

Review of the Effect of Continuous Use and Limited Reuse of N95 Respirators on Respirator Fit

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ABSTRACT

Background: Coronavirus disease 2019 (COVID-19) has led to severe shortages of filtering facepiece respirators (FFRs). As a result, extended use, limited reuse, and FFR decontamination have been utilized to extend the life of single-use FFRs. Although some studies have raised concerns that reuse could affect the FFR's ability to form a seal, no comprehensive literature review of the effect of extended use or limited reuse on FFR seal exists.

Objective: The goal of this review was to assess the effect of extended use and reuse on respirator fit, with and without decontamination.

Methods: Searches of PubMed and Medrxiv yielded 24 papers that included assessment of fit after extended use or limited reuse on a human. One additional handpicked paper was added.

Results: Studies report a wide variation in the number of donnings and doffings before fit failure between different models of respirators. Additionally, while seal checks lack sufficient sensitivity to reliably detect fit failures, individuals who failed fit testing were often able to pass subsequent tests by re-positioning the respirator. Even with failure, respirators often maintained a substantially higher level of fit than a surgical mask, so they may still provide a level of protection in crisis settings.

Conclusion: Based on currently available data, this literature review was unable to establish a consensus regarding the amount of time a respirator can be worn or the number of uses before fit failure will occur. Furthermore, variations in reuses before fit failure between different models of N95 respirators limit the ability to offer a comprehensive recommendation of greater than one reuse or a specific amount of wear time.

Keywords: Continuous Use, Limited Reuse, N95 Respirator, Mask, Personal Protective Equipment (PPE), Filtering Facepiece Respirator (FFR), Coronavirus (COVID-19), Decontamination

INTRODUCTION

In the context of the ongoing pandemic, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the associated Coronavirus Disease-19 (COVID-19) illness have resulted in nearly 500 million infected individuals worldwide. In the United States alone, there have been over 79 million cases and 975,000 deaths as of April 7, 2022 (World Health Organization, 2020). The pandemic has created demand for personal protective equipment (PPE), particularly Filtering Facepiece Respirators (FFRs) that has far exceeded supply, resulting in shortages of equipment and reuse of single use respirators that would not be permitted in a conventional situation (United States Food and Drug Administration, 2021).

In the United States, the dominant FFR most often used by healthcare workers to prevent COVID-19 is the N95 respirator, which is approved by the National Institute for Occupational Safety and Health (NIOSH), (1997). Respirators form a seal, known as “fit,” around the face of the wearer, and must have a $\geq 95\%$ filtration efficiency of $0.3\ \mu\text{m}$ non-oily particles to qualify as an N95 (National Institute for Occupational Safety and Health, 1997). Respiratory fit is determined by either qualitative or quantitative fit testing. Qualitative fit testing involves a wearer being exposed to an aerosolized scented sweet (saccharin) or bitter (denatonium benzoate) solution while performing a standardized set of activities. Qualitative fit tests provide a binary “pass” or “fail” score, depending on whether the wearer detects the scent during the exercises. Quantitative fit testing provides a “fit factor,” which is a numerical value derived from the amount of particulates inside and outside of the respirator during the standardized activities. A fit factor greater than or equal to 100 is considered passing (Occupational Safety and Health Administration, 2009).

To help conserve the limited supply of N95 respirators during the pandemic, the Centers for Disease Control and Prevention (CDC) released an article titled, “Strategies for Optimizing the Supply of N95 Respirators,” which described strategies for typical infection control practice, known as conventional capacity, as well as strategies for stretching a limited supply of respirators during shortages, known as contingency capacity (Centers for Disease Control and Prevention: National Center for Immunization and Respiratory Diseases, 2021). These capacities are described in Figure 1. When respirator demand is unable to meet the needs of healthcare workers after conventional and contingency capacity strategies are exhausted, crisis capacity is initiated, resulting in the implementation of strategies that do not normally align with US standards of care. For each of these capacities, the CDC outlined techniques, such as administrative controls that are centered around reducing the number of healthcare workers who interact with patients, engineering controls that rely on physical barriers, such as partitions and negative pressure ventilation systems, as well as PPE utilization strategies. For example, while disposable PPE, such as N95 respirators are typically discarded after putting on the respirator (donning) for a single patient encounter in conventional capacity, contingency capacity allows for extended use, referring to wearing the same respirator for encounters with multiple patients without removing (doffing) the respirator. Similarly, in crisis capacity, strategies include respirator storage after doffing for later use with other patients, as well as decontamination of the respirator. The CDC later updated their crisis capacity guidelines stating that respirators should only be reused a maximum of four times, for a total of five donnings and doffings, regardless of whether they were decontaminated (Centers for Disease Control and Prevention: National Center for Immunization and Respiratory Diseases, 2020).

