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SYNOPSIS

(ARCHIVED) COVID-19 – What We Know So Far About… Reuse of Personal Protective Equipment

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Introduction

"What We Know So Far" documents are intended to provide an overview of some of the published and unpublished reports related to emerging issues with respect to coronavirus disease 2019 (COVID-19). The reports are found through ongoing scanning of the published literature and scientific grey literature (e.g., ProMed, CIDRAP, Johns Hopkins Situation Reports), as well as media reports. It is recognized that there may be additional information not captured in this document. As this is a rapidly evolving outbreak, the information will only be current as of the date the document was written.

Key Points

- Most personal protective equipment (PPE) is designed for single use, but in situations where supply is limited, extended use (continued use between patients without doffing when providing care to patients infected with the same pathogen) and reuse may be considered.
- PPE designed for reuse (e.g. elastomeric respirators) is a safe alternative to single-use PPE. Cleaning and disinfection of the product must follow the manufacturer's instructions for use.
- Expired stockpiles of single-use PPE (e.g. masks, N95 respirators), if available and intact, are preferable to decontaminating single-use PPE.
- If reuse is considered, it should not occur without adequate disinfection processes. Contamination of respirator surfaces is common, and doffing or re-donning of the same respirator without adequate disinfection may result in infection transmission.
- Disinfection and reuse of disposable PPE for reuse (N95 respirators) may be possible, but the processes used may compromise the integrity of the product and impact its effectiveness. Considerable logistical issues need to be considered for this approach to be feasible.

Background

Currently, a significant proportion of PPE, including gloves, gowns, procedure masks, respirators, and eye protection (face shield or goggles), is recommended for single use. However, during a pandemic, increased demand for PPE can lead to lack of supply. As a result, strategies have been explored to conserve single-use PPE through extended use and development of procedures to allow for reuse. These procedures may involve removing, storing and re-donning PPE in such a way that contamination is avoided; extended use (i.e., continued use between patients with the same diagnosis); and/or decontamination protocols. This synopsis provides a summary of the existing evidence and recommendations around PPE decontamination.

The term "decontamination" refers to a process of destruction or otherwise rendering non-infectious the surface of an object.[1] The term reprocessing refers to cleaning, disinfection and sterilization of reusable devices and equipment in healthcare settings.

N95 Respirators

There is some evidence that decontamination of N95 respirators may be possible, particularly through the use of UV radiation. N95 filtering face piece respirators are designed to achieve close facial fit and very efficient filtration of airborne particles. They are disposable, designed for single use and the outer surface may be contaminated after use, potentially acting as a vehicle of transmission. Reprocessing may decontaminate the surface of the respirator but may compromise the filtering efficiency and fit of the respirator. As a result, once reprocessed, N95 respirators lose their National Institute for Occupational Safety and Health (NIOSH) certification. When evaluating whether reprocessing can be recommended, there are several considerations including:

- The effectiveness of the reprocessing at rendering organisms non-infectious, noting that data on the infective dose of COVID-19 is unknown, so the relevance of log reductions of viruses as a means of measuring decontamination is also unknown.
- The effect on the integrity of the respirator (penetration, resistance, material strength, shape).
- The safety for the user (possible end-user exposure to harmful chemicals used in decontamination).
- The number of reprocessing cycles that can be performed and number of times a respirator can be worn without loss of integrity:
    - A study (Bergman et al.) evaluating the impact of multiple consecutive donnings on respirator fit found that respirators can be donned and doffed 5 consecutive times before fit drops below the acceptable threshold (fit factor <100; fit factor is a quantitative estimate of the fit of a specific respirator to an individual).[2]
    - However, a study (Vuma et al.) evaluating the impact of multiple consecutive donnings of respirator fit by 25 users found that 52% of wearers had ≥100 for overall fit factor after 6 donnings. Two subjects (8%) had a fit factor <100 on the second test, 6 (24%) on the third test, 8 (32%) on tests 4 to 6. Infrequent users had overall higher fit factors when compared to frequent users after all 6 donnings. The authors concluded that donning practices probably accounted for the fit test failures.[3]
- The feasibility of reprocessing from an operational standpoint (e.g., equipment and materials availability) and at the scale required for the situation.
- From a system perspective, alternatives to reprocessing may be available, e.g., elastomeric half masks intended to be disinfected and reused; expired respirators.

The evidence for various methods of N95 respirator decontamination is summarized below.

