Wait & Reuse Method - Example Implementation

Much of the available literature on decontamination of N95 FFRs is a result of recent efforts to relieve the shortage of N95 FFRs during the COVID-19 pandemic. Because of this, some of the research cited in this document is not yet peer reviewed. For clarity, wherever non-peer-reviewed results are cited in this document, the citation is preceded by a “*”.

Purpose
In this document, we provide example logistics for implementation of the ‘Wait & Reuse’ risk reduction method for N95 filtering facepiece respirators (FFRs), which uses a seven-day FFR rotation. This method does not require expensive equipment and can be implemented with minimal staff training and minimal capital and recurring expenditures. However, the logistics of storing and tracking multiple N95 FFRs per healthcare worker (HCW) can become cumbersome for large numbers of HCWs. For this reason, the Wait & Reuse method is likely most viable for small clinics or healthcare facilities (e.g., dental offices, outpatient clinics, health centers, or small hospitals). In this document, we provide example logistics to support safer N95 FFR reprocessing and reuse, as well as to lay out the necessary cautionary guidance for healthcare facilities which choose to use this method. For more detailed information a technical report (*N95DECON, 2020a) and fact sheet (*N95DECON, 2020c) are available on the Wait & Reuse method at N95Decon.org.

Caveats & cautions
For FDA EUA applications, the minimal degree of viral bioburden reduction required for N95 respirator reuse is 3-log, or 99.9% reduction (FDA, 2020). There is currently very little published data on inactivation of SARS-CoV-2 on surfaces. As such, it is difficult to draw concrete guidelines about how much time is needed to achieve 3-log viral inactivation on N95 FFRs.

Reusing the same N95 FFR within a day (i.e. at next shift) is not expected to allow sufficient time for viral inactivation and is not recommended if the N95 FFR is not also decontaminated via another effective method. The CDC recommends waiting a minimum of 5 days to allow for viral inactivation prior to N95 reuse (CDC, 2020b). The N95Decon technical report refers to a 7-day waiting period, as 7 days encompasses the time to achieve 3-log decay in reviewed studies of SARS-CoV-2 on N95s and surgical masks in room temperature conditions. Given the sensitivity of the virus to material and local environment, we do not have enough data to make a precise recommendation that encompasses all N95 FFR models in reasonable room temperature conditions. In accordance with our technical report (*N95DECON, 2020a), this document references a waiting time of 7 days prior to N95 reuse.

For an N95 FFR that is stored individually in a clean and breathable environment at room temperature and moderate humidity (35-65% RH), a 7-day waiting period before reuse is expected to significantly decrease risk of exposure to SARS-CoV-2 via the N95 FFR (*Kasloff et al., 2020; *N95DECON, 2020a). Viral inactivation is sensitive to both temperature and humidity,
and storage at higher or lower temperatures and relative humidity may change viral inactivation time (*Kwon et al., 2020; *N95DECON, 2020a).

The studies reviewed in “Technical Report for Room Temperature Storage of N95 FFR for Bioburden Reduction and Reuse” (*N95DECON, 2020a) consider only a specific coronavirus and do not give any evidence for how the Wait & Reuse method may or may not inactivate other pathogens that may be present on N95s. Other literature suggests that bacterial and fungal growth on stored N95 FFRs is uncommon (Majchrzycka et al., 2010; Wang, 1999), and it is routine to store and reuse respirators without concern for contamination from other pathogens when treating diseases without contact-based transmission (e.g., tuberculosis) (Fisher & Shaffer, 2014). Even so, respirators must be returned to the original user to prevent potential cross-contamination.

**Designating a reprocessing area**
For the Wait & Reuse method as specified based on available data, the key requirement for a reprocessing area is that it be at room temperature (~22°C) with moderate (40–65%) relative humidity (*N95DECON, 2020a). The space should also have adequate ventilation to prevent the growth of mold and bacteria. Because the N95 FFRs are considered fomites, the storage area should be large enough to allow the N95 FFRs or bags containing N95 FFRs to be stored without contacting each other and other objects (CDC, 2020b). Possible spaces include tables, shelves, carts, clotheslines, or pegboards.

**Designated personnel**
Because the Wait & Reuse method does not require the use of specialized tools, this method can be performed either by individual HCWs or by designated reprocessing staff. For larger healthcare facilities, it may be helpful to have designated staff to maintain the organization of the N95 FFRs as they are being reprocessed, improve industrial hygiene practices, as well as to streamline the pick-up and drop-off logistics.

**Training**
The WHO suggests that all personnel involved in N95 FFR reprocessing should have, at minimum, basic infection prevention and control (IPC) training to handle contaminated respirators (WHO, 2020b). Please review the World Health Organization (WHO)'s open course on IPC for COVID-19 on their website (WHO, 2020a) and their guidance on water, sanitation, hygiene (WASH), and waste management for SARS-CoV-2 (WHO, 2020c).

**PPE requirements**
Reprocessing staff or other personnel handling contaminated N95 FFRs should wear a long-sleeved gown, gloves, a surgical mask, and eye protection.
Labeling for return to & reuse by original user
Reprocessing containers should be labeled with the name of the original user, the original user’s unit, the date on which the FFR was last used, and the date at which the FFR will be considered ready to be worn again (i.e., seven days later).

The N95 FFR itself should also be labeled with the name of the original user, as well as a tally count of the number of reuse cycles. Labeling strategies include tagging or writing on the elastic straps of the N95 FFR, as well as labeling the facepiece directly (*N95DECON, 2020b). If labeling the N95 facepiece, permanent felt-tipped marker is recommended over ballpoint pens, pencils, or any other writing utensils that might poke holes in or otherwise damage the N95 FFR. Minimize the amount of N95 surface area covered with writing to prevent damage to the N95. The effect of writing on an N95 facepiece has not yet been characterized in the literature.

