Maintaining adequate supply of N95 filtering facepiece respirators (FFRs) during a shortage by safely decontaminating and reusing equivalent alternatives

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Highlights

1. Disposable N95 filtering facepiece respirators (FFRs) are expected to be, and in some cases already are, in short supply during the ongoing SARS-CoV-2 pandemic[1].
2. Filters that offer NIOSH-approved N95 filtering capacity exist in other fields of work such as the automotive and construction industries and may still be available from commercial suppliers[2,3] even when medical supply is used up. These filters are used in conjunction with a reusable silicone facepiece that is easily sterilized with hypochlorite solution[4]. These reusable silicone facepieces, ("masks"), are approved for use in industrial applications with far more stringent particulate and vapour-filtering requirements than disposable N95 FFRs commonly used in healthcare.
3. UV germicidal irradiation (UVGI) and dry heat treatment[5,6] are accessible, inexpensive, and reasonable means of decontaminating the filters without compromising their filtering capacity[7–9].
4. We offer a review of current knowledge on this subject and a framework for hospitals and health care providers to follow that includes the use of reusable facepieces in conjunction with filters that can be decontaminated in order to conserve resources in a time of need such as the ongoing SARS-CoV-2 pandemic.
5. It is very possible that with proper handling procedures these reusable masks may prove superior both in terms of performance and cost compared to disposable FFRs and may warrant adoption for use beyond the duration of the current pandemic.

Introduction

N95 FFRs remain the personal protective equipment (PPE) of choice to mitigate exposure to airborne pathogens. The Centers for Disease Control and Prevention (CDC) and the Public Health Agency of Canada (PHAC) specifically recommend this as the PPE to control exposure of care providers from patients with suspected or confirmed Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection[10,11]. A shortage of N95 FFRs is a major concern of health care experts and practitioners during viral respiratory illness pandemics[12]. The H1N1 pandemic of 2009 demonstrated how quickly stores of PPE, specifically FFRs, can become exhausted[1].

The ongoing SARS-CoV-2 pandemic has led to N95 FFR shortages around the world. The CDC has suggested a framework of optimizing supplies and mitigating shortages. The CDC defines three specific situations relating to the capacity of a health care settings involved in treating conditions requiring the use of N95 FFRs: (1) conventional capacity; (2) contingency capacity, and (3) crisis capacity. Contemporary practice of disposable FFR use dictates that health care providers (HCPs) doff and discard masks after exiting a patient room and closing the door. In a pandemic situation, this practice pattern can result in rapid consumption of FFR reserves. The CDC suggests that HCPs maintain daily contemporary practices with regard to FFR use during a period of conventional capacity, until a situation such as the ongoing

pandemic, at which point more advanced measures may be taken. They suggest that at contingency capacity, measures may be taken to change daily contemporary practices, but must not have a significant impact on care delivered or safety of the HCP; importantly, they suggest that these practices may be used temporarily when demand exceed resources. When faced with crisis capacity (an extended period where demand exceeds resources), such as the ongoing SARS-CoV-2 pandemic, the CDC suggests that "alternate strategies not commensurate with contemporary U.S. standards of care may be employed". These measures may need to be considered during periods of expected or known N95 respirator shortages[13].

The CDC elaborates on two measures aimed at optimizing inventory of FFRs: (1) extended use of FFRs, such that FFRs are not removed between individual patient interactions; and (2) reuse of FFRs, such that they are donned before and doffed after each interaction[14]. The reuse and extended use of FFRs reasonably reduce FFR consumption, but also come with downsides:

- Risk of contamination by touching the reused FFR when donning and doffing, followed by self-inoculation through touching one's own mucous membranes or indirect/direct transmission to others[15];
- Concomitant contamination of FFR with other pathogens acquired from patients; and
- Reduction in the respirator's ability to filter effectively due to excessive use[16]

Even though reuse and extended use measures aim to reduce the number of disposed-of FFRs, they do not fully solve the issue of sustainability in a situation where new FFRs are not being restocked at adequate rates because of worldwide shortages. Because of this, decontamination or sterilization of FFRs for reuse has been a topic of great interest throughout this current pandemic. HCPs are exploring sterilization of disposable FFRs using heat, liquid disinfectants such as isopropyl alcohol or chlorine-containing solutions, microwave-generated steam, or UVGI. A 2012 study suggests that UVGI was superior over microwave-generated steam and moist heat for decontaminating N95 masks from influenza[9]. A 2004 study showed that the coronavirus responsible for causing SARS-CoV was completely inactivated after being subjected to 75ºC for 45 minutes[5]. Dr. Liu Haixa, a doctor from Beijing, found that spraying masks with liquid disinfectant and autoclaving the masks reduced their filtering capacity to below 95%, while UVGI and dry heat (70ºC for 30 minutes) did not degrade filtering capacity[17]. Another study suggests only a modest increase (up to 1.25%) in particle penetration of N95 filters when the filters were subjected to germicidal levels of UVC radiation[7]. Yet another study suggests no increase in aerosol penetration when treating filters with germicidal levels of UVC radiation[8]. Coronaviruses are susceptible to destruction by UVGI, and SARS-CoV-2 is no exception[18]. Germicidal UV-C lamps are available from commercial sources[19], as well as pet stores as the lamps are also used to sterilize aquarium water.

