A Brief Guidance for Cardiologists for Resource Containment Measures to Mitigate Anticipated Shortages of N-95 Filtering Facepiece Respirators during COVID-19 Pandemic

Background
The COVID-19 pandemic has had an enormous impact on healthcare systems across the world. It is important to rapidly identify and triage patients who have suspected COVID-19 infection and evolving acute coronary syndrome (ACS). Whether the patients are initially managed conservatively or transferred to cardiac cath lab for interventions, it is imperative to ensure availability of personal protective equipment (PPE), including N-95 filtering facepiece respirators (N-95 FFRs) for all cardiologists and intensivists who are managing such patients. This is because patients with ACS (who are often sick) may need emergency anesthetic intervention either by oxygen therapy, noninvasive ventilation (NIV), or emergent intubation, which all are aerosol generating procedures.

However, widespread shortage of these PPEs during the COVID-19 pandemic has meant that many healthcare workers (HCWs) including interventional cardiologists, anesthetists, and intensivists are managing patients and performing procedures with inadequate protection or with sub-optimal protection. Lack of availability of sufficient N-95 FFRs for cardiologists/intensivists exponentially increases their risk of exposure to COVID-19 and underscores the vital need for ensuring an uninterrupted supply of N-95 FFRs for cardiology and anesthesia services.

Data reported from the US Strategic National Stockpile in March 2020 projected a grim picture of rapidly depleting stocks, which were just about 1% of the projected annual need in the current situation. While manufacturers are working overtime to ramp up production and supplies, the sheer numbers required to meet the needs of HCWs worldwide mean that a huge gap will continue to exist between supply and demand. Recently, the American College of Cardiology (ACC), the American Heart Association, and 11 other cardiovascular and healthcare societies issued a joint statement expressing concerns and seeking federal action “over the critical shortages of medical equipment, including ventilators, test kits and PPE (masks, face shields, and gowns) to address the public health crisis due to COVID-19.”

It is therefore very important to be aware of indigenous solutions available in this regard, which may not be standards of care till now, but are being considered acceptable as a crisis management strategy to conserve N-95 FFRs in times of the COVID-19 pandemic. During previous influenza pandemics and outbreaks of infectious respiratory diseases, a similar depletion of N-95 respirators was reported. Existing Centre for Diseases Control and Prevention (CDC) guidelines recommended multiple approaches for healthcare institutions to conserve these supplies in times of crisis:

- Prioritizing the use of N-95 respirators for those HCWs who are at the highest risk of contracting infection
- Implement practices allowing extended use and/or limited reuse of N-95 respirators, when acceptable.

The following strategies proposed by the CDC as resource containment measures for N-95 respirator use in the times of COVID-19 pandemic are discussed herewith:

1. **Mask Rotation**: One strategy for reuse is to **issue five respirators to each**

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who is looking after patients with suspected or confirmed COVID-19. One respirator is used daily, following which it is stored in a breathable paper bag. This order of FFR use is then repeated for the next day, meaning thereby that each worker needs a minimum of five FFRs. It is imperative that the N-95 respirators are stored properly each day (after use) in the individual paper bags provided. At the end of the 5-day cycle, a new set is issued and the cycle repeated. The previous lot is disposed off, taking all precautions. Each HCW should also be strictly instructed that masks once used and put in the paper bags, do not touch each other and individual respirators should not be shared with other people.

However, if resources get even more constrained, making 5 respirators available for each worker who needs them, may also not be possible. In such crisis situations of a pandemic, CDC advises that FFR decontamination may become necessary. While this practice would be inconsistent with the approved use of FFR’s, CDC advisory states that this option may need to be considered in times of FFR shortages. FFR decontamination and reuse has previously been shown to be effective and studies have validated decontamination procedures against different respiratory pathogens.

