Disinfection of reusable elastomeric respirators by health care workers: A feasibility study and development of standard operating procedures

Mary T. Bessesen MD\textsuperscript{a,b,*}, Jill C. Adams BSN\textsuperscript{a}, Lewis Radonovich MD\textsuperscript{c,d}, Judith Anderson MD\textsuperscript{a}

\textsuperscript{a}Department of Veterans Affairs, Eastern Colorado Healthcare System, Denver, CO
\textsuperscript{b}Division of Infectious Diseases, School of Medicine, University of Colorado, Aurora, CO
\textsuperscript{c}Department of Veterans Affairs, National Center for Occupational Health and Infection Control, Gainesville, FL
\textsuperscript{d}Department of Veterans Affairs, National Center for Occupational Health and Infection Control, Washington, DC

\textbf{Background:} This was a feasibility study in a Department of Veterans Affairs Medical Center to develop a standard operating procedure (SOP) to be used by health care workers to disinfect reusable elastomeric respirators under pandemic conditions. Registered and licensed practical nurses, nurse practitioners, aides, clinical technicians, and physicians took part in the study.

\textbf{Methods:} Health care worker volunteers were provided with manufacturers’ cleaning and disinfection instructions and all necessary supplies. They were observed and filmed. SOPs were developed, based on these observations, and tested on naïve volunteer health care workers. Error rates using manufacturers’ instructions and SOPs were compared.

\textbf{Results:} When using respirator manufacturers’ cleaning and disinfection instructions, without specific training or supervision, all subjects made multiple errors. When using the SOPs developed in the study, without specific training or guidance, naïve health care workers disinfected respirators with zero errors.

\textbf{Conclusion:} Reusable facial protective equipment may be disinfected by health care workers with minimal training using SOPs.

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Respirators must fit the face of the individual wearer, and fit testing is required by the Occupational Safety and Health Administration (OSHA). To achieve proper fit for the broad range of facial shapes and sizes, the VHA has purchased half-face elastomeric respirators from 3 different manufacturers. Each manufacturer provides its own instructions for cleaning and disinfecting the respirator.4,6,7 The OSHA and, more recently, the National Institute for Occupational Safety and Health (NIOSH) have also issued guidelines for cleaning and disinfecting respirators. Both agencies advise that manufacturers’ instructions for cleaning and disinfecting respirators should be followed.8,9

The effectiveness of a dilute solution of hypochlorite (household bleach) for killing influenza on respirators has been demonstrated.10 Bleach is also effective against a broad range of other health care–associated pathogens.5 Bleach is readily available from a number of sources, making it attractive for use in an emergency setting such as a respiratory infection pandemic or high-consequence outbreak.

Pandemic conditions would be likely to cause personnel shortages, which may require health care facilities to use large numbers of temporary health care workers. We aimed to provide a standard method for disinfecting elastomeric respirators that could be rapidly implemented with minimal training, would be feasible under pandemic conditions, and would adhere to manufacturers’ recommendations for each respirator type in the VHA cache.

METHODS

Subjects

The study was approved by the Colorado Multiple Institutional Review Board. Subjects provided written informed consent for participation. Subjects were registered and licensed practical nurses, nurse practitioners, aides, clinical technicians, and physicians. A total of 21 subjects were recruited. Six subjects tested manufacturers’ instructions for cleaning and disinfection of a respirator and repeated the process 2 weeks later using a different respirator and the NIOSH guidelines, 6 subjects participated in development of the standard operating procedures (SOPs) for each respirator type, and 9 subjects tested the final SOPs. Subjects had no previous experience with elastomeric respirators and were blinded to the research aim to compare processes. They were informed that the purpose of the project was to develop cleaning protocols for elastomeric respirators. The six participants who participated in the development of the initial SOP, and the nine participants who tested the final SOP were completely naive; they were not involved in any of the earlier testing.

Respirators

New respirators were provided from the VHA cache for the study. Tested models were 3M model 7501 (3M, Saint Paul, MN), Scott 7421 (Scott Safety, Monroe, NC), and Sperian Survivair 1050 (Honeywell Safety, Smithfield, RI).

NIOSH’s and manufacturers’ instructions

The manufacturers’ and NIOSH’s instructions made no mention of using personal protective equipment (PPE) to protect subjects from disinfectants when cleaning and disinfecting respirators. To protect the subjects in the study from accidental exposure to bleach when attempting to follow manufacturers’ or NIOSH’s instructions, a test disinfectant solution was made by mixing tap water and red dye instead of hypochlorite. This allowed for mistakes to be made and splash potential to be recorded without danger to the participants should they elect not to use PPE on their own.