Other industries use respiratory protection for their workers, such as automotive painters, welders, and construction workers. Filters that are more amenable to sterilization already exist, such as the 3M 5N11[2] and the 3M 5P71[3], which offer NIOSH-certified N95 and P95 protection, respectively. These filters are used in conjunction with adaptors (such as the 3M 603[20]), a filter retainer (such as the 3M 501[21]), and a reusable facepiece (such as the 3M 7500 series[22] or 3M 6000 series[23]), which themselves can be individually sterilized, which is particularly important where the device may have been contaminated with SARS-CoV-2[4]. In the case of a shortage of

reusable adaptors and retainers, 3D-printed replacements can be easily and cheaply made and distributed[24–26].

Sterilization procedures based on currently available evidence

We have tested the procedures below with the following equipment without any loss of device integrity. We were not able to test for residual viral activity post-procedure.

Mask: 3M model 7502 half facepiece reusable respirator, size medium[22]. The 6500-series half facepiece reusable respirators similar in function.

Particulate filters: 3M model 5P71 particulate filter, P95[15]
Associated supplies: 3M model 501 prefilter retainer[21] & 3D printed alternative[25], 3M model 603[20] & 3D printed alternatives[24,25].

Cleaning solution for facepiece: 5,000ppm free chlorine solution[4]. Use Public Health Ontario's Chlorine Dilution Calculator[27] for sodium hypochlorite (bleach) or Glia's ChlorineCalc[28] for calcium hypochlorite granules.
Decontamination device: 16L UV sterilizer, 6W UV-C, 200W heating element[29].

Reusable facepiece, 501 prefilter retainer, and 603 adaptor decontamination protocol: Facepiece, retainer, and adaptor were soaked in solution with 5,000ppm free chlorine for one minute[4]. They were then rinsed with water and hung to dry.

Particulate filter decontamination protocol – UVGI & heat:

Always ensure that the decontamination device is OFF prior to opening the door. When on, the UVC light is harmful to your skin if directly exposed, as well as harmful to look at directly.

The inside of the decontamination device and the stainless-steel basket were cleaned with 5,000ppm free chlorine solution. The removable stainless-steel basket was removed from the decontamination device. The particulate filters were placed into the basket with the side labelled "mask side" face-down. The device was then turned on and left for 60 minutes. The temperature was monitored and maintained a temperature above 70ºC for the 60 minutes. At 60 minutes, the device was switched off. The door to the device was opened and the interior was allowed to cool for ten minutes. The basket and filters were then removed in a clean fashion using clean non-sterile gloves after they had cooled enough to handle safely. The filters maintained their structural integrity and were not visibly different compared to when new.

If filters are visibly soiled, or if they make breathing through the reusable facepiece difficult, they may need to be replaced. Ensure that the interior surface of the heated device is decontaminated with 5,000ppm free chlorine solution both prior to and after heat decontamination of the filters. After decontamination, inspect the filters for any signs of physical degradation. If the filters appear to be losing their structural integrity, they may need to be replaced.

Conclusion

We propose a more sustainable framework for respirator use to be employed during periods of disposable FFR shortage, such as the ongoing SARS-CoV-2 pandemic. This framework conforms to CDC[10] and PHAC[11] guidelines relating to PPE use with airborne and droplet precautions as the materials proposed already have NIOSH ratings for N- and P95 filtering capacity. The decontamination protocol of the reusable facepiece is published by the manufacturer specifically for those contaminated by coronavirus[4]. The decontamination protocols for the filters are based on previous research in this field specific to coronaviruses and other viral agents. Dry heat is recognized as a reasonable means of inactivating the virus if treated for 45 minutes at 75ºC, which is easily achieved with a household slow cooker or rice cooker. The literature on UVGI suggest that it is an effective means of decontamination with low impact on filtering capacity[7–9]. There are devices that combine the two modalities of decontamination that are commercially available and can be easily deployed in a health care setting[29].

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