Based on research by the NIOSH’s National Personal Protective Technology Laboratory (NPPTL) and other studies assessing the impact of various decontamination methods on functionality (filtration, fit) and ability to reduce viable bio-organism load, the methods which hold the most promise are (VHP) and ultraviolet germicidal irradiation. Hence, the CDC recommends that healthcare institutions should focus efforts on the following technologies as decontamination methods [Table 1]:

1. Vaporous hydrogen peroxide (VHP): Various systems have been evaluated using vaporized hydrogen peroxide to decontaminate N-95 masks. Depending on the set up, the amount of hydrogen peroxide dosed is 300–750 ppm, with a holding or gassing time of ~20–40 min, followed by de-gassing (for about 2–4 h) before the decontamination chamber is safe for the personnel to enter. Kenny et al. evaluated the virucidal activity of VHP using a BQ-50 system (Bioquell, Horsham, PA) after inoculating 3M 1870 N-95 respirators with aerosolized virus and reported effective virucidal effects.

Schwartz et al. reported that using the Bioquell Z-2 VHP generator, it was possible to decontaminate nearly 1,250 masks per cycle. A similar decontamination unit for N-95 respirators that are contaminated or potentially contaminated with SARS-CoV-2, operated by Battelle (Columbus, Ohio), has been reported to reprocess 80,000 used N-95 masks per day. The implications of resource conservation of such a strategy of reuse in a pandemic situation are tremendous. On March 28, 2020, FDA issued an Emergency Use Authorization (EUA) allowing the Battelle Decontamination system to be authorized for use in decontaminating “compatible N95 respirators.”

Now VHP is being utilized for decontamination in industrial facilities such as Battelle (up to 20 cycles) as well as individual hospitals via Sterrad (up to 2–3 cycles) or Steris equipment (up to 10 cycles). It is important to note that VHP should only be used on N-95 models that do not contain cellulose. These units are also available in India and effective re-sterilization of N-95 FFR’s can lead to enormous cost savings to hospitals, depending on the number of FFR’s sterilized and the sterilization cycles used. Low temperature hydrogen peroxide gas plasma can be done using the STERRAD® sterilizers (that generates H2O2 vapor which is then electromagnetically excited to a low-temperature plasma state with 50–60 min cycles). VHP treatment can be performed with the VHP® Steris systems, that use 35% liquid H2O2, to generate hydrogen peroxide vapor, often with 60 min cycles.

2. Ultraviolet germicidal irradiation (UVGI): UVGI has been demonstrated to be effectively human respiratory viruses, including coronaviruses, on various models of N-95 FFRs with the needed levels to do so, being well below the level of irradiation that can potentially affects the filtration and close-fit features of N-95
Previous studies have reported that UVGI exposures of 1 J/cm² can decontaminate influenza virus on N-95 FFRs while exposures of 2–5 ml/cm² are capable inactivating coronaviruses on surfaces. Researchers at University of Nebraska Medical Center, Lincoln, Nebraska have evaluated the efficacy of UV radiation and reported that 15 min of UVC radiation was enough to kill the COVID-19 virus. In the system evaluated by Lowe et al., (ClorDiSys UVGI Light System, https://www.clordisys.com/products.php) UV sensor readings of 60 ml/cm² equated with a total mask exposure dose of 180–240 ml/cm² while a sensor reading of 300 mJ/cm² represented a total mask exposure dose of 900–1,200 ml/cm² depending on the position of mask placement on the mask hanging lines. The amount of delivered UVGI is monitored with a room UVGI meter that is remotely controlled by the technician from outside the UV room, so that potential damage to the eye or skin of the operator is avoided.

3. Moist heat (heating at 60–70°C and 80–85% relative humidity) has been previously used to decontaminate FFRs with minimal loss of functionality. While it is effective against flu viruses, there is limited data on the parameters (temperature, humidity, and time) required to completely inactivate SARS-COV-2 viral particles. Hence based on current evidence, it may be unwise to use this method for FFR decontamination.

