

Halo Respirator Assessment of Reprocessing and Cleaning (ARC)

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ABSTRACT

Background: Reusable respirators are an important alternative source of respiratory protection in healthcare to alleviate N95 supply shortages faced during surge demand. These respirators must be cleaned and disinfected after use to assure safety for reuse.

Objective: This study aimed to evaluate whether use of conveniently available hospital chemical disinfectants alone removes influenza virus and facial contaminants similarly to use of a soap and water-based cleaning regimen along with disinfectant.

Methods: CleanSpace® Halo reusable respirators were contaminated with simulated facial oils and influenza A virus via fine mist spray. Facial contamination was verified by use of fluorescent lotion. Half of the respirators were processed by cleaning in soap and water followed by wiping with a standard hospital chemical disinfectant; the other half were only wiped with chemical disinfectants. Disinfectants included: 70% isopropyl alcohol, 0.5% hydrogen peroxide, 0.55% quaternary ammonium compound and 0.1% bleach. Respirators were tested for influenza presence and viability following initial contamination, after wiping with disinfectant and then spraying with disinfectant. Results of quantitative RT-PCR to quantify influenza virus and TCID₅₀ assays to titrate viral infectivity results were compared between the two processing strategies, among the four disinfectant types, and in comparison to the pre and post disinfectant spray step. The decrease in the presence of facial contaminants and disinfectant residue was expressed as percent reduction from baseline.

Results: The lowest levels of influenza viral loads and the lowest levels of residual facial contaminants were observed on respirators undergoing cleaning with soap and water, disinfection with a chemical disinfectant, and with sleeve protection of the power unit. This was shown by both PCR and the TCID₅₀ assays.

Conclusion: The findings from this study provide an evidence base to design hospital cleaning and disinfection protocols for reusable Halo respirators. The most protective protocols should include cleaning with soap and water and disinfection of the respirators after use.

Keywords: reusable elastomeric respirators, virus, disinfection, decontamination, N95 supply shortage

INTRODUCTION

The National Academies of Sciences, Engineering and Medicine recommends that reusable elastomeric respirators be considered for routine and surge use in healthcare respiratory protection programs (RPP), provided cleaning and disinfection protocols are specified (NASEM 2018). Additionally, with the evolution of the coronavirus disease 2019 (COVID19) outbreak in early 2020, the Centers for Disease Control and Prevention (CDC) recommends that healthcare facilities consider inclusion of reusable elastomeric respirators and powered air-purifying respirators (PAPRs) as one strategy to preserve N95 filtering facepiece respirator (N95 FFR) supplies during periods of shortage (CDC, 2020^a).

Reusable elastomeric respirators while infrequently used in healthcare are in common use in general industry (Hines, Health 2019). One concern that may curb widespread uptake of reusable devices in healthcare settings relates to effective cleaning and disinfection protocols (Hines 2017, NASEM 2018). Limited data do exist, however, suggesting that elastomeric respirator reprocessing can be accomplished in healthcare settings. Previous studies have shown that healthcare workers can clean and disinfect respirators according to a standardized protocol with no errors (Bessesen, 2015). Common hospital disinfectants have been found to effectively remove viable influenza virus from elastomeric respirator surfaces (Subhash, 2014). Elastomeric respirator cleaning using detergent reduces influenza contaminants to a similar degree as cleaning in detergent followed by disinfection with bleach solution (Lawrence, 2017).

Disinfectant wipes and alcohol swabs are usually readily available on hospital wards under normal conditions. They could conveniently be available at point of use to remove contaminants from a used respirator. Respirator reprocessing protocols that incorporate cleaning with detergent do so by respirator submersion in warm, soapy water in sinks, pans or buckets (Bessesen, 2015; Lawrence, 2017). This task is less convenient to accomplish near patient rooms and involves ready access to warm running water and space to facilitate sequential washing steps. Although studied in disposable N95 respirators, no studies have evaluated whether use of a disinfectant wipe alone is adequate to remove viral contaminants from reusable elastomeric respirators (Heimbuch, 2014). If use of a disinfectant wipe alone successfully accomplishes adequate viral contaminant removal, the cleaning step requiring additional space, running warm water, detergent and time could be eliminated. This would remove a logistical barrier to incorporating reusable elastomeric respirators into a hospital RPP.

The Occupational Safety and Health Administration's (OSHA) respiratory protection standard states that respirators must be cleaned and disinfected after use (OSHA 1910 Subpart 1 1910.134 App B-2). This standard applies to respirator use in general and is not specific to healthcare settings. Cleaning involves removal of soiling agents such as dusts or facial oils, while disinfection involves destruction of microbial pathogens by physical or chemical means (CDC, 2016). Although cleaning of respirators in general industry jobs such as construction, where respirators are likely to become soiled makes sense, disinfection takes a higher priority for reusable respirator use in a non-dusty environment like a hospital.

