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SPECIAL COMMUNICATION

N95 Usage During the COVID-19 Pandemic

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Personal Protective Equipment (PPE), formerly ubiquitous and disposable in the hospital and healthcare environment, has become scarce during the COVID-19 pandemic. As of March 27th, nearly one-third of facilities were in short supply of face masks, 13% had exhausted supply of plastic face shields, and approximately 25% were nearly out of gowns.[1] This shortage has precipitated creative solutions to re-use and/or extend the lifetime of PPE, most notably the N95 mask.[2] When supplies are inadequate or unavailable, it is important to ensure PPE is used appropriately and not wastefully. This article attempts to summarize options regarding re-use of N95 respirators and is for informational purposes only.

Appropriate usage of PPE significantly reduces risk of viral transmission. PPE should be matched to the potential mode of transmission: contact, droplet, or airborne.[3,4] COVID-19 has been found to predominantly spread by droplet and contact routes and proper PPE includes gloves, apron, and a fluid resistant surgical mask with potential use of eye protection. Personal

eyewear is considered inadequate. Healthcare workers (HCW) involved in patient care during aerosol generating procedures require extensive PPE including gloves, fluid repellent long-sleeved gowns, eye protection such as a visor or goggles, and a high-performance filtration mask, such as the N95.[3,5-7]

Appropriate donning and doffing of PPE is also essential to reduce viral transmission. This became apparent during the 2014 Ebola outbreak in West Africa, when HCW were infected late in the epidemic despite wearing protective equipment. The lack of PPE and insufficient knowledge regarding proper donning and doffing were contributing factors, and necessary guides were placed at facility exits to ensure proper technique and decrease infection rates.[8]

There are different types of PPE masks. A fluid resistant (Type II-R) surgical face mask is used to protect against droplets. If worn by the patient it can protect the staff from both droplet and contact transmission, and if worn by the staff, it protects against droplets within 1-2m of the patient. Risk reduction is estimated at 80%.[3] While a surgical mask may be effective in blocking splashes and large-particle droplets, it does not filter or block exceedingly small particles that may be transmitted by coughs, sneezes, or certain medical procedures. Surgical masks also do not provide complete protection because of the loose fit between the surface of the mask and face.[9]Alternatively, the N95 mask is a high-performance filtering facepiece respirator (FFR) with filtration achieved by a web of polypropylene microfibers and electrostatic charge. Under test conditions, the respirator blocks at least 95% of the solid and liquid aerosol test particles. The mask does not work unless it is properly fitted to the face and creates a seal. Facial hair may

alter fit and the mask may not provide full protection.[7,9] Professional fit-testing must therefore be performed prior to use. N95 respirators are not designed for children.

The KN95, is a respirator from China considered an "equivalent" to the N95 of the United States, based on its 95% filtration capacity.[10] While KN95s were not initially sanctioned for import by the U.S. Food and Drug Administration's Emergency Use Authorization (EUA), drastic shortages of N95s led to a revised EUA, making KN95s eligible.[11] Certain performance criteria was required, and analysis could be performed outside the United States.[12] In mid-April, the CDC started to oversee testing, and data revealed some KN95s failed to meet performance efficiency and protection against COVID-19. As a response, the FDA banned more than 65 of the 80 authorized manufacturers in China from exporting KN95s to the United States. To date, only 14 authorized manufacturers remain on the approved list, see Figure 1.[13]

With respect to the overall use of face masks, the CDC identifies 3 levels of operational status: conventional, contingency, and crisis. Conventional relates to normal daily usage but when health care systems are stressed, they enter contingency mode. During this mode, the CDC recommends conserving resources by selectively canceling non-emergency procedures, deferring outpatient encounters, and removing face masks from public areas. In crisis mode, the CDC recommends cancellation of all elective procedures and appointments, the use of face masks beyond the designated shelf life during patient care activities, limited re-use, and prioritization of use for activities where splashes, sprays or aerosols are likely. If face masks are

all together unavailable, the use of homemade masks from bandanas or scarves becomes necessary.[2]

During the COVID-19 pandemic the subjects of extended use, re-use, and re-processing of masks have been discussed due to the lack of availability. The CDC reports that prolonged N95 mask use can be safe for up to 8 hours, but referral to each manufacturer's recommendations is advised.[14] Extended use refers to the practice of wearing the same N95 respirator for repeated close contact encounters with several patients, without removing the respirator between patient encounters. Extended use is favored over re-use because it involves less touching of the mask, and therefore less risk of contact transmission.[15] The N95 respirator should be discarded following use during aerosol generating procedures, if it becomes contaminated with blood or any other bodily fluids, or following close contact with, or exit from, the care area of any patient co-infected with a disease requiring contact precautions. Respirators are also recommended to be discarded if they are obviously damaged or become hard to breathe through. Current guidelines encourage wearing a face shield over the N95 to decrease the chances of soiling the mask.[14] Proper hand hygiene before and after touching or adjusting the respirator for comfort or fit is advised and should be strictly enforced.

