ARA Disclaimer

ARA is a private research and development (R&D) company and we are not providing guidance or direction on the decontamination of FFRs. ARA was asked by United States Food and Drug Administration (FDA) to make publically available this report relating to the FFR decontamination work performed for the FDA under contract number HHSF223201400158C.

As of this writing: (i) no regulatory agency that we are aware of has approved or cleared decontaminated FFRs for use in the US; and (ii) manufacturers of FFRs have not provided approval to use the decontamination techniques discussed on their products. ARA in no way represents or warrants the effectiveness on these decontamination techniques for any purpose whatsoever.

This article is for informational purposes only. We do not recommend any particular course of action. A decision as to whether or not to decontaminate and reuse FFRs should be made in careful consideration with your legal, medical and public health advisors after considering all available information sources.

FDA Disclaimer

The data provided to you was generated by an FDA contractor. The FDA does not endorse or guarantee the efficacy of any method and/or data or potential applications described in the report. Additionally, the views expressed in this report are those of the authors and do not necessarily represent those of the U.S. Food and Drug Administration nor should they be interpreted as official Agency policy or guidance.

Final Report

Contract number: HHSF223201400158C
Title: Research to Mitigate a Shortage of Respiratory Protection Devices During Public Health Emergencies

Report for the Period:
September 30, 2014 – September 30, 2019

Submitted to:

Ms. Suzanne Martella Contracting Officer US FDA Office of Acquisition & Grants Services Suzanne.Martella@fda.hhs.gov	Dr. Aftin Ross FDA Commissioner's Fellow US FDA - CDRH Office of the Center Director Emergency Preparedness/Operations & Medical Countermeasures Tel: (301) 796-5679 Aftin.ross@fda.hhs.gov	Christopher Le Contracting Officer Representative US FDA Christopher.Le@fda.hhs.gov

Submitted by:

Brian Heimbuch, M.S., Associate Division Manager
Del Harnish, M.S., Senior Research Microbiologist
Applied Research Associates
Engineering and Science Division
430 W 5th St, Ste 700
Panama City, FL 32401
850-914-3188
bheimbuch@ara.com
dharnish@ara.com

SEPTEMBER 30, 2019

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1. EXECUTIVE SUMMARY

Under Contract # HHSF223201400158C, Applied Research Associates, Inc. (ARA), in collaboration with the National Institute for Occupational Safety and Health (NIOSH)–National Personal Protection Technology Laboratory (NPPTL), developed and evaluated methods for decontamination and reuse of respiratory protection devices (RPDs) in an effort to mitigate a shortage during a public health emergency. A two-phase approach was implemented (**Figure 1**): 1) Optimize UV decontamination of single-use N95 Filtering Facepiece Respirators, 2) Optimize reprocessing of reusable respirators – Half-Mask Elastomeric Respirators (HMERs) and Powered Air-Purifying Respirators (PAPRs).

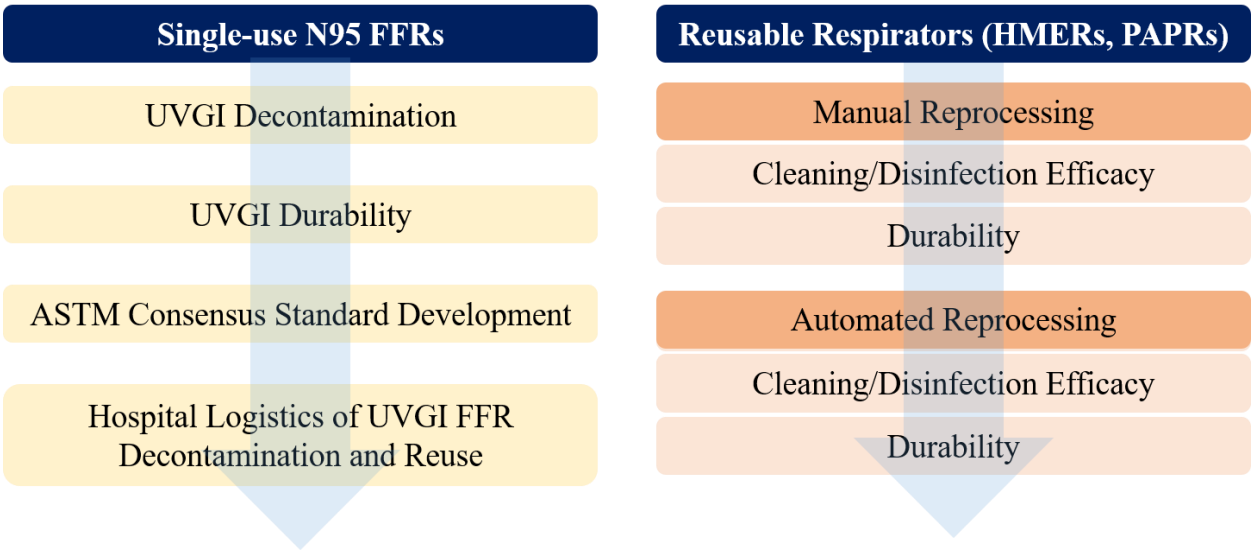


Figure 1. Task Overview

FFR decontamination and reuse (FFR-DR) has previously been shown to be effective for decontaminating FFRs contaminated with influenza.[1] The focus of this study was to build on ARA's past research to provide more confidence in the experimental decontamination data, understand durability of FFRs following multiple decontamination cycles, and to understand hospital logistics for implementation. The experimental decontamination methodology included 15 FFR models, accounted for multiple soiling events using artificial saliva and a skin oil simulant, and optimized the dose to reduce the disinfection time. Influenza was the primary microorganism studied.

In addition to the decontamination studies, durability studies were performed on the 15 FFR models following multiple decontamination cycles to evaluate how UVGI affects FFR straps and FFR filtration component, filtration performance, pressure drop analysis, fluid resistance, and flammability characteristics will be evaluated. The results of these studies were used to develop two ASTM consensus standards describing how to evaluate and optimize UVGI decontamination on FFRs for threat agents of interest.

Implementation of FFR-DR in hospitals was evaluated by working with multiple U.S. hospitals. FFR-DR implementation was discussed with health care workers (HCWs) and other key hospital staff to understand their concerns for logistics, safety, policy, operations, etc.

For reusable RPDs, the use of HMERs and PAPRs in hospitals raises many concerns surrounding cleaning of the devices. ARA optimized HMER and PAPR cleaning/disinfection via both manual and automated reprocessing methods. The five most common models of HMERs and three most common models of PAPRs used in U.S. hospitals were used for the study. Influenza virus deposited with appropriate soil loads was used to evaluate decontamination efficacy. Durability of the HMERs and PAPRs following 75 and 150 decontamination cycles were evaluated to understand fit and overall durability of the devices.

Overall, the research performed as part of this effort generated significant data pertaining to the feasibility of reprocessing existing RPDs for reuse as a means to mitigate a potential shortage resulting from a public health emergency. Below are key conclusions and recommendations from the two approaches studied as part of this effort to help mitigate a potential N95 shortage.

UVGI Treatment of N95 FFR for Decontamination and Reuse (UVDR)

Key Conclusions

- UVGI decontamination can be effective against influenza in the presence of soiling agents on N95 FFRs
- UVGI decontamination can be adversely affected by certain FFR materials (e.g., hydrophobic), FFR shapes, and the UV exposure device (e.g., UV distribution) if not designed for compatibility with UVDR applications.
- FFRs can withstand multiple cycles of UVGI decontamination without significantly impacting performance, but the maximum level of UVGI exposure allowed will be dependent on the FFR model.
- The repeated act of donning/doffing will likely have more of an adverse impact on FFR performance than UVGI under reuse conditions.
- UVGI decontamination can be effective against multiple influenza and coronavirus strains in the presence of soiling agents on N95 FFRs
- UVGI decontamination can be performed without significantly impacting flammability or fluid resistance.
- HCWs prefer to keep FFRs for their own use as opposed to sharing.
- HCWs favor having UV decontamination near point-of-care.
- Information regarding logistics and effectiveness of UVGI strategy in hospitals will need to come from respected authority.
- ***There is a need for N95 respirators designed for hospital decontamination and reuse to meet the needs of HCWs.***
- ***It was noted that FFRs following UVGI treatment contained a singed odor.***

Reprocessing Studies using HMERs and PAPRs

Key Conclusions

- The cleaning protocol used is effective at reducing viable influenza on HMERs and most PAPR surfaces, but can be limited by the material (e.g., fabric strap).
- Manual reprocessing is time consuming and relies on the ability of the reprocessor to be effective.
- The design of some PAPR components limit the ability to be reprocessed using either manual or automated methods (e.g., inaccessible crevices, electrical components, fabric straps).
- HMERs and PAPRs can be manually reprocessed up to 150 times with no significant degradation to performance.
- Most HMER models can be reprocessed using automated methods (e.g., washer-disinfector), but the temperature conditions must be reduced for compatibility with existing commercially available HMERs.
- Automated reprocessing of PAPR components has limited utility due to the incompatibility of the blower unit with a washer-disinfector and potential reduction in visibility when visors are treated with the same method.
- ***There is a need for reusable respirators designed for hospital decontamination and reuse to meet the needs of HCWs.***

2. INTRODUCTION

Overview

A study conducted by the Institute of Medicine found that during a public health emergency, such as pandemic influenza, there will be an expected shortage of FFRs.[2] FFR use dramatically increased during the 2009 H1N1 pandemic,[3] and if the strain had produced a higher mortality rate, severe shortages would have occurred. The threat of alternative pathogens such as H7N9 avian influenza and the Middle East Respiratory Syndrome (MERS), both abroad and in the United States, has previously raised concerns over the ability to mitigate the spread of high-mortality viruses. FFRs are a primary barrier to mitigating disease spread, and both OSHA and the Centers for Disease Control and Prevention (CDC) advocate their use for workers exposed to aerosolized influenza virus.[4,5] Given that vaccines can be difficult to produce, as was demonstrated with the H7N9 avian influenza strain,[6] adequate supplies of primary infection control measures, including respiratory protection, must be maintained.

FFR Decontamination and Reuse

FFR decontamination and reuse (FFR-DR) has previously been shown to be a viable option. ARA, in collaboration with NIOSH-NPPTL, the Air Force Research Laboratory, the University of Florida, the University of Nebraska Medical Center (UNMC), and the Technical Support Working Group (TSWG), developed three decontamination technologies (**Figure 2**) that were shown to be effective at inactivating H1N1 and H5N1 deposited on FFRs as respiratory aerosols and droplets.[1,7] FFRs exposed to these technologies were also evaluated for filtration performance and fit —no significant decay in performance was observed following three

consecutive decontamination cycles.[8,9,10] The technologies, while similar in effectiveness, do provide varying degrees of logistical concerns for implementation. The microwave-generated steam (MGS) was the shortest decontamination cycle (two minutes), but concerns over wattage variability among microwave ovens and the overall supply of microwave ovens raised concerns about implementing this technology in medium- and large-scale hospital settings. The Warm Moist Heat approach (WMH) was the longest decontamination cycle (30 minutes) and required the use of an oven set to 160 °F. This technology was primarily developed for home use where rapid reprocessing and large volumes would not be needed.

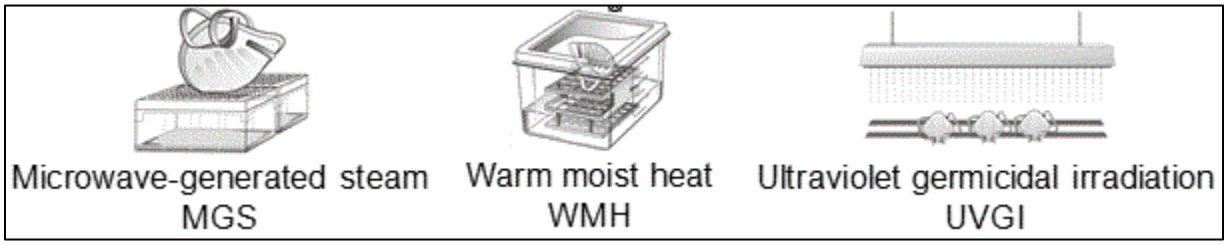


Figure 2. Filtering Facepiece Respirator Decontamination Technologies

Ultraviolet Germicidal Irradiation (UVGI) is most applicable for large-scale applications due to simplicity of use and the ability to rapidly scale the process by adding inexpensive FFR UVGI exposure units. UVGI technology has also been developed for whole room decontamination for hospitals,[11] which provides opportunities for dual-use technologies and reduce implementation costs. The current method calls for 15 minutes of exposure, but no attempt was made to optimize the process, which could significantly reduce the necessary exposure time. A combination of the WMH and UVGI could also be developed, if needed, as it is our goal to mature this technology to provide solutions for FFR-DR in health care settings.

There are limitations for FFR-DR that must be accounted for (Table 1). Current FFR models cannot be effectively cleaned which is a requirement for reprocessing medical devices as defined in the Medical Device User Fee and Modernization Act (MDUFMA).[12] Cleaning is generally performed prior to decontamination to ensure soiling materials do not interfere with the decontamination process. If the decontamination process can disinfect in the presence of other organic material, then the goal of producing a decontaminated device will not require cleaning. Cleaning contaminated devices may also create infectious aerosols that potentially aid the pandemic spread.

Table 1. FFR Decontamination Risk Reduction Strategy

Risk Element	Proposed Mitigation Research
Repeated exposures may limit effectiveness of the decontamination tool	Perform research using multiple loadings and optimize the decontamination methods to ensure effectiveness

It is unclear how many times FFRs can be decontaminated until they no longer provide protection.	Expose FFRs to optimized decontamination technologies and test them until they fail (penetration, fit, and strap breakage)
It is not clear if the decontamination technologies will work on all FFR models	Test multiple models of FFRs and evaluate each one for performance following multiple decontamination cycles
It is not clear how this technology will transition to be readily available during a public health emergency	• Standard FFR decontamination devices will be designed and tested to ensure simple operation • Transition strategies and concept of operations will be developed with large and moderate-sized health care facilities
Decontamination may not work on all virus strains	Develop standard test method that optimizes the decontamination strategy to ensure it works on the pandemic strain

Another concern for FFR-DR is stability of FFRs over multiple uses. The major concern is strap breakage, but integrity of the filtration component is also a concern. Bergman et al, evaluated six FFRs, in which 20 donnings were performed, and demonstrated that strap breakage was uncommon.[13] They found fit decayed with multiple donnings, but they also showed that for the six models tested, 53% - 75% of the FFRs tested still provided fit factors ≥ 100 after twenty donnings. These data support that FFRs are robust devices and can be used many times.

Limited research has been performed on evaluating the stability of the FFR filtration component regarding shape and effectiveness following multiple donning and decontamination cycles. Bergman et al. noted that a nosepiece break occurred in one model of FFR tested in the multiple donning study. They also noted terminal failures (three consecutive fit tests with fit factors < 100) occurred for some FFRs. The authors suggest this was due to a reduction in strap elasticity. Bergman et al. also studied FFR fit after applications of UVGI, MGS, and WMH and found no significant changes in fit resulting from any of the three methods.[10] Additionally, UVGI did not cause any noticeable physical degradation. More study is needed, but the data suggest FFRs are robust devices that can withstand multiple donning and multiple decontamination cycles.

Reusable Respiratory Protection Devices

HMERs and PAPRs are regulated as reusable devices that can be shared among multiple users. HMERs and PAPRs are not currently cleared for use in hospitals by the Federal Drug Administration (FDA), despite a path for FDA clearance of these devices defined in the MDUFMA.[12] However, some medical institutions are using them as they understand their potential for mitigating an FFR shortage. These devices also provide some advantages for daily

use (e.g,. TB clinics). The Veterans Health Administration (VHA) made a large purchase of HMERs for their employees in the wake of the 2009 H1H1 pandemic.[14]

Specific protocols for cleaning HMERs and PAPRs are available from the device manufacturers; however, during the H1N1 pandemic, the 3M Company provided guidance that "the respirator user is ultimately responsible for determining the suitability of cleaning and sanitizing procedures for their workplace."[15] During the outbreak of the severe acute respiratory syndrome (SARS) virus, 3M provided guidance that their decontamination methods were not demonstrated to be effective against the SARS virus.[16] Minimal data is available to understand if the protocols defined by manufacturers or OSHA[17] will be effective for removal/disinfection of viruses or what effect long-term exposure to decontaminants has on fit characteristics of the device.

3M performed multiple decontamination tests (150 cycles) on some of their RPDs using multiple decontamination agents. 3M also evaluated disinfection using bacteriophage loaded on multiple components of their devices and only demonstrated a 2 – 3 log reduction for a majority of their tests, yet no operationally-relevant strains were used. Subhash et al., performed research in which small quantities (10^2 PFU) of H1N1 influenza were inoculated on rubber coupons of FFR seal materials and subsequently exposed to various decontamination agents.[18] They found quaternary ammonium compounds to be effective at eradicating the virus, but isopropyl alcohol was ineffective. They indicate no degradation of the masks was apparent by visual inspection, but they did not report fit test data. The MDUFMA requires that functional performance be demonstrated, which means fit tests must be performed to validate that fit was not altered. A relatively low concentration of viruses was used and higher log reductions (10^6) would be required for FDA approval. It is unclear how effective the decontamination method would have been 1) at higher virus concentrations; 2) if the virus had been suspended in respiratory secretions or other soiling agents; or 3) if the virus had been deposited on different surface types of the respirators.

3. TECHNICAL DESCRIPTION

3.1. FFR Decontamination and Reuse

3.1.1. Base Task 3: UVGI Exposure of N95 FFRs Contaminated with H1N1 Influenza

3.1.1.1. Overview

To build upon the 2011 *AJIC* study,[1] a preliminary assessment was performed to determine the optimal dose for UVGI decontamination effectiveness against influenza-contaminated FFR coupons. The optimal UV dose is the minimum dose resulting in no detectable viable virus. This assessment evaluated multiple UV doses under various soiling conditions – artificial saliva (mucin) and artificial skin oil (sebum). Once the optimized UVGI dose is determined, optimization will continue to reduce the time required for decontamination by increasing the UV intensity.

3.1.1.2. Materials and Methods

H1N1 Influenza

H1N1 influenza A/PR/8/34 (ATCC® VR-1469™) was propagated in embryonic chicken eggs (Charles River Premium Specific Pathogen Free Eggs 10100326, Wilmington, MA) using standard World Health Organization (WHO) protocols. Virus titers were determined by a median tissue culture infectious dose ($TCID_{50}$) assay. The host cells, Madin-Darby canine kidney (MDCK) cells (ATCC ® CCL-34™), were passaged and maintained using WHO-approved cell culture techniques.

Test Substrates

Circular coupons, 3.8-cm diameter, were prepared from 3M 1870 N95 FFRs using a tabletop arch punch. Respirator layers were held together using a staple on the outer edge of each coupon. A standard ballpoint ink pen was used to mark ten locations to be inoculated with the virus challenge.

Soiling Agents

Two soiling agents were used for this study – artificial saliva (mucin buffer) and artificial skin oil (synthetic sebum). Mucin buffer was prepared and stored at 4 °C. Synthetic skin oil (Scientific Services S/D; Sparrow Bush, NY) was purchased, divided into 2.5-mL aliquots, and stored at 37 °C until use. For testing, aliquots were heated to 70 °C and poured into the base of a 100-mm Petri dish which was rotated to spread the sebum evenly. The plate was then allowed to cool to room temperature.

Three soiling conditions were evaluated: no soiling agent, artificial saliva (mucin buffer), and artificial skin oil (sebum). Cytotoxity assays were performed for each soiling condition prior to virus testing. For mucin-treated coupons, five 1-µL droplets of mucin buffer were applied directly over each dried influenza inoculation, allowing approximately 10 minutes of drying between droplet applications. For sebum-treated coupons, a synthetic sebum overlay was prepared by pipetting 2.5 mL of liquefied sebum into a 100-mm Petri dish, which was then swirled to create an even monolayer. A sterile triangle-shaped spreader was used to collect the sebum from the Petri dish. The collected sebum was then spread over the inoculum area at a density of approximately 1.25 mg/cm^2.

UV Source

A Mineralight® XX-20S 20-W UV bench lamp was used to treat inoculated FFR coupons with UV light (**Figure 3**). The UV lamp was secured to the top of an acrylic box and three acrylic stands were placed inside the box to serve as platforms for the coupons during UV treatment. The heights of the acrylic stands vary based on their position along the UV bulb. As distance increases from the center of the UV bulb, the UV output decreases. Similarly, as distance increases from the bulb in a perpendicular direction, the UV output also decreases. Thus, to

ensure all three coupons receive similar UV doses during a test, the two outer acrylic stands are taller than the center stand to account for the loss in UV output along the axis of the bulb.

A UVX radiometer with a UVX-25 probe was used to measure and validate UV output at the positions where the coupons were placed. Preliminary validation testing demonstrated an average UV output of 4.2 ± 0.0 mW/cm^2 between all three coupon locations (**Table 2**).

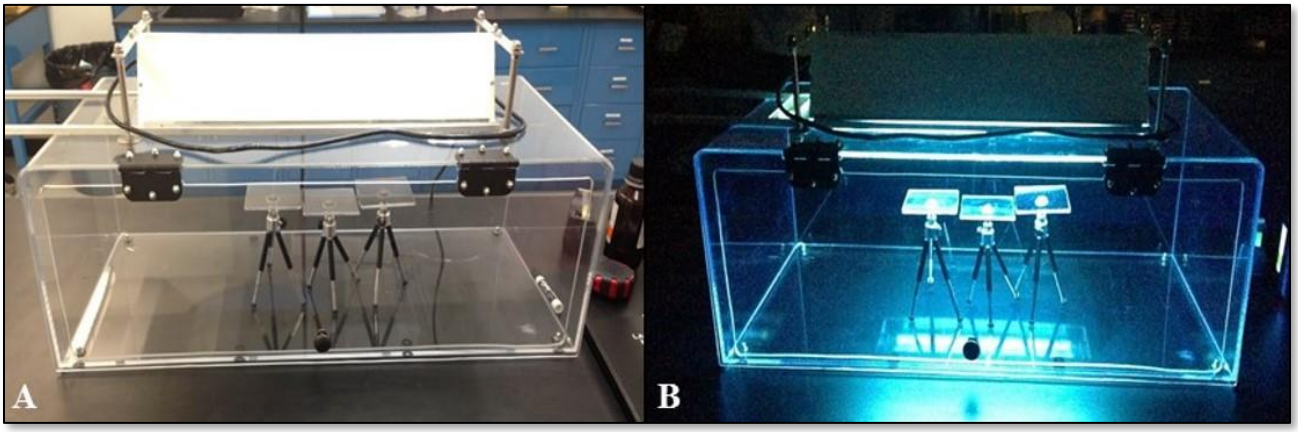


Figure 3. UV device: A) Power off, B) Power on.

Table 2. Validation of UV Dose.

Distance from center (in.)	Distance from lamp (in.)	Exposure (mW/cm^2)
0.0	5.0	7.0
4.0	4.5	7.0
4.0	4.5	7.0

Decontamination Studies

For each test, six FFR coupons were each inoculated with ten 1-µL droplets of virus within a 2 cm^2 area and allowed 15 minutes to dry. All six FFR coupons were treated similarly with the same soiling agent (if used). Three of the six inoculated coupons were treated with UV, while the remaining three inoculated control coupons were held at room temperature in a biological safety cabinet until UVGI treatment of the UV-treated coupons was complete. Four UV doses were evaluated: 1×10^3, 5×10^5, 1×10^6, and 2×10^6 µJ/cm^2.

After UV treatment, all six coupons were each placed in a 50-mL tube containing 15-mL of virus maintenance media using sterile forceps and vortexed for 20 min. Following this process, coupons were manually pressed using a cell scraper against the inner wall of the 50-mL tube to squeeze out as much liquid as possible, then removed and discarded. An aliquot of the extraction sample was ten-fold serially diluted in dilution medium and inoculated onto the host cells using a median tissue culture infectious dose ($TCID_{50}$) assay. To maximize the assay sensitivity, the entire recovery solution from each coupon was inoculated onto host cells. Inoculated plates were

incubated at 36 ± 2 °C in 5 ± 3% CO_2 for 4 – 6 days for influenza virus stains and 4 – 9 days for coronavirus strains. Infectivity was determined by visual observation of cytopathic effect.

Data Analysis

The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the Spearman-Karber method. In the case where a sample contains no detectable virus, a statistical analysis was performed based on a Poisson distribution to determine the theoretical maximum possible titer for that sample. The test results are reported as the reduction of the virus titer due to treatment with UV, expressed as log_{10}. Statistical comparisons between data sets were performed using an unpaired, two-tailed *t*-test.

3.1.1.3. Results

For all three soiling conditions, influenza viability decreased significantly as the UV dose increased (**Figure 4**). No viable virus was detected after UV treatment ≥ 1 J/cm^2. Based on the control coupons, virus recovery was significantly lower for soiled coupons ($p < 0.0001$) than non-soiled coupons.

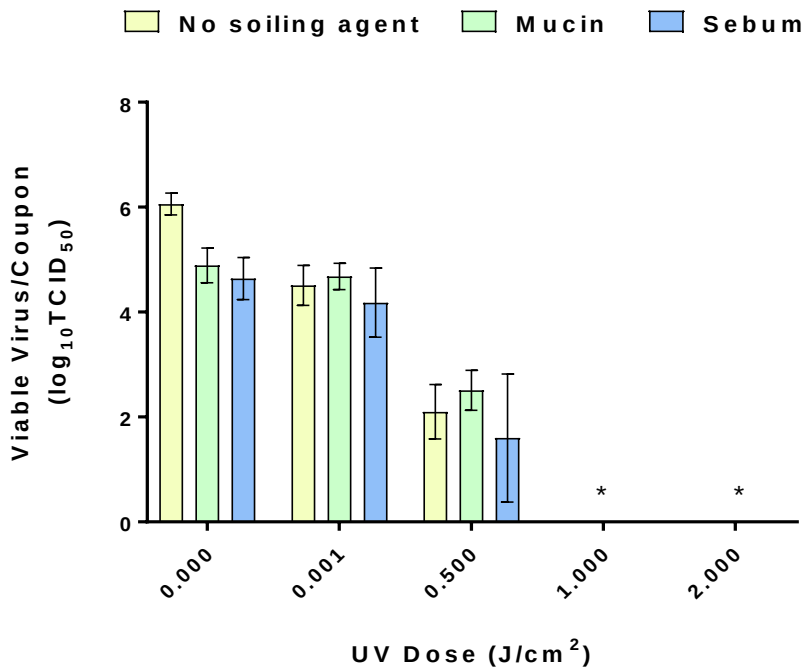


Figure 4. Recovery of viable H1N1 influenza from UVGI-treated FFR coupons. (* = Below Detection Limit)

3.1.1.4. Discussion/Conclusions

Discussion

The completed data set demonstrates a direct relationship with UV dosage and influenza decontamination. Soiled coupons give an extra layer of protection, reducing the germicidal capability of UV by approximately 1 – 2 log. As UV increases from 1×10^6 µJ/cm^2 to 2×10^6 µJ/cm^2, there is a minimal increase in log reduction value (LRV), influenced by a few limiting factors, mainly virus recovery. The maximum LRV is based upon the amount of viable virus recovered from the control coupons. If an inoculated coupon is exposed to UV and shows no viable virus remaining, the maximum measurable LRV is achieved; a higher UV dose will also show no viable virus remaining, but cannot demonstrate a higher LRV. Because the maximum LRV was reached using the 1×10^6 µJ/cm^2, a higher dose is not required, but could be used to shorten overall exposure time.

Conclusions

A UV dose of 1 J/cm^2 was found to be the minimum dose providing maximum disinfection under these study conditions.

3.1.2. Base Task 4: UVGI Decontamination of 15 FFR Models

3.1.2.1. Overview

Using the optimal UV dose defined by the previous task (1 J/cm^2), a UV exposure device was developed to deliver this UV dose in the quickest timeframe possible in a 360° orientation around an FFR. Once the device was developed and validated, 15 N95 FFR models contaminated with H1N1 influenza in multiple locations and in the presence of either artificial saliva or artificial skin oil were UV treated and assessed for decontamination efficacy. A description of this task was published in the *American Journal of Infection Control*.[19]

3.1.2.2. Materials and Methods

H1N1 Influenza

H1N1 influenza A/PR/8/34 (ATCC® VR-1469™) was propagated in embryonic chicken eggs (Charles River Premium Specific Pathogen Free Eggs 10100326, Wilmington, MA) using standard World Health Organization (WHO) protocols. Virus titers were determined by a median tissue culture infectious dose ($TCID_{50}$) assay. The host cells, Madin-Darby canine kidney (MDCK) cells (ATCC ® CCL-34™), were passaged and maintained using WHO-approved cell culture techniques.

Soiling Agents

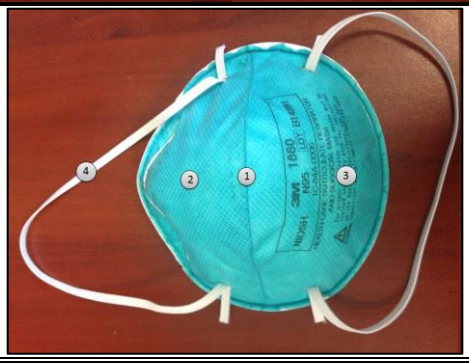
Artificial saliva buffer was prepared and stored at 4 °C.[20] Synthetic skin oil (Scientific Services S/D, Sparrow Bush, NY) was purchased and divided into 1.5-mL aliquots, then stored at 37 °C.

For each test, an aliquot would be heated to 70 °C and poured into the basin of a 100-mm Petri dish. Continual heat was applied until the layer became even and allowed to cool.

N95 FFRs

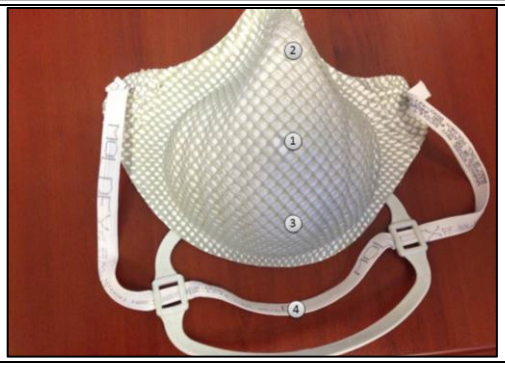
Fifteen commercially available N95 FFR models were chosen for this study based upon FDA regulation, commercial availability, and for their unique shapes and materials (**Table 3**). Fourteen models are FDA-cleared; the fifteenth model, Moldex EZ-22, is not currently FDA-cleared. Six replicates per model were tested for each soiling condition – three UV treated and three non-treated (controls). Each replicate was inoculated with influenza and soiling agent on four unique locations that corresponded to the nose, mouth, chin, and strap of the respirator.

Table 3. Fifteen N95 FFR Models.

N95 FFR Model	Inoculated Surfaces
3M 1870	
3M 1860	
Kimberly-Clark PFR	

Moldex 1512	
Precept 65-3395	
Gerson 1730	
Sperian HC-NB095	

U.S. Safety AD2N95A	
Moldex 1712	
U.S. Safety AD4N95	
3M VFlex 1805	
Alpha Protech 695	

Prestige Ameritech RP88020	
Sperian HC-NB295F	
Moldex EZ-22	

UVGI Device

An effective UVGI dose of 1×10^6 µJ/cm^2 using FFR coupons was determined in Task 3, serving as the basis for establishing a target dose 1×10^6 µJ/cm^2 in under one minute for whole-FFR decontamination in Task 4. Although UVGI devices are commercially available, none have the capacity to reach the target dose within one minute. To achieve the target dose, a laboratory-scale UVGI was built for the purpose of N95 whole-FFR decontamination. Eight 32” 254-nm UV-C bulbs rated as 390 µW/cm^2 at 1 m were obtained (Fresh-Aire UV, Jupiter, FL). These bulbs were arranged within a chamber constructed of aluminum sheet metal (Alloys 6061-T6 and 2024-T3, OnlineMetals.com, Seattle, WA) measuring 16” W × 12” H × 40” L with an extended tunnel measuring 8” W × 6” H × 18” L (**Figure 5, Figure 6**).

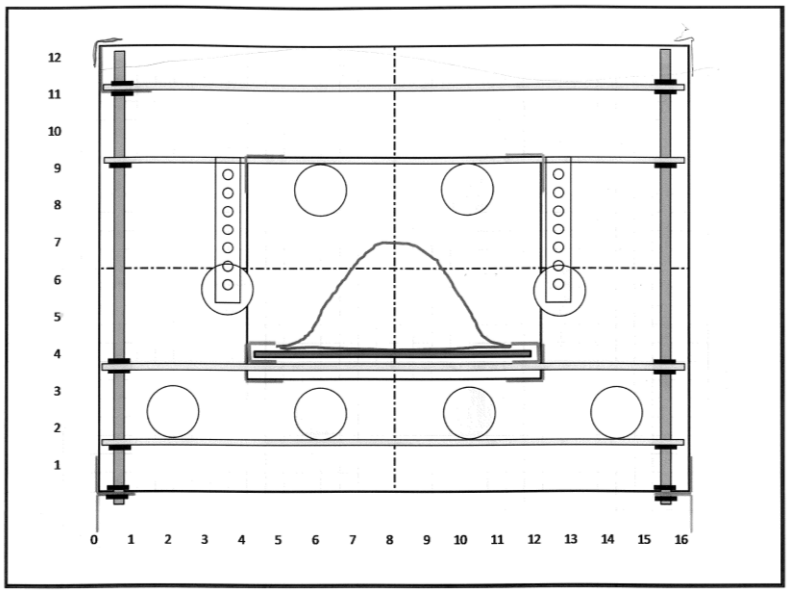


Figure 5. UVGI Device - Coronal Cross-Section.

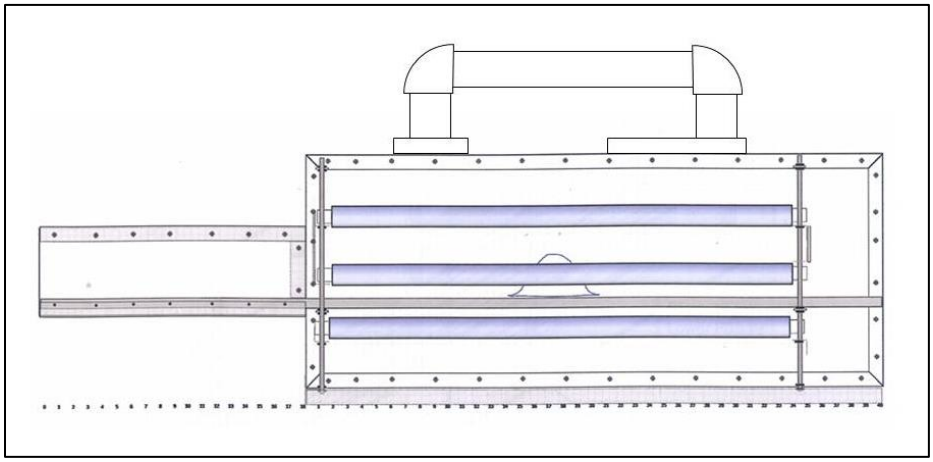


Figure 6. UVGI Device – Sagittal Cross-Section.

Respirators were centered on a 24" L wire rack and then centered within the chamber. The UVGI device also included a heat dampening system consisting of a RTE-140 bath circulator (Neslab, Portsmouth, NH), AS06-16G01SB and AS06-08G01SB heat exchangers (AMS Technologies, Martinsried, DEU), two 80-mm 70-CFM double ball bearing high airflow fans (Vantec, Fremont, CA), and both polyvinylchloride and aluminum materials to create an airflow tunnel to circulate chilled air within the chamber (**Figure 7**).

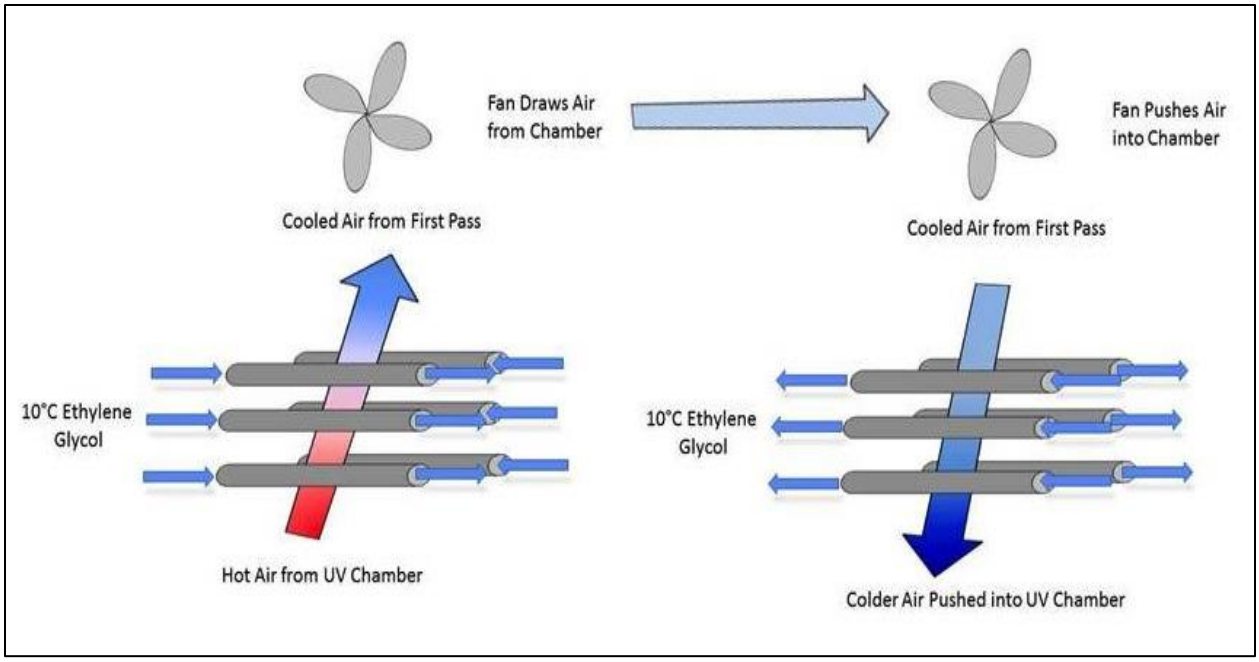


Figure 7. UVGI Chamber Cooling System.

The UVGI device was monitored for UV irradiance and temperature during each test using an ILT-1254/W radiometer (International Light Technologies, Peabody, MA) and an OM-EL-USB-2 temperature and humidity data logger (Omega Engineering, INC. Stamford, CT). Based on validation testing of the chamber, a reference point was used for monitoring each test to ensure the UV exposure and temperature remained consistent between tests (**Figure 8**).

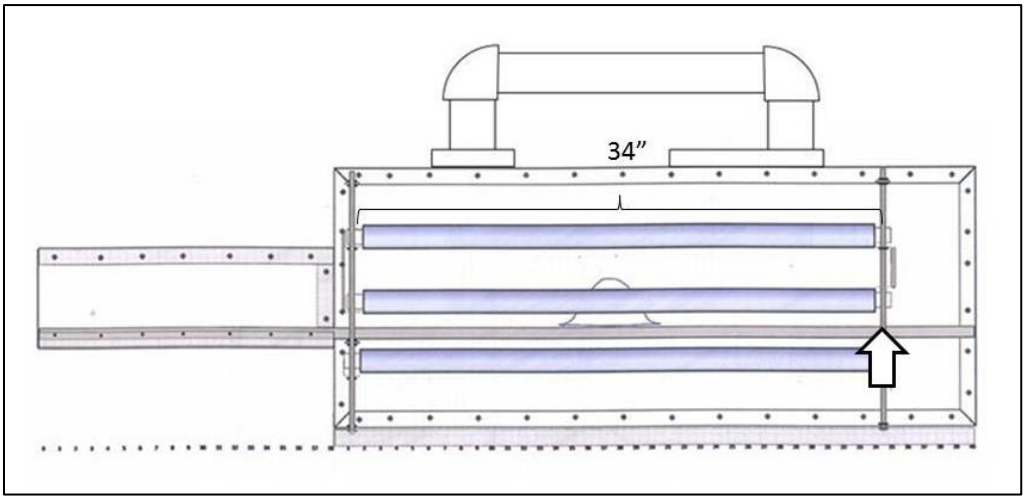


Figure 8. UV Radiometer Location within UVGI Chamber.

N95 FFR Cleaning Study

For each test, FFRs were inoculated in a Class II biological safety cabinet (BSC) with ten 1-µL droplets of ~10^9 $TCID_{50}$/mL H1N1 influenza onto each of the four surfaces selected for inoculation (**Table 3**). Inoculated surfaces were allowed to dry in the BSC at room temperature for approximately 10 minutes. After the droplets had dried, a soiling agent (synthetic skin oil or artificial saliva buffer) was applied over each inoculated surface to act as a protective factor. The synthetic skin oil was applied in a solid state using a triangle-shaped cell spreader to apply approximately 2.5 mg to the inoculated area. The artificial saliva buffer was applied in liquid form with five 1-µL droplets over each influenza inoculum droplet. The artificial saliva was allowed approximately 10 minutes to dry between applications.

For each test, the circulating bath was turned on to chill ethylene glycol to 10 °C, and fans initiated to circulate the air within the chamber. The UV lamps were turned on and allowed to warm up for 60 seconds. Each contaminated test mask was individually placed on the UVGI exposure rack and exposed for 70 seconds, except for the 3M 1870 and 1860 models which were exposed for 60 seconds to account for variability in UV output. The center of the chamber reached an irradiance of 16–18 mW/cm^2, equating to a dose of 1.0–1.2 × 10^6 µJ/cm^2. After exposing the mask, the UV lamps would then be turned off for five minutes to keep the chamber temperature at 22.5 ± 1 °C and maintain a consistent UV irradiance. After UV treatment of all three test masks, 1.5-cm^2 coupons were cut from the inoculated areas of both the UV-exposed respirators and control respirators using a steel punch (McMaster-Carr, Santa Fe Springs, CA) and 6-ton bench press (Northern Tool, Burnsville, MN). Strap coupons consisted of the entire strap and made by cutting the strap at point of attachment. Coupons were each placed in a 50-mL tube containing 15 mL of serum-free EMEM and mixed using a multi-tube vortexer for 20 minutes. Samples were stored at 4 °C when not being vortexed.

Extractions were serially diluted in 1:10 ratio in serum-free EMEM and subsequently plated into 24-well plates with confluent monolayers of MDCK cells. Plates were incubated at 37 °C in 5% CO_2 for one hour. After the one-hour incubation, 0.1 mL of an EMEM-1% BSA-trypsin mixture was added to each well to promote virus infectivity. The plates were then incubated at 37 °C in 5% CO_2 for seven days. After the incubation period, each well was observed under a microscope for cytopathic effects (CPE) demonstrated by the disruption of the cell monolayer.

Data Analysis

UV dose was calculated based on standard methods for mathematical modeling of UVGI using Equation 1.[6]

$$\text{UV dose}\left(\frac{\mu J}{cm^2}\right) = \text{Irradiance}\left(\frac{mW}{cm^2}\right) \times \text{Time (s)} \qquad \text{(Eq. 1)}$$

To determine the level of viable virus recovered from each sampled location, the Spearman-Kärber formula was used to calculate the $TCID_{50}$ values.[21] Log reduction values were calculated using Equation 2.

$$\text{Log reduction value} = R_C - R_U \quad \text{(Eq. 2)}$$

R_C = Mean viable recovery from control coupons (log $TCID_{50}$)
R_U = Viable recovery from UV-exposed coupon (log $TCID_{50}$)

3.1.2.3. Results

UVGI performance varied considerably for all 15 FFR models tested with log reductions ranging from 0.00–4.85 $\log_{10}$ $TCID_{50}$, based on inoculation location, soiling agent, and control recovery. Based on viable recoveries from facemask materials, the Moldex EZ-22 had the highest mean log reduction when soiled with artificial skin oil (> 4.48 $\log_{10}$ $TCID_{50}$), while the 3M 1860 had the highest mean log reduction when soiled with artificial saliva (4.79 ± 0.05 $\log_{10}$ $TCID_{50}$). Based on viable recoveries from straps, the Kimberly-Clark PFR had the highest mean log reduction when soiled with artificial saliva (4.26 ± 0.00 $\log_{10}$ $TCID_{50}$), while the U.S. Safety AD4N95 had the highest mean log reduction when soiled with artificial skin oil (4.35 ± 0.00 $\log_{10}$ $TCID_{50}$).

Table 4. UVGI Decontamination Results for 15 N95 FFR Models using Whole FFRs.

FFR Model	Soiling Agent	Log Reduction Values (LRV) Mouth	Nose	Chin	Average	Strap
3M 1870	Mucin	4.37 ± 0.83	4.68 ± 0.00	4.35 ± 0.00	4.47 ± 0.19	2.48 ± 1.11
	Sebum	4.26 ± 0.00	3.79 ± 0.83	3.79 ± 0.83	3.95 ± 0.28	3.23 ± 1.00
3M 1860	Mucin	4.85 ± 0.00	4.76 ± 0.00	4.76 ± 0.00	4.79 ± 0.05	1.08 ± 0.29
	Sebum	4.68 ± 0.00	4.76 ± 0.00	4.01 ± 0.00	4.49 ± 0.41	2.14 ± 1.11
Kimberly-Clark PFR	Mucin	4.43 ± 0.00	4.26 ± 0.00	4.60 ± 0.00	4.43 ± 0.17	4.26 ± 0.00
	Sebum	3.83 ± 0.00	4.00 ± 0.00	3.83 ± 0.00	3.89 ± 0.10	3.42 ± 0.87
Moldex 1512	Mucin	3.76 ± 0.00	3.76 ± 0.00	3.76 ± 0.00	3.76 ± 0.00	3.45 ± 0.54
	Sebum	4.43 ± 0.00	4.51 ± 0.00	4.18 ± 0.00	4.37 ± 0.17	2.95 ± 0.83
Precept 65-3395	Mucin	4.60 ± 0.00	4.60 ± 0.00	4.68 ± 0.00	4.62 ± 0.05	4.12 ± 1.11
	Sebum	3.43 ± 0.00	2.53 ± 1.26	2.79 ± 0.97	2.92 ± 0.46	3.43 ± 0.00
Gerson 1730	Mucin	1.42 ± 0.29	1.58 ± 0.29	1.42 ± 0.14	1.47 ± 0.10	2.73 ± 1.24
	Sebum	1.50 ± 0.76	1.17 ± 0.52	2.39 ± 1.38	1.69 ± 0.63	2.42 ± 0.29
Sperian HC-NB095	Mucin	1.83 ± 0.14	1.67 ± 0.00	1.00 ± 0.52	1.50 ± 0.44	3.01 ± 0.00
	Sebum	1.58 ± 0.66	1.42 ± 0.14	0.75 ± 0.38	1.25 ± 0.44	3.43 ± 0.00
U.S. Safety AD2N95A	Mucin	2.08 ± 0.14	1.42 ± 0.14	0.75 ± 0.43	1.42 ± 0.67	0.25 ± 0.38
	Sebum	2.81 ± 1.05	2.25 ± 0.14	2.87 ± 0.97	2.64 ± 0.34	1.17 ± 0.25
Moldex 1712	Mucin	4.01 ± 0.00	3.85 ± 0.00	3.29 ± 0.83	3.72 ± 0.38	2.93 ±0.00
	Sebum	4.51 ± 0.00	4.56 ± 0.00	3.14 ± 0.91	4.07 ± 0.80	2.56 ± 1.00

> 3 LRV
< 3 LRV (low control recovery)
< 3 LRV (high variability)
< 3 LRV

The Gerson 1730, Sperian HC-NB095, U.S. Safety AD2N95A, 3M VFlex 1805, and Precept 65-3395 models demonstrated < 3 log reduction for facemask inoculations. The log reduction for the 3M VFlex was limited by low control recovery. Respirator straps had a high degree of variability due to low control recovery on two models and potential variability causes such as shadowing effects. The only models that demonstrated >3 log reductions on straps for both soiling agents were the Sperian HC-NB095, Kimberly-Clark PFR, Precept 65-3395 and Prestige Ameritech RP88020. Unlike their respirator material counterparts, the Kimberly-Clark PFR and Precept 65-3395 did not demonstrate full decontamination on strap materials.

3.1.2.4. Discussion/Conclusions

Discussion

UVGI was shown to be effective (≥ 3 mean log reduction) for the facemask material of 11 FFR models and the straps of 4 FFR models. UVGI efficacy is dependent upon direct exposure to the target surface for decontamination and is influenced by the presence of soiling agents, surface type, and the design of the UVGI device. Based on observation, a number of respirator models have materials that demonstrated hydrophilic characteristics when inoculated, such as the facemask material of the Gerson 1730, Sperian HC-NB095 and U.S. Safety AD2N95A models or the strap material of the 3M 1860, U.S. Safety AD2N95A, Prestige Ameritech RP 88020and Alpha Protech 695 models. All of these seemingly hydrophilic surfaces showed consistent mean log reduction < 3 $\log_{10}$ $TCID_{50}$, except for the Prestige Ameritech RP 88020. The strap material for this model is relatively thin compared to the other strap materials, meaning that UV was potentially able to penetrate from both sides to inactivate the virus. Conversely, seemingly hydrophobic materials consistently demonstrated a mean log reduction >3 $\log_{10}$ $TCID_{50}$. In particular the 3M 1860, 3M 1870 and Kimberly-Clark PFR models shared similar material construction that likely contributed to increasing the UVGI performance. Very often strap materials that were hydrophobic would still demonstrate recoverable virus after UV exposure. At times, the strap materials would contort and twist and either move underneath the respirator facing away from UV light or lay inoculation side down onto the wire rack, limiting UV exposure. Future design iterations of the UVGI chamber will need to account for strap position and movement.

Consistent UV performance is an important metric to monitor when performing UV decontamination studies. Fractional differences in performance over time can build up to cause differences in dosage. During this study, radiometer data indicated a slight decrease in UV output, prompting an adjustment from a 60-seconds exposure time for the 3M 1870 and 3M 1860S models to 70 seconds for the other 13 models tested. Additionally, temperature must be monitored to ensure consistent UV performance. Incorporation of the cooling system was required to maintain the UV chamber temperature at the proper level to provide optimal UV performance. Also, an increase in environmental temperature in the laboratory led to an increase in temperature within the UV chamber, increasing the dose from 1×10^6 to 1.2×10^6 µJ/cm^2. Temperature influences from the environment must be accounted for if the UVGI exposure device cannot adequately control internal temperature.

It is important to note that the findings of this study do not qualify or quantify the effectiveness of each N95 FFR model's capabilities as a respiratory protection device, nor does this study examine the current standards of N95 FFRs and their subsequent effectiveness. It only examines the effectiveness of UVGI decontamination of H1N1 influenza on 15 N95 FFR models.

Conclusions

Decontamination of influenza in the presence of soiling agents on N95 FFRs can be effective, but is dependent on the material being treated. The shapes of respirators, their materials, and UV light arrangement can significantly affect decontamination efficacy.

3.1.3. Base Task 5: FFR Durability and Performance after Multiple UVGI Cycles

3.1.3.1 Overview

Fifteen N95 FFR models were exposed to 10 UVGI cycles using the optimized dose of 1 J/cm^2 per cycle. Subsequently, 6 of the 15 FFR models were treated with 20 UVGI cycles. FFRs were donned/doffed between each UVGI cycle to simulate actual use. After UVGI treating the FFR models in triplicate, ARA staff traveled to the National Personal Protective Technology Laboratory of the National Institute for Occupational Safety and Health (NIOSH-NPPTL) in Pittsburgh, PA to conduct durability and performance testing.

3.1.3.2 Materials and Methods

Test respirators

Fifteen N95 FFR models were evaluated for durability and function after being treated with 10 UVGI cycles using the ARA-designed UVGI chamber described previously (**Table 5**). Subsequently, six N95 FFR models were evaluated for durability and function after being treated with 20 UVGI cycles using the same UVGI chamber.

Table 5. N95 FFR Models Tested.

10 UVGI cycles	20 UVGI cycles
3M 1860	3M 1860
3M 1870	3M 1870
3M VFlex 1805	3M VFlex 1805
Alpha Protech 695	Kimberly-Clark PFR
Gerson 1730	Moldex 1512
Kimberly-Clark PFR	U.S. Safety AD4N95
Moldex 1512	
Moldex 1712	
Moldex EZ-22	
Precept 65-3395	
Prestige Ameritech RP88020	
Sperian HC-NB095	
Sperian HC-NB295	
U.S. Safety AD2N95A	
U.S. Safety AD4N95	

For the 10-cycle treatments, four conditions were evaluated for each FFR model in triplicate (**Table 6**). For each cycle, an FFR was placed into the UVGI chamber, treated with 1.0 – 1.2 J/cm^2 over the course of 70 seconds, removed from the chamber and donned onto a medium-sized headform with a 22" circumference (Only Mannequins; East Orange, NJ). Once the respirator was donned on the headform for 5 minutes, the respirator was then doffed. For the 20-cycle treatments, Condition B was not included in the test plan.

Table 6. N95 FFR Test Conditions.

Variables	Conditions A	B	C	D
UV-exposed strap	+	-	-	-
UV-exposed mask	+	+	-	-
Donning and doffing	+	+	+	-

FFR durability testing

For each FFR model, durability and functionality was assessed by evaluating strap elasticity, NaCl particle penetration, breathing resistance, and fit factor. Strap elasticity was determined via the use of an Imada force tester (Imada, Northbrook, IL) with either an 11-lbf or a 220-lbf gauge. Duplicate 12-cm strap coupons from Condition A, B, and C respirators were pulled five times to 200% their original length and held for 5 minutes; strap coupons from Condition D respirators were pulled 15 times in similar fashion to approximate the 10 donning/doffing cycles experienced by the straps from Conditions A–C respirators.

For particle penetration and breathing resistance measurements, a TSI 8130 automated filter tester (TSI, Shoreview, MN) was used to generate a polydisperse NaCl aerosol with a count median diameter of 0.075 μm and a concentration of 12–20 mg/m^3 (**Figure 9**). Respirators were waxed to a Plexiglas plate with a central 2.25" diameter opening to allow passage of the NaCl aerosol. Using vacuum grease, the plate was then sealed into a Plexiglas enclosure to contain the aerosol and placed into the TSI 8130 for penetration testing. Penetration tests were performed using a flow rate of ~85 LPM. The maximum penetration allowed for a N95 is 5% to be considered a passed test. For breathing resistance, the maximum resistance allowed per 42 CFR part 84 is 25 mmH_2O.

Figure 9. Automated Filter Tester 8130.

For fit testing, a static advanced headform (StAH) connected to an automated breathing machine was used which simulates human respiratory functions and consequently allows fit testing to be performed without a human subject. The headform (**Figure 10**) is located within a Plexiglas chamber connected to a tube, simulating a trachea, which connects to a breathing simulator (**Figure 11**). Respirators donned onto a StAH were connected to a TSI Portacount 8038 (**Figure 12**). Two StAHs were used for this study – medium and large – depending on each respirator model's ability to achieve fit on a given StAH.

Figure 10. Fit Test Static Headform During Fit Test.

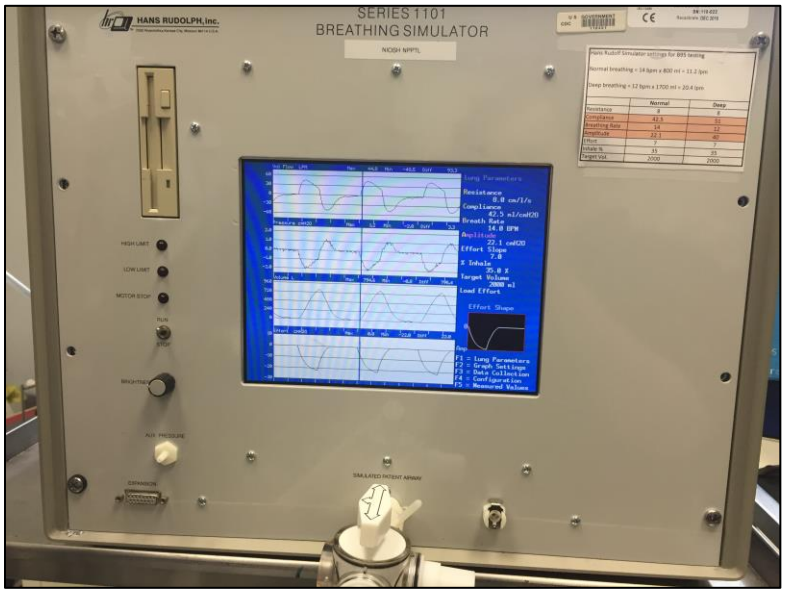


Figure 11. Hans Rudolph Series 1101 Breathing Simulator

Figure 12. TSI Portacount 8038.

Prior to the fit test, the breathing simulator was set to simulate normal breathing (11.2 LPM) through the StAH. A polydispersed NaCl aerosol was generated and dispersed inside the Plexiglas chamber ($2.0 \pm 0.5 \times 10^3$ particles/cm^3) while HEPA-filtered compressed air (30 LPM) was fed into the chamber, providing particle dilution and air circulation. After ensuring the proper aerosol concentration, a respirator was then donned and adjusted for fit until a fit factor above 200, the upper limit of the Portacount display in N95 mode, was reached. If a respirator's fit factor stayed above 200 for 30 seconds, the fit test was initiated. If a respirator's fit was above 100, the minimum passing score, but below 200, the respirator remained in place for 2 minutes before the fit test was initiated. This excess time allowed any particles trapped in the sampling tubes to be expelled before measurement began for the fit test. FFR models that could not reach a fit factor of 100 or above on the medium headform were subsequently trialed on the large headform. The headform size that demonstrated the better fit was used for the full evaluation. If a fit factor ≥ 100 could not be demonstrated by either headform, three fit attempts were performed for each of three control FFRs on the medium-sized headform to ensure the model was adequately trialed. Each donning period was a maximum of 10 minutes to allow adjustment for improving the fit factor. If a fit factor > 100 could not be achieved within the three fit attempts, an actual fit test was not performed.

The fit test went through three consecutive phases: 80 seconds of normal breathing (11.2 LPM; Figure 5.4), 80 seconds of deep breathing (20.4 LPM; Figure 5.5), and 80 seconds of normal breathing. Breathing rates during sedentary and light work rates are considered to be ~10 LPM and ~20 LPM, respectively. The harmonic mean of the fit factors from all three breathing phases determined the overall fit factor.

Data Analysis

Using the fit test data generated by the PortaCount 8038, the geometric mean fit factors and associated 95% confidence intervals were calculated for each condition tested. Fit factors are determined by taking the ratio of the concentration of particles outside the respirator to the concentration inside the respirator. As the concentration inside the respirator approaches zero, the fit factor number can increase by many orders of magnitude. For the particle penetration and air flow resistance measurements, the arithmetic mean and standard deviation were calculated for each condition. Data across all conditions tested for each FFR model were compared using a one-way ANOVA with a Tukey post-test.

3.1.3.3 Results

Strap testing

The peak force required to pull untreated FFR straps from 15 FFR models to 200% extension on the initial pull ranged from 3.1 – 15.1 Newtons (N), except for the U.S. Safety AD2N95A and the Moldex EZ-22 models which required 66.3 N and 117.5 N, respectively (**Figure 13**). All force curves were relatively similar in shape over the course of 15 pulls – an initial decline in peak force which then leveled out after approximately 4 – 5 pulls.

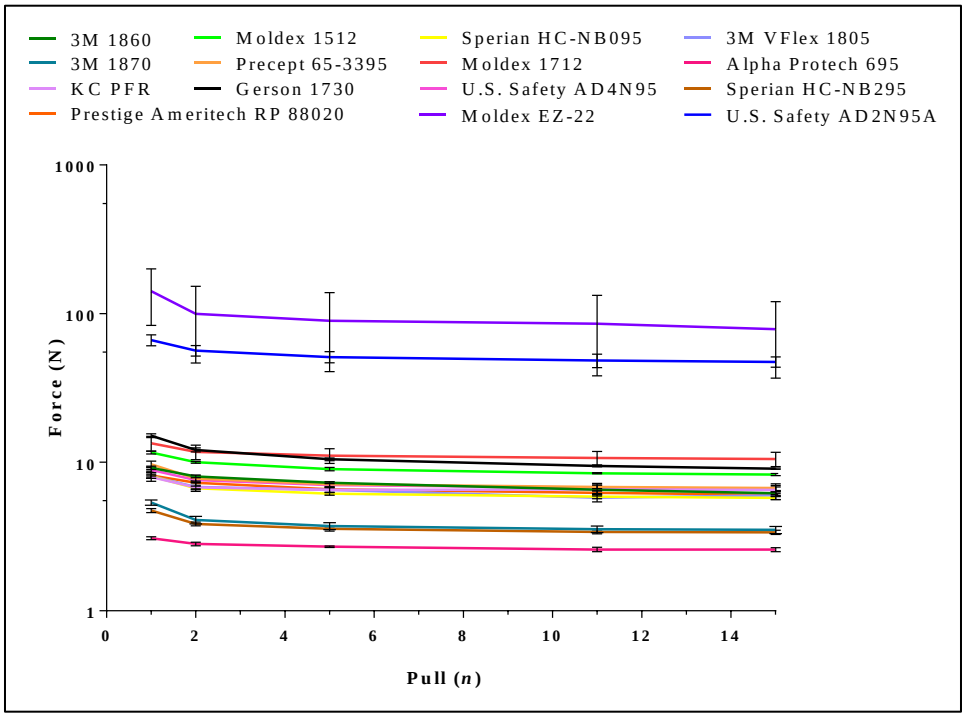


Figure 13. Mean Peak Force Data for Untreated Straps from 15 FFR Models Across 15 Pulls.

The mean peak force demonstrated by each condition tested using 15 FFR models after 10 UVGI cycles is presented in (**Figure 14**). Using this data, a statistical comparison across the four

conditions tested indicated a significant difference for seven of the 15 FFR models tested (**Table 7**). Of these seven FFR models, all indicated a significantly higher peak force for untreated straps compared to at least one of the other conditions tested. All 15 FFR models tested – except for the Moldex 1512 – showed no significant difference between UV-treated and non-UV-treated donned FFR straps.

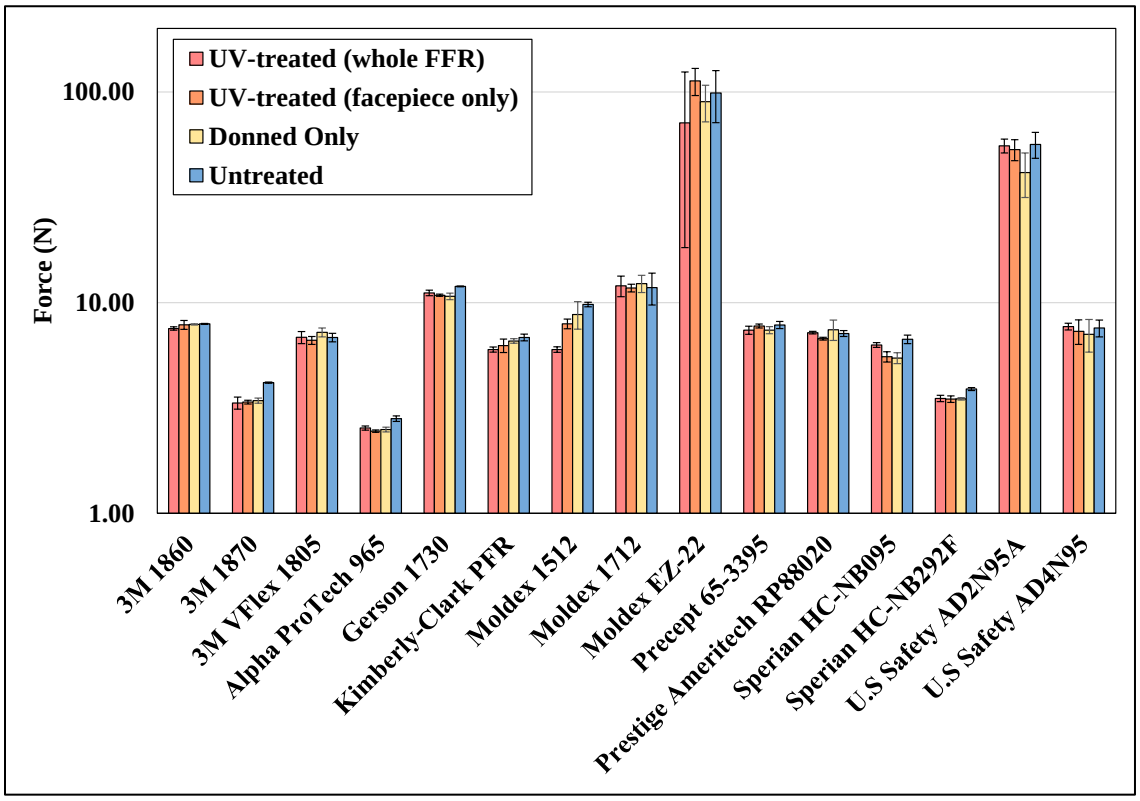


Figure 14. Mean Peak Force for FFR Straps from 15 FFR Models after 10 UVGI Cycles.

Table 7. Statistical Comparison of Mean Peak Force between Conditions Tested for FFR Straps from 15 FFR Models after 10 UVGI Cycles.

FFR Model	P-value
3M 1860	0.17
3M 1870	<0.0001
3M VFlex 1805	0.29
Alpha ProTech 965	0.0005
Gerson 1730	0.002
Kimberly-Clark PFR	0.03
Moldex 1512	0.001
Moldex 1712	0.95
Precept 65-3395	0.20
Prestige Ameritech RP88020	0.34

Sperian HC-NB095	0.003
Sperian HC-NB292F	0.002
U.S Safety AD2N95A	0.12
U.S Safety AD4N95	0.82
Moldex EZ-22	0.51

The mean peak force demonstrated by each condition tested using six FFR models after 20 UVGI cycles is presented in (**Figure 15**). Using this data, a statistical comparison between the three conditions indicated a statistically significant difference for three of the six FFR models (**Table 8**). Of these three FFR models, the mean peak force for the untreated straps was significantly higher than at least one other condition for the 3M 1870 and Moldex 1512, while the mean peak force for the UV-treated straps of the Kimberly-Clark PFR were significantly lower than the donned only straps. Other than the Kimberly-Clark PFR, there was no significant difference between UV-treated and non-UV-treated donned straps for the six FFR models tested after 20 UVGI cycles.

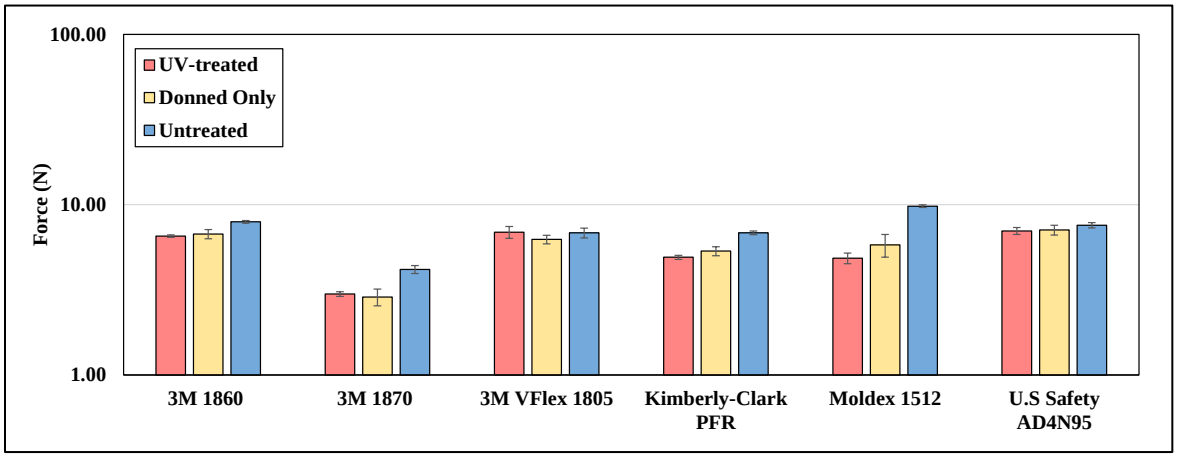


Figure 15. Mean Peak Force Data for FFR Straps from Six FFR Models after 20 UVGI Cycles.

Table 8. Statistical Comparison of Mean Peak Force Data between Conditions Tested for FFR Straps from Six FFR Models after 20 UVGI Cycles.

FFR Model	P-value
3M 1860	0.60
3M 1870	0.03
3M VFlex 1805	0.25
Kimberly-Clark PFR	0.01
Moldex 1512	0.002
U.S Safety AD4N95	0.27

Comparing the mean peak data for untreated FFR straps from six FFR models treated with 0, 10, and 20 donning/doffing cycles (**Figure 16**), five FFR models indicated a statistically significant difference (**Table 9**). The mean peak force demonstrated by untreated straps was significantly higher than FFR straps treated with 10 donning/doffing cycles for the 3M 1870 model only and significantly higher than FFR straps treated with 20 donning/doffing cycles for the 3M 1860, 3M 1870, Kimberly-Clark PFR, and Moldex 1512. The mean peak force demonstrated by FFR straps treated with 10 donning/doffing cycles was significantly higher than those treated with 20 donning/doffing cycles for the 3M 1860, 3M VFlex 1805, Kimberly-Clark PFR, and Moldex 1512 models.