The CleanSpace® Technology Halo respirator was approved for use by the National Institute for Occupational Safety and Health (NIOSH) in 2019. This reusable respirator combines features of a reusable elastomeric respirator with the protective technology of a PAPR. Marketed for use in healthcare, the Halo requires appropriate cleaning and disinfection strategies as do reusable elastomeric respirators. Through an investigator-initiated collaboration with CleanSpace® Technology, cleaning protocols were investigated as part of the Halo Assessment of Reprocessing and Cleaning (ARC) study.

The primary objective of the Halo ARC study was to a) determine whether reusable respirator facemasks (FMs) contaminated with facial contaminants and influenza virus have similar reductions in viral surface contamination following a cleaning and disinfection protocol compared to disinfection alone. Secondary objectives were to b) compare whether there are significant differences in the quantity of residual influenza virus following use of four commonly-used hospital disinfectants, c) determine whether disinfection with a wipe alone is adequate for virus removal, or whether an additional disinfectant spray step is needed, d) determine whether facial contaminants were similarly removed following cleaning and disinfection versus disinfection alone and finally e) to evaluate the presence of residual disinfectant following respirator processing.

MATERIALS AND METHODS

Respirator

All tests were performed using the CleanSpace® Technology Halo respirator (NIOSH approval #1102, March 21, 2019) as illustrated in Figure 1. The Halo contains a transparent silicone FM that covers the nose and mouth, similar to the FM of a non-invasive positive pressure delivery system. The FM side-arms connect to a circular power-unit that rests behind the neck. The polycarbonate-based power-unit entrains air from behind the neck through a high efficiency particulate air (HEPA) filter into the face mask and breathing zone. Air remains under positive pressure and is exhaled through a valve on the front of the FM. An adjustable head harness stabilizes the FM via non-porous, stretchable rubber and polyester straps connected to the FM. An optional protective sleeve pre-filter may be used to cover the power-unit during use. The sleeve is made of melt blown synthetic (SMS) non-woven material that is meant to protect against coarse particulate and splash.



Figure 1. CleanSpace™ HALO respirator (photo from CleanSpace™ Technology).

Facial Contamination

Prior to commencement, the study was approved by the local university human research protections office. Glo Germ™ lotion was used to simulate transfer of facial contaminants to the FM surfaces for quantification (Glo Germ, n.d.). This lotion is composed largely of Cetearth-20, a non-ionic

surfactant, and other fats, like white petrolatum and glycerin, and used to simulate transfer of facial cosmetic products and skin oils. The lotion also contains a proprietary fluorescent powder that can easily be viewed under ultraviolet (UV) light but is otherwise invisible. After providing informed consent, eight volunteers applied a dime-size amount of lotion to their faces and wore the FMs for thirty minutes. The FMs were then viewed by three reviewers under light-emitting diode (LED) UV light for contamination with Glo Germ. Reviewers were trained on mask scoring using standardized contamination reference images and then independently scored the masks. Scoring was based on providing grades of either zero (no contamination) or one (contamination present) for each of the five mask sections, for a possible maximum total score of five.

Influenza Contamination

All work with influenza specimens occurred in a Biosafety Level 2 lab inside a biosafety cabinet with appropriate laboratory personal protective equipment (PPE) donned by workers. Influenza A virus (A/Puerto Rico/8/34, PR8) was propagated in Madin-Darby canine kidney (MDCK) cells. Culture supernatant cleared by centrifugation and 0.22- μ m filtration were aliquoted and stored at -80 C. Prior to contamination, PR8 virus stock containing 2.07×10^{10} virus particles/mL (determined by PCR assay described below) was thawed and transferred into a fine mist spray bottle (DNAZap, Thermo Fisher). Bottles were washed and disinfected prior to use and fitted with new sprayers from the same kit.

Components of Halo respirators were placed against the back wall of a biosafety cabinet. Head harnesses remained attached to FMs, but not connected to power units. Operators then sprayed the Halos from approximately 20 cm away in six different positions: directly facing the mask, right of the mask, left of the mask, above left of the mask, above right of mask, and above middle angled down to get inside the mask. To test the efficacy of a sleeve marketed to reduce surface contamination of the Halo power-unit, one CleanSpace® sleeve was applied to one power-unit, connected to its storage and cleaning plug. The entire unit was then placed in the biosafety cabinet and sprayed with influenza in a similar fashion to the power-units connected to FMs and harnesses.