Re-use refers to the practice of using the same N95 respirator for multiple encounters with patients but removing it after each encounter. The respirator is stored in between encounters to be put on again prior to the next patient encounter. This re-use of masks is based on a rotation schedule and the CDC suggests that masks can be reused up to 5 times;[14] however,

there is no way to determine the maximum possible number of safe reuses for an N95 respirator.[15]The CDC recommends obtaining at least 5 masks, and rotating them daily, allowing them to dry (>72 hours) so that the virus is no longer viable. Proper storage involves hanging to dry, or keeping in a clean, breathable, paper bag between uses.[14] If re-using is occurring in your practice, proper donning/doffing to avoid contamination is mandatory. Labeling the bag or the respirator itself (e.g. on the straps) can help to avoid accidental usage.

There are risks involved with the extended use and re-use of FFR, most significantly the risk of contact transmission from touching the surface of a contaminated respirator. Contact transmission occurs through direct contact with others, as well as through indirect contact by touching and contaminating surfaces that are then touched by others. One study found that nurses averaged 25 touches per shift to their eyes, face, or N95 respirator during extended use.[15,16] Pathogens can remain infectious on respirator surfaces for extended periods of time and can potentially be transferred by touch to the wearer's hands, thus risking self-inoculation. In a small study of 10 participants, HCW were responsible for almost 20% of cases spread during the SARS epidemic, and larger viral contaminants were noted to the dominant hand from removal of mask and goggles.[17] Extended use can also cause additional discomfort to HCW from wearing the respirator longer than usual. A study based in Singapore during the COVID-19 pandemic examined the prevalence and characteristics of de novo headaches and aggravated pre-existing headaches among frontline healthcare personnel[18] and showed an increase in both categories secondary to extended use of the N95 respirator.

Numerous proposals regarding reprocessing or decontamination have also been suggested. Agents range from ethylene oxide, UV or gamma irradiation, ozone and alcohol. There have also been proposals involving mask impregnation with copper or sodium chloride prior to this COVID-19 pandemic but there remains uncertainty of structural integrity of the PPE after use of these agents.[2,19] General principles of reprocessing include inactivating the viral load on the mask, the filtration capacity and electrostatic charge must be preserved as much as possible, and the fit of the mask cannot be compromised. The mask also cannot be soiled (including makeup) in order to be reprocessed. It is important to note that there are many styles of N95 masks with different strap materials and shapes, and one method is not universal.[14]

Hydrogen Peroxide Vaporization (HPV) is a decontamination method that can only be used on N95 models that do not contain cellulose, such as the 1860. This HPV process is being used in decontamination facilities such as the Battelle CCDS™ (up to 20 cycles),[20] Sterrad sterilization systems (up to 2 cycles) or Steris V-Pro EUA equipment (up to 10 cycles).[14] There are five decontamination stages during HPV method: conditioning, pre-gassing, gassing, gassing dwell, and aeration. N95 decontamination using this method currently shows no change in the physical characteristics of the mask, and fit testing on 2 individuals showed no loss of seal after the decontamination,[21] with only small changes of the aluminum noseband.[22] Dosing protocol is complex and could result in incomplete decontamination or explosion risk, therefore only trained personnel should operate equipment.[23] HPV is a promising method with a potential for high capacity throughout, but certain HPV systems, such as the Clarus® R HPV generator, may be more compatible with FFR decontamination.[24]

Ultraviolet Germicidal Irradiation (UVGI) is another method put forth by Nebraska Medical Center College in Omaha, which requires specific dosing protocols and full surface area illumination to ensure proper inactivation of viral particles with minimal mask degradation. The process is extensive, with respirators secured on wires that are strung across a room with two UVGI towers (ClorDiSys UVGI Light System) on either side. The UVGI exposure dose is monitored with a UVGI meter that can be initiated and monitored from outside the room to verify that the desired exposure has been achieved. Prior to initiating the decontamination program, the walls and ceiling are covered with a UV-reflective coating (Lumacept™).[20] Due to the extensive precision required, home UV light is not recommended. UVGI is unlikely to kill all viruses and bacteria on FFR due to shadow effects produced by the multiple layers of the mask's construction.[24] UVGI treatment should be viewed as risk management rather than complete decontamination and implemented only if it is approved during a dire shortage of N95 masks.[25]

