An Institutional Protocol for Collecting, Decontaminating, and Reservicing Reusable Respirators and Filters

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This summary will focus on how institutions can safely and effectively reuse both disposable N95 respirators, known as filtering facepiece respirators, and the detachable filter components of reusable respirators, known as elastomeric facepiece respirators, by health care institutions with a focus on:

1. Procedures surrounding the collection of disposable N95 respirators / disposable filters and documentation of sterilization procedures
2. A four-step protocol for sterilizing disposable N95 respirators / disposable filters using vapor phase hydrogen peroxide (VPHP) with existing evidence of efficacy
3. A process for sterilizing the facepiece part of reusable respirators known as elastomeric facepiece respirators
4. The redistribution of N95s to health care workers (HCWs) after sterilization

Introduction

The COVID-19 pandemic has forced healthcare systems to look at the efficiency of existing personal protective equipment (PPE) available to front-line HCWs. As we enter a contingency and eventually crisis capacity supply situation in Ontario, conflicting recommendations regarding the appropriate use of PPE are emerging from both Canadian and American governing bodies. The Centers for Disease Control and Prevention (CDC) quickly released recommendations for PPE use with specific strategies for optimizing respirator supply chains. These recommendations discuss rationing PPE for medically necessary procedures, canceling elective procedures and reusing PPE when possible[1,2]. Conversely, a joint statement by the Ontario Ministry of Health (MOH), Ministry of Labour, Training and Skills Development (MLTSD) and Ontario Nursing Association (ONA) states that, following a point of care risk assessment, "All health care workers who are within two metres of suspected, presumed or confirmed COVID-19 patients shall have access to appropriate PPE. This will include access to: surgical/procedure masks, fit tested NIOSH-approved N-95 respirators or approved equivalent or better protection, gloves, face shields with side protection (or goggles), impermeable or, at least, fluid resistant gowns"[3]. Such a mandate in Ontario will almost certainly strain the current supply of existing disposable N95 respirators within the province if health care workers continue to discard respirators after each use.

Prior to the H1N1 influenza pandemic, the Institute of Medicine (IOM) published a report discussing methods of extending the use of disposable N95 respirators, including decontamination followed by reuse[4]. This was later refined in 2009 in a publication entitled 'Project BREATHE' which proposed a list of consensus statements for targets regarding the manufacture and reusability of PPE, including the capacity for reuse after 50 decontamination cycles[5]. In 2016, the research and development group 'Battelle' released a pilot publication funded by the U.S. Food and Drug Administration (FDA) that looked at the feasibility of VPHP in the decontamination of disposable N95 respirators (using the 3M 1860)[6]. A follow up study in the wake of COVID-19 by faculty at Duke University, although not yet peer reviewed, also outlines similar methods of decontamination[7]. The original FDA-funded study consisted of three phases:

1. Optimizing the method of FFR decontamination using *Geobacillus stearothermophilus*, a gram-positive bacterium resistant to hydrogen peroxide, as a surrogate.
2. Assessment of respirator durability after decontamination including aerosol penetration, breathing resistance and user fit
3. Assessment of decontamination efficacy after 50 cycles of decontamination

The objective was to establish parameters to ensure a 6-log reduction in organism viability for both droplet and aerosol contamination. Within this study, disposable N95 respirators were placed in a 310 L static glove box which was attached to a dehumidifier, a hydrogen peroxide vapour generating decontamination system and a high-efficiency particulate air (HEPA) filtered air circulation system. The final recommended protocol consisted of 4 phases which together took 480 minutes. A brief summary of these steps is below:

1. The Conditioning Phase – 10 minutes

   Involved the circulation of air from the decontamination chamber through a dehumidifier to remove water vapor that could inactivate the vaporized hydrogen peroxide.

2. The "Gassing" Phase – 20 minutes

   Involved coating the respirators in a film of VPHP by injecting 2 g/min of VPHP into the 310 L chamber. This can be thought of as a 'loading dose' of VPHP on the surface of the respirator. Different methods of vapor production were not considered as the authors concluded that "each proprietary technology on the market, which is designed to convert hydrogen peroxide to a vaporized state, achieves this end". The follow up study by Duke University targeted a VPHP level of 480+ PPM inside a designated decontamination room during this phase, instead of using a small decontamination chamber.