Reprocessing cycle limits
Because the Wait & Reuse method itself does not affect the fit and filtration performance of the N95 FFR, the number of reprocessing cycles for this method is expected to be limited by degradation of respirator fit due to donning and doffing. According to a peer-reviewed study (Bergman et al., 2012), the number of don and doff cycles over which an N95 FFR is expected to retain acceptable fit is highly dependent on the respirator model, with some models losing acceptable fit after five cycles. For this reason, CDC recommends limiting reuse to five donning cycles per N95. Some N95 models may retain acceptable fit for more than five cycles (Bergman et al., 2012; Degesys et al., 2020). When re-donning respirators after each cycle, a user seal check should be performed, as described by NIOSH guidelines (CDC, 2018) and the N95DECON “Healthcare Worker Instructional Handout” (*N95DECON, 2020b). If the seal check fails despite attempting readjustments, the respirator should be discarded.

Equipment & consumables
- Breathable containers that will not crush or deform the respirators. Some examples include:
  - Reusable containers, such as Tupperware or Ziploc food storage containers with holes punched in the top and sides (up to seven containers per HCW, if planning for daily shift work)
  - Single-use containers, such as paper bags or paper food storage containers (one per use)
  - CAUTION: Storage of N95 FFRs in airtight containers may increase risk of mold and bacterial growth. (Decker, 1995; Majchrzycka et al., 2010; Pasanen et al., 1993; Wang, 1999)
  - CAUTION: If paper bags will be used for storage, ensure they are non-laminated, non-coated, single-layer paper bags for breathability
- Post-it notes or label stickers
- Permanent marker
- If using reusable containers, disinfectant for container reprocessing. Some examples (EPA, 2020) include:
- 0.5% chlorine solution
- >70% alcohol solution
- **CAUTION:** Alcohol and chlorine solutions have been shown to compromise the filtration efficiency of N95 FFRs (*N95DECON, 2020d*). Do not apply these disinfectants directly to the respirators.
- **CAUTION:** Disinfectant solutions such as bleach can pose a respiratory hazard if fumes penetrate the N95 FFR. Ensure the disinfectant has dried completely before placing the respirator in the storage container. If a noxious odor is present when donning the N95 respirator, do not use it.

- Shelving, clotheslines, pegboards, or other storage solutions to organize N95 FFR containers

**Wait & Reuse Implementation Process**

**N95 collection from HCWs**
- HCW obtains clean container and labels it with the following information:
  - HCW’s name
  - HCW’s unit or department
  - “IN” date: the date on which the FFR was last used
  - “OUT” date: the date at which the FFR will be considered ready to be worn again (i.e., seven days after the “IN” date)
- New N95 FFRs are labeled with user name, unit, and one tally mark (to represent the first use cycle) prior to initial donning.
- After use, HCW doffs the N95 FFR.
- Follow hand hygiene (CDC, 2020a) and doffing (N95DECON, 2020b) best practices. (Fisher & Shaffer, 2014)
- HCW or reprocessing staff examines the N95 FFRs for damage, soiling, and labeling. N95 FFRs that are soiled, damaged, or unlabeled should be discarded (N95DECON, 2020b).
- If the maximum number of tally marks have **not** been reached, and the N95 visually appears suitable for reuse, HCW puts the N95 into a container. The maximum number of reuse cycles should be determined by the facility based on the respirator model.
- For non-porous containers only, the HCW or reprocessing staff wipes down the outside of the container with disinfectant (EPA, 2020).

**N95 transport**
- HCW or reprocessing staff return the labeled container with the N95 FFR inside to the storage area. The container should be added to the stack or collection of containers with N95 FFRs specific to that individual HCW.
  - For larger-scale reprocessing with dedicated staff, containers can be returned to the storage area at the end of each shift.
If containers will be transported through the healthcare facility, clean and dirty transport carts should be designated and labeled. Carts should be disinfected after each use.

**Wait and Reuse method bioburden reduction**

- Leave the N95 FFRs in containers for at least seven days to reduce the SARS-CoV-2 bioburden to a level likely to reach 99.9% viral inactivation (*N95DECON, 2020a*)
- The used N95 FFRs are considered fomites. Avoid handling the N95 FFRs until the seven-day period is over.

**Distribution**

- HCW or reprocessing staff collect the container with an “OUT” date labeled for that day or earlier with the stored N95 FFR inside
  - For larger-scale reprocessing with dedicated staff, containers can be collected from the storage area and laid out for HCWs to pick up prior to each shift.
- HCW must verify that the “OUT” date labeled on the container is on or before the day of use, to ensure seven days have passed since the N95 was last used.
- HCW verifies the respirator label matches their name to prevent cross-contamination
  - CAUTION: Respirators undergoing the Wait & Reuse method should be handled as though potentially contaminated. Caution should be exercised to avoid mixing the respirators between users; respirators must be returned to and worn by the original user.
- HCW removes the N95 FFR from the container and adds one tally mark to the N95 FFR to indicate one additional reprocessing cycle.
- HCW disinfects the marker used to add tally mark on the N95 FFR after use
- HCW again examines the N95 FFR for damage or soiling. Before entering a patient care area, the user should don the N95 and perform a user seal check.
  - CAUTION: When handling respirators, follow hand hygiene (CDC, 2020a) and donning (*N95DECON, 2020b*) best practices.
- HCW discards the container, if it is single-use, or disinfects the container, if it is reusable.
  - Reusable containers are manually or mechanically cleaned. To manually clean, follow the three-sink/bucket system (Lifebox & SPECT, 2019). Once the container is clean and dry it can be wiped with a disinfectant (EPA, 2020).
  - Disinfected reusable containers are returned to the “clean” area of the storage unit for reuse.

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