In response to critical respirator shortages, many of these strategies were implemented during the COVID-19 pandemic, including rationing, extended use, reuse, and decontamination. Widely cited was a 2016 study conducted by the Battelle Memorial Institute (Columbus, USA), which demonstrated that non-cellulose based N95 respirators could maintain fit after exposure to hydrogen peroxide decontamination (H_2O_2) for 20 cycles, at which point strap failure occurred (Battelle, 2016). A large manufacturer of N95 respirators, 3M Company (St. Paul, USA), began to publish technical bulletins with data on how their respirators were affected by various decontamination methods (3M, 2021) and the US Food and Drug Administration (FDA) began to issue Emergency Use Authorization (EUA) for decontamination of respirators using specific technologies. However, few studies accounted for the impact of wear time or repeat donning and doffing on the ability of a respirator to maintain its seal. NIOSH’s “Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings” cites contact transmission from touching the contaminated respirator as “the most significant risk” of reuse; however, they also note concerns that “rough handling” or “excessive reuse” could reduce the protection for the wearer (Centers for Disease Control and Prevention: National Center for Immunization and Respiratory Diseases, 2020). Although there have been numerous studies and literature reviews investigating the filtration performance of respirators subjected to various decontamination methods, we believe this to be the first literature review of the effect of extended use and reuse on respirator fit, with and without decontamination.

Conventional Capacity Strategies (Everyday)	Contingency Capacity Strategies (During Expected Shortages)	Crisis Capacity Strategies (During Known Shortages)
Personal Protective Equipment: Proper use (including medical clearance, training, and fit testing) that comply with OSHA's Respiratory Protection Standard of sanctioned equipment with the goal to limit Healthcare Provider (HCP) exposure		
• N95 respirators • Alternatives to N95 respirators	• Prioritize respirators for HCP using them for PPE • Extended use of N95 respirators	When supplies are running low: • Use of respirators beyond the manufacturer-designated shelf life • Limited re-use of N95
Administrative Controls: Policies and practices created by an employer for the workplace that aim to prevent exposure		
• Telemedicine • Limit face-to-face encounters with patients • Limiting visitation • Source control • Qualitative fit testing	• Decrease length of hospital stay for medically stable patients • Temporarily suspend annual fit testing	When no respirators remain: • Exclude HCP at increased risk for severe illness from contact with patients with known/suspected infection
Engineering Controls: An attempt to place a barrier between the hazard and the HCP to reduce exposures		
• Use of airborne infection isolation rooms • Use of physical barriers • Use of ventilation systems	• Use of airborne infection isolation rooms • Use of physical barriers • Use of ventilation systems	When no respirators remain: • Expedient patient isolation rooms for risk-reduction • Ventilated headboards

Figure 1. CDC strategies to optimize supply of N95 respirators (Centers for Disease Control and Prevention: National Center for Immunization and Respiratory Diseases, 2021).

METHODS

A literature review was conducted of PubMed (National Library of Medicine, Bethesda, USA) for peer-reviewed and MedRxiv (Cold Spring Harbor Laboratory, Cold Spring Harbor, USA) for relevant pre-publication papers up to June 12, 2021. The search terms used for PubMed are listed in Appendix A, and all resulting papers were manually screened using Abstrakr, an abstract screening platform (Wallace et al., 2012). As the search capabilities of MedRxiv are more limited, Medarxivr, an open-source R package, was used to query medRxiv via the Cold Spring Harbour Laboratory API to allow the usage of boolean operators (McGuinness and Schmidt, 2020). Results were imported into Microsoft Excel 2019 (Microsoft Corporation, Albuquerque, USA) for screening. The search terms used for MedRxiv are shown in Appendix B.