Halo Processing

Two processing strategies using four different disinfectants were used to process eight FM-harnesses and four power-units, as in Figure 2. Disinfectants included I) 70% isopropyl alcohol, II) 0.5% hydrogen peroxide (Oxivir®, Oxivir, 2018), III) a 0.5% quaternary ammonium compound (QAC)/55% isopropyl alcohol wipe (Super Sani-Cloth®, Super Sani-Cloth, 2015), and IV) 0.1% dilution sodium hypochlorite or bleach (Dispatch®, Dispatch, 2015). For each different disinfectant group, one FM-harness was cleaned in liquid dish soap and water followed by wiping with a disinfectant wipe ("cleaned and disinfected," (C&D)). A second FM-harness was only wiped with a disinfectant wipe ("disinfected only," (D)). The processing protocol was developed based on a combination of manufacturer recommendations for cleaning, a protocol that had previously demonstrated feasibility of use among trained HCWs using elastomeric respirators (Bessesen, 2015) and prior data exploring efficacy of common hospital disinfectants (Subhash, 2015; Lawrence 2017). All of the disinfectants except the 70% isopropyl alcohol are Environmental Protection Agency registered hospital disinfectants with kill claims against influenza A virus, including Avian influenza ([EPA, 2020](#)).

Cleaning protocol: A washing station was set up by placing absorbent bench top pads on the floor and filling two buckets. The first bucket was filled with one gallon of warm 29-38 °C water mixed with 15mL of liquid dish soap (Dawn, 0.04% concentration). A thermometer was taped inside of the bucket for constant measure of temperature. A second bucket was filled with two gallons of water. For each "Group A" FM-harness in each disinfection group, the exhalation valve cover was removed and all components placed in the bucket of warm soapy water. All surfaces were scrubbed gently with a soft brush for approximately 90-120 seconds. The FM-harness was removed and then rinsed in the second bucket for

approximately 15-96 seconds, then removed and gently shaken to remove excess water, but were not dried further with a cloth or airhose.

Halo ARC Study Procedural Flow

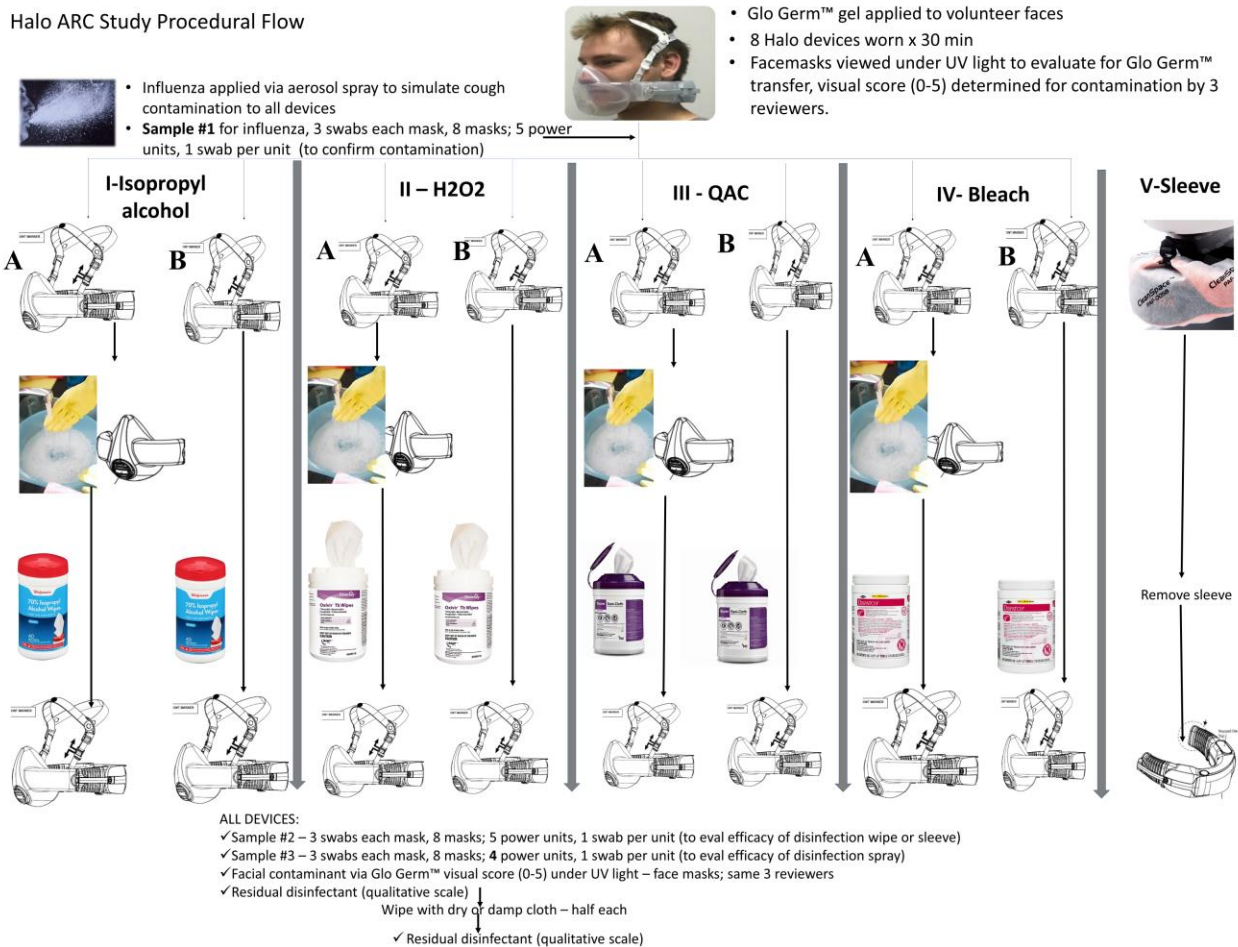


Figure 2. HALO ARC Study Procedural Flow.