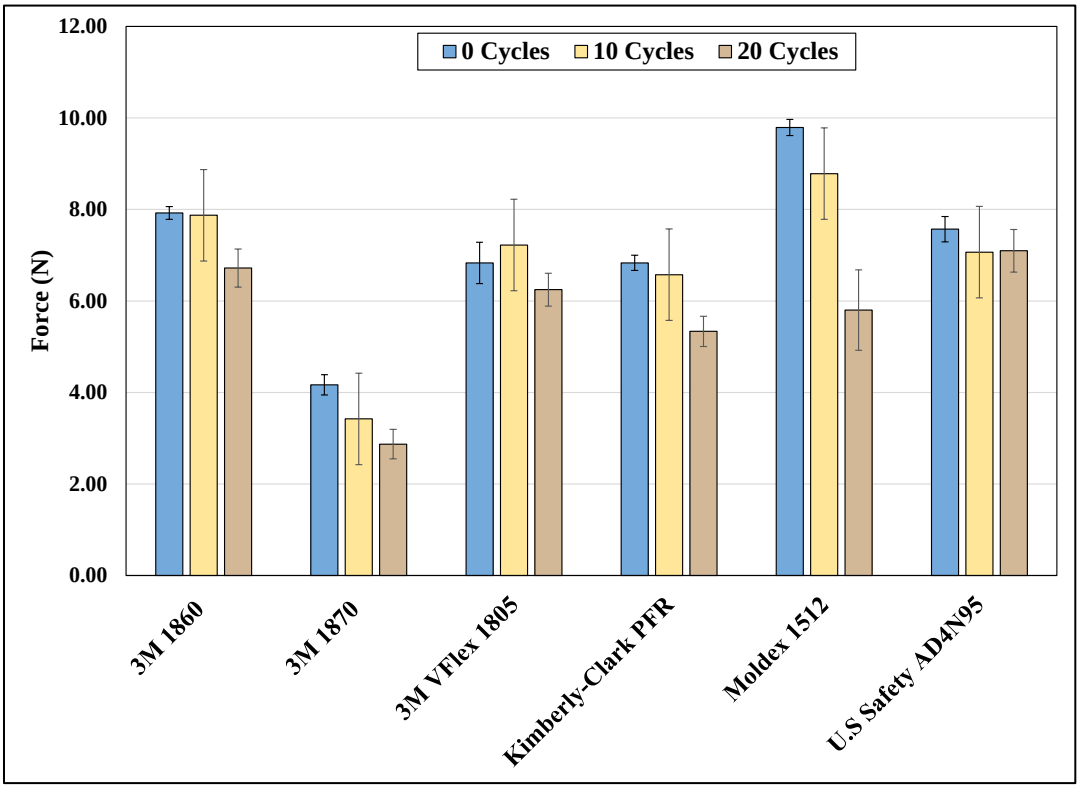


Figure 16. Mean Peak Force for Non-UV-treated FFR Straps from Six FFR Models Treated with Multiple Donning Cycles Only.

Table 9. Statistical Comparison of Mean Peak Force for Non-UV-treated FFR Straps from Six FFR Models Treated with Multiple Donning Cycles Only.

FFR Model	P-value
3M 1860	0.008
3M 1870	0.001

3M VFlex 1805	0.048
Kimberly-Clark PFR	0.004
Moldex 1512	0.0004
U.S Safety AD4N95	0.59

Comparing the mean peak data for UVGI-treated FFR straps from six FFR models treated with 0, 10, and 20 cycles of donning/doffing (**Figure 17**), four FFR models indicated a statistically significant difference (**Table 10**). The mean peak force demonstrated by untreated straps was significantly higher than UVGI-treated FFR straps treated with both 10 and 20 donning/doffing cycles for the 3M 1860, 3M 1870, Kimberly-Clark PFR, and Moldex 1512 models. The mean peak force demonstrated by UVGI-treated FFR straps treated with 10 donning/doffing cycles was significantly higher than those treated with 20 donning/doffing cycles for the 3M 1860, 3M 1870, and Kimberly-Clark PFR models.

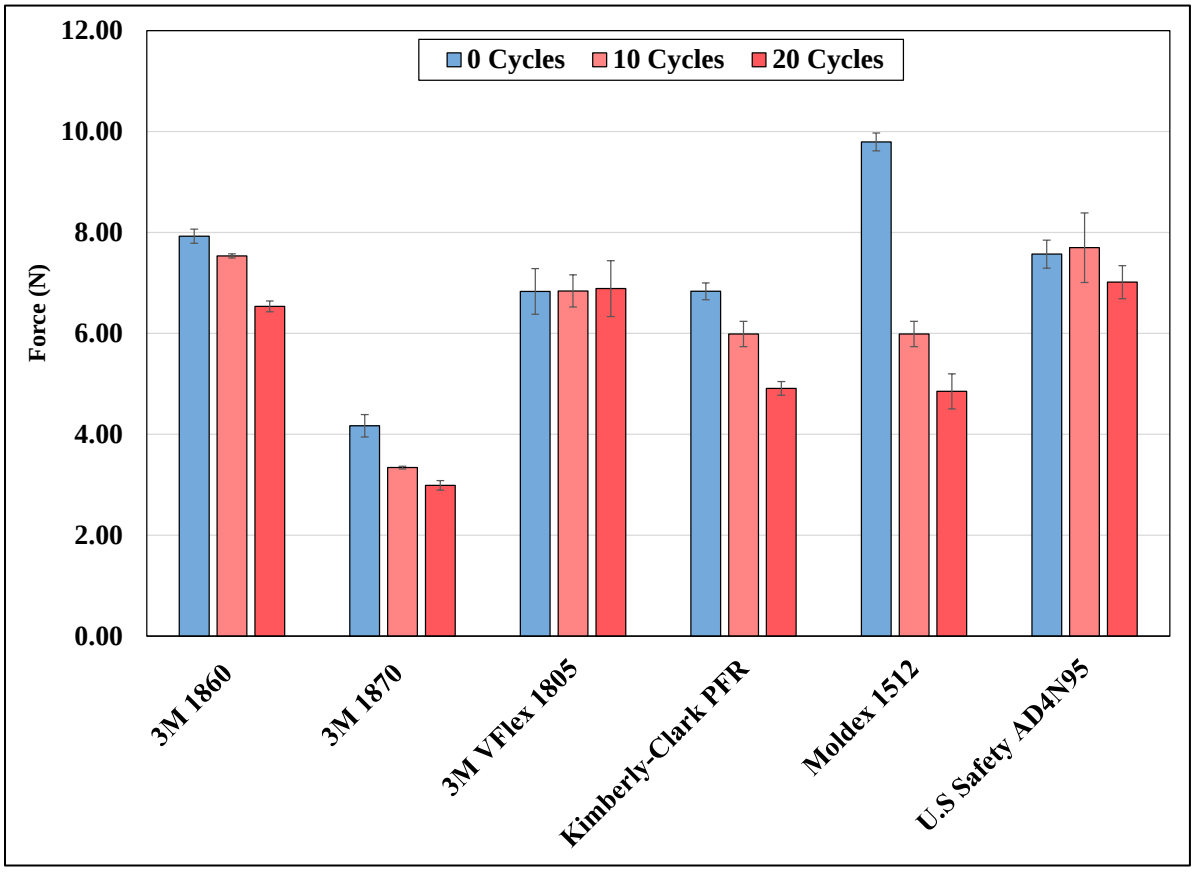


Figure 17. Mean Peak Force for FFR Straps from Six FFR Models Treated with Multiple Donning and UVGI Cycles.

Table 10. Statistical Comparison of Mean Peak Force for FFR Straps from Six FFR Models Treated with Multiple Donning and UVGI Cycles.

FFR Model	P-value
3M 1860	0.009
3M 1870	0.007
3M VFlex 1805	0.88
Kimberly-Clark PFR	0.009
Moldex 1512	0.004
U.S Safety AD4N95	0.10

Fit testing

Using the control respirators, only 12 of 15 FFR models demonstrated an ability to achieve a preliminary fit factor ≥ 100 using the Portacount 8038 on one of the two StAHs (Figure 14); three models did not (Sperian HC-NB095, Sperian HC-NB295F, Alpha Protech 695). Of the 12 models with preliminary fit factors ≥ 100, all were fit tested using the medium-sized StAH, except for the Kimberly-Clark PFR and U.S. Safety AD4N95 which were fit tested using the large StAH.

The geometric mean of fit factors from the 12 FFR models mentioned above ranged from 142 – 10,210 for all conditions tested after 10 UVGI cycles, exceeding the minimum requirement of 100 (**Figure 18**). When comparing mean fit factors among the four conditions for each FFR model tested, only two FFR models demonstrated a statistically significant difference – 3M 1860 and Gerson 1730 (**Table 11**). For the 3M 1860, the mean fit factor demonstrated by the UV-treated whole FFRs were significantly higher than untreated straps. For the Gerson 1730, the mean fit factor produced by the UV-treated facepiece only FFRs was significantly higher than all other conditions tested. None of the 12 remaining FFR models tested demonstrated a statistically significant difference between UV-treated whole FFRs and donned only FFRs.

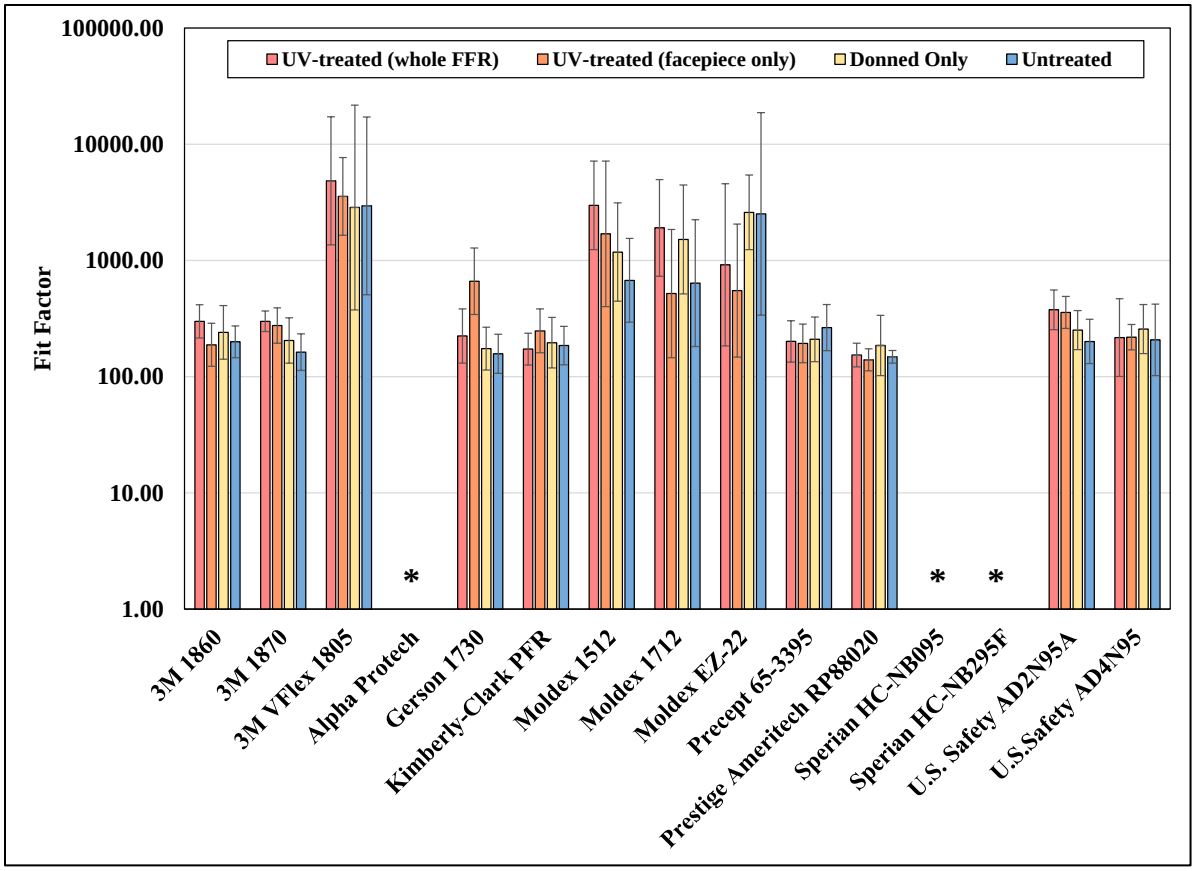


Figure 18. Mean Fit Test Data for 15 FFR Models Treated with 10 UVGI Cycles. (Note: * indicates FF > 100 was not achieved)

Table 11. Statistical Comparison of Mean Fit Factor between Conditions Tested for 15 FFR Models Treated with 10 UVGI Cycles.

FFR Models	P-value
3M 1860	0.03
3M 1870	0.13
3M VFlex 1805	0.67
Alpha ProTech 965	-
Gerson 1730	0.002
Kimberly-Clark PFR	0.36
Moldex 1512	0.06
Moldex EZ-22	0.21
Moldex 1712	0.28
Precept 65-3395	0.47
Prestige Ameritech RP88020	0.44
Sperian HC-NB095	-

Sperian HC-NB292F	-
U.S Safety AD2N95A	0.05
U.S Safety AD4N95	0.94

The geometric mean of fit factors from the six FFR models tested after 20 UVGI cycles ranged from 21 – 6,997 for the donned only and UV-treated FFRs; the fit factor data from previously tested untreated straps was used for comparison (**Figure 19**). When comparing mean fit factors between conditions tested for each of the six FFR models tested, only one model – 3M 1860 – indicated a statistically significant difference (**Table 12**). UV-treated 3M 1860 masks demonstrated significantly higher fit factors than untreated masks of the same FFR model.

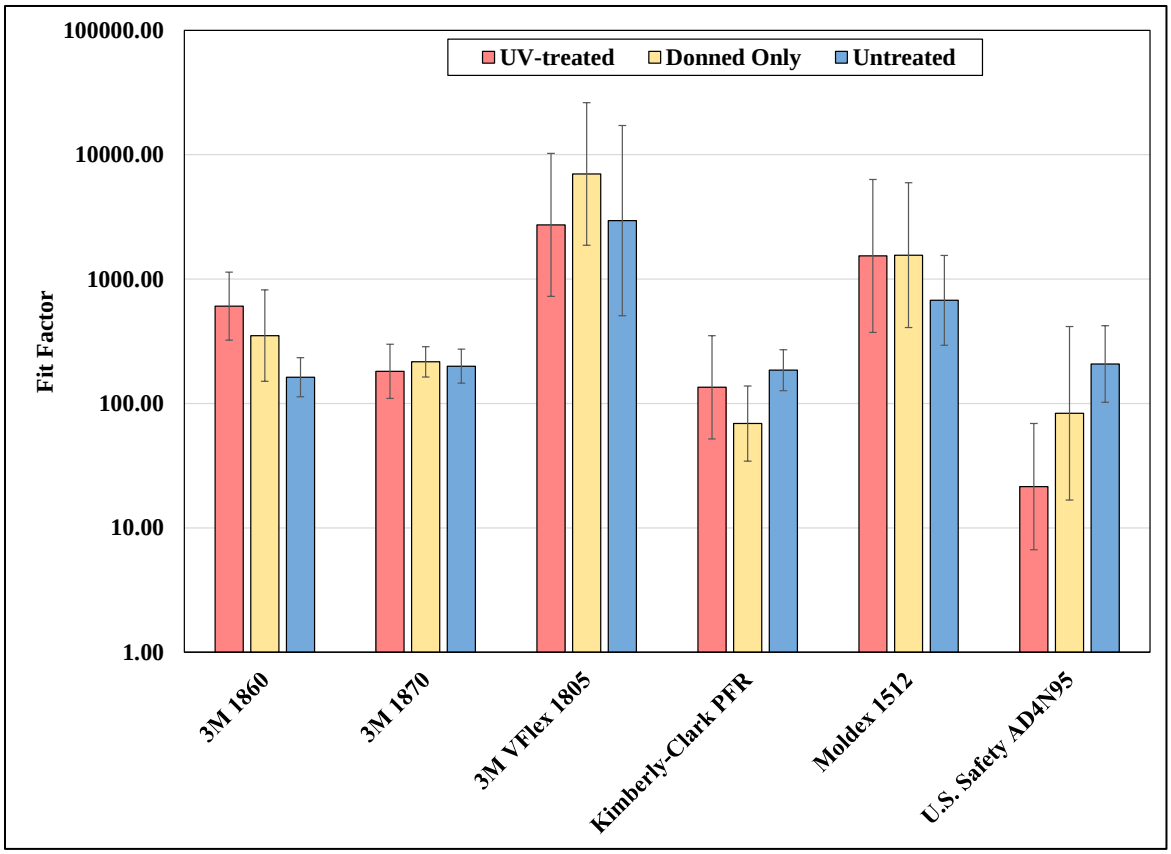


Figure 19. Mean Fit Test Data for Six FFR Models Treated with 20 UVGI Cycles.

Table 12. Statistical Comparison of Mean Fit Factor between Conditions Tested for Six FFR Models Treated with 20 UVGI Cycles.

FFR Models	P-value
3M 1860	0.05
3M 1870	0.06
3M VFlex 1805	0.25

Kimberly-Clark PFR	0.07
Moldex 1512	0.49
U.S Safety AD4N95	0.39

Of the six FFR models tested after 20 UVGI cycles, two FFR models demonstrated mean fit factors less than 100 from at least one condition tested – the donned only masks for the Kimberly-Clark model and the UV-treated masks for the U.S. Safety AD4N95 model (**Table 13**). The Kimberly-Clark model had two donned only masks that each failed one of the three fit tests performed and one UV treated mask that failed all three fit tests. All three donned only masks and all three UV-treated masks for the U.S. Safety AD4N95 model failed at least one of the three fit tests performed.

Table 13. Pass Rate of Fit Tests for Six FFR Models Tested after 20 UVGI Cycles.

		Passing Fit Tests (FF>100)		
FFR Model	**FFR Replicate**	**Condition A**	**Condition C**	**Condition D**
3M 1870	1	3/3	3/3	3/3
	2	3/3	3/3	3/3
	3	3/3	3/3	3/3
3M 1860	1	3/3	3/3	3/3
	2	3/3	3/3	3/3
	3	3/3	3/3	3/3
Kimberly-Clark PFR	1	3/3	2/3	3/3
	2	3/3	2/3	3/3
	3	0/3	0/3	3/3
3M VFlex 1805	1	3/3	3/3	3/3
	2	3/3	3/3	3/3
	3	3/3	3/3	3/3
Moldex 1512	1	3/3	3/3	3/3
	2	3/3	3/3	3/3
	3	3/3	3/3	3/3
U.S. Safety AD4N95	1	1/3	0/3	3/3
	2	0/3	2/3	3/3
	3	0/3	0/3	3/3

Comparing the mean fit factors for six untreated FFR models treated with 0, 10, and 20 donning/doffing cycles only (**Figure 20**), only one FFR model - Kimberly-Clark PFR - indicated a statistically significant difference (**Table 14**). The mean fit factor for the Kimberly-Clark masks treated with 20 donning/doffing cycles was significantly lower than masks from the same model treated with 0 or 10 donning/doffing cycles.

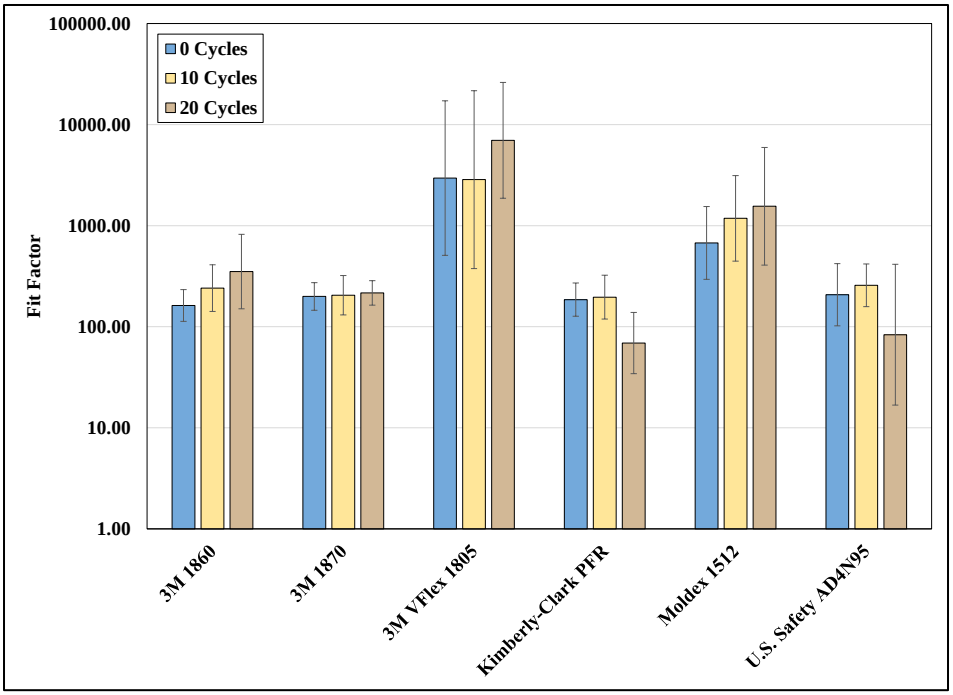


Figure 20. Mean Fit Test Data for Six FFR Models Treated with Multiple Donning Cycles Only.

Table 14. Statistical Comparison of Mean Fit Test Data for Six FFR Models Treated with Multiple Donning Cycles Only.

FFR Models	P-value
3M 1860	0.13
3M 1870	0.49
3M VFlex 1805	0.64
Kimberly-Clark PFR	0.007
Moldex 1512	0.39
U.S Safety AD4N95	0.87

Comparing the mean fit factors for six UVGI-treated FFR models treated with 0, 10, and 20 donning (**Figure 21**), only one FFR model – 3M 1860 - indicated a statistically significant difference (**Table 15**). The mean fit factor for the 3M 1860 masks treated with 20 donning/doffing cycles was significantly higher than masks from the same model treated with 0 or 10 donning/UVGI cycles.

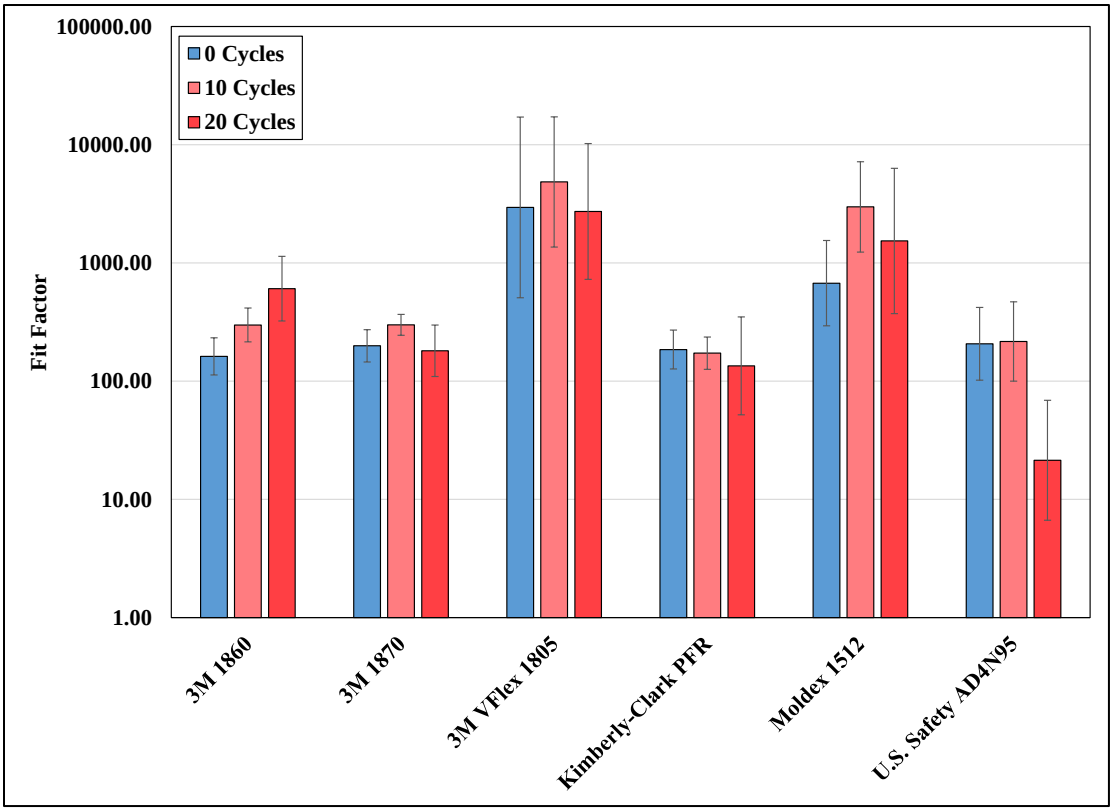


Figure 21. Mean Fit Test Data for Six FFR Models Treated with Multiple Donning and UVGI Cycles.

Table 15. Statistical Comparison of Mean Fit Test Data for Six FFR Models Treated with Multiple Donning and UVGI Cycles.

FFR Models	P-value
3M 1860	0.002
3M 1870	0.22
3M VFlex 1805	0.86
Kimberly-Clark PFR	0.95
Moldex 1512	0.29
U.S Safety AD4N95	0.11

Airflow Resistance

The mean air flow resistance for all 15 FFR models ranged from 4.53 – 14.93 mmH_2O for all conditions tested, less than the 25-mmH_2O maximum requirement for non-powered air purifying respirators as defined by 42 CFR part 84 Subpart K (**Figure 22**). When comparing mean air flow resistance among the four conditions for each FFR model tested, three FFR models demonstrated a statistically significant difference (**Table 16**). For the Precept 65-3395, the mean air flow

resistance for UV-treated whole FFRs is significantly higher than untreated FFRs. For the Gerson 1730, the mean air flow resistance for untreated FFRs is significantly higher than other conditions tested. For the Moldex EZ-22, a specific comparison was not identified by the Tukey's post-test as being significantly different.

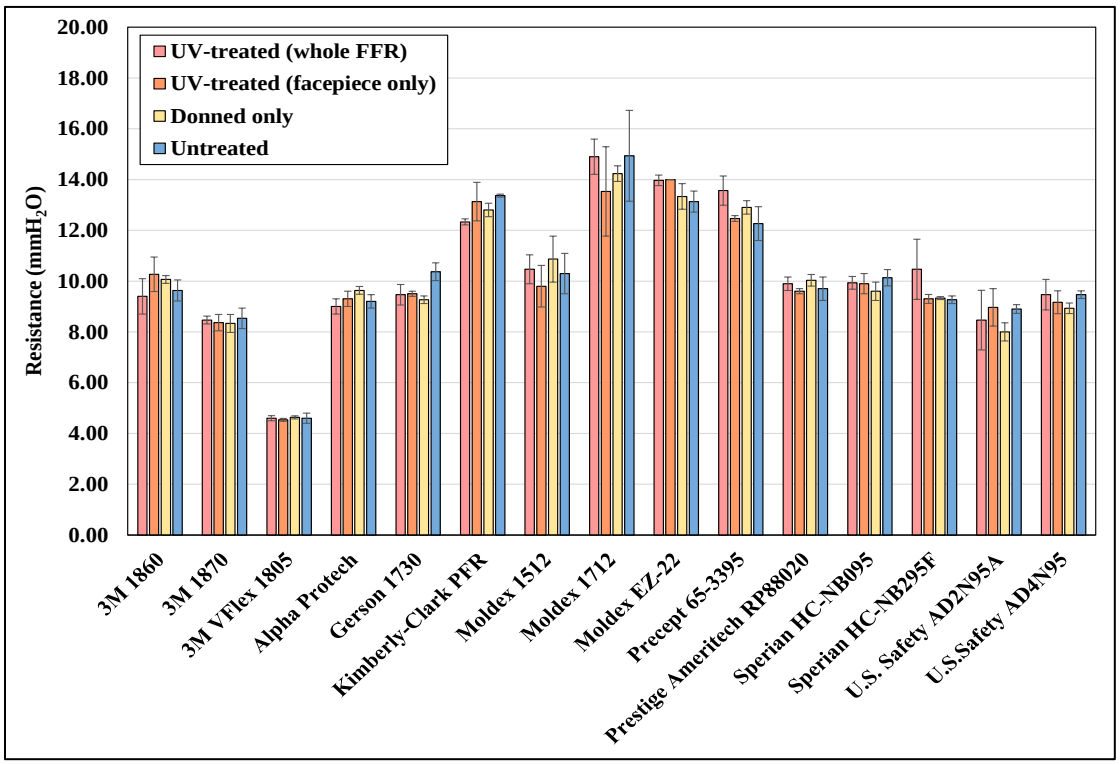


Figure 22. Mean Air Flow Resistance Data for 15 FFR Models Treated with 10 UVGI Cycles.

Table 16. Statistical Comparison of Mean Air Flow Resistance Data of 15 FFR Models Treated with 10 UVGI Cycles.

FFR Models	P-value
3M 1860	0.26
3M 1870	0.86
3M VFlex 1805	0.76
Alpha Protech	0.09
Gerson 1730	0.006
Kimberly-Clark PFR	0.06
Moldex 1512	0.46
Moldex 1712	0.55
Moldex EZ-22	0.03
Precept 65-3395	0.04
Prestige Ameritech RP88020	0.33

Sperian HC-NB095	0.35
Sperian HC-NB295F	0.11
U.S. Safety AD2N95A	0.38
U.S. Safety AD4N95	0.35

The mean air flow resistance for six FFR models treated with 20 UVGI cycles ranged from 4.40 – 13.37 mmH_2O, less than the 25-mmH_2O maximum requirement for non-powered air purifying respirators as defined by 42 CFR part 84 Subpart K (**Figure 23**). When comparing mean air flow resistance among the three conditions for each FFR model tested, two FFR models demonstrated a statistically significant difference (**Table 17**). The untreated masks of the Kimberly-Clark and Moldex 1512 models demonstrated significantly higher air flow resistance than the donned only masks, and also the UV-treated masks for the Moldex 1512 model. No significant difference was indicated between the donned only and UV-treated masks for all six FFR models tested.

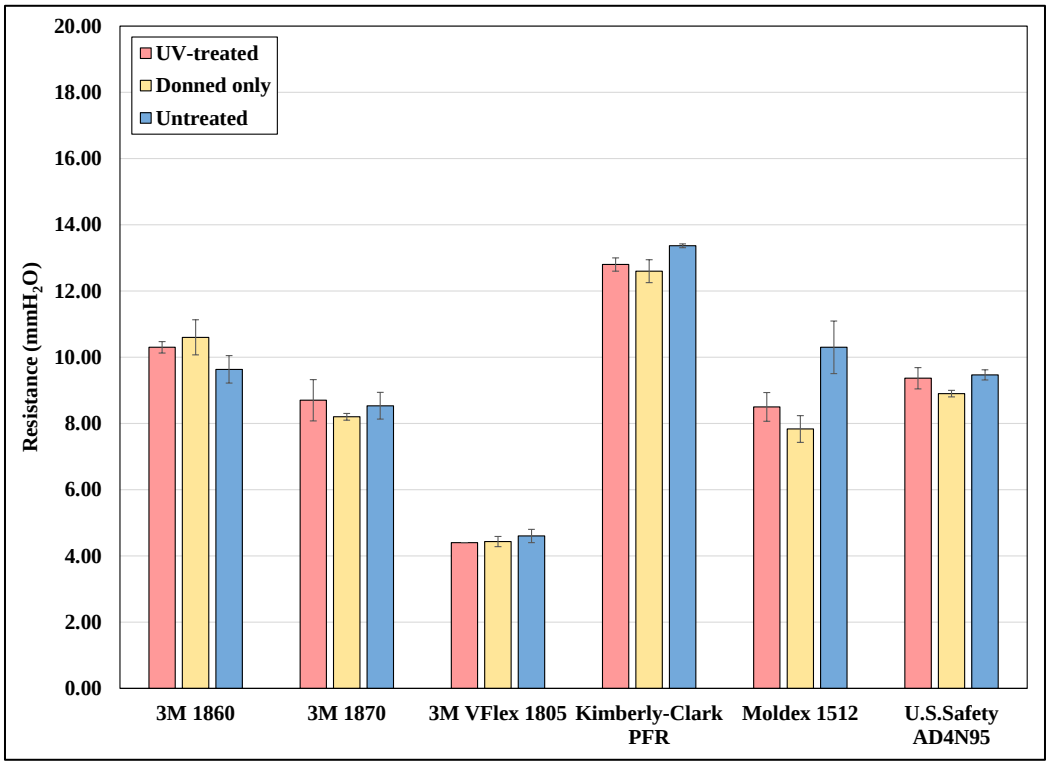


Figure 23. Mean Air Flow Resistance Data for Six FFR Models Treated with 20 UVGI Cycles.

Table 17. Statistical Comparison of Mean Airflow Resistance Data between Conditions Tested for Six FFR Models Treated with 20 UV Cycles.

FFR Models	P-value
3M 1860	0.06

3M 1870	0.41
3M VFlex 1805	0.27
Kimberly-Clark PFR	0.02
Moldex 1512	0.005
U.S. Safety AD4N95	0.06

Comparing the mean air flow resistance for six untreated FFR models treated with 0, 10, and 20 donning/doffing cycles only (**Figure 24**), three FFR models indicated a statistically significant difference (**Table 18**). The untreated masks of the U.S. Safety AD4N95 demonstrated significantly higher air flow resistance than masks treated with 10 donning cycles, and significantly higher air flow resistance than masks treated with 20 donning cycles for the Kimberly-Clark, Moldex 1512, and U.S. Safety AD4N95 models. The only significant difference observed between masks treated with 10 and 20 donning cycles was for the Moldex 1512 model.

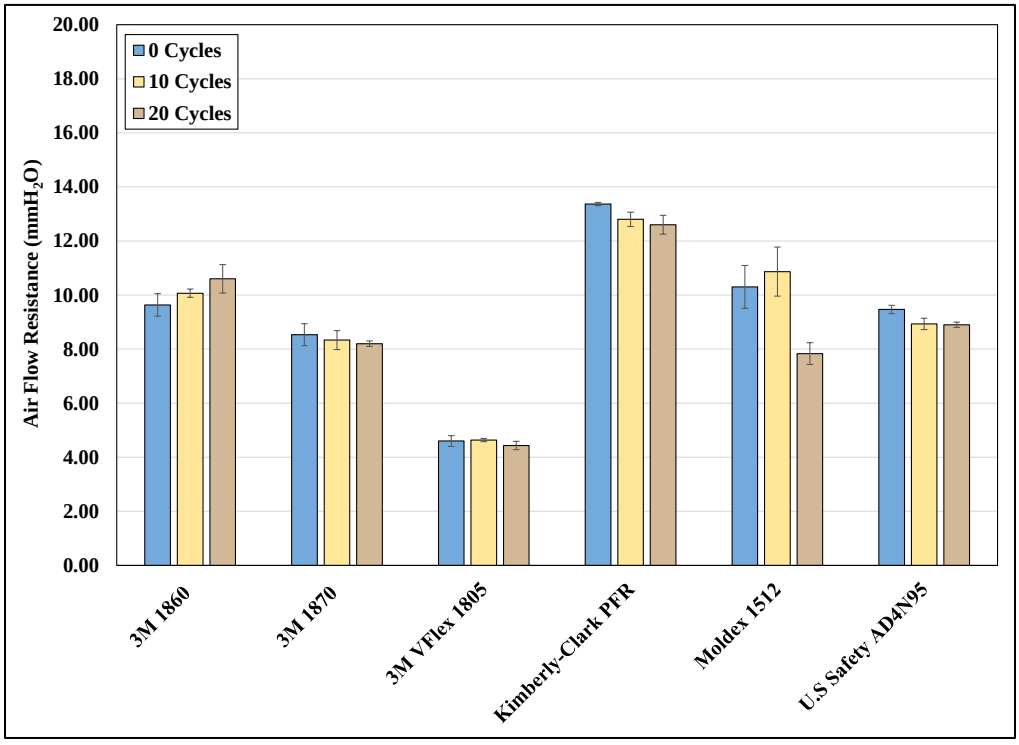


Figure 24. Mean Air Flow Resistance Data for Six FFR Models Treated with Multiple Donning Cycles Only.

Table 18.Statistical Comparison of Mean Air Flow Resistance Data for Six FFR Models Treated with Multiple Donning Cycles Only.

FFR Models	P-value
3M 1860	0.07

3M 1870	0.47
3M VFlex 1805	0.29
Kimberly-Clark PFR	0.02
Moldex 1512	0.005
U.S. Safety AD4N95	0.008

Comparing the mean air flow resistance for six UVGI-treated FFR models with 0, 10, and 20 donning/doffing cycles (**Figure 25**), two FFR models indicated a statistically significant difference (**Table 19**). The untreated masks of the Kimberly-Clark and Moldex 1512 models demonstrated significantly higher air flow resistance than masks treated with 10 and 20 donning cycles. The only significant difference observed between masks treated with 10 and 20 donning cycles was for the Kimberly-Clark model.

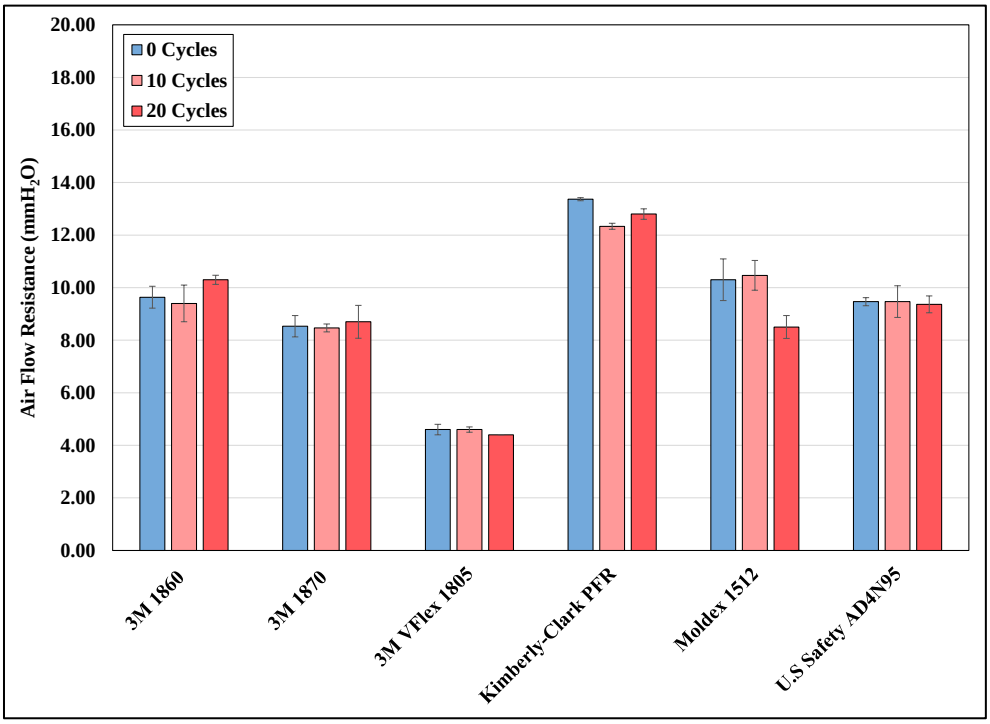


Figure 25. Mean Air Flow Resistance Data for Six FFR Models Treated with Multiple Donning and UVGI Cycles.

Table 19. Statistical Comparison of Mean Air Flow Resistance Data for Six FFR Models Treated with Multiple Donning and UVGI Cycles.

FFR Models	P-value
3M 1860	0.14
3M 1870	0.80
3M VFlex 1805	0.11

Kimberly-Clark PFR	0.0003
Moldex 1512	0.01
U.S. Safety AD4N95	0.94

Particle Penetration

The mean particle penetration for all 15 FFR models treated with 10 UVGI cycles ranged from 0.18 – 3.29%, less than the 5% maximum penetration allowed for non-powered air purifying respirators as defined in 42 CFR part 84 Subpart K (**Figure 26**). When comparing mean particle penetration values among the four conditions for each FFR model tested, only one FFR model demonstrated a statistically significant difference – U.S. Safety AD2N95A (**Table 20**). For this FFR model, the mean particle penetration for UV-treated whole FFRs was significantly higher than all other conditions tested.

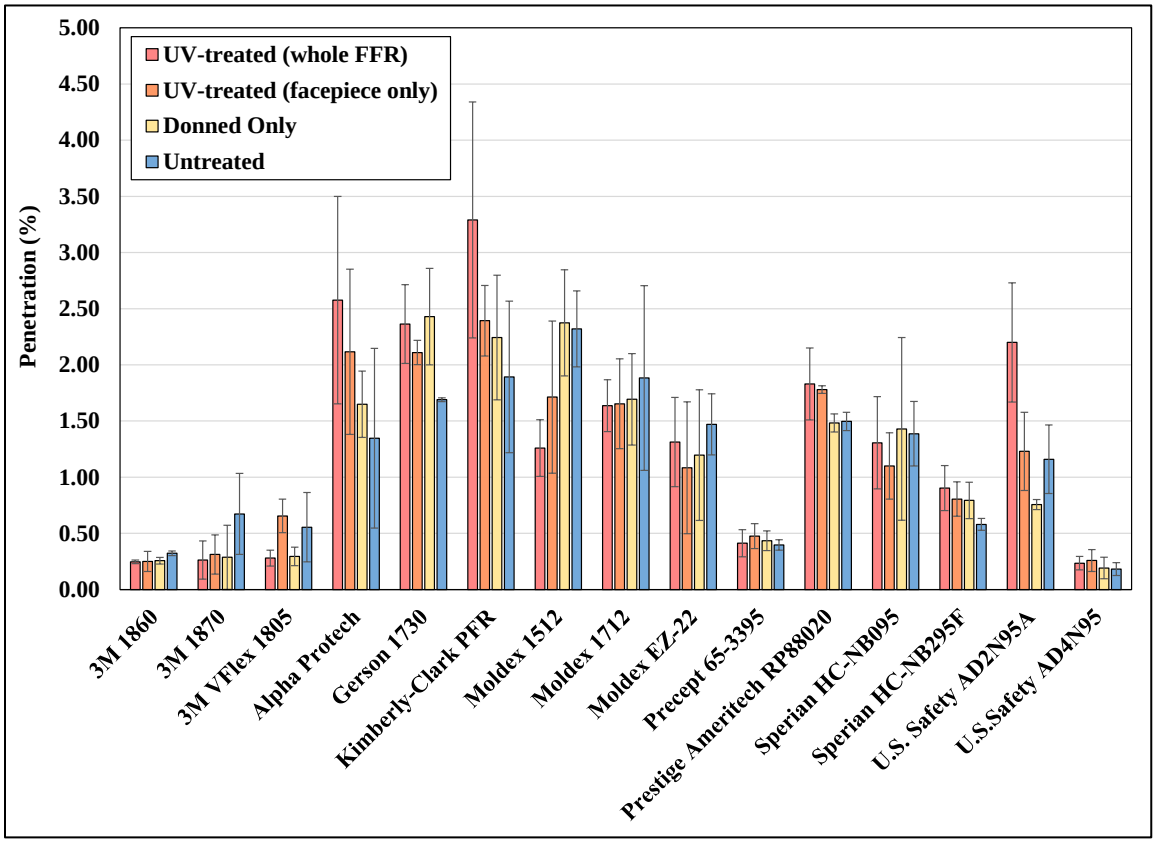


Figure 26. Mean Particle Penetration Data for 15 FFR Models Treated with 10 UVGI Cycles.

Table 20. Statistical Comparison of Mean Particle Penetration Data between Conditions Tested for 15 FFR Models Treated with 10 UVGI Cycles.

FFR Models	P-value
3M 1860	0.25
3M 1870	0.25
3M VFlex 1805	0.08
Alpha Protech	0.26
Gerson 1730	0.05
Kimberly-Clark PFR	0.17
Moldex 1512	0.05
Moldex 1712	0.15
Moldex EZ-22	0.36
Precept 65-3395	0.77
Prestige Ameritech RP88020	0.07
Sperian HC-NB095	0.26
Sperian HC-NB295F	0.14
U.S. Safety AD2N95A	0.006
U.S. Safety AD4N95	0.63

The mean particle penetration for all six FFR models treated with 20 UVGI cycles ranged from 0.12 – 2.74%, less than the 5% maximum penetration allowed for non-powered air purifying respirators as defined in 42 CFR part 84 Subpart K (**Figure 27**). When comparing mean particle penetration values among the three conditions for each FFR model tested, only one FFR model – 3M 1870 - demonstrated a statistically significant difference (**Table 21**). For the 3M 1870, the mean particle penetration of the untreated masks was significantly higher than the donned only masks. No significant difference was observed between UV-treated and donned only masks for all six FFR models treated with 20 UVGI cycles.

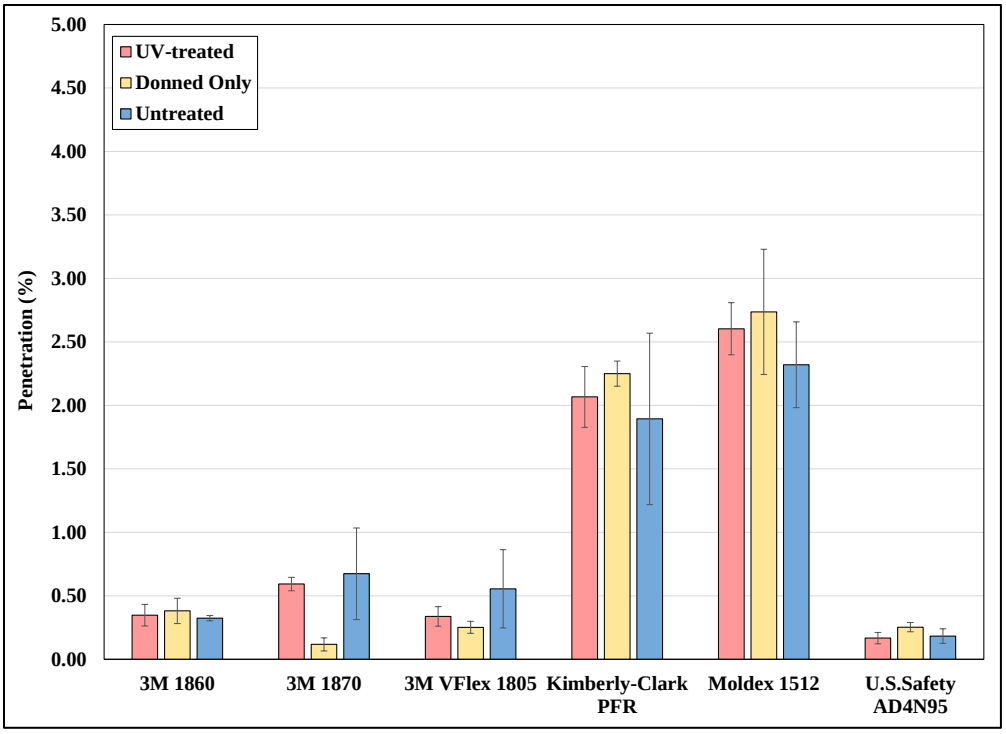


Figure 27. Mean Particle Penetration Data for Six FFR Models Treated with 20 UVGI Cycles.

Table 21. Statistical Comparison of Mean Particle Penetration Data between Conditions Tested for Six FFR Models Treated with 20 UVGI Cycles.

FFR Models	P-value
3M 1860	0.43
3M 1870	0.04
3M VFlex 1805	0.20
Kimberly-Clark PFR	0.60
Moldex 1512	0.42
U.S. Safety AD4N95	0.14

Comparing the mean particle penetration for six untreated FFR models treated with 0, 10, and 20 donning/doffing cycles only (**Figure 28**), no statistically significant difference was observed (**Table 22**). Comparing the mean particle penetration for six UVGI-treated FFR models with 0, 10, and 20 donning/doffing cycles (**Figure 29**), no statistically significant difference was observed (**Table 23**).

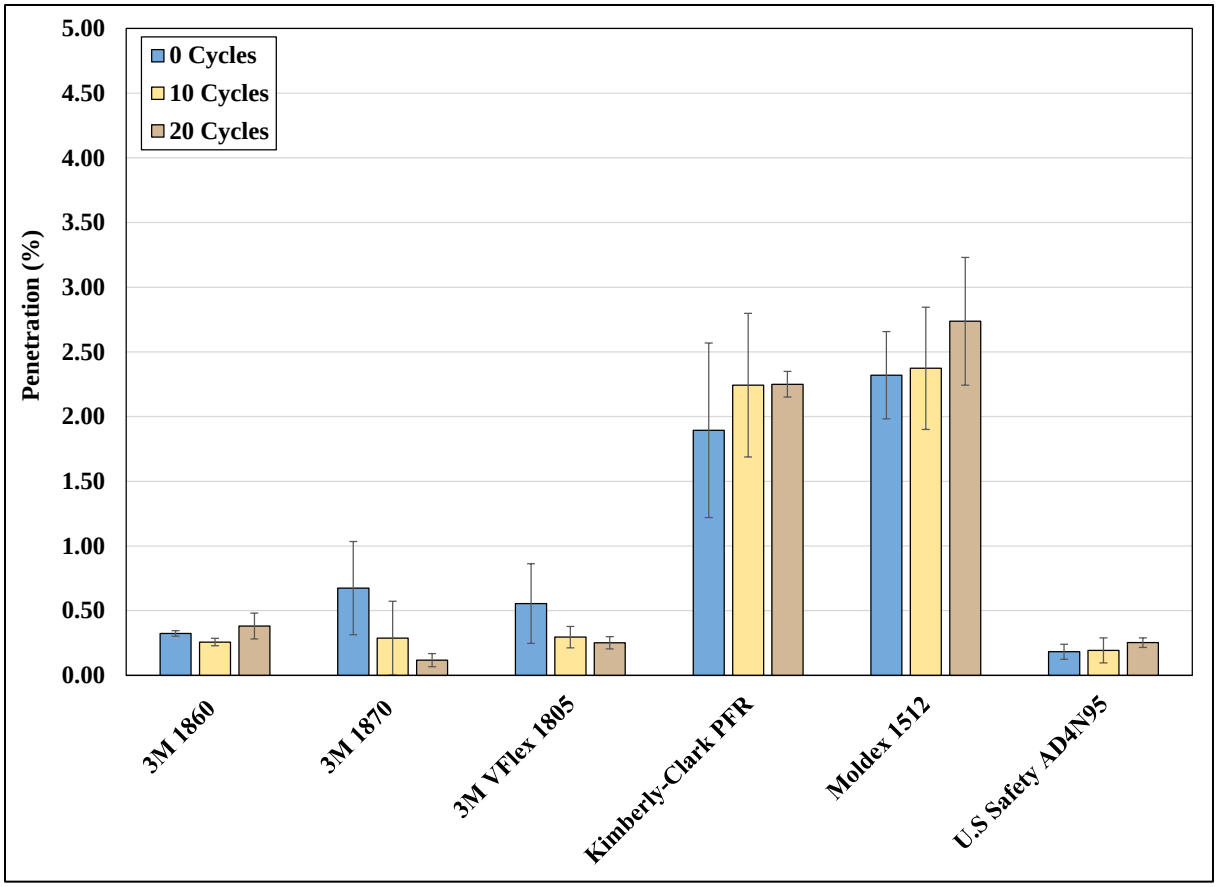


Figure 28. Mean Particle Penetration Data for Six FFR Models Treated With Multiple Donning Cycles Only.

Table 22. Statistical Comparison of Mean Particle Penetration Data for Six FFR Models Treated with Multiple Donning Cycles Only.

FFR Models	P-value
3M 1860	0.12
3M 1870	0.10
3M VFlex 1805	0.18
Kimberly-Clark PFR	0.64
Moldex 1512	0.49
U.S. Safety AD4N95	0.44

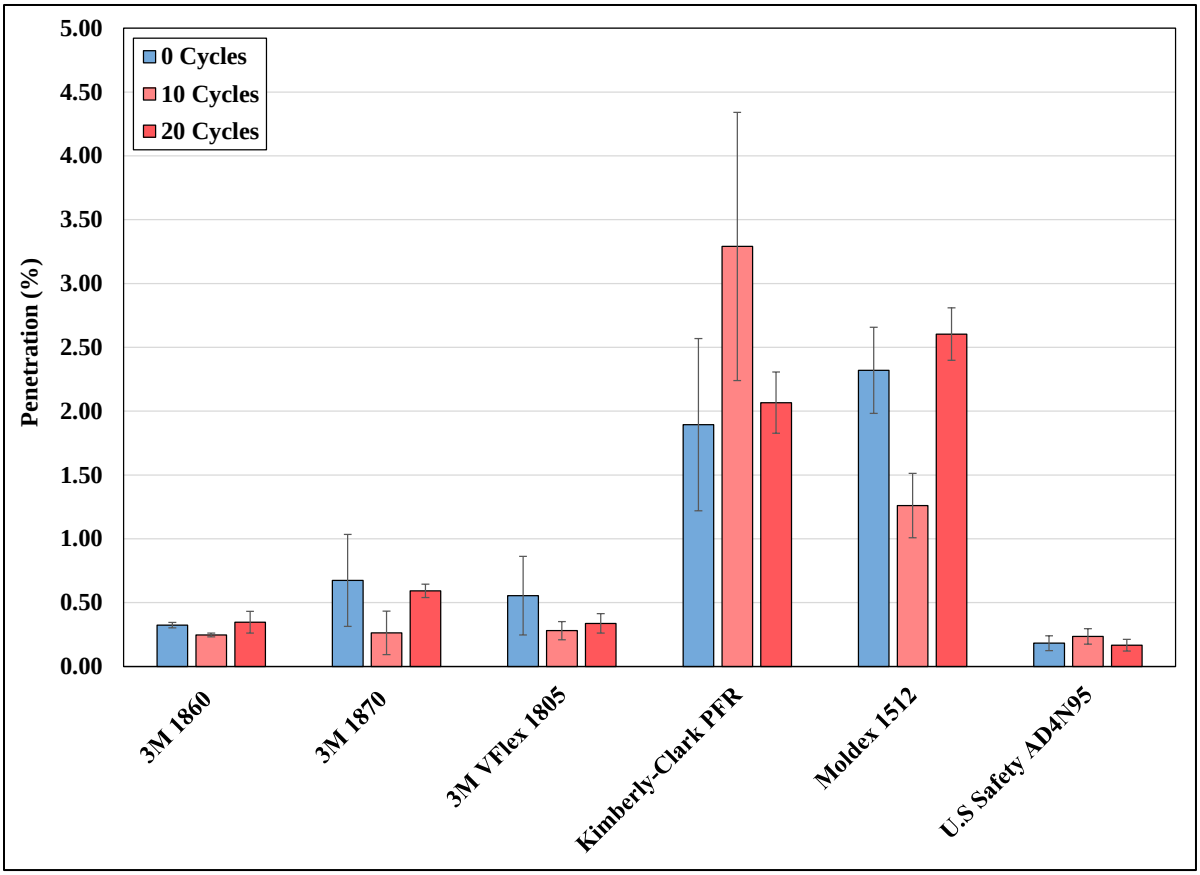


Figure 29. Mean Particle Penetration Data for Six FFR Models Treated with Multiple Donning and UVGI Cycles.

Table 23. Statistical Comparison of Mean Particle Penetration Data for Six FFR Models Treated with Multiple Donning and UVGI Cycles.

FFR Models	P-value
3M 1860	0.12
3M 1870	0.15
3M VFlex 1805	0.27
Kimberly-Clark PFR	0.11
Moldex 1512	0.61
U.S. Safety AD4N95	0.34

3.1.3.4 Discussion/Conclusions

Discussion

Building upon UVGI decontamination efficacy data generated in Tasks 3 and 4, Task 5 evaluated the effect of UVGI on N95 FFR durability and performance. A wide array of N95 FFR models were evaluated – 15 different models – that come in an assortment of shapes, sizes, and designs. A variety of tests were conducted to evaluate key characteristics relevant to FFR performance – ability to achieve fit, filtration efficiency, air flow resistance, and strap tension. Two of these characteristics – filtration efficiency and air flow resistance – are defined in the guidance used for NIOSH certification, 42 CFR part 84 Subpart K. Ability to achieve fit is crucial to FFR performance, but is not currently part of NIOSH certification for N95 FFRs. Strap tension is an important variable in regards to fit testing and thus the measurement of strap tension changes is important to be able to understand changes in fit testing outcomes, if any.

Fit testing is the main determinant of FFR effectiveness for health care workers in the healthcare setting. This testing is often performed using a qualitative method based on the user's sense of smell, rather than a more precise quantitative method like using a Portacount to measure particle concentration to measure fit, as was performed in this study. Twelve of the fifteen FFR models selected as part of this study demonstrated adequate fit (greater than 100) on at least one of the two StAHs at NIOSH-NPPTL. The inability of three FFR models to achieve a passing fit factor using brand new respirators indicates their ability to provide N95-level protection may be in question. Fit testing is not required for NIOSH or FDA approval, leaving the responsibility to evaluate how well an FFR fits to the end user and ultimately their employer.

The lack of significant difference in mean fit factor between respirators that were either UV-treated or only donned/doffed after 10 and 20 cycles indicates UVGI does not have a significant impact on the level of protection provided by these devices. However, multiple failed tests were observed for two FFR models – Kimberly-Clark and U.S. Safety AD4N95 – after 20 cycles of either UVGI and donning/doffing or donning/doffing only, indicating this level of donning/doffing may hinder the ability of these two FFR models to achieve appropriate fit. Overall, this data indicates 20 UVGI cycles will not significantly affect FFR fit using the UVGI application method defined as part of this study, but 20 cycles of donning/doffing could result in a failed fit test for some models. Future studies using larger sample sizes and evaluating other levels of use can provide additional resolution into the effect of doffing/donning on FFR performance.

In addition to fit testing, strap elasticity was also evaluated to understand if multiple cycles of UVGI treatments or donning/doffing significantly affect the material properties of FFR straps. Of the 15 FFR models tested, straps from only one model – Moldex 1512 - demonstrated significantly lower peak force required to reach 200% extension after 10 UVGI cycles compared to straps that were treated with 10 donning/doffing cycles only. Similarly, only one of the 15 FFR models - Kimberly-Clark - demonstrated significantly lower peak force after 20 UVGI cycles compared to straps treated with 20 donning/doffing cycles only. Despite the results of

FFR strap performance for the Moldex 1512 after 10 UVGI cycles, the lack of significant difference in peak force for this FFR model after 20 UVGI cycles indicates this difference is likely not meaningful. The significant reduction in peak force between Kimberly-Clark straps treated with 10 and 20 donning/doffing cycles, along with the failed fit tests observed after 20 donning/doffing cycles, indicate this level of use for the Kimberly-Clark PFR may negatively affect the performance of this FFR model in a significant manner. While strap tension is an important factor for fit, it is only one variable and cannot be used to predict fit. The U.S. Safety AD4N95 FFR had very little reduction in strap tension between the 10X and 20X cycles, but failed the fit test at 20X. Conversely, the Moldex 1512 FFR had significant reduction in force of the straps after the 10X and 20X treatments, but it did not affect fit of the FFR. These data are important to understand for not only this application, but also for developing more comfortable FFRs.

Air flow resistance and particle penetration are both mechanical characteristics evaluated for NIOSH certification for N95 FFRs. All 15 FFR models tested as part of this study demonstrated adequate air flow resistance (less than 25 mmH_2O) and particle penetration (less than 5%) as defined by 42 CFR Part 84 Subpart K based on untreated FFRs from each model. Although one FFR model (U.S. Safety AD4N95) demonstrated a significantly lower air flow resistance after 10 donning/doffing cycles only and three models (U.S. Safety AD4N95, Kimberly-Clark, Moldex 1512) demonstrated a significantly lower air flow resistance after 20 donning/doffing cycles only, these are not considered meaningful differences as the resulting reduced air flow resistance is not a negative consequence. For particle penetration, the lack of significant differences between UVGI-treated and donned only respirators indicate UVGI does not have a significant effect on filtration efficiency. Although a significant difference was observed between the untreated and UVGI-treated U.S. Safety AD2N95A FFRs after 10 cycles, the resulting filtration efficiency was below the maximum 5% penetration allowed. Additionally, donning/doffing was not observed to have a significant effect on particle penetration. Overall, UVGI treatment up to 20 cycles using the UVGI application method defined in this study does not have a meaningful effect on air flow resistance or particle penetration.

The wealth of data generated from this study will provide the first assessment of FFR performance for 15 commercially-available N95 FFRs based on fit, strap performance, air flow resistance and filtration efficiency. The results of this study not only provides valuable information to determine the viability of using UVGI as an FFR-DR approach, but other FFR-DR strategies as well. UVGI treatment up to 20 cycles using the UVGI decontamination method defined in Tasks 3 and 4 was shown to not degrade FFR performance, but donning/doffing after 20 cycles was shown to be a negative factor for FFR performance for certain FFR models.

Conclusions

Based on the results of this study, up to 20 cycles of UVGI treatment (approximately 1 J/cm^2 per cycle) does not have a meaningfully significant effect on, fit, air flow resistance, or particle

penetration for the 15 FFR models tested. Strap tension data indicate 10 UVGI cycles do not have a significant effect on FFR straps, but 20 UVGI cycles may have a significant effect on straps from the 3M 1860, 3M 1870, and Kimberly-Clark PFR models. While 10 donning/doffing cycles did not demonstrate a meaningful effect, 20 donning/doffing cycles may in fact have a meaningful effect on FFR performance for certain FFR models. UVGI is a viable FFR-DR strategy, and along with other FFR-DR approaches, may be limited by the number of times FFRs can be reused based on the wear and tear of use alone.

3.1.4. Option Task B: Threat Agent Virus Susceptibility to UVGI Decontamination

3.1.4.1 Overview

To assess potential variability in UV resistance between different influenza strains and other types of pathogenic viruses (e.g., coronaviruses), Microbac Laboratories (Sterling, VA) performed a GLP study evaluating UVGI efficacy against six different pathogenic virus strains, ranging from BSL-2 to BSL-3, under various soiling conditions. Testing included H1N1 influenza to provide a comparison with the results obtained by ARA.

3.1.4.2 Materials and Methods

Test Organisms

For this study, six virus strains were evaluated for disinfection efficiency after being exposed to a specific UVGI dose under various soiling conditions (**Table 24**). Madin-Darby canine kidney (MDCK) cells (ATCC CCL-34) were used as the host cells for all influenza virus strains evaluated. Vero-E6 cells (ATCC CRL-1586) were used as the host cells for all coronavirus strains evaluated.

Table 24. Virus strains evaluated for this study.

BSL[1]	Virus Type	Strain	Stock concentration ($TCID_{50}$/mL)	Source
2	Influenza A virus (H1N1)	A/PR/8/34	7.25	CRL[2]
3	Avian influenza A virus (H5N1), low-pathogenic, NIBRG-14	2006719965	7.25	CDC[3]
3	Influenza A virus (H7N9)	A/Anhui/1/2013	7.00	CDC[3]
3	Influenza A virus (H7N9)	A/Shanghai/1/2013	7.25	CDC[3]
3	Middle Eastern respiratory syndrome (MERS) coronavirus	EM/2012	8.00	BEI Resources[4]
3	Severe Acute Respiratory Syndrome (SARS) coronavirus	200300592	8.25	ZeptoMetrix[5]

[1] *Biosafety level*
[2] *Charles River Laboratories, Wilmington, MA*
[3] *Centers for Disease Control, Atlanta, GA*
[4] *Biodefense and Emerging Infections Research Resources Repository, Manassas, VA*
[5] *Buffalo, NY*

Test Substrates

Circular coupons, 3.8-cm diameter, were prepared from 3M 1870 N95 FFRs using a tabletop arch punch. Respirator layers were held together using a staple on the outer edge of each coupon. A standard ballpoint ink pen was used to mark ten locations to be inoculated with the virus challenge.

Soiling Agents

Two soiling agents were used for this study – artificial saliva (mucin buffer) and artificial skin oil (synthetic sebum). Mucin buffer was prepared and stored at 4 °C. Synthetic skin oil (Scientific Services S/D; Sparrow Bush, NY) was purchased, divided into 2.5-mL aliquots, and stored at 37 °C until use. For testing, aliquots were heated to 70 °C and poured into the base of a 100-mm Petri dish which was rotated to spread the sebum evenly. The plate was then allowed to cool to room temperature.

Three soiling conditions were evaluated: no soiling agent, artificial saliva (mucin buffer), and artificial skin oil (sebum). Cytotoxity assays were performed for each soiling condition prior to virus testing. For mucin-treated coupons, five 1-µL droplets of mucin buffer were applied directly over each dried influenza inoculation, allowing approximately 10 minutes of drying between droplet applications. For sebum-treated coupons, a synthetic sebum overlay was prepared by pipetting 2.5 mL of liquefied sebum into a 100-mm Petri dish, which was then swirled to create an even monolayer. A sterile triangle-shaped spreader was used to collect the sebum from the Petri dish. The collected sebum was then spread over the inoculum area at a density of approximately 1.25 mg/cm^2.

UV Source

A Mineralight® XX-20S 20-W UV bench lamp was used to treat inoculated FFR coupons with UV light (**Figure 30**). The UV lamp was secured to the top of an acrylic box and three acrylic stands were placed inside the box to serve as platforms for the coupons during UV treatment.

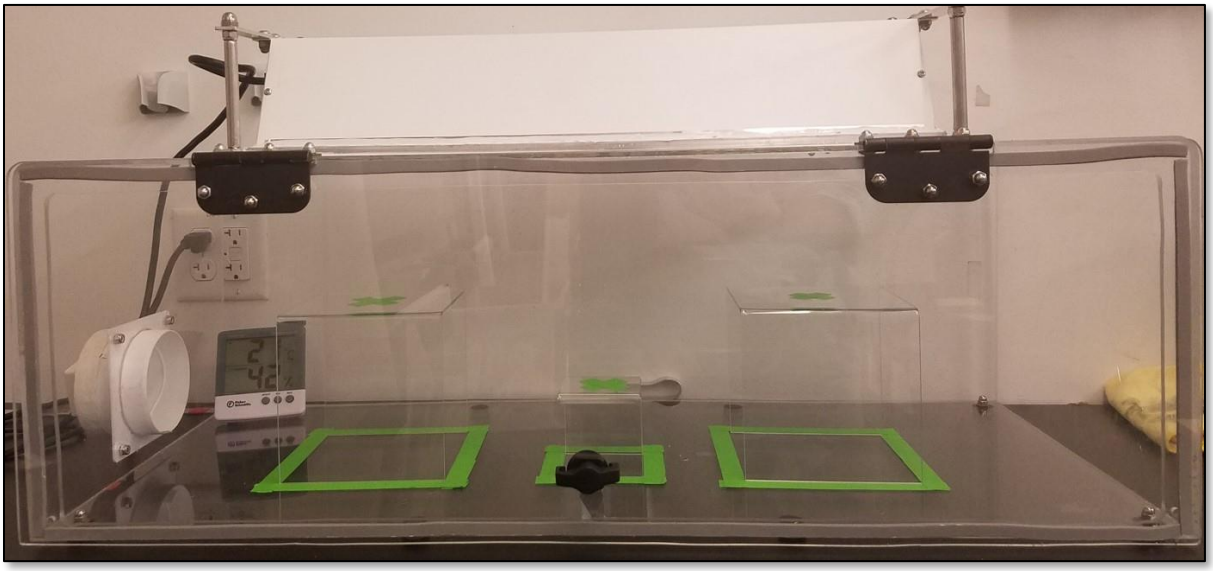


Figure 30. UV Exposure Device.

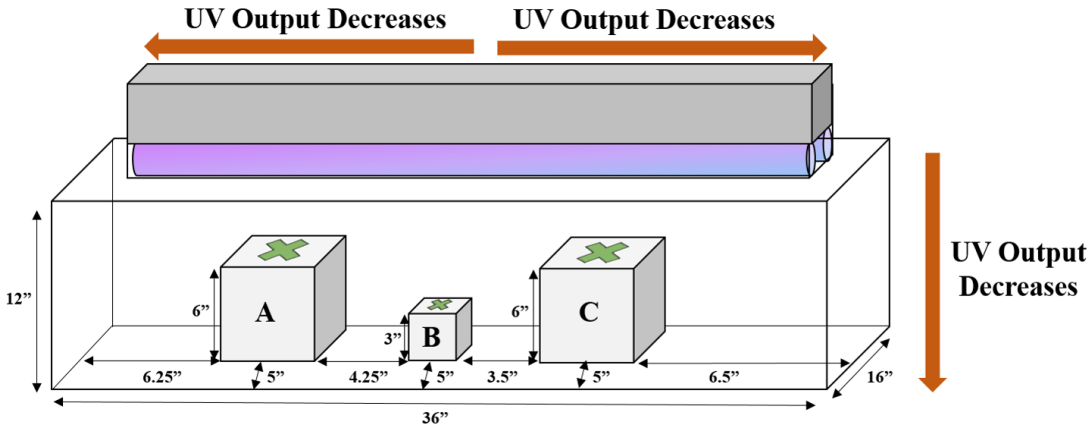


Figure 31. UV Exposure Device Layout.

The two outer acrylic stands are 6” H × 6” W × 6” D while the center acrylic stand measures 3” H × 3” W × 3” D (**Figure 31**). The heights of the acrylic stands vary based on their position along the UV bulb. As distance increases from the center of the UV bulb, the UV output decreases. Similarly, as distance increases from the bulb in a perpendicular direction, the UV

output also decreases. Thus, to ensure all three coupons receive similar UV doses during a test, the two outer acrylic stands are taller than the center stand to account for the loss in UV output along the axis of the bulb.

A UVX radiometer with a UVX-25 probe was used to measure and validate UV output at the positions where the coupons were placed. Preliminary validation testing demonstrated an average UV output of 2.3 ± 0.0 mW/cm^2 between all three coupon locations. The "X"s shown in (**Figure 31**) indicate the locations for each coupon to ensure similar UV doses were delivered.

Decontamination Studies

For each test, six FFR coupons were each inoculated with ten 1-µL droplets of virus within a 2 cm^2 area and allowed 15 minutes to dry. All six FFR coupons were treated similarly with the same soiling agent (if used). Three coupons were UV-treated for 7 minutes and 15 seconds, resulting in a UV dose of 1 J/cm^2. The remaining three inoculated control coupons were held at room temperature in a biological safety cabinet until UVGI treatment of the UV-treated coupons was complete.

After UV treatment, all six coupons were each placed in a 50-mL tube containing 15-mL of virus maintenance media using sterile forceps and vortexed for 20 min. Following this process, coupons were manually pressed using a cell scraper against the inner wall of the 50-mL tube to squeeze out as much liquid as possible, then removed and discarded. An aliquot of the extraction sample was ten-fold serially diluted in dilution medium and inoculated onto the host cells using a median tissue culture infectious dose ($TCID_{50}$) assay. To maximize the assay sensitivity, the entire recovery solution from each coupon was inoculated onto host cells. Inoculated plates were incubated at 36 ± 2 °C in 5 ± 3% CO_2 for 4 – 6 days for influenza virus stains and 4 – 9 days for coronavirus strains. Infectivity was determined by visual observation of cytopathic effect.

Data Analysis

The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the Spearman-Karber method. In the case where a sample contains no detectable virus, a statistical analysis was performed based on a Poisson distribution to determine the theoretical maximum possible titer for that sample. The test results are reported as the reduction of the virus titer due to treatment with UV, expressed as $\log_{10}$. Statistical comparisons between data sets were performed using an unpaired, two-tailed *t*-test.