All materials needed to clean and disinfect respirators were placed in a room near a large sink, faucet, and hospital air source. Subjects were told that they would be cleaning a soiled respirator contained in a large plastic bag located on a counter near the sink. A paper copy of the applicable instructions (both the manufacturers’ and NIOSH’s instructions) was provided at the point of use. A container labeled chlorine bleach was pointed out, and subjects were told that red dye had been added to the bleach to check for splashes. Subjects were informed that no additional instructions would be given during the study session and no questions would be answered; however, they could ask questions or make comments or suggestions. Subjects were also informed that their voice would be recorded and video would be taken of their hands during each study session. This allowed observers reviewing the sessions to note times involved in each step, tasks completed correctly or incorrectly, and questions or comments made by the subjects.

Development of new SOPs

After observing a high error rate in subjects’ disinfection technique when using manufacturers’ and NIOSH’s instructions, SOPs were developed for each respirator model. An iterative process was used to design, test, redesign, and retest SOPs. Incremental knowledge gained with each design was used to improve instructions, which were crafted to maximize ease of use and minimize errors.11-13

Cleaning and assessing head straps for loss of elasticity

Manufacturers’ instructions stated that straps should be removed prior to disinfection of the respirator. Because of concern for contamination of straps when worn by subjects caring for patients with respiratory viral infection and the need to include them in the disinfection process, we tested the effect on the straps of repeated exposure to the disinfection solution. Prior to any disinfection treatment, each strap was stretched to its maximum length, and the applied pressure was measured with a luggage scale (Travelon, Elk Grove, IL). The luggage scale was tested for reproducibility of measurements. On 20 independent replicates, the scale gave a mean weight ± SD of 13.54 ± 0.14 kg. Straps were soaked in hypochlorite disinfection solution for the prescribed time and then air dried daily for 45 days. After this, the straps were measured under application of the same amount of force applied at baseline.

Statistical analysis

The proportion of subjects who made errors when following manufacturers’ and NIOSH’s instructions was compared with those using the final SOPs. Fisher exact test was used to test significance of the differences. All tests were 2 tailed. Calculations were performed in GraphPad Prism (GraphPad Software, La Jolla, CA). P values <.05 were considered significant.

RESULTS

Evaluation of manufacturers’ and NIOSH’s instructions

The manufacturers’ and NIOSH’s instructions did not make mention of wearing PPE to prevent exposure to disinfectants when cleaning and disinfecting respirators. After each cleaning and disinfection episode, examination of all 21 subjects and their environment demonstrated test disinfectant solution on gowns, the floor, and around the sink.

All manufacturers’ instructions were printed in a small font, which made them difficult to read. In addition, the manufacturers’
The 3M and Scott respirators. The Scott mask and included in the SOPs. Workers found it diff-
sionally dislodged or displaced the delicate inhalation valves. To instructions, vigorous scrubbing on the inside of the mask occa-
tongs on the mask to weigh it down and keep it submerged. the mask in the solution to remove air bubbles and then placing with disinfectant. This problem was solved by using tongs to turn