Disinfection protocol: Chemical disinfection included two steps: wipe with four disinfectant wipes and spray with disinfectant spray. Each FM-harness was wiped with its respective disinfectant wipe according to the following protocol: one wipe covering the exterior surface of the FM, a second separate wipe covering the interior surface of the FM, and a third covering the straps and harness. Each of the four power-units assigned to disinfectants was wiped on all surfaces with a fourth, single wipe, including each arm's corrugated wells and plastic extension tubing, for a total of four wipes. Total wiping time duration averaged 72 seconds, ranging from 50-100 seconds. In order to assess whether inclusion of a final spray with disinfectant removed an additional significant amount of viral contaminants, after two minutes of contact time with the disinfectant wipes followed by sampling, each respirator was sprayed with its respective assigned disinfectant via spray bottle.

Influenza Sampling

Post-contamination (swab 1): 30 minutes after the initial influenza spraying, post-contamination swabs were obtained from standardized locations on each Halo: a) exterior surface of the FM, 0.5 by 2

in. vertically from the bridge of the nose down to the top of the valve cover, b) interior surface of the face mask, 0.5 x 2 in. horizontally across the widest portion of the mask, c) entire length of the right-sided strap (outward facing surface), and d) the right sided arm of the power-unit. The power-unit swab was collected by performing three separate down-up passes in the first three corrugation wells on the outermost surface (closest to the FM) and the outer surface of the plastic extension piece overlying the corrugated arm.

Post-wipe processing (swab 2): Following processing with either C&D wipe or with D wipe alone and waiting two minutes, the second influenza samples were collected. In order to avoid areas where influenza could have already been removed mechanically from the prior sampling, swabs were collected from similar, but slightly different locations: a) exterior surface of the FM, 0.5 x 2 in. horizontally across the right arm of the face mask, b) interior surface of the face mask, 0.5 x 2 in. diagonally along the right side of the surface that would contact skin, c) entire length of the left-sided strap (outward facing surface), and d) the left sided arm of the power unit in a manner similarly described for the right sided arm post-contamination.

Post-spray with disinfectant processing (swab 3): Following final spray with disinfectant and waiting two minutes, a third set of swabs were obtained from locations that previously had not been mechanically disturbed by a sampling swab: a) exterior surface of the FM, 0.5 x 2 in. horizontally across the left arm of the face mask, b) interior surface of the face mask, 0.5 x 2 in. diagonally along the left side of the FM that would contact skin, c) entire length of the right-sided strap internal surface, and d) the right sided arm of the power-unit. This time three separate down-up passes in the last three corrugation wells on the outermost surface (farthest from the mask) and the inner surface of the plastic extension piece overlying the corrugated arm.

Pre- and post-sleeve removal (swabs 1 and 2, Group V): Influenza samples were collected 30 minutes following influenza application from a 0.5 x 2 inch length along the outer surface of the right sleeve that had been applied to a power-unit prior to influenza spray contamination. After the sleeve was removed, the left sided corrugated arm of the power-unit and outer surface of the extension piece were swabbed as previously described.

All samples were labeled and placed in 15 ml tubes with 1 ml phosphate buffered saline (PBS) containing 0.1% bovine serum albumin (BSA). Samples were then vortexed for 1 min and centrifuged at 1200 rpm for 1 minute. 50 μ L and 400 μ L aliquots were placed into 1.5 ml tubes, with the rest aliquoted in a 1.5 ml tube. Samples were then placed in a -80°C freezer until further processing.

Quantitation of influenza virus and titration of viral infectivity

Quantitative real-time polymerase chain reaction (qRT-PCR): Nucleic acids were extracted from 200 μ L of samples using MagMAX Pathogen RNA/DNA Kit (Applied Biosystems) and KingFisher Duo Prime automated system (Thermo Fisher Scientific), and eluted in the volume of 50 μ L. qRT-PCR was carried out in 20 μ L reaction mixes containing 1X TaqMan Fast Virus 1-Step Master Mix (Applied Biosystems), primers and probes designed by the CDC

(http://www.who.int/csr/resources/publications/swineflu/CDCRealtimeRTPCR_SwineH1Assay-2009_20090430.pdf), and 10 μ L of extracted nucleic acid. Thermal cycling was carried out on an Agilent Stratagene Mx3005P with the following program: 5 min at 50°C, 20 sec at 95°C, followed by 45 cycles of 15 sec at 95°C and 30 sec at 55°C. Standard curves were established by performing nucleic acid extraction and qRT-PCR on a serial dilution of electron microscopy-counted PR8 virus particles (Advanced Biotechnologies Inc., Columbia, MD). A sample is titrated if the quantity is above the limit of quantification (10 virus particles per reaction or 250 virus particles per 1 mL sample).