3.1.4.3 Results

No cytotoxic effects were observed for any of the three soiling conditions for all virus strains tested. Initial UVGI testing using H1N1 influenza indicated similar reductions in viable virus (**Table 25**). Differences in virus recoveries from control coupons between ARA and Microbac Labs were statistically significant for mucin (p = 0.02) and sebum (p = 0.006), but not for control coupons with no soiling agent (p = 0.25). The mean viable recovery of virus across all strains

tested by Microbac ranged from 4.53 – 6.67 log $TCID_{50}$ (**Table 26**). No detectable virus was recovered from coupons after being UV treated.

Table 25. H1N1 Influenza Data Comparison

Performer	UV Dose	Soiling Conditions	Mean Log $TCID_{50}$ Control	Mean Log $TCID_{50}$ Treated
Microbac Labs	1 J/cm^2	No Soiling Agent	6.67 ± 0.52	ND
		Mucin	6.03 ± 0.14	ND
		Sebum	6.17 ± 0.29	ND
ARA	1 J/cm^2	No Soiling Agent	6.11 ± 0.14	ND
		Mucin	5.19 ± 0.38	ND
		Sebum	4.98 ± 0.25	ND

ND = No detectable viable virus

Table 26. Microbac Labs UVGI Decontamination Testing

Virus Type	Soiling Condition	Mean Virus Recovered ($Log_{10}TCID_{50}$) Control	UV-treated	Log Reduction
Influenza A (H1N1)	No Soiling Agent	6.67 ± 0.52	ND	≥ 6.01
	Mucin	6.03 ± 0.14	ND	≥ 5.37
	Sebum	6.17 ± 0.29	ND	≥ 5.51
Avian influenza A virus (H5N1), low pathogenic	No Soiling Agent	5.12 ± 0.38	ND	≥ 4.46
	Mucin	4.69 ± 0.38	ND	≥ 4.03
	Sebum	4.86 ± 0.14	ND	≥ 4.20
Influenza A (H7N9), A/Anhui/1/2013	No Soiling Agent	5.78 ± 0.14	ND	≥ 5.12
	Mucin	5.28 ± 0.14	ND	≥ 4.62
	Sebum	5.41 ± 0.29	ND	≥ 4.75
Influenza A (H7N9), A/Shanghai/1/2013	No Soiling Agent	5.97 ± 0.25	ND	≥ 5.31
	Mucin	5.93 ± 0.00	ND	≥ 5.27
	Sebum	5.78 ± 0.14	ND	≥ 5.12
MERS-CoV	No Soiling Agent	5.16 ± 0.29	ND	≥ 4.50
	Mucin	4.53 ± 0.14	ND	≥ 3.87
	Sebum	4.72 ± 0.25	ND	≥ 4.06
SARS-CoV	No Soiling Agent	5.47 ± 0.25	ND	≥ 4.81
	Mucin	4.61 ± 0.14	ND	≥ 3.95
	Sebum	4.94 ± 0.38	ND	≥ 4.28

ND = No detectable viable virus

3.1.4.4 Discussion/Conclusions

Discussion

The objective of this task was to evaluate the potential for differences in UVGI efficiency across various virus types and strains. A UV dose of 1 J/cm^2 resulted in no detectable viable virus for all six virus strains tested by Microbac Labs and one virus strain tested by ARA even when treated with two soiling agents – artificial skin oil and artificial saliva. The results from this study indicate UVGI can be effective against multiple threat agent viruses on FFR surfaces.

A comparison of the viable recovery from control coupons between ARA and Microbac Labs indicated significant differences when mucin and sebum were used. These differences are likely attributed to two differences in the test protocols between the two labs. When performing the viability assay, ARA plated dilutions in quadruplicate while Microbac Labs plated the entire volume of each dilution. Plating the entire volume of the coupon extract increases the resolution of the recovery data. Also, Microbac Labs used a cell scraper post-extraction – this likely helped recover virus especially when soiling agents were present, which is supported by the data. Although higher recoveries were observed for Microbac control coupons when soiling agents were present, both labs demonstrated no detectable virus after UV treatment.

Several limitations of the study were identified. Although all virus strains tested demonstrated significant reductions in virus viability on the FFR coupons used, there is potential for variability in UVGI effectiveness for other types of materials used for different FFR models due to varying material properties like hydrophobicity. Additionally, the levels of soiling agents used were based on simulating a worst-case scenario, and thus may be higher than levels observed in a real-world scenario.

The results of this study help mitigate the risk for potential differences in UVGI effectiveness between virus strains of threat agent viruses and can likely be used to help set a baseline for UVGI doses required for decontamination during a pandemic. These data also support the utility of a UVGI-based approach for the decontamination and reuse of FFRs to prevent a potential shortage.

Conclusions

Based on the results of this study, UVGI is effective against multiple strains of pathogenic influenza virus and coronavirus, even when shielded with artificial skin oil and artificial saliva at the levels used in this study.

3.1.5. Option Tasks C and D: FFR Fluid Resistance and Flammability

3.1.5.1 Overview

N95 filtering face piece respirators (FFRs) used in hospitals and other health care environments are subject to performance requirements in addition to NIOSH approval. N95 FFRs must be cleared by the U.S. Food & Drug Administration (FDA) if the respirator is used as a surgical mask in exposure settings where maintenance of a sterile field is required.[22] Based on guidance for industry pertaining to premarket notification [510(k)] submissions,[23] the FDA recommends evaluating surgical masks and surgical respirators for fluid resistance and flammability, in addition to other performance characteristics that could potentially create a health risk to the user.

Fluid resistance is the ability of the mask's material to resist the penetration of blood and bodily fluids. The FDA recommends evaluating surgical masks or respirators using ASTM F1862, "Standard Test Method for Resistance of Surgical Mask to Penetration by Synthetic Blood."[24] The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. For this method, devices are tested on a pass/fail basis at three velocities corresponding to the range of human blood pressure (80, 120, 160 mm Hg), and correlate respectively to Level 1, 2, and 3 barriers as defined by ASTM F2100.[25] Per FDA guidance, fluid resistance may be claimed if the device passes ASTM F1862 at any level. Surgical masks that show passing results at higher velocities are more fluid resistant.

To evaluate the flammability of surgical masks and respirators, the FDA recommends three methods, one of which is 16 CFR 1610, "Standard for Flammability of Clothing Textiles."[26] The purpose of this procedure is to measure the ease of ignition and the speed of flame spread across the textile. For plain surface textiles, the burn time defines the flammability classification for the substrate: Class 1 for burn times ≥ 3.5 seconds and Class 3 for burn times < 3.5 seconds; Class 2 does not apply to plain surface textiles. The FDA recommends that Class 1 and Class 2 flammability materials be used in surgical masks intended for use in the operating room.

Six models were UV-treated with 20 UVGI cycles (1 J/cm^2 per cycle) then evaluated by a third-party lab (Nelson Labs, Salt Lake City, UT) for flammability and fluid resistance per standard test methods.

3.1.5.2 Materials and Methods

Test respirators

Six FFR models were evaluated for Tasks C and D (**Table 27**). These models were selected based on their use in Task 5.2, which evaluated FFR performance after 20 UV cycles with a dose of approximately 1 J/cm^2 per cycle.

Table 27. Filtering Facepiece Respirator Models Tested for Tasks C and D

FFR Model
3M 1860
3M 1870
3M VFlex 1805
Kimberly-Clark PFR
Moldex 1512
U.S. Safety AD4N95

Fluid resistance testing

All six FFR models were evaluated for fluid resistance based on ASTM method F1862. For each model, 32 respirators were each dosed with approximately 20 J/cm^2 of 254-nm UV-C light using the whole-FFR UV exposure device developed for Task 4.

Subsequent to UV treatment, FFRs were shipped to Nelson Laboratories (Salt Lake City, UT) for fluid resistance testing. The exterior surface of the FFRs were exposed to a 2 mL volume of synthetic blood using a high velocity stream (635 cm/s) at a fluid pressure of 160 mm Hg. The fluid stream was directed at the center for all 32 masks for the 3M 1860 and Moldex 1512 models. For the remaining four FFR models, the fluid stream was directed at the center for 16 masks, at the left seam for 8 masks, and at the right seam for 8 masks.

A pass/fail determination is made based on visual detection of synthetic blood penetration on the interior of the FFR. The ASTM method defines an acceptable quality limit of 4.0%, allowing up to 3 failures out of 32 masks tested. Testing was performed in compliance with U.S. FDA good manufacturing practice regulations 21 CFR Parts 210, 211, and 820.

Flammability testing

All six FFR models were evaluated for flammability based on 16 CFR Part 1610. For each model, 14 respirators were each dosed with approximately 20 J/cm^2 of 254-nm UV-C light using the whole-FFR UV exposure device developed as part of Tasks 3 and 4.

Subsequent to UV treatment, FFRs were shipped to Nelson Laboratories (Salt Lake City, UT) for flammability testing. The textile sample is placed in a rack and held over a flame for 1 second, and the time required for the flame to proceed across the fabric for a distance of 5” is recorded. If no flame spread is observed, only five samples are tested per sample type. An additional five samples are tested if flame spread is observed. The remaining four samples are required by Nelson Labs to perform preliminary testing. Testing was performed in compliance with U.S. FDA good manufacturing practice regulations 21 CFR Parts 210, 211, and 820.

3.1.5.3 Results

Fluid Resistance

The mean UV exposure for all respirators tested under Task C was 20.9 ± 1.0 J/cm^2 (**Table 28**). Three FFR models had at least one failed sample – 3M 1860, Kimberly-Clark PFR, and Moldex 1512 (**Table 29**). All six FFR models passed the ASTM F1862 method.

Table 28. UV Doses for FFR to be Evaluated for Fluid Resistance.

FFR Model	Sample size (*n*)	Mean UV Dose (J/cm^2)
3M 1860	32	20.6 ± 0.3
3M 1870	32	21.1 ± 0.3

3M VFlex 1805	32	20.7 ± 0.5
Kimberly-Clark PFR	32	21.4 ± 2.2
Moldex 1512	32	20.6 ± 0.4
U.S. Safety AD4N95	32	21.2 ± 0.9

Table 29. Fluid Resistance Testing of UV-Treated FFR Models

FFR Model	Pressure (mm Hg)	# passed	# failed	ASTM F1862 result
3M 1860	160	29	3	Pass
3M 1870	160	32	0	Pass
3M VFlex 1805	160	32	0	Pass
Kimberly-Clark PFR	160	30	2	Pass
Moldex 1512	160	30	2	Pass
U.S. Safety AD4N95	160	32	0	Pass

Flammability

The mean UV exposure for all respirators tested under Task D was 20.7 ± 0.6 J/cm^2 (**Table 30**). Per 16 CFR 1610, if no flame spread is observed upon preliminary testing, only five samples are tested. Ignition was observed for only one FFR model – Kimberly-Clark PFR – but did not spread, which is deemed as equivalent to no ignition. All six FFR models demonstrated Class 1 flammability per the 16 CFR 1610 method (**Table 31**).

Table 30. UV Doses for FFRs to be Evaluated for Flammability.

FFR Model	Sample size (*n*)	Mean UV treatment (J/cm^2)
3M 1860	14	20.5 ± 0.2
3M 1870	14	21.0 ± 1.4
3M VFlex 1805	14	20.8 ± 0.3
Kimberly-Clark PFR	14	20.8 ± 0.3
Moldex 1512	14	20.7 ± 0.3
U.S. Safety AD4N95	14	20.6 ± 0.4

Table 31. Flammability Testing of Six UV-Treated FFR Models.

FFR Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	16 CFR 1610 result
3M 1860	DNI	DNI	DNI	DNI	DNI	Class 1
3M 1870	DNI	DNI	DNI	DNI	DNI	Class 1
3M VFlex 1805	DNI	DNI	DNI	DNI	DNI	Class 1
Kimberly-Clark PFR	DNI	DNI	IBE	IBE	IBE	Class 1
Moldex 1512	DNI	DNI	DNI	DNI	DNI	Class 1
U.S. Safety AD4N95	DNI	DNI	DNI	DNI	DNI	Class 1

DNI = Did not ignite
IBE = Ignited, but extinguished

3.1.5.4 Discussion/Conclusions

Discussion

The test methods used – ASTM F1862 and 16 CFR 1610 – are specified by ASTM F2100, a standard specification that defines the minimum performance requirements for materials used in medical face masks.[13] These test methods are also recommended by the FDA to be used for premarket notification [510(k)] submissions for surgical masks.[11] All six FFR models passed both the fluid resistance and flammability test methods.

For fluid resistance testing, all masks were challenged using the highest velocity available and passed, indicative of a Level 3 barrier per ASTM F2100. Although some synthetic blood penetration was observed, the number of failures for each model were within the acceptable quality limit as defined by ASTM F1862. The target locations for the synthetic blood stream varied between FFR models based on the presence/absence of seams. Seams were included as part of the 32 samples for four of the models tested to ensure these areas (likely most vulnerable) were evaluated. Although seams are specified to be tested separately in ASTM F1862, it is unclear if each seam is required to have a sample size of 32 masks. Based on feedback from the test lab, the interpretation of this portion of the test method varies based on the customer, who is responsible for defining the testing approach. More clarification is needed in ASTM F1862 to ensure face masks are being appropriately and uniformly evaluated for fluid resistance.

Per ASTM F2100, the flammability of medical face masks must meet the requirements for a Class 1 textile. To be classified as Class 1, the textile must demonstrate ≥ 3.5-second burn time, no ignition, or ignition without flame spread when evaluated using 16 CFR 1610. Samples are cut out of the masks and placed into sample holders designed for flat substrates. If the samples were to ignite and spread, variability in results may arise from differences in FFR shape (e.g., flat fold vs. cup). The flammability test method defines separate requirements for plain surface and raised surface textiles. Plain surface textiles are defined as any textile fabric which does not have an intentionally raised fiber or yarn surface such as a pile, nap, or tuft, but shall include those fabrics that have fancy woven, knitted or flock-printed surfaces. Raised surface textiles are defined as any textile fabric with an intentionally raised fiber or yarn surface, such as a pile, including flocked pile, nap, or tufting. It is unclear whether raised surface refers to surfaces with raised textures or non-flat surfaces. For the FFRs tested, no flame spread was observed, indicating Class 1 flammability.

The results of Tasks C and D demonstrate that the six FFR models tested can be treated with at least 20 J/cm^2 using the whole-FFR UV exposure device developed for Task 4 without compromising their fluid resistance and flammability properties for use as surgical N95 FFRs.

More clarification is needed for both ASTM F1862[12] and 16 CFR 1610[14] to ensure materials are being appropriately and uniformly evaluated.

Conclusions

All six FFR models passed both the fluid resistance and flammability testing performed by Nelson Labs using respirators dosed with approximately 20 J/cm^2 of UV-C 254-nm light using the whole-FFR UV exposure device developed for Task 4. These results indicate that the UV-treated respirators from this study are in compliance with the fluid resistance and flammability requirements for 510(k) clearance of surgical masks by the FDA.

3.1.6. Option Task E: ASTM Standard Development for UVGI Decontamination of FFRs

3.1.6.1 Overview

Working with the American Society for Testing and Materials (ASTM) E35.15 subgroup, ARA developed two consensus standards describing the methodology for evaluating antimicrobial efficacy of UVGI against microorganisms on substrates in the presence of soiling agents.[27,28] These standards will allow validation of the UVGI technology on pandemic strains and other emerging pathogens at the early stages of a pandemic to ensure effectiveness.

3.1.7. Option Task F: Logistics Evaluation of UVDR Use in U.S. Hospitals

3.1.7.1 Overview

The following section provides an overview of the research within a sample of U.S. hospitals to understand attitudes, and identify preferences, barriers and logistic issues related to implementation of UVGI-based decontamination during a pandemic event.

A pandemic can place unsustainable demands on supplies of FFRs, i.e., N95s. Respirators protect health care workers (HCWs) (also referred to as clinicians in this report) from the inhalation of infectious aerosols and droplets carrying influenza (e.g., SARS and MERS). The premise for this study is that the pandemic strain will be high in mortality, similar to past outbreaks such as the 1918 influenza pandemic, and that supplies of FFRs would be limited. As a genuine and current threat to health,[29,30] protection from a potential high mortality influenza pandemic merits concerted effort to understand and prepare for it.

UVGI has the potential to mitigate potential shortages by extending FFR service life. Applied Research Associates, Inc. (ARA) conducted research on behalf of the Food and Drug Administration (FDA) to explore the potential use of UVGI-based decontamination during a pandemic event. In Task F, ARA performed interviews, organized focus groups, and conducted a survey to identify how UVGI-based decontamination might fit into hospitals' existing respiratory protection plans and to clarify the procedural preferences and needs of hospital clinicians and staff members who would use FFRs during a pandemic. A description of this effort has been accepted for publication in the *Journal for Patient Safety*.[31]

3.1.7.2 Materials and Methods

Research Sites

The University of Nebraska Medical Center (UNMC) clinicians provided care for Ebola virus patient Rick Sacra, MD in 2014 giving their care staff expertise to care for patients who have been infected with a high mortality disease. On 22 April 2016, the research team spoke with two registered nurses at the Biocontainment Unit (BU) of UNMC to inform our research by learning from their experience caring for three Ebola patients. Notes from that interview are included in (Appendix H).

In addition to the UNMC interview, the research team also collected data from staff and front-line HCWs at three hospitals, including a small, large-suburban, and large-metro area hospital, to understand the needs and considerations associated with FFR-UVDR implementation.

Gulf Coast Regional Medical Center (GCRMC): GCRMC is a small medical center located in Panama City, FL. It contains 218 beds, nearly 400 physicians and a support staff of more than 900 employees. GCRMC belongs to the Hospital Corporation of America, providing a link to a large network of hospitals.

Stony Brook University Hospital (SBUH): SBUH is the university hospital of Stony Brook University located in the East Campus in Stony Brook, NY. It contains 603 beds, 5,777 employees, and 1,093 physicians. Annual inpatient admissions are ~32,000 and ~96,000 emergency room visits. SBUH also has a rich history of research with annual research expenditures exceeding $95 million.

University of Chicago Medical Center (UCMC): UCMC is an academic medical center on the campus of the University of Chicago, located on the on the south side of Chicago, IL. It contains 617 beds, 8,500 employees, and 878 attending physicians. Annual inpatient admissions are ~ 28,726 and ~ 87,856 emergency room visits. In 2015, revenues for patient care at the University of Chicago were $1.5 billion.

Collecting data from hospitals that vary in size and patient population, as well as diverse employee demographics, improved our ability to generalize our findings to other U.S. hospital systems. GCRMC is smaller in size and is affiliated with a national commercial hospital organization. Both SBUH and UCMC are comparable in size, yet both offered different perspectives based on the populations they serve. UCMC serves an urban area on the south side of Chicago that includes a high percentage of African-American and indigent patients, while SBUH is a suburban metropolitan hospital. All three facilities represent the type of U.S. hospital that may need to triage and treat patients in the event of an influenza pandemic.

Research Approval

The team provided the research plan and consent forms to comply with the Office of Management and Budget (OMB) Paperwork Reduction Act. ARA received notification in June 2016 that the FDA's generic clearance for focus groups applied to this project.

Before engaging with the three hospitals and collecting data, the team submitted the research plan to the US FDA Institutional Review Board (IRB) and received approval with an exempt status in October 2016. The SBUH IRB conducted their own review and approved the study. Neither UCMC nor GCRMC required local IRB review.

At US FDA's request, research team members took the National Institutes of Health (NIH)'s course on Protecting Human Research Participants (PHRP), located at: *http://phrp.nihtraining.com/users/login.php*

Research Design

ARA built our research around three considerations and related topics about hospitals and UVGI FFR-Decontamination/Reuse (UVDR):

1. Can they do this?
   - *Organizational and process barriers to implementing of FFR-UVDR*
   - *Barriers and challenges to compliance with FFR use*
2. Will they do this?
   - *Pros and cons of using FFR-UVDR*
   - *Frequency of FFR reuse*
   - *Attitudes and preferences related to successful adoption of the FFR-UVDR process*
3. How would they do this?
   - *Changes to processes as function of FFR-UVDR implementation*
   - *Preferences among alternative mitigation strategies for FFR shortages*
   - *Coordination and planning among staff including challenges, effective practices, etc. Recommended procedural considerations*

In each collection method from interviews to surveys, the research team described the mortality threat, and what UVGI-based decontamination does in order to learn about clinician perceptions. The team then asked for responses to "Would you feel safer?" for each of the conditions that are illustrated in (**Figure 32**): no respirator (NR), respirator only (R), and respirator decontaminated using UV (R/UV).

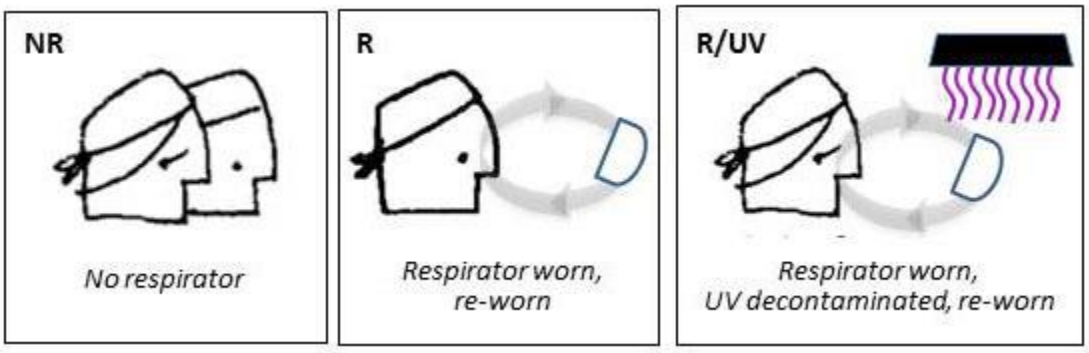


Figure 32. Options for Respiratory Protection During a Pandemic

Data Collection

The research team used several methods to collect data on participant responses and demographics (e.g., hospital, role/position, time in role/position): individual interviews, focus group interviews, and surveys.

Cognitive Task Analysis (CTA) Interviews

The team used Cognitive Task Analysis (CTA) to conduct individual and focus group interviews. The CTA approach consists of a family of data collection and analysis methods that are used to identify and describe cognition and behavior in complex environments.[32] These interviews sought to capture work processes and context-rich examples of tasks and challenging situations associated with FFRs that resulted in either good or poor outcomes. Simulation interviews presented hypothetical decontamination and reuse scenarios to allow participants to imagine and discuss potential behaviors and decisions in relation to FFR-UVDR use in a flu pandemic.[33]

Focus Group Interviews

Use of focus group interviews made it possible to gather opinions about FFRs among existing working groups or gather data when individual interviews were not possible.[20] While individual interviews and surveys probed for detail, focus group interviews captured the nature and scope of shared views among participants who have similar experience (e.g., a group of nurses, or environmental service staff). Group interviews among 6 to 10 participants provided an opportunity to gather perceptions, opinions, beliefs, and attitudes about using FFR-UVDR technology and processes.

Two research team members (a primary interviewer and a secondary note taker) conducted individual and focus group interviews. Individual interviews typically lasted around 45 minutes. The length enabled interviewers enough time to make more than one pass through topics and to probe for relevant data.

The primary interviewer provided an overview of the project and research approach using an approved script (Appendix A). Participants signed a form to indicate their consent, willingness to participate, and agreement for the session to be recorded. The form also included a brief

questionnaire to collect information such as age, position, and years of experience. SBUH also required their own consent form as a supplement to the research team's sign-in form. These forms were distributed and collected by the SBUH coordinator and escort for SBUH's records.

The team conducted interviews using a semi-structured interview guide (Appendix B). The guide was modified to fit each hospital and participant role. Interview participants were also provided with a conceptual illustration and description of what a tabletop FFR-UVDR unit might look like (Appendix C).

Audio recordings of the interviews, made with participant permission, ensured interview notes were accurate. Approximately 3 to 4 interviews/focus groups were scheduled per day, allowing for 9 to 12 interviews over the 3-day data collection period. We used the fourth day to debrief the hospital and to gather any follow-up information.

Surveys

Schedule conflicts prevented some clinicians from participation in interviews. The team developed surveys to supplement interviews by gathering information on topics associated with FFR-UVDR use during a flu pandemic. Survey questions focused on topics relevant to a large number of participants across a variety of scenarios, rather than being specific to the incidents that were discussed in the interviews. The team deferred to each site's preference on how to administer the survey which was accomplished using either an intranet (SBUH, UCMC) or hard copy (GCRMC).

The survey started with a question on whether the participant had been part of an individual or focus group interview. For the online surveys, a "yes" answer routed the participant to the survey exit and thanked them for their interest and support, to prevent double counting. For the handwritten surveys, those respondents who answered yes for the first question were sorted out and not included in analysis.

Sample Population

The team collected data from a variety of individuals with diverse perspectives on the use of FFRs including participants from emergency departments (ED) who are often responsible for patient triage in an influenza pandemic. (**Table 32**) shows the distribution among roles for each of the three research sites.

Table 32. Sample Composition by Research Site

Site	*Method*	*Mgt.*	*RT/PT /OT*	*Nurse*	*Physician**	*Pharmacist*	*Academic*	*Other**	*Total*
SBUH	Individual interview	5	0	1	2				8

	Focus group interview	7	11	0	6				24
	Survey	3	0	20	41		14	5	83
GCRMC	Individual interview	6	0	0	0				6
	Focus group interview	9	2	10	6				27
	Survey	8	7	105	2		3	34	159
UCMC	Individual interview	5	0	0	0				5
	Focus group interview	10	9	13	8	3	1	8	52
	Survey	3	3	27	1	9			43
	Total	56	32	176	66	12	18	47	407

**"Physician" includes medical students: 4 at GCRMC, and 7 at UCMC*

**"Other" includes respondents in these roles: social worker, central sterile technician, phlebotomist, Electrocardiogram technician, Echocardiogram technician, fellow, transporter, transport manager, Certified Medical Assistant (CMA), Environmental Services, and lactation consultant.*

Data Analysis

The research team gathered in person within one to two weeks after each site visit to analyze the collected qualitative data.

Team members analyzed interview and focus group data using systematic content analysis methods[32,33,34] to identify topics and themes within and across roles. Our analysis process followed three iterative stages:

1) *Data review*. Each member of the research team reviewed the notes from all interviews and focus group sessions and identified clusters (comments that appeared multiple times) and possible themes.

2) *Category coding and data extraction.* The initial themes were assigned a number and category to begin to organize findings. The research team then took a second pass through the data to pull out quotes in the notes which supported the coded themes. From this, the team refined the themes, theme definitions, and added and collapsed themes. This evolved as the team pulled in data from each site until the themes and coded data were sufficiently matched.

3) *Theme synthesis and translation into findings and conclusions*. The team assembled clusters of themes that shared similar meaning and wrote statements (findings) that answered the research question. The team then assembled findings into their own clusters that shared similar meaning and wrote statements (conclusions) expressing what the results meant for the project.

3.1.7.3 Results

Interview participants reviewed the 3-panel description shown in Figure 1 and were asked to rate safety in a pandemic on a scale from 1 (unsafe) to 10 (safe) (**Figure 33**).

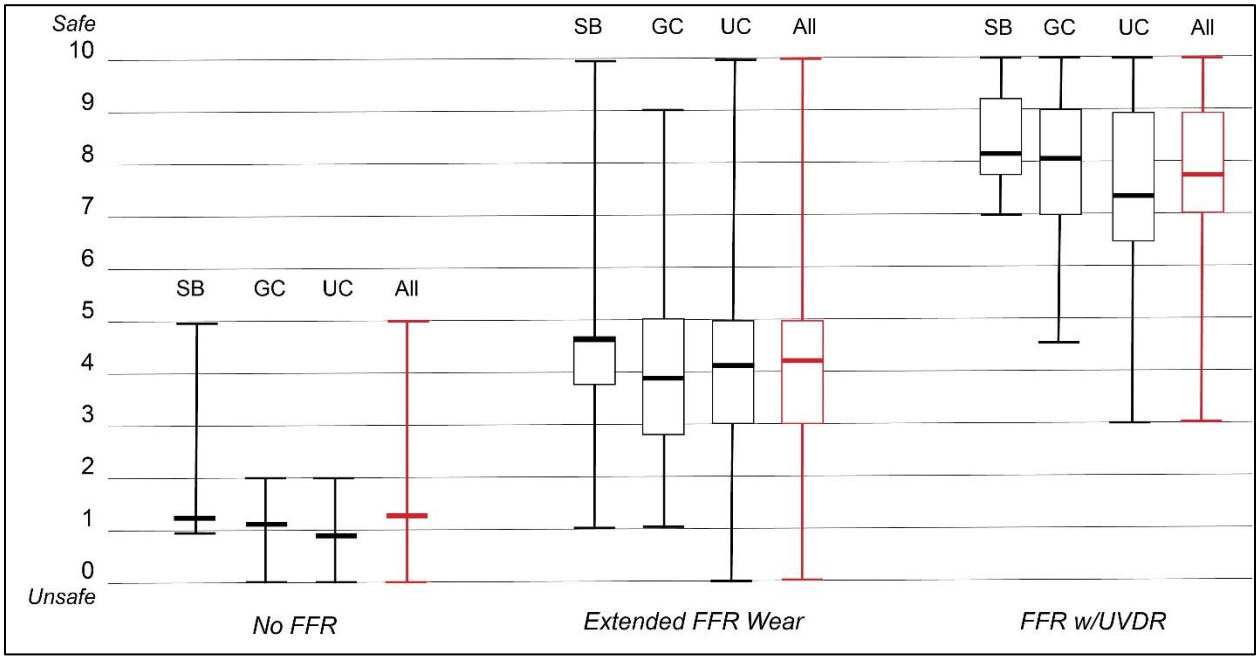


Figure 33. Healthcare Worker Respiratory Safety Perceptions in Pandemic

Individual, focus group interviews

Median ratings among each of the research sites (SBUH, GCRMC, and UCMC) for each of the three conditions were relatively consistent. The range in ratings was fairly large, which might be attributed to speculation about a condition (i.e., use of UV to decontaminate FFRs) that the respondents have not experienced. At SBUH, for example, some responded they would have been vaccinated against flu, or would have already recovered, which would make the "no FFR" option much more tenable for them than those at other sites. While we offered a scale of "1" to "10," it was not unusual for some to respond with "0" to indicate their concern over how unsafe the condition might be.

The data we coded from our research, which is included in (Appendix D), formed the basis for 17 findings.

Findings

F1. Personal considerations impose a strong gradient between those who may, and those who would not, be willing to share masks

The issue of mask reuse provoked strongly held opinions. Opinions ranged from willingness to share FFRs, willingness to wear one's own FFR for an extended period, acceptance in spite of discomfort about reuse acknowledging that survival matters more than convenience, to refusal to consider either reuse or extended use. Some participants noted that a decontaminated FFR could still be soiled and that "ick factor" would make reuse undesirable.

F2. Training and management of PPE, including FFRs, varies

Some frontline HCWs are fit tested annually and receive training in proper FFR use. Others reported being fit tested regularly, but not consistently. It appears that not everyone at a hospital is fit tested, and some go for years without being refit. PPE, including FFRs, is typically staged near point of use. Some Infection Control staff members make routine rounds to verify proper PPE use, while others make spot checks in critical care areas such as ICUs.

F3. Health Care Worker FFR use poses a compliance challenge

Attitudes about PPE use, including FFRs, was a noticeable concern. Some HCWs admitted they did not get refit after a change (e.g., gain or loss of 15 pounds), or would enter a patient room without correctly conforming the FFR to their face. Perceptions of fit and of FFR brands differ. Individuals know they need to follow, but report inattention to, the proper use of PPE. This can be due to impatience with frequent and complicated donning and doffing or from the immediacy of rushing to attend to a patient in distress.

F4. Clinicians strongly favor unit location near point of care

Frontline HCWs strongly favor having the decontamination unit at a location near the point of care. Fewer clinicians suggested the unit could become the responsibility of central processing, while some suggested outsourcing the decontamination process to a third party location. There were factors that affect the decision about where to locate units which will need to be considered, including distance to get to a unit without creating cross-contamination while the clinician transports their used mask, time in relation to distance traveled, and space for storing the units themselves and FFRs that are waiting decontamination.

F5. Hospital FFR par stocks are based on historical use rates

Hospital logistics staff pay close attention to supporting FFR preferences of lead HCWs such as their Infection Control department, but ensuring an available supply of FFRs is less certain. Resupply rates are based on historical use rates. Some facilities rely on Kanban (just-in-time) supply or are in areas, such as Long Island, NY, that may be difficult to resupply due to competition for resources and their remote location. While all facilities had a buffer supply, all

acknowledged that supply was limited and unlikely to be sufficient for any more than a few days of peak demand.

F6. Hospital contingency FFR supplies vary among sites

Hospitals typically have some buffer stocks of FFRs on-site, but acknowledge the reserve is not sufficient in the case of even a moderate increase in demand. One facility ran out of FFRs simply while training for a potential Ebola outbreak. At that same facility, the rest of the staff expressed unqualified confidence that no shortages would ever occur because their national organization could easily resupply them whenever necessary.

F7. Hospitals envision a minimum of 4 to 8 weeks to implement prior to need

Staff members who deal with logistics, Infection Control staff, and nurse educators estimated it would take one to two months to implement a UVDR program and get their staff prepared for a pandemic.

F8. Infection control and employee health are aware of demands that may arise during a pandemic

Both Infection Control as well as Employee Health departments have clear views on how to manage their facilities and staff during a pandemic. They fully expect to assemble infected patients into cohorts who will be cared for in dedicated wards even though the size of the wards is far below what a pandemic census would be. While some HCWs are expected to be reluctant, others are expected to self-select as care providers to these wards. They also expect other organizations to request assistance (e.g., healthcare facilities, municipal government) and also will need to rely on outside organizations (e.g., municipal, state, and federal health authorities).

F9. Education and training will play a major role in implementation

Lead HCWs, such as nurse educators, at each of the facilities are certain sufficient advance training will be essential to successful implementation of any UVDR program. The programs would be based on regulations from authoritative sources such as the National Institute of Occupational Safety and Health (NIOSH) and the Centers for Disease Control (CDC) or the US FDA as to how the units and decontaminated FFRs would be used. Training would specify how to use the units, roles that would be necessary such as supervising UVDR unit use and maintenance, and how often FFRs would need to be decontaminated.

F10. Trust in UV relies on proof from authoritative sources and indication of effectiveness

Frontline HCWs need some means to confirm that UV decontamination is trustworthy from authoritative sources as listed above, or professional peer-reviewed publications. They also need a way to verify that the UVDR unit is operating correctly. Even if the UV process is trustworthy, having a way to verify that the unit is in fact working correctly matters.

F11. Doubts exist about FFR availability and durability

Prior experience that hospitals have had with actual or potential disease outbreaks (e.g., H1N1, Ebola) proved to them that HCWs will hoard FFRs in order to assure they have a sufficient supply for themselves. HCWs typically discard FFRs after a single use, making them skeptical about how durable they are and how many times they could be reused and still remain effective.

F12. Potential infection by pathogens other than influenza is a concern

HCWs have been trained in the risks and causes of contamination. They need information on how effective UVDR is on pathogens other than influenza viruses. There was a good deal of concern over clinicians carrying the virus from an infected area into public spaces as they walk to a UVDR unit, as well as using the mask and being infected by a disease other than the influenza virus.

F13. HCWs need thorough training in nature of actual threat and protection

Training, practice and understanding of the threat of infection varied widely among HCWs and staff pointing to a need for what amounts to “Infectious Disease 101”-level education on contamination threats, disease, mask performance, and UV use. This education would likely improve trust in the ability of UV decontamination to protect HCWs, patients, and others.

F14. UV unit use will need to avoid potential conflicts with clinical practice

The UVDR unit use procedures will need to respect HCW behaviors and work requirements. Some ICU staff reported that a cycle time lasting 60 seconds could be too long in the event of patient care demands. Some speculated the habits they developed through training in procedures could conflict with the need to adapt to new procedures as a pandemic breaks out, or HCWs might try to short-cut or skip procedures altogether as they focus on patient care.

F15. HCW preferences can guide unit design and use

Participants willingly offered observations and recommendations about UVDR unit design. Their experience with receiving sterilized items in a sleeve indicating they were ready for use also led to expectation the FFRs should have some visible indication of decontamination. They also mentioned practical concerns such as who will ensure the units are calibrated, continue to work correctly, or repair them. UVDR unit design traits and use context were a particular interest, including how it would work, and how any size unit would be accommodated in care units having very little to no available space.

F16. Practical requirements will need to be worked out

Participants offered constructive recommendations and posed questions about how the UVDR program might be implemented. These ranged from the space needed for used/contaminated FFRs on unit, how the hospital would put expected UV decontamination procedures into practice, and how HCWs would keep track of and manage their own FFR.

F17. Hospitals would need sufficient opportunity to evaluate cost and risk

Hospital staffs understand there are acceptable ways to mitigate the potential risk and liability of implementing a new system and those who already use UV decontamination devices were even

more confident. Each of the hospitals was cautious about the capital commitment, particularly for a unit that might not be used often enough to amortize the cost. Some considered other options, such as third-party decontamination or having municipal or state health authorities maintain a stockpile in case of need.

3.1.7.4 Discussion/Conclusions

Seven conclusions can be drawn from the above findings. Each conclusion is shown in (**Table 33**) along with the findings that support them.

Table 33. Conclusions and Supporting Findings

Conclusion	*Finding*
C1. UV units with expert staff support would be located near patient cohorts in flu wards	*F4. Clinicians strongly favor unit location near point of care*
C2. Advanced training in conjunction with CDC on pathogen threat and protection would be essential	*F10. Trust in UV relies on proof from authoritative sources and indication of effectiveness* *F12. Potential infection by pathogens other than influenza is a concern* *F13. Health Care Workers (HCWs) need thorough training in nature of actual threat and protection*
C3. Current practice in PPE (including FFR) use may compromise UVDR success	*F1. Personal considerations impose a strong gradient between those who may, and those who would not, be willing to share masks* *F2. Training and management of PPE, including FFRs, varies* *F3. HCW FFR use poses a compliance challenge*
C4. Successful UV implementation will depend on coordination across hospitals and agencies	*F7. Hospitals envision a minimum of 4 to 8 weeks to implement prior to need* *F8. Infection Control and Employee Health are aware of demands that may arise during a pandemic*
C5. Further study is needed to ensure UV unit design and procedures complement clinical practice	*F9. Education and training will play a major role in implementation* *F14. UV unit use will need to avoid potential conflicts with clinical practice* *F15. HCW preferences can guide unit design and use* *F16. Practical requirements will need to be worked out*

C6. Further development of UV decontamination is warranted as hospital FFR supplies risk depletion in a pandemic	*F5. Hospital FFR par stocks are based on historical use rates* *F6. Hospital contingency FFR supplies vary among sites* *F11. Doubts exist about FFR availability and durability*
C7. Hospitals will want to explore alternatives before assuming cost and risk burden	*F17. Hospitals would need sufficient opportunity to evaluate cost and risk*

Special Interest Topics

Legal and infection control issues are of particular interest in this study. The following section summarizes the main points that legal and infection control interview participants made on their particular topics. The site where they were mentioned is included in parentheses. Selected notes from legal and infection control interviews are included in (Appendices F and G). Paragraphs that follow each summary statement here are drawn from infection control and legal participant interview notes.

Infection Control

Infection control will be managed more deliberately during a pandemic.

In the non-pandemic timeframe people have become somewhat lazy in terms of maintaining awareness and supply of their own fit tested N95s (SBUH)

…once you reach a point of a pandemic and looking along the line of armories the contribution of the aersolization in the air flow becomes minimal. Once you start getting to alternative care facilities and – gymnasium…not worried about aersolization. (SBUH)

I would look to my background in infection and epidemiology to cohort patients to limit the number of healthcare personnel that would be caring for the patients in the cohort. (SBUH)

If we go into emergency mode we have a practitioner that stands outside door of patient and monitors the PPE – based on organism (by the way, we've had plague, Ebola, small pox virus here), we have a whole plan if we had a pandemic. (UCMC)

It wouldn't be pretty. We do direct observation for isolation patients in care (to observe that people are wearing masks correctly). (UCMC)

…our employees are biggest vulnerability, patients are good to say I have this or that, our employees come to work even if not feeling well. (UCMC)

There is a need for data on how effective UV is against various pathogens.

…we are not always initially certain of modes of transmission (like for H1N1). In a true pandemic, we don't know right away how to prepare. It's one thing to talk about one strain. What about SARS, MERS, new fungal infection? UV light is not approved for those. (GCRMC)

Space limitations constrain hospital ability to manage PPE stockpiles.

We don't have the space/capacity. We bring in suppliers from an off-site warehouse. Storage/retention of pandemic suppliers would be a challenge, especially for one-time use products. Big limitation for us - to be able to care for patients and remain safe. (GCRMC)

The ED, ICU and key wards would be priorities for UV unit location

ED is going to see the most, then how sick are they so then the ICU, if going to certain nursing units then to them. (UCMC)

Simple decontamination is contrary to the current practice to clean, then decontaminate.

…think a little more cleaning needs to be required to make sure it's 100% clean from decontamination. If there is any organic matter on it then I'm worried that something is hiding in that matter. ... with our sterilization we hammer in you have to clean it before you disinfect it. (GCRMC)

How we are suggesting throwing it in without cleaning it. With UV, you need to do an initial disinfection, and then UV is a second layer. Concerned about what they are made of – the fibers – crisscrossing fibers – how do you ensure that everything in the middle didn't get contaminated? That's why you have to decontaminate the whole room – you leave blood somewhere, and you just UV the surface, you're not getting below that layer. (UCMC)

The state health department would play a role in implementation.

…could see health department saying you have to use one of these we have 50 in the reserve and we're giving them out. (UCMC)

I see them [state health department] as a resource because I can't see most hospitals buying this unless there's a cost benefit. (UCMC)

Q. Information would be needed to believe it is effective? A. The state health department or the FDA – because in this one we are being told to reprocess something that is a single use item. From liability standpoint if the manufacturer says single use and we use it multiple times then are we legally liable? (UCMC)

Legal

A smaller number of better trained users would pose less potential risk.

Legal standpoint ensures that whoever is doing it is appropriately trained and competent on the process – typically easier to do when centralized to train a few people rather than every person who would use a mask (UCMC)

The device manufacturer/supplier would need to protect the hospital in case of malfunction

From a contractual standpoint, I'd expect the hospital to enter an agreement with the supplier or manufacturer so that we can protect the hospital against product defects and injuries from the unit. I'd be looking for a contract from beginning to end, all duties involved in between. Fair market value compensation for our involvement. In addition, the appropriate caveats or disclaimers or identification provisions, where the hospital is agreeing to be liable for any failure or breach of contract. But would not be responsible for any defective equipment, for example. This is where I come in. If there can be any injury or damage associated w/the machine. (GCRMC)

Hospitals would rely on city, state, federal government.

Think the city is capable, good infrastructure in place; it's about timing and how effectively they can roll it out. And some has to do with supplies and, if they fall short, they need to rely on federal government. (UCMC)

CDC would need to affirm that UVDR is effective, and is required.

We follow the CDC guidelines, there are pubs out there around limited use and extended use of these masks, and we would not go beyond their guidelines. We would need for them to come out and stand behind it that the sterilizing works for me to feel comfortable. (UCMC)

UVDR acceptance by unions will be difficult, and will rely on CDC corroboration.

Have a lot of unions and a lot of our front-line clinical providers belong to the unions and they look at the CDC guidelines and recommendations and that our policies align with the CDC. Don't know if our unions would ever go for it – would be an uphill battle. We would get the union stewards involved immediately, don't go and ask for permission, but would have to go and present a change in practice and educate them why it's safe and proven. But we would need backup from CDC, very challenging to go to them and say we are going to use the masks without having the CDC backing in hand. Clinical engineering would need to get involved, they would need to assess the PMs, whole process for taking on new piece of equipment. (UCMC)

UVDR would need to be proven as the standard of care.

You would have to prove it [UVDR] is standard of care, sufficiently tested, enough data out there that it's safe, backing of CDC, IC, ID that we would feel comfortable allowing this type of reuse. Now that's in standard course of things, if it's an emergency pandemic you would revisit this on a daily basis. (UCMC)

Survey Results

We used surveys to obtain basic data on UV and FFRs from those who would otherwise not be able to participate due to time demands that work load or shifts impose. Survey data from all three research sites are included in (Appendix I).

Sample Population

While (**Table 34**) showed the entire study sample, (**Table 35**) shows the number of survey respondents by role, which differed notably among the research sites. At SBUH, physicians comprised 49% of the respondents, nurses 24%, and academics in non-clinical roles 17%. At GCRMC, nurses accounted for 66%, while multiple miscellaneous roles accounted for 22% of those who responded. UCMC fielded the smallest number of responses, in which nurses comprised 62%, pharmacists 23%, and administrators and technicians 7% each.

Table 34. Survey Respondents by Research Site

Site	Admin	RT/PT/OT	Nurse	Physician	Pharmacist	Academic	Other*	Total
SBUH	3	0	20	41		14	5	83
GCRMC	8	7	105	2		3	34	159
UCMC	3	3	29	1	10			45

**"Other" includes respondents in these roles: social worker, central sterile technician, phlebotomist, EKG technician, Echo technician, and lactation consultant.*

Table 32 provides selected survey responses shown in full in (Appendix I).

Table 35. Selected Survey Responses by Research Site

Topic	SBUH	GCRMC	UCMC
Experience			
Mean Years in Role	11.6	10.5	12.4
Mean Years in Healthcare	17.1	10.6	16.1
Using FFRs in an emergency (%)	13	13	24
FFR Training and Use (%)			
Received FFR Training	79.5	89	93
Receives FFR training each year	55	90	90
Trained in FFR decontamination	7.32	12	6
FFR Policies, Procedures (1=easy,7=difficult)			
Ability to get an FFR	3.7	1.9	2.2
Ability to follow FFR procedures	3.4	1.4	1.9
FFR-UVDR Use (%)			
Familiar with use of UV to decontaminate	27.6	24	36

Perception of safety in a pandemic (1=agree, 7=disagree)			
Wearing no FFR is safe	6.6	5.7	5.4
Wearing an FFR is safe	3.9	1.7	2.4
Extended FFR use is safe	5.9	6.0	5.8
Wearing FFR with UVDR is safe	4.1	3.3	3.5
Use of UV would mitigate FFR shortage (%)	82.9	80	87

Experience

Respondents reported a range of 10.6 to 12.4 mean years of experience in their role. Mean years of experience in hospital work was higher at SBUH (17.1) and UCMC (16.1) compared with GCRMC (10.6).

Respondents had some experience using FFRs in an emergency, although few of these occasions were during an influenza outbreak.

FFR training and use

While 20% of those who responded at SBUH reported they had not received any FFR training, a majority of respondents at each site reported they had received training in the proper use of FFRs at some time, although frequency varied. Ninety percent of respondents at GCRMC and UCMC reported receiving training annually. At SBUH just over half (55%) reported receiving it annually, which may reflect policy that not all staff are required to wear an FFR.

Twelve percent of the GCRMC respondents reported they had been trained in FFR decontamination, which is slightly more than SBUH (7.3%) and UCMC (6%).

FFR policies and procedures

Respondents reported their experience on a scale of 1 (very easy) to 7 (very difficult). Getting an FFR appeared to be easier at GCRMC and UCMC than SBUH. The same was true for following FFR procedures, which SBUH respondents found a bit more difficult than those at GCRMC and UCMC.

FFR-UVDR use and perception of safety in pandemic

Some respondents were familiar with the use of UV to decontaminate. Respondents reported their perceptions on a scale of 1 (agree) to 7 (disagree). Mean responses on feeling safe going to work during a high mortality pandemic with no FFR were fairly low. Safety perception improved noticeably when asked about going to work with an FFR. Perceptions were not as positive when asked about extended wear using only one FFR. Safety perception improved when asked about use of an FFR that has been decontaminated using UV light.

Perception was generally positive that using UV to decontaminate FFRs will help to mitigate a shortage. Making FFRs more available was the most popular advantage that UV decontamination would provide. Trust in decontamination and an UVDR unit cost and availability for use were more frequently cited barriers to implementation. The most frequently cited need respondents expressed was for the decontamination process to be efficient, taking the least amount of time to get to a unit and use it.

Discussion

Two items deserve further discussion: inviting participants to consider a future work condition, and future research meriting consideration.

Envisioned World

The FFR-UVDR is a product that does not currently exist, yet could. This makes the project what is referred to as an "envisioned world" problem[19]. While the problem is in a work context that exists, that context would be substantially changed by the introduction of a new technology: FFR-UVDR. Designing technology to fit the cognitive work of a setting that is "under development" presents a number of challenges for research, design, and development. An envisioned world study such as this one probes both how people will operate in their world and how to support the way the world is expected to work.

The new use of UV technology serves as a hypothesis about the effects of interventions on the cognitive work patterns that individuals and teams perform[24]. The hypotheses are embodied in design prototypes that can then be used to discover additional support requirements. That is why we provided a brief description and illustration of what a small UV decontamination unit might look like (Appendix C) that elicited responses grounded in the participants' own experiences. In this way, analyses of operators and their cognitive work in the current world can be used to generate hypotheses about ways to improve performance.

Future Research

A number of areas covered under this study would benefit from further research.

FFR Alternatives—One assumption of this study is that FFRs are limited to traditional N95 designs. Data show substantial HCW concern over soiling, whether FFRs can be sufficiently decontaminated, and how long the current FFRs would last when worn multiple times. New FFR designs should be developed to account for health care worker concerns.

UVDR Program—Responses to queries that the team posed showed that participants were ready to explore what the FFR-UVDR system might be. Further research can learn information from HCWs about practical implementation needs as well as from authoritative sources on UV effectiveness in decontaminating FFRs against multiple pathogens including high mortality influenza. It can also reconcile perceived mismatch between current sterile practice and the manner in which a UVDR program would be implemented.

UVDR Device Design--HCW observations provide a basis to move forward with further UVDR unit development. The comments addressed portions of the Spiral Model[15], that would make it possible to foresee how the UVDR would be conceived, designed, built, tested, fielded, refurbished, upgraded, redesigned, retired, and replaced

Community Health— Some of our participants pointed out that municipal health authorities had asked their hospital for PPE during a previous threat. Learning how these organizations anticipate and plan for such circumstances would inform the FDA's future vision.

Federal, state and municipal health organizations have a vested interest in protection of public health and would need to manage response to a widespread virulent threat. Regulatory agencies need to use data collected in this project to provide guidance to health care facilities

Expanded Scope—This study is based on a research using a fairly small sample of three hospitals; one on the East, one in the South and one in the Midwest. The scope of an influenza pandemic can have far-reaching effects that a broader study could reveal. Our research indicated significant aspects that need to be further understood, from needs for training and education, to logistics that would influence UVDR decisions, to relationships among various organizations that will be essential to protect health during a pandemic.

Conclusions

We can offer the following answers regarding hospital attitudes, and identify preferences, barriers and logistic issues related to UVGI FFR-Decontamination/Reuse (UVDR).

Can they do this?

Staff members at each research site who are responsible for infection control and employee/occupational health are well-versed in how to engage a large-scale event. They also know that their ability to mount a response relies on collaboration with others from outside organizations to HCWs at their facility. More than one site expressed doubts about clinician compliance due to causes from time pressure caring for those who are critically ill to lack of motivation to be personally accountable.

Procurement staff members at the academic centers are aware of the limits to PPE availability if demand spikes. Staff members at GCRMC are confident in the Hospital Corporation of America would have sufficient supplies. However, those GCRMC staff members who saw shortages during training for a potential Ebola outbreak realize the same could occur in the event of an influenza pandemic. As a result, UV decontamination appears to be a reasonable way to mitigate an FFR shortage. Whether hospitals will pay for the capital investment is another issue, particularly if it would only be used in rare circumstances. UCMC suggested the units might be made available through the state health department.

The intimate nature of FFRs evokes strongly held opinions among health care workers about sharing masks. The majority expressed a preference for keeping an FFR for their own use. This tends to favor the use of UV units for individuals to decontaminate their own FFRs.

Will they do this?

Management level staff at each of the three sites had positive opinions about using UV for decontamination. SBUH uses UV to decontaminate toys in their pediatric care ward. The Medical Director at GCRMC is an advocate for increased UV use across healthcare facilities. UCMC uses Surfacide [407 Pilot Ct., Suite 300, Waukesha, WI, 53188, 844-895-3549, http://www.surfacide.com] UV towers for room decontamination.

Hospitals will need guidance from an authoritative source that decontamination is effective and that a pandemic care model would pre-empt traditional procedures. The CDC was often cited as the source that is most trusted for such guidance.

Front line health care workers have more varied responses, based more on unfamiliarity with UV decontamination. Many posed questions to learn about how reuse and decontamination would square with sterile practice they have been trained to follow so rigorously. Comments described aspects of the unit design that would have to be carefully considered, and how procedures would need to be trained well in advance of need.

How would they do this?

Front-line HCWs strongly favor having decontamination available near point of care. Infection Control staff members are certain that influenza patients would be assembled into cohorts on wards dedicated to their care with select staff. However, hospital capacity is limited. For example, UCMC could care for a cohort of up to 88 patients under their current plan. Collaboration plans among healthcare facilities and government organizations have used a fairly small census model to plan for patient transfers and sharing resources during a pandemic. In our limited sample for this study, it is not clear how well that model would be able to sustain care.

Alternatives to FFRs appear to be limited. UCMC mentioned that they maintain a reserve stock of FFRs they no longer use, but have available, and could place up to 100 PPRs into use. SBUH supply chain experts stated it was a challenge to stockpile spare FFRs due to manufacturer-assigned expiration dates.

The FFR-UVDR study did reveal preferences and practices that have import for the use of UV decontamination to mitigate likely FFR shortages during a high mortality influenza pandemic. Findings from the field study interviews and survey data enabled us to provide conclusions based on qualitative and quantitative data that support them.

3.2. Reusable Respirator Decontamination and Reuse

3.2.1. Base Task 6: Manual Reprocessing of Reusable RPDs – Disinfection Evaluation

3.2.1.1 Overview

An option for mitigation of an FFR shortage in hospitals is to use HMERs or PAPRs. However, neither device is cleared by the FDA for use in hospitals, yet some medical institutions are using the devices as they understand their potential for mitigating an FFR shortage despite very little being known about cleaning these devices once they are contaminated with infectious agents. Manufacturers' standard guidelines for cleaning are geared for other applications and may not be optimal for cleaning in a health care setting. The goal of this task is to optimize cleaning and disinfection protocols for devices contaminated with influenza in an attempt to minimize effort. The experimental plan will purposefully separate the cleaning and disinfection protocols because it is not clear if both will be needed for removing/inactivating viable influenza virus. Guidance for HMER decontamination is provided by OSHA and was the basis for our starting point in the study. There were some differences between what OSHA recommended and the manufacturers' guidance (**Table 36**), but we elected to use the OSHA guidance for the study.

Table 36. Manufacturers' and OSHA Cleaning Guidance for HMERs.

	3M™ 6000 Series	3M™ 7500 Series	North® by Honeywell 7700 series Half Mask	Modified Scott XCEL[29]	Modified Sperian (Survivair Blue 1)[30]
Manufacturers' Cleaning Protocols	Remove cartridges, clean with 3M™ 504 Respirator Wipes or soak in bleach solution (30 mL bleach in 2 gal water), rinse in warm water (120^{O}F max) and air dry	Remove cartridges, clean with 3M™ 504 Respirator Wipes or soak in bleach solution (30 mL bleach in 2 gal water), rinse and air dry	Remove cartridges and all components from facepiece, wash facepiece and components in cleaner sanitizer solution, rinse in warm water, air dry	Remove cartridges, sponge mask with 70% isopropyl alcohol, or spray 3 pumps of SCOTT Multi-Wash Mini (iodine-based) on both sides of mask and let sit for 10 minutes before	Remove cartridges, soak facepiece for 2-3 min in bleach solution (1 tbsp. bleach per 1 gal water), rinse in warm water

				thoroughly rinsing	
OSHA Cleaning Protocols	Remove cartridges, wash facepiece in warm water (110 °F max) with a mild detergent, rinse thoroughly, immerse in bleach solution (1 mL bleach in 1 L water) for 2 min, rinse in warm water (110 °F max), hand dry or air dry				

The guidance provided to clean PAPRs is limited and very little useful guidance was found on the OSHA website. We reached out to colleagues at the Veterans Health Administration and the NIOSH, and they confirmed the lack of OSHA guidance for PAPRs in health care settings. The manufacturers' guidelines we have received thus far are for the 3M Breathe Easy PAPR. For the hood, they only suggest using soap and water to clean the PAPR hoods. They do have disinfection protocols for the blower unit and the breathing tube as shown in (**Table 37**). Their guidance for disposal of the canisters must be ignored for this effort because it is likely the canisters will be in short supply during a pandemic. It is also common practice to leave the canisters on the PAPR blower until they no longer pass the pressure drop evaluation. We found additional guidance from Oregon Health and Science University (OHSU) on disinfection of their PAPRs after use around tuberculosis patients. They use SaniCloth™ disinfecting wipes for both the hoods and the blower units. They also use the wipes to clean and disinfect both the interior and exterior of the hood. This will be important if the hoods are to be shared between users. As a starting point for our effort, we will use a sponge dampened with soap and water to first clean the PAPR hoods and blower units followed by wiping with a disinfecting wipe. The wipe we chose is the PDI™ Super SaniCloth™, similar to OHSU and is commonly used in the hospital setting. The SOP for cleaning the PAPRs is listed below.

Table 37. Manufacturers' and OSHA Cleaning Guidance for PAPRs.

	3M™ Air-Mate™	3M™ Breathe Easy™	Syntech International MAXAIR
Manufacturer's Cleaning Protocols	Hood: wipe with cloth or sponge dampened with warm water and liquid household soap, air dry (do not soak in any solution or wipe with any strong solvents)	Hood: wipe with cloth or sponge dampened with warm water and liquid household soap, air dry (do not soak in any solution or wipe with any strong solvents)	Helmet: Use a damp cloth with mild detergent to clean the outer and inner exposed surfaces of the Helmet. Isopropyl alcohol may be used to clean the Helmet. However, repeated long term use of isopropyl alcohol
	Cleaning: wipe blower unit and battery pack with a	Cleaning: wipe blower unit and battery pack with a mild cleaning	

	mild cleaning solution; dispose of used cartridges/filters; soak breathing tube in mild cleaning solution and flush, immediately connect breathing tube to blower and let run for 30 min with tube hanging downward until dry Disinfecting: wipe blower with a cloth dampened with warm water and a bleach solution, followed by wiping with clean water; wipe battery with a disinfection solution; flush or soak breathing tube with disinfection solution, then flush with clean water and immediately connect breathing tube to blower and let run for 30 min with tube hanging downward until dry	solution; dispose of used cartridges/filters; soak breathing tube in mild cleaning solution and flush, immediately connect breathing tube to blower and let run for 30 min with tube hanging downward until dry Disinfecting: wipe blower with a cloth dampened with warm water and a bleach solution, followed by wiping with clean water; wipe battery with a disinfection solution; flush or soak breathing tube with disinfection solution, then flush with clean water and immediately connect breathing tube to blower and let run for 30 min with tube hanging downward until dry	may deface the Helmet.
OSHA's Cleaning Protocols	After doffing: place all reusable PAPR components in an area or container designated for the collection of PAPR components for disinfection. The facility should follow manufacturer's instructions for decontamination of all reusable components and, based upon those instructions, develop facility protocols that include the designation of responsible personnel who assure that the equipment is appropriately reprocessed and that batteries are fully charged before reuse. Hoods are single-use.[35]		

	http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html
OHSU Cleaning Protocols	Wipe the outside of the PAPR system with a SaniCloth™. Disinfect the inside and then the outside of the PAPR hood with a SaniCloth™ (hoods may be shared between healthcare workers).[35]

In addition to the cleaning protocols that were considered, thought was given to where the contamination was added and the addition of a fouling contaminant. Both HMERs and PAPRs have multiple material surfaces that may be cleaned with different efficacies. Various surfaces from various HMERs and PAPRs were either cleaned only or cleaned and disinfected to separate the effect of cleaning from disinfection. A description of this task was published in the *American Journal of Infection Control*.[36]

3.2.1.2 Materials and Methods

H1N1 influenza

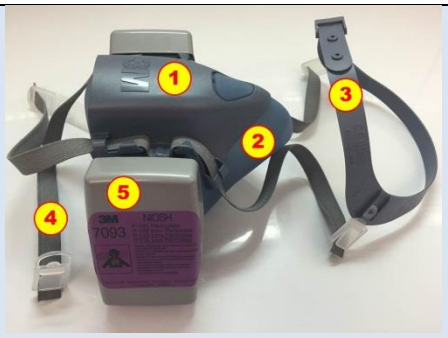
H1N1 influenza A/PR/8/34 (ATCC® VR-1469™) was propagated in embryonic chicken eggs (Charles River Premium Specific Pathogen Free Eggs 10100326) using standard World Health Organization (WHO) protocols.[31] Virus titers were determined by tissue culture infectious dose ($TCID_{50}$) assay. Madin-Darby canine kidney (MDCK) cells (ATCC ® CCL-34™) were passaged and maintained using WHO-approved cell culture techniques.

HMERs and PAPRs

Five commercially available HMER models (**Table 38**) and three commercially available PAPR models (**Table 39**) were chosen for this study based on a National Institute of Occupational Safety and Health (NIOSH) survey, discussions from the FDA summit,[37] VHA usage of HMERs, and usage of HMERs by Ciconte and Danyluk.[38] Each model was inoculated with influenza on five separate surfaces to ensure the effect of cleaning on different surface types was accounted for.

Table 38. HMER Models Selected for this Study.

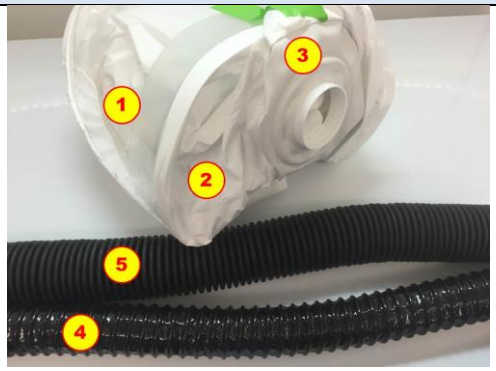
HMER Model	Inoculated Surfaces
3M™ 6000 series*	

3M™ 7500 series‡	
North® by Honeywell 7700 series^	
Modified Scott XCEL‡	
Modified Sperian (Survivair Blue 1)	

*Ciconte and Danyluk
‡VHA use of RPDs
^Texas Center for Infectious Disease use of RPDs

Table 39. PAPR Models Selected for this Study

PAPR Model	Inoculated Surfaces

3M™ Air-Mate™	
3M™ Breathe Easy™	
3M™ Hood, 3M™ Air-Mate™ Breathing Tube (Surface 4), 3M™ Breathe Easy™ Breathing Tube (Surface 5)	
Syntech International MAXAIR	

^ Texas Center for Infectious Disease use of RPDs

HMER cleaning studies

For each test, three replicates of a given HMER model were inoculated in a Class II biological safety cabinet (BSC) with ten 1-µL drops of ~ 10^7 $TCID_{50}$/mL H1N1 influenza on the surfaces defined in **Table 38**. Inoculated surfaces were allowed to dry in the BSC at room temperature for

approximately 20 minutes. After the droplets had dried, approximately 5 mg of synthetic skin oil (Scientific Services S/D, Sparrow Bush, NY) was applied over each inoculated surface with a triangle-shaped cell spreader to act as a protective factor and soiling agent.

For each test, three replicates of a given HMER model were inoculated in a Class II biological safety cabinet (BSC) with ten 1-µL drops of ~ 10^7 $TCID_{50}$/mL H1N1 influenza on the surfaces defined in Table 1. Inoculated surfaces were allowed to dry in the BSC at room temperature for approximately 20 minutes. After the droplets had dried, approximately 5 mg of synthetic skin oil (Scientific Services S/D, Sparrow Bush, NY) was applied over each inoculated surface with a triangle-shaped cell spreader to act as a protective factor and soiling agent.

Of the three HMER replicates, one was cleaned and disinfected, one was only cleaned, and the third was neither cleaned nor disinfected and served as a control mask to quantify the challenge concentration. Procedures for cleaning and disinfecting were based on protocols defined by the Occupational Safety and Health Administration (OSHA). After inoculating the HMERs with both influenza and sebum, HMERs were aseptically transported to a Class I BSC. Cartridges, if present, were removed from the mask and placed in a separate empty reservoir. HMERs and cartridge covers were placed in a 12.75" L × 10.125" W × 4.25" D Nalgene pan with 1 L of a 42 °C of 0.5% Neutrawash detergent solution (Getinge USA, Inc., Rochester, NY) and wiped with an autoclavable sponge. The external face of the mask was first wiped, and then the sponge was folded over each strap for wiping; the inside of the mask was wiped last. Each HMER and cartridge cover was then rinsed with 1 L of 42 °C tap water over the same pan. The external face of the mask and the straps were rinsed first and then the inside of the mask was rinsed. For cartridges, the front side of each cartridge was wiped with a sponge soaked in 0.5% Neutrawash solution and then wiped with a sponge soaked in water only to remove any detergent. For HMERs that were also disinfected, HMERs and covers were transferred to a another Nalgene pan measuring 12.75" L × 10.125" W × 4.25" D containing 3 L of a 0.1% bleach solution (Clorox, Oakland, CA). Each side of the HMER and cover was immersed in the bleach solution for 2 minutes. Each HMER and cover was then rinsed with 1 L of water to remove any bleach. For cartridge disinfection, a Super SaniCloth® (PDI, Orangeburg, NY) with an alcohol quat antimicrobial was used to wipe the exterior surfaces and allowed to dry at room temperature for approximately 2 minutes in the Class I BSC.

After cleaning and/or disinfecting, each surface was sampled using a sterile polyester swab moistened with serum-free Eagle's minimal essential media (EMEM). Each swab was placed in a 50-mL tube containing 10 mL of serum-free EMEM and vortexed for 5 minutes to extract the influenza virus if present. Extracts were subsequently serially diluted in serum-free EMEM and, using a median tissue culture infectious dose ($TCID_{50}$) assay, plated in quadruplicate in 24-well plates with confluent monolayers of MDCK cells. Plates were subsequently incubated at 37 °C in 5% CO2 for 1 hour. After the 1-hour incubation, 0.1 mL of a bovine serum albumin and trypsin solutions was added to each well to promote virus infectivity. Plates were then incubated at 37

°C in 5% CO_2 for 7 days. After the incubation period, each well was observed under the microscope for cytopathic effects (CPE), generally demonstrated by a disruption of the cell monolayer. Plates were subsequently stained with crystal violet-glutaraldehyde to confirm the presence of CPE.

PAPR cleaning studies

No OSHA protocols exist that define cleaning and disinfecting procedures for PAPRs; instead, OSHA defers to the manufacturers' protocols. As suggested by the manufacturer, the motor blower and hoods were wiped with a mild cleaning solution.[39] Following Oregon Health and Science University's (OHSU) protocol for disinfection, the motor blower and hoods were then wiped with a SaniCloth®.8We modified the manufactures protocols as described above to arrive at the final test conditions. Each PAPR was wiped with an autoclavable sponge moistened with a 42 °C, 0.5% Neutrawash detergent solution and subsequently wiped with another autoclavable sponge soaked in 42 °C water only to remove any detergent. PAPRs to be disinfected were then wiped with a Super SaniCloth® similar to the HMERs and allowed to dry for 2 minutes. The 3M™ Breathe Easy™ PAPR motor was first wiped around the cartridges, and then the sides and back of the motor were wiped. The battery was wiped next, taking care to avoid wiping near the switch. The belt clip was wiped last. The front of the 3M™ Air-Mate™ was wiped first, followed by the back and the sides. The sponge was then used to wipe the front and then the back surfaces of the belt. The belt clip was wiped last. The Syntech International MAXAIR was first wiped across the top of the helmet and then the clear visor was wiped. The battery was wiped last, taking care to avoid the plug for the battery cable. The 3M™ Hoods were first wiped on the crown of the hood and then the clear visor and breathing tube insert were wiped. Long wipes were then made down the hood while rotating the hood, making sure all areas were wiped.

The manufacturer's cleaning and disinfecting protocols for the 3M™ breathing tubes suggest soaking the tubes in a detergent solution and then in a bleach solution, as necessary.[39] No specific details were given regarding length of soak. After soaking, the breathing tube must be flushed with clean water and then be connected to the PAPR blower unit with the breathing tube hanging downward and the unit running for a minimum of 30 minutes to dry the inside of the tube. Rather than soaking the tubes, the external surfaces of the breathing tubes were wiped using the same methods as the PAPR blower motors and hoods. The 3M™ Breathe Easy breathing tube was stretched and held in place by clamps attached to a ring stand for cleaning, disinfecting, and sampling.

Data analysis

To determine the level of viable virus recovered from each sampled location, the Spearman-Karber formula was used to interpret the $TCID_{50}$ assay data.[40] An unpaired t-test was performed using Prism (Graphpad, La Jolla, CA) to compare the recovery values between sampling locations of a given mask.

3.2.1.3 Results

All five HMER models demonstrated an approximate 5-log reduction in viable influenza (below detection limit) for both cleaned and disinfected masks. The 3M 6200 model demonstrated a mean log reduction of 3.90 ± 0.55 log $TCID_{50}$ for all surfaces of both cleaned only and cleaned and disinfected (**Figure 34**). The 3M 7500 model demonstrated a mean log reduction of 4.07 ± 1.06 $TCID_{50}$ for all surfaces of both cleaned only and cleaned and disinfected (**Figure 35**). The North by Honeywell 7700 series demonstrated a mean log reduction of 4.79 ± 1.06 $TCID_{50}$ for all cleaned surfaces and 4.83 ± 0.98 $TCID_{50}$ for all cleaned and disinfected surfaces (**Figure 36**). The Scott XCEL model demonstrated a mean log reduction of 4.95 ± 1.11 $TCID_{50}$ for all surfaces of both cleaned only and cleaned and disinfected (**Figure 37**). The Sperian model demonstrated a mean log reduction of 4.92 ± 0.95 $TCID_{50}$ for all cleaned surfaces and 4.98 ± 0.81 $TCID_{50}$ for all cleaned and disinfected surfaces (**Figure 38**). With all 5 HMERs, Surface 4, the elastomeric strap, shows the lowest log reduction. In two of the tests with the 3M 7502 mask, no influenza was extracted from the control straps, resulting in no error bar due to lack of variability. With the North 7700 mask and Sperian masks, disinfection of the strap did show a small increase in log reduction due to some viable influenza still present on the cleaned only mask, although cleaning alone still showed a significant log reduction. The difference in log reduction between the cleaned only and cleaned and disinfected data of both the North 7700 and Sperian masks were not statistically significant (p = 0.96 and p = 0.91, respectively). Surface 5 of the Scott XCEL mask has no error bar due to the log reduction being the same for all three runs.