Errors made during disinfection of elastomeric respirators

<table>
<thead>
<tr>
<th>Errors made</th>
<th>Manufacturers’ instructions</th>
<th>NIOSH’s instructions</th>
<th>Initial SOP, first attempt</th>
<th>Initial SOP, second attempt</th>
<th>Final SOP, first attempt</th>
<th>Final SOP, second attempt</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPE not used</td>
<td>5/6 (83%)</td>
<td>5/6 (83%)</td>
<td>0/6 (0%)</td>
<td>0/6 (0%)</td>
<td>0/9 (0%)</td>
<td>0/9 (0%)</td>
</tr>
<tr>
<td>Unable to remove filters</td>
<td>3/6 (50%)</td>
<td>0/6 (0%)</td>
<td>0/6 (0%)</td>
<td>0/6 (0%)</td>
<td>0/9 (0%)</td>
<td>0/9 (0%)</td>
</tr>
<tr>
<td>Removed inhalation valves</td>
<td>2/6 (33%)</td>
<td>1/6 (17%)</td>
<td>0/6 (0%)</td>
<td>0/6 (0%)</td>
<td>0/9 (0%)</td>
<td>0/9 (0%)</td>
</tr>
<tr>
<td>Poured detergent directly onto brush</td>
<td>3/6 (50%)</td>
<td>0/6 (0%)</td>
<td>0/6 (0%)</td>
<td>0/6 (0%)</td>
<td>0/9 (0%)</td>
<td>0/9 (0%)</td>
</tr>
<tr>
<td>Poured undiluted bleach directly on mask</td>
<td>1/6 (17%)</td>
<td>0/6 (0%)</td>
<td>0/6 (0%)</td>
<td>0/6 (0%)</td>
<td>0/9 (0%)</td>
<td>0/9 (0%)</td>
</tr>
<tr>
<td>Did not immerse mask in soapy water</td>
<td>4/6 (67%)</td>
<td>2/6 (33%)</td>
<td>0/6 (0%)</td>
<td>0/6 (0%)</td>
<td>0/9 (0%)</td>
<td>0/9 (0%)</td>
</tr>
<tr>
<td>Did not clean filter covers or splash guards</td>
<td>4/6 (67%)</td>
<td>4/6 (67%)</td>
<td>0/6 (0%)</td>
<td>0/6 (0%)</td>
<td>0/9 (0%)</td>
<td>0/9 (0%)</td>
</tr>
<tr>
<td>Immersed filters in soapy water or disinfectant</td>
<td>0/6 (0%)</td>
<td>2/6 (33%)</td>
<td>0/6 (0%)</td>
<td>0/6 (0%)</td>
<td>0/9 (0%)</td>
<td>0/9 (0%)</td>
</tr>
<tr>
<td>Did not mix disinfection solution correctly</td>
<td>4/6 (67%)</td>
<td>2/6 (33%)</td>
<td>1/6 (17%)</td>
<td>0/6 (0%)</td>
<td>0/9 (0%)</td>
<td>0/9 (0%)</td>
</tr>
<tr>
<td>Did not complete disinfection step correctly</td>
<td>4/6 (67%)</td>
<td>6/6 (100%)</td>
<td>1/6 (17%)</td>
<td>0/6 (0%)</td>
<td>0/9 (0%)</td>
<td>0/9 (0%)</td>
</tr>
<tr>
<td>Did not complete all steps correctly</td>
<td>6/6 (100%)</td>
<td>2/6 (33%)</td>
<td>0/6 (0%)</td>
<td>0/6 (0%)</td>
<td>0/9 (0%)</td>
<td>0/9 (0%)</td>
</tr>
<tr>
<td>Total errors made on first attempt/opportunities for error</td>
<td>31/66 (47%)</td>
<td>22/66 (33%)</td>
<td>0/99 (0%)</td>
<td>0/99 (0%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NIOSH, National Institute for Occupational Safety and Health; PPE, personal protective equipment; SOP, standard operating procedure.

Table 1

*Manufacturers’ instructions versus final SOP (P < .002).

Table 2

<table>
<thead>
<tr>
<th>Final hypochlorite concentration</th>
<th>Volume of 5.25% bleach in 2 gallons water</th>
<th>Volume of 8.3% bleach in 2 gallons water</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 ppm 0.02% hypochlorite</td>
<td>1 oz (30 mL)</td>
<td>20 mL</td>
</tr>
<tr>
<td>400 ppm 0.04% hypochlorite</td>
<td>2 oz (60 mL)</td>
<td>40 mL</td>
</tr>
<tr>
<td>800 ppm 0.08% hypochlorite</td>
<td>4 oz (120 mL)</td>
<td>80 mL</td>
</tr>
<tr>
<td>1,250 ppm 0.125% hypochlorite</td>
<td>6.25 oz (188 mL)</td>
<td>126 mL</td>
</tr>
<tr>
<td>5,000 ppm 0.5% hypochlorite</td>
<td>25 oz (750 mL)</td>
<td>500 mL</td>
</tr>
<tr>
<td>1:10 bleach/water dilution</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The mean time ± SD needed to complete cleaning and disinfection using the SOPs for the first time was 23 ± 3.3 minutes and 16.1 ± 2.5 minutes on the second attempt.

Impact of disinfection process on straps

After daily treatment with the disinfection process for 45 days, the Sperian respirator strap stretched 3.9% longer than baseline, the 3M respirator strap stretched 7.1% more than baseline, and the Scott respirator strap did not change.