Ultraviolet Germicidal Irradiation (UVGI)

UVGI has the potential to decontaminate N95 respirators from respiratory viruses, including coronaviruses:

- UVGI effectively inactivates a wide range of microorganisms, including coronaviruses, by causing photochemical changes to nucleic acids and therefore disrupting replication; this occurs optimally at a wavelength of around 260nm (range 200-320nm).[4] The UVGI dose required to disable 90% of coronaviruses in water is 2.1 mJ/cm^2, and for SARS coronaviruses the range in one source is 22-304 mJ/cm^2 [4,5,6]. For Influenza A it is 2.3 mJ/cm^2, and for adenoviruses it is 90.3mJ/cm^2, all in the 200-320nm wavelength range.[4]
  - Heimbuch et al. evaluated UVGI at 254 nm on 6 types of respirators. This process resulted in virus recovery below the detection limit, or a >4 log reduction in viable H1N1.[7]
  - Lore et al. evaluated UVGI at 254 nm (15 minutes convex side) on two N95 respirator models. This process resulted in a >4 log reduction in detectable H5N1.[8] Both respirator models had <5% penetration by 300 nm particles and thus still met N95 filtration criteria.[8]
  - Tseng et al. evaluated the presence of single stranded RNA viruses on surfaces and estimated an inactivation dose of 1.3-3.2 mJ/cm^2, at a wavelength of 253.7nm.[9] Although coronaviruses are single stranded RNA viruses, these were not specifically tested.
- UV radiation has been shown to be less effective in reducing virus viability on respirator straps, which may require the additional step of use of a virucidal disinfectant on strap surfaces.
  - A study (Mills et al.) evaluating UVGI with 1,000 mJ/cm^2 on N95 respirators for 1 minute resulted in a $\geq$ 3 log reduction in H1N1 on respirator straps in the presence of artificial soil in only 7/15 models tested.[10]
  - Some types of N95 respirators are not amenable to UVGI because of shadowing due to differences in shape.[10]
- Integrity of the respirator may be impacted by very high UV intensities (much higher than what is required for efficacy) and increased number of cycles performed.
  - A study (Lindsley et al.) evaluating the effects of N95 respirator function (particle penetration, strap breaking strength, and flow resistance) after application of UVGI in doses between 120-950 J/cm^2 to 4 different N95 models found a minimal increase in particle penetration (up to 1.25%), a minimal change in flow resistance, but a significant reduction in material integrity which varied by dose and model.[11]
  - UVGI at 40 W UV-C light for 15 minutes did not significantly affect the function / appearance of 9 different respirators.[12]
- In the context of the COVID-19 pandemic, the University of Nebraska has developed an N95 respirator decontamination procedure which applies UVGI at 60mJ/cm^2. Two 254nm UV lamps are directed towards wire hanging masks in a UV chamber for approximately 5 minutes per cycle.[13] The procedure also includes an elaborate method for collecting, transferring, decontamination, and repackaging to deliver back to the same healthcare user.[13]

Vaporized Hydrogen Peroxide

Vaporized hydrogen peroxide is an airborne disinfectant which can be used for room disinfection. Limited studies to date suggest that it may be effective at decontaminating N95 respirators, but safety concerns exist around off-gassing of residual disinfectant.

- Also with reference to the COVID-19 pandemic, a protocol at Duke University recommends vaporized hydrogen peroxide (480 ppm), applied over a 45-minute cycle to N95 respirators. They note a 6 log reduction in *Geobacillus stearothermophilus* spores and no harmful chemical by-products or residues identified on the decontaminated masks.[14]
- An FDA-funded study found that N95 respirators could potentially withstand up to 30 cycles of vaporized hydrogen peroxide decontamination and continue to function adequately, after which the elastic straps began to show degradation.[15]
- On March 29, 2020, the US Food and Drug Administration issued an Emergency Use Authorization for the Battelle Critical Care Decontamination System which uses vaporized hydrogen peroxide for decontaminating N95 respirators. [16] This system requires approximately 180 minutes of processing and 300 minutes of aeration and is not compatible with cellulose-based materials.
- A small pilot noted changes in odor post decontamination.[17]

Further data are needed on the safety of reuse and the potential for inhalation of residual disinfectant.

Microwave Generated Steam

There are several studies showing that microwave steam bags are effective at reducing influenza virus respirator contamination, but more information is needed on the impact on the integrity of the respirator.

- Heimbuch et al. evaluated microwave-generated steam to disinfect 6 commercial types of respirators and found a >4 log reduction in viable H1N1.[7]
- Lore et al. evaluated microwave-generated steam to disinfect two N95 respirator models and found a >4 log reduction in detectable H5N1.[8] Both respirator models had <5% penetration by 300nm particles and still met N95 filtration criteria.
- Fisher et al. evaluated microwave steam and found that water absorption varied by model (hydrophilic materials absorbed more water) which could be a concern. Steam did not impact filtration efficacy and the steam bags tested were 99.9% effective at inactivating bacteriophage MS2 (pathogenic virus surrogate) on respirators.[18]

Additional Considerations

Several other processes have been studied in small experiments. Further data on efficacy and safety are needed before they can be recommended.