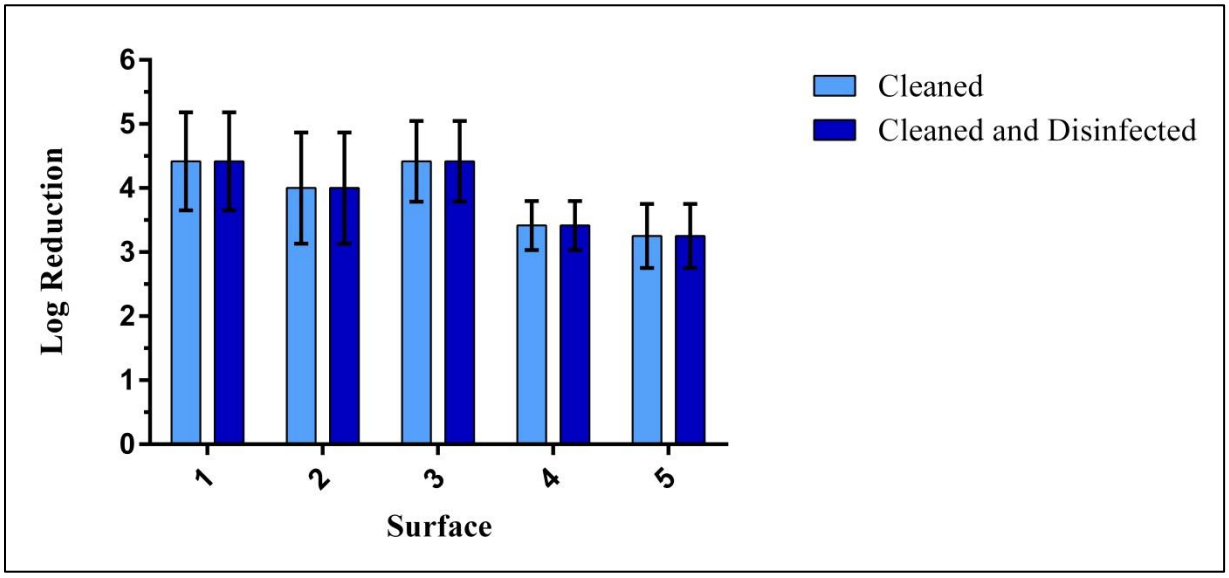


Figure 34. Log Reduction Values for Cleaned and Disinfected 3M™ 6200 HMERs.

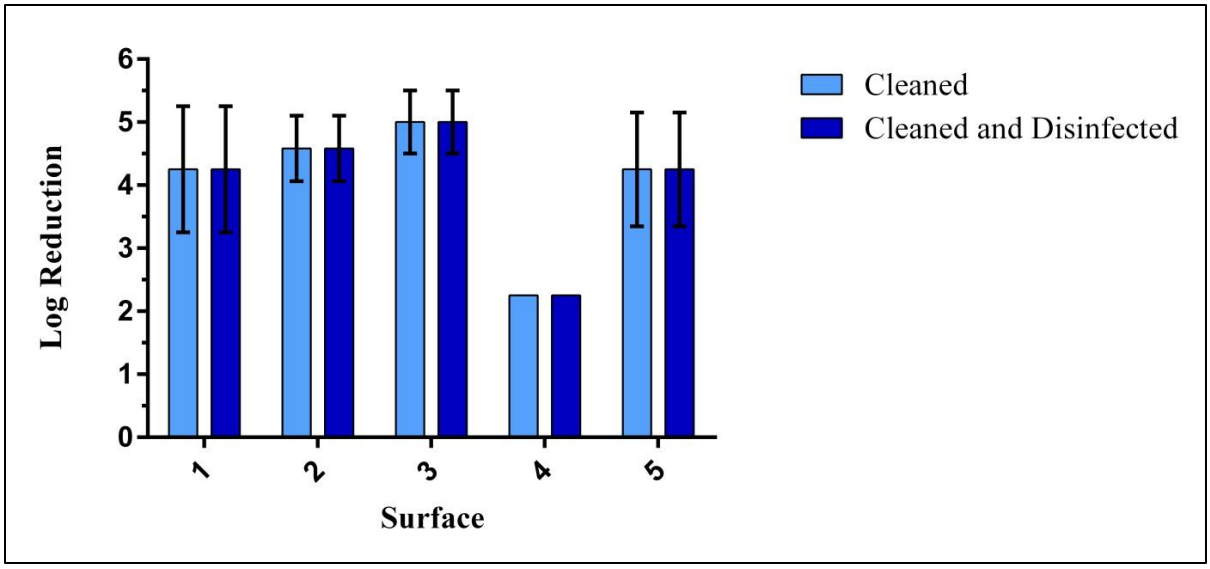


Figure 35. Log Reduction Values for Cleaned and Disinfected 3M™ 7500 HMERs.

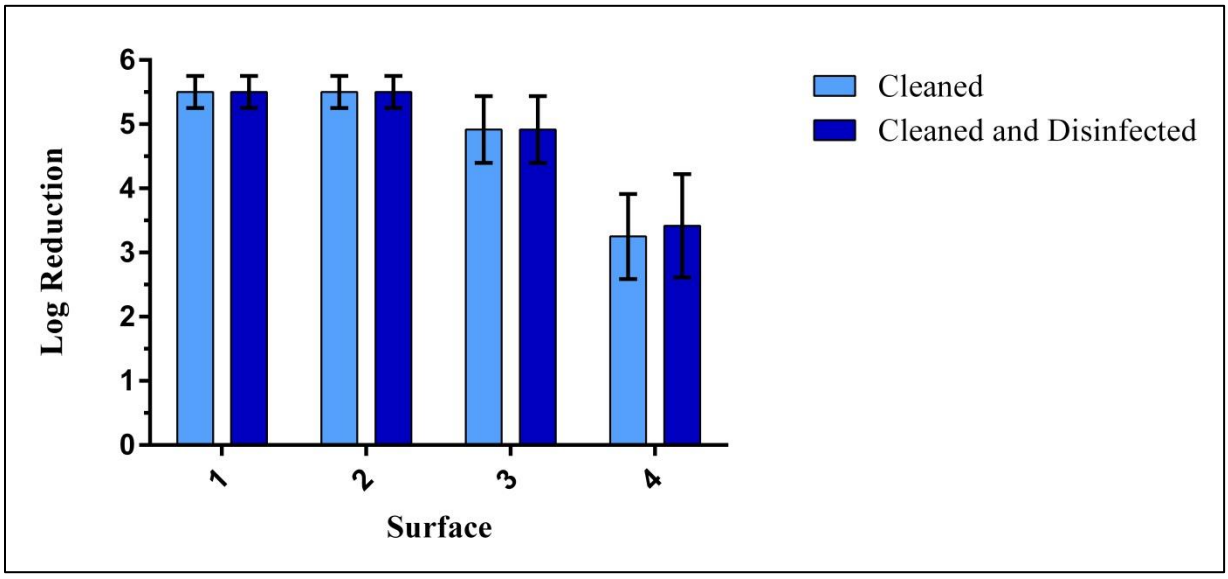


Figure 36. Log Reduction Values for Cleaned and Disinfected North® by Honeywell 7700 HMERs.

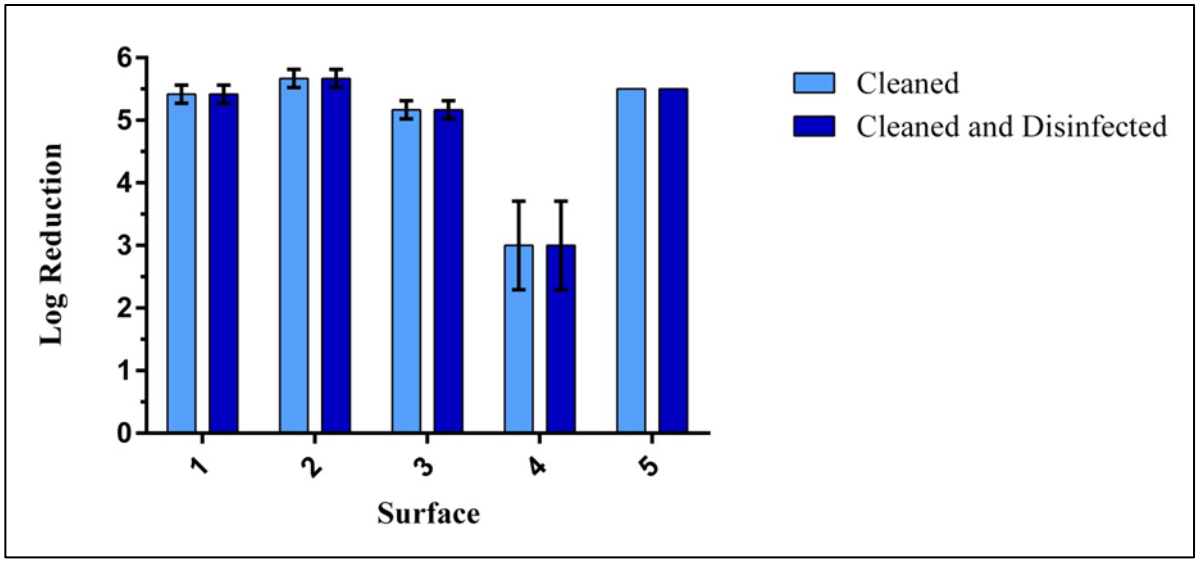


Figure 37. Log Reduction Values for Cleaned and Disinfected Scott XCEL HMERs.

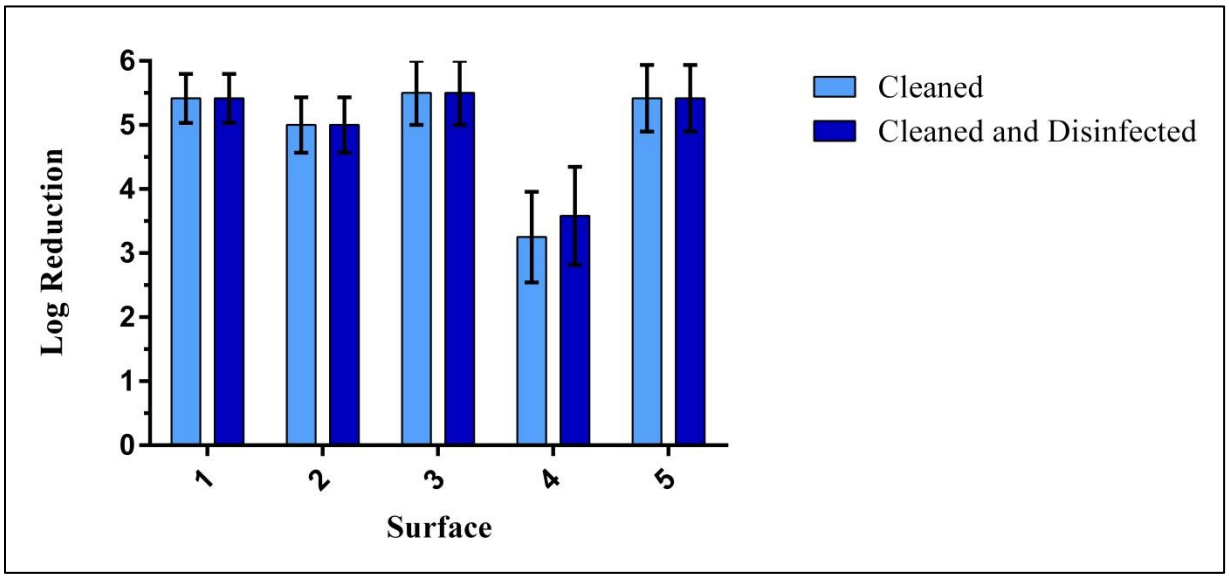


Figure 38. Log Reduction Values for Cleaned and Disinfected Sperian Survivair Blue 1 HMERs.

Log reduction values for the PAPRs are very similar to the HMERs, and no viable influenza was detected on a majority of surfaces. Surface 4 for the Breathe Easy PAPR was unable to be tested due to the belt piece shredding upon being cut for vortex mixing. The 3M Air Mate model demonstrated a mean log reduction of 4.39 ± 0.21 $TCID_{50}$ for all surfaces of both cleaned only and cleaned and disinfected (**Figure 39**). The 3M Breathe Easy model demonstrated a mean log reduction of 4.94 ± 0.21 $TCID_{50}$ for all surfaces of both cleaned only and cleaned and disinfected

(**Figure 40**). The Syntech International MAXAIR demonstrated a mean log reduction of 4.56 ± 0.13 $TCID_{50}$ for all surfaces of both cleaned only and cleaned and disinfected (**Figure 41**). The 3M hoods demonstrated a mean log reduction of 4.78 ± 0.24 $TCID_{50}$ for all surfaces of both cleaned only and cleaned and disinfected (**Figure 42**). The 3M Air Mate breathing tube showed a mean log reduction of 4.67 ± 0.38 $TCID_{50}$ for all surfaces of both cleaned only and cleaned and disinfected (**Error! Reference source not found.**). For the 3M Breathe Easy breathing tube, o nly two dilutions per sample were plated from the cleaned only tube. All wells showed cytopathic effects, making the assay inconclusive. Cleaning and disinfecting, however, was effective. The cleaned and disinfected Breathe Easy breathing tubes showed a mean log reduction of 3.33 ± 0.38 $TCID_{50}$ (**Table 40**).

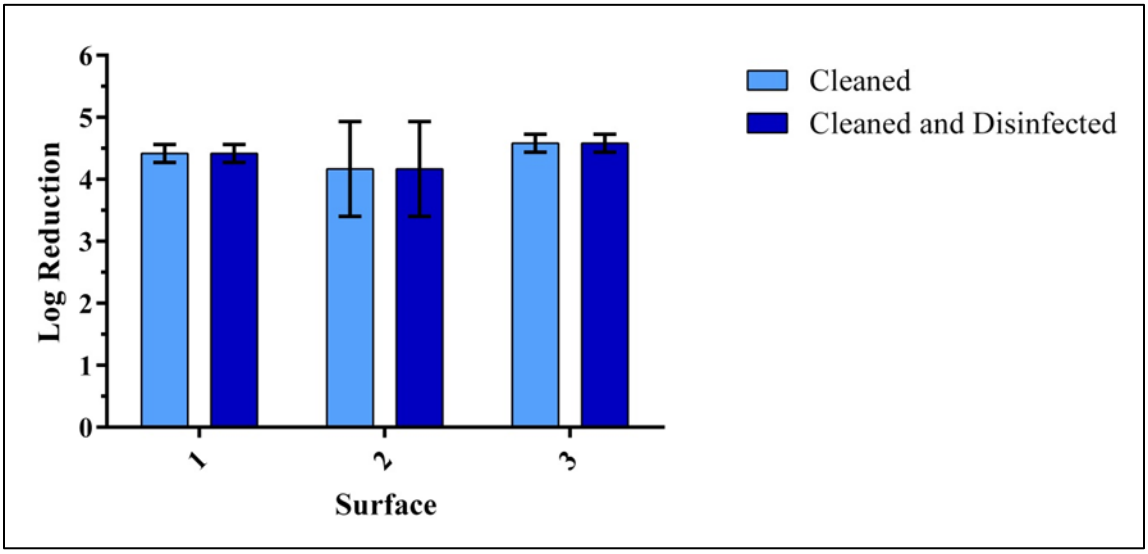


Figure 39. Log Reduction Values for Cleaned and Disinfected 3M™ Air Mate PAPRs.

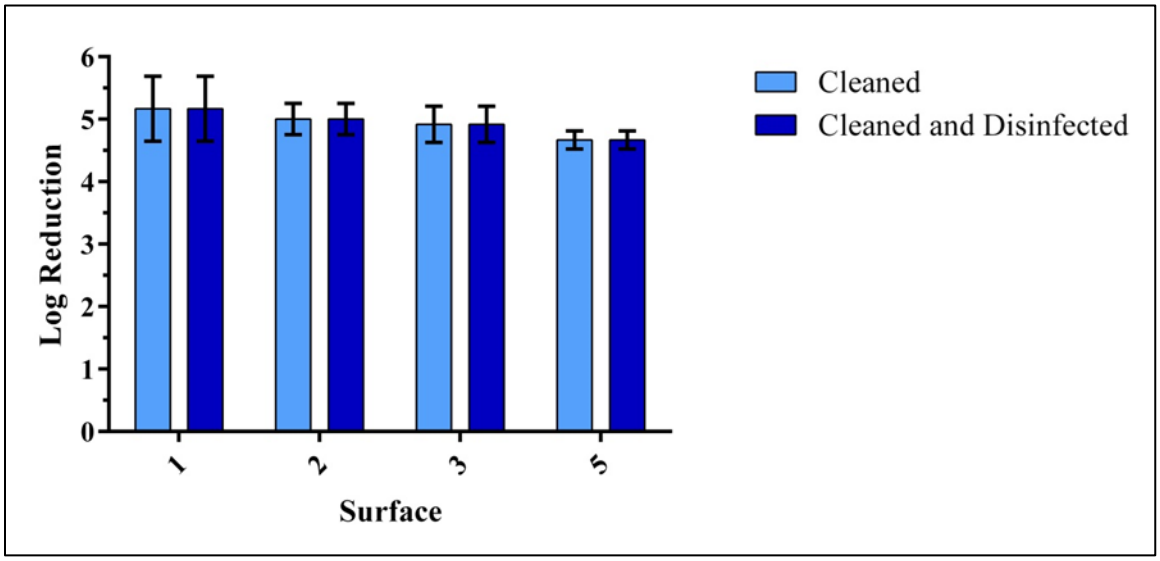


Figure 40. Log Reduction Values for Cleaned and Disinfected 3M™ Breathe Easy PAPRs.

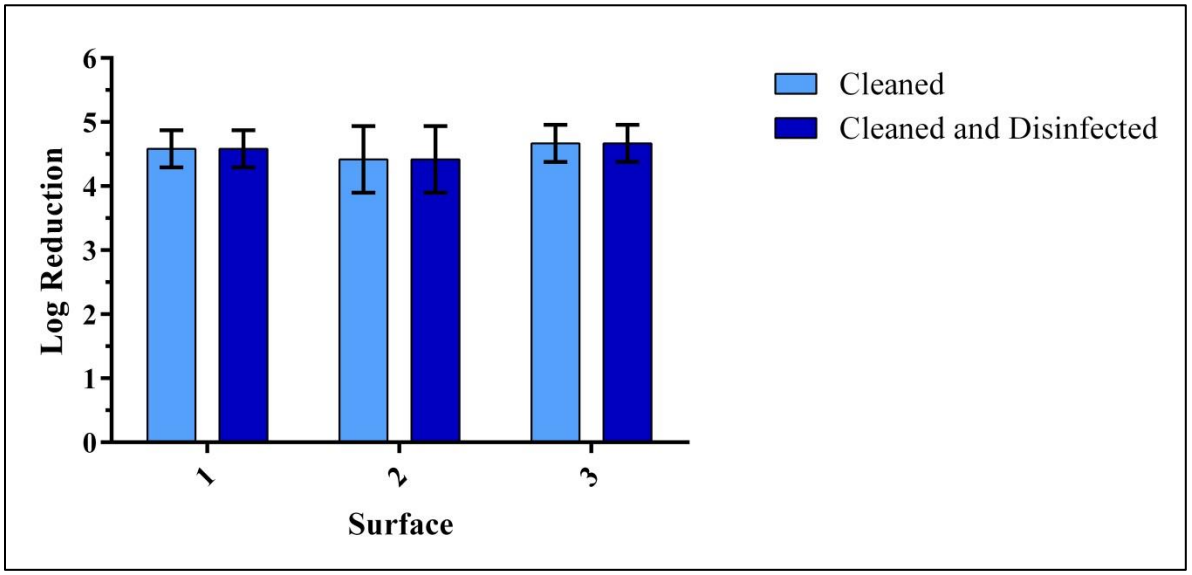


Figure 41. Log Reduction Values for Cleaned and Disinfected Syntech International Maxair PAPRs.

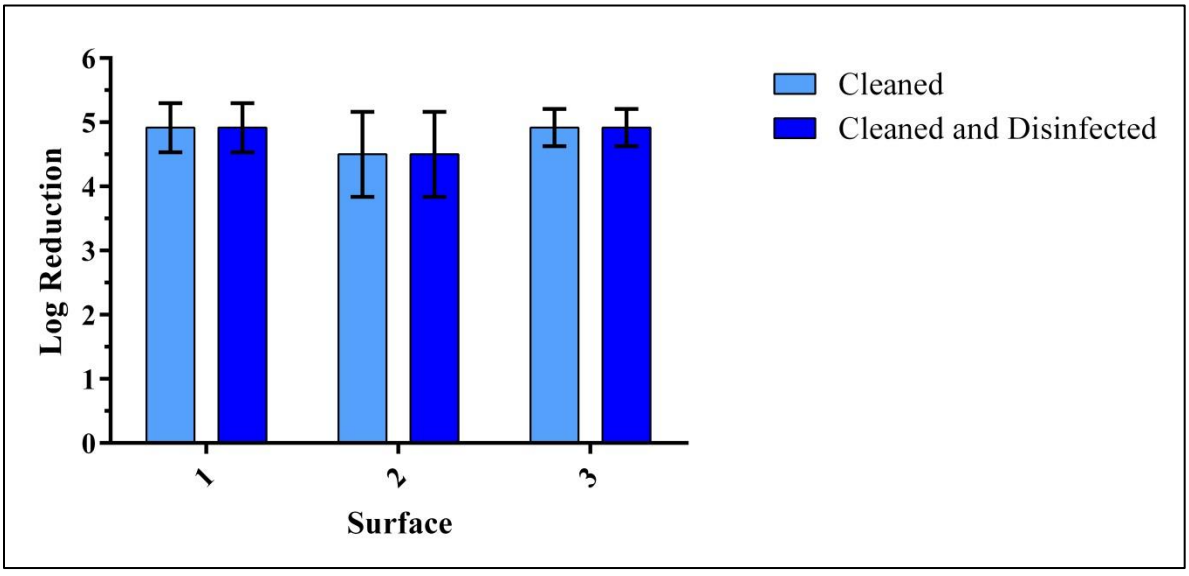


Figure 42. Log Reduction Values for Cleaned and Disinfected 3M™ Hoods.

Table 40. Log Reduction Values for the 3M™ Breathing Tubes.

Run	3M AirMate					3M Breathe Easy				
	Ctrl	C	LRV	C&D	LRV	Ctrl	C	LRV	C&D	LRV
1	5.25	0.25	**5.00**	0.25	**5.00**	3.25	>2.50	**<0.75**	0.25	**3.00**
2	5.00	0.25	**4.75**	0.25	**4.75**	4.00	>2.50	**<1.50**	0.25	**3.75**
3	4.50	0.25	**4.25**	0.25	**4.25**	3.50	0.25	**3.25**	0.25	**3.25**

C = Cleaned Only
C&D = Cleaned and disinfected
LRV = Log reduction value

3.2.1.4 Discussion/Conclusions

Discussion

For all five HMER models, cleaning was effective in decontaminating all surfaces, even with heavy soiling. The disinfection step showed the same log reduction as the cleaning step for most surfaces. Surface 4 on all HMERs, the elastomeric strap, was difficult to extract influenza from, accounting for the lower log reduction. Tween-80 was used to increase virus extraction from the straps, but even at 0.01%, the surfactant was cytotoxic to the MDCK cell monolayer, invalidating the assay. The 3M™ 7500 strap lacked a hydrophobic coating and the influenza droplets immediately soaked into the strap, making extraction very difficult. In two of the runs with this mask, no influenza was extracted from the control strap. The disinfection step for the straps of the North® 7700 mask and Sperian mask showed a slight increase in log reduction, but the log reduction from the cleaning step alone was still significant.

Cleaning alone was also effective for all three PAPRs, 3M™ hoods, and 3M™ Air Mate breathing tube, despite only being wiped with a sponge and not being immersed or rinsed. The 3M™ Breathe Easy breathing tube, however, was challenging. The tube had to be fully stretched and held in place by clamps attached to a ring stand to expose all external surfaces. Even while fully stretched, cleaning alone was not effective because the sponge was not able to reach into the bottom of each groove. Disinfection with a PDI® Super SaniCloth® was necessary to show a significant log reduction. Because of the difficulty associated with wiping this tube and the additional equipment required, it may be necessary to soak the tube according to the manufacturer's protocol. The manufacturer's protocol also calls for the tube to be connected to the PAPR motor and hang downward with the motor blowing for 30 minutes in order to dry the inside of the tube. This method is time consuming and would take a PAPR out of service and drain the battery. Covers for the breathing tubes do exist but were not included in this study due to the likelihood of a shortage of these covers during a pandemic.

Conclusions

- The manual reprocessing protocol is effective at reducing viable influenza on HMERs and most PAPR components.
- Cleaning alone (without disinfection) is effective at reducing viable influenza on HMERs and most PAPR components.

- The Breathe Easy breathing tubes cannot be wiped and will require full submersion in bleach for disinfection.

3.2.2. Base Task 7: Manual Reprocessing of Reusable RPDs – Durability Evaluation

3.2.2.1 Overview

In addition to evaluating the cleaning and disinfection efficacies of manual reprocessing of HMERs/PAPRs, durability of these devices after experiencing multiple reprocessing cycles must be assessed to ensure their performance and level of protection is not hindered as a result of reprocessing. For this task, five HMER models and three PAPR models were cleaned and disinfected 75 and 150 times. ARA staff traveled to National Institute for Occupational Safety and Health (NIOSH) labs in Pittsburgh, PA to conduct durability testing. A portion of the NIOSH-established tests for HMERs and PAPRs was completed by ARA staff at NIOSH, and the NIOSH certification lab completed the remainder of the testing. The loose-fitting headgear worn with the PAPRs was sent to IPS Testing, Inc. (Appleton, WI) for material testing. Since there are no regulations for the headgear, a comparison was made between the material strength of new (control) headgear and headgear that was cleaned and disinfected 150 times to ensure there was no degradation.

3.2.2.2 Materials and Methods

Test respirators

Five HMER models and three PAPR models (**Table 41**) were cleaned 75 and 150 times according to the protocol defined in Task 6. Briefly, HMERs were manually cleaned with 0.5% Neutrawash and subsequently disinfected using 0.1% bleach. HMER cartridges that were cleaned were done so by wiping with a 0.5% Neutrawash solution and then with a PDI SaniCloth wipe. PAPRs were manually cleaned with 0.5% Neutrawash and subsequently disinfected with PDI SaniCloth wipes. Three respirators were cleaned for each HMER model, and three respirators were cleaned for each PAPR model. New respirators that have not been cleaned were used as controls.

Table 41. Respirators cleaned and evaluated for Task 7.

Respirator type	Respirator Model
HMER	3M 6200
	3M 7502
	Scott XCEL
	Sperian SurvivAir
	North 7700
PAPR	3M Breathe Easy
	3M AirMate
	Syntech MaxAir

HMER durability testing

Functionality of treated and untreated HMERs was evaluated using a variety of performance tests recommended by NIOSH (**Table 42**). Tests were performed by either ARA personnel at the NIOSH-NPPTL facility or by NIOSH personnel in their certification lab.

Table 42. Performance tests used to evaluate HMER functionality.

Performance Tests	Protocol	Performer
Particle penetration test using a NaCl aerosol	TEB-APR-STP-0051	ARA/NIOSH
Particle penetration test using a DOP aerosol	TEB-APR-STP-0051	NIOSH certification lab
Fit test	No standard	ARA/NIOSH
Inhalation resistance test	TEB-APR-STP-0007	NIOSH certification lab
Exhalation resistance test	TEB-APR-STP-0003	NIOSH certification lab
Exhalation valve leakage test	TEB-APR-STP-0004	NIOSH certification lab

Particle penetration was only evaluated for HMER models with cleaned cartridges (3M 6200 and 3M 7502). Cartridges for other HMER models were not cleaned due to their open filter design. To evaluate the NaCl penetration of cleaned HMER cartridges, an Automated Filter Tester 8130 (TSI, Shoreview, MN) was used which generates a polydispersed NaCl aerosol with a count median diameter of 0.075 µm and a concentration of 12–20 mg/m3. Prior to testing, sections of the HMERs that serve as filter attachment points were cut from the mask, secured to the filters, and wax-sealed to a Plexiglas plate with a central 1.5” diameter opening to allow the NaCl aerosol to pass through. The plate is then sealed onto a Plexiglas enclosure used for aerosol containment and placed into the TSI 8130 for penetration testing. Penetration tests were performed using a flow rate of 42.5 LPM, the standard flowrate used for testing a single P100 filter from a HMER model with a dual filter design. If a HMER used a single filter design, then the flowrate required for the test would be 85 LPM. The maximum penetration allowed for a P100 filter to be considered “passing” is 0.03 %. Flow rate resistance is also measured by the TSI 8130; the maximum resistance permitted for a P100 filter is 35 mmH_2O.

Fit testing was performed by donning HMERs onto a medium-sized NIOSH headform connected to an artificial breathing system while being exposed to a polydispersed NaCl aerosol with a concentration of 2.5–5.0 × 104 particles/cm3 (**Figure 43**). The breathing protocol used for this testing consisted of three consecutive breathing periods: 80 seconds of normal breathing, 80 seconds of deep breathing, and 80 seconds of normal breathing. Normal breathing is defined as breath volumes of 800 mL, while deep breathing is 1700 mL per breath. Once the HMER was donned on the headform, a preliminary fit factor was determined using a PortaCount 8038 (TSI, Shoreview, MN) during normal breathing; a minimum factor of 1000 was required for passing as

specified by NIOSH. Once a passing fit factor was established, the fit test would proceed using the breathing protocol defined above.

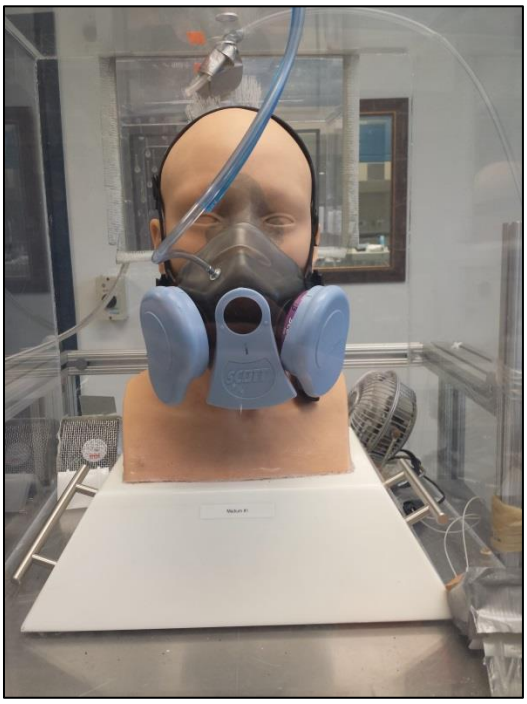


Figure 43. HMER donned on medium-sized NIOSH headform.

The NIOSH certification lab performed inhalation resistance, exhalation resistance, exhalation valve leakage, and DOP penetration testing on the HMERs according to established NIOSH standard testing procedures[34]. Resistance testing is conducted by mounting the respirator on a head form and using a vacuum source and manometer to determine resistance. Exhalation valve leakage is conducted in the same way, but the exhalation valve is cut out of the mask and sealed into a funnel and therefore, only done at 150 cycles as it is destructive. DOP penetration is a modified version of the particle penetration test, using DOP rather than NaCl aerosols. DOP is a toxic chemical, and filters must be discarded after this test. Exhalation valve leakage and DOP penetration testing are destructive, so these evaluations were conducted only after 150 cycles.

PAPR durability testing

Functionality of treated and untreated PAPRs was evaluated using a variety of performance tests recommended by NIOSH (**Table 43**). IPS Testing, Inc. (Appleton, WI) performed the durability tests associated with the PAPR hoods and breathing tubes.

Table 43. Performance tests used to evaluate PAPR functionality.

Performance Tests	Protocol	Performer
Total inward leakage	No standard	ARA/NIOSH
Air flow velocity	RCT-APR-0012	NIOSH
DOP penetration	TEB-APR-STP-0001	NIOSH

Fluid resistance (Tyvek)	AATCC 127	IPS Testing
Material strength (Tyvek)	ASTM D6797	IPS Testing
Seam strength (Tyvek-Tyvek)	ASTM D1683	IPS Testing
Seam strength (Tyvek-visor)	ASTM D1683	IPS Testing
Optical transparency	ASTM D1003	IPS Testing
Material strength (visor)	ASTM D6797	IPS Testing

For PAPRs, a total inward leakage (TIL) test and an air flow velocity test were performed for each unit. Three units were tested for two of the PAPR models (3M Air-Mate and Syntech MAXAIR) at 75 cycles. It was found that the breathing tubes for the 3M Breathe Easy lacked the correct connection adapter to be used with the appropriate hood, thus they were not able to be used for the TIL test at 75 cleaning cycles. The correct tubes for the Breathe Easy were subsequently obtained and three units were tested for all three models at 150 cycles.

For the TIL testing, each PAPR was donned onto a medium-sized headform inside a large fit testing chamber and exposed to a NaCl aerosol with a concentration of ~1–2 × 105 particles/cm3 (**Figure 44**). The headform was connected to a breathing machine and a similar breathing protocol was used as the HMER fit testing. A PortaCount 8038 was used to determine the TIL through a port in the PAPR visor located in front of the manikin mouth.

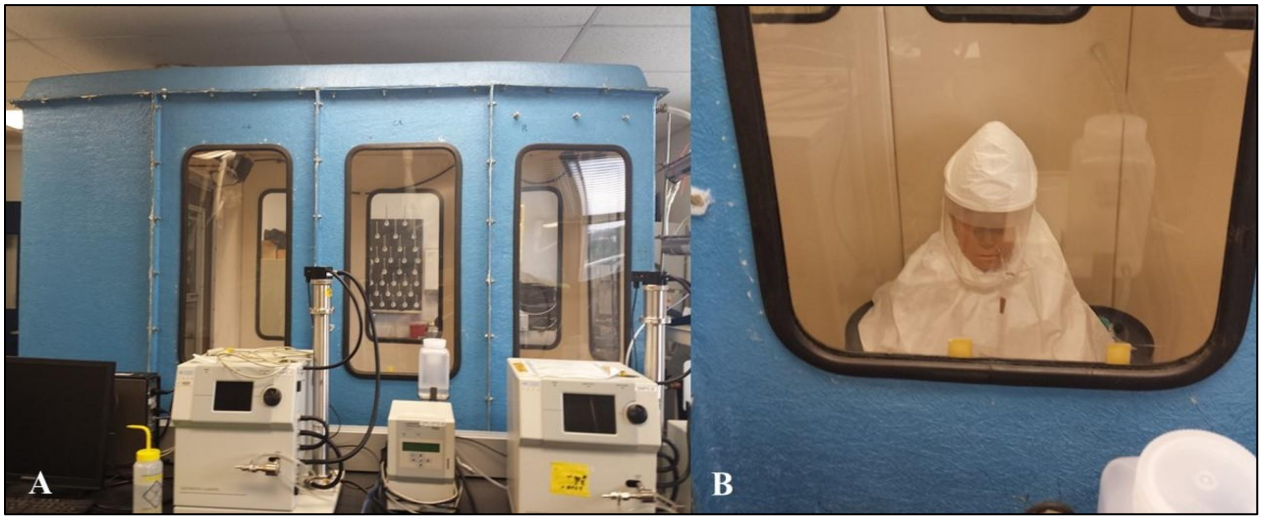


Figure 44. A) Large fit testing chamber, B) PAPR donned on headform in chamber.

Subsequent to the TIL testing, The NIOSH certification lab performed air flow velocity and DOP penetration tests on the PAPRs to evaluate the motors and cartridges, respectively. DOP is a toxic chemical, so this test was conducted only after 150 cleaning cycles.

Durability tests for the PAPR hoods and breathing tubes were conducted only after 150 cleaning cycles due to their destructive nature. A fluid resistance test (AATCC 127) and material strength test (ASTM D6797) were conducted on the Tyvek material of the hood. An optical transparency (ASTM D1003) and material strength test (ASTM D6797) were conducted on the visor. Seam

strength tests (ASTM D1683) were performed on the Tyvek-Tyvek seam and Tyvek-visor seam as these seams were the most exposed during cleaning (**Figure 45**). Fluid resistance testing was conducted by applying 1000 psi of water against the material; the opposite side of the material was observed for water droplet penetration. The ball burst test was used to measure material strength; the force at which the ball was able to burst the material was recorded. Optical transparency was determined with a light source and a photodetector. Seam strength was determined by gradually pulling the seam with a grab force tester.

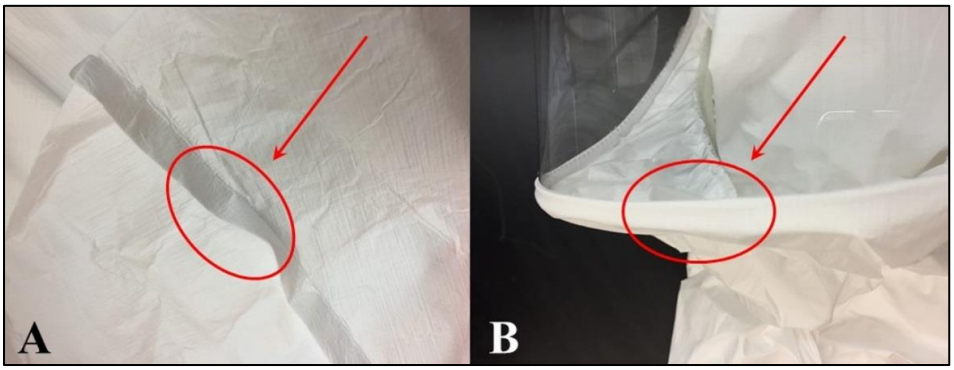


Figure 45. A) Tyvek-Tyvek seam, B) Tyvek-visor seam.

Data Analysis

The geometric mean and geometric standard deviation were used to calculate the average fit factor due to the data varying in many orders of magnitude. Fit factors are calculated by taking the ratio of the concentration of particles outside the respirator to the concentration inside the respirator. As the concentration inside the respirator approaches zero, the fit factor number can increase by many orders of magnitude. The geometric standard deviation is the number by which the geometric mean can be multiplied or divided by and contain two-thirds of the data.

The control and cleaned hoods were compared using a two-tailed paired t-test (GraphPad Prism, La Jolla, CA) for all six durability tests due to no regulations existing for loose-fitting headgear.

3.2.2.3 Results

HMERs

All 3M cartridges passed the NaCl and DOP penetration tests at 75 and 150 cleaning cycles (**Table 44**), ranging from 0.003 – 0.005% penetration. All five HMER models passed fit testing at 75 and 150 cycles, with fit factors ranging from 0.65 – 7.3 × 104. The Scott XCEL HMER at 75 and 150 cycles was significantly different ($p \leq 0.05$) from the control mask, but with much higher fit factors, indicating better performance. As with the Scott, the North 7700 at 150 cycles was significantly different, but had better performance. With the exception of the Scott XCEL, all HMERs passed inhalation resistance with pressures ranging from 17.7 – 25.3 mmH2O. The Scott XCEL model failed the inhalation resistance test after 75 cycles, but the same replicates passed after 150 cycles. The failed result may be due to the wrong size mannequin being used

during the initial test. The Scott XCEL HMER inhalation resistance at 75 cycles was significantly different from the control, but was not at 150 cycles and demonstrated passing results. The North 7700 HMER inhalation resistance was significantly different from the control at 75 cycles but had lower resistance and therefore better performance. All HMERs passed exhalation resistance testing, ranging from 4.7 – 9.3 mmH2O. The 3M 7502, Scott XCEL, and Survivair Blue 1 exhalation resistance were all significantly different than control masks at 75 cycles, but with lower resistance and therefore better performance. The exhalation valve leakage for all HMERs was 0 mL/min, below the pass rate of 30 mL/min.

Table 44. Performance evaluation of five HMER models after 0, 75 and 150 cleaning/decontamination cycles.

Durability test	Cycles	3M 6200	*p*-value	3M 7502	*p*-value	Scott XCEL	*p*-value	Survivair Blue 1	*p*-value	North 7700	*p*-value
NaCl penetration test	0	0.004 ± 0.002%		0.004 ± 0.002%		-		-		-	
(Passing: ≤ 0.03%)	75	0.005 ± 0.002%	0.80	0.004 ± 0.001%	0.60	-		-		-	
	150	0.004 ± 0.003%	0.81	0.003 ± 0.002%	0.53	-		-		-	
Fit testing	0	35,500 x/ 5		13,800 x/ 8		8,390 x/ 4		32,900 x/ 5		17,000 x/ 5	
(Passing: ≥ 1000)	75	43,400 x/ 7	0.81	21,300 x/ 4	0.62	63,900 x/ 3	**0.0026**	72,900 x/ 3	0.22	14,300 x/ 5	0.82
	150	25,000 x/ 4	0.62	6,540 x/ 2	0.32	71,099 x/ 4	**0.01**	24,700 x/ 3	0.65	86,900 x/ 2	**0.01**
Inhalation resistance	0	25.2 ± 0.4		24.9 ± 0.5		24.0 ± 1.0		21.7 ± 0.5		19.4 ± 0.8	
(Passing: ≤ 35 mmH$_2$O)	75	25.1 ± 0.7	0.84	25.0 ± 1.4	0.91	39.3 ± 2.6	**0.0007**	21.5 ± 0.4	0.67	17.7 ± 0.2	**0.02**
	150	25.3 ± 0.3	0.60	25.0 ± 0.9	0.61	23.5 ± 0.8	0.53	21.8 ± 0.3	0.40	19.1 ± 0.4	0.77
Exhalation resistance	0	7.2 ± 0.3		5.2 ± 0.1		8.2 ± 0.4		8.5 ± 0.8		9.2 ± 0.4	
(Passing: ≤ 25 mmH$_2$O)	75	7.0 ± 0.4	0.41	4.7 ± 0.1	**0.004**	6.5 ± 0.5	**0.01**	6.6 ± 0.3	**0.02**	8.8 ± 0.3	0.19
	150	7.5 ± 0.1	0.26	5.2 ± 0.1	0.52	7.8 ± 1.0	0.45	8.7 ± 0.1	0.27	9.3 ± 0.0	0.53
Exhalation valve leakage	0	0.0 ± 0.0		0.0 ± 0.0		0.0 ± 0.0		0.0 ± 0.0		0.0 ± 0.0	
(Passing ≤ 30 mL/min)	75	-		-		-		-		-	
	150	0.0 ± 0.0	NaN	0.0 ± 0.0	NaN	0.0 ± 0.0	NaN	0.0 ± 0.0	NaN	0.0 ± 0.0	NaN
DOP penetration test	0	0.002 ± 0.001%		0.002 ± 0.001%		-		-		-	
(Passing: ≤ 0.03%)	75	-		-		-		-		-	
	150	0.002 ± 0.001%	0.17	0.002 ± 0.001%	0.21	-		-		-	

** x/ = multiplied or divided by*

***NaN = Not a number*

PAPRs

All PAPR motors and filters passed total inward leakage, air flow velocity, and DOP penetration testing. For both control and cleaned PAPRs, DOP penetration ranged from 0.000 – 0.005%, fit factors during TIL testing ranged from 0.24 – 6.40 × 104, and air flow velocity ranged from 225.6 – 319.1 LPM (**Table 45**). The only statistical difference observed was between the Syntech MAXAIR air flow at 150 cycles and the control respirators. However, the air flow result of 225 LPM was still much higher than the minimum air flow of 170 LPM. For all material tests listed in (**Table 46**), no statistically significant difference was found between control and cleaned materials.

Table 45. Performance evaluation of three PAPR models after 0, 75, and 150 cleaning/decontamination cycles.

Durability test	Cycles	3M Breathe Easy	*p*-value	3M Air-Mate	*p*-value	Syntech MAXAIR	*p*-value
DOP penetration test	0	0.000 ± 0.000%		0.006 ± 0.006%		0.005 ± 0.003%	
(Passing: ≤ 0.03%)	75	-		-		-	
	150	0.000 ± 0.000%	NaN	0.003 ± 0.001%	0.46	0.002 ± 0.002%	0.27
Total inward leakage	0	53,700 x/ 3		54,100 x/ 2		4,010 x/ 1	
(Passing: ≥ 1000 FF)	75	-	-	43,400 x/ 2	0.51	3,770 x/ 2	0.81
	150	64,000 x/ 2	0.73	43,200 x/ 3	0.59	2,410 x/ 2	0.02
Air flow velocity	0	316.2 ± 5.9		252.0 ± 2.9		237.9 ± 5.7	
(Passing: > 170 LPM)	75	-		253.0 ± 4.3	0.77	245.0 ± 4.9	0.18
	150	319.1 ± 1.6	0.47	248.7 ± 2.1	0.18	225.6 ± 4.3	**0.04**

** x/ = multiplied or divided by*
***NaN = Not a number*

Table 46. Material testing of 3M™ PAPR hoods after 150 cleaning cycles.

Durability test	Cleaning Cycles	3M™ Hoods	*P*-value
Fluid resistance test (mbar)	0 150	954 ± 80 865 ± 73	0.23
Material strength test: Tyvek (N)	0 150	119.9 ± 5.6 118.3 ± 5.4	0.73
Seam strength test: Tyvek-Tyvek (N)	0 150	253 ± 11 251 ± 7	0.77
Seam strength test: Tyvek-visor (N)	0 150	191 ± 21 202 ± 6	0.43
Visor optical transparency (transmission %)	0 150	93.5 ± 0.3 93.3 ± 0.4	0.53
Material strength test: visor (N)	0 150	511.0 ± 0.6 508.7 ± 4.7	0.45

3.2.2.4 Discussion/Conclusions

Discussion

The NIOSH test protocols and material testing indicate that at 75 and 150 cleaning cycles, all HMER and PAPR models maintained their integrity. All HMERs passed fit testing and exhalation resistance testing. With the exception of the Scott XCEL, all HMERs passed inhalation resistance testing. The Scott XCEL at 75 cleaning cycles showed failing values for inhalation resistance. However, after these same HMERs were cleaned an additional 75 times,

they showed passing results for inhalation resistance. It's possible during the first inhalation resistance test, the wrong sized headform was used, leading to inaccurate results. All 3M P100 cartridges passed NaCl penetration tests at 75 and 150 cleaning cycles and DOP penetration tests at 150 cleaning cycles. DOP is toxic, so this test was only conducted at 150 cycles because the cartridges must be discarded after this test. The results of this task support that masks of all five HMER models evaluated could provide the same level of respiratory protection to healthcare workers whether new or cleaned 150 times using the cleaning protocol defined in Task 6.

Both the Air-Mate and MAXAIR PAPR models passed the total inward leakage test at 75 and 150 cycles and the DOP penetration test at 150 cleaning cycles. A total inward leakage and air flow test was not performed for the Breathe Easy model at 75 cleaning cycles because the breathing tubes initially obtained did not have a connection compatible with the hood. Compatible tubes were obtained and cleaned 150 times, then tested similar to the other PAPR models, producing passing results. No regulations currently exist for material performance requirements of loose-fitting PAPR headgear, so material testing was conducted on these hoods to compare new hoods to hoods cleaned 150 times. These tests are all destructive and were therefore not done until 150 cycles. There was no statistically significant difference ($P > 0.05$) between the hoods in material strength (Tyvek and visor), seam-strength, visor optical transparency, and fluid resistance. While these hoods will likely never be exposed to the same levels of force used in the material testing, these results give the confidence that these hoods can withstand the harshest conditions, even after being cleaned 150 times.

Some potential limitations of the study are the relatively small sample sizes for each model and not all HMER/PAPR models were evaluated due to cost and time restraints. Additionally, the fit and TIL tests inherently have a high degree of variability, making comparisons between control and cleaned respirators challenging. Based on pass/fail criteria, all respirators passed the fit and TIL testing. Future testing using increased sample sizes and a broader model selections could increase the strength of the data set.

The results from Task 7, along with the results from Task 6, indicate that during an influenza pandemic, ARA-developed cleaning protocols using OSHA and manufacturer guidance are effective at reducing viable influenza by 4.5- log and allow for HMERs and PAPRs to be reused up to 150 times.

Conclusions

HMERs and PAPRs can be cleaned up to 150 times with no significant degradation to function.

3.2.3. Option Task A: Automated Reprocessing of Reusable RPDs

3.2.3.1 Overview

Based on the presentation by Ciconte and Danyluk at the FDA summit,[38] a major hurdle for using HMERs in a hospital is the time required for cleaning and reprocessing the devices. The use of hospital washer-disinfectors (WDs) may be a solution for solving this problem. However, 3M current guidance on use of washer-disinfectors is that temperatures must not exceed 122 °F (50 °C), 31 which is lower than typical temperatures used for these devices (55-75 °C). Evaluation of manual reprocessing methods for HMER and PAPR indicated these methods were effective for most surfaces, but for implementation in a hospital environment, these methods could be deemed as too time-consuming, supporting the conclusions by Ciconte and Danyluk. Also, the safety and effectiveness of these methods rely heavily on the reprocessor.

An automated method could mitigate many of the concerns associated with manual reprocessing of reusable RPDs. WDs are commonly used in hospitals to clean and disinfect reusable medical devices. The settings of a validated WD cycle can vary based on the different parameters available, but generally consists of a cold water rinse to remove gross contamination, a wash cycle with detergent, a rinse cycle to remove the detergent, a high-temperature (> 90 °C) rinse for disinfection, and a drying period. For HMERs and PAPRs, the maximum allowed exposure temperature is typically around 50 °C, requiring that the rinse temperature of the WD be lowered to avoid damaging the RPDs, but must still adequately disinfect the devices. The two main objectives of this task are to 1) optimize the decontamination efficacy of using a WD to treat influenza-contaminated HMERs and PAPRs, and 2) evaluate the effect of 50 and 100 cycles of WD treatment on HMER/PAPR durability and performance.

3.2.3.2 Materials and Methods

H1N1 influenza

H1N1 influenza A/PR/8/34 (ATCC® VR-1469™) was propagated in embryonic chicken eggs (Charles River Premium Specific Pathogen-Free Eggs 10100326) using standard World Health Organization (WHO) protocols.3 Virus titers were determined by tissue culture infectious dose ($TCID_{50}$) assay. Madin-Darby canine kidney (MDCK) cells (ATCC ® CCL-34™) were passaged and maintained using WHO-approved cell culture techniques.

Test respirators

Five HMER models and three PAPR models were evaluated for this task (**Table 47**). The Syntech Max-Air evaluated as part of Tasks 6 and 7 was not included in Task A because of its incompatibility with an automated washer due to electrical components of the device.

Table 47. Respirators treated with automated reprocessing methods.

Respirator type	Respirator Model

HMER	3M 6200 3M 7502 Scott XCEL Sperian Survivair North 7700
PAPR	3M Breathe Easy 3M AirMate

Washer-Disinfector

Automated reprocessing was performed in a Miele® G7899 (Miele & Cie. KG, Gütersloh, Germany) washer-disinfector (WD). The unit was pre-programmed to include two wash cycles, two rinse cycles, and a drying cycle. Customization of three variables (water temperature, water temperature duration, detergent dosage) allowed for the WD unit to be evaluated for optimal inactivation of H1N1 influenza from the surfaces of contaminated HMERs/PAPRs. Three conditions (low, medium, high) were defined for each variable (**Table 48**).

Table 48. Test conditions using the washer-disinfector.

	Condition		
Description	**Low**	**Medium**	**High**
Water temperature (°C)	30	50	93
Water temperature holding time (min)	1	7	15
Detergent volume (mL)	0	50	110

Low conditions were defined by the lowest programmable settings for the WD unit. Medium temperature conditions correlated to the upper limit of the recommended water temperature for cleaning HMERs as indicated by manufacturer's guidance. High temperature conditions correlated to the standard temperature used for disinfection. For water temperature holding time, the WD unit allows for a programmable time of 1 to 15 minutes, thereby establishing the range from low to high conditions. The detergent used in Tasks 6 and 7, Neutrawash™ (Getinge USA, Inc., Rochester, NY), was used with the WD during the wash cycle at the recommended amount (50 mL) by the detergent manufacturer, establishing the midpoint for this variable.

A wastewater decontamination system was integrated with the WD unit to ensure proper decontamination prior to disposal of any potential viable influenza extracted from contaminated HMERs/PAPRs (**Figure 46**). The decontamination system included a plenum space around the rear exhaust of the WD to allow for proper ventilation of exhausted air. Wastewater from the WD unit was captured and disinfected with 0.1% bleach (Clorox Company, Oakland, CA) preceding proper disposal.

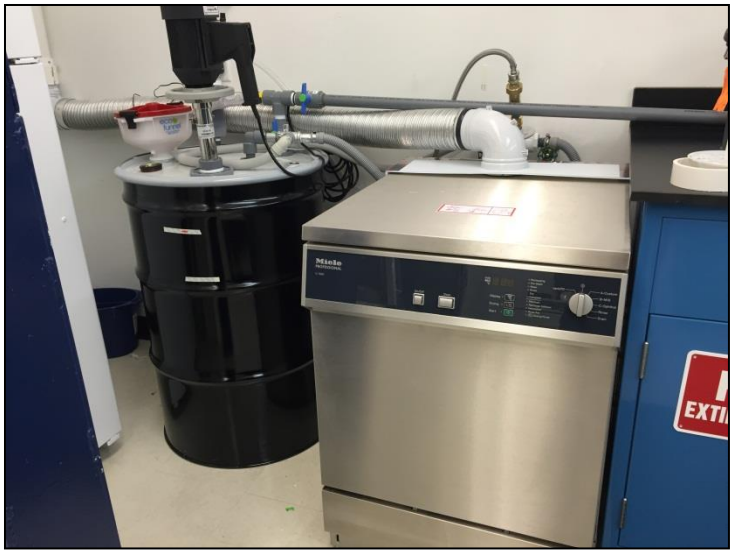


Figure 46. Miele G7899 washer-disinfector with wastewater decontamination system.

3.2.3.2.1 Disinfection

HMER disinfection testing

Optimization of the WD conditions was performed using the 3M 6200 HMER model only. The least aggressive challenge provided by the WD that demonstrated no recoverable viable virus from the 3M 6200 respirator was deemed to be the optimal condition and subsequently used to treat the remaining HMER and PAPR models.[41]

For each evaluation, six replicates per HMER model were aseptically inoculated in a Class II biological safety cabinet (BSC) with 10 1-µL drops of ~10^9 $TCID_{50}$/mL H1N1 influenza onto each of the five separate surfaces selected for inoculation (**Table 49**). Inoculated surfaces were allowed to dry in the BSC at room temperature for approximately 10 minutes. Synthetic skin oil (Scientific Services S/D, Sparrow Bush, NY) was applied in a solid state using a triangle-shaped cell spreader to apply approximately 5 mg to each inoculated surface serving as a protective factor to the inoculum.

Table 49. Surface type inoculated with H1N1 influenza on each respiratory protection device.

Respirator Type	Respirator Model	Surface Type
HMER	3M 6200/3M 7502	Plastic face piece Rubber seal Plastic head strap Bottom fabric strap Top fabric strap
HMER	North 7700	Rubber seal Plastic face piece

		Plastic head strap Bottom fabric strap Top fabric strap
HMER	Sperian Survivair	Rubber seal Plastic face piece Plastic head strap Fabric strap Filter cover
HMER	Scott XCEL	Rubber seal Rubber face piece Plastic head strap fabric strap Filter cover
PAPR	3M BE-12 Hood	Visor Tychem material Breathing tube insert
PAPR	3M Breathing Tubes	AirMate breathing tube Breathe Easy breathing tube

Three HMER replicates were aseptically transferred to the WD unit. A method for securing both the plastic head strap and bottom fabric strap of each replicate to the inner side of the WD racks using plastic cable ties was established to limit the HMER mobility during the wash treatment. For the HMER models with filter covers, each filter cover was placed on the bottom rack of the WD unit. The three HMER replicates to be cleaned were subsequently treated with the appropriate WD conditions. The three remaining HMER control replicates were covered and kept in the BSC at room temperature during the wash treatment and were not cleaned.

Following completion of the WD washing and drying cycle, three HMER replicates were aseptically removed and transferred from the WD unit to the BSC. Each inoculated surface on all six HMER replicates was sampled using a sterile polyester swab moistened with serum-free Eagle's minimum essential medium (EMEM) (Hyclone; GE Healthcare, Pittsburgh, PA). Swabs were placed in a 50-mL conical tube containing 10 mL of serum-free EMEM and mixed using a multi-tube vortexer for five minutes for extraction purposes. Extracts were serially diluted in a 1:10 ratio in serum-free EMEM and subsequently plated using into quadruplicate wells in 24-well plates (Corning, Inc., Corning, NY) containing confluent monolayers of MDCK cells. Plates were incubated at 37 °C in 5% CO2 for one hour. After the one-hour incubation, 0.1 mL of an EMEM-1% bovine serum albumin (BSA) (Sigma, St Louis, MO)-trypsin (Worthington Biochemical Corp., Lakewood, NJ) mixture was added to each well to promote virus infectivity. The plates were then incubated at 37 °C in 5% CO2 for seven days. Cytopathic effects (CPE) demonstrated by a disruption or clearing of the cell monolayer was observed by microscopy after

the incubation period. Plates were subsequently stained with crystal violet-glutaraldehyde to confirm the presence of CPE.

PAPR disinfection testing

Six replicates of each PAPR component were aseptically inoculated in similar fashion as the HMERs with both influenza and sebum. Three of the surfaces were on the PAPR hoods and the two remaining surfaces were on the two different breathing tubes. The same hood type is recommended for use with both PAPR models, thus only one hood model was evaluated. Also, the BE-12 hood model was used in place of the 3M BE-10 used in Tasks 6 and 7 due to space considerations in the WD (**Figure 47**).

Figure 47. 3M PAPR hoods: (A) BE-10 model (B) BE-12 model.

Three replicates of each PAPR component were aseptically transported to the WD, and treated at the appropriate WD conditions. Three control PAPR replicates from each component were not cleaned and remained in the BSC for the duration of the cleaning cycle. Cleaned replicates were aseptically returned to the BSC after completion of the WD cleaning cycle. Subsequent sampling and extractions of inoculated areas and $TCID_{50}$ assay methods were consistent with HMER evaluations.

3.2.3.2.2 Durability

HMER durability testing

Triplicate respirators were treated with multiple WD cycles (50 and 100 cycles) set at the medium condition and then evaluated for durability. Functionality of treated and untreated HMERs was evaluated using a variety of performance tests recommended by NIOSH (**Table 50**). Tests were performed by either ARA personnel at the NIOSH-NPPTL facility or by NIOSH personnel in their certification lab.

Table 50. Performance tests used to evaluate HMER functionality.

Performance Tests	Protocol	Performer
Fit test	No standard	ARA/NIOSH
Inhalation resistance test	TEB-APR-STP-0007	NIOSH certification lab
Exhalation resistance test	TEB-APR-STP-0003	NIOSH certification lab
Exhalation valve leakage test	TEB-APR-STP-0004	NIOSH certification lab

Fit testing was performed by donning HMERs onto a medium-sized NIOSH headform connected to an artificial breathing system while being exposed to a polydispersed NaCl aerosol with a concentration of 2.5–5.0 × 104 particles/cm3 (**Figure 48**). The breathing protocol used for this testing consisted of three consecutive breathing periods: 80 seconds of normal breathing, 80 seconds of deep breathing, and 80 seconds of normal breathing. Normal breathing is defined as breath volumes of 800 mL, while deep breathing is 1700 mL per breath. Once the HMER was donned on the headform, a preliminary fit factor was determined using a PortaCount 8038 (TSI, Shoreview, MN) during normal breathing; a minimum factor of 1000 was required for passing as specified by NIOSH. Once a passing fit factor was established, the fit test would proceed using the breathing protocol defined above.

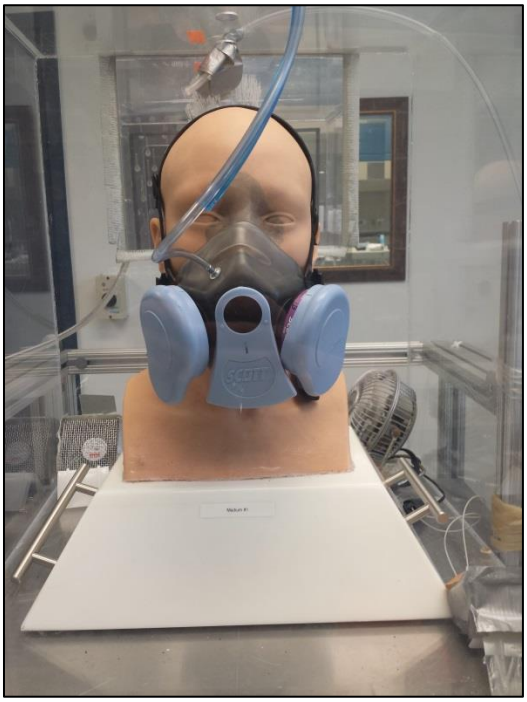


Figure 48. HMER donned on medium static advanced headform.

The NIOSH certification lab performed inhalation resistance, exhalation resistance, and exhalation valve leakage testing on the HMERs according to established NIOSH standard testing procedures. Resistance testing is conducted by mounting the respirator on a head form and using a vacuum source and manometer to determine resistance. Exhalation valve leakage is conducted in the same way, but the exhalation valve is cut out of the mask and sealed into a funnel.

PAPR durability testing

Functionality of treated and untreated PAPRs was evaluated using a variety of performance tests recommended by NIOSH (**Table 51**). Integrated Paper Services (IPS) Testing, Inc. (Appleton, WI) performed the durability tests associated with the PAPR hoods and breathing tubes.

Table 51. Performance tests used to evaluate PAPR functionality.

Performance Tests	Protocol	Performer
Total inward leakage	No standard	ARA/NIOSH
Air flow velocity	RCT-APR-0012	NIOSH
Material strength (Tychem)	ASTM D6797	IPS Testing
Seam strength (Tychem-Tychem)	ASTM D1683	IPS Testing
Seam strength (Tychem-visor)	ASTM D1683	IPS Testing
Optical transparency	ASTM D1003	IPS Testing
Material strength (visor)	ASTM D6797	IPS Testing

For PAPRs, a total inward leakage (TIL) test and an air flow velocity test were performed for each unit. For the TIL testing, each PAPR was donned onto a medium-sized headform inside a large fit testing chamber and exposed to a NaCl aerosol with a concentration of ~1–2 × 105 particles/cm3 (**Figure 49**). The headform was connected to a breathing machine and a similar breathing protocol was used as the HMER fit testing. A PortaCount 8038 was used to determine the TIL through a port in the PAPR visor located in front of the manikin mouth. Subsequent to the TIL testing, the NIOSH certification lab performed air flow velocity tests on the PAPRs to evaluate blower unit performance.

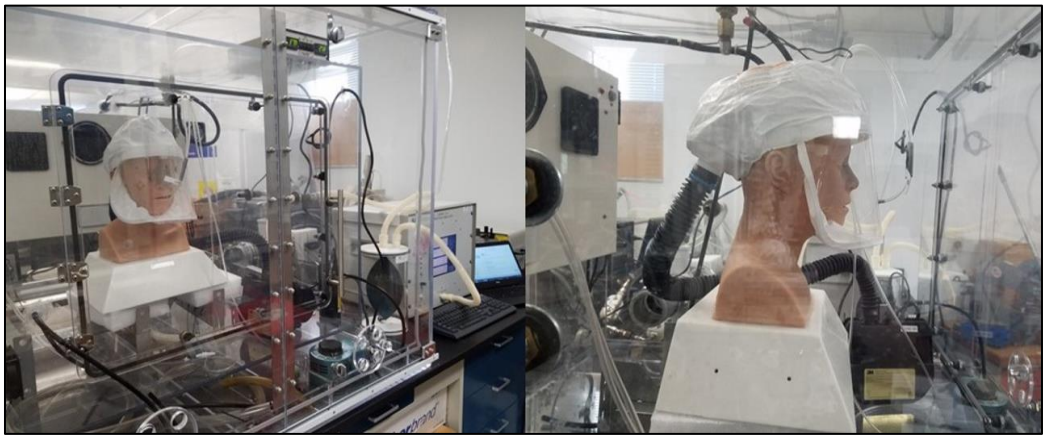


Figure 49. PAPR testing using medium static advanced headform.

Similar to Task 7, PAPR hoods were evaluated using a number of different material tests performed by Integrated Paper Services (IPS; Appleton, WI) – burst strength of the Tychem and visor materials, seam strength of both a Tychem-Tychem seam and a Tychem-visor seam (**Figure 50**), and visor optical transparency. The fluid resistance test performed for Task 7 was not able to be performed for Task A due to different PAPR hood models being evaluated. A larger version (3M BE-10) was used for Task 7, while a smaller version (3M BE-12) was used

for Task A due to space considerations in the washer/disinfector. The smaller hood model did not have enough Tychem material to perform the fluid resistance test.

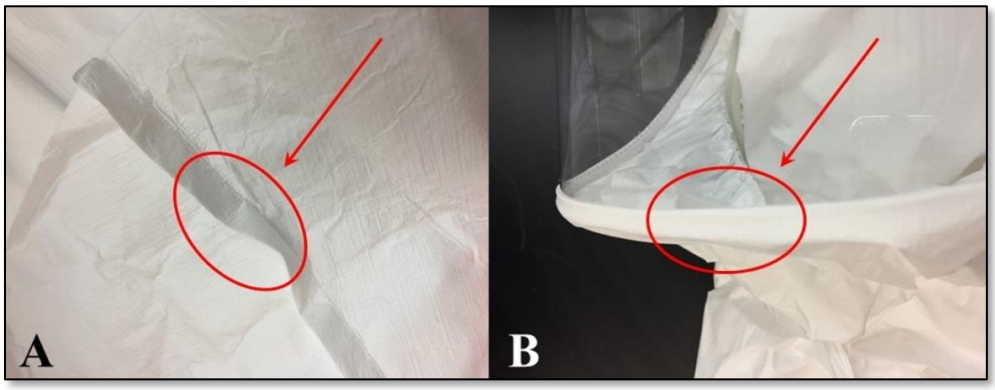


Figure 50. A) Tychem-Tychem seam, B) Tychem-visor seam.

Additionally, the breathing tube test performed for Task 7, where sections of the tubes were cut out and evaluated for breaking force, was not performed for Task A due to the high degree of variability observed previously and the inability of the test method to accurately determine breaking force depending on the sample's original location in the breathing tube.

Data analysis

The Spearman-Kärber formula was used to determine the viable virus concentration from the $TCID_{50}$ assays. Log reduction values were then calculated from the differences of the means of three control replicates and three cleaned replicates per HMER/PAPR model. For samples with no detectable recovered virus, half the detection limit of the viable assay (0.20 log $TCID_{50}$) was used to calculate the reduction per EPA guidance. A one-way analysis of variance (ANOVA) with a Tukey post-test was performed using Prism 6 (Graphpad, La Jolla, CA) to compare the virus recoveries on each inoculated surface, and $p \leq 0.05$ was considered statistically significant.

The geometric mean and geometric standard deviation were used to calculate the average fit factor due to the data varying in many orders of magnitude. Fit factors are calculated by taking the ratio of the concentration of particles outside the respirator to the concentration inside the respirator. As the concentration inside the respirator approaches zero, the fit factor number can increase by many orders of magnitude. The geometric standard deviation is the number by which the geometric mean can be multiplied or divided by and contain two-thirds of the data. The material data from IPS was compared using a two-tailed, unpaired t-test.

3.2.3.3 Results

HMER disinfection

The mean viable influenza recovered from all untreated HMER and PAPR surfaces was 4.76 ± 0.77 $\log_{10}$ $TCID_{50}$. Using the low WD conditions, viable influenza was recovered from two of

five surfaces evaluated – top and bottom fabric straps – on triplicate 3M 6200 respirators (**Figure 51**). No significant difference was found between control recoveries obtained from the surfaces tested ($p = 0.30$). For all five surfaces, virus recovery from treated surfaces was significantly lower than their respective control surfaces ($p < 0.05$).

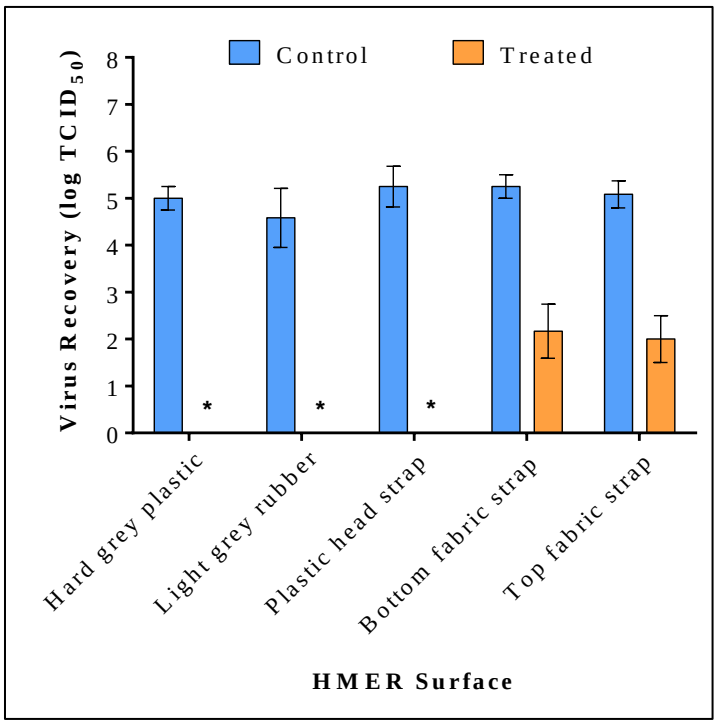


Figure 51. Viable influenza recovered from triplicate 3M 6200 respirators treated with low washer/disinfector conditions. (* = below detection limit)

Using the medium WD conditions, no viable influenza was recovered from all five surfaces on triplicate 3M 6200 respirators (**Figure 52**). No significant difference was found between control recoveries obtained from the surfaces tested ($p = 0.71$). For all five surfaces, virus recovery from treated surfaces was significantly lower than their respective control surfaces ($p < 0.05$).