DISCUSSION

This study demonstrates that clear and concise SOPs for cleaning elastomeric respirators can be developed using iterative design concepts. Input from subjects who are the likely end users contributed to the final design of the SOPs. Reliance on manufacturers’ instructions or NIOSH’s instructions alone was associated with a large number of errors. Naïve health care workers performed error-free cleaning and disinfection of elastomeric respirators using the final SOPs that were developed.

In the event of a respiratory viral infection pandemic, the health care system must be prepared to act quickly and effectively to protect health care workers. During the 2009 influenza pandemic, spot shortages of disposable N95 respirators were encountered, prompting the VHA to stockpile reusable elastomeric respirators in preparation for a future pandemic. Stockpiles of PPE are useful only if health care workers are prepared to use them properly. This study provides SOPs for cleaning elastomeric respirators that can be deployed in many health care settings, using supplies that are readily available from numerous sources.

There is a growing recognition that human factors engineering can be used to improve efficiency and accuracy in health care
Respirator Cleaning Procedure

FOLLOW INSTRUCTIONS EXACTLY

Do not don PPE until instructed

ASSEMBLE THE FOLLOWING EQUIPMENT ON A WORK SURFACE NEAR A SINK WITH A WARM WATER SOURCE:

- Protective equipment: Nitrile gloves-2 pairs, 1 mask with eye shield, and 1 liquid resistant gown
- 1 canister of hospital-approved bleach disinfectant wipes
- 1 bottle of mild dishwashing liquid such as Dawn®, etc.
- 1 container of chlorine bleach (__________% hypochlorite)
- 1 soft bristle brush
- 2 plastic medication cups or other graduated container to measure ml and/or ounces
- Clock or timer
- 2-2 gallon buckets
- 1 pair of metal tongs
- 2 Chux pads 24" X 16"
- 1 clean plastic container large enough to hold mask and components after cleaning
- Hospital air and hose if available or clean, soft cloth

THEN TURN THIS PAGE UNDER AND FOLLOW CLEANING AND DISINFECTION INSTRUCTIONS ON THE NEXT PAGE

Do not don PPE until instructed

Fig 1. Standard operating procedure. PPE, personal protective equipment; SOP, standard operating procedure.

operations. We sought to apply human factors principles to pandemic preparations. A human factors study of SOPs developed for endoscopy cleaning has demonstrated improved adherence to manufacturers' guidance when SOPs were developed and implemented.12 Our results with the SOPs for elastomeric respirator cleaning and disinfection were similar, showing significantly fewer errors when following our SOPs than when using manufacturers' or NIOSH's instructions.

SOPs may be written with a goal of good initial performance to ensure that workers perform at a high level on initial efforts. If the goal of the SOP is training and transition to independence from the SOPs, a more abstract instruction set may be used, sacrificing initial performance.14 Our goal was to ensure highly accurate initial performance of the process under challenging conditions with minimal training. Therefore, we wrote detailed procedural instructions with pictures.

Our study has several limitations, including the relatively small number of subjects and the single-center design. Selecting the proper volume of bleach requires attention to detail because chlorine concentrations are not standard among commercial products. Bleach purchased from hospital supply firms had hypochlorite concentrations of 5.25%-6.0%. Bleach purchased from retail stores for consumer use had a hypochlorite concentration of 8.25%. If supply shortages during a pandemic force hospitals to use consumer markets, the hypochlorite concentration of the product selected must be carefully assessed. Our initial objective was to create a single SOP that could be used for all respirator types during a pandemic spread by the respiratory route. We were unable to accomplish this because each manufacturer specified a different concentration of bleach for its respirator. Users may insert the proper volume of bleach (Table 2) into the SOPs (Fig 1). A disadvantage of bleach disinfection of respirators that has been noted by others is the residual chlorine odor. When chlorine off-gassing was quantified, it was found to be very low after air drying the respirator overnight.15 Measurements of changes in elasticity after exposure to disinfection conditions did not include subjects wearing the respirators. Therefore, the impact of stretching the straps between exposures to bleach was not assessed. The minimal changes in elasticity that we identified could be mitigated by adjusting the straps.

The SOPs were developed for a single health care worker to disinfect a single respirator at one time. The amount of time required for health care workers to disinfect a respirator averages 16 minutes on the second attempt. Application of these SOPs to a large number of health care workers completing their duty at the same time may result in excessive wait times for a single sink. This could be addressed by staggering shifts or by providing multiple work areas for cleaning and disinfection. Filling and mixing the solutions in buckets for each disinfection episode was the most time-consuming part of the procedure. This could be remedied...
with the use of laboratory water bath for cleaning and disinfection solutions. By making warm soapy water and disinfecting solutions every 8-12 hours and keeping them at a constant temperature, health care workers would be able to clean and disinfect the respirators more quickly and efficiently.