- Isopropyl alcohol (70%), bleach, soap and water, dry heat sterilization (160 ^{o}C) were all found to reduce respirator filtration efficiency in one study.[12]

CDC Recommendations on Decontamination of Respirators[19]

- In times of limited supply, including the current COVID-19 pandemic, the US Centers for Disease Control and Prevention (CDC) suggests strategies such as extended use and use beyond the manufacturer's shelf life. They recently updated their strategies to optimize PPE supply, providing an overview of respirator reprocessing/decontamination as a "crisis capacity strategy." They note that decontamination processes may impact function and fit of respirators, and as such do not recommend decontamination as standard of care, but that in times of crisis may need to be considered.
- In this overview, they discuss UVGI, vaporous hydrogen peroxide, and moist heat (60°C and 80% RH) as having the greatest potential for decontamination of N95s.[19] Where decontamination is implemented where the intended N95 function cannot be verified, they recommend against using the decontaminated respirators for aerosol-generating procedure, i.e., reserve new respirators for aerosol-generating procedures.
- In all cases, reuse will require training for workers to properly inspect, handle, don, and seal check reprocessed N95s.
- Ethylene oxide is not recommended by the CDC as it may confer toxic effects to the wearer.

In summary, several methods show potential as possible options for reprocessing N95 respirators. However, logistical challenges would need to be addressed for reprocessing to be practicable for mass delivery. These include the availability of equipment; the capacity to meet the reprocessing need; and validated processes accounting for decontamination and integrity checks, and number of times respirators are reprocessed.

Gowns

Gowns are recommended for the care of suspected or confirmed COVID-19 patients by the CDC[20], the World Health Organization (WHO)[21], and Public Health Agency of Canada (PHAC)[22] for contact precautions. Reprocessing of disposable gowns is impractical due to the inability to launder, remove contamination and maintain integrity.

- A scoping literature search was completed using the SCOPUS database using the search terms "decontamination" and "gown" and no studies were found on decontamination and reuse of gowns.
- The CDC[23] recommends cloth gowns be laundered after each use. A combination of mechanical, thermal, and chemical factors results in the antimicrobial action of the laundering process – protocols may vary.[24]
- The CDC cites easy breakage of disposable gown ties and fasteners, making them less amenable to washing and reuse than reusable gowns. When disposable gowns are in short supply, they suggest a number of alternatives, e.g., extended use of gowns; using reusable (washable) patient gowns and laboratory coats.[23]

Eye Protection

Eye protection is available in various forms, such as face shields, goggles, and visors attached to surgical masks. Both disposable and reusable options are available. The CDC[20], WHO[21], and PHAC[22] recommend their use as part of droplet precautions. One study was found on decontamination of eye protection, using ultraviolet radiation (UV):

- Ziegenfuss et al. used a germicidal UV light cabinet (at 253.7 nm wavelength) using the bacterium *Staphylococcus aureus* as the indicator organism. Using minimal UV doses, 2.4 log reduction was achieved in *S. aureus* post-UV treatment. This study context was of lateral transmission e.g., between wearers of the same device with decontamination between uses, such as visitors at an industrial site.[25]

- The CDC's strategies for optimizing eye protection supply include[26]:
  - Shifting from disposable to reusable eye protection (e.g., goggles, safety glasses with tight adherence to the face and arms without vented areas, powered air purifying respirators).
  - Considering extended use (not removing eye protection between patients, unless visibly soiled or condensation is present), assuming clinical use is confined to patients infected with the same pathogen.

Face Masks

Face masks contain the droplets and secretions of the wearer and also protect the wearer from droplets, splashes, or sprays from landing in their mouth and nose. No studies were found on decontamination and reuse of disposable face masks.

- However, Lore et al. studied two models of N95 respirators, one of which was a combination N95 respirator/surgical mask inoculated with influenza. UVGI, microwave-generated steam, and moist heat all reduced the viral load by more than 4-log median tissue culture infective dose.[8] Both respirator models still met N95 filtration criteria; however, the respirator models were not tested post-contamination to determine if criteria for particle filtration efficiency, bacterial filtration efficiency, and fluid resistance for surgical masks were still met.[8]
- The CDC discusses, as examples, extended use (using the same mask for multiple patient encounters without removal) and use beyond the manufacturer's shelf life.[26]

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