Tissue culture infectious dose (TCID₅₀) assay: TCID₅₀ assays were performed as previously described (Lawrence, 2017). Briefly, samples were serially diluted in serum free Dulbecco's Modified Eagle Medium (DMEM) containing 1µg/mL Trypsin and plated in quadruplicate of 96-well plates containing confluent monolayers of MDCK cells. Plates were incubated at 37°C in 5% carbon dioxide for 3 days and observed under a microscope for cytopathic effects. Wells were counted as positive for cytopathic effects when significant cell rounding and disruption to the monolayer was observed as compared to negative control wells. For samples in which qRT-PCR values were less than the assay limit of detection (250 virus particles/sample), TCID₅₀ analysis was not performed.

Post-processing scoring

FMs were re-scored for evidence of remaining fluorescent contaminants under the LED UV light by the same scoring system. The FMs were also evaluated for visible disinfectant residue or odor on separate three-point scales: zero = no residue or odor, one = possible residue or odor and two=definite residue or odor present. Finally, to assess whether a dry cloth was similarly effective as a portable wet cloth to remove disinfectant residue, the FMs were wiped with either a wet saline wipe or a dry cloth paper towel and re-scored.

Data Analysis

Influenza samples: To determine the level of influenza recovered from different sites on face masks disinfected with 4 disinfectant wipe types by cleaning strategy, Wilcoxon and Kruskal-Wallis tests were used for statistical analysis of the influenza viral load by qRT-PCR and TCID₅₀, and the influenza viral load by log₁₀ TCID₅₀ was analyzed by analysis of variance (ANOVA) with Tukey's posttest. The TCID₅₀ limit of detection was 1.7×10^2 . For samples where TCID₅₀ values were zero, half of the limit of detection was used in place of zero in order to calculate log₁₀ TCID₅₀ values, which would not be possible using zero values. Log₁₀ TCID₅₀ reduction factors were calculated by subtracting the processed sample value from the post-contamination or control value (Ruppach, 2014). TCID₅₀ values associated with swabs with qRT-PCR values < 250 particles/sample were considered to be zero. If cytopathic effect was visible at first dilution, but TCID₅₀ was not able to be calculated, the TCID₅₀ value was analyzed as half of the limit of detection.

Facial contaminant and residue scores: Reviewer scores were averaged and compared to assess for differences in post-processing Glo Germ™ and disinfectant residue on masks that had undergone C&D versus D only. Average post-processing scores were compared to pre-processing scores to determine the percent reduction in either facial contaminant, visual or olfactory evidence of disinfectant residue.

RESULTS

Removal of Viral contamination

All FMs, harnesses and power-units demonstrated presence of influenza virus following initial contamination, according to both qRT-PCR and by TCID₅₀ assays (Figure 3). C&D respirators demonstrated greater reductions in influenza by log₁₀ TCID₅₀ compared to D only respirators (Figure 4), with reduction factors of 2.09 vs 1.34, $p=0.06$ (Table I). Face masks and harnesses that had been cleaned and disinfected (C&D) demonstrated significantly lower influenza viral load by qRT-PCR ($p<0.05$) and by TCID₅₀ ($p<0.05$) assays compared to those that had only been wiped with a disinfectant (D only). Most samples obtained from C&D respirators (92%), demonstrated no viable virus immediately post-processing while 83% of samples obtained from D only respirators still showed a low level of viability

based on TCID₅₀ testing, with values ranging from 0 to a max of 10,000 TCID₅₀/ml (recovered from the strap of the harness disinfected only with isopropyl wipe).