3. The "Dwell" Phase – 150 minutes

   Involved the continuous injection of 0.5 g/min of VPHP into the 310 L decontamination chamber to allow for adequate time of decontamination in the presence of VPHP. Several dwell phase times were studied in 5 minute increments from 30 to 120 minutes. All growth samples were negative at day 1 and 7 after 105 minutes of dwell phase and a recommendation of at least 120 minutes of dwell phase was made with a final recommendation of 150 minutes. Interestingly, the Duke study recommended only a 20 minute dwell phase with a 25 minute gassing phase and also looked at a *Geobacillus stearothermophilus* 6-log decrease in biological indicators. Some manufacturers claim this is adequate with novel technology, however the authors express strong doubts about this position without further experimental research.

4. The "Aeration" Phase – 300 minutes

   The final stage involves aerating the N95 respirator to remove any VPHP from the mask. This was an important step as VPHP has been shown to be cytotoxic after use for sterilization of medical equipment[8]. Aeration was achieved using a HEPA filtered air circulation system in the FDA-funded trial and an HVAC filtered circulation system by the Duke group. The purpose was to introduce room air to the decontamination environment which would react with the hydrogen peroxide film

converting it to water and oxygen. The Occupational Safety and Health Administration (OSHA) allows a permissible level of hydrogen peroxide of 1 ppm[9], which was used as a baseline. After 180 minutes of aeration a level below 1 ppm was achieved with a value of 0 ppm detected by the Battelle group after 300 minutes. The Duke group used a protocol of 240 minutes of aeration and recorded 0 ppm of hydrogen peroxide after this time.

Phase III of this study looked at the performance of the disposable N95 respirators after repeated VPHP sterilizations and found no change in filtering ability after 50 cycles. However, after 30 cycles there was observed fragmentation of the elastic material during stretch, potentially affecting the fit of the respirator. Indeed, the group from Duke recommended a maximum of 30 decontamination cycles for disposable N95 respirators. Of note, disposable filtering units designed to fit onto reusable respirators were not tested in either trial, but extrapolation based on this data suggest that they could be sterilized up to 50 times as they do not rely on the elastic material that disposable respirators use. As of March 2020, 3M has released a statement not recommending attempts to sanitize, disinfect or sterilize disposable respirators[10]. However, the FDA simultaneously approved the use of VPHP for decontamination of N95 or N95 equivalent respirators during the COVID-19 pandemic[11]. Our group has previously made recommendations on how individuals can sanitize their respirators[12], but as institutions move toward crisis contingency supply situations, institutional procedures for collection, sterilization and re-distribution of respirators are imperative. Here we propose a protocol to do so.

Of note, detachable filters that are encased in plastic and attached to the reusable respirator should NOT be used in this decontamination process. If the filter fabric is not in direct contact with the VPHP there is no guarantee of decontamination.

STEP 1: Collecting disposable N95 respirators / disposable filters and documenting sterilization procedures

In order to streamline the reuse of disposable N95 respirators and filters for reusable respirators, a process for collecting the current supply of N95 respirators must exist. This process should be treated similarly to the collection of other reusable materials in the hospital, such as instruments or reusable fabrics. A recommended protocol is outlined below for disposable N95 respirators as an example and can be used for detachable filters for reusable respirators as well:

1. The used disposable N95 respirator should be examined by the user after use to ensure it is not grossly contaminated with bodily fluids, is wet, or is difficult to breathe through.
2. If any of the above exist, the respirator should be discarded in a biohazard or waste bin. Otherwise, it should be stored in a bin marked “unsoiled N95 respirators” lined with a plastic biohazard bag.
3. Biohazard bags should be collected by hospital service staff and should be treated as contaminated. Staff should be in appropriate PPE during collection and transport as per best practice protocols for handling contaminated materials and hospital policy.
4. Unsoiled disposable N95 respirators should be transported directly to a dedicated decontamination room where staff will collect and process each unit, including re-checking the mask for any obvious soiled areas.

5. Each disposable N95 respirator should be marked with a line or dot indicating that it has been reprocessed for sterilization. These markings can be clustered in groups of five to allow easy identification of the number of cycles. Disposable N95 respirators that have undergone >30 cycles should be discarded.
6. Disposable N95 respirators should then be placed in the sterilization chamber for decontamination. Multiple disposable N95 respirators can be placed in the same sterilization container but care should be taken to not "stack" them. Instead, they can be placed in a fallen domino pattern as demonstrated in the original study.
7. The decontamination chamber should be sealed and the staff should proceed to STEP 2.