Moist heat has been shown to be effective for influenza but there is little data on its use to deactivate SARS-COV-2 viral particles. This method involves heating at 60-70 degrees Celsius with 80-85% relative humidity and is currently not recommended.[14]

Dry heating of masks is another method which has been recently studied at the NIH. The mask is heated at 70 degrees Celsius for 30 minutes and has suggested to adequately kill the virus while preserving filter integrity. The NIH testing revealed that this could be used for up to 2 cycles without compromising fit. Optimal parameters are still being tested. In a study by Viscusi

et al, N95 mask treatment with dry heat for 60 minutes does not cause visible change in the mask but can increase mask penetration.[22]

In a recent study pending peer review, an ethanol solution of 70% was prepared with 200 proof laboratory grade ethanol and deionized (DI) water. This solution is within the CDC guidelines for disinfection.[26] Approximately 50 mL of ethanol solution was poured over each mask, until complete saturation. Excess liquid was blotted off with a paper towel, and the masks were air dried for 2-3 hours. Once dry, the masks were pumped in a vacuum chamber to a pressure below 6 mBar and 98% of the filtration efficacy of the N95 mask was restored. If the vacuum was not utilized, there was a decrease in efficiency of ~40% after air-drying. To date, this study has conducted 18 wet/dry/vacuum cycles on 6 different masks, all of which decline in performance after wetting, but return to within 98% of their initial filtration efficiency after vacuum treatment. This method has been verified for up to 5 cleaning cycles on specific N95 respirators.[26]

Other methods which have been cited but are not approved include usage of bleach, alcohol, baking, boiling, ethylene oxide, sanitizing wipes, soapy water, autoclave, and lastly microwave use. Viscusi et al, used microwaves as a source of dry heat and found that 2 minutes of treatment does not melt the respirator portion of N95 mask, and deactivates 4 types of viruses.[22] Microwaves are variable regarding settings and metal portions of the masks may catch fire.

Implementation of any policy permitting extended use or reuse of N95 respirators should be made by professionals who manage the institution's respiratory protection program, in consultation with their occupational health and infection control departments, and with input from the state and local public health departments.[15] The decision to implement these practices are on a case by case basis and must take into consideration the type of pathogen, local conditions, and N95 mask availability.

Figure 1. Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China

Manufacturer	Respirator Model
3M	9001, 9002, 9501, 9501+, 9501V+, 9502, 9502+, 9502V+, 9505+, 9541, 9541V, 9542, 9542V, 9552, 9552V
AOK Tooling Ltd. (aka Shenzhonghai Medical)	20130040, 20130045A, 20180021, 20130038, 20190019
Bei Bei Safety Co Ltd.	B702, B702V, B704, B704V
BYD Precision Manufacture Co. Ltd.	BYD KN95 Particulate Respirator (Model Number: DG3101)
Fujian Kang Chen Daily Necessities Co, Ltd.	K0450, 57793
Guangzhou Harley Commodity Company Limited	L-103V KN95
Guangzhou Powecom Labor Insurance Supplies Co., LTD	KN95
HeiQ Materials	AG HVB-FFP2-01

Hangzhou San Qiang Safety Protection Products Co., Ltd.	9420 (FFP2), 9420V (FFP2), 9480 (FFP2), 9480V (FFP2), 9980V (FFP3), 9920V (FFP3)
Rizhao Sanqi Medical & Health Articles Co., Ltd	RIZ100CVb, 3Q KN95, 3Q FFP2 NR, RIZQ100Sb, 3Q KN95 9505
Shanghai Dasheng Health Products Manufacture Company, Ltd.	DTC3X-1, DTC3X-2, DTC3X-3, DTC3B-1
Suzhou Bolisi Medical Technology Co., Ltd	BS-9501L, BS-9501FL, BS-9502C, BS9502FC
Suzhou Sanical Protective Product Manufacturing Co., Ltd	Model 8015, Model 9015
Weini Technology Development Co., Ltd	FFP2 NR E-300, FFP2 NR E-680, FFP2 NR 952, FFP2 NR F-820

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