All articles first underwent a title and abstract screening in accordance with Cochrane Guidelines for a Rapid Evidence Review by two blinded reviewers (Garritty et al., 2021). All reviewers screened the first 20 papers together and discussed any discrepancies before continuing. Articles were only excluded if both reviewers independently eliminated them based on relevance, with any discrepancies resulting in a full text review. During the full text review, agreement between two reviewers was again required to exclude an article, with all discrepancies broken by a third blinded reviewer. Selected articles found in citations of papers, as well as additional hand-picked articles, were added to the final review. The screening process is shown in Figure 2.

To meet inclusion criteria, the paper must have presented experimental data, with literature reviews eligible for inclusion only if they cited studies not already encompassed by the search. Studies must specifically have evaluated N95 respirators for fit, measured either quantitatively or qualitatively, for respirators donned and doffed a minimum of two times or worn for an extended period by a human.

RESULTS

Ultimately, 25 papers were selected to include in this review. Summaries of the parameters utilized and conclusions of these papers are shown in Tables I-III.

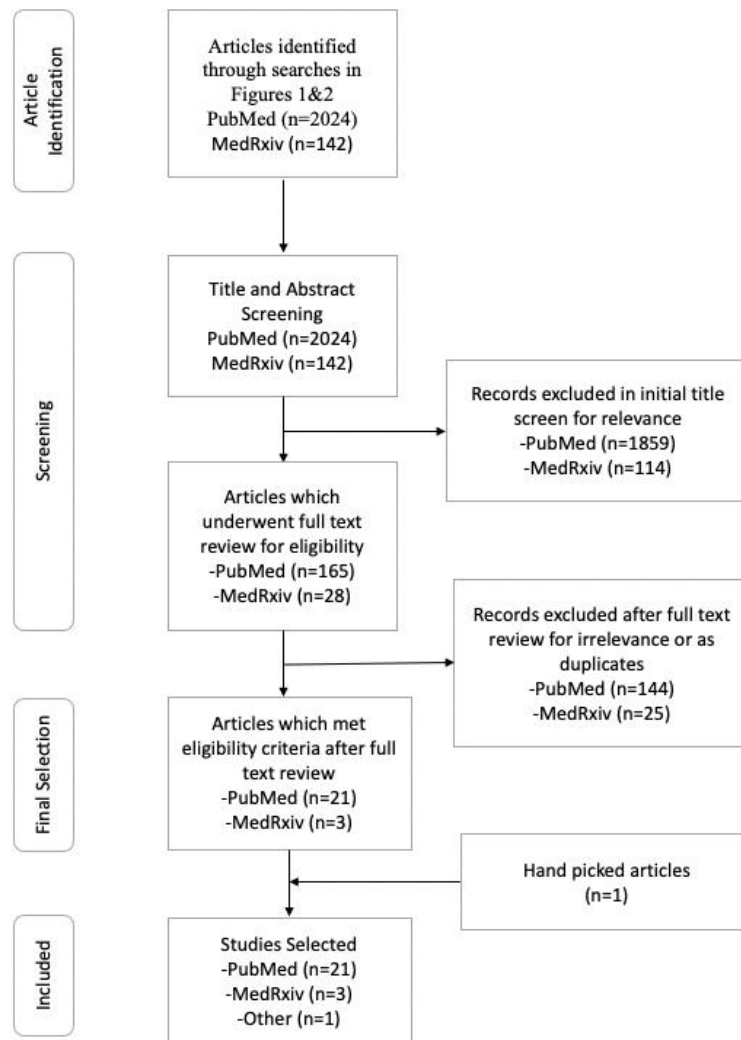


Figure 2. Article screening process.