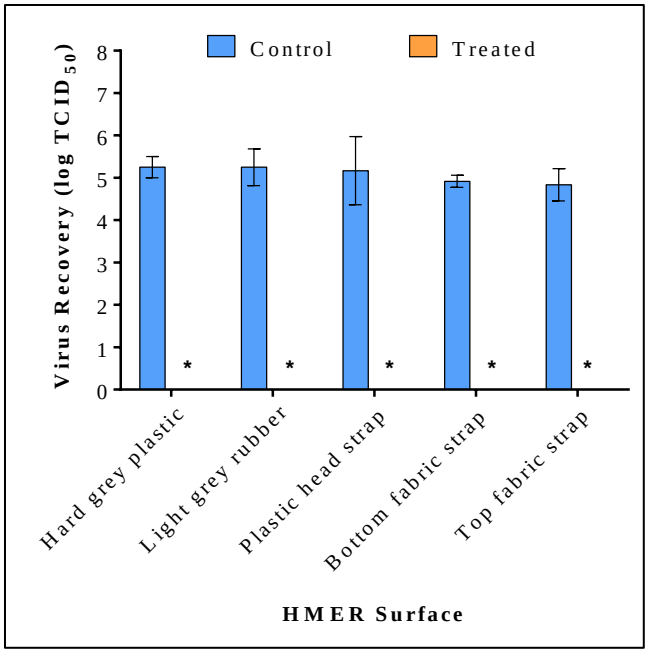


Figure 52. Viable influenza recovered from triplicate 3M 6200 respirators treated with medium washer/disinfector conditions. (* = below detection limit)

Using the medium WD conditions, no viable influenza was recovered from all five surfaces on triplicate 3M 7502 respirators (**Figure 53**). Comparing the control recoveries, the fabric straps were significantly lower than the other three surfaces tested ($p < 0.0001$); no significant difference was found between the two fabric straps ($p = 0.37$). For all five surfaces, virus recovery from treated surfaces was significantly lower than their respective control surfaces ($p < 0.05$).

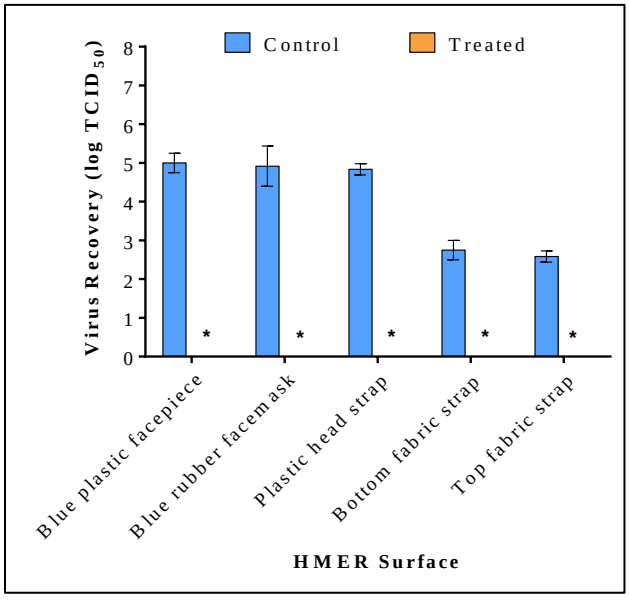


Figure 53. Viable influenza recovered from triplicate 3M 7502 respirators treated with medium washer/disinfector conditions. (* = below detection limit)

Using the medium WD conditions, no viable influenza was recovered from all five surfaces on triplicate North 7700 respirators (**Figure 54**). Comparing the control recoveries, the fabric straps were significantly lower than the other three surfaces tested ($p < 0.0001$); no significant difference was found between the two fabric straps ($p = 0.64$). For all five surfaces, virus recovery from treated surfaces was significantly lower than their respective control surfaces ($p < 0.05$).

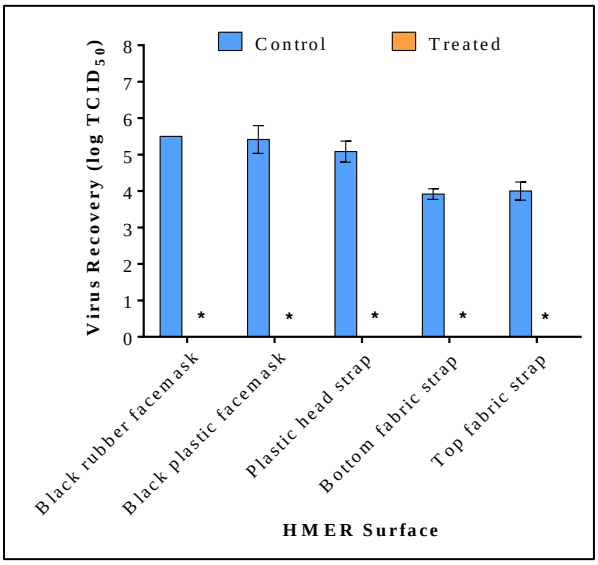


Figure 54. Viable influenza recovered from triplicate North 7700 respirators treated with medium washer/disinfector conditions. (* = below detection limit)

Using the medium WD conditions, no viable influenza was recovered from all five surfaces on triplicate Scott XCEL respirators (**Figure 55**). Comparing the control recoveries, a one-way ANOVA indicated a significant difference ($p = 0.02$) – the blue rubber facemask surface being significantly higher than the fabric strap. For all five surfaces, virus recovery from treated surfaces was significantly lower than their respective control surfaces ($p < 0.05$).

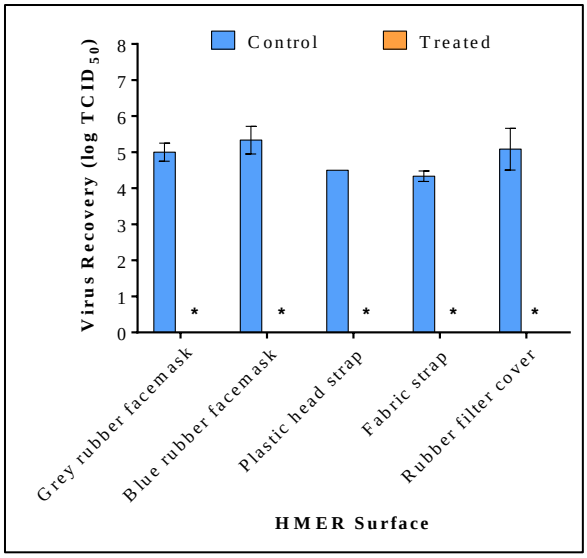


Figure 55. Viable influenza recovered from triplicate Scott XCEL respirators treated with medium washer/disinfector conditions. (* = below detection limit)

Using the medium WD conditions, no viable influenza was recovered from all five surfaces on triplicate Sperian Survivair respirators (**Figure 56**). No significant difference was found between control recoveries obtained from the surfaces tested ($p = 0.31$). For all five surfaces, virus recovery from treated surfaces was significantly lower than their respective control surfaces ($p < 0.05$).

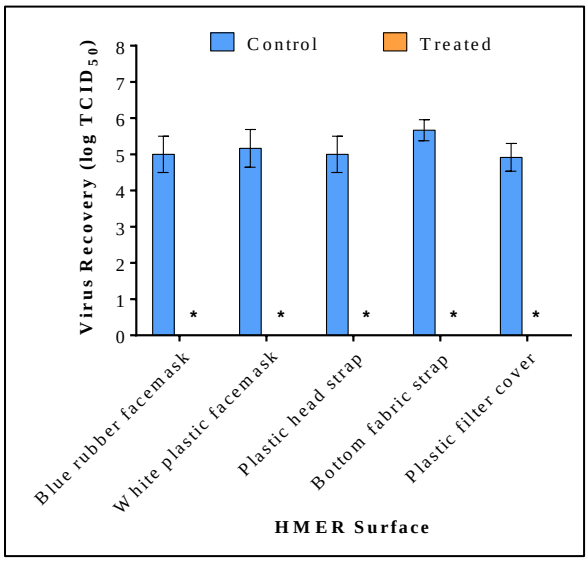


Figure 56. Viable influenza recovered from triplicate Sperian Survivair respirators treated with medium washer/disinfector conditions. (* = below detection limit)

PAPR disinfection

Using the medium WD conditions, no viable influenza was recovered from all three surfaces on triplicate 3M BE-12 PAPR hoods (**Figure 57**). No significant difference was found between control recoveries obtained from the surfaces tested ($p = 0.30$). For all three surfaces, virus recovery from treated surfaces was significantly lower than their respective control surfaces ($p < 0.05$).

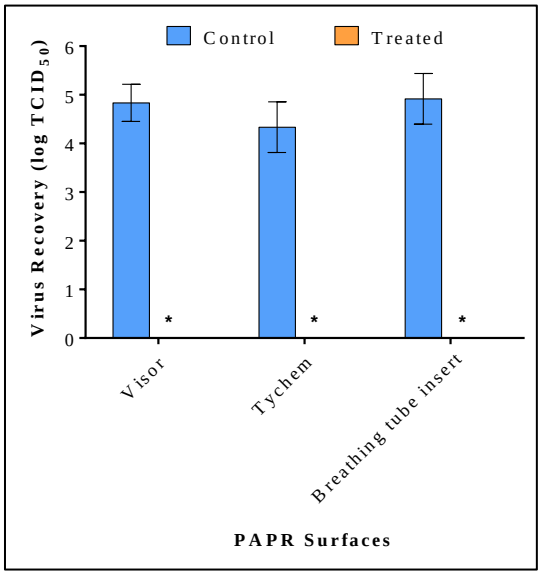


Figure 57. Viable influenza recovered from triplicate 3M BE-12 PAPR hoods treated with medium washer/disinfector conditions. (* = below detection limit)

Using the medium WD conditions, no viable influenza was recovered from surfaces evaluated on both breathing tubes for the 3M AirMate and 3M Breathe Easy PAPR models (**Figure 58**). No significant difference was found between control recoveries obtained from the surfaces tested ($p = 0.11$). For both surfaces, virus recovery from treated surfaces was significantly lower than their respective control surfaces ($p < 0.05$).

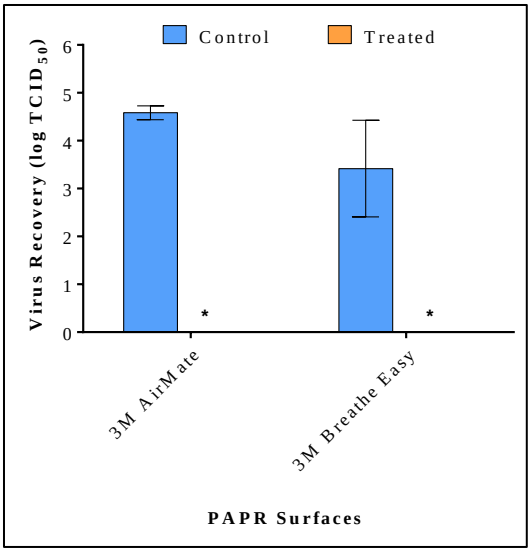


Figure 58. Viable influenza recovered from triplicate breathing tubes of two 3M PAPR models treated with medium washer/disinfector conditions. (* = below detection limit)

HMER durability

Mean log fit factors (FFs) ranged from 1.54 – 5.01 for all five HMER models across all three conditions tested (0, 50, or 100 cycles) (**Figure 59**). All models demonstrated mean log fit factors above the minimum threshold (log FF = 2), except for the Scott XCEL masks after being treated with 50 cycles (log FF = 1.54). No statistically significant difference was found between conditions of each HMER model except for the Scott XCEL which indicated the FFs obtained from masks treated with 50 cycles was significantly lower than untreated masks (p = 0.0009).

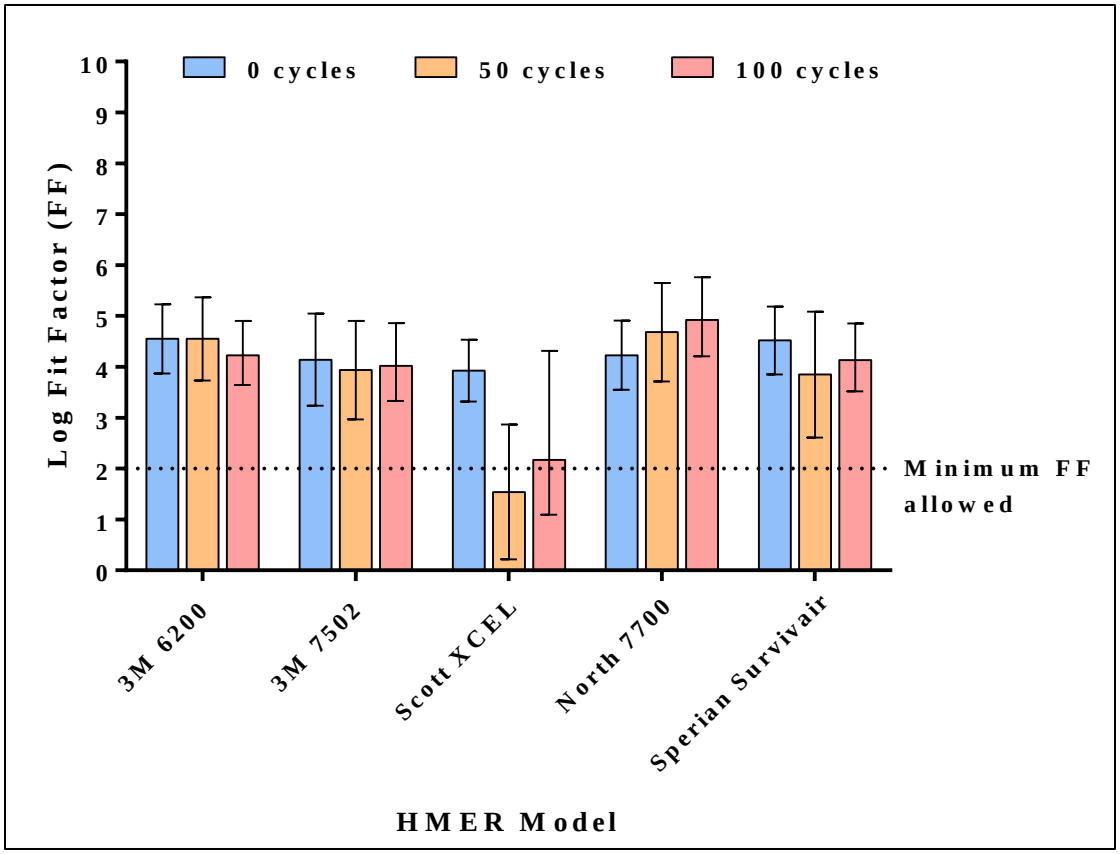


Figure 59. Fit test data of five HMER models treated with washer-disinfector using medium conditions.

Although the mean log FF for Scott XCEL masks treated with 100 cycles was above the minimum threshold, not all fit tests passed (**Table 52**). The Sperian model was the only other model to demonstrate at least one failed fit test after being treated.

Table 52. Fit test pass rate for Scott XCEL and Sperian Survivair models.

HMER Model	Cycles	Replicate	Pass Rate
Scott XCEL	50	1	0/3
		2	0/3
		3	1/3
	100	1	1/3
		2	3/3
		3	2/3
Sperian Survivair	50	1	3/3
		2	3/3
		3	2/3
	100	1	3/3
		2	3/3

		3	3/3

For all HMERs tested, exhalation valve leakage (EVL) ranged from 0.00 – 25.77 mL/min (**Figure 60**). A one-way ANOVA with a Tukey's post-test comparing the EVL values between the three sample populations (Control, 50X, 100X) for each HMER model demonstrated no significant difference ($p \geq 0.05$), except for the North 7700 ($p = 0.007$) which indicated the EVL of respirators for this model treated 100 times was significantly higher than respirators treated 50 times or not treated at all.

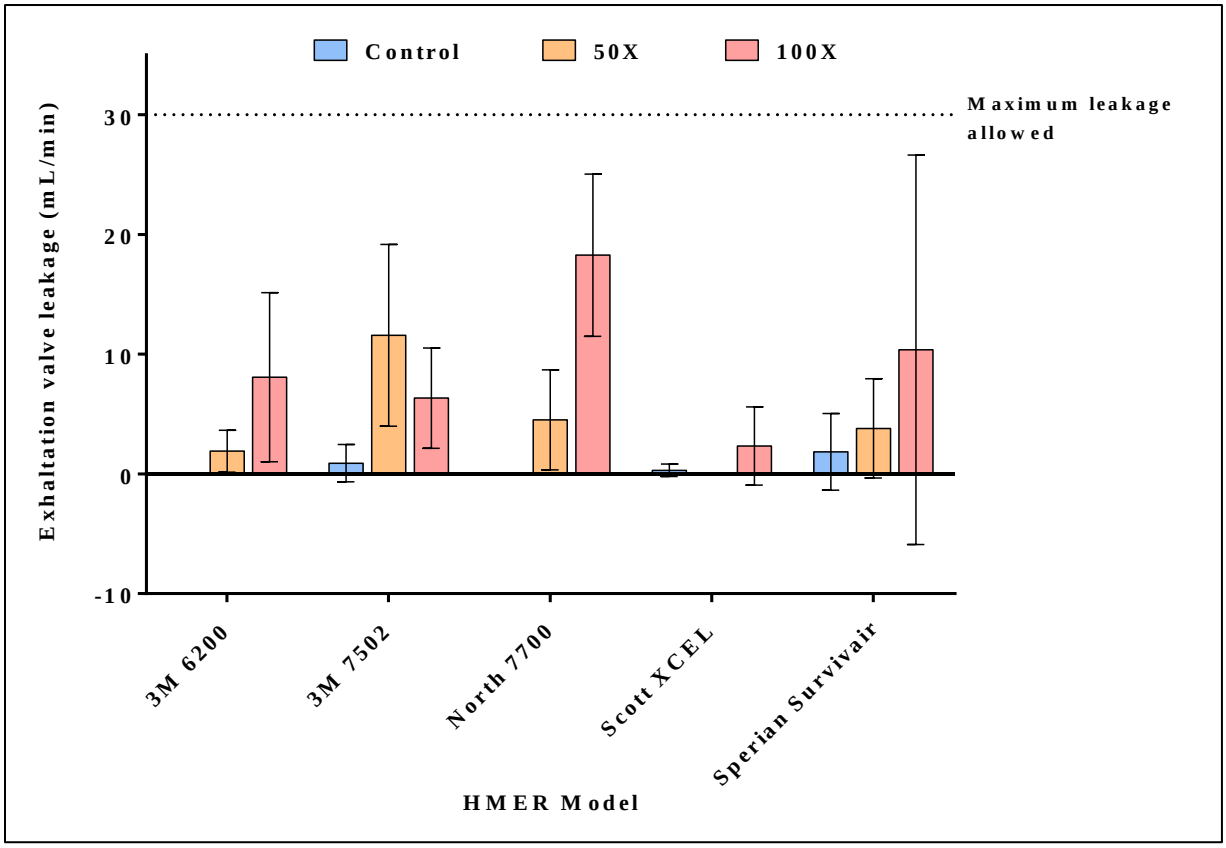


Figure 60. Exhalation valve leakage of five HMER models treated with washer-disinfector using medium conditions.

For all HMERs tested, exhalation resistance ranged from 3.10 – 24.03 mmH_2O (**Figure 61**). A one-way ANOVA with a Tukey's post-test comparing the three sample populations indicated no statistically significant difference for all five HMER models ($p \geq 0.05$).

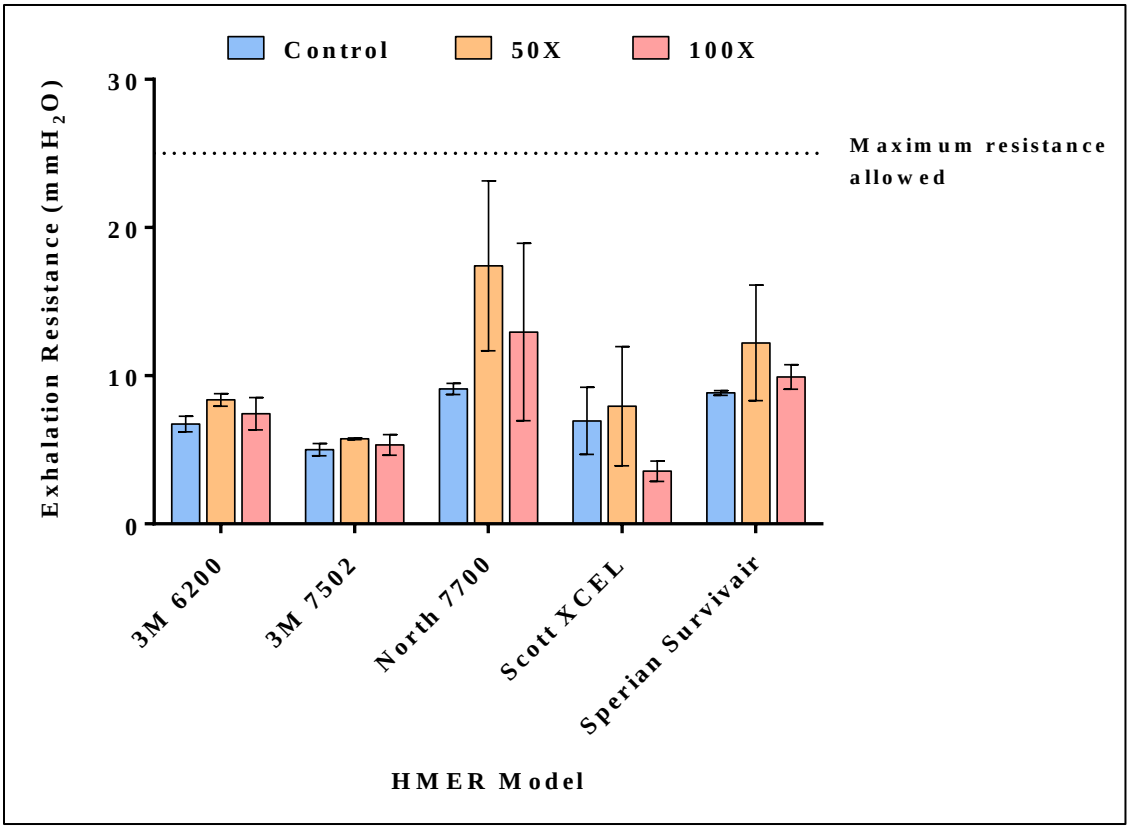


Figure 61. Inhalation resistance of five HMER models treated with washer-disinfector using medium conditions.

PAPR durability

The mean log FFs ranged from 4.88 – 5.44 across all three conditions tested for both PAPR models (**Figure 62**). Both models demonstrated mean log fit factors above the minimum threshold (log FF = 3). A statistical comparison of all three conditions for the 3M AirMate ($p < 0.0001$) indicated the FF measured from the 100-cycle treated respirators was significantly lower than the untreated or 50-cycle respirators of the same model. A statistical comparison of all three conditions for the 3M Breathe Easy ($p = 0.04$) indicated the FF measured from the 50-cycle treated respirators was significantly higher than the untreated respirators of the same model.

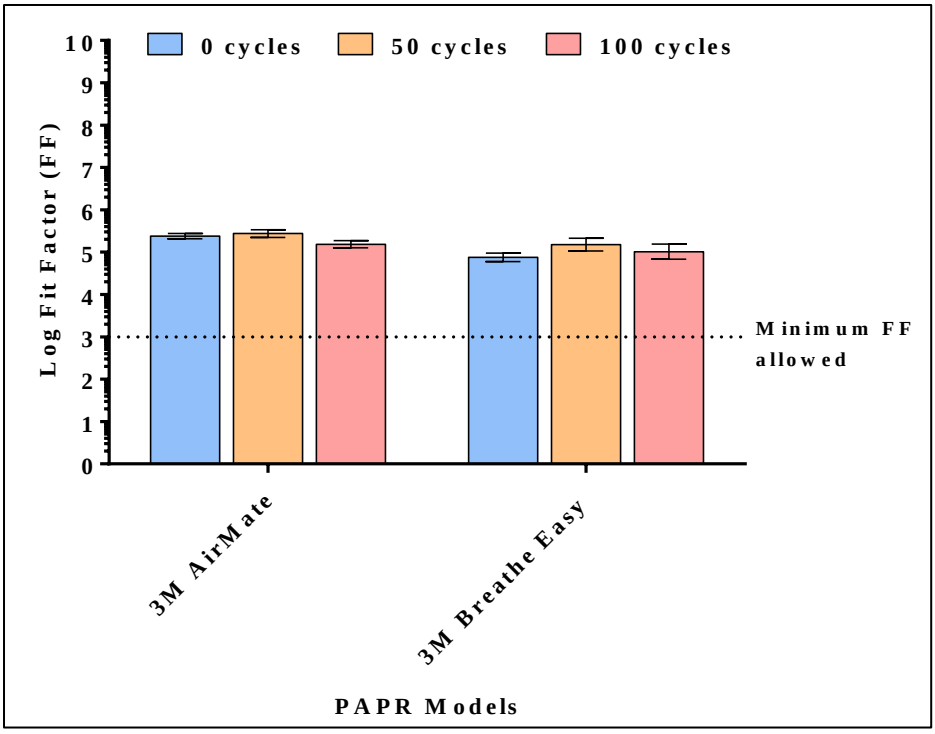


Figure 62. Total inward leakage for two PAPR models treated with washer-disinfector using medium conditions.

For all PAPRs tested, air flow rate ranged from 234.1 – 321.3 LPM (**Figure 63**). A one-way ANOVA with a Tukey's post-test comparing the three sample populations indicated a statistically significant difference only for the 3M AirMate model ($p = 0.01$). The post-test indicated the mean air flow rate measured from the AirMate PAPRs treated 50 times was significantly higher than the AirMate PAPRs treated 100 times. Although statistically significant, this is not considered by ARA to be a meaningful difference.

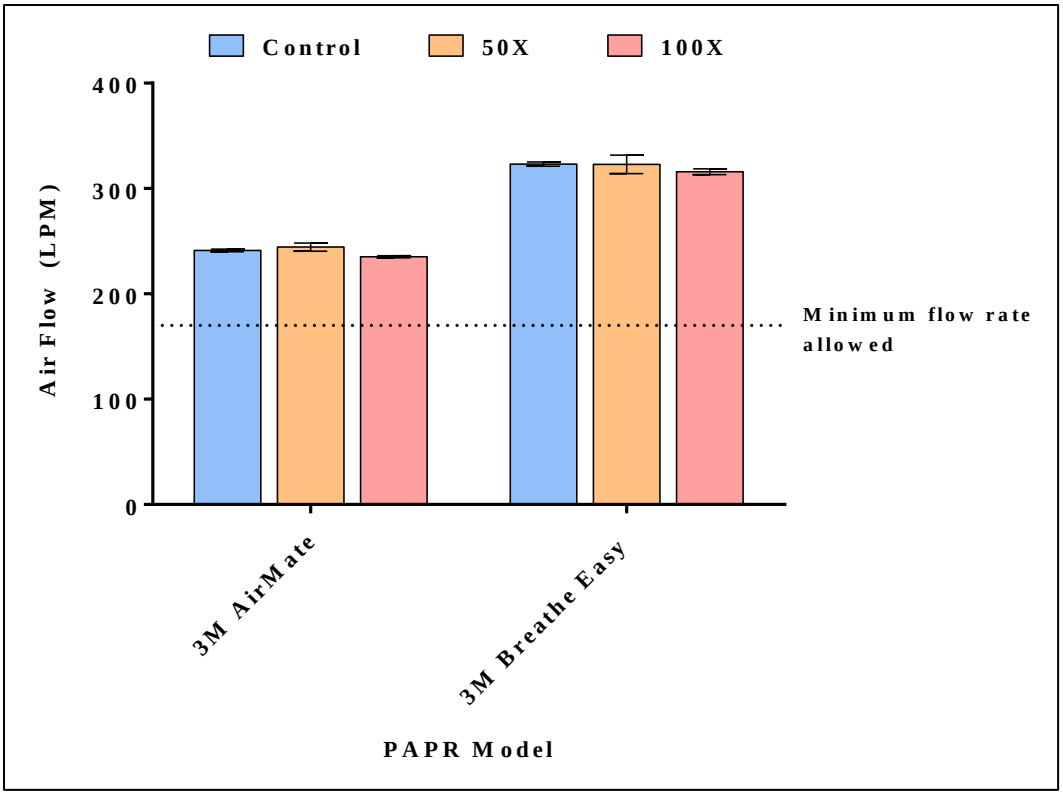


Figure 63. Air flow of five HMER models treated with washer-disinfector using medium conditions.

Material test data for the 3M PAPR hoods indicated a significant increase in haze with level of treatments, demonstrating significant differences between 0 and 50 treatment cycles and also 50 and 100 treatment cycles (**Table 53**). Clarity measurements indicated significant differences between untreated PAPR visors and treated visors, but no significant difference between the treated groups (50 and 100 cycles). For ball burst testing, the Tychem material ANOVA indicated a significant difference (P = 0.04), but no significant comparisons between sample groups using the Tukey post-test. The ball burst data for the visor material only indicated a significant difference between the 0 and 50 treatment cycle data. For seam strength, the Tychem-Tychem ANOVA indicated a significant difference (P = 0.03), but no significant comparisons between sample groups using the Tukey post-test. The Tychem-visor seam indicated no significant difference in seam strength after treatment.

Table 53. Durability test results of 3M PAPR hoods.

	Treatment Cycles			
Durability test	**0 cycles**	**50 cycles**	**100 cycles**	***P*-value**
Visor optical transparency				
Haze (%)	1.51 ± 0.29	3.74 ± 0.52	6.16 ± 0.90	0.0003
Clarity (%)	99.53 ± 0.06	99.10 ± 0.26	99.13 ± 0.12	0.02
Ball burst strength (N)				

Tychem	122.90 ± 10.93	109.48 ± 8.91	106.05 ± 8.73	0.04
Visor	1002.00 ± 1.92	980.60 ± 19.48	995.28 ± 9.73	0.02
Seam strength				
Tychem-Tychem	84.23 ± 16.70	86.10 ± 19.37	87.23 ± 8.86	0.03
Tychem-Visor	228.00 ± 17.08	231.33 ± 29.87	216.00 ± 7.43	0.60

3.2.3.4 Discussions and Conclusions

Discussion

The use of an automated method for reprocessing reusable RPDs provides several advantages over manual methods – safer for the reprocessor, decontamination efficacy that does not rely on reprocessor's skill level or attentiveness, and efficiency due to the ability to batch process. An automated reprocessing method using a WD programmed with reduced temperatures for RPD material compatibility was shown to be effective at removing/killing influenza from contaminated HMER respirators and PAPR components.

Across all HMER surfaces tested, a mean log reduction of 4.58 ± 0.76 log10 $TCID_{50}$ was achieved against influenza contamination in the presence of a heavy soiling agent (sebum). For PAPRs, the mean log reduction across all surfaces tested was 4.22 ± 0.60 log10 $TCID_{50}$. No viable influenza was recovered from any of the treated RPD surfaces treated with the medium WD conditions. The maximum log reduction achievable was largely dictated by the control recoveries from the various surface types. For three HMER models (3M 7502, North 7700, Scott XCEL), the viable virus recovery from the untreated fabric straps were significantly lower than the other surfaces of the same mask, thereby limiting the log reduction value. For the Breathe Easy breathing tube, the virus recovery from the control surface demonstrated more variability than other surfaces tested. The multi-log reductions in viable influenza observed after WD treatment using the medium conditions indicate the ability of these devices to be decontaminated using lower water temperatures that are within the RPD manufacturer's guidance.

After 100 treatment cycles using a WD programmed with the medium conditions defined in this study, all five HMER models performed within NIOSH certification requirements in terms of exhalation valve leakage, exhalation resistance, and inhalation resistance. All five HMER models demonstrated mean fit factors above 100 after being treated with 100 WD cycles, but one model, the Scott XCEL, produced a mean fit factor below 100 after being treated with only 50 cycles. Although the mean fit factor for the Scott XCEL was above 100 after being treated 100 times, there were several failures within that data set, indicating the Scott XCEL is not compatible with ≥ 50 WD cycles. The Sperian Survivair model also had a failed fit test in the 50-cycle data set, but passed all fit tests after 100 cycles, indicating the failed fit test was an outlier.

After 100 cycles using a WD programmed with the medium conditions defined in this study, the treated PAPR components did not negatively impact overall PAPR performance. Although statistically significant differences were observed between data sets in two instances, they are not

considered meaningful due to the PAPR performance being well above the minimum threshold in these cases. Performance tests demonstrated no concerns with functionality using treated PAPR hoods and breathing tubes. Material testing demonstrated no concerns related to material or seam strength after 100 treatment cycles, but visibility through the visors may be a concern. Although visibility decreased after the W/D treatments, we are not aware of any guidelines that define acceptable haze and clarity measurements for visor use, thus the practical meaning of the observed changes in visibility are yet to be determined.

The results of this study demonstrate that the automated WD method was more effective at disinfecting HMERs and PAPR components than the manual method performed in Task 6. Using the manual method, viable virus was recovered from Scott XCEL fabric strap(s) after being either cleaned only or cleaned and disinfected, as well as Sperian Survivair fabric strap(s) after being cleaned only. No viable virus was recovered from these surfaces after treatment using the automated WD method at the medium conditions. Viable virus was also recovered from the 3M Breathe Easy breathing tube after only being cleaned using the manual method in Task 6, but not after being treated using the automated WD method.

Conclusions

Based on the results of this study, four of the five HMER models tested can be effectively reprocessed after being contaminated with influenza using the medium washer-disinfector conditions defined as part of this study. All five HMER models demonstrated the ability to be disinfected, but only four of the five HMER models passed all durability tests conducted. The Scott XCEL model produced fit factors below acceptable levels after being treated ≥ 50 times. Although fit testing is not a NIOSH certification requirement, the low fit factors obtained from treated Scott XCEL respirators indicate they are not compatible with the reprocessing method used in this study. The PAPR components tested as part of this study showed they can be disinfected and still perform as intended, with the exception of decreased

4. PRESENTATIONS & PUBLICATIONS

Publications

- Mills DM, Harnish DA, Lawrence C, Sandoval-Powers M, Heimbuch BK. Ultraviolet germicidal irradiation of influenza-contaminated N95 filtering facepiece respirators. *Am J Infect Control*, July 2018; 46(7):e49–e55.
- Lawrence C, Harnish DA, Sandoval-Powers M, Mills D, Bergman MS, Heimbuch BK. Assessment of half-mask elastomeric respirator and powered air-purifying respirator reprocessing for an influenza pandemic. *Am J Infect Control*, Dec 2017; 45(12): 1324–1330.
- Nemeth C, Laufersweiler D, Polander E, Orvis C, Harnish D, O'Connor M, Hymes S, Nachman S, Heimbuch BK. Preparing for an influenza pandemic: Hospital acceptance study

of filtering facepiece respirator decontamination using ultraviolet germicidal irradiation. *J Patient Saf* (in press).

- ASTM E3135-18. Standard Practice for Determining Antimicrobial Efficacy of Ultraviolet Germicidal Irradiation against Microorganisms on Carriers with Simulated Soil. West Conshohocken, PA. ASTM International.
- ASTM E3179-18. Standard Test Method for Determining Antimicrobial Efficacy of Ultraviolet Germicidal Irradiation against Influenza Virus on Fabric Carriers with Simulated Soil. West Conshohocken, PA. ASTM International.

Presentations

- Mills D, Sandoval M, Lawrence C, Heimbuch B, Harnish D. Ultraviolet germicidal irradiation of influenza-contaminated N95 filtering facepiece respirators. American Society of Microbiology Conference (Boston, MA). June 17, 2016. Poster No: FRIDAY-331.
- Lawrence C, Mills D, Sandoval M, Harnish D, Heimbuch B. Assessment of half-mask elastomeric respirator and powered air-purifying respirator reprocessing for an influenza pandemic American Society of Microbiology Conference (Boston, MA). June 17, 2016. Poster No: FRIDAY-344.
- Heimbuch BK, Harnish DA, Nemeth C. Extending Respirator Supply for an Influenza Pandemic. Health and Human Services RPD Integrated Product Team WebEx. March 1, 2018.
- Heimbuch BK. Use of Elastomeric Respirators in Hospitals. National Academies of Sciences. March 22, 2018.

5. APPENDICES

A. SUBJECT INFORMATION AND CONSENT FORM

Name of Research Study:	Logistics Evaluation for Implementation of FFR-UVDR in Hospitals
Sponsor:	U.S. Food and Drug Administration
Principal Investigator Name:	Mr. Brian Heimbuch
Research Site Address:	Applied Research Associates Engineering Sciences Division

430 West 5th Street, Suite 700
Panama City
FL 32401-6357

Daytime telephone number(s) 850-832-7344

Purpose of this Form
The purpose of this form is to give you information about the U.S. Food and Drug Administration (FDA) study that seeks to understand attitudes, and identify preferences, barriers and logistic issues related to implementation of UVGI FFR-Decontamination/Reuse (UVDR) in a hospital setting during a pandemic to mitigate an FFR shortage.

If signed, this form will give your permission to take part in the study. The form describes the purpose, procedures, benefits, risks, discomforts and precautions of the research study. You should take part in the study only if you want to do so. You may refuse to take part or withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. Please read this Subject Information and Consent Form and ask as many questions as needed. You should not sign this form if you have any questions that have not been answered to your satisfaction.

Your interviewers are employed by the sponsor (Applied Research Associates) to conduct this research study.

Purpose and Description of the Research Study
This study will involve up to 50 interview participants per facility at 3 different hospitals in the United States. You are being asked to take part in a research study to describe your personal experience and knowledge related to the use of filtering facepiece regulators (FFR) and logistic issues in the event of a possible future pandemic. Participation in this study will consistent of one of these three methods:

- Individual interview lasting no longer than 1 hours
- Focus group interview lasting no more than 1 hour
- Response to a survey, lasting an estimated five minutes

ARA will analyze the data that is collected and use the findings to develop a plan that defines an implementation strategy for filtering face piece respirator decontamination and reuse. By exploring the potential for decontaminating respirators, this project supports sustainable protection of our nation's health workers and first responders, which is an important part of public health emergency preparedness

Study Procedures
If you agree to take part in this study, you will first sign this Subject Information and Consent Form before starting any study-related procedures. You will then be asked a series of questions

about the nature of your work as it relates to the supply and use of FFRs, and issues in the event of possible insufficient FFRs in the event of a pandemic.

Information will be recorded in a manner that subjects cannot be identified, directly or through identifiers

Possible Benefits
There are no direct benefits to you for participating in this study. There are indirect benefits to all who participate in this study, as the findings from this study will inform FDA understanding about protection from infectious disease and FFR logistic considerations in the event of a possible pandemic.

Risks or Discomforts
There are no known risks associated with this study.

Payment to Subject for Participation
You will not receive any payment for taking part in this research study.

Costs
The only cost for participating in this study is your time: up to one hour (individual interview, focus group), or 5 minutes (survey).

Confidentiality
We will protect information about you and your taking part in this research study to the best of our ability. The interview will be audio-recorded for research purposes if you are comfortable with that; otherwise, hand-written or typed notes will be taken. At the conclusion of this study, the audiotapes/notes will be stored in a secured area and only the project members will have access to the data. De-identified portions of this interview, verbatim quotations or paraphrases, may be included in the research report and related documents. Your responses will be kept confidential. We will not report your name or any other information that could be used to identify you.

Voluntary Participation
Your decision to take part in this research study is completely voluntary. There will not be any penalty or loss of benefits to you if you decide not to take part. In addition, you may withdraw from the study at any time. There will be no penalty if you decide to withdraw from the research study. Those who withdraw from the study are considered to have withdrawn consent, and their data will not be included in the study results

Contact for Questions
If you have any questions or concerns about your participation in this research study, or if you feel that you have experienced negative effects from the study, or have a complaint about the research study, contact:

Investigator Name: Mr. Brian Heimbuch

Daytime telephone number(s): 850-914-3188

Subject's Statement of Consent

- I have been given sufficient opportunity to consider whether to participate in this study.
- My taking part in this research study is voluntary. I may decide not to take part or to withdraw from the research study at any time without penalty.
- I have been told that the interviewers conducting the research are contracted by the sponsor.
- I have had an opportunity to ask my study interviewers questions about this research study. My questions so far have been answered to my satisfaction.
- I have been told how long I may be in the research study.
- I have been told about the interview process.
- I have been told what the possible risks and benefits are from taking part in this research study. I do not give up my legal rights by signing this form.
- I have been told that prior to any study related procedures being performed, I will be asked to voluntarily sign this subject information and consent form.
- I have been told that I will receive a signed and dated copy of this subject information and consent form.
- I voluntarily agree to take part in this research study.

Signature of Subject Date

_____

Printed Name of Subject

I certify that the information provided was given in language that was understandable to the subject.

_____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

B. RESEARCH PLAN AND INTERVIEW GUIDE

Research Plan and Interview Guide

Task F: Logistics Evaluation for Implementation of FFR-UVDR in Hospitals

Contract #: HHSF223201400158C

Prepared by:
Christopher P. Nemeth, Ph.D.
Laura Zimmerman, Ph.D.
Brian Heimbuch, M.S.

Cognitive Solutions Group

March 31, 2016

3.1.7 Task F: Logistics Evaluation for Implementation of FFR-UVDR in Hospitals

Research Plan and Interview Guide

I. Overview

A pandemic can place unsustainable demands on supplies of filtering face piece respirators (FFRs) that are needed to protect health care workers from the inhalation of infectious aerosols and droplets (Ebola, SARs, and MERs). The premise for this study is that the pandemic strain will be high in mortality, similar to past outbreaks such as the 1918-19 influenza pandemic, and that supplies of FFRs would be limited. Ultraviolet Germicidal Irradiation (UVGI) promises to mitigate potential shortages by extending FFR service life. Applied Research Associates, Inc. is conducting research on behalf of the Food and Drug Administration to explore the potential use of ultraviolet decontamination during a pandemic event. We will use interviews, focus groups, and a survey to identify how ultraviolet decontamination might fit into hospitals' existing respiratory protection plans and to clarify the procedural preferences and needs of hospital clinicians and staff members who would use FFRs during a pandemic.

II. Study Objective

This task seeks to understand attitudes, and identify preferences, barriers and logistic issues related to implementation of UVGI FFR-Decontamination/Reuse (UVDR) in a hospital setting during a pandemic to mitigate an FFR shortage.

III. *Data Collection Sites*

The University of Nebraska Medical Center's care for Ebola virus patient Rick Sacra, MD in 2014 gave their care staff expertise in caring for patients who have been infected with a high mortality disease. We will conduct conference call interviews with team members who cared for Dr. Sacra that we will use to refine this plan.

We will collect data from stakeholders at three hospitals, including a small, large-suburban, and large-metro area hospital to understand the needs and considerations associated with FFR-UVDR implementation. Collecting data from hospitals that vary in size and patient population will improve our ability to generalize our findings to other U.S. hospital systems. These three hospitals are our potential data collection sites.

1. **Gulf Coast Medical Center (GCRMC):** Gulf Coast Medical is a regional medical center located in Panama City, FL. It contains 218 beds, nearly 400 physicians and a support staff of more than 900 employees. GCMC belongs to the Hospital Corp of America and thus provides a link to a large network of hospitals.

2. **Stony Brook University Hospital (SBUH):** SBUH is the university hospital of Stony Brook University located in the East Campus in Stony Brook, New York. It contains 603 beds, 5,777 employees, and 1,093 physicians. Annual inpatient admissions are ~32,000 and ~96,000 emergency room visits. SBUH also has a rich history of research with annual research expenditures exceeding $95 million.

3. **University of Chicago Medical Center (UCMC):** UCMC is an academic medical center on the campus of the University of Chicago, located on the on the south side of Chicago, Illinois. It contains 617 beds, 8,500 employees, and 878 attending physicians. Annual inpatient admissions are ~ 28,726 and ~ 87,856 emergency room visits. In 2015, revenues for patient care at the University of Chicago Medicine were $1.5 billion.

While SBUH and UCMC are comparable in size, both offer different perspectives based on the populations they serve. UCMC serves an urban area on the south side of Chicago that includes a high percentage of African-American and indigent patients; SBUH is a suburban metropolitan hospital. Both facilities represent the m of U.S. hospital that may need to triage and treat patients in the event of an influenza pandemic.

IV. *Methods*

Our research is built around three considerations about hospitals and UVGI FFR-Decontamination/Reuse (UVDR):

1. Can they do this?

Organizational and process barriers to implementing of FFR-UVDR
Barriers and challenges to compliance with FFR use

2. Will they do this?

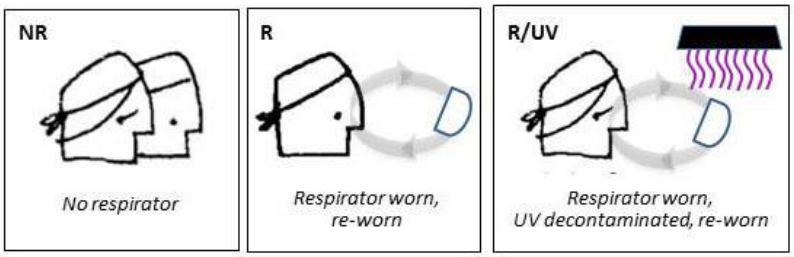
Pros and cons of using FFR-UVDR
Frequency of FFR reuse
Attitudes, preferences related to successful adoption of the UVDR process

3. How would they do this?

Changes to processes as function of FFR-UVDR implementation
Preferences among alternative mitigation strategies for FFR shortages
Coordination and planning among staff including challenges, effective practices, etc.
Recommended procedural considerations

To learn about clinician perceptions, we will describe the mortality threat, and what ultraviolet decontamination does, then ask for responses to “Would you feel safer?” among each of the conditions: no respirator (NR), respirator only (R), and respirator decontaminated using UV.

Options for Respiratory Protection During a Pandemic



We will use several methods to collect data on participant responses and demographics (e.g., hospital, role/position, time in role/position): Cognitive Task Analysis (CTA) interviews, focus groups, and surveys.

CTA Interviews: CTA is a family of data collection and analysis approaches used to identify and describe cognition and behavior in complex environments (Crandall, Klein, & Hoffman, 2006). These interviews will seek to capture work processes and context-rich examples of tasks and challenging situations associated with FFRs that resulted in good (or poor) outcomes. We may also use simulation interviews (Hutton & Militello, 1996) to present hypothetical decontamination and reuse scenarios that will allow participants to imagine and discuss potential behaviors and decisions in relation to FFR-UVDR use in a flu pandemic.

Focus Groups: Group interviews among 6-10 participants provide an opportunity to gather perceptions, opinions, beliefs, and attitudes about using FFR-UVDR technology and processes. While individual interviews and surveys can probe for detail, focus groups can capture the nature and scope of shared views among participants who have similar experience (e.g., nurses, or environmental service staff). We may use focus groups when individual interviews are not possible or to gather group opinions about FFRs among existing working groups.

Surveys: We will use surveys to supplement interviews by gathering information on a topics associated with FFR-UVDR use during a flu pandemic. Survey questions will focus on topics that are relevant to a large number of participants across a variety of scenarios, rather than specific to the incidents that will be discussed in the interviews.

If a participating hospital requests review through their Institutional Review Board, we will provide the support that would be needed for their approval process.

V. *Participants*

We plan to collect data from a variety of individuals who offer diverse perspectives on the use of FFRs. We plan to interview approximately 12 health care workers (HCWs) at each hospital, chosen from those who are most likely to use FFRs during a pandemic. We will include participants from emergency departments (ED), as they are often responsible for patient triage in the event of an influenza pandemic. We also plan to interview individuals in other roles and will identify these participants as this effort progresses. A point of contact at each hospital will recruit participants who are willing to volunteer their time. We anticipate the following roles will participate, although actual participants may vary by hospital and staff availability.

- Health Care Workers
  Physicians (2)
  Nurses (6)
  Respiratory therapists (2)
  Clinicians who have not had FFR training (2)
- Sterile processing groups (1-2)
- Infection control (1-2)
- Hospital safety (1-2)
- Procurement/warehousing (1-2)

- Hospital administration (policy and communications) (1-2)
- Legal counsel (1-2)
- Risk analysis (1-2)
- Central Supply (1-2)
- Regulatory consultants (1-2)
- Environmental services (1-2)
- Nursing education (1-2)
- Hospital epidemiologist(s) (1-2)
- Occupational health (1-2)

VI. *Interview Procedure*

Two interviewers (a primary interviewer and a secondary note taker) will conduct interviews with individual participants. Individual interviews in clinical settings typically last around 45 to 60 minutes, which enables interviewers enough time to make more than one pass through topics and to probe for relevant data. Focus group interviews require time to enable participants to reflect and react to comments by others, and for more reluctant members to come forward. The methods we use and the time we take to listen thoroughly to the participants will enable us to provide richer and more insightful responses to the research question. We will coordinate in advance with each hospital POC to agree on session duration.

We will make an audio recording of the interviews with participant permission to ensure our notes are accurate. Our goal is to schedule 3 to 4 interviews/focus groups per day, allowing for 9 – 12 interviews over the 3-day data collection period. The fourth day will be used to debrief the hospital and to gather any follow-up information.

We will provide participants with a consent form to read and sign when they arrive for their session. The team will conduct interviewers using a semi-structured interview guide (see Interview Guide Draft later in this plan). We will modify the guide to fit each hospital and participant role. Following the interviews, participants will complete a brief questionnaire to collect information such as age, position, and years of experience.

VII. *Schedule*

Focus Groups. We plan to schedule sessions with homogenous members (e.g., six staff members from Environmental Services):

- Supply/Logistics
- Environmental Services
- Respiratory Therapists
- Physical/Occupational Therapists
- Physicians

Individual Interview. We plan to schedule sessions with individuals to cover more in-depth information:

- Infection Control
- Management/operations
- Legal
- Procurement

- Sterile Processing
- Risk Analysis

The schedule for each facility will combine individual interviews, focus group interviews, and surveys. Sessions will be scheduled to last for 45-60 minutes, with a brief break for participant arrival and departure, and interviewer notes review and preparation. The research team will work with the hospital point of contact before and during the visit to develop and follow a schedule that is compatible with times when participants are available. Here is an example of how a schedule might be configured:

Day One		
Time	*Method*	*Role*
8:00-9:00	Set-up, survey briefing	Hospital POC
9:30-10:30	Focus Group	Nurses
11:00-12:00	Focus Group	Supply/Logistics
Break		
2:00-3:00	Focus Group	Environmental Services
3:30-4:30	Interview	Infection Control

Day Two		
Time	*Method*	*Role*
8:00-9:00	Set-up	Hospital POC
9:30-10:30	Focus Group	Respiratory Therapists
11:00-12:00	Focus Group	Physical/Occupational Therapists
Break		
2:00-3:00	Interview	Management/operations
3:30-4:30	Interview	Legal

Day Three		
Time	*Method*	*Role*
8:00-9:00	Set-up	Hospital POC
9:30-10:30	Focus Group	Physicians
11:00-12:00	Interview	Procurement
Break		
2:00-3:00	Interview	Sterile Processing
3:30-4:30	Interview	Risk Analysis

Day Four		
Time	*Method*	*Role*
8:00-9:00	TBD	[window for any remaining sessions]
10:30-11:00	TBD	[window for any remaining sessions]
1:00-2:00 themes, commonly iterated	Visit Summary	Hospital POC

VIII. *Data Analysis*

We will analyze qualitative data using systematic content analysis methods (Crandall, Klein, & Hoffman, 2006; Hammersley 1992; Kvale, 2006) to identify topics and themes within and across roles. We will use a 3-stage iterative content analysis process: 1) data review, 2) category coding and data extraction, and 3) synthesis and integration of findings. We will use descriptive statistics (means, standard deviations, median, and mode) to analyze quantitative data from surveys. Depending on sample size, we may compare responses across roles using inferential statistics.

IX. *Projected Outcomes*

The outcome of this effort will describe perceptions, attitudes, considerations related to liability and logistics (e.g., resources, cost), implementation preferences, and potential barriers to implement FFR-UVDR technology in hospitals of different sizes. We will offer a representative overview by gathering a variety of perspectives ranging from administrators to clinicians.

INTERVIEW GUIDE
March 2016

[Research team will provide form to confirm participant consent.]

INTERVIEW SCRIPT

We are from Applied Research Associates and conducting a study on behalf of the Food and Drug Administration to learn about the needs and processes surrounding the use of filtering face piece respirators (FFRs) during a flu pandemic.

A high mortality influenza pandemic can be as deadly as smaller scale infectious disease outbreaks we have seen in past years: Ebola, SARS, MERS. The pandemic is likely to cause unsustainable demands on supplies such as filtering facepiece respirators. Using ultraviolet decontamination can mitigate an FFR shortage by allowing FFRs to be decontaminated and reused. We are interested to learn how this process might fit into your hospital's work practices.

We would like to make an audio recording just to make sure our notes are accurate. They will not be shared with anyone outside the project team. Are you okay with us recording this interview?

We will not report any data that identifies you as the source of the information. So please feel free to be candid. If you want to stop at any time just let us know.

We appreciate your time and contribution to this important study. Do you have any questions before we start?

GENERAL QUESTIONS

Background/Experience: We'd like to start by learning a little about your background. How long have you worked at [*hospital X*] and in what roles? What is your current role?

As we talk with you, we would like to get an understanding about [*what, how, when, and where*] in your work you interact [*select, order, manage, label, store, process, obtain, use, dispose, etc.*] with filtering face piece respirators.

- Please describe these interactions in detail by focusing on situations that require multiple tasks/steps.
- [*If appropriate given role*] Where is the FFR use process most likely to break down during a pandemic, and why? What do you see as the biggest vulnerabilities in the processes? Please describe the types of situations that require you to use FFRs.

ROLE-SPECIFIC QUESTIONS

Health Care Workers (nurses, physicians, RTs, PT)

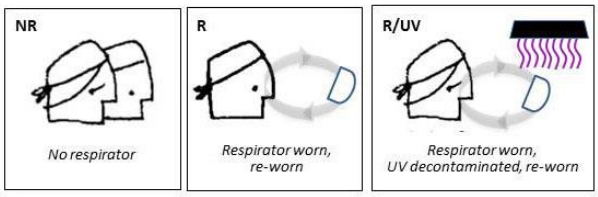
- Where do you go to get FFRs when you need them?
- What model of FFR do you use?
- Where do you dispose of used FFRs?

- What training do you receive, and how often, regarding personal protection such as FFRs and their proper use? Do you follow it in actual practice? If not, why?
- How is FFR compliance evaluated and monitored?
- What is your hospital's policy for reusing FFRs during normal operations?
- What are you expected to do in case FFRs are in short supply?
- Have you ever been in a situation of an FFR shortage? If so, please describe. How did you manage this situation? How did others here manage the situation?
- What concerns you the most about FFR supply and use during a high mortality pandemic?

"What if" questions about FFR-UVDR

[Research team provides interviewee with description of the FFR-UVDR approach, including general description of UV, how it decontaminates, tabletop device and decontamination process. Detail level TBD]

Options for Respiratory Protection During a Pandemic



- Please look over this diagram and tell me how safe (1-unsafe to 10-completely safe) would you feel going to work in each of these three conditions: (NR, R, R-UV).
- Would such a system fit in here in your hospital? Into your work flow?
- What logistical or technical barriers might affect FFR-UVDR implementation?
- Where would such a system be located?
- How far would you be willing to travel in your hospital to pick up FFRs? Do you see issues with time needed to decontaminate? Frequency?
- Would you decontaminate your FFR yourself or have someone else do it for you?
- Are you concerned about wearing an FFR that was worn by another person?
- What preferences of yours would have to be met for you to use FFR-UVDR during a high mortality pandemic?

Legal Counsel

- What are your legal considerations for maintaining an adequate supply of FFRs during a pandemic? For implementing FFR-UVDR?
- What are the legal tradeoffs for FFRs shortage versus FFR-UVDR? How do you manage this risk?
- What regulatory support would have to be in place for your hospital to implement FFR-UVDR during a high mortality influenza pandemic?
- What published research data and papers would you need to adopt FFR-UVDR?
- What FFR manufacturer considerations might be relevant?

- What preferences of yours would have to be met for you to use FFR-UVDR during a high mortality pandemic?

Support: Admin, Infection Control, Hospital Safety, etc.

- What type of FFRs does your hospital use? Do you currently stockpile FFRs? If so how often do you replenish your stockpile?
- How do you estimate need? For standard operations? Seasonal variation? Pandemic preparedness? Any other considerations?
- Do your estimates account for patients using FFRs?
- What is your current plan to maintain an adequate supply of FFRs during a pandemic? Where do you go to restock your FFR supply? Do you have a surge plan?
- What groups/divisions/departments are involved in making decisions regarding FFRs?
- What kind of training/education do you provide for FFR use? Is it the same for each unit of hospital, or different?
- How do you monitor compliance and ensure FFRs are actually used? Used correctly?
- What is your plan to communicate critical information during an influenza pandemic? Would you use different means depending on the type of information?
- Are Local, State, and Federal pandemic preparedness activities adequate?

Questions specific to FFD-UVDR

- Are you aware of and/or do you use UV decontamination? If so, what are your impressions of them? Would you consider using them routinely? Why or why not?
- How might FFR-UVDR be implemented here?
- What safety considerations matter to you regarding FFR-UVDR?
- What organizational, policy barriers might get in the way of implementing FFR-UVDR?
- What personnel, equipment and written protocols would be needed to implement FFR-UVDR?
- What are the barriers to FFR-UVDR use by frontline staff?
- What information would frontline staff need to effectively use FFR-UVDR?
- What procedures would need to be developed to ensure FFR-UVDR is used properly and FFRs are reprocessed correctly?
- What regulatory support/interactions are needed to implement FFR-UVDR?
- What published research data and papers would you need to adopt FFR-UVDR?
- What considerations matter when selecting user departments? Would you target high usage departments, or implement FFR-UVDR across all hospital departments?
- What preferences of yours would have to be met for you to use FFR-UVDR during a high mortality pandemic?
- How do you think FFR-UVDR would fit with current pandemic preparedness activities?
- When would/should a hospital begin to prepare to implement FFR-UVDR?

FOCUS GROUP

- We will conduct interviews with groups from 6-10 participants who have similar experience:

- Nurse (ED, ICU)
- Environmental Services
- Technician
- Central Supply/Logistics
- Physician (attending , resident, physician assistant) (if possible)

- The moderator will introduce and guide discussion. An observer will take notes, maintain response sheets, and manage audio recording.

SCRIPT

We are from Applied Research Associates and conducting a study on behalf of the Food and Drug Administration to learn about the needs and processes surrounding the use of filtering face piece respirators (FFRs) during a flu pandemic.

A high mortality influenza pandemic can be as deadly as smaller scale infectious disease outbreaks we have seen in past years: Ebola, SARS, MERS. The pandemic is likely to cause unsustainable demands on supplies such as filtering facepiece respirators. Using ultraviolet decontamination can mitigate an FFR shortage by allowing them to be decontaminated and reused. We are interested to learn how this process might fit into your hospital's work practices.

We would like to make an audio recording just to make sure our notes are accurate. They will not be shared with anyone outside the project team. Are you okay with us recording this interview?

We will not report any data that identifies you as the source of the information, so please feel free to be candid. If you want to stop at any time just let us know.

We appreciate your time and contribution to this important study. Do you have any questions before we start?

To start, we'd like to ask you to please enter the correct information on the sheet we have provided to let us know:

<u>Background/Experience</u>:

- How long have you worked at this hospital?
- In what roles?
- What is your current role?

Please tell us what you currently do with filtering face piece respirators:

Clinicians: how do you select, process, obtain, use, and dispose of them? Any other things you do with them? It might help if you'd lead us through a typical case.

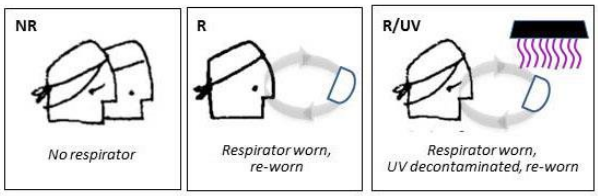
Support/Management: how do you order, manage, label, store, process, and dispose of them? Any other things you do with them? It might help if you'd lead us through a typical case or process you follow.

[provide interviewee with a description of the FFR-UVDR system, detail level TBD]

Now that we have described the decontamination process that is being considered.

- Do you see any drawbacks in this decontamination process?
- What are your ideal preferences that would allow FFR-UVDR to be used during a high mortality pandemic?
- Do you think the FFR decontamination process might break down during a high mortality pandemic? Why? In what way(s)?

Options for Respiratory Protection During a Pandemic



- Please look over this diagram and tell me how safe (1-unsafe to 10-completely safe) would you feel going to work in each of these three conditions: (NR, R, R-UV).
- Given that there will be an FFR shortage, which of these three FFR use options do you prefer. What other options might exist?
-

Is there anything we haven't covered that you would like to comment on?

Thanks very much for your time and your helpful thoughts.

SURVEY

A brief survey will be made available using a web-based service (e.g., Survey Monkey). The hospital POC will encourage clinicians and support staff to complete the survey, particularly those who are not able to participate in interviews. The POC will send an email message to potential participants with a link to the survey, a short description of its value, and estimate of time to complete it.

We will ask to each interview and focus group participant to complete the survey during their sessions. These participants will fill out a paper version of the survey and the ARA team will incorporate their data with the online data collected from staff members that were not available for focus groups or individual interviews. The goal will be to collect as large a set of responses to the particular survey questions as possible at each facility.

The survey will be posted on line for use during the week of the research team's visit and remain available until two weeks after the visit. Web-based services are typically self-tabulating, which will help the team to develop results and findings.

QUESTIONNAIRE

Background: A high mortality influenza pandemic can be as deadly as smaller scale infectious disease outbreaks we have seen in past years: Ebola, SARS, MERS. The pandemic is likely to cause unsustainable demands on supplies such as filtering facepiece respirators. Using ultraviolet decontamination can mitigate an FFR shortage by allowing them to be decontaminated and reused. We are interested to learn how this process might fit into your hospital's work practices Applied Research Associates, Inc. is conducting research on behalf of the Food and Drug Administration to explore the potential use of ultraviolet decontamination during a pandemic event. We will use this survey, interviews, and focus groups, to identify how ultraviolet decontamination might fit into your hospital's existing respiratory protection plans and to clarify the preferences and needs of hospital clinician and staff members who use FFRs during pandemics.

1) Job title: _____

2) Years of experience in this role: _____

3) Total years of experience in hospital setting: _____

4) Have you had training on the proper use (donning and doffing) of FFRs
Yes No If yes, how often_____

5) Have you had training to decontaminate FFRs? Yes No

6) Have you used FFRs during an emergency event? Yes No

If yes, was this emergency event an influenza pandemic? Yes No

If yes, in how many emergency events have you used FFRs? _____

If you have used FFRs during an emergency event,
please circle a number to indicate your response for questions 7-9.
If you have not used FFRs in an emergency, circle "NA"

7) How easy was it to obtain an FFR?

Very easy 1------2------3------4------5------6------7 Very difficult NA

8) How easy was it to follow FFR procedures?

Very easy 1------2------3------4------5------6------7 Very difficult NA

9) How easy was it to dispose of your used FFR?

Very easy 1------2------3------4------5------6------7 Very difficult NA

10) Provide any additional comments about current FFR training, policies, and implementation procedures: _____

11) Are you familiar with Ultraviolet Germicidal Irradiation (UVGI)? Yes No

Please circle a number to indicate your response for questions 12-14:

12) I would feel safe going to work during a high mortality pandemic with no respirator

Agree 1------2------3------4------5------6------7 Disagree

13) I would feel safe going to work during a high mortality pandemic with a respirator

Agree 1------2------3------4------5------6------7 Disagree

14) I would feel safe going to work during a high mortality pandemic with a respirator that had been decontaminated using FFR-UVGR.

Agree 1------2------3------4------5------6------7 Disagree

15) I would feel safe going to work during a high mortality pandemic with a respirator that I have to reuse many times without any decontamination.

Agree 1------2------3------4------5------6------7 Disagree

16) Do you think implementing UVGI FFR Decontamination/Reuse (UVDR) will help mitigate FFR shortages? Yes No

17) What would be the greatest advantage to using FFR-UVDR during an emergency?

_____

_____

18) What would be the biggest barrier to implementing FFR-UVDR during an emergency event?

_____

_____

19) What are your ideal parameters that would allow FFR-UVDR to be used during a high mortality pandemic?

_____

_____

Thank you for taking the survey! Your participation will help the US FDA to learn about issues related to FFR decontamination.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete (the time estimated to read, review, and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRAStaff@fda.hhs.gov

C. UV DECONTAMINATION UNIT DESCRIPTION

APPLIED RESEARCH ASSOCIATES, INC.

Full Face Respirator (FFR) Ultraviolet Decontamination/Reuse (UVDR) Product Description

Power: 110 V

Shape: Cube with multiple ports (4-8) to place respirators for simultaneous disinfection.

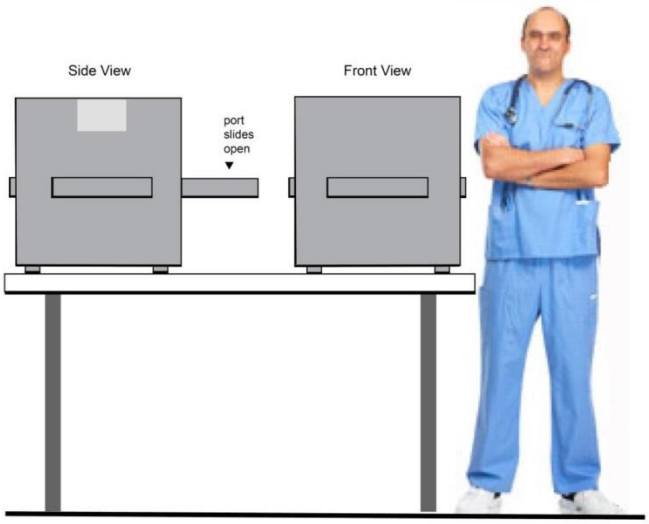
Size: Similar to a microwave oven

Safety: Would contain/shield UV light from users when in operation and when loading and unloading respirators

Controls:
- On/Off switch with power indicator
- Meter that indicates the appropriate level of UV dose is being provided.

Operation:
- Turn on device. Allow it to warm up for 10 minutes
- Insert the respirator into one of the ports
- An automated timer will start when the respirator is inserted.
- After the 1 minute exposure an alarm will sound and an indicator light will come on to indicate the FFR decontamination is complete.
- Each port can be operated independently.

Other features:
- Requires a refrigeration unit to maintain constant temperature.
- Fan circulates air for cooling and rapidly remove odors
- HEPA filter contains any particles/viruses that would come off the respirator.



Artist concept of FFR UVDR unit to indicate size

4300 San Mateo Blvd. NE, Suite A-220 • Albuquerque, NM 87110
(505) 881-8074 • Fax: (505) 883-3673 • www.ara.com

D. DATA CODING THEMES AND DEFINITIONS

	Theme	*Definition*
1	Discard vs. Reuse FFR	
1a	Reuse any FFR	Would share FFRs
1b	Reuse own FFR	Would only reuse own FFR
1c	Discard used FFR	Would not reuse an FFR
1d	Ultimately, would share an FFR	Convenience is secondary to survival
1e	FFR decontaminated, but soiled	Undesirable; the "Ick" factor
2	Assurance	
2a	HCW need to trust FFR decontamination is thorough	HCW confidence in UV, and related procedures, to protect them, patients, others
2b	Prevent cross contamination	Prevent contamination from pathogens other than influenza
2c	Need way to show UV unit is operating correctly	While UV process may be trustworthy, need way to verify unit is working correctly
2d	Education on health threat	Disease, Mask Performance, and UV use. Infectious Disease 101.
2e	Concerns about people as virus vectors	Concerns over carrying pathogens elsewhere
3	Compliance	
3a	Fit testing regularly but not consistently	Not all at hospital are fit tested, and some go for years without retest
3b	Short cut on FFR UV protocol to care for patient	Clinician trade off to treat patient in crisis
3c	Fit but not compliant	Clinician has FFR but fit is inadequate
3d	Surveillance	Hospital ensures compliance
4	Central vs. Local UV Unit	
4a	UV unit at point of care	Locate UV unit at point of care
4b	UV unit in Central Sterile	Locate UV unit in Central Sterile
4c	Offsite	Rely on 3rd party contractor away from facility
5	Space	
5a	UV unit near point of care would require precious space	Need space for decontamination and contaminated FFRs, but little is available at point of care
5b	Distance to get to UV decontamination unit	How far to walk to decontaminate FFR's on unit
5c	Where to store "used" masks	Space needed for used/contaminated FFR's on unit
6	Training	

6a	Trained at fit testing	FFR training only during fit testing
6b	Annual refresher training	FFR training provided each year
6c	Training essential to prepare HCW	Need program to develop safe practice in advance
7	Availability	
7a	Hospital manages FFR supply	How healthcare facility handles FFR supply
7b	FRR par supply	How hospital determine how many FFRs to stock
7c	Unfounded trust (in organization)	Faith that organization will provide FFRs, regardless
7d	Demand for FFR from outside facility	Potential for other organizations in community to rely on hospital in a pandemic
7e	Staging PPE at point of care	How hospital makes PPE available for use
7f	Local FFR buffer stocks	FFR stockpile available at facility
7g	Hoarding FFRs	Individuals save own personal FFR supply
8	Using decontamination process	
8a	Confirmation needed to trust UV decontamination	Where hospital and clinicians would turn for information to trust UV decontamination
8b	Expected UV decontamination procedures	How hospital would put process into practice
8c	Decontamination frequency	How often clinicians would need to decontaminate FFR
8d	Need visual indication FFR has been decontaminated	Some evident sign FFR is in fact decontaminated
8e	Doubt UV decon process compliance	Doubts about how orthodox people will be
8f	Keeping track of own FFR	How clinicians can manage their own FFR
9	UV decontamination unit	
9a	UV unit maintenance	Tasks that will be needed to manage UV unit
9b	UV unit operating cost	Costs that will be needed to operate UV unit
9c	UV unit staffing needs	Staff who will ensure UV unit quality control
9d	UV unit design	UV unit traits of interest to clinicians
9e	UV unit training would set expectations	How training should guide UV unit use
10	Current Process	
10a	How the front line HCW uses now	How hospital, healthcare workers use FFRs
10b	How infection is controlled now	How hospital manages infection control
10c	Regulations and policy	Regulations that influence FFR use
11	Artifact (FFR)	
11a	Uncomfortable fit, brands differ	Perceptions of FFR brands, fit, comfort vary
11b	FFR durability for reuse	Actual issues related to FFR longevity
11c	Hospital selection of FFR	How hospital chooses FFRs
12	Pandemic Management	

12a	Initial pandemic demand, response	Expected pandemic care demand at outset
12b	Cohorting	How hospital plans to manage pandemic
12c	Self-selection; fear	How clinicians may make choices related to exposure
12d	Communication in pandemic	Resources to coordinate staff during pandemic
12e	Planning and coordination	Expected inter-agency activity
13	Cost and risk	
13a	Cost analysis	Willingness to bear cost of UV decontamination units
13b	Risk analysis	Willingness to accept risk of UV decontamination
13c	Selection of UV decontamination unit	Issues hospital would consider in unit choice
14	Personal Accountability	Individual HCW commitment needed for success
15	Barriers	
15a	PPE inconvenience as a barrier	Burden of dealing with PPE, processes
15b	Time pressure as a barrier	Pressure to quickly care for patient; patience
15c	Habit interference	Conditioning that conflicts, e.g. sterile practice

E. CODED QUALITATIVE DATA

Merged for all sites 28 Oct. (Note: the information below is comprised of real-time notes captured during interviews and presented verbatim).

