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Perspective

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Impact of Extended Use and Decontamination of N95 Respirator Fit

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Severe acute respiratory syndrome coronavirus 2 is an emerging pathogen that is spreading worldwide. It is primarily transmitted by respiratory droplets and by direct and indirect contact; however, airborne transmission can also occur in the context of aerosol generating medical procedures, necessitating the usage of N95 respirators for protection of healthcare workers (HCWs). The Severe acute respiratory syndrome coronavirus 2 pandemic has caused a global shortage of N95 respirators that can represent a risk to HCWs performing aerosol generating medical procedure.

To solve this shortage, alternative strategies have been considered such as decontamination with vaporized hydrogen peroxide (VHP) based on promising pre-existing research available. This technique was able to reduce pathogen burden while maintaining filtration performance. The respirator fit and elastic band integrity, as measured on a surrogate robotic manikin head form, were also determined to be maintained for up to 20 decontamination cycles.

Based on these encouraging data, the FDA and Health Canada have approved the emergency use authorization of some VHP decontamination systems such as the STERIS V-PRO max Low Temperature Sterilization System. These VHP methods allow cellulose-free N95 respirators to be decontaminated and re-utilized up to 10 times. However, the aforementioned studies supporting these claims were mainly performed in laboratory settings and may overestimate post-decontamination quality of respirator fit, as the respirators were not used for extended periods between decontamination cycles.

After enrolment, participants received teaching on proper quality check, seal check, and donning and doffing of the respirator. Each participant was fit-tested with their current N95 respirator or with the ProGear model using qualitative fit-testing method by trained technicians and a bitter solution (denatonium benzoate, Bitrex FT-32, 3M). The alternative solution for participants who could not taste the Bitrex was a sweet saccharin solution (FT-12, 3M). The participants were placed under a hood and the solution was administered through a hole. If the participant could taste the bitter or sweet substance, the procedure was considered to represent respirator fit-test failure.

Participants were expected to wear the respirator during their regular scheduled work hours for a total of 4 consecutive hours. Of note, participants were advised not to wear the study's respirator for patients under airborne or droplet isolation precautions as the objective was to investigate the impact of reprocessing and prolonged usage. Participants were instructed to minimize the donning and doffing during this 4-hour time; however, temporary removal of the respirator was permitted, if necessary, for example to drink. The N95 respirator was then collected for decontamination at the end of each usage period.

Decontamination was performed with VHP (V-PRO maX Low Temperature Sterilization System; Steris, Mentor, OH) in the medical device reprocessing unit. The decontamination was set to a non-lumen setting and lasted 28 minutes. Each respirator was separately placed in a Tyvek 8 × 14 inch pouch identified for use in low-temperature sterilization with VHP. A verified vaporized H2O2 process indicator adhesive label was added on each pouch to validate exposure to the sterilant and to ensure that the cycle is complete and respects the quality standards in reprocessing. Before reusing the decontaminated respirator, each mask was visually inspected for loss of integrity. Participants were then re-fit-tested on the mask they previously used to assess the respirator's structural and functional integrity. Each cycle, which consisted of a 4-hour period of respirator use, the decontamination with VHP, and fit-testing after decontamination, was repeated until failure of the fit test occurred (eg, leak detected on fit-test) or mechanical failure of the respirator was detected (eg, rupture of the elastic bands). The occurrence of either of these 2 aspects determined the end of the study for that participant.

The primary endpoint of the study was respirator failure, defined as either fit-test failure or mechanical failure, and the primary outcome was the overall number of cycles required for half of the respirators to fail. In the case of mid-cycle mechanical failure, we added a 0.5 value to the number of cycles completed. Secondary outcomes included fit test failure (ie, number of cycles that can be performed before failure of fit testing), capacity of user seal check to predict fit test failure, and the number of times the respirator was donned and doffed during a 4-hour period.

We used survival curves to compare mask failure of different models. Two different figures were created: The first one included both mechanical failures and failures of fit testing in the outcome in order to explore the global survival of masks. The second figure only included failures of fit testing (and censored mechanical failures) to explore the number of times respirators could be reprocessed before loss of fit testing. In both figures, in case of loss to follow-up, participants were censored at the beginning of each next cycle.

Even though some expert organizations and respirator manufacturers claim that N95 respirators can be safely decontaminated up to 10 times using the Steris V-PRO system, our data indicates that this may not be the case in the context of extended respirator use, as most respirators would lose their fit after a few cycles of extended use and decontamination. We also detected wide variation between brands in the number of cycles that can be performed before failure, which questions the "one size fits all" recommendations that have been published. Changes in respirator fitting over multiple donning's and prolonged wear have been associated with an increased fit test failure. Respirators cannot provide optimal protection without a proper seal and most aerosolized contaminants that enter a worn N95

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respirator result from seal leakage rather than insufficient filtration performance – the latter of which is preserved for up to 50 cycles with VHP decontamination. As the capacity to decontaminate respirators is further hampered by mechanical failures, our study indicates that the number of decontamination cycles that can be safely performed is lower than previously reported.

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