Table I. Summary of Papers Involving Continuous Use

Authors	FFR Tested	Methods	Results/Conclusion
Rivard, Pester, McMahon, Check, Kelly, Balakrishnan, Jeanmonod, Jeanmonod (2021)	1860, 8210, Aura 1870 (3M, St. Paul, USA), Kimberly-Clark 46727 (Kimberly-Clark, Irving, USA), Milwaukee 50-73-4010 (Milwaukee Tool, Brookfield, USA), H801 (Honeywell Safety Products, Smithfield, USA)	51 participants who passed fit testing at or near the beginning of their shift recorded how many hours the mask was worn and the age of the mask. Qualitative fit testing was performed periodically throughout their shift.	88% percent of participants passed fit testing after 2-12 hours of continuous use. Of the 12% who failed repeat fit testing, failure occurred after 3-10 hours of use. Respirators used longer than 2 days were more likely to fail initial fit testing. However, if they passed, they were not more likely to fail than those worn for 2 days.

Table II. Summary of Papers Involving Limited Reuse without Decontamination

Authors	FFR Tested	Methods	Results/Conclusion
Bergman, Viscusi, Zhuang, Palmiero, Powell, Shaffer (2012)	Moldex 2200 (Moldex, Culver City, USA), Kimberly Clark PFR95-270 (Kimberly Clark, Irving, USA), 8000, 8210, 1860, 1870 (3M, St. Paul, USA)	10 subjects donned each model of respirator up to 20 times with 2 minutes between each donning. Quantitative fit testing (TSI PortaCount Plus Model 8020A, TSI, Shoreview, USA) was conducted using an abbreviated procedure and in between each donning. Testing was terminated if 3 tests were failed.	For all models, the mean FF for donnings 16-20 were statistically reduced compared to donnings 1-5. Three of the six models showed significant reductions in fit factor for donnings 11-15 compared to 1-5. Five donnings can be performed before fit factors drop below 100. The study found a gradual decrease in fit over multiple donnings, however also noted that 55%-65% (depending on model) of respirators still had passable fit factors on the 20th donning. The study set an arbitrary acceptable failure rate of 5% and stated that to achieve this, no more than 5 donnings (4 reuses) should be performed without risking failure that would not be easily detected by the wearer.

Degeysys, Wang, Kwan, Fahimi, Noble, Raven (2020)	1860 (3M, St. Paul, USA), Kimberly-Clark 46727 (Kimberly-Clark, Irving, USA), Halyard 46867 (O&M Halyard Health, Alpharetta, USA)	68 participants self-reported use and reuse. Qualitative fit testing at various stages (Bitrex).	Overall respirator fit test failure rate was 38.2%, with a failure rate of 70.6% for Kimberly-Clark 46727 and Halyard 46867 respirators (duckbilled) compared to 27.5% for 3M 1860 respirators (dome-shaped). Further analyses performed for 3M 1860 respirators found that failure rate was associated with increased hours worn and number of donning/doffings.
Duncan, Bodurtha, Bourgeois, Dickson, Jensen, Naqvi (2020)	1870 (3M, St. Paul, USA)	Wearers donned and doffed respirators for 3-4 simulated "uses" over 5 days. Each simulated use consisted of 1 hour and 20 minutes of exercises. The respirator was doffed and rested for 15-30 mins before the next wear. Quantitative fit testing (PortaCount Model 8026, TSI, Shoreview, USA) and simulated workplace protection factor testing were conducted on days 1,3,5.	Fit factors were lower for all subjects at the end of the 5-day study period but did not sequentially decrease with the number of uses. Fit factor fell below 100 for 4 of 7 subjects after the first day of testing (3-4 use cycles) and 6 of 7 subjects by day 2 (7-8 use cycles). However, some subjects who previously failed fit on day 1 passed fit on day 3. All respirators had an Assigned Protection Factor (APF) greater than 10 for up to 19 uses during the 5 day study period, constituting up to 30.25 hours of wear time. Two of seven subjects experienced respirator strap failure on days 3 and 4, respectively.
Fabre, Cosgrove, Hsu, Jones, Helsel, Bukowski, Sobota, Sck-Samuels, Milstone, Maragaki, Rock (2021)	1860, 1870 (3M, St. Paul, USA)	99 participants self-reported length of wear and donnings. Qualitative (Saccharin) with confirmatory Quantitative (PortaCount Model 8020, TSI, Shoreview, USA) fit testing if the user failed the qualitative test. Seven participants failed a seal check or qualitative fit test but did not complete quantitative fit testing.	Of the 92 participants who completed the protocol, 74 (80%) passed the seal check and qualitative fit testing with 18 (18%) failing a qualitative fit test. The median number of reported donnings was 40 and the median longest length wear time was 2.5 hours. Respirators passed fit testing >95% of the time for up to 23 donnings (for failures verified with quantitative fit testing). At 40 donnings, the failure rate for quantitatively verified failures was 82%. There was no difference in result based on the respirator model tested. The paper excluded respirators from the primary analysis which failed either a seal check or qualitative fit test but were not quantitatively fit tested.