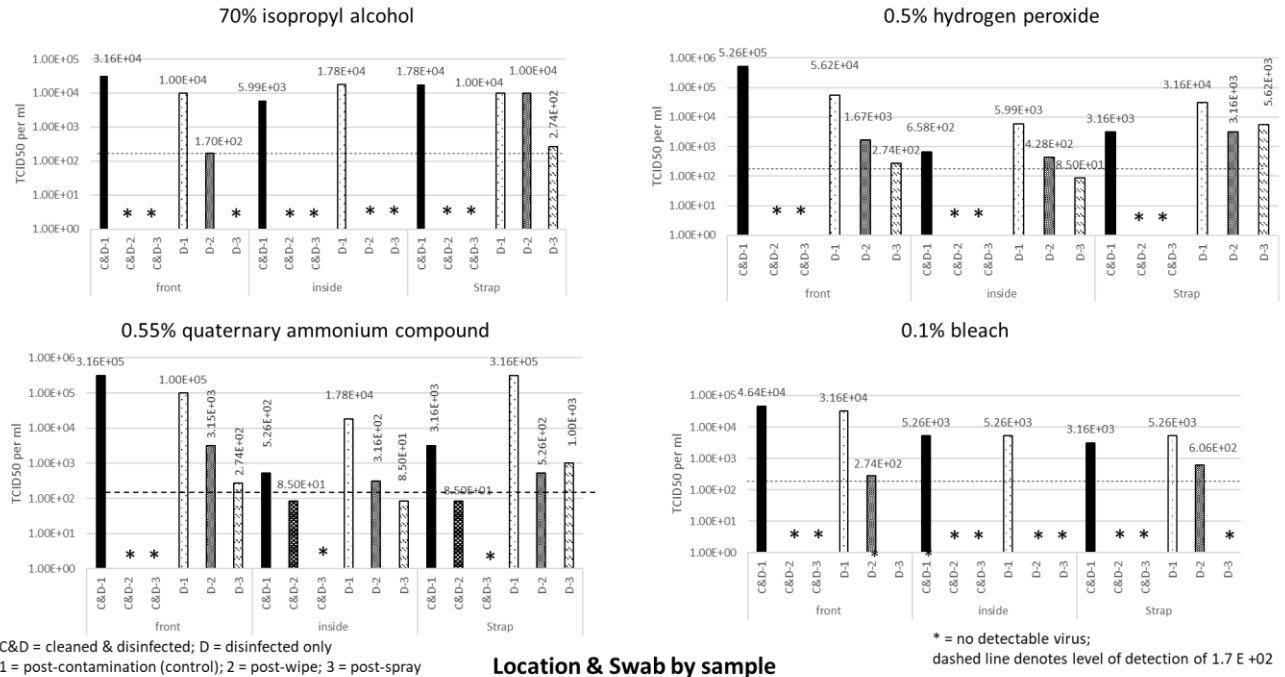


Figure 3. Mean log recovery in viable influenza from 3 sites on facemasks processed with different disinfectants.

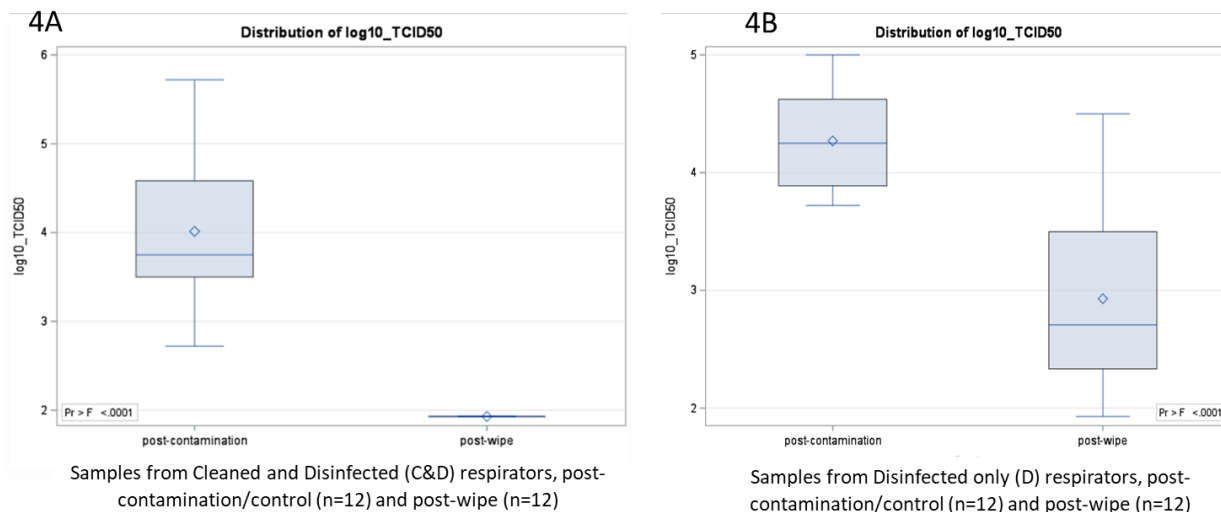


Figure 4. Box-plot of Log 10 TCID₅₀ results among 4A) Cleaned & Disinfected and 4B) Disinfected-only respirators, showing significant difference between post-contamination (control) and post-wipe samples.

Table 1. Influenza Log 10 TCID50 Results Following Contamination (Control) and Following Disinfection with Wipe (or Sleeve Removal) and Resultant Reduction Factors

	Average log 10 TCID 50		Reduction factor (log 10 TCID50)
	Post contamination (control)	Post wipe/ processing	
Processing Strategy			
Cleaned & Disinfected	4.01	1.93	2.09
Disinfected only	4.27	2.93	1.34
Disinfectant Type			
Isopropyl	4.33	2.67	1.65
H2O2	4.26	2.63	1.63
QAC	4.46	2.72	1.75
Bleach	4.09	2.20	1.89
Power Unit Processing Strategy			
Sleeved	4.50	2.75	1.75
Disinfected with wipe	5.13	3.29	1.84

There were significant differences of log 10 TCID50 values between control vs post-wipe ($p < 0.0001$) and control vs post-spray with disinfectant ($p < 0.0001$) and no difference between post-wipe and post-spray ($p = 0.1765$). Although viral load was reduced following the additional spray disinfection step, there was not a significant difference between the reduction factor induced by wiping compared to the additional spray step. Among the FM and harnesses, evidence of virus viability was reduced further with use of the additional spray step but remained slightly above the limit of detection of 170 TCID50/ml from samples obtained from D only respirators.

