 2014, Subhash et al[27] performed a study evaluating the effectiveness of common health care disinfectant wipes against H1N1 influenza on HMERs. Using viable assays, they determined quaternary ammonium/isopropyl alcohol and bleach detergent wipes eliminated live virus, whereas 70% isopropyl alcohol alone was ineffective, albeit based on only 1 surface per respirator and 1 HMER model. Other limitations of this study were the inoculum titer used in the study is unknown and the highest viable recovery was only 73 plaque-forming units, capping the maximum demonstrable effectiveness at <1-log reduction in viability. Additionally, the influenza virus was applied in the absence of protective factors such as soiling agents. In general, very few data are available from viral decontamination studies on HMERs and PAPRs using soiling agents. The spread of viruses is expected to occur primarily via large droplets or contact, indicating that the presence of soiling agents like skin oil or saliva is likely. Soiling agents can shield viruses from environmental factors (eg, temperature, humidity, and ultraviolet light) as well as physical and chemical decontaminants.[14]

The objectives of this study were to define detailed, comprehensive methods for cleaning and disinfecting HMERs and PAPRs when challenged with influenza virus in the presence of soiling agents, and subsequently assess their effectiveness. These methods are largely based on existing practices recommended by OSHA and RPD manufacturers, while addressing guidance gaps to ensure these procedures are being performed in a safe and effective manner. Five HMER models and 3 PAPR models were contaminated with H1N1 influenza and artificial skin oil, then were either cleaned only or cleaned and disinfected using the methods defined as part of this study.

MATERIALS AND METHODS

H1N1 influenza

H1N1 influenza A/PR/8/34 (ATCC VR-1469) was propagated in embryonic chicken eggs (Charles River Premium Specific Pathogen Free Eggs 10100326) using standard World Health Organization (WHO) protocols.[28] Virus titers were determined by 50% tissue culture infectious dose ($TCID_{50}$) assay. Madin-Darby canine kidney cells (ATCC CCL-34) were passaged and maintained using WHO-approved cell culture techniques.

Test respirators

Five commercially available HMER models and 3 commercially available PAPR models were tested for this study (Table 1). RPD