Jung, Kim, Yang, Lim, Kwak, Hong, Kim, Kim (2021)	1870+ (3M, St. Paul, USA)	10 female practitioners were quantitatively fit tested (PortaCount Pro+ Model 8038, TSI, Shoreview, USA) after respirators worn for 2 hours (2 donnings), 3 hours (3 donnings), and 4 hours (4 donnings). They were separately tested using a new respirator after a single 3-hour wear period (2 donnings) and a 6-hour wear period (3 donnings).	In the first experiment, 60%, 70%, and 90% percent of participants experienced a fit failure after 2, 3, and 4 consecutive donnings, respectively. For the 3-hour periods, 50% experienced fit failure after the first donning and 70% had failures after 2 consecutive periods. However, all participants were able to pass a re-test using the same respirator every time a fit failure occurred.
Nakamoto, Saraya, Kurai, Fukukawa, Taneoka, Shimasaki, Ishii (2021)	HPR-R/HPR-S (Hogy Medical Co. Ltd, Tokyo, Japan), Hi-Luck 350 (Koken Ltd, Tokyo, Japan), 9211 (3M, St. Paul, USA)	41 healthcare workers who wore respirators once per week for approximately 2 hours underwent quantitative fit testing (Model MT-03 (Sibata Scientific Technology Ltd, Saitama, Japan)) each week for a total of 3 weeks.	Overall, 85.4% of participants passed all 4 fit tests (3 reuses), with no significant differences identified between participant age, sex, or respirator model.
Vuma, Manganyl, Wilson, Rees (2019)	1860, VFlex (3M, St. Paul, USA), Kimberly-Clark 46727, 46827 (Kimberly-Clark, Irving, USA)	9 men and 16 women donned each of the tested N95s 6 times. Quantitative fit testing (TSI PortaCount Plus Model 8038, TSI, Shoreview, USA) following each of 6 consecutive donnings for 25 subjects.	During the study, 52% percent of subjects passed all 6 donnings, with 48% failing one or more fit tests. 42% of subjects who failed a fit test (16% of total) never passed a subsequent test after. 50% of those who had a fit failure were able to pass a subsequent fit test, resulting in 65% of participants passing their fit test at the end of 6 donnings. The authors believed subjects who failed and then passed a subsequent test may have done so due to improper donning. Both the average and median fit factors were lower after 6 donnings than the first donning.