Development of optimized SOPs solved many of the problems encountered by subjects using manufacturers’ instructions. Still, some issues may require redesign of respirators. For example, subjects had difficulty reattaching filters on some brands of respirators after cleaning and disinfection. Arrows to indicate correct filter placement could be added by these manufacturers in a color which could be distinguished from the masks and filters to facilitate correct reattachment.

New modalities, such as special washers-sterilizers, which would not damage elastomeric respirators, countertop ultraviolet light disinfections units, or even designated rooms with ultraviolet light to hang clean respirators, could be considered in the future.

The final concentrations of bleach used in the SOPs were selected to adhere to manufacturers’ recommendations, which ranged from 50-400 ppm. The concentration previously tested and

**TO CLEAN AND DISINFECT THE RESPIRATOR, FOLLOW THESE STEPS:**

1. Place unopened bag containing the contaminated respirator mask near sink by instructions
2. On the other side of the sink, place opened Chux pad and lay tongs on top. Place the second opened Chux by the clean bin.
3. Place the 2 buckets in the sink and run 1 gallon (4 quarts) of comfortably warm (not hot) water into the first bucket and 2 gallons (8 quarts) of warm water into the second bucket.
4. Perform hand hygiene and then don protective equipment—gloves, gown, and mask with eye shield
5. Pour 15 ccs (1/2 oz.) of DISHWASHING LIQUID in the first bucket containing 1 gallon of water
6. Pour ______ ccs (________ oz.) of BLEACH in the second bucket containing 2 gallons of water. Mix bleach solution with tongs, and lay them back on the Chux.
7. Open biohazard bag, remove respirator and place it on the top of the bag.
8. Pop off the splashguards (if equipped) on each side of the mask and immerse them in the soapy water.
9. Remove the filters by unscrewing or turning them to the left.
10. Wipe the filters with disinfectant wipes and place them in the clean bin.
11. Without removing the straps, immerse the mask in the soapy water.
12. Clean mask and splashguards (if equipped) with the brush and soapy water-gently on the inside of the mask to avoid damaging the valves. Then rinse them well in running water.
13. Place rinsed splashguards and mask (face up) into bleach disinfecting solution. See photograph # 1 at bottom of page.
14. Submerge mask completely into the solution; then while the mask is submerged, use the tongs to turn the mask over until it is facedown. This will avoid air pockets.
15. Place the end of the tongs gently inside the mask to keep it submerged. Then lean the tong handles against the side of the bucket. Leave tong handles submerged in the disinfectant solution. See photograph # 2 at bottom of page.

16. **Set timer for 2 minutes.**
19. After the 2 minute immersion (TIMED), remove mask and splashguards from the disinfecting solution with the tongs and set them on the Chux by the side of the sink, along with the tongs.
20. Rinse mask and splashguards (if equipped) completely in running water and place them on the second Chux by the clean bin.
21. Dry mask and splashguards with hospital air hose if available; if not available, dry with clean cloth or allow to air dry.
22. When dry, reassemble mask, filters, and splashguards. Check integrity of respirator and store in a plastic bag.
23. Empty and rinse buckets, clean sink area with bleach wipes. Then remove PPE and perform hand hygiene.
shown to inactivate influenza virus was 1,000 ppm. Tests of elastomeric respirators treated with these higher concentrations of bleach have not been reported. 3M has published online guidance stating that the 5,000-ppm concentration may be used for their respirator and advising users to carefully examine the respirator for damage with each use.4 Bleach may be used to disinfect respirators contaminated with other agents (eg, Ebola, *Bacillus anthracis*). However, there are numerous additional considerations that would need to be included in SOPs for safe disinfection of these pathogens, including additional PPE to protect workers from higher bleach concentrations, contact time, bleach concentration, and pH. Our final SOPs deviate from manufacturers’ instructions to remove the strap before disinfection. We demonstrated that daily exposure of the straps to the cleaning and disinfection process for 45 days resulted in minimal change (<10%) in the elasticity of the straps. We believe complete disinfection of the respirator includes disinfection of the straps, and we designed the SOPs to reflect this.

In summary, we have designed and tested SOPs for elastomeric respirators that can be rapidly deployed in the event of a large-scale airborne infectious disease outbreak.

References


