Concise Communication

Evaluation of N95 respirator ultraviolet decontamination and clinical reuse with quantitative fit testing

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Abstract

The supply of N95 respirators has been severely strained by the coronavirus disease 2019 (COVID-19) pandemic. We used quantitative fit-testing to evaluate 16 participants and 45 respirators through up to 4 rounds of ultraviolet decontamination and clinical reuse. The mean fit-test failure rate was 29.7%, and the probability of failure increased through N95 reuse.

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The ongoing coronavirus disease 2019 (COVID-19) pandemic has severely disrupted the N95 respirator supply chain, causing tremendous challenges for healthcare facilities.1-4 Proposed strategies to extend the use of disposable respirators include decontaminating respirators for reuse in a crisis-level shortage.1-4-6-8-10 Two recent systematic reviews have evaluated the effectiveness of decontamination and maintenance of N95 filter performance.2,3 Ultraviolet germicidal irradiation (UVGI) and vaporized hydrogen peroxide (VHP) appear to be the most frequently studied and recommended, but few studies have evaluated the continued appropriate fit of N95 respirators after decontamination and clinical reuse.5-6-8-9-10 Three small studies have evaluated maintenance of respirator fit after reuse during the COVID-19 pandemic.4-6 Degesys et al3 reported a 38.2% qualitative fit-test failure rate overall and increased failure rates with each additional shift worn. Lieu et al6 evaluated 4 N95 models after extended clinical use and VHP decontamination with qualitative fit-testing. The probability of failure increased with each cycle of decontamination and reuse, with a median of 2 cycles before fit failure.6 Fischer et al4 concluded that respirators could be reused up to 3 times when using UVGI decontamination.

The goal of this performance improvement project was to evaluate for respirator fit-test failure during up to 4 rounds of UVGI decontamination and clinical reuse.

Methods

Due to critical supply-chain shortages, our health system developed an N95 decontamination method based upon the University of Nebraska protocol (UVGI with ClorDiSys UVGI Light System) using our existing UVGI equipment (Clorox Optimum UV system, Clorox, Oakland, CA).1 Each N95 respirator (3M 1870, 3M, St Paul, MN) was used for up to 4 days of clinical reuse with 4 rounds of decontamination. Respirators were inspected and round numbers were marked by environmental services decontamination staff, then the respirators were returned to the individual clinician for reuse. Respirators were discarded after the fourth decontamination round or if visibly soiled or broken. Clinicians were encouraged to monitor their N95s for signs of wear and to perform user seal checks before each use. Respirators used clinically were evaluated by quantitative fit-testing using a PortaCount 8038 Fit-Tester (TSI, Minneapolis, MN) via a fit-testing port inserted through the respirator. During clinical use, the fit-testing port was covered with a tight-fitting cap. Four study physicians confirmed the integrity and seal of the cap during pilot testing by installing and testing a second fit-testing port in 4 respirators that were not used clinically or decontaminated. The use of the performance improvement data was approved by the facility’s institutional review board.

Participants and settings

Nurses and physicians working in our high-volume emergency department (~105,000 patients/year) were recruited via e-mail and word-of-mouth, and they voluntarily participated during May–July 2020. Inclusion criteria included successful clearance fit-testing on the 3M 1870 model and regular clinical use of UVGI-decontaminated N95 respirators. Participants reused their N95 during regular clinical shifts according to hospital protocol, which also promoted extended use (wearing for multiple patients) to the extent possible during each shift. After each round of clinical use and UVGI decontamination, the participants were asked to have quantitative fit-testing performed. A fit factor score of 100 was considered passing. The highest quantitative score reported by the machine was 200, and any score >200 was reported as “201.” Failing respirators were removed from clinical use. All respirators were visually inspected for wear and/or abnormalities by the participant and fit-tester prior to fit-testing. Additionally, participants reported the estimated number of times they donned and
doffed their respirator, along with the approximate number of hours the respirator was worn during each shift. This project was designed to evaluate safety of this new and critically necessary process during a rapidly evolving pandemic rather than as a formal research study; thus, no blinding or randomization was used.

Statistical analysis

We analyzed participants’ demographics, initial clearance fit-testing scores, and scores for each reuse round for correlation. We used \( \chi^2 \) tests for categorical variables and Wilcoxon rank-sum tests for continuous variables. We created a Kaplan-Meier curve with 95% confidence intervals to show the probability of a respirator moving on to the next round of reuse. We imputed missing data in the following manner: If fit-testing data were not available for an earlier round, but the N95 was later tested and failed, we assumed that it would have failed in the earlier round. If a respirator passed in a later round but results were unavailable for an earlier round, we assumed that it would have passed in the earlier round. We performed all statistical analyses using R version 3.4 software (R Foundation for Statistical Computing, Vienna, Austria).

Results

Overall, 16 clinicians (9 nurses, 7 physicians) tested 45 respirators used clinically. We conducted 74 fit-tests related to this project (64 respirators used clinically and 10 pilot fit-tests). The overall mean fit-test failure rate for clinically used respirators was 29.7% (19 of 64) and 10% (1 of 10) for pilot-tested respirators. Younger age was significantly associated with fit-test failure (Table 1). Lower fit-factor scores on clearance fit-testing suggested an increased risk for failure, but this was not statistically significant. The Kaplan-Meier estimate of a respirator passing the third round was 54%, and 17 data points were imputed due to missing data (Fig. 1).

Discussion

Our project appears to be the first to use quantitative fit-testing to evaluate clinically reused and decontaminated respirators during...
the COVID-19 pandemic. We observed a relatively high fit-test failure rate in each round of decontamination and reuse, with a progressively decreasing probability of passing. Our data validate other small studies suggesting a progressive increase in N95 fit-test failure rate through repeated reuse and decontamination. Our data also support current CDC recommended limits of 5 donnings and doffings per N95.\(^4\) It is unclear whether fit failure is related to physical stress on the N95 components (eg, straps or nosepiece) from reuse, from the decontamination process, or a combination. Lower scores on clearance fit-testing suggested increased risk of fit-test failure, as did younger age. This latter finding was surprising, and further study is needed for confirmation. Although inadequate fit may presumably increase risk of COVID-19 infection, none of our participants were diagnosed with COVID-19 during the evaluation period.

During this project, we capped the fit-testing ports, which appeared to be an effective method of reusing fit-tested respirators. This method could be used to increase the supply of available N95s for clinical use.

Our project has several limitations. All participants were aware of the scope of the project, and blinding or randomization was not used. Our sample size was small, and only 1 N95 model was tested; therefore, the generalizability of our findings may be limited. Participants were not always able to be fit-tested repeatedly due to clinical responsibilities or availability of fit-testing, which required imputation of data and potential inaccuracies, although we took a conservative approach. We did not observe correlation between failure and hours worn or number of donning and doffing episodes, as other studies have suggested; however, this finding may have been subject to recall bias.

Although the initial supply-chain constraints identified early in the COVID-19 pandemic have eased somewhat, they have not been eliminated. Additionally, as the pandemic continues, N95 respirator supplies may yet again worsen. N95 respirators are designed for single use, not for extended use and reprocessing; this study has identified possible safety implications of this approach, necessitated by this crisis. As a result of this project, our health system significantly increased the use of half-face elastomeric respirators and initially limited N95 decontamination to 2 rounds, eventually discontinuing N95 reprocessing entirely. Resources must be devoted to improving the respirator supply chain and optimizing nondisposable alternatives to protect our healthcare personnel during this and future pandemics.

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