Table III. Summary of Papers Involving Decontamination

Authors	FFR Tested	Methods	Results/Conclusion
Autoclave			
Czubryt, Stecy, Popke, Aitken, Jabusch, Pound, Lawes, Ramjiawan, Pierce (2020)	1054S (Aearo Company, Indianapolis, USA)	Respirators were worn for 2-8 hours, decontaminated in a Steris Amsco 400 Series Prevacuum Steam Sterilizer Model 20 (Steris Life Sciences, Mentor, USA) at 121°C for 30 minutes plus a 15 minute drying cycle, then distributed for reuse and qualitatively fit tested (Portacount PRO+ 8038) after donning.	All respirators had a fit factor >100 after the first cycle of use and decontamination. After a second cycle of use and decontamination, 2 of 14 respirators had a fit factor less than 100.
Heat			
Anderegg, Meisenhelder, Ngooi, Liao, Xiao, Chu, Cui, Doyle (2020)	1860, 1870, 8210+ (3M, St. Paul, USA), Chen Heng V9501 KN95	1 respirator of each type was quantitatively fit tested (TSI Portacount 8038, TSI, Shoreview, USA) and then decontaminated using heat (Despatch LAC1-38-8, Illinois Tool Works, Lakeville, USA) with at 85°C with 60-85% humidity. Respirators were quantitatively fit tested between each cycle and the process was repeated 5 times for a total of 6 fit tests. To detect variability in the seal, selected respirators underwent additional fit testing cycles without additional decontamination. Paired controls underwent 6 consecutive fit tests without decontamination.	The 3M 8210+ and 3M 1860 passed all fit tests and had fit factors >200 after 5 cycles of decontamination and up to 8 donnings/doffings. While the 3M 1870 also passed all fit tests, the respirator subjected to decontamination had lower fit factors than its corresponding control and experienced some delamination of the foam nosepiece. Some respirators in the study, particularly the 3M 1860, experienced increasing fit factors among both the control and experimental respirator. The authors believed this to be caused both by user familiarity in donning the respirator as well as the respirator “breaking in” and better conforming to the wearers’ face. Chen Heng V9501 KN95 showed initial fit factors below passing range.

Loh, Clark, Cherrie (2020)	8833, 8835+, 1873, 1863, 9332+, 9320+, 8810, 1863(T1), (3M, St. Paul, USA) AlphaSolway S-3V (Alpha Solway, Annan, UK), Honeywell532 1 (Honeywell Safety Products, Smithfield, USA)	4 participants tested 9 different models of respirators. After an initial fit test, respirators were treated for 1 hour at 85°C, then cooled for 30 mins before fit testing (TSI PortaCount Pro+ 8038)	5% of respirators failed after treatment, while all others passed. Aside from the 3M 8810, all respirators that passed fit testing had lower post-treatment fit factors.
Massey, Borucki, Paik, Fuhrer, Bora, Kane, Haque, Baxamusa (2021)	8210 (3M, St. Paul, USA)	2 participants and 18 respirators were utilized in the study. Respirators were donned and doffed once prior to decontamination and then quantitatively fit tested (PortaCount Respirator Fit Tester 8038, TSI, Shoreview, USA) after either 1 or 10 treatment cycles of either dry heating at 75 °C (Cascade Tek TFO-1, Cascade Tek, Plano, USA). Humid heating, at 75 °C and 90% humidity, was used.	All samples subjected to dry heat cycles passed the quantitative fit tests, with all 4 respirators achieving the highest measurable fit factor after 10 cycles of treatment. However, 1 respirator experienced a strap failure during doffing after the fit test. The samples subjected to moist heat all passed quantitative fit testing after both 1 and 10 cycles, with no significant correlation between fit factor and number of treatment cycles.
Vaporized Hydrogen Peroxide (VHP)			
Jatta, Kiefer, Patolla, Pan, Harb, Marr, Baffoe-Bonnie (2021)	8211, 9210 (3M, St. Paul, USA)	Respirators were fit tested by a participant before being subjected to either 5, 10, or 15 cycles of VHP decontamination (V-PRO maX Low Temperature Sterilization System, Steris Life Sciences, Mentor, USA). Respirators were then quantitatively fit tested (PortaCount Pro 8038, TSI, Shoreview, USA).	All respirators in the study passed a second fit test after 5, 10, and 15 decontamination cycles. However, respirators treated for 15 cycles were reported to be tight and uncomfortable to wear.