STEP 2: Sterilizing disposable N95 respirators / filters for reusable respirators using vapor phase hydrogen peroxide

The actual decontamination of disposable N95 respirators and filters for reusable respirators should follow the same evidence-based protocols as described above.[6,7] In order to ensure safety of the decontamination staff, the decontamination chamber should be placed in a negative pressure or HVAC capable room. The following steps should occur after the disposable N95 respirator has been placed in the decontamination chamber:

1. The Conditioning Phase – As described above, the air in the decontamination chamber should be run through a dehumidifier to remove any excess moisture from the air and respirators to ensure efficacy of the VPHP during the gassing and dwell phases of the decontamination. This should be done for a minimum of 10 minutes. Any air moving from inside the decontamination unit to the dehumidifier should first be filtered through a HEPA filter as it exits the decontamination chamber.
2. The Gassing Phase – A vaporized solution of 35% hydrogen peroxide mixed with HEPA filtered air should then be injected into the chamber at a rate of 6.5 mg/min · m^3 ¶, depending on the size of the decontamination chamber. Alternatively, the levels of VPHP in the chamber could be detected within the chamber with a target of >480 ppm. This should be done for a minimum of 20 minutes.
3. The Dwell Phase – A vaporized solution of 35% hydrogen peroxide should be injected into the chamber at a rate of 1.6 mg/min · m^3, depending on the size of the decontamination chamber. This should be done for a minimum of 120 minutes, but 150 minutes is recommended.
4. The Aeration Phase – Discontinue the flow of VPHP and introduce a flow of room air into the chamber. This should be done using HEPA filtered air for a minimum of 3 hours to inactivate and remove any VPHP from the surface of the mask. Following this, staff should move to STEP 3.

¶ As calculated using the parameters of the Battelle study's decontamination chamber where 2 g/min was used in a 310 L decontamination box.

STEP 3: The redistribution of N95 respirators to health care workers (HCWs)

Prior to removal of the disposable N95 respirators and detachable filters from the decontamination chamber, the chamber itself should be sterilized with 5000 ppm free chlorine (such as found in bleach) or isopropyl alcohol. Each filter should then be placed in a sealed plastic bag for redistribution to HCWs (this could be done in the same way speculums or surgical tools are repackaged). Ideally, this would be

done as the filters are removed from the decontamination chamber and the technologist should use clean gloves to prevent cross-contamination. Once repackaged, the respirators and filters should be distributed within the hospital and should be used according to existing manufacturer packaging and protocols. Detachable N95 filters for reusable respirators can be moved to a central pick up point and distributed to HCWs based on their respirator model. New and redistributed N95 respirators should not be stored or taken home by HCWs.

STEP 4: Sterilizing reusable respirators (elastomeric facepiece respirators). This does not apply to disposable N95 respirators

This protocol refers to the sterilization of the reusable respirator (elastomeric facepiece respirators) after the filters are removed:

1. The reusable N95 respirator and filters are to be considered contaminated and as such, appropriate PPE must be worn while handling them.
2. Prepare five litres of 5000 ppm free chlorine solution using sodium hypochlorite or calcium hypochlorite and water. The proportion of sodium hypochlorite solution to water required is dependent on the initial concentration of your sodium hypochlorite solution. The amount required can be calculated using ChlorineCalc, a free online tool (https://gliax.github.io/chlorine-calculator/sodium-hypochlorite). This can also be accessed by scanning the following QR code using your smartphone:

3. Safely remove the filters from your reusable N95 respirator. These should be processed as described in STEP 1.
4. Completely submerge the respirator in the free chlorine solution for 1 minute.
5. Remove the respirator with new gloves and rinse with clean water for one minute, ensuring that the entire respirator is rinsed.
6. Hang the respirator in a clean place to dry.

Conclusion

In Southwestern Ontario, the COVID-19 pandemic is likely in its infancy as cases continue to rise daily. Despite government and corporate intervention, the supply of PPE, particularly disposable N95 respirators, continues to be a matter of great concern for both HCWs and health care institutions. There is no doubt that the current practice of disposing of N95 respirators after a single use is unsustainable. Interventions by health care institutions aimed at the re-use of scarce PPE resources, as outlined by the CDC, is pivotal. Within this framework, we have outlined an FDA-approved protocol for the collection, decontamination and re-distribution of disposable N95 respirators and detachable filters for reusable respirators, as well as the decontamination of the reusable respirator facepieces by health care institutions. If institutions do not adopt and centralize these or similar protocols and instead remain idle while the current supply of PPE is depleted, the entire community serviced by the institution will suffer as HCWs

become infected and unable to work. Every effort should be made by both institutions and individual HCWs to prevent a no-supply situation of respirators.

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