1	Discard vs. Reuse FFR		
1a	Reuse only own FFR	I would use whatever I was told to use	78
		Be okay if the data shows the process works; definitely prefer my own	94
		No	119
1b	Reuse own FFR		
		Concerned because of the unknown of how it was used by the previous owner "longer than they should have worn it"	93
		Sterilized and everything. Seems weird, but if it was sterilized, I'd be ok with it. Rather have my own [FFR back].	30
		If it was sterilized I'd be ok with it. Rather have my own [FFR back].	30
		How safe is it for me – using someone else's mask even if it's decontaminated still wouldn't want someone else's – something going to go in my face.	77
		If only me, I'll use my own mask, UV, fine. To protect whole community? This is a very important question.	49
		I'd want to use my own. Your nose and my nose aren't the same. Then you would be responsible to make sure yours goes into the UV.	25
		Would need to have a number on them…so you know the mask you are talking about	4
		They're going to want their own respirator back	10
		I'd wait a minute for minute for my own	55, 56
		If you have the same pathogen, multiple patients, I'll wear the same one through all patients	57
		I'd be more likely to use my own mask that goes through alone. I don't know if I'd use my coworkers' b/c they could be symptomatic and not show it.	39
		And how's the filtration process of the respirator, since it traps particles in it? The integrity of the surface would have to be perfect for me to use it. I just really don't know that I'd use another person's mask. Or maybe it was touched by someone else's mask. All I can	39

		guarantee is my own; I know I am safe with how I do things.	
		Are we talking about one person putting their own mask in the machine? Or will I be putting someone else's mask on after? Because I don't feel comfortable sharing germs - from my IC background. Does the machine take care of everything?	62
		I'd want my own back. Every time the nurse goes in and out, it has to be decontaminated?	42
		Want my own mask back	38
		Certain people may want to keep their masks. The ability for an individual to put their own in and know they cleaned it themselves.	8
		Absolutely would not wear someone else's	101
		Trust myself to get my own mask back	93
		More inclined to use my own mask again rather worn by someone else, we don't know the cleaning process. From my perspective, it's no different I use the drywall mask and save them and use them. If it was yours I'd feel more comfortable than a stockpile of recently used. If I was Joe off the street more apprehensive not knowing the cleaning piece.	105
		Nurses in general would prefer to reuse their own mask. You could potentially go from someone using 12 masks in a shift to 1 or 2	106
		Prefer to keep my own mask	108
		Keep my own	109
		My own	103
		My own mask	104
		If it's decontaminate or someone else's? I would wear my own in an event of a shortage	77
		Wouldn't want to wear someone else's	75
		At some point the employee doesn't want to wear something that was on someone else's' face.	81
		No sharing masks. We are all fit for our own. It goes everything against I know as a nurse. Even if it's decontaminated. You pop out of a room, throw it in, then you know you're good to go.	92
		Would feel most comfortable to decontaminate my own mask;	71
		Most comfortable to take responsibility with my own mask.	73
1c	Discard used FFR		
		Reuse? Doubt it. I guess you could. But they aren't comfortable. Once I get rid of it I get rid of it. We were both OR nurses. This is not a fun mask. Not fun to breathe through.	47

		Reuse?- Not that I'm aware of	48
		I would be hesitant to put one on my face that someone else has used	79
		Most people don't think – don't feel so great now in terms of quality. They work and do what they are supposed to do, donning and doffing, can be ripped or elastic loosens. They are really considered at this time for short term use; not reuse.	11
1d	Ultimately, would share an FFR		
		Given choice of exposure I would wear someone else's mask but not ideal	74
		Only if it was a deadly virus! Then I'd share	58
		Would have to be a catastrophic situation when there's no other choice - I think if there's a choice people would utilize that choice	118
		If there was down to no choice it I could see using this but you would have to be down to no choice.	81
		I'd want peace of mind. I wouldn't want to share masks. I'd be ok with re-using my own. Especially if you can do it yourself. I would share my mask if it's between that or dying (92-agrees). And if it means everyone is protected instead of me.	91, 92
		Theoretical risk of wearing a mask that you are breathing what someone else breathed out – what's the alternative to not wearing a mask?	28
1e	FFR decontaminated, but soiled		
		Don't feel comfortable going back in with same masks. It gets moist.	77
		It's not cleaning it, the mask is still dirty just disinfected – would rather not wear someone's saliva covered mask	102
		I'd want my own back… I don't want to breathe Pam's air. I feel like I'll be kissing her. She can keep her sicknesses…. difference between this and pulse oximeters is my lips vs fingers. Very different.	58
		The moisture issue is real – it's having to wear them long periods of time – would it dry them out too. Even if it's technically disinfected the ick factor of a slightly moist mask would be hard to overcome	79
		Would not like putting someone else's face – Makeup No way want someone else's.	14
		Drool, breath particles…	15

		If mask is soiled, you wouldn't use it. Any visible splash, liquid. For ex: If the patient coughs, we are throwing it away.	56
		Droplet on other surface v if it's on the mask – different transmission modes. Coughing, you inhale that. How likely are you to transmit it if It's on a surface vs aerosol droplet (cough)?	55
		Don't usually use more than one shift; it's sitting out and who is touching it – don't like using the mask repeatedly in the same bag b/c if you've flipped it over and there was sputum on it then you contaminate – and then the bag sides touch each other. Only use it for one shift.	24
		When they tried to breathe in and there's not enough air means it's blocked from mucus	4
		How long are they good Soiled When they are wet, visibly soiled or not holding Their shape	22, 23, 19
		Depending on what you are doing – transporting a patient, sweating, or if someone codes and you have a gown and gloves and you are drenched in sweat and the sweat from your face gets mask wet and you have to	23
		Wet with spit	24
		When you exhale it's pretty damp and moist	23
		Makeup gets on it	22
		I think using someone else's would be gross. When I wear it your hot in there, your nose is running, and then take that off any somebody else's face was in there.	69
		If the mask has any soiling that would be a problem… so… "Ewww.."	74
		This is going to sound gross, when I put a surgical mask on then it's covered in makeup and nobody would want to put it back on	89
		In Ebola people were getting really funny about the shrouds and sharing them – I write my name on it b/c I want mine back. Even with blue caps God forbid my colleague had lice – don't know what they were thinking – a lot of ick factor. People saying I don't' want to touch that or reuse that.	81
		[Wearing another's mask] that's nasty, that's disgusting - people are nasty. So you say that, there is gunk on people, I see people picking nose, picking ears and am sure that stuff is still on the mask, doesn't eliminate debris and that's disgusting. [I] think there are things you shouldn't share like condoms	117

		A respirator is basically like a condom for your lungs	121
		Gets rid of germs but not grease	120
		There's a gross-out factor for me. And idk that I trust it would work. It gets hot, sweaty, icky. So I'm going to put an icky mask in a microwave and think it's safe when it comes out?	107
		How do you clean the respirators though, the nature of it it's on your face, just putting this in doesn't necessarily render it disinfected it if there is mucosa on the respirator.	105
		Imagine if they are visibly soiled they would have to be discarded and not eligible for re-processing – any bodily fluid that gets on the mask does that take it out of consideration	96
2	Assurance		
2a	HCW trust in UV decontamination		
		If it is soiled in any way so even if you decontaminate it, it won't work	5
		So, I don't know if I'd trust this UV process. I wouldn't trust it for my surfaces, so why for something I breathe through? Why would I want to breathe it into my lungs and expose myself? Maybe I'm more cautious than most, but its b/c of my experience.	39
		I'm very familiar with it. Absolutely for it. It's under-utilized. Particularly w/certain pathogens like C-diff	45
		I'd use UV routinely if I could	45
		How do you know what is clean and not?	8
		Does it do just the surface or the layers?	19
		N95 masks are stratified …material. UV hitting one area could be shading in another area	23
		General reaction that UV Decont seems feasible - if my mask -yep	21, 19
		Don't believe the decon of the mask.	28
		Can I make sure this product is safe for the person who is going to put it on?	7
		[How about if someone else decontaminated?] wouldn't bother me as long as I knew that someone was doing it.	104
		You said this takes a minute to clean, is that enough time to really get it clean?	110
		Don't know guess I trust easily, same way you trust the soap you are using has an antibacterial quality to it.	106
		Big one: is it safe to put back on or carry with me?	71

		think different technique that's not usually how we do the FFR. I don't like it – I believe the size – a little loss for words – questions process….don't think it would 100% really clean.	83
		From an infection control standpoint, if there is any organic matter on it then I'm worried that something is hiding in that matter.	81
		About what they are made of – the fibers – crisscrossing fibers – how do you ensure that everything in the middle didn't get contaminated? With filters as you breathe in the filter becomes better as it gets dirtier. Does the UV light get under that load? How did you test it, was it effective – did you cut up the mask. If you just wiped the surface of them you didn't get into the mask.	81
		Let's say if it goes into this machine, 90% of viruses are killed. Well, a pandemic is a pandemic. I'd rather have it working at 90% than 0, or have this over having nothing.	84
		It might decontaminate but.. with our sterilization we hammer in you have to clean it before you disinfect it. How we are suggesting throwing it in without cleaning it. My immediate response is: is it really killing the virus?	81
		If they could swab/test it to tell me the virus is gone, …	93
		How do we know it's working?	55
		Being in central sterile for years, it has to be cleaned removed of gross soil before they can be disinfected	105
2b	Prevent cross-contamination		
		Does all UV kill all strains? To my knowledge the strains do evolve and change so that's something to think about as well, will it kill a mutated strain.	73
		What all does UV light protect against?	55
		does the UV light get rid of everything, if someone has a cold sore or skin diseases on their mouth… other oral infection	116
		Only good for flu? Because we've used these masks for SARS, measles, Ebola. Negative airborne isolation rooms too. Someone comes in presenting symptoms and they're put in an airborne room until we know what they have. So if this UV only works for flu, you'd essentially have to wait for patient results and then it'd only be good for that (flu).	107

		What about TB and other things?	98
		different strains	22
		also the other bacteria that could be on the mask and may still be there	93
		what happens if that mask gets a glob of mucous or snot that's a little more tenacious than an aerosolized viral particle – want to also make sure the mucus is being decontaminated	23
		Other things that may be on it from the other person if you aren't sharing a mask…what isn't killed by UV is going to a problem—what other things are killed…lice, etc. doesn't have any flu no telling what else it has	18
		What does the UV kill other than flu? Anything else? There is also micro-plasma, etc. Am I getting his mask? And catching something else? There would be reluctance from people who are not assured it's killing everything. I am very uncomfortable sharing if so.	50
		If it kills flu, does it kill anything else? Cold-kills that too, right? If not, then I wouldn't want it to go to central.	43
		Besides flu, there are other viruses and organisms. How are you testing for all of that? People usually have more than one issue. I don't know that I'd be comfortable with this, if you're talking about sharing masks of other people.	57
		Does it matter if someone has 5 different pathogens - Spores, viruses, bacteria?	55
		What are the kill claims for different influenza strains? It's one thing to talk about one strain. About what about SARS, MERS, new fungal infection? UV light is not approved for those. Most hospital disinfectants are not approved. We just use Clorox - That's how bad it is.	39
		If it kills flu, does it kill anything else? Cold-kills that too, right? If not, then I wouldn't want it to go to central. Wouldn't be possible to keep up w/everyone's mask unless they have names on them	43
		But you just tested the flu virus…so could something else live through UV process?	43
		The body of literature on UV decontamination is very good. One of the concerns of health care providers, though, is to see if it kills things outside of flu.	45
		A lot of times we'll have a H1 in one room and H3 in another and they are different bugs, then we've had people with other pathogens, (CRE) Carbon errice (sp) – a bug resistant to	93

		antibiotics. If you could say it could kill influenza but a lot of bugs then I think it would be	
		Do you trust someone to do it? I would stand there for the 60sec	24
2c	Need way to show UV unit is operating correctly		
		After its disinfected, cleaning or wiping it so that it visually appears clean so people are naturally inclined to wear it. If I'm seeing something that's dirty and someone is telling me it's been decontaminated -- it looks dirty… do I trust that it's been decontaminated, do I trust the process they told me to use, then you have people modifying the process that was built to protect them. The system is guiding them to do the right thing all the time.	86
		How do we know the UV rays – what if something happens internally how do we know if it's decontaminating the mask itself? It needs 4 UV bulbs and 2 are out and I pull my mask out is it safe still.	71
		how do you know the disinfectant is even effective, know the machine is working;	117
		We do this for our sterile compounds areas where they swab to make sure there are no microbes growing. If they could do some spot checking? With some of the mask, swab the mask to see if any microbes grow on it after being placed in this machine	94
		When we sterilize, before we put an implant in a patient, you need to run a biological. We have a control test to make sure it is actually sterilized. We have a control that tests positive. We run the same file for each implant to see if it comes through negative. So if you could run a test like that w/the respirator - If it's something that would die from UV but isn't harmful, you could run a test. We have filters that change color once a certain level of steam has been exposed. Maybe the mask could change color when its 'ready,' but I can only see that being done once.	65a
		How do I know the mask was zapped correctly and it's decontaminated?	58
		Decontaminated masks will need to be re-packaged. Not a peel pack, but a paper bag. So that you know it's been run through. Needs to be in something so you know it's been decontaminated – we won't want mistakes,	45

		picking up a dirty one from the wrong bin. And environmental things in the air.	
		If I looked at that machine, can I tell that it's working right?	62
		That cycle is recorded w/ biomarkers so that the process maintains its integrity. Also, evidence that it worked.	48
		how do I know someone else decontaminated it if it's in a spot, do I trust it or just do it again	102
		how would you keep track of how many times it's been decontaminated, how do you know it's been decontaminated,	116
		Thinking of scrubs again. I put my scrubs in the machine. I know when I pick them up, I know what new scrubs look like. I can tell. If there's an indication the mask is clean, maybe?	114
		In OR, things are labeled as sterilized, vacuum-sealed, dated - I know there's a whole process. Unless I physically saw my mask go in and out…	112
		I would also want to see evidence that it's decontaminated if you go from patient room and room. Compliance using the machine, and changing everyone's thought process.	93
		I want to see it go into the machine. Then I'll trust the process/person after that. I err more on the paranoid side, and I'd like to know that it was put in the machine, so if its mine, it's got the same label and it's been decontaminated. Medical errors do occur and it's often when something slips through the cracks. I can trust, or I can verify/witness	112
		Think anything is possible, it would take significant education and it would have impact on workflow as far as turnaround time in seeing patients.	94
2d	Education on health threat		
		What's the point of de-contaminating your own mask? I'm not going to decontaminate my own mask, I'm going to keep wearing it and then get new one.	78
		Two different divisions – even safety concern not addressed. 20% change in staff since Ebola training, so less knowledge. Feel big vulnerability for the institution. If you say knowledge ---- going to say awareness when something like this happens are you thinking of the next step… affects next shift, immediate	18
		What's the point of disinfecting your own mask, in my mind in a pandemic if you are using your	79

		own mask the education focus is what the safe way to doff and don and store – bigger concerns for me. Think there is some use in this in terms for people to reuse masks can reduce perception of shortage.	
		We have people who change their clothes before going home because they are afraid of bringing something home, or they wear a mask here although there is no risk of infection to them because they are afraid of bringing things home, a lot non-scientific based fear out there.	5
		Had baby born from a mother exposed to Zika—needed to take the baby down to have procedure done…staff had masks and face shields … asked in baby had Zika. The baby was not contaminated, but they [staff] were dressed to the nines. I was in my scrubs and the pacifier – holding in the mouth. A lot of our staff doesn't want to ….. We looked at the guidelines to know how to handle it.	18
		Even [after training] people think they are telling them what will benefit the team rather than their self to get the job done. The news is posting one thing, they hear something else – they don't know who to believe.	18
		How can we facilitate how do I actualize it…big concern and how to get staff to believe that it's safe – can't call in sick every day. Would sell as an autoclave for your mask.	18
		Educational push about equipment	15
		Not trained in it, patient care is priority. Sounds scary and decont and UV to people	11
		not just education that we could do for our staff – they want to know the answers to know they are safe and their patients are	31
		I'm sure people will ask questions, and some people aren't as easy to convince. They're cautious b/c they know they are higher risk.	39
		think some people walk in and out of room and think I didn't' touch anything – which is not the case	93
		I think there will be employee resistance, but they resist everything. Some clinicians. And environmental services workers. They usually don't have medical backgrounds, so there may just be trust issues w/how the employer protects them. Education could help. Who would do it? IC, us, Nursing - Professional development places like that.	107

		amt of exposure – if you are in room for 5 sec do you have to do it [decontaminate] or if you are in there for hour and half do you do it	118
		wouldn't it not work the seal if it's already molded to face	22
		if we are talking Spanish flu pandemic – every patient in this joint – you're going to have 40 pats on a floor doing this, realistically where will they take mask off when it will not be covered in flu	23
		we don't follow CDC guidelines or any hosp that does follow – instead of 5 pats on the floor with flu don't see any place on a pat care area being safe or not contaminated wherever you can take it off to clean it or take it off between patients – it will be put a little mask over it like when you use 95 for all patients	23
		You would take reg surgical mask and put it over her respirator and take that surg mask to go to new patient's room. You would have the 95 mask on 24x7 if that was the case	23
		if you need something to protect against, say patient A had it – it goes through the surgical mask then I put the new surgical mask on what's to say that particle that is coming from aspiration off the 95 and through the surgical mask	23
2e	Concerns about people as virus vectors		
		[break down in a pandemic] walking the hallways with the dirty mask	78
		We are at the bedside and taken off our PPE and then we are going to go to the unit – who else are we transmitting to?	72
		How often can we do it…?	55
		Is the virus still alive on the mask before you put it in the unit? There are concerns about contaminating the unit	89
		How do you make sure that you don't re-contaminate the mask with what's on your body?	84
		And in order to get to the toaster, I have to go to the toaster room, wipe myself, and wash my hands. This is really important. If you touch it without gloves, you've re-contaminated your hands. This needs to live in a Dirty-in Clean-out room. How does that work/look?	84
		If only one on the unit and you had to carry the mask to a central place you could contaminate a lot of different sites along the way.	68

		My concern is how we get to the patients room and through the halls	72
		You would have to put it in anteroom so people don't want to walk away with it. You don't want anything you touched leaving that room you don't want anything walking down the hall	81
		it could go to soiled room but I'm going from A to B with the mask	75
		how do we carry contaminated masks	74
		Also worry about patients who are coughing more than others and it gets on the mask then you take it off and touch it, and then you have to walk from one room to decontamination unit. What happens if you get called to something else, emergencies happen?	100
		They do have a window for emergency response when people run in and out of room it's counting every time. When we make huge efforts "this is hand washing day" we are 100% but if you aren't reminding people	93
		usually doff all equipment in anteroom and you don't want to expose other areas	102
		My concern is if we are concerned enough to decontaminate a mask, is it mostly in the name of saving product and making it more efficient or to stop the spread of a disease. There's a risk of spreading a disease just by leaving a room with your mask so much so that you have to decontaminate your mask, that distance that you are walking between the room and machine is that a risk?	118
		Says HEPA filter contains particles from the resp. – how do you dispose of that?	118
		I feel like the outside of the machine would be contaminated. So if you touch it, you're putting spores on your face. It's not like its constantly being cleaned on the outside. Cross-contamination potential.	113
		How do you get your mask safely from room to machine without contaminating the environment? Maybe sealing it is a solution?	115
		Where's this machine? On the unit? So you're going from a neg-pressure room into a hallway, with a mask with spores?	112
		now the unit is contaminated	99
		similar to food trays coming out of isolation rooms, have to make sure you get them safely in the bin/tray holder thing	100

		[barrier] Would dirty masks be right there waiting, exposed to everything? How long does the flu live on surfaces? Long enough.	43
		Who disposes of the HEPA filter itself? They will be contaminated. What about the fridge? Is that part of the device itself?	42
		And you'd still have to have the 'if not, then' requirements. What if it's exposed to a droplet of moisture? And how do you remove it from your face without contaminating the whole thing?	39
		coming out of an airborne room right now I take gown off in the room, go out take off gloves wash my hands, take off mask, then maybe wash hands again then go back in room. Think that's the bigger concern.	79
		visitation is a huge issue, you have patients that are sick and coughing up then mom dad and two kids are in the room and now they're walking around the joint touching everything, gift shop and cafeteria. When you start about that – how much of that is related to healthcare worker and handwashing rather than the family visiting. This is a "visitors as vectors." so they import/export some bio pathogen of some kind – moving in and out of the care setting – two diff conditions involved there	23
		With every extra step, there is a potential for mistake. Might make a mistake where you take it off. By the machine? Now everyone gets a whiff. In the bag in the patient room? How do you carry it to machine? Maybe I forget to wash my hands. Now my hands are dirty b/c I'm the one that put the hand in the bag. Who takes it off the machine? Not allowed to pick it up until you wash your hands? If not, you don't get the mask out of the machine? That could negate the whole process. Physicians only have a 40% hand-wash rate. You'd re-contaminate your mask. Unless you have reduced tremendously the number of steps/people involve - b/c it's a process involving humans – it won't work	49
		So yes, more masks are essential. But that is a small part of the story. All of the minutia will be confusing (where do I hold it, when do I wash my hands, etc.)	49
		This would provide a solution to sterilize the mask, maybe. But it is not a solution for the masks in the h1n1 pandemic. If I am a new med student, a Dr. who doesn't know the process,	49

		then yes their mask may become sterile, but their behavior could potentially jeopardize the mask.	
		What happens if you mess up part of the procedure? Then what's the procedure? How do you fix any given mistake?	52
		Is there a way to have it stay decontaminated right afterwards? Would it go into a container or something? How would you store it afterwards? We re-sterilize things in CS- you need to contain them immediately or they could be re-contaminated again.	65a
		This would be like having a great autoclave for sterilizing surgical equipment, but not doing the surrounding behaviors/procedures right.	50
		Let's say you get the mask, it gets contaminated w/liquid on outside. You take it off. You got that on your gloves. And the machine. Maybe you pull clean ones out and contaminate those	56
		If it's transmitted by drop or aerosol, what is the purpose of the UV light then? You'll be contaminating the mask, but not the bedrail we touch. So why am I only treating the mask? I don't see it from the surface/patient side. Now it'll be everywhere.	55
		In a pandemic, if you run short on masks, you'll run short on other PPE too, getting contaminated. Then you've still got the dirty PPE, with a clean mask. Mask is part of the problem, but not all of it.	57
		Short intervals of care needed – running in and out – area of concern	45
3	Compliance		
3a	Fit testing frequently but not consistently	yeah cinch it under my chin, make sure it's not fogging my glasses	79
		We carry two different N95's. Everyone is fit tested.	5
		We don't really renew fit testing just remember doing it once.	29
		If only using a couple times a decade, might need to make sure I know what to do when the time comes.	28
		I can only wear one size – could taste the sweetener in the smaller size	30
		Three sizes (S,M,L) but two manufacturers. 3M and Moldex.	5
		When I started working here we were fitted and go every year but maybe 7 years ago that stopped.	26

		You gain and lose 15 pounds and the N95 is not a correct fit compared to when you were originally tested	10
		Have many different masks.. neo nates, adults, and adolescents. Different sizes.	8
		You do get fit for these upon hire; there are units who are mandated to be fit and they do the sweetie thing.. some units don't get involved and that's my unit. We are considered very low risk so choose not to do us – at least we know what size you are	31
		Anyone on unit that deals how people are using them no, Up to individual clinician attention	32
		here is a card that is issued to me on march of 2015 during orientation from SBUH environmental health and safety – respirator fit test card, you name, the mask type, make model and size and the person doing the fitting acknowledges a good fit, date of fit test and has contact info for further questions. Says to keep with your ID badge. Quick facts on the back 1-5	32
		usually on the staff's birthday you get notified to do your annual clearance	32
		N95s, Midline brand..only one I've seen. And we do the fit testing every year all of our staff. Everyone in the OR and those in-patient areas. Everyone in my area of responsibility. Small grp in labor and delivery less likely to need them, other units do even housekeepers b/c they are cleaning around the patients	11
		fit testing once a year, and that is for everybody on the units you manage Everyone, all the nurse, Res, MDs, physicians and our extended practitioner (MPS, pas) Housekeeping, don't think central sterile – endoscopy does. There is a place for decontamination – people are wearing the appropriate attire in in central sterile so you have to treat everything as infectious… Hope they are fairly good about it to protect themselves, if they know they should be wearing them	11
		Because FFR are sized, changes in current weight can impact fit.	6
		B/c particular team does fit, the opportunity for retest is limited.	6
		Individual card carrying with fit info	12
		Evaluated on an annual basis	12
		Not used a lot; somewhere in desk	15

		95s for TB; use a different mask for Flu	16
		In plastic marked with year	12
		Facial hair ….	12
		I could potentially see some issues arise if we had a pandemic, b/c we all haven't been fit tested	44
		We have expert nurse educators that are actively involved in every level of the org. They are integrated well into orientation piece – fit testing all the way to deployment. Formal education, Just In Time, online training, etc.	44
		When we do our yearly, we have a fit test. An enclosed mask over us, spray something to see if you can taste or smell it. Facial hair – less effective.	64
		Fit testing happens for everyone, absolutely. Patients usually get a blue surgical mask – yes, even if they have high mortality virus/flu.	55
		Fit testing is stringent	56
		Part of TB risk assessment is to determine if we fit test everyone annually. Currently here, it is required for everyone.	39
		Fit testing – we need to be confident about them fitting – otherwise we can't ensure their protection. We have to trust the products we use. With fluid resisting gowns, for example – we didn't know at the beginning of Ebola that we needed fluid resisting gowns. Once we learned about mode of transmission, we had to take fluid barrier precautions. We just don't know what we're dealing with right away.	39
		Training is upon hire, and annually. We make sure there is a secure fit (fit test). Don't have quant tests. But we do a spray test w/saccharine. Old fashioned test. It's sufficient and meets standard of care.	39
		Selection process occurs when we do our fit testing – annual for N95. Fit test team will sort of measure us for size and facial structure and give us the best mask to fit contours of our face. Then we are supposed to use that mask at the bedside if necessary. How we get fitted and tested to determine the mask we should be using. They give us a little sticker (on ID) that tells us which mask – I use 3m 870. They should receive the sticker once completing the fit testing.	72
		Annual testing to be fitted correctly.	42

		FFR brand has changed since I've been here. Annual fit test - we make sure we are fitted for the new brand	43
		Well. I never taste the spray	41
		Me either. But there are only 3 sizes – s,m,l, maybe xs. It works fine. Never had any issues. Takes less than 15 min to get fit tested	42
		100% success if it's on right - Barring any defects. From what I'm told, M fits 80% of the population. But then you have user error. So maybe 50% success	43
		I don't interact w/patients, so I haven't been fit tested.	45
		All depts. I can't afford to lose anyone in the hospital. Anyone who could be wearing them or exposed.	45
		I'm the gatekeeper of them. Every employee that could interact w/a patient needs to have a mask, go through me to get testing. I set up that testing/test them.	62
		When we change brands, I have to re-test everyone. It's an annual test. Or if they have a change in facial structure/weight loss or gain. Questions about fit testing, they come to me. I refer to CDC or OSHA if I don't know. Maybe it's obvious that it's not on right.	62
		Many of them have trouble even putting it on. They're trying to put the straps over their head and fumbling. Some of them don't use it on a daily basis and they don't get practice/aren't comfortable w/them. Then you have you germaphobes that come to me like "are you sure this fits me and is working?" So, it's person to person.	62
		Annually, in February. And as a new employee during orientation. The way we know it fits – they put a mask on us that fits our size. They spray a bitter agent; have you sing the ABCs, see if we can smell/taste the agent. Recently switched to a different spray/scent because we were getting used to the other one.	35
		been fitted with them not too often here b/c of my role, previously in my other job used them primarily for TB patients – would not use surgical mask	103
		every year	116
		We do qual and quant testing. Porta-count machine for quant testing. Counts air particles. We can do this is the employee fails testing. If that doesn't work, then they're fit for a PAPR. If	107

		they cannot wear either, they get documents saying they can't work with airborne patients. Fit testing takes 20 min. We focus on the fit check and making sure people put it on properly. They walk out of fit testing and we just have to trust that they're doing it right	
		…, which includes procedures for initial and annual fit testing for N95	107
		every year	121
		Last time used the machine that tests. My most recent facility does the squeegee ball which I think is a less sensitive test than the one with the machine, but ever since I've used the squeegee ball I've had facial hair and passing the fit tests.	121
		We're fit tested every yr.	115
		[model you would use] - when we do our fit testing they tell us	118
		[model you would use] I don't have any stickers	118
		[model you would use] we have the sticker yeah, the white one or blue one	119
		[model you would use] oh, I have one too here it is	116
		Go through the breathing process with big hood over your head and spray mist in your mask to see if you can smell it.	104
		annual fit testing, put mask on and hood overhead and then spray to see if we can taste it	94
		we go for our test and have training, did fit test (everyone looks at sticker on ID)	109
		When we get approved for our sizing, we go through the typical "make sure you can breathe"	113
		Fit testing - they have us put it on without instruction. Based on how we put it on, they give us feedback.	114
		we took the class, that's on back of ID	108
		we are all fit tested to wear them just in case, for procurement, distribution, etc.	105
		CBT as well as yearly fit test as to which one to use and how to use them	106
		make you do a counting test, move your head side to side, up and down	93
3b	Short cut on FFR decontamination protocol to care for patient	Problem would be going back into a room; if there is an alarm in a patient's room and you have to get your mask on before you go there. This is the ICU – when you are responding to an alarm you have to respond to an alarm. Even on the floor we have bed alarms they don't have 30	79

		ft. to go get a mask they will need to have a mask there.	
		Think they would feel they are trading something.. nurses they feel they are being pulled into something constantly – they really need to be taking care of patient. Would prefer to get rid of them right now.	11
		Example from Ebola training. In NICU, we would have few staff to realize the process. Neo natal area is limited – those areas would be focusing on the mother.	18
		Unfortunately people need to be managed. Think there will be a large group who will be responsible. There will be who will rush through, have an excuse.	15
		In my practice environment things are well controlled, this would be a matter of a personnel concern – who is the resp person that day.	28
		If you have a patient who is crashing, the ease of grabbing another mask vs spending 1 min waiting is an issue. We often go through path of least resistance	50
		Issue is, you're standing there for 60 sec. and there is an emergency somewhere. You don't have your mask ready. Deadly pandemic, you're going to have a lot of patients. Cannot run through this process after every patient.	57
		[Barrier]- 1 min. can be long in a crisis	41
		And the availability of them if some patient is in dire need? I'm not going to fumble with this machine and wait around	62
		Sometimes you need to do the task at hand quickly. You may not be putting the mask on right. Nursing instinct - Do what you need to do. In a crisis, how concerned can you really be – with something you can't see? We're often rushing.	33
		I'd worry about provider safety. Because of limited access to masks, inappropriate use, or going in without PPE to still take care of patients.	113
		to the best of our ability unless an emergency situation	93
		60 seconds is a long time if you need to get into a patient's room for an urgent matter. Which, here, could happen frequently. Could you decontaminate right after you exit a patient room, instead of right before entering? I think you'd be willing to go further if you didn't have	115

		to go to another patient immediately - if you could do it right after you see a patient.	
		Usually it's when a patient is actively dying. If it's a room you don't know or patient you don't know you are part of doctor cart [code for patient going down] team you just run in there. Feel like the masks are apparent and wear fewer gowns.	93
		[decon break down in pandemic]guess you'll grab a soiled one – if the patient is sick and it's an emergency (crashing and coding) to stand at the microwave for a minute…	69
		if a patient codes in a room there is no way to verify the staff running into to save the person are following the procedures correctly – not always but you might see someone grab the mask and put it on while they are entering the room. Are they exposed? Don't' know but it's a touchy scenario that you don't know.	71
3c	Fit, but not compliant	Then when in a patient room I wonder if it's actually sealed – just have to trust it.	66
		[Do you follow the procedures about PPE?] I do but don't think everyone does	99
		Nuances – facial hair. If the person has gain or lost more than 10-15 lbs. In part of our instructions, Kim talks about that. If you don't have a good fit let us know.	39
		For me, I double check that my mask is sealed by seeing if they fog up my glasses. If so, it isn't on properly. We're taught a trick, breathe in and out to see if it's sealed. We don't have a formal test, though.	39
		That's another thing w/ re-wearing someone else's cleaned N95 - Fitting will be all over the place! Maybe we should look at filtering PAPRs better…	62
		95s don't fit my face so I've had to use a Kimberly Clark bill.	35
		Don't feel 100% confident, you do the fit testing once a year and you adjust a mask and in there you have a guide or signal to know there is a leak, but when you walk into a patient's room it's not…you adjust to how it feels but um and I guess you can blow against to assess if there is air escaping - but there's no smell indicator to judge so my confidence level is about 65%	116
		[Could things break down during a pandemic?] Two ways – 1) Access to masks. Employees grabbing the right ones when they're busy. Meaning, they should be on the units. But	107

		sometimes employees grab whatever mask they want, not the one they're fit with. Some people just don't use them frequently - it depends on their unit.	
		They can do a re-demonstration for us here. We assess if they understand and pass the fit testing. We mark them as compliant and that's the end. We don't do observations. I don't know if anyone does. We just hope they follow instructions. I know they don't always, though. I've seen them pull the mask down in the lunchroom, etc. But we do the best we can during our 30 minutes with them during fit testing.	107
		If you were unsure of the fit -In terms of leaks in the mask, probably depends on how comfortable you are going to be and depends on what's wrong with the person. TB – [SHRUGS] – MERS – more concerned.	118
		I had one scenario where a person thought it wouldn't fit, so we traded patients	113
		I would say the PPE is not followed at that time, my background is in ER and you just react and forget about all the other stuff at that time. Normally you aren't slowly walking in and thinking check list – you are reacting. When you are walking in a patient' room you are thinking about the patient as you are walking in. Not looking at the PPE sign on the door. In the ER we don't have these signs.	94
		(beard)- No. its crossed my mind that it may not fit anymore. I'd make an adjustment if needed, but it hasn't been an issue yet. I guess I'd be concerned about the fit if I had a TB patient today. But I'd bring it up to my senior residents and see if there were any other resources available. Or if I had to shave right now I would.	112
		Personally no, if you are in the situation with someone with Ebola probably by the book if it's your "rule out" TB patient who doesn't probably have it you're more routine	106
		We do re-testing/fitting if they've had dental work, had trouble w/mask, facial changes, etc.	107
3d	Surveillance		
		We have Infection Disease come on our unit – once a shift	78
		Rounding and nurse management would pay attention to that; falls into the area of needles sticks, wearing lead in radiology	11

		….but never on night shift (9-5 Mon – Fri)	79
		We do direct observation for isolation patients in care (to observe that people are wearing masks correctly). Not just for flu – any isolation.	39
		We go around every week and we do visual looks throughout the whole unit to see if there are any safety hazards – if you are in IC area and if you have a mask on. Facilities also test the room every day for neg/pos pressure. I don't check on people every single day, though. I can't tell by looking if it's sealed on someone. I can just ask them if they feel air. Or	62
		Infectious Disease goes through and spot checks	65
		We track their compliance w/a compliance report twice a month to all managers	107
		[Anyone paying attention to compliance?] No	113
		Depends on the room. If they have CDIP (contact plus) supervisor comes and monitors you cleaning. Just started and want the curtains removed they realized cleaning the room and not taking out curtain not clean. They gown up while removing the curtains – if you went in and put clean linens on the bed the curtains still had the germs	111
		When you have contact plus a mgr. watching you – takes about an hour to clean.	108
		[What model do you use? (all look at badge)] • 3M 1860S • 3M medium • 3M large • 3M regular	112 - 115
		Think we keep each other accountable but no active surveillance. We give each other friendly reminders	116
		We do audits weekly, usually my assistant mgr. for all the units. Do a sample of 5 people regarding use of gowns masks, etc. and typically pick the isolation units to watch	98
		Personally didn't come in contact with any Ebola patients don't' think there were positive ones here during my time, in that scenario would be a little more cautious with donning the mask. Searching the resources for how to stay by the book.	106

		Just know it's the green mask that I have to wear – no don't have sticker on there [ID] think it fell off	104
		they tell you about the gloves and mask	104
		in new hire orientation the IC shows you how to properly use PPE	103
		they show you how to take it on and off, we do CBT for PPE as an initial hire	94
		they'll walk around as an internal audit to observe people wearing PPE	94
		They just do the spot checking, someone in the corner watching being sneaky. Or just reporting, colleagues reporting when someone doesn't use it	94
4	Central vs. Local UV Unit		
4a	UV unit at point of care	Still think it needs to be outside the patient's room. Think patients would need to be geographically located. Important to not expose ourselves and others.	65
		Is this an item that would be used in doctor's office or doc in the box rather than medical center?	1
		The way our hospital is setup right now – possible share these machines. They have cores where they share and in this hospital can work in my unit we share our hallways with labor and delivery – might be able to share with units on the same floor.	31
		Power users are ICU, they have airborne isolation rooms. ER - even if they don't have an airborne isolation room. Dealing with people w/respiratory symptoms, they have to put one on. If they suspect TB, Ebola. The first point of contact there would be in the ER – both children's or adult.	107
		Nurses would be the primary ones using it	113
		current practice we do have the TB or neg pressure room and have an anteroom; if you have a pandemic not every room will have an anteroom b/c that would be perfect place for anteroom. You want it to be in the 4 workflow and closest the staff for that patient	32
		If you reuses other's peoples might make more sense for logistics. We had lavage patients in Montreal (H1N1) if you force it.. major procedures – here's a mask and then decontaminate right there and then when you come back you use another mask that has been decontaminated.	30
		would need to be whatever floor we are on	24

		[where would unit go] the supply rooms	97
		Urgent care. Ambulatory area. Sure, outliers/other clinics too. I think we have 8. They're opening up or buying existing practices all the time.	107
		In theory it's good b/c it takes a minute to work so not delaying patient care, and the fact that there are 8 drawers which is roughly the size of a team. Think it would be effective on the unit	116
		don't think people would go into a locked dirty utility room with the effort to open the door [to get to the unit]	118
		Would you keep it at the nursing station?	121
		Where would you put it in the unit? Some central location. Hallways? If it could even be in a hallway. If not, I don't know what kind of rooms we have up there available for that. For our units there isn't a good central location and hallways aren't as big.	115
		Maybe front desk, because nurses will use it way more than we would	113
		How many machines would we have in the hospital here? One per floor maybe?	115
		Or in a call room	115
		In ICU, I feel like you'd need more	113
		I'd say at a bare minimum, 1 per floor where patients are. It's hard because it's a device that would be used very infrequently. MICU would need one. Most of our patients end up in MICU. But in a pandemic, they'd be all over. ICUs would each need one if not more than one.	115
		Can't have one for each room. Anteroom?	112
		[where would unit go] the anterooms	100
		One per unit. We have so long to get to a room I have a discharge on 5 and have to get my mask on 1 – a lot of time being lost between there - going to one whole area that's killing my time. You will have people who will use the distance to slide duties	108
		Also depends on way hospital is designed, it's like a football field or stadium – you would have to have 2 or three on each end. For us we would need it on every unit. Mainly on top 3 floors because we also have the ICU.	110
		all our respirator isolation rooms are close together would think you would have one for each pair	98
		Would also depend on the shortage and the availability of these machines. Sure you would have one outside each pt room. You would have	96

		it unit based I imagine. Would depend on my earlier question – are you going to use your own individual mask as you go into room or a bulk of masks at end of shift	
		would not personally leave my unit	93
		Would be in every neg. press room ante area if we could have all we wanted, then probably one more in every IC main area b/c that's where the sickest patients would go. If low resources or availability, we would have 1 in each ICU area. Even lower resources then 2 in MICU. And actually 2 in the ER as well	94
		Another place it should be is in the ER; and sometimes we don't' know until after the fact.	104
		co-located where patient is – on cart outside room and between rooms – an ease of use	64
		Where would this be located – if this is located near the room, I'm taking a contaminated mask and carrying it to the unit.	75
		anteroom is ideal spot for it	74
		Suggesting having the device on the patient area. The person that uses it would be responsible and then get their own mask back	73
		That is a decision. 600 nurses - that doesn't even count everyone else. 4-8 masks at a time centrally is not enough.	60
		I think this would fit into our work flow. Put this in a central location on each unit. Determine how many you'd need per unit. How big is it? (space concerns)	55
		Needs to be on my floor. One per floor	58
		If we're talking about running our own masks though, then our own unit.	55
		As a clinician our priority is the patient's care, it's very frustrating to run around… If we have units close to where the patients are we can quickly get them decontaminated.	71
		where do you put it, is it in patient's room, do I take my respirator out and put it in the anteroom, somewhere else	81
		If you have one mask per shift being closer to do it yourself – pop it in between patients, clean it and then pop it back on. We see multiple patients in a row throughout the day. If we had larger supply and send it centrally … if it's a pandemic for efficiency and patient care you need it close to the patient.	72
		I think it needs to be de-centralized, which means each unit would have their own. Only	84

		reason I mentioned CS was to speak to their dirty/clean flow.	
		Is this going to be centrally located? Or is it more fast food restaurant style in the ED? The question becomes whether you centralize or de-centralize. I think where there's a really high volume of patients, you want it decentralized. Figure out the core geographical region and put the process in place there. Imagine a construction area or zip lining. Toss all your material in one place, pick it up at the same place. I'd go for that model.	84
4b	UV unit in Central Sterile		
		[central sterile?] The kind of equipment they use daily - maybe it would make sense for them to do it in-house. But they don't currently do anything like this w/a disposable product and UV. Could they? Maybe. Maybe it would make sense to have CS do it since they're used to doing stuff like that every day.	80
		If you were to have a central process transport to it and turnaround	20
		If it's a free-for-all? Guess it would be a bin you throw it in, and they go to a central place. Like pulse oximeters.	
		In a real situ you would go through a lot of masks 100s per unit.. supersize machine…ideally centralized; can't imagine someone – about 45 nursing units and can't imagine training 1000s of people on use and safety. And then the capital investment to put them everywhere. So centralized would be more control	11
		Central - they could have a bag on the unit, then they bring them all back when done	55
		Like an autoclave. Put it in a container, then a trained tech takes it to central. Then the person can put the clean masks back onto the unit.	50
		This would take too long if you need one right away. Maybe you could grab a new one, throw the old one in a bag, then someone takes them all to central	52
		Unless it's a recycle process. People would have to go in and out to decontaminate several times a day, or there is a central recycle process	42
		Staff have to check on the patients every hour every day, or more if they call for stuff. That's a lot of masks that have to be processed- or one person doing their own many times	42

		If it were possible to do a mass cleaning, it'd be better in that type of environment because time is of the essence. To have to wait would be cumbersome for workflow. And depending on how many patients you have. Mass cleaning may be ideal, then.	42
		Would these be on each unit or central? Pros and cons to both. When central – better compliance. More control overseeing that it's done correctly.	47
		I'd prefer central. You'll have a standardized process that you believe will be followed. As nurses, we know if there's a way to circumvent the system, we will.	48
		Doesn't make any sense to have the clinician do it at all. It's an extra step for them. Unless we buy one for every unit, which doesn't make sense, it won't fit into their workflow. Looks like a central sterile process thing.	45
		I guess so – can't imagine them really doing that on the units.. very cluttered places to think about a non –patient care space that wasn't a closet they don't' exist too much. Imaging if you were going to do it you would have to do it house wise	11
		Ours is higher risk but smaller unit – PICU has a max capacity of small beds. Where 31 is they are next to oncology unit to have ta TB patient there not a good idea. In a pandemic we could put one in a common sharing space.	32
		I envision more of a central process. If we are in a pandemic, then those would be housed in a central area. Someone there is mass-decontaminating and re-storing them, and they circulate throughout as needed.	61
		Needs to be in a controlled, central environment with only people that know how to use it.	61
		No way everyone is going to be able to do it at the same time, especially in a rush	62
		People doing their own at each site is not going to be feasible. And it will compromise the process.	60
		Honestly don't think this process would work if we rely on the diffused population of caregivers to disinfect their mask – they don't have time to do all the other things they have to do. Think we could only de-centralize this process. If we make the expectation on the front line workers as little as possible – put these in a bin – different bin.	89

		Central where you have quality control to ensure a few people are trained to use it – as simple as it may be there could still be a breakdown of communication for how to use it properly if a lot of people are expected to use it	106
		Hope the control for the unit variability from that perspective, even in centralized model – if you do end user and make it simple and put guard rails you wouldn't have the issue. If it's centralized you are not getting your mask back you're getting someone else's. Idiot proof, you can't deviate from the prescribed specs for decontaminating. And disinfection is the simplicity of the cycle and the unit is the guard rail for people not to mess with it. If I put a lot of buttons on the front that people can play with them then that's variability. No different than guard rail in Engineering Design with breakaway gas pumps	105
		We also have 12 people going into a room at the same time, they are rounding on them then there is another team on the other end – we are an academic medical center – there would be a line at the unit. Think we would have to limit access to conserve supply, or we would have to have more of these machines	94
		[location requirement] testing sites (radiology, anywhere they would take patients on reg. basis, ultrasound, CT) testing sites are left in the dark sometimes when it comes to supply – think these would help out – could put the mask in the thing wherever she is.	104
		Depends on how user friendly the unit is – more inclined to say here is your mask and here's the unit. Would think you would get more compliance and usage out of it to let the end user run the unit rather than someone else doing it for them.	105
		[location requirement] also 5TH and 6th floor where they do procedures. We have to transport patient to procedure – to the holding area – like surgery – good to have it on the 5th and 6th floor. [Pre-op; post-op?] - yes	103
		Makes me think of scrubs. I pick up my scrubs every morning from the scrub machine. Someone else sterilizes them. But then again, I don't change scrubs every patient.	114

		Masks could be sterilized overnight in bulk. I think it'd be fine if you had enough to not rotate masks every 10 min. Maybe decontaminate a large batch every day.	113
4c	Offsite	Leveraging a 3rd party vs doing it [UV decontamination] in-house – Re-processors/vendor/3rd party may be a good option.	76
		We may be more comfortable if a 3rd party did it because they'd be held to a certain standard. They do it regularly. But if its super simple process, maybe I'd be easier for us to do it in-house. But we'd still be worried - Are we really doing it right? Is this working? But if a 3rd party is doing it, we may have more confidence in that solution.	80
		Maybe someone like Cardinal, Medline (a regional distributor with a presence that re-packages and sterilizes) could collect them in mass and get them back to us in short order.	80
		[potential barriers?] The normal concerns around space, cost of equipment, of funding and resources. But beyond that, I don't think so. Recently in GI, we couldn't get ERCP scopes cleaned through normal reprocessing, so we explored setting up something internal, but there were too may safety risks so we ended up going through a 3rd party. Looked at costs and risks of doing it here vs an outside 3rd party.	80
5	Space		
5a	UV unit near point of care would require precious space	Space demands… no place for a microwave.	67
		No, but seems large – I don't know where it would fit. Maybe it should go in an ante-room, airborne isolation room. Close to the patient.	107
		If you are taking patients to public places: 9CT, MRI, and X-ray. That's where all other patients go.	25
		This (pointing to diagram) is not the kind of space that most hospitals have extra-certainly this hospital. Then you have a place to store, once they come out, place to load them, the unit itself is not very big, holding place for them, someone has to put them through	10
		Think probably local ones within areas of the hospital rather than a central location.	8
		Could be all over the hospital	8
		One system – true clear maybe- idea was it would be used in empty room to decon. Anything in a patient room has to be trashed..	11

		Potentially we waste millions a year. Potentially we could decon unused and unopened supplies and put them back. There were a few housekeepers that were trained – thought was on top of it to use it cycling on a monthly basis; or when Infec control could use it for a room where there was a TB patient for along gimte4. Hasn't really taken off – couldn't find a place /room to decontaminate supplies.	
		[barrier] space	71
		[barrier?] Space. Size of a microwave…but still, real estate.	44
		Is it noisy? If so, can't put near a patient area. Especially Neo natal ICU. No stimulation there.	44
		Says there is a refrigerator unit. I'm assuming its size of a microwave. If it's all self-contained. So I don't think space would be an issue.	64
		I think this would fit into our work flow. Put this in a central location on each unit. Determine how many you'd need per unit. How big is it? (space concerns)	55
		I can see one on each end of a floor, east and west. Think about your soil utility room	55
		Right away I see a space issue. We don't even have microwave space. For us, it'd have to go in hallway. Guess it could go in anteroom on shelf.	43
		Space on the units could be an issue.	63
		ER would have high volume. You'd need a lot of units.	43
		Barriers to adoption? • Space is biggest	43
		Barriers to adoption? • ER - where would we even put it? Patients are in hallways until expansion is done	41
5b	Distance to get to UV decontamination unit		
		would not want to walk across the unit, think for bedside nurse you don't have a lot of time, walk across the unit, stand there for 60 seconds and then walk back	99
		depends if you have to do it between patients; how many of machines you can get – travel around this place is atrocious	24
		Just one per floor. If I have to go to another floor to do mine, forget it. My floor is very long, too.	58

		Every time you leave the unit, someone has to take care of your patient. It's not realistic to leave your unit.	57
		I'd need 2 or 3 on the unit	56
		If you are going to take it out, something may or may not fail – I would need a station nearby to wash my hands, then the next person needs to have handwashing, etc.	18
		That's where compliance becomes an issue. I can imagine this would be challenging if it was far at all	114
		Anything longer than 20 ft. away, you'll start seeing compliance drop off. And you can't put a machine within 20 ft. of every patient	113
		Probably go into an anteroom, unless you are talking about a broad problem.	118
		take you about 30 minute to walk around one unit [Floor]	108
		W/in – in setting of pandemic and trying to triage the resources and work as best as you can, doing it yourself on your unit maybe in supply room so you are not getting too far from patients room. Again, to me my clinical experience was in ICU and ER so always in eyeshot of my patients. Maybe different with general nurses who are comfortable to step away. In ICU or ER you would need to be close enough to respond to emergency needs.	106
5c	Where to store "used" masks		
		Sort of like the pulse ox.. they have to decontaminate. Probably similar that you would need a collection area for the masks	25
		Think it's very small, a minute is fast, sounds like it would take a whole person's job to be the passer of masks	11
		Maybe if you put it in a central location on the floor, like in the soil utility room	58
		We'll perform therapy, leave, won't come back for 4-6 hr. So, where would you keep it in the meantime? Would it stay in the unit? When I worked at another hospital, they told us to save it w/our name on it. The masks would just be sitting there together. I was just told to do it. Sometimes your mask would be gone.	43
		[barrier] Would dirty masks be right there waiting, exposed to everything? How long does the flu live on surfaces? Long enough.	43
		So the device stays on, and then it only takes 1 min? If we had anterooms back, it would be	43

		perfect. But sometimes all you have is the hallway. Can you hang it on a door? Is there room?	
		[barrier] After it's been cleaned, do you have to store it somewhere? More space for storage?	43
		[barrier] Would dirty masks be right there waiting, exposed to everything? How long does the flu live on surfaces? Long enough.	43
		What do you put the mask in to transport it to this unit? We need a step by step process.	34
6	Training		
		[barriers?] - learning curve	118
6a	Trained at fit testing		
		Fit testing you get a sheet for how to use it, how to know if it's fitting correctly, think there is something on line and a policy as well for when to wear them	11
		We provide documentation that they've passed/been trained. And they're given a colored sticker for their badge that reflects the mask they wear. They can only wear that one	107
		don't think there's training – just a fit test	108
		[training?] just during our fit test	116
		The training we provide is on how to use it.	107
		Then someone needs to be available to fit the mask on the patient as well. We have to make sure they're fitted before going anywhere.	25
		[How do you hear about any information you need to make sure you are protected, email, and training sessions?] - fit test	109
		[training?] just during our fit test	116
		All – not really. During the Fit test (orientation/annual testing) – they instruct you how to don it	33-38
		We did an orientation for the special PPE	90
		Well, they watch you at the annual fitting to see if you're putting it on right, but that's about it.	37
		ER and respiratory may get more intensive department training, that I'm not aware of yet. But everyone who uses FFR or could potentially use FFR receives the same training. Every frontline healthcare worker. Every single healthcare worker who has a patient healthcare	39

		role. If you have any relationship w/a patient at all. Case management even, b/c they have face to face contact. Some Volunteers at front desk don't take care of patients.	
		I don't know of any training here other than the fit test. When I was a paramedic, they would observe us doing exercise/different activities with the mask on, test our O2 sats to see I few dropped or stayed the same.	64
		We tell them why they're using it and when, during fit testing. Nothing outside of that.	107
6b	Annual refresher training		
		Like anything else - We can educate people on how to use something or document its use. But if they don't use it often, they're uncertain about how it's used. So, revisiting this information is important. Our education team does a great job, very unit based. Constantly drilling so people do stay up to date.	44
		[training do you get for respirators?] - once a year we do	109
		on line where we have modules to complete	117
		on line annual stuff tells you order to put stuff on	118
		they discuss it in our Infection control as a quick refresher	93
		Just fit testing, and we are sized every year during annual testing. We also do PPE training with a separate, annual training - Computer modules where you have the dress the cartoon patient up. Different than fit testing. There are different patient scenarios. "What kind of PPE would you use here?"	91
		think they give us more information and they display a video and tells you about masks and other protection	110
		all PPE included [online CBT]	99
		Yearly fit test requirement where they check what mask is best for your face, cover how to place the mask and know they are working. Also yearly CBT on PPE in general	106
		on line where we have modules to complete	117
		Training is consistent. There's a sheet w/every nurse's name on the unit. Let's say they're focusing on NICU. They in-service them. Everyone has to sign in. They try to reach everyone - Mon-Fri. because someone might be absent. I don't know if there's additional effort	76

		to reach remaining nurses. But they try by coming in frequently throughout the day/week.	
		Then illustrating and showing people how it's done, walking them through the process – have a video to show them. Comes down to the trust of it – comes down to education, one pager reminders everywhere, understanding of code color	86
		Think of hand hygiene – signs everywhere and when you come out of a patient room and a larger percentage of health care workers don't do that. Then this is a once or twice a year and easier to forget. The more you get it wired into the system, thinking of a process to say there is a point once or twice a year – anybody who has a mask – wellness visit or mandatory job think – you have them disinfect their mask.	87
		on line annual stuff tells you order to put stuff on	118
		[How do you hear about any information you need to make sure you are protected, email, and training sessions?] yearly we have to be compliant, like fire safety	111
		Occupational health watches them put it on and off, talk about fit check, sizing and your ID tag. Once a year they go back to be fit tested. It's part of N95 refresher.	81
		Go through a process – we have on line personal protective skill set training – taking your gown off, remove the mask one of the last things you do, then remove your gloves, remove from the straps and pull them over and away from your face then in reg. trash unless soiled by blood stain or something.	71
		IC does annual training which includes mask review and PPE training – computer based training.	107
		[Other PPE equip training and PPE] online CBT	100
6c	Training essential to prepare HCW		
		Proper education/testing to inform people how many times you run the mask through the UV	65
		But older people are afraid even if you are wearing it. Also, staff that are not in clinical areas aren't used to them. But they need to know about them too.	60
		When you do the training, it has to be training for everything we talked about because it impacts all of us.	110

		FDA, they should come out and train people – show you what a mask would look like contaminated or decontaminated	108
		From an education standpoint, if every unit has their own machine, is that something we would have in advance of a pandemic? Like, next month every hospital gets 10 units? So we're trained to use it when a pandemic does ever hit.	60
		train doctors and nurses so they come down and train us – trickle down	109
		think that we would have someone there to teach us how to do that	119
		You may get part-time people, etc. You need to be sure to capture all of them. Those that have low volume (of shifts) and are high-risk, particularly – such as PRN ED staff. Or Locum's physicians that come here 1-2 times a month at most. They're busy when they're here. So that could be difficult to educate them.	44
		[front line staff would need] Policy, training, cheat sheet w/bullet points/steps	44
		We'd need a team for this. The janitor should not be trained on how to clean a mask.	49
		This would be more of a guideline than protocol. CDC Hic-PAC (healthcare infection control) guidelines would need to be updated – tells you how to prep for patients that are infectious. Thought they'd update it when Ebola came out but they didn't b/c it was under another category. This is the resource that everyone follows.	39
		Information they'd need on how to use this? Training on the process, sure. You can't change the process without training our people. In-service training.	39
		Would require a lot of education.	94
		And putting the processes in place. We don't have time for a learning curve in a pandemic. If it's going to be successful, needs to be here in advance.	61
		Again, basing it on the Ebola thing. And Zika. There is confusion and chaos even with training. CDC changed their mind all the time. Health dept. was not in alignment. Assuming all that stays the same, I'd assume we'd need 30 days as a minimum. To make sure they're in place, that they work, we know how to maintain them, and the staff are trained	60

		It's not that we can't. You get into efficacy issues. How reliable is our use of the equipment. For it to really be the impact we hope it will be, it needs to be a part of our infrastructure in advance. We need to include it in drills.	60
		At a bare minimum, understanding how to operate the machine, where the process flow is from dirty to clean, the more comfortable we are w/that the better. Same with the people that don't wear these often. We want staff to be comfortable and recognize the machine and know how it works.	61
		We are all nurse educators, so we'd be the ones helping to educate [said by 1 person to represent the group]	33-38
		proper education in place [of decontamination process]	35
		Within Nursing, we have a specific section – typically for something this large, they may take ownership of it and commit to training for EVS, fellow faculty, respiratory therapists, etc. I think that's what I saw w/Ebola.	84
		Have to have the training regarding the monitoring of it	71
		Training, be hard for someone to monitor bedside or in station where it is kept. CBT like a lot of things we do. Or in annual fit testing there is a device there [training to monitor process]	72
		We'd need a policy. Standardized process. Education. Cheat sheet (steps) for staff. Show that it's working – surveillance/quality control from infection control – oversight from infection control. I don't know who else. That would be a decision support team meeting decision.	44
		A manual. How are staff trained to use it, how do you know if it's working. What do you do if it's not working? How do you remove it from service?	44
		If we let 100 different people doing this, there are 100 different ways to do it. That's a problem	62
		In terms of training competencies, you can once again centralize or decentralize it. But I think they may want to centralize/standardize the training.	84
		Legal standpoint ensure whomever is doing it is appropriately trained and competent on the process – typically easier to do when centralized to train a few people rather than every person who would use a mask.	96

		[Who would provide you with the training?] - ICU nurse educators	118
		makes more sense to have one person who knows the machine well, to troubleshoot if there's anything wrong with it – rather than train 100 people who don't use it often	116
7	Availability		
7a	Hospital manages FFR supply	We use Kanban system here l there are bins and each is labeled, shelf Is labeled. When empties they take the card label and drop it into the re-order bin and it gets reordered.	81
		If CDC sent out an announcement or notice that, e.g., SARS is in the area or has been, patients you can expect to come in and N95's are required, we would implement that protocol for those patients	5
		Generally speaking everyone's been notified and that results in shortages.	2
		We would also like to see analysis that it is cost effective. Part of the dilemma if we don't have enough masks available. Probably need to be able to clean the old ones.	8
		I would have them put out there for at least 5 years unless there's some compelling reason to put a date on them	8
		Don't really have equip as part of our.. – mostly supeopley based – at this point we've talked about short termed shortages and how resolve and sustain ourselves for an extended period of time.	11
		Think gotten better in general in stockpiling in the last 7-8 years not to say it would last to a certain extent. Used to have to stock in department b/c we couldn't find them on the floor	11
		Tried to come up with an agreement if unused but vendor would not allow that	8
		The university owns it…falls under supply chain and managed and inventoried by our emergency management group.. they look at expiration dates,	23
		Sometimes have no access to FFRs. Hospitals not good at distributing them.	5
		Availability and efficiency of product. Most important is availability. And that people know when, how to use them.	44
		Most ordering is automated, from supply chain…. They are on auto-order. If anything comes about, we have a central supply	55

		warehouse in Jacksonville that gets divvied up between hospitals	
		if in short supply, we ask for more from warehouses	56
		[Have you ever run out of FFRs?] All- no	55-58
		We do not store massive amounts of supplies here. We don't have the space/capacity. We bring in supplies from an off-site warehouse. Storage/retention of pandemic supplies would be a challenge, especially for one-time use products. Big limitation for us - to be able to care for patients and remain safe.	39
		In AL where I was, we had an emergency coalition that communicated w/other areas, so we always knew what supplies we had on hand. Received daily reports during pandemics. I don't know if that exists here. I know there's a patient report, but I don't know about for supplies. It's been a culture shock for me. This area seems more at risk of pandemic to me - more international folks, tourist area, more germs b/c of humidity, water.	39
		You should talk w supply chain, if you're talking about volume for the machines/respirators. We have "Just in Time" supply chain services for our hospitals. Our division HQ is in Tallahassee. I don't know enough about warehouse locations, but if you had a number of masks to be distributed, our supply chain people would be the ones involved. Loading in to trucks, delivering around FL, etc.	59
		That's hard. I don't analyze tradeoffs. But my facilities would be interested in having whatever backup or failsafe mechanism is available to prevent a shortage. So, having the decontamination unit would be paramount.	59
		We have an internal system w/HCA – each one is assigned a unique identifier separate from reference number, placed on par sheets. Each dept. has a user set. It's not centrally ordered, it's ordered at the user level. Once submitted, it goes through our system and the order is dropped at warehouse, pulled, sent here, then my team takes it to the end user.	48
		Every [unit director] can order their own [numbers]…	47
		We have warehouses in Jacksonville. Things come here every day from there. Also have an emergency mgmt. room on outside of hospital.	46

		We could probably find a larger quantity there, along w/PAPRS.	
		[Do you need to replenish regularly?] When you have someone in isolation - its supply and demand. They check out a box of FFRs. Scan them. That notifies supply folks in Jacksonville to send more on the next shipment. It's all linked.	46
		PAPRs – I could get 50 easily. When Ebola happened we bought 50 and we already had 50. Our weak point is the disposable shields that go on the PAPR – it's the shroud part that you zip around the PAPR. It's much more resilient than an N95 if it got torn or damaged we'd be in trouble.	81
		With the current supply we have, yeah. We don't stock a lot because we are Outpatient. We need to go to CS [central supply] for stuff we need. That takes time. Turnaround is not fast. Maybe it'd be different. Then I'd hope they'd rush it.	92
		We use Cardinal (supplier); concern is everybody uses Cardinal.	81
		Well, most products have an expiration date. I'm not sure what it's always driven by. We strive to have no expired products on our shelves. We replenish in our nursing areas – managing par level of 6 days (using Kanban – a just in time supply method)… Maybe 1-3 years on most products, but I don't know about FFRs.	80
		As someone takes the last of a product, they drop it in the board in the room. This triggers an order for that product to Cardinal. Then when it comes in, they shift the product in the bin, and that keeps the cycle going. We replenish that in the stat capacity during the day. But we have a pretty small inventory set-up. Cardinal fills a large % of our items, so they're sort of our warehouse.	80
		"Just in time" approach creates challenges. Most of our peers have warehouses. If there are backorders or recalls, other hospitals have supplies on site. We don't have that. We rely heavily on Cardinal and our Resourcing team to get us something quickly. So we have some dependence issues.	80
		We order from stores, but I don't know about the logistics. We just order our supply for fit testing.	107
		[Strategy if in short supply?]	113

		I think everyone would search in the local vicinity, and then ask around.	
		Cardinal distributor – could be Kimberly Clark – not sure	105
		[Think could be an issue if there is big demand due to pandemic?] - yes think so	104
		In event of pandemic could see it working, imagine some backlash and a lot of questions ask from staff as to why we don't have a good supply. If it came from perspective of not having enough masks in the US it would be accepted, if it's because of supply of medical center -- harder to accept. We are triaging our supplies.	106
		[When you say who gets it is it on the unit, which hospital gets them] all of the above	116
		[Where could things break down during a pandemic?] 2) If there is a pandemic, that would be a problem getting them to all the hospitals b/c everyone needs multiple boxes of them.	107
		Distributor in Long Island or New Rochelle	1
		Concern of supply if we have an unusual number of patients. As far as the city of Chicago there is some flex to be covered – feel like we are well prepared but don't know exactly what those quantities look like.	94
		After you brought up that issue, if there is not enough supply to get the med center you could have a catastrophe spreading it around to medical workers.	106
7b	FFR par supply		
		Managed by supply chain, par level and they are stocked based on par level.	81
		Orders are generated from the storeroom based on set par levels. When we reach a par level an order is auto generated to distributor to restock.	5
		The volume of supplies didn't run low because of patient volume, but because of PPE training. It's extensive during Ebola training. That's where our par level struggled.	84
		3 days' worth of PPE – supply chain. Have our own secret stash – keep par level of N95s respirators in our own department (5 boxes)	81
		Can you show me a picture of an N95? We do store these in our central supply area which come up to our carts order via computers, keep a	11

		par and when that depletes they replenish. They come up from supply and they count and refill.	
		The turns, data drive that conversation, if we are short on nursing units they adjust par level s-usage drives those decisions. Other large stock decisions probably by Prepare group.	11
		They're required to stock a 6 week supply for us	5
		Clinical group-head of nursing, physicians, too… get the info and funnel the info into clinical (could be many small groups) and they would supply the info through hearing about what they think, then a buyer will develop the need. ~1800 masks.	8
		Working with the nursing unit we replace 6 days a week so it's kind of an avg. storeroom open 24/7 – during a hurricane we are self sufficient	11
		if not there you have to go to clerk and ask it be ordered takes a lot of time	21
		they usually become hard to come by b/c of number of people out of the room, you have nurse for the day, nurse who helps cover, the CA helping the floor and then CA who is helping cover that area and then you have the same thing at night – [NOTE, CA = clinical assistant]. Plus you have housekeeping, and maintenance personnel, attending, nutrition, residents. Quite a lot then you fig there are 20 masks in a box –	23
		or go to the other side steal	23
		Central storeroom on campus – large supermarket size room.. basic hospital supplies (syringe, gauze band aids, masks gloves gowns) standard stock on every nursing unit. Every nursing unit has a PAR base..PAR is the expected amt. of supply, e.g. six boxes of masks – you are down two you will restock tow. You can make specialized orders. On nursing units themselves not a lot of specialty orders – the adult units. NICU different for size	11
		In a pandemic, if you run short on masks, you'll run short on other PPE too, getting contaminated. Then you've still got the dirty PPE, with a clean mask. Mask is part of the problem, but not all of it.	57
		Look at what was purchased prior year. Basic use. Same as with hand sanitizer, etc.	39
		How do they estimate need? • I don't know. I came in during the non-flu season.	45

		• Infection control nurse is great. She's new to facility but not new to the position.	
		Can fluctuate in areas if we have a real respiratory season. Also look at normal seasons for flu. During the flu time, that increases demand – that's when majority of products are used. 25% of products are spread throughout rest of year. In our area, we even see flu in summer months. I do take that into account (flu season path).	39
		I don't know. I came in during the non-flu season. {estimating need}	45
		We don't stockpile them. We keep a certain amount on each floor depending on par level (something that happens b/w supply chain and director of a dept.) of any given dept.	46
		The turns, data drive that conversation, if we are short on nursing units they adjust par level s-usage drives those decisions. Other large stock decisions prob by Prepare group.	11
		During Flu season, we work with Cardinal. At the room level we don't increase par level for the flu, but Cardinal will increase their inventory. We may just see our usage in the room spike at that time. Our inventory locations are full - we don't increase how much we keep in a supply room. We just turn faster. But, we make sure that Cardinal can support that increase in need/turn-around.	80
		But when there are backorder issues, like IV, we try to look at seasonal issues, trends, and we send Cardinal updated forecasts. So if there was an N95 issue, we'd have to identify how granular can we get about how many staff are using it, etc.	76
		We have a surge plan – typical spike process where we have a stat store location that can fill stock outs. If par levels need adjusted because of unplanned usage, we'll plan for that. We work really hard to communicate well about predicting different trends in usage.	80
		have a Kanban system - masks are on shelf with the card; we have two rows of masks, when the first row is empty we pull the "low stock" card, second row empty we pull the "out of stock" card, we put it in the card reader and the chip sends message to supply chain for new stock	98

		I'd think need is higher in flu season. If we have a lot more admissions for flu or something that requires the masks, then we'd have an uptake. For us (training purposes), it's a steady need.	107
		In general, we replenish as needed. Comes the next day after we order. Must be based on ordering patterns/needs of diff departments/units. There are probably par levels.	107
7c	Unfounded trust (in organization)		
		[ever been short on N95s] don't think N95s, no	98
		What is the shortage on masks, why wouldn't we have enough masks?	108
		COO/CFO approves requisitions. If I say we need something, they'll get it for me.	45
		We also have warehouses all across the US. So, we can get shipped what we need. We have one in Nashville. If there's a hurricane in Jacksonville, we can get supplies from Nashville.	56
		Our company is large. Jacksonville can even ship to California	55
		[concerned about the supply during a potential pandemic] We're fortunate - the company is so big, they would reach out to suppliers immediately. We are the largest healthcare org. The suppliers have good reason to keep us stocked. We have good relationship w/our suppliers.	56
		We have 3 division offices in FL. 45 hospitals in FL that are HCA facilities. Division HQ are in Tallahassee, Ft Lauderdale and Tampa. I believe we have supply chain HQ in those locations but I'm not that familiar w/the network of the JIT delivery schedule. But that's for everything from drugs, supplies, etc.	59
		Our company has a significant infrastructure for emergency mgmt./coordination. We've done well with hurricanes, armed intruders, electrical system failures, etc. We've got a nationally coordinated effort for these matters. I'm certain in the case of a pandemic, we've got phone calls already in place to provide all equipment suppliers that would be necessary, rushed to the appropriate location	59
		We don't have much to do w/the supply of them. HCA says this is what you'll have.	62
		We have a great amount of trust in HCA. But we found with Ebola, it didn't work.	60