Disinfectant type

Surfaces disinfected with 70% isopropyl alcohol demonstrated higher average viral load by qRT-PCR after treatment, compared to the other three hospital disinfectants used; however, there was no significant difference overall among the four groups ($p = 0.5895$). Virus titration results did not differ significantly among the four disinfectant types ($p = 0.5$). All four disinfectants showed similar log 10 TCID50 reduction factors, $p = 0.9763$ (Table I).

Respirator power units

More virus was detected following initial contamination on the unsleeved power unit compared to sleeved power units. Log 10 TCID50 reduction factors were similar between power units disinfected with wipes compared to the power unit covered with the sleeve, $p = 0.9436$ (Table 1). All power units showed low levels of detectable viable virus following wipe with disinfectant or removal of the sleeve. Only the sample obtained from the power unit disinfected with 0.1% bleach demonstrated no detectable viable virus, which was following the spray step.

Removal of Facial Contaminants

Glo Germ™ was visible under LED UV light in all areas of the masks worn by the volunteers. On post-processing scoring, Glo Germ was completely removed from two of eight masks, both which had

been cleaned and disinfected. Total mean percent reduction from preprocessing contamination of C&D masks was 90% vs. 15% for D only masks. Residue was visible on all masks before a final wipe. Masks wiped with a wet cloth demonstrated a 33% reduction in visible residue, compared to a dry cloth with a 4% reduction. None of the masks wiped with a wet cloth had detectable odor at baseline, and no odor was detected post-wipe for these masks. Masks wiped with a dry cloth had very mild detectable odor on pre-wipe that was not reduced after wiping.

DISCUSSION

The lowest levels of influenza viral loads and the lowest levels of residual facial contaminants were observed on CleanSpace® Halo respirators when they underwent cleaning with soap and water, disinfection with a chemical disinfectant, and with sleeve protection of the power unit. This was shown by both qRT-PCR recovery and the TCID50 assay. FMs and harnesses that were processed only with disinfectant wipes retained more viable virus than did those that were cleaned and disinfected. This was more consistently seen on the samples obtained from the rubber straps and head harness. This suggests that reusable FMs and harnesses should undergo cleaning and disinfection after use when they are likely to be heavily contaminated with viral-laden aerosols, specifically influenza. Also, use of disinfectant wipe alone does not assure complete removal of facial contaminants as simulated by transfer of Glo Germ gel from face to mask. Disinfectant residue, which ideally should be removed prior to reuse to avoid potential skin or respiratory irritation to the user, may be present if a water-based rinse is not the last step in a reprocessing protocol.

Consistent with prior studies, we used both real-time PCR and TCID50 assays to assess viral presence (Subhash, 2014; Lawrence, 2017). Of most importance is a determination of whether viable, infectious virus remains following processing, which could allow the respirator to serve as a fomite. While all of the disinfectant wipes studied here reduced viral presence by orders of magnitude, low levels of viable virus remained following disinfectant wiping of the respirators without a soap and water cleaning step.

In this study, masks were sprayed with influenza-containing aerosol, leading to average surface contamination of 2.3×10^7 viral particles/sample and ranging from 2.1×10^5 to 1.2×10^8 . This falls at the upper range of expected surface contamination that could occur on a filtering facepiece respirator due to influenza aerosols in a previously modeled study, where the high estimate was determined based on airborne influenza virus measured in a health center and day care center during the 2009-10 influenza season (Yang 2011; Fisher, 2014). Respirator contamination in our study may represent a surface contamination scenario resulting from work in an environment with significantly high airborne burden of influenza or one that might be encountered if a respirator were in near contact to respiratory aerosols from a patient.

Like prior reports (Subhash, 2014), influenza viral load was reduced to a greater extent by EPA registered hospital disinfectants than by isopropyl alcohol. In this analysis of disinfection of Halo respirators, however, the difference in viral content was not significantly different among the four strategies, although the isopropyl alcohol wipe resulted in highest and the bleach wipe resulted in lowest residual viral content. This suggests that facilities may select among a variety of products that are approved for removal of the appropriate pathogen, in this case being influenza.