4. Steam treatment (Microwave generated steam or steam bags with humid microwave sterilization or humid hot air oven sterilization) using 1,100–1,250 W microwave models (range: 40 s to 2 min) have also been investigated as approaches for decontaminating FFRs. Fisher et al. reported that microwave steam bags (used for disinfecting infant feeding equipment) could effectively decontaminate FFRs with 99.9% inactivation of MS2 bacteriophages and no compromise of filtration performance up to 3 cycles of sterilization. In a recent meta-analysis pertaining to decontamination of N-95 FFRs using microwave and heat-based techniques, Gertsman et al. reported that microwave irradiation and moderate temperature heat (< 90°C), in both moist and dry conditions, provided safe and effective decontamination and did not significantly impact the functional parameters of FFRs. However, using steam microwaves to decontaminate FFRs is not without limitations since different microwave have different settings and power outputs and the effect of higher power microwaves on FFRs is unknown. Metal nosebands of FFRs can produce arcing and sparks inside the microwave oven, during exposure to microwaves.

5. Other techniques that are not currently recommended for decontamination of respirators are autoclave, 160°C dry heat, 70% isopropyl alcohol, soap and water, bleach, dry heat, microwave, and Ethylene oxide.

6. In a recent comparative study from the NIH’s Rocky Mountain Laboratories (RML), Fischer et al. analyzed four different decontamination methods: UV radiation (260–285 nm), 70°C dry heat, 70% ethanol and VPH to test their ability to decontaminate N-95 respirators from the SARS-CoV-2 with maintenance of functional integrity. Multiple cycles of ethanol and heat decontamination caused drop in the filtration efficacy and the study concluded that VHP treatment exhibited the best combination of rapid inactivation of SARS-CoV-2 and preservation of integrity.

7. No published data for direct sunlight sterilization of N-95 FFRs is available in current literature. Although the filtration of submicron-sized airborne particles by a single surgical mask is minimal, using multiple masks may theoretically provide higher filtration efficacy and using double masks (multiple surgical masks or one surgical mask over the respirator), has been practiced, especially in previous severe acute respiratory syndrome (SARS) pandemics. Derrick et al. however reported that a combination of multiple surgical masks filtered ambient particles poorly and should not be used as a substitute for N-95 masks. Whether using a surgical mask over a N-95 FFR offers extra defense remains speculative since a single functional N-95 FFR is by itself protective enough and therefore does not mandate any extra protection.

It is important that cath lab personnel involved in active intervention procedures especially primary angioplasty in acute MI or other urgent life saving procedures don full PPE along with N-95 FFRs because such procedures are often done in sick patients and may entail emergent NIV or intubation, which are aerosol generating procedures. The MOHW guidelines also specify that healthcare personnel involved in critical care management in ICU, etc., need to don N-95 FFRs. For resource containment, PPE and N-95 usage should not be advised for nursing and administrative staff not actually involved in the procedures. It is also mandatory to fragment the cath lab staff into smaller teams not only to conserve PPE and N-95 usage, but also to potentially limit the number of staff who may get quarantined in case of inadvertent exposure to a COVID positive case.

**Conclusion**

While N-95 respirator rotation or decontamination may be done in the unprecedented times of the COVID-19 pandemic, this practice should be done ensuring that it does not impact the performance of the respirator. Due to rapid evolution of the limited available research supporting the effectiveness of above-mentioned decontamination methods, further research on this topic shall give impetus to these strategies. It is imperative that HCWs still observe all precautions prior to using decontaminated FFRs, including visually inspecting it each time to look for any structural defect, checking all components such as the straps, nose...
bridge, and nose foam material and user seal check. Despite data supporting decontamination, FFRs contaminated with blood, respiratory or nasal secretions or other bodily fluids from patients should not be decontaminated.

Healthcare systems should consider reuse and decontamination strategies before critical resource shortages are observed. Policies outlining decontamination and reuse of N-95 FFRs should be made by teams managing the COVID-19 programs, in collaboration with the local infection control/microbiology departments. These policies need to be implemented considering the local logistics (e.g., number of N-95 respirators available and current and future usage rate) as well as institutional validation of procedural protocols of the chosen decontamination strategy (VHP or UVGI). Awareness about such measures will result in optimal resource management of N-95 FFRs and reduce the risk of exposure of cardiologists and intensivists to possible COVID-19 infection, who can help implement these policies in their institutions.

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Conflicts of interest
There are no conflicts of interest.

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