7d	Demand for FFR from outside facility		
		My bigger question is - if you have the Panama City population (50k) at our hospital – they would be the primary managers of the FFRs and their cleaning? So are you wanting to hand these masks out to the community? Will these units be located around town? Only the hospital? Is the hospital in charge of them?	59
		We also had a Scabies outbreak. Donned almost $10k of gowns and gloves a day. But we didn't have an issue getting those, b/c no one else in HCA had the outbreak. We went through them like water. The whole hospital was on contact precaution. Had 70-80 people in-house w/scabies. But that was just us affected here. It was in the community but the others are not HCA supplied.	62
		As with many products in a warehouse, if there's a sudden drain in the need, we won't have enough. Or we'll need to purchase locally. Or reach out to a sister facility.	44
		We don't personally, assume supply chain does, good relationship with suppliers and our neighbors, we've drilled this – lending and sharing for pretend events. We are on an island which makes us unique. We have to be fairly self-contained for a while. Then some of our neighbors we realize we are interdependent. We are prepared to handle if we have to	11
		But we did have an issue w/the health dept. b/c they were calling us for supplies	60
7e	Staging PPE at point of care	sometimes in the PPE cabinet in anterooms and the alcoves (cabinets) outside patient room	82
		a lot of times in anteroom, probably differs on unit	94
		We have containment rooms where the anteroom is positive and patient room is negative. Backup is in the supply room. We have PAPRs here – everyone has one. We have two carts (highly infectious disease carts) – 6 ft. tall cabinets.	81
		All my units have 95s stocked – the units don't choose their own and all standardized through the main department; 95s are pretty standard so there are not options unless there's an allergy.in the OR – we have patients with TB so there concerning. With endoscopy we use them b/c our rooms are low pressure – they are outside every procedure room. There are some	21

		identifiers standardized outside rooms to use the 95s to let the clinical team know…for an OR case usually 5-7 people per room who often relieve each other…an OR case can be 14-15.	
		generally in the anteroom or on a cart in the front of room we call them isolation carts	31
		Lab doesn't order them. If nurses need one, they get it off the patient door. So, nursing really is establishing those par levels. The ancillary depts. use the ones in nursing depts.	46
		Kits are set up on the wall along w/eye protection, body protection, and these. Multiple kits within the dept. I don't how the location of each was decided. But they are in each one of the procedure rooms, and in the recovery area there is a central location. Near the entrance/exit of the dept.	64
		In some cases I guess – think there should be some kind of way for them to be more readily available – a lot of the times the nurses are not right there so we have to go look for them to find out where they are. Other than that it's okay.	104
		Normally right outside the patient's room, if they say the patient is airborne or droplet then we have to use them. It's normally in a cabinet that has the gloves and gowns; otherwise it's in a drawer. It's right by patient room, the other ones nurses have to get for us	104
		Usually they just have the mask on the cart and say you need to wear. If you are on 8 or 9 south you only have 4 rooms with an anteroom	93
		shelf in supply room in boxes	99
		Most of the time we have to ask the nurse so they go into the supply room area and will bring the box out if we need a diff kind of mask. Otherwise it's the yellow mask that's right there… go in patient room, could be in bed or on a cart or wheelchair	104
		Fit is also an issue. I have a standard fit, so grabbing one hasn't been an issue for me. But if someone doesn't, I can imagine some difficulty grabbing one.	114
		Even if you failed fit tests and you need a PAPR, they're very difficult to get a hold of. Could take hours.	113
		We only have so many neg pressure rooms. We have carts either outside room or inside the anteroom	94

		No. Everyone said they know where the N95s are and I don't; the PAPRs tried on but don't know where that is	117
		In the past heard that PPE carts aren't placed obviously outside rooms, some nursing units are better than others as to where they store PPE.	94
		[vulnerabilities] patient emergencies – cardiac arrest – 20 people going into the room at one time and notice that PPE is less abundant	94
		Only exposure we really have is don/doffing. N95s are kept outside of patient rooms, especially ones that have a need for N95. …Provide both small and normal masks outside of patient rooms.	115
		older building [newer facility] has isolation carts that sit outside the room, here there are anterooms or isolation stations with drawers and cabinets	103
		this hospital has been good at keeping them stocked	118
		be beside the room and sometimes and you have to go to another room and then go back to claim it – you don't have your correct mask available; you can go to the supply room	109
		Biggest issue – Code situations where you have 10s of people in one room at the same time and a patient who requires a mask. There are maybe 1-2 boxes at patient bedside. But during an emergency, the boxes are exhausted.	115
		[process could be improved?] sometimes they don't have all the stuff there, depends on the signs outside the patient room	109
		located outside a room in a cabinet, sometimes in a box setting out, Mitchell different than CCD there are shelves there	108
		talking about masks, sometimes they're in a cabinet most of the time we go to supply room to get them	109
7f	Local FFR buffer supply	*How did FFRS fit into that; pulse of going to par to some other stage?* That lives in a separate category. There is an inventory that doesn't get touched in the unit stock – an emergency supply. Separate from where we live there are emergency supplies, bottled water, fans, blanket – we also have our power plants – during Sandy we were the only who had light. Not on the grid.	11
		[Anything to do with the stockpile of buffer stocks]	105

		Not particularly, if things aren't stocked might get a complaint and have to go to supply chain	
		Do think our hospital is better prepared than the avg. because we do stockpile. Would be concerned for long-term access – longer than our supply would last.	94
		Difficult to find N95s sometimes. Small supply, we may run out. Usually have to ask nursing staff or someone who knows where they're stored on the unit somewhere. They may have to call someone to bring some up if there aren't any on the unit.	113
		I don't know how big the supply is in the warehouse.	39
		I've heard that there is in the basement of this building. Technol brand masks. I think they stocked it a while ago for purposes of a pandemic. Our supply chain has changed in the past few years, so maybe there is no such room. We just get fast shipping here. So, I don't know if those are still down there. But we don't use those now, anyway.	107
		During the Ebola scare/prep – I don't remember mask supply being an issue. Although, people were clamoring to build up a reserve supply. That may be when Granger got involved. So if Cardinal quickly runs out and everyone needs supplies, I think that's when we looked to Granger for PPE supply. I don't remember N95s being a particular concern, but in general we were in a scramble to get adequate stock, and were challenged with how to balance that need with other centers in the region that we have to share supplies with if there's a spike in need.	80
		Yes, in all the units. Our supply rooms hold 6 days of supply, this is normal capacity. We also have the masks in reserve, but I don't know how many. We replace the stockpile when it expires. Constant replenishing cycle w/the 6 day supply. We don't buy them from 3M – we go through Cardinal Health for med surge distribution. Cardinal stocks them. We put in specific orders for each area of the hospital. As they need masks, they get ordered/delivered from Cardinal.	80
		We don't want to have to do the PPE for that many people. Think that's what would tax our system. We have JIT order on hand, minimum of 3 day stock, if it's a national issue we'll buy pallets. We would need to be first in the area to	81

		do that or other hospital of similar size will do the same things	
		We have 72 hr. worth of buffer stock here, in our supply chain, of critical items. Including n95s.	55
		Also, as you're leveling out, it's continuing to spread in the community. Your patient influx will stay the same or increase. So, it's overwhelming your system. Other hospitals are also using our resources from that storage unit/suppliers, so it's not just us affected. I think [location] would use it, I don't know who else (1-2 at least) – I'm too new. And for things they don't store there, we need 3rd party management system company to supply. We don't have a stockpile.	39
		Maybe you have an extra stock of masks that you pull from if there is Code.	61
		Based on experience, we keep a certain safety stock here. It's simply a guess of what we'd need if some sort of emergency came up, or if we had an influx, until we could get more from the warehouse or manufacturer. I usually go with 4-day stock as an estimate – worst case scenario. But that's just me.	48
		(At my previous job) I'm used to having pandemic supplies on site – for H1N1, Ebola, natural disasters. Makes me nervous that here we don't.	39
		We have 500-600 masks in house at any given time	56
7g	Hoarding FFRs		
		worried about like any perceived shortage would cause hoarding – within the institution and nationwide	79
		Employees always find workarounds for everything. They'll hoard respirators. They hoard equipment if they find out things won't be supplied anymore or they won't have enough. Or let's say they like a particular needle. They'll hoard those kits if supply chain changes to a different brand. They maybe even hoard antibiotics.	107
		Problem is if people hear "pandemic" they start stealing. With H1NI people became alarmed and as they pass the stock that is on the floor they just grab them – lost tons as they were walking out with employees. That's why we distributed them through the managers. Happens a lot if there is any kind of outbreak in the community.	81

		even if hospital told you to change think most people would leave the mask on and be encourages that they would clean it at the end of that round	21
		Don't think anyone would use another's mask – maybe if they were forced if there was nothing else in the building thing people would hoard their mask rather than reuse it.	21
		even if hospital told you to change think most people would leave the mask on and be encourages that they would clean it at the end of that round	21
		If we had an epidemic, probably not enough in stores. Seeing people work 7 out of 14 days; you can hand it to every patient, nursing assistant, nurse, cleaning staff… don't think anyone thinks about the stored stock. Then, you get the problem of people hoarding ones for later.	18
		I find supplies stuck in a lot of projects too that have been hoarded.	S6
		We're not the only hospital and people start to hoard	1
		Do think storage is very real; can't tell you as many things that come up…concerned there is a shortage from these masks	18
		Will break down [if] the masks are used faster than …	30
		Also, hoarding masks - I think a lot of people would. We've been in situations with low supplies and people did hoard (Ex: caps for IVs). It would be a really serious issue especially for our [outpatient] patients, because their immune systems are so bad.	91
8	Using decontamination process		
8a	Confirmation needed to trust UV decontamination		
		[evidence?] could you do parts per million for how many killed – so how do they do it for other medical equipment	93
		No. I anticipate more employee acceptance barriers. I think they won't trust that it will protect them, and they'd want similar evidence to what I mentioned. I think you're better off getting PAPRs for everyone, compared to this. Yes, PAPRs cost more, like $500, but the protection is much better. N95s are probable $1 each. Much cheaper, but if staff aren't using it properly, they're not being protected anyway.	107

		Think it would take a lot of convincing on the part of the FDA that it is safe to reuse the masks	5
		Data on the amount of influenza exposure on mask before and after decontamination	27
		Biological stuff; data on cultures after it's been depleted, really pull from anywhere; use AAP for pedes, Association of women's health and children (A1) for standards (women's and children's). We would look at the guidelines they have. Great to publish in a lot of diff places	31
		Two step thing: peer review that science is well founded; second is the expert of facilities, 3 is an in service – description of hand washing demo.	18
		The folks responsible for the process are the contact experts; I would go to them to show me the evidence. I have a lot of confidence this org. is patient safety, think the breakdown is more related to individual clinician practice. I have a lot of confidence if the institution decides a process is in the best interest of patients and clinicians I would follow that	65
		Think it would take a lot of convincing on the part of the FDA that it is safe to reuse the masks	5
		Peer reviewed, independent studies-not manufacturer studies	5
		After the mask has been decontaminated-does it go into a sleeve that says I've protected it?	4
		Standardize the process. Infection control would never allow it to happen.	7
		If we are to reprocess those masks we need to keep absolute confidence in that	7
		Need to sell that early in the game and that anyone can use it regardless of who's it was before	7
		[UV is] A great idea depending on value analysis. Does it have good value for us to use and spend? How much would it cost for the units?	8
		Data on the amount of influenza exposure on mask before and after decontamination	27
		Data from scientific research. Well-designed study. Good journal	30
		Peer reviewed	29
		If Infectious Disease has done the research and endorsing it and saying what I'm supposed to do – I'd do it	70
		I know UV would be killing the virus, but what decontaminates the machine? What makes the machine still 100% functional over time so it	64

		can continue to be effective over time? And how do you know its working? How do I know it's ready for use?	
		[research?] A Business plan. Determined effectiveness of product.	44
		I'd hope there's enough research out there to identify that it's a safe procedure. Would like it to come from fed govt. CDC. (All agree). And answer questions such as: How many times can I decontaminate a mask? We'd have many questions.	55-58
		We'd look to our clinical nurse specialists to do the evidence based research	44
		When Joint Commission rules something out, it's because something isn't evidence based. So if it came from JC, we wouldn't need anything else	44
		Knowing that the FDA has approved the product. I have faith in the FDA process. Having proper procedures in place.	64
		With UV, you need to do an initial disinfection, and then UV is a second layer. Also, has to be a product that can be cleaned w/ a liquid agent first. You can't just throw UV at it. You can't get the mask damp, it will decrease its effectiveness.	39
		What are the kill claims for different influenza strains? It's one thing to talk about one strain. About what about SARS, MERS, new fungal infection? UV light is not approved for those. Most hospital disinfectants are not approved. We just use Clorox - That's how bad it is.	39
		High risk suites, for surfaces, sure. But, specific to respiratory? I'd need more than a white paper to prove it works. Peer reviewed pubs, yes.	39
		1 min exposure sounds great. Is that really true? I'd need to see peer reviewed pubs.	39
		Potential barriers among frontline workers? No, as long as I can convince them it's safe. Our ER folks and respiratory are the ones who are focused on anything they could inhale and make them sick. Like RSV, which is worse for kids, so our folks don't want to bring that home?	39
		I always say that nature's Clorox is the sun. I'd feel safe sitting on a park bench on a hot sunny day, next to someone with TB, without a mask on. Because it would kill it before it got to me. I've bought into nature's Clorox. But that's killing what's in the air. It's these unknown things that cause droplets and remain moist. It	39

		can't get through that barrier. That's why you have to decontaminate the whole room – you leave blood somewhere, and you just UV the surface, you're not getting below that layer. Back to the surface cleaning issue mentioned before.	
		FDA. Research behind it. Case studies. I get Respiratory journals and I look through those.	41
		Papers. Clinical trials. FDA. I'd want to know if UV will take care of all pathogens. Because you're claiming it's safe, but safe for one thing. If I'm re-wearing, I want to know it's safe for whatever I'm going into. A lot of our patients have comorbidities. But you don't know until after the tests are run. We also read Chest journal. People bring new papers/studies w/them when they bring a new equipment. We'd want it to be unbiased. FDA is always good.	42
		ARC puts out white papers (American Association of Resp Care), and Respiratory journal.	43
		Data - Here is extensive testing. We did XYZ w/these pathogens. After going through the UV machine, the tests came back negative	45
		[users would have to hear] Subjective – testimonials – [Hypothetical]"I've worn one post-processing and it didn't seem any different than coming out of packaging	45
		CDC endorsement would be fantastic.	45
		Publication in MMWR (morbidity mortality weekly review) – a CDC pub – would be great	45
		Need to understand; proven to be effective and clean; potentially putting themselves at risk – see the data and formal process understanding/ FDA consensus is clear this is affective to kill and decontaminate.	11
		Data from scientific research. Well-designed study. Good journal	30
		Peer reviewed	29
		multiple studies	21
		I'd go to the CDC website	65
		We have access to research articles and read about the proof, on line publications – the University of Chicago has relationships with medical journals.	66
		Good ideas like anything else like a ventilator and the FDA approves it we are trusting that – couldn't ask for more than that. As long as they verify the effectiveness of it I'd be trustworthy.	72

		manufacturer of it, maybe more than one third part – FDA or some other group evaluates it – like to see our national boards back it – observed testing or done our own and feel this is reputable and works. American Assoc. Respiratory Care	71
		We have a department for Infectious Disease; I have to trust what they are giving me I do for other stuff. They give us all the parameters – I provide care and they are making me safe.	74
		[assurance needed?] The state health department or the FDA – because in this one we are being told to reprocess something that is a single use item.	81
		I'd look to Infection Control for approval – ask them what information they need in terms of study data or manufacturer data.	80
		Needs CDC endorsement/approval, even from a med legal perspective, how do we know this works, etc. Maybe other societies would be relevant - Like AMA. Not that they have to approve it. But some content experts from a higher level need to have been pulled into the discussion. But if CDC says it's ok, I'd say ok.	84
		What is the data behind it and how would I know it worked?	102
		Journals (CCM) don't know if this would show up there. New England Journal	99
		think I'd want to know the micro count	93
		[Evidence] CDC	113
		[Evidence] CDC	112
		[Evidence] Pub med search for reputable journals. New England journal. JAMA.	115
		You would have to prove it is standard of care, sufficiently tested, enough data out there that it's safe, backing of CDC, IC, ID that we would feel comfortable allowing this type of reuse. Now that's in standard course of things, if it's an emergency pandemic you would revisit this on a daily basis	96
		Good studies. NOT by the manufacturer, who could be biased. From objective, gov't-run groups – like NIOSH. Peer-reviewed pubs. Maybe from New England Journal.	107
		Scientific journals, peer reviewed medical publications	96

		And our infection control, that sampling would be nice.	94
		Hopefully the FDA. We are in pharmaceuticals we trust what they approve.	94
		infection control would have to approve – our Infection Control guru is very thorough	98
8b	Expected UV decontamination procedures		
		But still the issue of, when do you decontaminate it? On a break? Lunch? Shift end? You couldn't take a new clean patient with a dirty mask.	55
		How many times can it be re-sterilized, and tracking that	1
		[concern for shortage] yes that you would have to put yourself at risk to protect the patient	99
		Another consideration is how many times it's been cleaned and can't be cleaned again. Bar coding.	8
		Think it's very small, a minute is fast, sounds like it would take a whole person's job to be the passer of masks; training would be needed if these were put everywhere. Does it belong in a patient area of somewhere more centralized…everything contained in OR…	11
		If you have the same pathogen, multiple patients, I'll wear the same one through all patients	57
		At the beginning of the day you would run a challenge – there are costs associated with that – wouldn't handle it any different or more than what we do and what FDA prescribes and there are standards for monitoring sterilization. Doesn't have the same level of risk as a sterile instrument would have.	105
		Some type of challenge test, you could have a bio challenge device that goes in every load, or run it every morning, we run a biological to make sure it's passing and an effective kill. If you can ensure it had an effective kill or disinfection.	105
		continual testing would be important	94
		Those who have gotten the flu could take care of patients without having to use the N95.	10
		What about outfitting all of the patients with N95s? Not a bad idea. But volume is the issue	42
		A lot of the patients are not only on respiratory restriction, you doff, you touch your mask, then touch the unit….you would have to have a very	65

		clear process. It would have to go through infection control to define all of that.	
		We'd need a policy. Standardized process. Education. Cheat sheet (steps) for staff. Show that its working – surveillance/quality control from infection control – oversight from infection control. I don't know who else.	44
		There needs to be checklists, just like surgery checklists, to reduce errors.	50
		A manual. How are staff trained to use it, how do you know if it's working. What do you do if it's not working? How do you remove it from service?	44
		You mentioned canister masks – in the military we used bleach and alcohol to sterilize. Could that be an approach for caregivers?	50
		Decontamination protocol specific to that machine/product	45
		are we talking about pandemic, if pat A needs to be decontaminated and then go to pat B – I can't' leave pat care area and go to machine sit for a minute – re-don it and finish with pat B, finish charting – leave pat B area and re-decontaminate – never in a safe way.	23
		Maybe one solution is you give each Dr./nurse 10 FFRs. And they have a name/barcode on it. Then once they've gone through UV, someone can just put them back into a slot. That way you have more available for the day	52
		Wouldn't be possible to keep up w/everyone's mask unless they have names on them	43
		You take it off and put in in a Ziploc bag, throw it in decont. bin that goes to where this is kept, one person puts them through and then restocks them somewhere w/in the org. it would be hard to send it back up to you specifically if we are sending down 10 an hour.	72
		If the device is in the anteroom and each user does their own, they are pretty sure the inside is decontaminated. If you take the user is throwing them into the bag and masks get layered "cupped" together do they get decontaminated on both sides – top to bottom – straps are decontaminated at central location.	71
		bagged scenario where we send them all down – does the device clean both sides of the mask when you put them through	72
		What kind of container are you putting it in – not only the front half of the mask are decontaminated but is it inside?	71

		You are in the patient's room, you would have to place it into something that will not contaminate as you walk through the halls.	72
		you would have to have at least 1 per floor, the transport from pt room to space an issue, who maintains it, are there safety feature (regulations to put a device in a closet) don't know from a safety perspective there are different things to determine.	72
		I want mine back – I put mine in a slot and I want mine back out of that slot	81
		So if I've been taking care of one patient, and you have a flu pandemic, doesn't that also require a gown and gloves? So you've got someone standing here w/normal scrubs…if you take it off w/ your gloves and put it in the toaster, then do you have to put those gloves back on to take it out?	84
		If we go into emergency mode we have a practitioner that stands outside door of patient and monitors the PPE – based on organism (btw we've had plague, Ebola, small pox virus here), we have a whole plan if we had a pandemic. It wouldn't be pretty.	81
		I do want to mention – I'm picturing this workflow. If you realize you don't meet the criteria to recycle the mask, then you need to dispose of it correctly at this point. So the way this room is set up - the door, the disposal areas. Dirty has to stay in dirty side, clean in clean. The whole Central Sterile (CS) is set up that way…. The OR has a very special elevator that takes dirty stuff, it lands on the dirty side, gets pre-cleaned….you put it in one door, pull it out the other. Very specific. I imagine this would need to be similar.	84
		[information needed?] Really good implementation plan for what it is and why we are doing it.	81
		Is this something we would see in central sterile? Same concept as SC - they come out clean? Then how do you package and store those for re-use?	61
		usually doff all equipment in anteroom and you don't want to expose other areas	102
		is there quality control on the machine itself	121
		Maybe someone would take it out after 30 seconds.	107
		Yes, IC would own that. Maybe Safety. You'd have to ensure people know how to get it to	107

		properly work. With flash sterilization, there's a certain protocol for sterilizing instruments. There's a specific order/process to it. I'd think the same thing would apply here. Putting it in properly, and whatever else is required to make it work.	
		I don't know how it would work in a real fast-pace unit like ER. There are a lot of patients coming in. So, you're waiting for the mask, but patients are lining up for you to evaluate them. So if you have to decontaminate in between patients, even 1 min is a long time. But I'm just speculating. ICU might be different since they're in there all the time - so maybe the need to replace masks isn't the same as ER, where you're seeing new patients all the time.	107
		Would maybe cause you to cluster the amt. of time with a patient so you might visit the patient a lot less.	121
		Our current system wouldn't work. You'd need to create a new system around this.	113
		But you don't think people will want their own [mask]?	114
		- If you're seeing multiple patients, you go in and out of rooms quickly. If you have to do this in between each one - you can't do that. Or maybe there could be a continual rotation of masks. Maybe you don't keep yours, but it's a collective of masks	113
		So I have one mask I use for the whole day – and every time I go in and out of a patient room I use this machine?	114
		If I use the mask I would put in there and be ready for the next person to use?	108
		don't know who would decontaminate it – if it was going to be my mask for the day I could see one person doing it	99
		what is the thought process for getting from a room to the unit – right now we do wash out and wash in and if I'm carrying my dirty mask so will keep my gloves on	102
		right now we are told to not take PPE outside of the anterooms – wonder if we are supposed to take them out into the common area	94
		and the testing of other bugs, or you just make it so you do not use this when a co-infection	93
		think these would be useful especially trying to preserve the masks, for instance if she is taking a patient to PT then while they are in there, she	104

		could take her mask off and "let it cook" and use it on the ride back	
		Would you change it once a day?	93
8c	Decontamination frequency	[PT] for us we are not in the patient's room multiple times a day, we can leave and decontaminate our mask and keep it and use it again when we come back. Not like a nurse who is in and out on a 12 hr. shift.	70
		or is it a daily mask – am I going to remember this is the 7th time I've used it	67
		Especially with large teams, a lot of patients. You'll prolong rounds a lot.	113
		Keeping track of how many times.	68
		[barrier] thinking of a stable patient, what if they are unstable you are in the room constantly and have 10-15-20 people coming in and out of there. No time to run them in there	100
		You are going to have pulmonologist, pharmacist, nurse, nephrologist– a big quantity – think the capital expense would be big. Thinking worst case scenario – high volume	94
8d	Need visual indication FFR has been decontaminated		
		Maybe you could pre-seal it, If the UV can go through that? Like the autoclave. Then you could close it first, and when it comes out its already sealed. Then no matter what it touches, the inside is clean.	113
		We have equipment where they use autoclaving – they put a strip that is sensitive to that pressure that changes the color…. Maybe there's a box of these strips next to the device and you take your mask, and a strip pull it out and the strip changes color then I know my mask was decontaminated.	71
		If it came out in an individualized wrapper. If It came out bare, I wouldn't	113
		I would want the masks that are going to be de-contaminated with UV to be labeled "for re-use." Currently, most of them are labeled "for one-time use." And, I don't trust the ones that say "for re-use" – people just throw them in plastic bags, and I will not do that.	39
		If you have a person there at a machine making sure of all steps are carried out. Maybe a marker after you sterilize your mask.	50
		Think some benefit of relieving the viral load on it. Do you have a quality indicator that shows it works? We have an Endo Cav Probe and it has a	81

		pellet it on it and then you put it in the machine and it shows if it's been decontaminated.	
		This almost sounds too simple. We're used to sterilizing and reprocessing but there is usually more to it than this. You have indicators to make sure this meets the parameters for decontamination. There is paperwork.	47
		Anytime you're sterilizing /reprocessing, there has to be a record of each time it cycled. That cycle is recorded w/ biomarkers so that the process maintains its integrity. Also, evidence that it worked.	48
		How do I know it's safe? Is there an indicator that tells it's been decontaminated—from red to green…okay, now it's ready to use	5
		When just like when we sterilize scopes – is there a thing there that lets us know that mask is ready vs. just a dirty bin and clean bin? Stamped? Sealed? Packaged? We need to be confident this is a clean mask, and there is an indicator of that	61
		Would masks coming out get marked as having been appropriately decontaminated?	59
		Problem is visually don't know if it's decontaminated unless is physically clean. There's an outbreak and could have been exposed to the virus, then you need to decontaminate – once you do it kind of for myself – there is nothing that tells me the mask has been cleaned – is as clean as anything sitting in my desk. It won't say a year or two years later whether I disinfected this or not	86
		if I was designing something like this, when you wore a mask there is a certain dot or color and once disinfected it will change in color –	87
		or even using sterilized packaging… not people dependent… indicator dependent	86
		It's really about having those indicators that I know that's its clean, there is a process that's wired in to what we are doing and it's not people dependent -that would be the biggest things.	86
		After the mask has been decontaminated-does it go into a sleeve that says I've protected it?	4
		Make sure when we say it is clean that it actually is clean. That kind of assurance that user has a used mask and is not afraid to use it.	8
		…need an indicator at the other end-like what we do for BT for processing in central sterile	10

		There will need to be some kind of indicator at the end of the cycle that it is safe to handle and reuse.	10
		Like with high level disinfectant process, w/different color bins	60
		[users would have to hear] Subjective – testimonials – [Hypothetical]"I've worn one post-processing and it didn't seem any different than coming out of packaging"	45
		Someone mentioned you put it through a machine and it changes color-has a red look to it and after decontamination it turns green, or a bar tag that indicates when cleaned	8
8e	Doubt UV decon process compliance		
		When we go in isolation room and you need to put your PPE on then you see a nurse w/out theirs on. Even doctors sometimes and they don't have a gown or gloves on; .don't know if they are different than us…but they come out and get everyone infected. They need to do the same; everyone needs to do the same.	108
		QI (infection control doing surveillance – is it killing the virus, is it effective) in place to determine its working	44
		[See any issues with how often you might need to decontaminate – between patients for example would that be a barrier?] It would be annoying but if you had to do it you have to do it.	121
		if you come to see your loved one – and they just go in there and they [nurses] need to tell them you can't go in there like that	111
		My father had MRSA and had his toe amputated and we're touching his toe…we're touching his toe, we questioned not having signs – they are gowned up and we aren't.. What the… That would be the major problem – everyone must comply	108
8f	Keeping track of own FFR		
		How would I know that it's my mask?	110
		Think it should be changed for each room you go to.	110
		do it myself so you know it's your own mask	106
		What happens to my mask – is it mine again? Does it have a label? Is it being stored somewhere waiting for me?	112
		I like the idea of re-using masks for the sake of supply.	112

		Would we store it [mask] and put the patient room number there – or clean-and-go for each patient we are seeing?	66
		way to label your mask at start of shift and then use your mask for your shift	75
		b/c M fits most, we could just give patients M	43
		Don't want the thought process of who used this before me. Rather clean it myself and use it and use it and use it…. If the situation was that I needed a mask and couldn't get my own and there was a coworker I trust – I might take their and sterilize it and then use it.	71
		I re-wear masks anyway – think the trick is to make it intuitive – every nurse has a spot for their own mask – also think there's like – interested in ways – low tech engineering ways – this is your mask hanger the clean side goes this way the decon this way. Procedure and training.	79
9	UV decontamination unit		
9a	UV unit maintenance	Multiple clinicians needing to use it at the same time, failure of the device (bulb or coil) – what's the downtime for the procedure. How long take to fix it.	72
		Cost analysis, and they last this long. Pay for maintenance, calibration. Does someone have to check the machine to make sure it's working right and who checks it and what is the cost of that?	8
		Always, there could be a power surge, not doing the job it's supposed to be doing; is it operating right. We would assume like any other machine on our floor …pretty well aware what's not operating. Would expect cheat sheet to troubleshoot. We have numbers to call and people to pull in	31
		Worried the machine will stop working. How do you have time to trouble shoot that?	27
		Anytime we have equipment in use, we need to have maintenance in place (biomed) – would it come from facility or manufacturer?	44
		What do we do when one goes down - Backup? Rentals?	44
		I think what needs to be tested most are these trays in the machine.	
		They'll be used all day. Will they break/wear down easily? Must be durable. Some people will be gentle, some won't	53
		There's a HEPA filter built into this unit? How often does that need to be changed?	56

		How do we maintain the machine? It's a push button, but there would be temp logs, etc.	60
		It would mirror a central sterile standard, like something we do in autoclave	61
		Mechanical issues if it breaks down, too.	60
		it wouldn't allow you to decontaminate the [HEPA] filter if it's currently being used	88
		if you have to take one off line for repair then you have to purchase a backup; what's that maintenance process look like	86
		[Let's say you have someone on the unit, on the ICU and they are in charge of making sure it's operating each day, warm it up for 10 minutes, would it make sense to run that bio challenge in the morning?] I would think so; you have to think that it could break down. You have 4 – 8 ports and how do they run at the same time.	105
		What kind of maintenance does the machine require?	121
		Maintenance surrounding it, how often does the HEPA filter need to be changed out, how often preventative maintenance, issues the unit hasn't presented yet – it could be deteriorating.	105
9b	UV unit operating cost	We are a union hospital. Would see our nursing union saying, "What do you mean you won't get us a new one?". Do everything you can to get a new one and then we'll consider, or you are trying to be cheap?	81
		Financial cost of replacing parts	44
9c	UV unit staffing needs	and who is going to decontaminate all of these, where is this going to be	78
		Maintenance of the device according to instructions. Biomed maybe.	44
		Identifying who would be the person doing this (maybe more than one person). What that would look like. Having a policy in place for the procedure.	44
		What kind of quality control would be run on this? Who does that fall on? Director of the unit it's on? Central sterile? How often would control checks be run?	58
		Anytime we have equipment in use, we need to have maintenance in place (biomed) – would it come from facility or manufacturer?	44
		The machines will eventually break, and you'll need a technician who is trained	50

		Someone there is mass-decontaminating and re-storing them, and they circulate throughout as needed.	61
		We had a patient last year that was quarantined and they watched how the clinician did every step and would assume that would happen for the pandemic.	65
		Are we assuming the user would do it themselves? We have central processing personnel would be involved with this	73
		Someone will have to do that work [maintenance], contract that work and watch out for it.	105
		Could be someone's job in the room with the machine - that all precautions are taken by family members, anyone coming in and out of that room, etc. Their whole job is to maintain the masks, machine, etc. But that's a lot of resources to have that person.	112
		Like I mentioned earlier, find out who would be responsible: centralized or unit-based. Who are the individuals who would be doing that?	106
		Allocation of resources – would it be the charge nurse, individual users, things could be different if faced with pandemic – people could be more receptive in going above and beyond – if not faced by the crisis may have trouble getting nurses in general to buy into it.	106
		Think – its labor so have to figure out the right labor model, workflow and pathway to get united as to where they need to go. [central vs. local]	105
9d	UV unit design		
		think if it takes too much time they'll take a new mask	69
		it would have to be idiot proof – very simple to operate – very clear cut as far as – pretty much – idiot proof	74
		Will the drawer lock for the 60 sec., or can you override? I can see people cutting corners, reaching in to grab their mask	52
		One minute sitting and waiting – depending on how many of these units you have on the floor – all 4 drawers are filled, now you have a back-up. Dr X. takes 8 min to document. He left his mask in the tray. Now there is a backup and you are waiting for him. (hypothetical situation)	50
		Could there be a bigger machine than this? One for every floor? How many per hospital?	53

		Each drawer has to be in the machine at the same time to run? If you have a lot of people on a floor for one machine, maybe each little team has their own drawer. If the drawers have to run at the same time, that is a barrier. If you have 10 masks for yourself – maybe you use #2 of 10. Put dirty #1 in. Have 8 more left. Have them all in central location, but have drawers numbered.	50
		We have to run it after every patient, or every so often?	55
		Run it only at the end of my shift?	57
		If you look at surgical technique that's been around for 50 yrs., there are still mistakes. This process is new. Not tested. Unless we do drills with it. We don't know how it will work in real time, though, even with drills. Especially when there is a pandemic. I'd try to reduce the number of steps. With every extra step, there is a potential for mistake.	49
		Maybe if you have a team only focused on this whole sterilization process. That may reduce error. Medical staff, someone trained on the machine.	54
		If you have a person there at a machine making sure of all steps are carried out. Maybe a marker after you sterilize your mask.	50
		Make everything modular, in case one part breaks down. So that one part breaking doesn't ruin the whole machine/process.	49
		If we're talking about running our own masks though, then our own unit. If it's a free-for-all? Guess it would be a bin you throw it in, and they go to a central place. Like pulse oximeters.	55
		But still the issue of, when do you decontaminate it? On a break? Lunch? Shift end? You couldn't take a new clean patient with a dirty mask.	55
		Refrigeration? Seems like that could involve moisture.	62
		So it zaps the germ like a bug zapper? Does it need to be at a certain temperature? No liquid involved, right? If they have moisture they become ineffective and need to be thrown away.	62
		Does this mean it cleans 4-8 masks at a time? I would think conceptually that we'd want something bigger, to clean a bigger quantity	61
		I think there could be a bottleneck to the machine. You've got 20 nurses, can only do 4 at a time.	60

		And is it something that plugs in? What if we don't have electricity?	62
		I have questions – do you put one mask in the unit at a time? How am I sure that Susie didn't put hers in there and it was exposed to a drop? Maybe she wasn't as careful w/hers and now it's damp?	39
		So you can use someone else's, or only your own? We'll perform therapy, leave, won't come back for 4-6 hr. So, where would you keep it in the meantime? Would it stay in the unit? When I worked at another hospital, they told us to save it w/our name on it. The masks would just be sitting there together. I was just told to do it. Sometimes your mask would be gone. Here they say you need to throw away every time.	43
		Who disposes of the HEPA filter itself? They will be contaminated. What about the fridge? Is that part of the device itself?	42
		(Barrier) What if all 4 trays are full? Do I need to touch each person's mask to get it out?	43
		[barrier] Workflow – how would the process go so it's seamless? You're adding in steps to what we already do. Everyone wants to be safe, but if you have 8 people rushing to this unit, trying to find their mask, they'll probably just grab a new mask. If the ambulance is coming in, you're not going to wait. So, you'd always have to have masks readily available. But that goes back to whose mask is whose.	42
		Anytime you're sterilizing /reprocessing, there has to be a record of each time it cycled.	48
		Can I just UV it, then keep it wherever?	34
		any smell from it	74
		durability – if I knock it over will it break	74
		how sturdy are the drawers	75
		could it function in a low light environment – nurses turn lights down at night	74
		transportability – how much does it weigh if we want to move them from room to room	74
		Way to check if it's functioning properly – doing what it's supposed to be doing.	73
		interface has to be simplistic	74
		Says [the handout] fan circulates air for cooling and rapidly removing odors…trying to think of airflow – where does that dirty air go?	86
		[ports located on] one side would be the best	88
		minimal place where we could store a four-sided unit	89

		Would people use it to decontaminate other things?	87
		From a compliance perspective, we need to have in place a verification process that the machines work as they should. Have parameters, much like we do for anything else. For example, every month we need to test it and make sure it's still working.	84
		Does it have a long plug?	99
		Is it a fire hazard?	99
		I would open it from the front not the side, you are going to be in areas on a counter tops the side opening will take space from shelves next to it.	105
		the smaller the better not necessarily realistic if it was something we had to have we would find a place to put it	99
		Push of a button – place mask here, push button, everything else is internal as far as timings, etc.	105
		Any odors created by the machine?	113
		User friendly is the biggest piece to it – you want people to push a button and people are more inclined to use it if it's not a pain in order to operate the unit. It's a 60 sec cycle…	105
10	Current Process		
10a	How the frontline HCW uses now	I do reuse them and just throw them away when they get gross – normally it's my makeup – on average 6 a shift – try to use it a couple of times in a row.	78
		Do have experience esp. with TB patients. Process is the staff has their own mask, keep for entire shift, sometimes we simple bag and keep that outside the patient's room that's your bag you have your supply. Kind of looks like a sandwich bag; initial on it	32
		They're a single-use item. So, if you're changing patients, you get rid of it. Or once it gets saturated with any fluid at all. Put in regular trash to dispose. If it's contaminated w/something biohazardous – goes in red bag trash. Ex: TB – goes in red bag.	47
		Mask can only be worn max of 1 hour and must be disposed of if soiled	5
		With the exposures we learn after the fact that the patient is on a higher level of isolation.	65
		There are different practices for diff people (nurse, physician, resp). I personally only see the patient once a day. One patient, one mask, mask gone. Nurse on the other hand repeatedly sees same person. There's a different volume of	49

		need there. It's different for Dr, nurse, RT, housekeeping, janitorial - based on how frequently you see the patient. Least needy are Drs.	
		[disposal] Normal trash. If contaminated, a red bag. If cleared, normal bag. If there's a scare, like the powder scare in china. Anytime there was a powder substance, it had to be cleared. Once it was cleared we threw it in normal trash. Also w/TB, transporting patients even across state lines sometimes. The masks were disposed of in a red bag at the arrival hospital, where they are then incinerated	64
		[disposal] We throw it in a red/biohaz bag that is in the patient room	49
		no re-use policy, you dispose	55
		After identifying an individual as high risk/contagious, they place these masks on the outside of the room. We have little choice of choosing the mask. We do the proper don/doff, depending on the situation. Most of respiratory illnesses, there is a risk and we use N95. Sometimes by mistake we get the flimsy ones on the door (surgical masks) and we know, for the most part, that this is not the right one to put on.	49
		We use FFRs on a daily/weekly basis - most of us (more so in ER). Everyone is fit tested every year. We know our sizes - s,m,l.	55
		We first identify if the patient needs to be in isolation. Put them in neg pressure room. Right outside of that is anteroom, where we gown up. Then we go in, take care of patient. Go out and disrobe. All goes into biohazard can for disposal.	56
		[FFRs] They're delivered on unit, sorted on unit in anteroom, right outside of isolation room. In cabinet with other PPE.	55
		How everything runs now, it goes well. People are consistent when they don/doff/dispose	56
		All – no one uses N95s more than once	49-54
		Right now, we use disposables – they are not re-usable. Tronex is the brand (cone-shaped). Also use Kimberly Clark duck bills.	39
		How can a person keep track of their fitted FFR? They know all of the information b/c Kim gives them a card w/all of the information they need to identify it. Packaging is much different for cone v duck bill.	39

		Just clinicians - unless for some reason a surgical mask is not appropriate/recommended for use for patients. For patients, who are spreading the germs, the masks are capturing the droplets they are breathing out. N95s capture what is coming in.	39
		The person needs to seal it themselves. Appropriate fit of the mask depends on the person's motivation and ability to make it fit.	39
		Disposal – trash can right there in the patient's room.	42
		That's just regular breathing. If they sweat, too much breathing, or spill something, the mask pores expand and more things get in there. Don't use a wet mask is what I've been taught.	62
		One nurse can easily use 6-8 masks in an hour, if they are going in and out. During scabies we had to limit nurses. Better time management for one patient so they didn't have to come in and out and use as many masks.	62
		[Masks]They're a single-use item. So, if you're changing patients, you get rid of it. Or once it gets saturated with any fluid at all. Put in regular trash to dispose. If it's contaminated w/something biohazardous – goes in red bag trash. Ex: TB – goes in red bag.	47
		Put them in the contact precaution, hanging outside the door. You don before entering. Patients requiring this have an entry room, which has a sink, etc. You doff it all before you exit the interim/entry room.	34
		NICU – only one negative pressure room, no ante-room. There is just on a cart outside the door. You dispose of the mask in a trash can. Rare to need a mask, though. Recalled one event where she needed it b/c the mom had TB.	35
		ER – 1 neg pressure room, not closed off from hallway, though. You don in there, and then go into the patient room. At the end, you remove the mask and dispose of it. People often want to keep it, re-use it, but they aren't supposed to. You do run out of them and have to fight for them.	33
		[ER/ICU] Same experience [as participant 33], [masks in] neg pressure room.	36
		Personal protection equipment (PPE) boxes in certain areas in the hall	33
		NICU/PICU – have a stock room, stored there until the masks are distributed to carts. There are people (unit clerks) that are designated to	35

		order/re-stock the masks. The storage is in a central location. If cart is empty, you know where to go to replenish.	
		I keep one in my car right now in case of a pandemic.	36
		depending on what days you are working – so working a block and have TB precaution patient you obtain it from the stock on the floor, get a baggy and use that mask in and out for as long as on the floor and depending your period of time e.g. 3 days then you'll toss it.	23
		Not very long – if TB patient generally are either q12, q6, q8 (quarantine rooms)– 4 times on avg. to turn on and 4 times to turn off at maybe 5-10 minutes per cycle – maybe used it for an 1.5 hrs. total entirety of the three days for regular therapist working 12 hr. shifts.	23
		Put it in a plastic bag with our names on it – usually put it on a shelf in anteroom	23
		Not really talked about the reuse process besides things that are truly reusable. The shift is to single use items as much as possible, even things we process and clean – endo handles, we moved to one use and disposable to be sure they were clean and sterile when a doc needed them. Gone the other way rather than re use of items, The push, the feeling is.. Institutions going to disposing of blood pressure cuffs, leads, been happening a couple of years. When they do the ATP testing and look at some of the turnover and the efficiency to move things along.. Let's say blood pressure cuffs can't be cleaned adequately.	11
		We throw them in the garbage right now. Don't use any version of recycling right now… we try to do a lot of recycle in general… we are recycling clean plastic bottles that are clean before OR is used but once patient gets in there it's dirty	11
		The FFRs go in the bio-hazard disposal? … They are collected – leave indiv operation rooms and suites and go downstairs where they are centralized and picked up by an outside. We have containers and huge bins (big garbage pail size), red bag waste contaminated, and clear plastic recycle.	11
		They keep a pretty good stockpile; build up a little bit during flu season. We have rule outs – patient who could potential have a TB; test take longer than a flu test so you treat them as if they	11

		have a need for an airborne isolation until deemed otherwise. During flu season 30% assumed have flu – 20% have it.	
		We have a few ways. Our staff up to the point until they del a flu emergency – if you don't have the sticker for a flu shot you are required to wear a mask when around patients. There are emails every day from CMO office, infection control. Also have signage at patient and family entrances – symptoms and wear a mask. Also ask that they don't visit people. We have a fairly closed door system. When visitors walk in expected to check in the desk and visitors get pamphlet.	11
		That's the most of it.. Urgent planning meeting call a code – leadership group get together in conf room, what we need to know, activate – not a standard epidemic – used to the norm.. call a group together similar to opening our emerg. Ops center… All the drills we've done involve the state and the county.. everyone reports to them – and every one can see it. New York has prob had most practice than most states 911/ sandy… stony brook also has good relationship with local law enforcement and leadership – we are very connected.	11
		Traditionally they are used and discarded, those people who don't get them wet will store and reuse them.	5
		Everyone knows about them, but don't have places to store them (not all have lockers)	5
		Get an FDR from our exchange cart: two bin – one in the back two supplies so you can beep something with scanner and then the come up	18
		Used to have saccharin flavor that would come up if mask didn't fit….	
		We only use them for TB. We have a room where they are in boxes where there are different sizes for people where most of the time someone will go in and label their mas for the course of the day, doesn't last forever.	29
		9 times out of 10 a clinician will put on a new one rather than the re-processed-don't have the confidence.	5
		We're not allowed to wear a mask during transport.	25
		usually patient on the floor and they are identified from a resp. panel – sometimes the exposure happens before you realize the patient has something	65

		they advertise them as one use now;	70
		Supposed to use it [N95] for respiratory disease/possible respiratory disease. We've used it on people we thought had shingles. We're only speaking for Outpatient. In-patient has a lot more exposure than we do. With most of our patients, this is not an issue.	92
		[how you were trained vs how you use it] Candidly probably – sure there is a specific technique. Would be lying to you that I follow it every single time. You put it on in the room and disposing them after taking off your dirty gloves so you are not rubbing your face with dirty gloves.	106
		Otherwise, we teach them that it's one-time use. If you're going into airborne isolation room and you have exposure, just like any other PPE, it's better that you discard it after contact w/patient. IC was part of that single use decision and also the other decision during H1N1.	107
		think we're used to not having to share	118
		throw them in trash	116
		[Any use beyond single use] - no	118
		throw in trash	117
		The other facility I worked you keep them for whole shift unless soiled. If you walk into a room and just touch the computer you can leave room and just put it in your pocket.	121
		people who are in AFB Isolation are in a negative pressure room we just put the respirator outside in the anteroom	118
		Sometimes I've run into where you go into a room and there's no sign and you see gowns in there and you know you've been exposed and you have to go to the nurse and tell them.	108
		Use it once, throw it out	113
		There's also a bigger mask, PAPR, that I've seen people use w/beards.	114
		Sometimes they take the signs off the door before we get to the room to discharge. We have to come back and ask what was it, droplet, MERSA, etc. – sometimes they have a class if it was MERSA, TB, etc. They take our names and make sure we are tested. If they find out the patient was positive they find the person who was in the patient room.	109
		As they were saying about the signs I experienced going into a room, no signs and	110

		whatever was in the room didn't agree with me and I had to come out. When we have to go into clean think the sign should stay there until we've cleaned. We don't know until something happens to us so we are exposed – think whoever put up the sign (nurses, etc.) they take the sign.	
		[weakness in process] Patients can vary in the way they present respiratory issues. Some are asymptomatic; some are very severely ill and symptomatic.	115
		you discharge everything, you have anteroom, where you have waste can you discharge everything and put it in the wastebasket	111
		Use them from supply room, use them and then throw them into the trash. They are in anteroom and also in the supply room.	100
		if you are doing a discharge and the room had MERSA, droplet, etc. you have to wear a respirator	108
		In reg. trash unless they were soiled with something that case go in biohazard bag	106
		[Anything in that process that doesn't work as well as it needs to or is it perfect?] 99 works well 97 – works good	99, 97
		throw them in garbage	99
		expect them to be stocked in the anteroom outside the negative pressure rooms, use them donning them as well as other PPE and disposing them according to policy after use	106
		Thinking about what the main things I need to look for depending on what our consul is. Identify things where we are needed. If the patient has an infectious disease then I think about PPE.	94
		soiled or not, after we use them we throw them	98
		one time use	97
		I worked at a different center and you could reuse them with the same patient… I guess but we would leave them in anteroom, people thought kind of gross	99
		not to reuse them	94
		then we take the mask off once away from the patient then get a new one is we have to take the patient back	104
		I throw it away then get a new one	104
		pretty comfortable with it; think it's good – it's not like we are completely in the dark and it's	104

		not like they are bothering us every two week for a policy change	
		Not involved in purchasing or selecting or inventory control. When we walk to patient's room and the PPE is there, we put on mask before entering patients room and dispose it on the way out.	94, 93 and 95
		unless it had bodily fluids (blood) or something other than that no just reg trash	94
10b	How infection is controlled now		
		usually if there is a patient suspected to have known – TB scenario – the areas, floors, units and ER have a major supply section that hosts all the boxes and sizes and brands, and typically they are brought to the anteroom for you to use, if you don't see the size you need you can go to the supply room. Usually when I go into the anteroom they are already there. Then you are required to follow the process, open the package and it fits the right way.	71, 72
		Ebola room on one of my units – they were and are bariatric rooms, larger and self-contained from other nursing units. By designating those rooms they are available there are things that are contained in that area that don't leave. We have a lot of isolation cabinets in general – sterile gowns, masks with face shields (patients with airborne isolation), colored yellow or red. There were drills led by Emergency Mgmt. program – robust gowning, decontamination.. next week doing a decontamination exercise outside	11
		Focus is on people who are mostly at risk (ED. Pulmonary, infectious diseases, etc.) as opposed to a pandemic where it will be everyone	10
		We looked at application of the surgical mask on top of the N95. If they don and doff the surgical mask correctly, would provide droplet protection then the N95 could be safely removed and reused	10
		Challenge to current process: Patients not clearly identified if having relevant disease (TB) [so people might not have mask on but need to]	5
		Instructions when masks are given out: how long to use them, a lot of clinical discussion, different codes they use (under this code you must wear this type of mask, and other clothing)	8
		Then question I still have: Do we have equipment we already have that can do this? Can we hit it with a spray?	8

		In NY state every health care provider has to have a flu vaccine by the time it was prevalent or they have to wear a mask during flu season. We'll put a mask on the patient but the provider has to follow the law If in prevalence of flu. Have to make sure people understand the educational backgrounds	31
		If you have a consult– you have to PPE outside of patient's room	32
		Right now we have a disaster plan in terms of overflow and kind of use it every day. If we had a unit of patients that had something infectious because we wouldn't have those flexibilities. In the new building all private rooms, and isolation rooms with true anterooms.	11
		Cohort to each floor – what we did with Ebola with adequate air turnaround and ventilation. Staff well trained in that area… had a super user concept.	18
		Have UV available – have a system not really in use… One system – true clear maybe- idea was it would be used in empty room to decon. Anything in a patient room has to be trashed.. Potentially we waste millions a year. Potentially we could decon unused and unopened supplies and put them back. There were a few housekeepers that were trained – thought was on top of it to use it cycling on a monthly basis; or when Infec control could use it for a room where there was a TB patient for a long time. Hasn't really taken off – couldn't find a place /room to decontaminate supplies.	11
		You have to come into the anteroom and change that mask	5
		If you are going to take it out, something may or may not fall [virus shedding]– I would need a station nearby to wash my hands, then the next person needs to have handwashing, etc.	18
		Sort of like the pulse ox… they have to decontaminate. Probably similar that you would need a collection area for the masks	25
		There is a stamp on it (made in Jan) so Jan two years from now it says expired	8
		If it becomes torn, straps break, bends, cracks- you can reuse it until it no longer has a correct fit test. Or its physical viability is shot.	10
		After 2 weeks on service the nosepiece starts to crack	10
		You might get away with using one N95 per shift, per person, but not two weeks	10

		not getting your mask back and the degradation of mask would be escalation worried about the seal and integrity of the piece - little metal piece you squeeze on nose	20
		Don't feel so great now in terms of quality. They work and do what they are supposed to do, donning and doffing, can be ripped or elastic loosens. They are really considered at this time for short term use; not reuse.	11
		Training told us we could reuse if mask was not wet.	5
		If you put plastic in the sun it will change; become brittle – I assume there will be a breakdown.	30
		Nurses also observe how people use them [FFR]. I do surveillance - so if I see breaches in infection control. Directors walk around and look. Executive leaders do "A day in the life of" (once a month in scrubs) to do surveillance and look for weak points.	44
		We can't fit test them all. Right now, they put a regular blue surgical mask on if we suspect flu	43
		Usually no N95 for patients though, just surgical masks	41
		[Do people pay attention to how you use it? (FFR)] No	64
		When we sterilize, before we put an implant in a patient, you need to run a biological. We have a control test to make sure it is actually sterilized. We have a control that tests positive. We run the same file for each implant to see if it comes through negative. So if you could run a test like that w/the respirator - If it's something that would die from UV but isn't harmful, you could run a test. We have filters that change color once a certain level of steam has been exposed. Maybe the mask could change color when it's 'ready,' but I can only see that being done once.	65a
		[Does anyone observe how respirators are being used?] Typically we have a buddy with us. If we see them doing something wrong, like maybe it's someone new, we'll speak up. We all know how to take care of patients during isolation. Someone more infectious, like Ebola - we have an infection disease action response team.	56
		We first identify if the patient needs to be in isolation. Put them in neg pressure room. Right outside of that is anteroom, where we gown up. Then we go in, take care of patient. Go out and	56

		disrobe. All goes into biohazard can for disposal.	
		During infection control rounds. She observes, does spot checks. As leaders, we do the same. But there is no structured audit/monitoring.	57
		The "unknown" - we are not always initially certain of modes of transmission (like for H1N1). We were donning and doffing everything. We didn't know what H1N1 was. Once we did know the mode of transmission, we could prepare appropriately. In a true pandemic, we don't know right away how to prepare.	39
		Where they are stored - hanging on the door/rack once a patient is on precaution. One room on 2nd floor has a room before the patient's room	41
		We don everything before going into the room	42
		Disposal - no biohazard bag. Regular trash can	41
		Policy, education, monitoring. Like w/anything else. Like w/handwashing.	45
		By the time someone comes through ER, we don't know for sure what the patient has - they don't have an AFB ordered right away.	33
		When we had the Ebola scare, it was a new fear, so everyone was being careful. With TB, we have gotten lax.	37
		ER is front line. You don't know what you'll be hit with - Cold, pneumonia, etc. You don't even know the physician ordered a certain test. Maybe a nurse provides their own protection in those cases. In that case, she would probably put the mask on and dispose of it in normal trash.	33
		They're a single-use item. So, if you're changing patients, you get rid of it. Or once it gets saturated with any fluid at all. Put in regular trash to dispose. If it's contaminated w/something biohazardous – goes in red bag trash. Ex: TB – goes in red bag.	47
		Have several patients on floor w/contact precautions, patients that require the mask, and the nurse will also then require one. We hang them on a contact precaution (on the door) so that staff can put them on before they enter the room. Keep the N95s stored in another supply area w gowns, gloves, etc.	34
		Our med and safety team round occasionally to view handwashing. Don't know if they have a metric for the donning of PPE equipment and if you are doing step 1, 2, 3 and 4 in the right	72

		order. Only verification of the process is in the training and the fit testing. If you are at the bedside alone can't tell if it's placed correctly but you were told how to use it and you don/doff how you learned it	
		Anyone with airborne disease, TB, SARS, MARS – we have 2 pack on each unit with respirators of each size and all the PPE and how to put it on and you are told to stay in room with patient until an ID person comes to get you out.	81
		No OR visitors - if someone has infectious disease, we do not let visitors in the room– they are not fit tested. With Ebola we would not allow parents in the unit. We restricted staff in the room for Ebola – only Attending (no nursing students, residents, etc.)	81
		We use SurfaceCide – used for rooms a 3-tower system. We had True-D for a while and ended up going with SurfaceCide – you can break the towers apart if needed and disinfect 3 rooms at the same time – would take longer. We have 12 towers – so could do UV disinfection in a discharged patient room.	81
		SurfaceCide or UV tower. We've used it for our rooms, and Candida Aureus virus recently. If it works for that why not for flu – can we put the masks in the room and lay them out and zap them with UV? What's the spectrum of UV light to disinfect?	81
		yes, the nurse is supposed to put the patient in mask	104
		Don't see that they [patient family] might have a yellow mask, sometimes they don't wear mask at all	104
		I know they do UV decontamination for rooms now. And in the ER they use UV too. I've heard about that.	107
		noticed recently with housekeeping for CDIP patients will now bring ultraviolet in to clean the rooms	118
		We had them re-use the N95s once when we had a shortage in '09 or '10 - H1N1. We said they could re-use it and put in a baggie if it wasn't visibly soiled. We don't tell them that now since we have an adequate supply. At that time, they couldn't supply the hospital in time. This lasted a whole season – Oct - April. It was under the direction of IC that we told them to do that.	107
		ER - same thing as well. I have minimal mask experience but there have been patients who	114

		may have fit the criteria for me wearing a mask. We'll use it then work the patient up to see if they have the illness or not.	
		I think majority of our patients have visitors daily. High volume of traffic. We have signs on the doors. Patients and family may not understand, though, unless the nurse assists them. In terms of contact precautions - you see them not wearing gloves, not washing hands, etc. Keeping family members precautions is probably a fail rate of 80%	113
		I think so. They're large colored signs. They stand out with nothing around them. They have large photos, with words. But it does require the people wanting to be curious and read it. Also with some PPE (yellow gowns) they're not easily seen. Maybe in a drawer.	113
		It has to do with personnel, too. Unless there's someone in the room ensuring people have PPE, ratios for nurses to patients can be anywhere from 2:1 or 4-6, or 20 overnight. There's no accounting in terms of personnel to ensure that everyone is following the precautions. You just hope the signs are enough.	112
		Also, family members not using equipment properly, then they catch a virus and spread it outside.	113
		everything has to be thrown out, they take UV machine (circles hand in air) and cleans the room	111
		you have people say' oh that's my mother – they have to realize that they can catch it and take it out and spread it to others	108
		You'll hear family members say, "I know what he's got, I don't need anything." We go to visit patient with family and I'm putting all this PPE, etc. to go into the room and there will be family members hanging out – ask them to put it on and you get, "it's okay that's my dad".	103
		you have people say "oh that's my mother" – they have to realize that they can catch it and take it out and spread it to others	108
		Yes we want to wear an N95 for TB but there have been no clinical trials to prove they are safer than other masks.	81
		N95 is meant for particles in the air, like TB/chicken pox - not flu. You say this is for N95 flu. Sometimes we do use N95 to be safer for flu. But not always. Flu is droplet.	62

10c	Regulations and policy	Joint Commission would have to be involved, procedural and protocols and what's on the floor and they monitor and accredit.	66
		how do you maintain and is there regulation to ensure everyone's doing it correctly, and the same for usage at the unit	71
		If we can't follow our protocol correctly on a daily basis, how will we do it during a pandemic?	50
		These are things Joint Commission (JC) may ask. They'd be involved. They're our regulatory body.	44
		Org/policy barriers that could get in the way? Yes, we'd have to change the policy to say 'this is now reusable' – easy to change.	39
		This is a change management issue that needs to be involved before a pandemic. There will be distrust. This new procedure needs to be implemented early. Create a vision. Don't spring it on everyone for the first time during a pandemic.	45
		If it's part of sustainability, this is no different today than tomorrow when there's a pandemic	45
		Only thing we've been told is if we didn't have any [FFR], we'd go down to the next best level of mask. Which is still better than the surgical mask. I can't remember the name.	64
		We get into very tight parameters on the elements of costs that are justifiable to the AG and the state comptroller who asks about how we did something	8
		Law trumps everything in NY. If you make it law they'll do anything.	5
		I would take a look at all of the policies and cross-reference workflows, language that addresses isolation or Emergency mgmt. standards. And OSHA regulations – I'm not the content expert for OSHA, but I'd pull in people that might be. I'm not key in these processes, but I connect a lot of people/dots to get you to your goal.	84
		What I'd need to know is, who owns the process after the decontamination 'box'? Then once they were able to be used again, it would probably go back to supply chain because they're responsible for keeping par levels up. It's a big cycle. I'm not in the cycle, but I'd write the protocol for the cycle.	84
		I think you also need to have a set of criteria that says "this mask is not appropriate to be re-used	84

		if…" For example, if you threw up on it - We need to know that that one does not get re-used. IC issues aside. We need very clear criteria about this – what defines when a mask can go back in, regardless of how you map out the pandemic/location.	
		If you had pediatric kids that need this kind of mask – we'd have to map out specific plans for parents visiting and wearing the mask. I'd be cognizant about that. It's not just going to be about the healthcare provider putting it on and going into the room. We also need to think about other considerations and processes – adults in the pediatric room, for example.	84
		The CDC or AMA needs to come up with that standardized process.	84
		You need to say, for example, "the dirty-entrance, clean-exit process looks like this." (Onboarding issues, sustainability issues, etc.)	84
		Typically what my manuals say is "define your process for onboarding new products and sustaining new products." And I think this wouldn't be any different.	84
		[Difficult for you in transport position and the authority like an attending to tell them what they do] 103 – I can tell the nurses	103
		We follow OSHA guidelines for training. Step by step on how to use it. Fit checking. Process for qual fit testing - number of sprays, exercises, sensitivity etc.	107
		It'd have to come from FDA or OSHA, someone saying this is the plan/process and its acceptable	107
		CDC and their TB recommendations - I'm sure there's something in there about N95s. NIOSH may be involved – maybe more for education purposes. Regulatory would be OSHA.	107
		[Guidance in case you run short on PPE?] - haven't heard of it	98
		IC policy – we follow OSHA standards...which is required for anyone entering airborne isolation rooms, and some research facilities.	107
		For N95s are going to have to be approved by IC and CDC. They are pretty prescriptive right now for when to use extended use.	96
		Don't know if our unions would ever go for it – would be an uphill battle. We would get the union stewards involved immediately, don't go	96

		and ask for permission, but would have to go and present a change in practice and educate them why it's safe and proven. But we would need backup from CDC, very challenging to go to them and say we are going to use the masks without having the CDC backing in hand. That was a challenge with the Ebola because the CDC was behind on some of their guidelines.	
		When they change something just period. IC will update the management, then on management site on our huddle topics once every couple of weeks and have employees sign off on the topics. Will demonstrate process as well. We do with IC fairly often – once every couple of months.	103
		We would need strong recs and statements from the CDC, Fed govt, national leaders out there telling us this is what you need to transition to. If it's an ID it's CDC – WHO potentially.	96
		We follow the CDC guidelines, there are pubs out there around limited use and extended use of these masks, and we would not go beyond their guidelines. We would need for them to come out and stand behind it that the sterilizing works for me to feel comfortable.	96
		Have a lot of unions and a lot of our front line clinical providers belong to the unions and they look at the CDC guidelines and recommendations and that our policies align with the CDC.	96
		It is custom to not to reuse them whatsoever – suspect it stems from policy –IC could speak to that more	106
11	Artifact (FFR)		
11a	Uncomfortable fit, brands differ	[fit test] Moderate confidence– I've fitted a few times, glasses fogging sometimes when we have the fit which you shouldn't have happen. Don't completely believe they fit	68
		Need to have a more comfortable mask	16
		Most people won't last long in an N95	10
		N95's are not comfortable or easy to work in	10
		People are used to going in and out, which is a different work style. When they are in there longer, they are incredibly uncomfortable in an N95	10
		don't think you can stay in that room for more than an hour	24
		Once fit to one person – would not fit another's face	12,13
		Don't think these masks are perfect	15

		Prolonged use of respirator of any type is fatiguing – people get tired of breathing through a filter, having sweat on your face. If you have to have it on for an hour – that's a long time to breathe thru a filter. Prolonged care of a patient, when you are bathing them, dressing wounds	45
		The more comfortable it is, the more likely it is to be worn	45
		If you're not using it all the time like she said, they don't always know how. I was one 7 years ago that I had difficulty b/c of facial changes. I think we should do a better job of explaining the weight change thing. Maybe we should do more frequent fit testing to make sure it's done properly.	61
		I also see cultural differences – if they have big hair, facial hair, it's hard to fit.	61
		This is not a fun mask. Not fun to breathe through.	47
		We believe it's [N95] safer however always a risk it's where you put it on and take it off and you have to make sure it fits you.	81
		Use what we call surgical mask which are the N95 respirators	105
		the fit isn't always that great	117
		yeah, people with long face or facial hair you won't get a good seal; with long face wont' go over chin so you are constantly trying to mitigate lower on your nose or over your nose.	121
		for me, my personal thing that bugs me about the respirator is the rubber band gets caught on your glasses	118
11b	FFR durability for reuse	think they could get stretched out and the bar [at nose bridge] wouldn't fit next time	68
		I'd hope there's enough research out there to identify that it's a safe procedure. Would like it to come from fed govt. CDC. (All agree). And answer questions such as: How many times can I decontaminate a mask? We'd have many questions.	55-58
		I'd want information on the frequency of how many times we can run a mask through	57
		If I've been nuking that mask for 15 years, I want a new one!	33
		How many times can they go through before they aren't good? And how do you tag that?	60
		[barrier] Our n95s are disposable, so how many times can they be sterilized? We send hard equipment to central sterile and it last 15 times. Can't imagine the N95 straps holding up	43

		How many times can it be re-sterilized, and tracking that	1
		How many times can the mask be decontaminated?	99
		[last how long?] Either 2-3 years; climate controlled area	5
		Does the UV degenerate the rubber part of the mask?	49
		Even though it's free of the viruses, what is the longevity of the mask? After wearing it for a long time, w/moisture from breathing, it gets softer. That's a concern to me. Sure, in a pandemic, it's better than nothing. But the fibers will eventually break down. The ability of it to do its original job will break down. Durability/longevity of it is important.	64
		Longevity is my main concern.	64
		Proper education/testing to inform people how many times you run the mask through the UV	65a
		How many times can you do this before a respirator loses its effectiveness?	55
		How would I know if I put mine in – 10, 15, 20 times? At what point am I not protected, and how do I keep track?	55
		And how's the filtration process of the respirator, since it traps particles in it? The integrity of the surface would have to be perfect for me to use it.	39
		[barrier] Our n95s are disposable, so how many times can they be sterilized? We send hard equipment to central sterile and it last 15 times. Can't imagine the N95 straps holding up	43
		[barrier] N95s go through normal wear and tear. The straps don't last long right now, as it is	42
		Some concern that the elastic could break down through multiple passes through UV – I don't know how many uses, though. A lot of things are sensitive to UV. Polymers. Not a cosmetic concern - If elastic loses its tension it may not fit correctly.	45
		Doesn't it take a while before that happens? If you think about it, we put the spray on during fit tests.	61
		Individual PAPRs at that time could be a good resource. Instead of cleaning them, the person can have their own PAPR which is good for a longer time. They are more expensive, but last longer hours.	62
		PAPR is $60/70 + the cost of a filter. May even be more now. A mask is ten cents. But, if it	62

		would get you through a pandemic in a safer way…We don't have many PAPRs available right now.	
		See if you can get rid of the toasty smell. Bad odor will make it even more fatiguing.	45
		Toasty smell may be a material issue. Can we find one that is more heat resistant? If it's only a minute, I bet there's another material that wouldn't de-nature in that time.	45
		Is there a max use on this? (How many times can it go through the UV machine and still be effective)	35
		And if this is an issue, how do you keep track of how many times you've treated it? Does it matter?	37
		Life expectancy of the mask, think they do breakdown. If it's used 50 times vs. 2 times would question their durability	68
		Then as you wear them the moisture builds up – so it decontaminates it but does it dry it. After the moisture builds up how effective is it?	75
		How long does the filter last?	74
		UV breaks down materials	74
		right now I don't know how long an N95 can be used	75
		We are taking out virulent particles – my concern does the fiber breakdown from the UV exposure and the moisture we are putting in it from the other side make it unusable. And what about the straps how long can they be "cooked." Anything is still better.	74
		It has an elastic does it make it stiffer or looser? The things that make it fit to your face. If there's heat then the elasticity of the rubber would compromise	82
		how long can it be worn before the integrity of the mask breaks down, the straps pop off	99
		yeah they lose their elasticity	100
		How long does the FDA think this is effective? How many times would we be reusing.	94
		Also how many times can you reuse your mask and you put it in your pocket all day, does that make it less effective? Where do you need to store it, etc.?	93
		how many times can you put them in machine	119
		how many times can we decon a mask before the mask itself becomes ineffective	121
		How many times can you put it through the machine before your mask needs replaced? Filter breaks down, etc.	113

		Will there be enough and how long are they good for? If it's pandemic you're going to have it on pretty much 24 -7 so how long is that good from	118
		how long do these masks last, designed to be a single use mask, can we use them 5 times, 10 times, 50 times – at that point the elastic on the band still snug – how would one keep track how many times used?	106
		With that, how long will the mask last before it falls apart?	110
		[how long before it falls apart] expires?	108
		Less about what type of cleaning, obviously soap and water – more the material of the respirator, can it withstand that type of activity w/out destroying the item	105
11c	Hospital Selection of FFR		
		An idea comes from someone about FFR brand from division or corporate level. At the local level, we have a SMAT (supply management action team) committee that looks at new products. Multi-disciplinary. Collectively they make decisions, and also look at the financial piece	44
		FFRs are chosen for us by the hospital (employee health nurse reviews that information – I don't know who makes actual decision).	42
		I'd have some involvement w/selection, but most of that comes from division/corporate level b/c it's purchased in bulk. Maybe by HCA HQ	45
		The whole thing sounds good but would not want to use N95 – reuse for any isolation airborne – don't think it's safe for me to do that.	77
		We don't have anymore, here are our options and this is the best option. It would go through the incident commander in making that decision.	81
		People driving respirator choice is the operation group. They fit tested the employees and narrowed it down to three masks, annual fit testing. Look who is passing on a mask and then decide – get input and then purchasing takes care of it. We had awhile where we were using 5 masks (Kimberly Clark) – had difficulty finding them.	81
		I think this is an exciting opportunity. Seems to me these units would be in high demand. I'd expect my company would be very interested in being on the leading edge of that.	59
		Q. Who is involved in decisions about N95s?	80