The need for respirator cleaning with soap and water creates an additional reprocessing step. This may impose implementation challenges during high volume use, such as in a respiratory viral pandemic, when the need to disinfect and reuse a device in the care of other patients or for multiple cycles through patient rooms are needed. In such a scenario, however, the protective equipment ensemble would include eye protection such as a face shield. Applied over the respirator, a face shield

would reduce the amount of surface contamination to the respirator. In a laboratory study of simulated patient coughs, use of a face shield reduced surface contamination of N95 FFRs by 76 to 97% immediately after generation of influenza-laden aerosols ranging from 3.4 to 8.5 μm median diameter respectively (Lindsley, 2014). Lawrence's study of disinfection of elastomeric respirators with dilute bleach solution achieved mean 4.5-log reductions in viable influenza. Our study showed lower log-10 reductions, but our loading post-contamination values were also lower, limiting the ability to show as large of a log reduction (Ruppach, 2014). Knowing these expected reductions, reuse of a face-shielded respirator following a thorough disinfection wiping step, without the soap and water step, might be one strategy to preserve immediately available PPE supplies in high demand or shortage scenarios, in the same way that limited reuse of N95 FFRs has been allowed (CDC, 2020^b).

Findings here can inform development of simple hospital protocols that are in agreement with manufacturer recommendations. CleanSpace® Technology currently advises Halo users to process the FM and harness by first, wiping with a cleaning or disinfectant wipe, then either cleaning the mask in warm soapy water or using an industrial washer (CleanSpace, 2018). These components can also be disinfected in a thermal bath for 1 minute at 90° C or sterilized in a STERRAD 1005 or NX processor. CleanSpace® recommends that the power unit be wiped with a disinfectant wipe after use. The Halo features a cleaning plug that can be inserted in place of the filter, allowing the power unit to be rinsed under running water if it has been heavily soiled.

The disinfectants used in this protocol are all EPA-registered hospital disinfectants with claims against influenza, with the exception of isopropyl alcohol. Although used widely in healthcare settings, the variability in results demonstrated here do not support the use of 70% isopropyl alcohol as a single means of disinfection of a reusable respirator.

This study was limited by a small sample size, but it was structured similarly to previous experimental models of respirator cleaning and disinfection that were able to determine important outcomes about disinfectant choice and processing modes (Subhash, 2014; Lawrence 2017). Even with the small sample size, significant differences were demonstrated in outcomes obtained to test the main hypothesis comparing utility of cleaning and disinfection versus cleaning alone. A single brand of respirator was studied, which may limit applicability to other respiratory protective devices. Many reusable elastomeric respirators, however, contain FMs composed of similar materials such as silicone, which would likely share physiochemical properties. The influenza samples were stored in a -80° C freezer before they were processed. This may have reduced the amount of viable influenza detected, but this would have affected results from all three sampling stages similarly. The quantities of influenza virus and viral infectivity determined by qRT-PCR and TCID50 assays in this study of Halo respirators are similar to those seen in studies of elastomeric respirators following disinfection, which supports comparability (Subhash, 2014; Lawrence, 2017). Our study was performed in a laboratory setting, which may not replicate conditions in a hospital setting. However, the cleaning protocol was designed based on a previous study in which healthcare workers could successfully clean and disinfect reusable elastomeric respirators without errors (Bessesen, 2015). Thus, this laboratory-based cleaning procedure could likely be replicated by healthcare workers as part of a routine protocol.

Finally, we simulated transfer of facial contaminants using a Glo Germ™ lotion, which contains Cetareth-20, a non-ionic surfactant, and other fats such as white petrolatum and glycerin. While not possessing the same constituents as skin oil, it is like many personal care products that may be worn by healthcare workers and thus can provide a relevant media for comparison. Some of the residue seen on FMs during the visual inspection may not have been disinfectant but rather Glo Germ lotion residue. This limits the reliability of the visual inspection score as an assessment of presence of disinfectant. Still, however, it is prudent and congruent with CleanSpace® and other elastomeric respirator manufacturer recommendations to remove any disinfectant chemical residue prior to use on the face.

CONCLUSIONS

The findings from this study provide an evidence base to design hospital cleaning and disinfection protocols for reusable Halo respirators. The most protective protocols should include cleaning with soap and water and disinfection of the respirators after each use. Use of a protective sleeve covering the power unit provides similar reductions in respirator contamination as does wiping with disinfectant. Additional steps including the use of disinfectant spray will reduce influenza contamination further but may not provide significant additional benefit. Facial contaminants should be removed with the use of a detergent, as disinfectant wipes alone do not assure removal. Residual facial contaminants may be acceptable when a mask is only worn by the same individual, but if a shared cache is to be used, cleanliness is likely to be a higher priority. With sound cleaning and disinfection protocols informed by this evidence, reusable elastomeric respirators and related products are useful adjuncts to single use N95s in both routine healthcare RPPs and during public health emergencies in times of surge demand.

Disclaimer

Conflict of Interest Statement: This investigator-initiated study was sponsored by CleanSpace® Technology through a research contract to the University of Maryland-Baltimore.

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