		A. A lot of people. Value analysis structure here - 20 teams across clinical and non-clinical. Clinical – who are the primary stakeholders of a product? We'll have discussions around product changes at our Med Surge Value Analysis Committee, led by Jennifer. Co-chaired by leaders from other depts. (ED, IC, etc.) When patient nursing is impacted by something, that's who we start with. If Infection Control, staff nursing councils, or Occupational Health needs to weigh in, for example, we will pull them in. That is our "hub" first if we're thinking of changing product. There are different levels of oversight, too. Different people for higher initiatives, etc.	
		Med Surg is comprised of managers and assistant managers, and we try to include staff nurses because they're the ones on the ground w/the patients. If there are a variety of opinions, then we go straight to the nurses. We may do trials. Maybe we have a backorder of N95s. We might have a trial on a substitute product, and the nurses would give feedback on an evaluation form	76
		Clinical engineering would need to get involved, they would need to assess the PMs, whole process for taking on new piece of equipment. Value analysis committed that works with supply chain then if it's clinical we get clinical engineering involved so looking at variety points of view. The clinical engineer will delve into mechanic of device, how often preventative maintenance, how often it needs to be checked by manufacture, lifespan, etc.	96
		We chose the mask brands with IC. We like the 3M brand – one size fits all. Also Esperian, larger mask. Duck bill never worked well for us	107
		We are, because of fittings. I remember during the pandemic we ordered from a certain company and they didn't work at all. There's a VAD committee to review new devices (value added device committee) anytime you want to introduce something new. We're a big part of the process, in general.	107
12	Pandemic Management		
12a	Initial pandemic demand and response	In a pandemic will they change care plan to reduce exposure and minimize the demand on masks?	66

		Early in the pandemic …you would try to limit procedures that would cause aersosolization of respiratory secretions	10
		When Ebola scare happened, Infection Control put these things into place. They got it up to speed quickly to support potential need for an Ebola crisis. Now we just maintain it along with other inventories. I think the FFRs are a part of that inventory.	80
		We have run out a few times and people know they can come to me b/c I have some stocked away for fit testing. That happened w/SARS and Ebola. We ran out w/Ebola. It was at least 2-3 days before we could get more stock. We were fortunate to have my cushion and what we had on hand. Might have taken a week. Ran out Monday, didn't get more until Friday. We weren't even an area that had high risk at all. We were running out just for regular care.	62
		Once you start getting into alternate care facilities and gymnasiums, we're not worried about aersosolization.	10
		Absolutely…we used it for SARS, MERS, and EBOLA. We held town hall meetings to talk about how we were handling EBOLA, nursing practice and Education Group. My team worried about quarantine staff, and first responders. They did town halls, here is your PPE and this is how it will work, do not go into the room, if you do need to go into the room here is your emergency pack and you are keeping it on and staying in the room. We did drills on this.	81
		Manufacturer back orders and supply and demand issues. Usually during times of increased need of some type of resp. illness. With EBOLA we had a hard time getting just about everything. N95s was one of the items.	81
		If we had to slow their use, supply chain would help us. Using the CHG model – they recover all the product and then re-dispense to the places needing it. With H1NI we pulled back all products to our offices and determined where the patients were likely to be and provided to managers to give to employees taking care of those patients.	81
		Environment of Care (EOC) – In charge of safety of the facility, for anyone in it – air concentration/flow, building structure, fire safety, water safety, backup supplies for electrical, room pressure. Also have oversight of	39

		plans that include surge. They coordinate w/emergency dept. During a surge of patients – maybe it's not infectious, but it's not just affecting ER, it affects everyone in the hospital.	
		so they need their meds from their nurses, prob not PT to conserve masks	70
		[If there is more than one highly infectious patient] we're screwed – we could ramp up to 2 patients. More than that we would transfer it out	81
		With EBOLA we were trying all kinds of stuff. Ended up going to cleaning room tech to give employees something to cover their heads.	81
		ED is going to see the most, then how sick are they so then the ICU, if going to certain nursing units then to them	81
		We would use N95 the first couple of days and then move to PAPRs. PAPRs issue is ability to hear – we have walkie-talkies and ear buds but they don't work very well.	81
		[Do you feel like you'd [outpatient] be second priority to Inpatient?] A. Yes. I think it'd be ED, ICU, surgical, inpatient, then we are low man on the totem pole	91
		We did Ebola screening as part of our assessment when we received a patient	91
		We built it around an Ebola plan, not a generic pandemic plan - but yes. We have protocols surrounding pop-up supply locations, with carts with necessary PPE to put in ED, etc. Units prioritized? In the patient unit, they turned an area into the quarantine unit. Very controlled. Special access and gowning rules. Special protocol w/carts. Somewhere in our CCD building. There's a process we started there – supply chain had to look at the specific carts/plan there. The carts were created to exchange supplies and keep that unit to par.	80
		We mobilized an Ebola center in a week.	84
		As far as staff educ. – people who use them are in patient care units. The staff outside of the units would be less prepared [in pandemic] for wearing a mask	94
		Think the federal governments needed to get involved much sooner, what we saw were these smaller hospitals that were unlikely to never come in contact with Ebola were hoarding things, when our supply found this we were able to pull back from these hospitals and direct	96

		those to the facilities they knew would be taking care of these patients.	
		Ideally, we'd always be prepared. But realistically, I think we could prep in days. We do just-in-time training for different things, like Ebola. As far as getting supplies? I don't know how that would go - depends on the manufacturer.	107
		If time is of the essence you maybe won't have the luxury of that info yet, if you are dealing with a pandemic situation you would bypass the natural step and base it on recs from the CDC. For any procedure tweak take it to our value analysis main things looking at efficacy and the published data about that.. not just the company that builds them saying it's okay.	96
		[who should have access to these (priority)?] Entry points - like ED, outpatient surgery	44
12b	Cohorting	In a real pandemic there would be whole flu wards where people are wearing their PPE all over the ward and then taking it off so the unit would be there.	79
		Cohort patients to limit the number of healthcare personnel that would be caring for patients in the cohort	10
		Previous point about cohorting – that would be the way.. that was set up for Ebola. That would be the way to go here. The question is where you put them. Every day we are over capacity	32
		We huddle every day and review available beds in which unit and moving and shaking where patients can go. We have conversations of normally cohorting patients.	31
		Probably cohort patients on each floor.	6
		We cohort within the NICU. We have pods, if there is a bug in one pod, we will put them together in the same pod.	28
		Cohort to each floor – what we did with Ebola with adequate air turnaround and ventilation. Staff well trained in that area… had a "super user" concept.	18
		we can have an airborne patient on any floor – think they would need to have a cohort process to put all the patients on the unit which is not what they do right now. Joint commission would have a say	69
		If it's a pandemic you would have everyone on that floor wearing the mask and if that's the case you can walk to where you clean it and store it.	72

		If not then you will have to transport in a bag and then would have to have storage of the bags	
		If pandemic and a large patient census – if certain units designated then have number of those devices in an area where those patients are.	73
		If we go into emergency mode we have a practitioner that stands outside door of patient and monitors the PPE – based on organism (btw we've had plague, Ebola, small pox virus here), we have a whole plan if we had a pandemic. It wouldn't be pretty.	81
		we would cohabitate all of these patients in one area of the hospital…similar to Ebola process – we were able to set up a whole unit with walls	89
		I've spent many years overseas when TB was prevalent. In Africa there was a TB wing. If this will be set up in a traditional WHO model - for this particular disease bundled in one area - whatever you design in terms of this workflow needs to work for that particular scenario. I imagine you don't want flu patients with oncology patients, but I guess sometimes you can't control it. I think you need to identify your geographic location, segregate them, then come up w/the logistics of pick up and drop off. The unit would be at that place.	84
		we will keep them [patients] in the ER?	118
12c	Self-selection; fear	I've been through a rule out small pox and I've had employees crying to not go into the room, then other staff who already did and said I'll just take care of them. Then had staff self-selected (comfortable in PPE – super users) – Feeling comfortable who don't have family issues – nurse who had 3 young children at home is very different than a nurse with 30 years who is I've been through this before and I can handle this.	81
		When we get to a pandemic point and you have staff self-select and they are self-selecting then they are more supported and confident. Trained and sure. For my team think we have that very trained and very ready. For a pandemic flu think we would need to ramp it up and get them there.	81
		We all worry about it—we have to treat every patient as if they have a deadly disease because we don't know what they're carrying. Worried about our family.	26
		Sick out	18

		in pandemic very few instances where you want to remove you mask, you will feel everywhere you are in the hosp a potentially infectious area	20
		people are going to have masks, “I had a mask… can’t find my mask and now I can’t go into the room,” -- you are going to find people with an excuse	111
		I practiced nursing during AIDS crisis and I worked on the North side and people did not want to go into those rooms. If there is an incurable disease out there that is highly infectious, it brings up a good point.	118
		think there would be a little hesitation about bedside patient care b/c you would not feel comfortable or safe w/o proper protection	
		let’s see if anyone shows up for work	118
12d	Communication in pandemic		
		It’s important for the public to have more information. John Smith doesn’t know anything about his flu symptoms. It’s like the bed bug issue. People come in with bed bugs. They come on public transportation. Get them on our chairs. They don’t even say anything. These patients aren’t even aware that they’re spreading things. They need more instructions on what to do/not to do. Even more important here because of our patients’ compromised immune systems. We had flu outbreak a few years ago. One patient spread the flu. They were able to identify people that caught it but it was scary and time consuming (around H1N1 days). It’s like wildfire	91
		In any emergency (e.g., hurricane), there’s a very standardized protocol that is coordinated very well from the emergency operation center. There is a director, and it’s well scripted. Checklists, zip lock baggies, dos and don’ts, walkie talkies, iPhone, computer use. We try to look at all modes of communication - because we’ve experienced losing electricity. So, more than 1 mode of communication. Battery backups. Cell phones could go dead. We have runners going from unit to unit. In that emergency packet, there are roles listed. No ambiguity. I feel really good about this.	44
		iMobile messaging – it’s good, but doesn’t extend to all providers. Every nurse has iMobile. But not off-shift. I’d have to check w/ the head nurse to know more about nursing	45

		Updated email listings for all physicians iMobile and email reaches everyone that is credentialed (Locums would be on that list as long as they're credentialed)	
		Methods of communication are better now than 20 yrs. ago…but not much	45
		You have to watch for daily CDC updates during an influx of disease/new pathogen, to learn more about it. I'm on the ListServe - they either host WebEx, or its phone based. There are so many people listening in on these calls, and they are recorded. Mostly for providers to provide guidance. CDC will post information as it becomes available and is confirmed. But, initially, there will be a lot of phone calls. They'll do phone calls initially. We go by those guidelines.	39
		[estimate to roll out program] 4-6 weeks. That's through normal processes. Could be compressed to 2 days if need be - If we make a big case b/c a virus is coming.	45
		We practice hurricane drills all the time, but until we had the hurricane…That drill changed completely. There's a learning curve even if you do drills. But yes, if you start early that's better	62
		Also, different strains manifest differently. The public isn't educated enough	92
		During a crisis we stand up the risk management team. Hospital Incident Command Center (HICCs) command structure. People take on roles outside of their roles. It's a structure that gets rolled out during a crisis. Gives us a hub where we can communicate to IDPH if we need to. We have done that numerous times. And we've had trial runs around that. Supply chain is usually a logistics/leader role within that. Very formal process to make sure that communication is happening and status reports are working well. Last time we formally stood it up (for a trial) was a recent active shooter drill. Recent formal use – we stood it up during a nursing contract renewal because there was a chance that nurses would strike. So, we stood it up then in case we needed to communicate about that.	80
		Supply chain, and Infection control team, Risk Managers – they are the experts and running the show and we would help to glue the pieces together and make sure all that communication is a happening appropriately	88

		Communication and education coming up with an institution wide mechanism to make sure everyone is hearing the same thing. Make sure directors and leadership is hearing the same thing	86
		it would take a lot of communicating and system building	86
		[How do you hear about any information you need to make sure you are protected, email, and training sessions?] - Email	109
		IC took the lead. By the time training was done? Several months. Initial training of certain people - maybe a month. They had to do build-outs.	107
		communication with the staff and that it isn't due to budget constraints – kind of in a sense a desperation move and doing best to keep people protected	106
		[Plans on how to communicate during the flu?] • Internal comm device – and we also have a plan for if that goes down. We don't have everyone use a hand radio, but we do have walkie talkies. Depending on the information, there are diff ways to communicate. Also depends on if a communication line is down. We use whichever one is working.	39
	12e Pandemic planning and coordination		
		Issue with that – how readily available are those masks? If the point is to reduce the amount of masks necessary, we have to have some way that these 5 masks will last me 30 days.	60
		I don't like emergency procedures to be just for emergencies. If you can engage them all the time, its more natural. It's not new, and we don't have to re-educate when it's a pandemic.	45
		Q. Do you have a surge plan? A. Yes, its required. CMS does that. And regulatory agencies, like joint commission.	39
		All the hospitals trying to figure out stuff. Training they sent didn't match the equipment they sent. So, knowing that that's what will happen, I like more lead time. I also think that if we're given 10 min we'll learn it fast. Wouldn't be the first time we put lipstick on a pig.	60
		In an emergency, we would do "just in time" fitting for those that will be coming into contact	39

		with patients. This training is done on the fly - Gather everyone who's here and give them quick training – maybe 10-15 min. but depends on the amount of hoods we have. We can do 4 people at a time.	
		We need better buy in from ambulance service. Don't know if they've been given enough resources for planning for how to actually move a patient. My guess they are anticipating the federal team coming in to help us.	81
		The ideal roll out would be before we need it, so that we have time to plan/prepare/preach. I'd say I'd want at least a couple of months.	44
		This is a change management issue that needs to be involved before a pandemic. There will be distrust. This new procedure needs to be implemented early. Create a vision. Don't spring it on everyone for the first time during a pandemic.	45
		Believe so. IC would be responsible for that, or Business Continuity – they do a lot with bio outbreak. Sarah Smith. But I think IC are the holders of that policy. And supply chain also gets involved.	107
		If we had to, we could turn two floors in our building to neg pressure floors…do not take that lightly. Probably close to 80 patients if we had to do full-fledged unit for pandemic flu. We could handle more but not advertising it.	81
		Could see health department saying you have to use one of these [UV units] … we have 50 in the reserve and we're giving them out.	81
		[Ebola] Very concerned but working closely with Chicago department of health and the CDC, and because we were one of the resources named here felt fairly confident we could handle it – only had 2 patients we took care of - if it would have continued we would have run out.	96
		Fed could be better We deal primarily with the city – living in Chicago, the Dept. of Health is significant and kind of dictates what happens for Illinois. The state DOH we work with them occasionally and primarily are colleagues. We were the first to receive a patient; they were held at O'Hare then went to Lurie and then came to us. Think the city is capable, good infrastructure in place; it's about timing and how effectively they can roll it out. And some has to do with supplies and if they fall short they need to rely on fed govt.	96

		Q. Do you have a preparedness plan for a pandemic? A. It's embedded - our supply list - is in our plan. I can't speak to numbers.	39
		It initially started as Ebola prep inventory. But now it's not specific to just Ebola. There are some supplies stored specifically for Ebola, but also other needs. Our intern just refreshed that area this summer - made sure nothing was expired, made sure things were still well-documented in terms of inventory control.	80
		Really no legal requirement but regulatory. We have to have 96 hours of all critical supplies on hand to maintain hospital operations – when you are looking at a pandemic situation and large influx you would need more on hand and would need to be included in the emergency preparedness. If we saw this situation, stand up HIC and assess the supplies we need and look at our census to determine what was needed or decrease our census to allow patients and staff to take care of.	96
		Additionally we have a business continuity team (disaster preparedness, and emergency). We stood up this infrastructure when Ebola happened so we have a really strong leadership team that stands up this command center – If there were some high mortality we would certainly stand up that infrastructure within the organization and the roles and responsibilities were clearly delineated across the organization and all the departments mentioned . Think we saw that structure with Ebola.	89
		If you are aware of a pandemic is evolving any idea how far in advance something like this should be arranged or made available. As soon as possible – two months to get a process like that up and running here for the whole facility, push from top down, expectation, this is what we have to do and the training involved. We've responded to reg. agencies before…	11
		When the Ebola scare happened, we learned how to don and doff. We had a whole course.	35
		Yeah, but that was different bc w Ebola, there is a certain way to don/doff/dispose. Very precise, Step by step.	33
13	Cost and Risk		

13a	Cost analysis	then cost, if it's going to cost a lot of money then can only get 2 then I would have to centralize it	81
		Reluctant to hold a lot of inventory.. is the expiration date. Date comes up-we have a loss expense carrying inventory	4
		Buying [UV units] is a huge capital outlay; what would the cost, would have to prepare – potentially a lot. Don't imagine it would be process it would have to be planned decision to have on hand in case of emergency	11
		Part of my background is in corporate sustainability and I am part of that program w/HCA. My interest lies within re-using something instead of discarding it. I'd be interested in making it part of our routine, not just for a pandemic.	45
		PAPR is $60/70 + the cost of a filter. May even be more now. A mask is ten cents. But, if it would get you through a pandemic in a safer way…We don't have many PAPRs available right now.	62
		I see them [state dept. of public health] as a resource because I can't see most hospitals buying this unless there's a cost benefit and again there's the ick factor with employees	81
		Again, we've got a purchasing group that has years of experience in developing research to compare products. Is this is a new product? I don't usually get involved in purchasing and putting it out for bid, or getting literature. But yes, before we embark on a program to use these, we'd want detailed information about the product and efficacy, whether there are competing products, etc.	59
13b	Risk analysis		
		What happens if we think it's working, but it didn't disinfect? I see liability if it fails. What does that look like? Is it a class action suit? Responsibility of hospital, company?	44
		Staying up to date w/what is the evidence based practice. What if standards change and we've made the investment in this? Could be a financial loss.	44
		From a contractual standpoint, I'd expect the hospital to enter an agreement w/the supplier or manufacturer so that we can protect the hospital against product defects and injuries from the unit.	59

		Still interested in understanding the equipment side. Sole source, multiple source, or companies that could make a product for what you are talking about?	8
		Our Infection Control (IC) group often looks for manufacturer instructions for use around things like this. So, the manufacturer of the mask needs instructions to support this. A note especially if it's a single-use product only. That can be a hurdle for us. For example, in our pediatric hospital, we have a bottle warmer product w/a disposal insert. It's expensive and a custom product. We're like, do we really need to change this out after every use? We could have liability issues w/ the manufacturer. We have to follow their instructions closely. We looked at it the instructions and said this doesn't make sense. So, we had to struggle with who has liability. I can see that being an issue. If they said "No, you can only use it once," then we may have the liability if something goes wrong. That would go to our legal counsel. Infection Control looks to manufacturer recommendations. If there isn't an agreement, med legal would need to get involved.	80
		Biggest issue from risk mgmt. wouldn't be the disinfection of the microbes on the mask as much as what our guarantees for reusing the mask if the respirator is still effective.	106
		That would go into the nature of extent of the situation. If it's reg. flu season we are not going to accept that risk. If we are dealing with Ebola type situation, the supplies didn't reach a shortage state. Still not go for the reuse. Unless the state comes out that we have to do this, if there is something worse than Ebola and a crisis in every hospital then you look at this-- don't want to say cutting corners -- but it is you will look at ….it's safe and been tested but not waiting for the data b/c imminent threat to clinicians and patient safety	96
		You wouldn't want to make a bad situation even worse to suggest it is safe and then have all your health care workers get sick b/c it is not safe. It is risk analysis b/c you are not going to start with this.	96
		What difference does it make if the manufacturer of the mask is the manufacturer of the unit? They know their product better than anyone else – that is something that would have	96

		to be tested by others outside of them. They would clearly have conflict. It would be loss of revenue for them.	
		From liability standpoint if the manufacturer says single use and we use it multiple times then are we legally liable?	81
		Are we able to afford more than one, whose going to pay for it the hospital?	99
		How many will be placed in the hospital?	110
		We'd want it to be a reputable manufacturer - not a start-up operation.	59
		I'd be looking for a contract from beginning to end, all duties involved in between. Fair market value compensation for our involvement. In addition, the appropriate caveats or disclaimers or identification provisions, where the hospital is agreeing to be liable for any failure or breach of contract. But would not be responsible for any defective equipment, for example. This is where I come in. If there can be any injury or damage associated w/the machine	59
13c	Selection of UV Decontamination Unit		
		Process would definitely need to start at HCA HQ. We couldn't secure the funding to purchase them without it.	44
		[research?] A Business plan. Determined effectiveness of product.	44
		HCA would need to be involved	45
		Nothing comes to mind. It's not something that is providing treatment, nor is it competitive in the marketplace. I don't see regulatory, state or local approval being required.	59
		This is at the forefront of sustainability, it's amazing. It's supposed to be for a pandemic, sure. But if we could do this with all PPE, boy that would save a lot of money.	84
14	Personal Accountability	Could see people not doing it, think we're a little lax right now – I could see a nurse trying to run out really fast to grab something. Think if it takes a lot of time and gets in your way they will not follow.	68
		In the non-pandemic timeframe, people have become somewhat lazy in terms of maintaining awareness and supply of their own fit tested N95's	10
		If we can't follow our protocol correctly on a daily basis, how will we do it during a pandemic?	50

		[pandemic breakdown?] Education. But there needs to be accountability. For the provider, nurse, etc. that hasn't been exposed to that level of expectation, compliance could be an issue. Ignorance. They have competing priorities and they don't always see/understand the value in something. The nurses are young. They haven't had a lot of experience yet	44
		We trust that who we are [fit] testing is telling us the truth. Most tell the truth. But there will also be those people that lie no matter how much we explain safety to them. Training is same for everyone, everywhere, any dept.	39
		Barriers to adoption? Getting compliance from people, because of the time required	42
		When you're fitted, you can still smell the saccharine but sometimes you just say its fine. That's a little worrisome…does that mean it's not working to keep you safe?	38
		To be honest, during fit testing, some people aren't 100% honest about tasting/smelling something. It's just such a routine test and they want to move on.	37
		Our new employees seem to have different employment philosophies. They're not all engaged, professionally invested. There's been a transition in the healthcare field (in my opinion) that's driven by economics. It pays well, there's always jobs available. Only takes 2 years in college. I fear that's what drives many.	44
		[pandemic breakdown?] Education. But there needs to be accountability. For the provider, nurse, etc. that hasn't been exposed to that level of expectation, compliance could be an issue. Ignorance. They have competing priorities and they don't always see/understand the value in something. The nurses are young. They haven't had a lot of experience yet	44
		All it takes is one small breach. You can tell people all day. But unless they are engaged and a part of the action piece and integrate the mindset, I don't know.	44
		But it's at the clinician level to follow the process and where it could breakdown.	65
		[drawbacks]People not following the protocols: taking off gloves, sanitizing, taking of the mask, etc. there will be people who break sterility and contaminate the outside of the machine	74

		In ER, you know you're already exposed to whatever walks in the door- you're front line. You start getting lax and not caring. Maybe the patient hasn't been tested yet, or had an AFB. Unless they're seeing symptoms, they don't worry too much. Not good practice, but I've seen it.	33
		Folks become complacent, may be less complacent when they actually see someone very sick whereas with handwashing they are not seeing what gets on their hands. Think with pandemic there would be less complacency.	94
		has to be something – there are days where you have trouble getting teams to put on a yellow gown much less a mask	118
		May need to use a scare tactic - serious fine/penalty for people not complying. Class will last for about a week or two – then back to routine.	108
		another issue I've seen you see the nurses coming out and doff in the area they come outside that door and then take it off	110
		The perception of the perceived danger you are isolating from effects compliance. When we have the Ebola here people were pretty serious. If we have an "oh shit" situation then they would take it seriously	74
		[vulnerabilities?] Our employees are biggest vulnerability, pts are good to say I have this or that, our employees come to work even if not feeling well. They deny not feeling well – come in contact with kid's school or grocery store illnesses – employees thinking of themselves as indispensable and that endangers everyone else.	81
		Concept around social norms and especially in community setting and hospital setting – people more than likely to do it because you trust them – then it is second nature. One piece I'd want to look into and understand… if you had the buy-in from leaders and trust of people in the community – get feedback from whom people respect.	85
		With that within the med community at each level who are those people. Front line staff you would need to have high level leadership and then still need someone on their unit.	86
		What troubles me in an ED setting – rush of 100 patients coming in, id who is managing the system, where will the sterilized masks be stored. Or if it's on the clinicians themselves to	28

		put it in the device and leave it there for the next person.	
15	Barriers		
15a	PPE inconvenience as a barrier	[barrier] user compliance	71
		think it's inconvenient; putting gowns on in isolation rooms, its either inconvenient and don't have time for it or that they are going to touch anything or that the patient has an infectious source	99
		During code, supply is quickly depleted. What 115 said earlier. Could be up to 30 people showing up in the room (I think b/c this is an academic institution and people show up for education). Out of 30, 5-7 may not be wearing a mask in that patient room.	113
15b	Time pressure as a barrier		
		Q. [You think staff would become impatient w/ waiting a minute?] A. Yes.	107
		10 minutes to warm up – if it's not on and someone has a dirty respirator they may discard it rather than wait on machine.	95
		we have a 24 bed MICU – I think the decontamination will be time-consuming, especially if you decontaminate outside the room then wear in your workspace, then decontaminate again before patient room that would be a lot of time	93
		another concern if you are wearing it in your work area and clean it before your patient's room, come out clean again and then put it back on – that's a lot	93
15c	Habit Interference	People that would have to wear the mask: they're the ones you have to convince because the culture here is they are disposable…	10
		So ingrained to use it one time, think it would take a lot to change my point of view.	93

F. INFECTION CONTROL NOTES (SELECTED)

(Note: the information below is comprised of real-time notes captured during interviews and presented verbatim).

Q. Comments on general use of N95 (selection of process, use, and disposal)?

- In the non-pandemic timeframe people have become somewhat lazy in terms of maintaining awareness and supply of their own fit tested N95s, we have two types (Moldex and the 3m) The size small of the Moldex is not same as size small for 3m. Think in an institution such as this it is an enormous undertaking to refit test every year; and goes by the way side in many institutions. Focus on people who are mostly at risk (ED, pulmonary, infectious diseases, etc.) as opposed in a pandemic where it will be everyone. Most facilities don't have a large cadre who are able to re-fit on a large scale. Just the process of fit testing, we have more than 5000 employees – we've done that in the gallery– almost like a pull-pod (if you have a product (e.g. vaccine)) you can pull ppl into an organized algorithm ala Disney end pt getting on the ride but the process quite long – do step along the way or push ppl out to where the workers are. Every year we practice our pull pod by distributing influenza vaccines. Think that's probably the most efficacious way of re-fit testing. You gain and lose 10-15 lbs. and the N95 is not a correct fit as to when you were originally fit tested.
- Fit testing – we need to be confident about them fitting – otherwise we can't ensure their protection. We have to trust the products we use. With fluid resisting gowns, for example – we didn't know at the beginning of Ebola that we needed fluid resisting gowns. Once we learned about mode of transmission, we had to take fluid barrier precautions. We just don't know what we're dealing with right away.
- You have to watch for daily CDC updates during an influx of disease/new pathogen, to learn more about it. I'm on the ListServe - they either host WebEx, or its phone based. There are so many people listening in on these calls, and they are recorded. Mostly for providers to provide guidance. CDC will post information as it becomes available and is confirmed. But, initially, there will be a lot of phone calls. They'll do phone calls initially. We go by those guidelines.
- People driving respirator choice is the operation group. They fit tested the employees and narrowed it down to three masks, annual fit testing. Look who is passing on a mask and then decide – get input and then purchasing takes care of it. We had awhile where we were using 5 masks (Kimberly Clark) – had difficulty finding them. Manufacturer back orders and supply and demand issues. Usually during times of increased need of some type of resp. illness. With Ebola we had a hard time getting just about everything. N95s was one of the items.

Q. How long to obtain them [FFRs]?

- 3-4 months – we have a proactive purchasing team so as soon as they are on the market we buy. ERCP scopes is an example - other hospitals were having issues with another brand so we switched brands and bought pallets
- Sage bath wipes – did voluntary slowdown and there wasn't going to be enough for us, found fast alternative and bought two pallets worth. We are really proactive about what is happening in the market and from an ID standpoint and do we have enough.

- H11O, we had 2 pallets of N95s and are probably too old now (8-10) years – are they use worthy – there's no date on them. Filter still effective, etc. when we unearthed them we decided to dump them – sitting in a hot warehouse for a long time – don't know how long they can.
- Managed by supply chain, par level and they are stocked based on par level. If we had to slow their use, supply chain would help us. Using the CHG model – they recover all the product and then re-dispense to the places needing it. With H1NI we pulled back all products to our offices and determined where the patients were likely to be and provided to managers to give to employees taking care of those patients. Normally they'd be out in the counter and supply cabinet. For residents because they are mobile – they would call hosp. epidemiologist – she would give it to them, and tell them how to protect and use it – don't fold it, don't squish it… here is the bag to keep it in. Then if something happened to it they would call for a new one. Real challenge.
- We'd have to run 3 shifts; one accessor can only do a half dozen to a dozen people – all that equip has to be reused for each person…probably be a week. I don't do environmental health and safety that's who does this. People have to be cleared for fit testing through employee health, process is environmental health and safety, and materials management has to ensure the equipment is available.
- Once you reach a point of a pandemic and looking along the line of armories the contribution of the aerosolization in the air flow becomes minimal. Once you start getting to alt. care facilities and – gymnasium…not worried about aerosolization. Primarily droplet concerns 2-6 ft. from a patient. Have talked about who you prioritized limited availability of flu vaccine.

Q. If there is more than one highly infectious patient?

- I wouldn't' utilize this approach as I would rely on large scale use. I would look to my background in infection and epidemiology to cohort patients to limit the number of healthcare personnel that would be caring for the patients in the cohort. Assuming this is the beginning of the pandemic; those who have gotten the flu could take care of patents w/o having to use the n95. Early on in the pandemic, you would try to limit the procedures that would cause aerosolization of respiratory secretion you would be using neo-dose inhalers instead of nebulizers, limiting bronchoscopies, and limiting intubation - going to limit opportunities for aerosolizing procedures. In which case droplet precautions should be adequate, we have to do things to patients in general to create an aerosol that will enter the lower resp. tract to the particle size that you are talking about with an N95. If they are incredibly sick and intubated I'm less concerned with the n95; we no longer have to remove from respirator and suction them because they have in line catheters so not creating that scenario of repeated aerosolization. How we approach then is diff than now
- We're screwed – we could ramp up to 2 patients. More than that we would transfer it out. Since [location] (CERN – [location] Ebola …) [3 hospital names] and us – at the time we all agreed we would take these patients if one happened. Our max is 2, [hospital name], can take 2 can't remember the others. We actually received 2 – to do this we had to relocate – the risk of moving an ICU patient is critical risk because it increases their mortality. Agreed to not do this until we had a quarantine unit. Our new ED has one unit – with trained observers. If we had to, we could turn to floors in our building to negative pressure floors do not take that

lightly. Probably close to 80 patients if we had to do full-fledged unit for pandemic flu. We could handle more but not advertising it.

- We don't want to have to do the PPE for that many people. Think that's what would tax our system. We have JIT order on hand, minimum of 3 day stock, if it's a national issue we'll buy pallets. We would need to be first in the area to do that or other hospital of similar size will do the same things. With Ebola we were trying all kinds of stuff. Ended up going to cleaning room tech to give employees something to cover their heads. Imaging if N95 reps and there's an issue then everybody buys. Then what do we do with our critical resource – do we reuse, we could go to our PAPRs as long as the filter is working – currently have 100 PAPRs – filtering the defining issue. At some point the employee doesn't want to wear something that was on someone else's' face.
- The PAPRs' filter have a light indicator that tells you when it's done – filter needs replaced. We would use N95 the first couple of days and then move to PAPRs. PAPRs issue is ability to hear – we have walkie-talkies and ear buds but they don't work very well.

Q. Compliance and monitoring use of respirators?

- 1 hr. for cycle time this institution observes for N95 use.
- We don't put a timeframe per say…most people won't last a long time in an N95; part of the Ebola program – they are not the way to go for a labor intensive patient – healthcare workers – I can't' even with last that long in and N95. When I'm going to evaluate a patient – tried fit testing in every one – if a patient requires intensive care as in a pandemic influenza patient and n95 is exceedingly difficult to work on. We've had some patients that were 1 to 1s and it was difficult (safety watch sitter; not necessarily) mental status changes – N95s are not comfortable or easy to work in. having trained personnel on both N95s and the PAPRs especially that cadre of patients and proportion of patients in this scenario…better cared for nursing staff who were trained in the PAPRs. We're not talking about Ebola patients, if someone is a pandemic patient and are intubated – once they are intubated not really in my mind an aerosolization risk, the risk is the intubation and removal.
- We really don't when we do rounds we assess that they have it on; employees are taught to do fit check but there is no one standing outside the door to check that. If we go into emergency mode we have a practitioner that stands outside door of patient and monitors the PPE – based on organism (btw we've had plague, Ebola, small pox virus here), we have a whole plan if we had a pandemic. It wouldn't be pretty. We could control in house transmission unless we were overwhelmed by staff being sick. We are different in flu season and will quarantine our sick employees – keep them out of the hospital.
- Respirators go in trash unless soiled. With an Ebola patient our disposal is red bin in anteroom then that gets bagged up and then taken away, we have team highly trained - we had a case of MERS - rule out MERS.
- We do direct observation for isolation patients in care (to observe that people are wearing masks correctly). Not just for flu – any isolation. Rarely have an airborne isolation patient. We do have TB in the community but we don't usually in-house. During that time, you need

to do daily monitoring of air flow, etc. but there is direct obs. [name] is very serious when she's training people, so they get it.

Q. Where do you think FFR use could break down during a pandemic?

- For the tuberculosis program, if it becomes torn, straps break, bends and cracks – you can reuse it until it no longer has a correct fit test or its physical viability is shot. If I'm on rounds or consul service I always have my N95 on me because after 2 weeks on service the nosepiece starts to crack – I exchange mine. Not sure how much extension you can get out of using UV light or using a surgical mask. You could probably extend if for some time but not actually sure it's going to extend its life significantly just by virtue of the fact donning and doffing, donning and doffing, the nose pieces are foam-- they crack. The straps are stapled.
- Right now, we use disposables – they are not re-usable. Tronex is the brand (cone-shaped). Also use Kimberly Clark duck bills.
- We do not store massive amounts of suppliers here. We don't have the space/capacity. We bring in suppliers from an off-site warehouse. Storage/retention of pandemic suppliers would be a challenge, especially for one-time use products. Big limitation for us - to be able to care for patients and remain safe.
- I don't know how big the supply is in the warehouse.
- (At my previous job) I'm used to having pandemic suppliers on site – for H1N1, Ebola, natural disasters. Makes me nervous that here we don't.
- Our employees are biggest vulnerability, pts are good to say I have this or that, our employees come to work even if not feeling well. They deny not feeling well – come in contact with kid's school or grocery store illnesses – employees thinking of themselves as indispensable and that endangers everyone else. Did this with SARS, everyone had to Purell when they came in the door, etc.
- Space constraints for patients
- The "unknown" - we are not always initially certain of modes of transmission (like for H1N1). We were donning and doffing everything. We didn't know what H1N1 was. Once we did know the mode of transmission, we could prepare appropriately. In a true pandemic, we don't know right away how to prepare.
- Also, as you're leveling out, it's continuing to spread in the community. Your patient influx will stay the same or increase. So, it's overwhelming your system. Other hospitals are also using our resources from that storage unit/suppliers, so it's not just us affected. I think [location] would use it, I don't know who else (1-2 at least) – I'm too new. And for things they don't store there, we need 3rd party management system company to supply. We don't have a stockpile.
- In [state name] where I was, we had an emergency coalition that communicated w/other areas, so we always knew what supplies we had on hand. Received daily reports during pandemics. I don't know if that exists here. I know there's a patient report, but I don't know about for supplies. It's been a culture shock for me. This area seems more at risk of pandemic to me - more international folks, tourist area, more germs b/c of humidity, water.

Q. How to prioritize?

- They use these in the GI lab every day - So I'd go in high-use areas first. B/c we do bronchoscopies in there. That's part of their everyday use. They use surgical masks.
- Respiratory uses surgical masks, but not many N95s. ER doesn't even use them every day. GI would be better at challenging limitations for re-use, too. They'd be a good group to talk to. I'll call to see who's around.
- ED is going to see the most, then how sick are they so then the ICU, if going to certain nursing units then to them. Have great HICs team here – hospital command – talked about where the sick patients are, etc. we don't have a lot of TB patients here – prioritizing would be pretty easy.

Q. Prep plans at state, and local adequate?

- [location] Department of Health is wonderful and with Ebola worked well as a team. We had some glitches for transporting patients. We need better buy in from ambulance service. Don't know if they've been given enough resources for planning for how to actually move a patient. My guess they are anticipating the federal team coming in to help us. Think they've done a great job in trying to get stockpile for us. They periodically put out a bulletin. This is what we have, have monthly meetings of CERN we participate in lead by the Department of Health.

Q. Do you use UV here at the center?

- We use Surfacide – used for rooms a 3-tower system. We had True-D for a while and ended up going with Surfacide – you can break the towers apart if needed and disinfect 3 rooms at the same time – would take longer. We have 12 towers – so could do UV disinfection in a discharged patient room.
- Hydrogen Peroxide vapor
- Use it at Argon labs – colleagues there helped train my team on using the PPE and the procedures
- Use this in labs if they have a spill.

Q. Thoughts about using the UV unit (Appendix C) in this report)?

- This can't be looked at in a vacuum (points to diagram) – yes they can sterilize the external and hopefully portion with UV…large scale they both sides have to be sterilized. That science is not my concern. They don't last very long….you might get away with using one N95 per shift, per person but not two weeks. Other thing is they go in and out of the rooms, you bundle your tasks you go in and do those tasks and then you get out…people used to going in and out which is a diff work style. When they are in there longer incredibly uncomfortable in an N95

- Bit questionable – think different technique that's not usually how we do the FFR. I don't like it – I believe the size – a little loss for words – questions process….don't think it would 100% really clean.
- Think a little more cleaning needs to be required to make sure it's 100% clean from decontamination. Any type of virus that's on the FFR – don't know it's going to be 100% - think I'd have to get over that.
- From an infection control standpoint, if there is any organic matter on it then I'm worried that something is hiding in that matter. If someone coughed in it, makeup and lipstick, etc. Can UV light get to it? I've been sick and worn a surgical mask all day and then go to lunch and then…ewww.
- It has an elastic does it make it stiffer or looser? The things that make it fit to your face. If there's heat then the elasticity of the rubber would compromise
- If you take gloves and leave them to UV light they discolor – will the UV do any damage to the product – it might decontaminate but. With our sterilization we hammer in you have to clean it before you disinfect it. How we are suggesting throwing it in without cleaning it. My immediate response is it really killing the virus. 0ther question is where do you put it, is it in patient's room, do I take my respirator out and put it in the anteroom, somewhere else. The other thing is I want mine back – I put mine in a slot and I want mine back out of that slot
- Is it going to be in the anteroom, or at nursing, I'm bringing my N95 in a plastic bag and then clean it, maybe in the anteroom
- What I was thinking in anteroom
- You would have to put it in anteroom so people don't want to walk away with it. You don't want anything you touched leaving that room you don't want anything walking down the hall
- Then cost, if it's going to cost a lot of money then can only get two then I would have to centralize it
- In Ebola people were getting really funny about the shrouds and sharing them – I write my name on it b/c I want mine back. Even with blue caps God forbid my colleague had lice – don't know what they were thinking – a lot of ick factor. People saying I don't' want to touch that or reuse that. If there was down to no choice it I could see using this but you would have to be down to no choice. We are a union hospital. Would see our nursing union saying, "What do you mean you won't get us a new one." "Do everything you can to get a new one and then we'll consider, or you are trying to be cheap?" We've heard that on other things. Would need to overcome that. Don't see this for all the time until for a pandemic – yeah – could see health department saying you have to use one of these we have 50 in the reserve and we're giving them out.
- I've seen these before. This is used in some facilities, but not ours. Looks similar to a unit used to disinfect handheld tablets.
- My concern - With UV, you need to do an initial disinfection, and then UV is a second layer. Also, has to be a product that can be cleaned w/ a liquid agent first. You can't just throw UV at it. You can't get the mask damp, it will decrease its effectiveness.

- What are the kill claims for different influenza strains? It's one thing to talk about one strain. About what about SARS, MERS, new fungal infection? UV light is not approved for those. Most hospital disinfectants are not approved. We just use Clorox - That's how bad it is.
- Back to Ebola, there were no clear guidelines– so we disposed of it and got new stuff. When we talk about a new pathogen/pandemic flu, you just don't know.
- So, I don't know if I'd trust this UV process. I wouldn't trust it for my surfaces, so why for something I breathe through? Why would I want to breathe it into my lungs and expose myself? Maybe I'm more cautious than most, but its b/c of my experience.

Q. Do you see the state health department as a resource?

- I see them as a resource because I can't see most hospitals buying this unless there's a cost b benefit and again there's the ick factor with employees; if you leave the product out most employees would take new. There is surgical equipment that gets reused on other patients – you have knee surgery and they use the bit and the burr that were used to drill someone else's bone – people don't realize the quality control for the original is only 10% but the quality control for the reprocessed is 100%. They're kept in same bin but they will still only use the new one because of their perception. I think we need to get over that part. If I didn't have any choice but to reuse I'd reuse the mask.

Q. What information would be needed to believe it is effective?

- The state health department or the FDA – because in this one we are being told to reprocess something that is a single use item. From liability standpoint if the manufacturer says single use and we use it multiple times then are we legally liable? I go overseas and they do it all the time because they believe they can do it safely and effectively. There are things we can reuse like bits and burs – do we want to take on liability – that's a risk management and legal issue. We don't have anymore, here are our options and this is the best option. It would go through the incident commander in making that decision.
- Think some benefit of relieving the viral load on it. Do you have a quality indicator that shows it works? We have an Endo Cav Probe and it has a pellet it on it and then you put it in the machine and it shows if it's been decontaminated.

Q. Anything else FDA needs to know?

- If you are talking UV light then can we use our Surfacide or UV tower? We've used it for our rooms, and Candida Aureus virus recently. If it works for that why not for flu – can we put the masks in the room and lay them out and zap them with UV? What's the spectrum of UV light to disinfect?
- Concerned about what they are made of – the fibers – crisscrossing fibers – how do you ensure that everything in the middle didn't get contaminated? With filters as you breathe in the filter becomes better as it gets dirtier. Does the UV light get under that load?

- How did you test it, was it effective – did you cut up the mask? If you just wiped the surface of them you didn't get into the mask.
- I don't think so. I always say that nature's Clorox is the sun. I'd feel safe sitting on a park bench on a hot sunny day, next to someone with TB, without a mask on. Because it would kill it before it got to me. I've bought into nature's Clorox. But that's killing what's in the air. It's these unknown things that cause droplets and remain moist. It can't get through that barrier. That's why you have to decontaminate the whole room – you leave blood somewhere, and you just UV the surface, you're not getting below that layer. Back to the surface cleaning issue mentioned before.

G. LEGAL INTERVIEW NOTES (SELECTED)

(Note: the information below is comprised of real-time notes captured during interviews and presented verbatim).

Q. Comments on UV unit artist concept (Appendix C) in this report)?

- Legal standpoint ensures that whoever is doing it is appropriately trained and competent on the process – typically easier to do when centralized to train a few people rather than every person who would use a mask. Would also depend on the shortage and the availability of these machines. Sure you would have one outside each patient room. You would have it unit based I imagine. Would depend on my earlier question – are you going to use your own individual mask as you go into room or a bulk of mask at end of shift
- My bigger question is - if you have the [location name] population (50k) at our hospital – they would be the primary managers of the FFRs and their cleaning? So are you wanting to hand these masks out to the community? Will these units be located around town? Only the hospital? Is the hospital in charge of them?
- I'd be looking for a contract from beginning to end, all duties involved in between. Fair market value compensation for our involvement. In addition, the appropriate caveats or disclaimers or identification provisions, where the hospital is agreeing to be liable for any failure or breach of contract. But would not be responsible for any defective equipment, for example. This is where I come in. If there can be any injury or damage associated w/the machine
- I don't analyze tradeoffs. But my facilities would be interested in having whatever backup or failsafe mechanism is available to prevent a shortage. So, having the decontamination unit would be paramount.
- It's not something that is providing treatment, nor is it competitive in the marketplace. I don't see regulatory, state or local approval being required.
- From a contractual standpoint, I'd expect the hospital to enter an agreement w/the supplier or manufacturer so that we can protect the hospital against product defects and injuries from the unit.
- We'd want it to be a reputable manufacturer - not a start-up operation.

Q. Potential concern(s)?

- Think the federal governments needed to get involved much sooner [in Ebola response], what we saw were these smaller hospitals that were unlikely to ever come in contact with Ebola were hoarding things, when our supply found this we were able to pull back from these hospitals and direct those to the facilities they knew would be taking care of these patients.

Q. Are the local, state, and fed plans adequate?

- Fed could be better

- We deal primarily with the city – living in [location name] the Department of Health is significant and kind of dictates what happens for [name of state]. The state DOH we work with them occasionally and primarily are colleagues. We were the first to receive a patient; they were held at [name of airport] then went to [name of hospital] and then came to us. Think the city is capable, good infrastructure in place; it's about timing and how effectively they can roll it out. And some has to do with supplies and if they fall short they need to rely on federal government.

Q. Any vulnerability in ability to protect care providers from respiratory infections?

- We follow the CDC guidelines, there are pubs out there around limited use and extended use of these masks, and we would not go beyond their guidelines. We would need for them to come out and stand behind it that the sterilizing works for me to feel comfortable.
- Have a lot of unions and a lot of our front line clinical providers belong to the unions and they look at the CDC guidelines and recommendations and that our policies align with the CDC.
- We're going to need – for N95s are going to have to be approved by Infection Control and CDC. They are pretty prescriptive right now for when to use extended use.
- Don't know if our unions would ever go for it – would be an uphill battle
- We would get the union stewards involved immediately, don't go and ask for permission, but would have to go and present a change in practice and educate them why it's safe and proven. But we would need backup from CDC, very challenging to go to them and say we are going to use the masks without having the CDC backing in hand
- That was a challenge with the Ebola because the CDC was behind on some of their guidelines.

Q. What are legal considerations for maintaining FFRS during a pandemic?

- Really no legal require but regulatory. We have to have 96 hours of all critical supplies on hand to maintain hospital operations – when you are looking at a pandemic situation and large influx you would need more on hand and would need to be included in the emergency preparedness.
- If we saw this situation, stand up HIC and assess the supplies we need and look at our census to determine what was needed or decrease our census to allow patients and staff to take care of.
- You would have to prove it is standard of care, sufficiently tested, enough data out there that it's safe, backing of CDC, IC, ID that we would feel comfortable allowing this type of reuse. Now that's in standard course of things, if it's an emergency pandemic you would revisit this on a daily basis.

Q. Managing risk, tradeoff between shortage of FFRs and decontamination. From your POV – what is acceptability of that risk?

- That would go into the nature of extent of the situation. If it's regular flu season we are not going to accept that risk. If we are dealing with Ebola type situation, the supplies didn't reach

a shortage state. Still not go for the reuse. Unless the state comes out that we have to do this, if there is something worse than Ebola and a crisis in every hospital then you look at this--don't want to say cutting corners -- but it is you will look at …it's safe and been tested but not waiting for the data b/c imminent threat to clinicians and patient safety.

Q. From the issues of risk analysis and liability and for this to be used on the premises here

- What difference does it make if the manufacturer of the mask is the manufacturer of the unit? They know their product better than anyone else – that is something that would have to be tested by others outside of them. They would clearly have conflict. It would be loss of revenue for them.
- Clinical engineering would need to get involved, they would need to assess the PMs, whole process for taking on new piece of equipment

H. UNIVERSITY OF NEBRASKA MEDICAL CENTER SME NOTES

On April 22, 2017, Dr. Nemeth and Mr. Heimbuch interviewed two anonymous registered nurses (RN #1 and RN #2) at the Biocontainment Unit of University of Nebraska Medical Center who had experience caring for three Ebola patients. Their experience provided insight into first person experience dealing with a high mortality virus that equals the threat that an influenza virus would present during a pandemic.

The Biocontainment Unit trains once a month, alternating either a physical drill or taking electronic education. Members of the unit staff are prepared to use two levels of personal protective equipment (PPE):

- High – Scrubs, underwear (so no items are taken home), disposable boots, washable shoes, Level 4 gowns, N95 respirators, face shield, three pairs of gloves, head cover.
- PAPR level – Same as High, but a "tent suit" and many disposable boots and the PAPR. Would use for airborne or blood splash contamination

They cared for a patient in 3-nurse teams over a 12-hour shift. Each wore their respirator continuously during a 4-hour rotation to avoid self-contamination. They used High-level PPE for the first and second patients they cared for. For the third patient, they wore PAPRs during transport and care due to the advanced state of his disease.

In their experience, four issues affect respirator use: pulmonary function testing, fit, seal, and don/doff procedures. RN #1 likened respirator use to "breathing through four sweatshirts," requiring more deliberate breathing and effort. This makes it necessary for healthcare workers (HCWs) to be evaluated for pulmonary function to ensure they can tolerate increased demand. Respirator fit seems to present less of an issue than seal. Each HCW must also be able to create an effective seal, but few know how to do that. Accessible, simple training in how to create a seal and don/doff PPE needs to include the rationale for procedures. They provide training to HCWs at the University of Nebraska Medical Center and have trained HCWs from 18 different disciplines in 1 hour. They make simple posters available with terms to remind HCWs of the correct order to don/doff PPE. They have also collaborated with Emory University in Atlanta and Bellevue Hospital in New York to develop a National Ebola Training and Education Center (NETEC) web site (http://netec.org/) for other facilities to learn from them. Not all facilities are as rigorous with such training as their facility because "ownership varies" (RN #1) and "priorities are different" (RN #2).

RN #2 expects that if appropriate equipment was not available to protect HCWs during a pandemic, they would not come to work. She has worn the mask for as long as seven hours with no problems. In her opinion, ultraviolet decontamination would help as long as she could ensure she would get her own mask back. Having the mask decontaminated while taking a break would be reasonable.

I. SURVEY DATA

Total number of respondents by location:

83 SUNY Stonybrook University Hospital (SBUH)

159 Gulf Coast Regional Medical Center (GCRMC)

45 University of Chicago Medical Center (UCMC)

Eleven GCRMC respondents were removed from the data because their answers did not fit the format to accurately calculate years of experience. (e.g., responded "over 20").

Total # of respondents by location

1. What is your job title?

Job Title	SBUH	GCRMC	UCMC
Physician	41 (49%)	2 (1%)	1 (2%)
Nursing	20 (24%)	105 (66%)	28 (62%)
Hospital Administration	3 (4%)	8 (5%)	3 (7%)
Academic	14 (17%)	3 (2%)	0 (0%)
Therapist	0 (0%)	7 (4%)	3 (7%)
Pharmacists	0 (0%)	0 (0%)	10 (22%)
Other*	5 (6%)	34 (22%)	0 (0%)

*Roles in Other include: social work, central sterile technicians, surgical technicians, phlebotomists, EKG Techs, Lab, Echo Techs, lactation consultants.

2. How many years of experience do you have in this role?

	SBUH	GCRMC*	UCMC
Minimum	0.5	0	.42
Maximum	48	40	36
Mean	11.61	10.65	12.38
Std. Deviation	10.74	10.61	10.29
Variance	115.36	112.52	105.99

Count	83	147	43

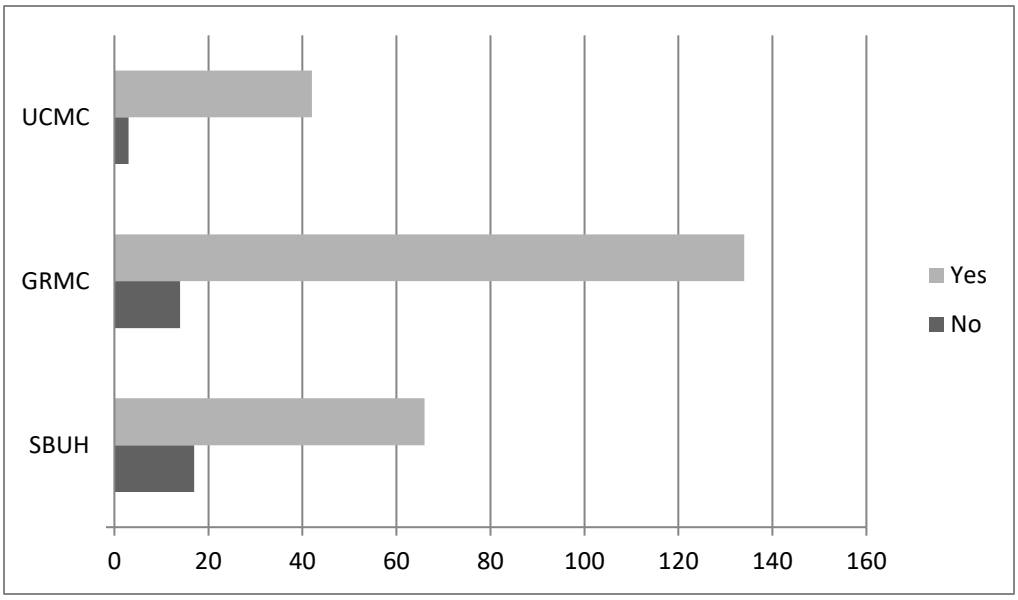
*Eleven GCRMC respondents and two from UCMC were removed from the data because their answers did not fit the format to accurately calculate years of experience. (e.g., responded "over 20").

3. How many total years of experience do you have working in a hospital setting?

	SBUH	GCRMC	UCMC
Minimum	0.00	0	1.5
Maximum	44.0	12.48	42
Mean	17.19	10.69	16.14
Std. Deviation	11.69	10.69	12.08
Variance	136.66	114.30	146.04
Count	83	146	43

4a. Have you had training on the proper use (donning and doffing) of FFRs?

	SBUH	GCRMC	UCMC
Yes	66 (80%)	134 (91%)	42 (93%)
No	17 (20%)	14 (9%)	3 (7%)
Total	83 (100%)	148 (100%)	45 (100%)



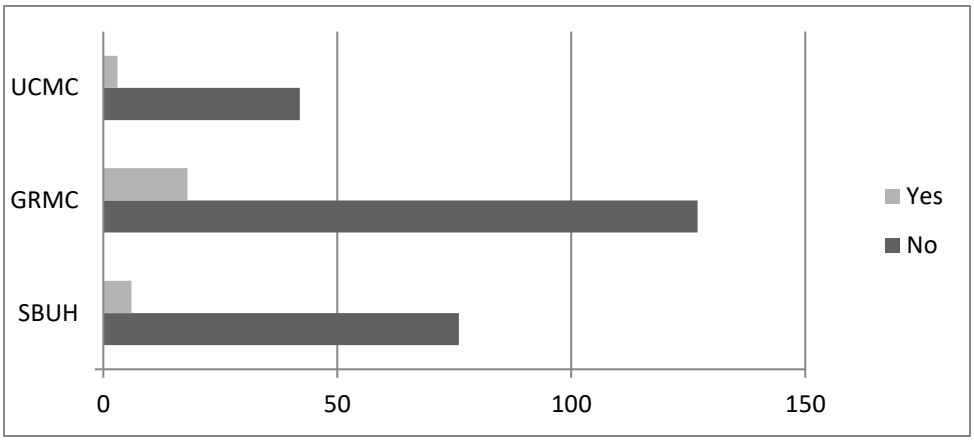
4b. How often have you had training on FFR use? (open-ended responses)

	SBUH	GCRMC	UCMC
Annually	26 (55%)	94 (90%)	35 (90%)
Once	5 (11%)	2 (2%)	3 (7%)
1 to 5 times	10 (21%)	8 (8%)	0 (0%)
Rarely	5 (11%)	0 (0%)	0 (0%)
Never	1 (2%)	0 (0%)	0 (0%)
As Needed	0 (0%)	0 (0%)	1 (2%)
Total	47 (100%)	104 (100%)	39 (100%)

Note: Only respondents who responded "yes" to Question 4a could respond.

5. Have you had training to decontaminate FFRs?

	SBUH	GCRMC	UCMC
Yes	6 (7.32%)	18 (12%)	3 (6%)
No	76 (92.68%)	127 (88%)	42 (93%)
Total	82 (100%)	145 (100%)	45 (100%)



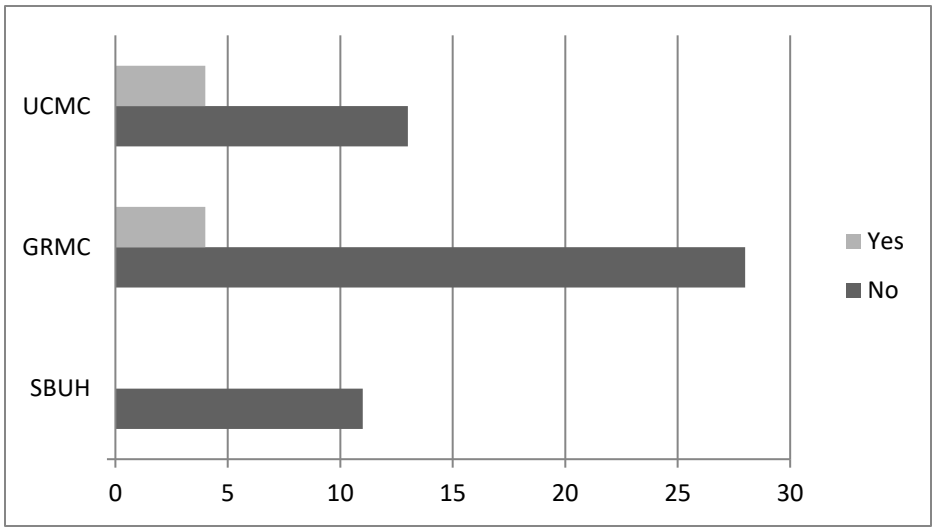
6a. Have you used FFRs during an emergency event?

	SBUH	GCRMC	UCMC
Yes	11 (13.41%)	19 (13%)	11 (24%)
No	71 (86.59%)	128 (87%)	34 (76%)
Total	82 (100%)	147 (100%)	45 (100%)

6b. Was this emergency event an influenza pandemic?

	SBUH	GCRMC	UCMC
Yes	0 (0.0%)	4 (13%)	4 (24%)
No	11 (100%)	28 (88%)	13 (76%)
Total	11 (100%)	32 (100%)	17 (100%)

Note: Only respondents who responded “yes” to Question 6a could respond.



6c. In how many emergency events have you used FFRs?

SBUH	GCRMC	UCMC
3	1	frequent patient care
6	100's	High Risk Delivery in OR
2	Once	1
1	N/A	2
too many to count	One Ebola scare in an HCA hospital in Myrtle Beach.	25
have no idea	N/A	4-5 suspected flu, TB and corona virus
1	1	
1	1	
only with TB patients	6	
1	1-5	
do not remember	2	
	1	
	1 code 1	
	More than 10	
	3	
	2	

Note: Only respondents who responded “yes” to Question 6a could respond.

7-9. How easy was it to… (Scale: 1=Very Easy; 7=Very Difficult)

Obtain an FFR

	SBUH	GCRMC	UCMC
Minimum	1.00	1.00	1.00
Maximum	7.00	7.00	5.00
Mean	3.73	1.89	2.19
Std. Deviation	1.96	1.29	1.47
Variance	3.83	1.66	2.15
Count	11	46	16

Follow FFR procedures

	SBUH	GCRMC	UCMC
Minimum	1.00	1.00	1.00
Maximum	7.00	6.00	4.00
Mean	3.00	1.71	1.89
Std. Deviation	1.54	1.17	1.20
Variance	2.36	1.36	1.43
Count	11	52	18

Dispose of your used FFR

	SBUH	GCRMC	UCMC
Minimum	1.00	1.00	1.00
Maximum	7.00	4.00	7.00
Mean	3.44	1.36	1.89
Std. Deviation	2.17	0.86	1.74
Variance	4.69	0.74	3.04
Count	9	50	19

10. Provide any additional comments about current FFR training, policies, and implementation procedures. ("Theme" column indicates data theme to which the comment was assigned.)

Comment	Theme	Source
Discard when soiled	10a - How the front line HCW uses now	SBUH
I have only used FFRs with patients on droplet and airborne precautions. I undergo training and testing for FFRs annually at recertification.	6a - Trained at fit testing	SBUH
if FFR includes N95s I have a beard so I could not be fit tested	6b - Annual refresher training	SBUH
I/m also military so know much more than stony brook provides	n/a	SBUH
I have used the bottom one exclusively at other hospital ERs where I was employed. Not at SBUMC	n/a	SBUH
difficult to schedule & attend a training	15 - Barriers	SBUH
Signage on doors is typically clear about what kind of FFR to utilize. Recently, I had a patient which required use of a respirator and I did notice that there was some difficulty in obtaining the appropriate stock of masks. Annual fit testing and instruction is adequate.	7e - Staging PPE at point of care	SBUH
Training is to occur annually for providers but this is not been implemented. To get training, one must make an appointment. Getting hospital units trained annually may be a smarter way to get this done with a train the trainer model.	6b - Annual refresher training	SBUH
I have worn them many times for scheduled OR cases	10a - How the front line HCW uses now	SBUH
They previously used to fit us for these masks on a regular basis at Stony Brook. This is one of many safety precautions that seem to have fallen by the wayside. I've had to use one in working with a TB patient but not for an emergency. I would have some concerns about whether every single area on the mask would be adequately exposed to ultraviolet sufficient for decontamination, especially in a crisis where staff may not be thinking clearly. In addition, when you are breathing and sweating on the inside of the masks, I would be concerned about unrecognized breakdown of the material with repeated decontaminations. I would feel much safer with new equipment.	3a - Fit testing regularly but not consistently 2a - HCW need to trust FFR decontamination is thorough 11b - FFR durability for reuse	SBUH
Yearly fit testing No need in my setting	6a - Trained at fit testing	GRMC
Once a year we get fit tested	6a - Trained at fit testing	GRMC
We are educated	2d - Education on health threat	GRMC

Unaware of practices of how to use	3c - Fit but not compliant	GRMC
I have always failed to mask fit test, I use the paper system	3c - Fit but not compliant	GRMC
None. Just new staff fitted during orientation.	3a - Fit testing regularly but not consistently	GRMC
Disposal information needed	6c - Training essential to prepare HCW	GRMC
Very easy	10a - How the front line HCW uses now	GRMC
Very easy	10a - How the front line HCW uses now	GRMC
Single use NAS	n/a	GRMC
I have used FFR but not in an emergent situation, yet.	n/a	GRMC
Staff most likely need instruction on proper donning of FFR.	6c - Training essential to prepare HCW	GRMC
Good	n/a	UCMC
Prev told not mandatory since I don't have direct patient care.	10a - How the front line HCW uses now	UCMC
training consistent, policies: don't have time to read them; implementation consistent	10c Regulations and policy	UCMC
employee health was thorough	10a - How the front line HCW uses now	UCMC
They are uncomfortable to wear. Disposing of them compels you to pick between two undesirable options: throw it out in the room and breathe the bad air until you are out, or dispose of it outside the room, which requires you to transport deadly pathogens outside the isolation zone.	10a - How the front line HCW uses now	UCMC
All works well	n/a	UCMC

Note: Respondents who answered “None”, “NA”, or “don’t know” were removed.

11. Are you familiar with Ultraviolet Germicidal Irradiation (UVGI)?

	SBUH	GCRMC	UCMC
Yes	21 (27.63%)	35 (24%)	16 (36%)
No	55 (72.37%)	108 (76%)	28 (64%)
Total	76 (100%)	143 (100%)	44 (100%)

12-15. I would feel safe going to work during a high mortality pandemic... (Scale: 1=Agree; 7=Disagree)

With no respirator

	SBUH	GCRMC	UCMC
Minimum	1.00	1.00	1.00
Maximum	7.00	7.00	7.00
Mean	6.61	5.72	5.37
Std. Deviation	1.09	2.32	2.03
Variance	1.20	5.39	4.14
Count	71	141	43

With a respirator

	SBUH	GCRMC	UCMC
Minimum	1.00	1.00	1.00
Maximum	7.00	7.00	5.00
Mean	3.91	1.65	2.37
Std. Deviation	1.65	1.48	1.49
Variance	2.73	2.20	2.23
Count	68	141	43

With a respirator that has been decontaminated using UVGI

	SBUH	GCRMC	UCMC
Minimum	1.00	1.00	1.00
Maximum	7.00	7.00	7.00
Mean	4.06	3.31	3.49
Std. Deviation	1.58	2.53	1.93
Variance	2.51	6.39	3.74
Count	66	134	43

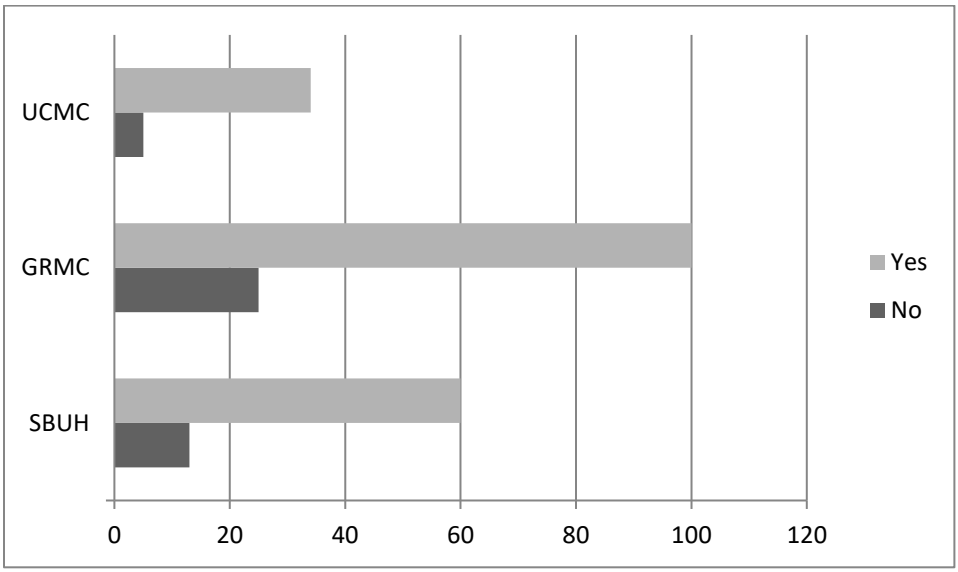
With a respirator that I have to reuse many times without decontamination

	SBUH	GCRMC	UCMC
Minimum	1.00	1.00	1.00
Maximum	7.00	7.00	7.00
Mean	5.93	6.03	5.84
Std. Deviation	1.50	2.10	1.52
Variance	2.26	4.40	2.32
Count	71	139	43

Note: At GCRMC, some respondents selected to answer "yes" or "no". The research team assigned all "yes" answers as 1 (agree), and all "no" answers as 7 (disagree).

16. Do you think implementing UVGI FFR Decontamination/Reuse (UVDR) will help mitigate FFR shortages?

	SBUH	GCRMC	UCMC
Yes	60 (82.91%)	100 (80%)	34 (87%)
No	13 (17.81%)	25 (20%)	5 (13%)
Total	73 (100%)	125 (100%)	39 (100%)



17. What would be the greatest advantage to using FFR-UVDR during an emergency?

	SBUH	GCRMC	UCMC
Availability	30 (60%)	41 (43%)	10 (33%)
Cost savings	3 (6%)	4 (4%)	1 (3%)
Increased safety and protection	7 (14%)	30 (31%)	9 (30%)
Efficiency	2 (4%)	5 (5%)	1 (3%)
None	0 (0%)	4 (4%)	2 (7%)
Trust	0 (0%)	3 (3%)	1 (3%)
I don't know	7 (14%)	9 (9%)	6 (20%)
TOTAL	49	96	30

Note: If respondents provided multiple parameters in their response, they were assigned to multiple themes.

18. What would be the biggest barrier to implementing FFR-UVDR during an emergency?

	SBUH	GCRMC	UCMC
Training	8 (16%)	10 (11%)	2 (6%)
Trust decontamination	11 (22%)	25 (27%)	6 (18%)
Refusal to share	1 (2%)	3 (3%)	1 (3%)
UV unit availability (cost or location)	14 (27%)	28 (31%)	1 (30%)
Time	7 (14%)	10 (11%)	2 (6%)
Other*	4 (8%)	6 (7%)	7 (21%)
I don't know	5 (10%)	9 (10%)	5 (15%)
TOTAL	50	91	24

*Examples of Other: Staff concerns for safety, bureaucracy, lack of organized plan/process, lack of electricity/battery support, control of use/supply, someone to take care of it, hoarding, lack of communication, equipment breakdown

Note: Respondents who provided multiple parameters in their response were assigned to multiple themes.

19. What are your ideal parameters that would allow FFR-UVDR to be used during a high mortality pandemic?

	SBUH	GCRMC	UCMC
Procedures in place/proper training	3 (6%)	6 (8%)	4 (16%)
Resources and/or policy to operate and maintain equipment	2 (4%)	5 (7%)	0 (0%)
Put into regular practice	1 (2%)	3 (4%)	0 (0%)
Evidence of decontamination (data, indicator)	5 (10%)	6 (8%)	3 (12%)
Get my own mask	3 (6%)	5 (7%)	0 (0%)
No other option	2 (4%)	9 (13%)	0 (0%)
Efficient Process (available, quick)	12 (23%)	11 (15%)	4 (16%)
Mask durability (tested and trust it's not be degraded)	3 (6%)	0 (0%)	2 ((8%)
Other*	0 (0%)	10 (14%)	0 (0%)
Don't know	22 (42%)	16 (23%)	12 (48%)
TOTAL	53	71	27

*Examples of Other: Remote area, suspension of harmful practice, one mask assigned to patient per RN, legitimate high morality pandemic

Note: One respondent from SBUH and one from UCMC answered "50%." The research team discarded this response. If respondents provided multiple parameters in their response, they were assigned to multiple themes.

6. ATTACHMENTS

Attachment	Document
1	Task 4 Publication: Ultraviolet germicidal irradiation of influenza-contaminated N95 filtering facepiece respirators (AJIC, 2018)
2	Task 6 Publication: Assessment of half-mask elastomeric respirator and powered air-purifying respirator reprocessing for an influenza pandemic (AJIC, 2017)
3	Task E Publication: ASTM E3135-18, Standard practice for determining antimicrobial efficacy of UVGI against microorganisms on carriers with simulated soil (ASTM, 2018)
4	Task E Publication: ASTM E3179-18, Standard test method for determining antimicrobial efficacy of UVGI against influenza virus on fabric carriers with simulated soil (ASTM, 2018)
5	Task 4 Presentation: Ultraviolet germicidal irradiation of influenza-contaminated N95 filtering facepiece respirators (ASM, 2016)
6	Task 6 Presentation: Assessment of half-mask elastomeric respirator and powered air-purifying respirator reprocessing for an influenza pandemic (ASM, 2016)

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