Levine, Grady, Block, Hurley, Russo, Peixoto, Frees, Ruiz, Alland (2020)	1860/1806S, 1870, 9210, (3M, St. Paul, USA) 46727 (O&M Halyard Health, Alpharetta, GA), Cardinal Health (Cardinal Health, Dublin, USA), Gerson 1730, Gerson 2130 (Gerson, McKean, USA)	Unworn respirators decontaminated using the Steris VHP Victory system (Steris Life Sciences, Mentor, USA) for up to 8 cycles. Sample of respirators were tested qualitatively (3M FT-10/30) and quantitatively (PortaCount Pro+, TSI, Shoreview, USA) Respirators that previously failed fit testing on 1 study participant were decontaminated using the Steris VHP Victory system (Steris Life Sciences, Mentor, USA) and then fit tested on a different user.	For the 1870 model, all 3 respirators passed fit on a second wearer after 3 cycles of decontamination and 2 of 3 passed fit after 6 cycles of decontamination. For the 1860 model, 3 respirators passed fit testing on a second wearer after 5, 6, 7, or 8 cycles of decontamination. For the 9210 model, all 3 respirators passed fit testing on a second user after 4 cycles and 7 cycles of decontamination, but 1 of the 3 respirators in the 6 cycle group failed fit testing. For the Halyard 46727, 2 of 3 respirators failed fit testing after 2 cycles of decontamination in both the group that was only fit tested by a single user and those that were tested on a second wearer. In all instances, with the exception of the 1870s decontaminated for 6 cycles, there was no significant difference in fit between respirators decontaminated and fit tested on a second user (2 donnings total) and those that only underwent 1 fit test on a single user after decontamination.
Lieu, Mah, Zanichelli, Exantus, Longtin (2020)	1860, 1860s, 1870+ (3M, St. Paul, USA) 1510, 1511, 1512, and 1517 (Moldex, Culver City, USA), 88020 (ProGear, Fort Worth, USA)	36 healthcare workers were recruited to wear N95 respirators for approximately 4-hour periods during their shift and instructed to minimize donning and doffing. Respirators were decontaminated with VHP (V-PRO maX Low Temperature Sterilization System, Steris Life Sciences, Mentor, USA) and qualitatively fit tested (3M Bitrex/Saccharin).	23 of 36 (64%) participants experienced fit failure by the end of the study. The median number of donning and decontamination cycles before failure was 2; however when mechanical failures of the respirators were excluded, the median number of reuse cycles before fit failure increased to 4. There was considerable variation between models, in ability to withstand decontamination and reuse. The 1860(S), 1870+, Moldex 151X and ProGear achieved a 50% fit failure rate at 1, 3, 4, and 4 cycles, respectively. When excluding mechanical failure, the number of cycles for a 50% failure rate for the 1870+ increased by 1 to 4. Additionally, 66% of 1860 respirators failed fit testing after their first cycle, compared to 22% of the 1870+, 22% of the Moldex, and 0% of the ProGear. Five of the model 1860 respirators were fit tested at the end of their first wear cycle before being decontaminated with 100% of wearers passing.

Maranhao, Scott, Scott, Maeng, Song, Baddigam, King, McCormick, Kangrga, Guffey (2020)	1860, 1804 VFlex (3M, St. Paul, USA)	74 participants self-reported length of wear, number of donnings, and decontamination with Bioquell Z-2 VPH (Bioquell, Horsham, USA). Qualitative fit testing (Bitrex) was used to determine respirator integrity.	Fit test failure rate was 46% after 4 days of wear, 50% after 10 days, and 55% after 15 days. Fit failure was associated with the number of times the respirator was decontaminated but not the number of times worn per day. The female fit testing failure rate was 67%, which was significantly higher than the male rate of 29%.
Aerosolized Hydrogen Peroxide (aHP)			
Derr, James, Kuny, Patel, Kandel, Field, Beckman, Hockett, Bates, Sutton, Szpara (2020)	8511, 1860, 1870+, 9211+, (3M, St. Paul, USA), Honeywell Sperian N11125 (Honeywell Safety Products, USA), Alpha Pro Tech (Alpha Pro Tech, Markham, Canada)	2 participants underwent qualitative fit testing of 63 3M 8511 respirators before decontamination with aerosolized hydrogen peroxide (7% H₂O₂) generated by the Curis decontamination unit (Curis Decontamination, Oviedo, USA). The same respirators were used through the trial with qualitative fit testing conducted after 1, 5, and 10 cycles of decontamination and a subset of respirators was removed for quantitative fit testing (PortaCount Pro+ Model 8038 Fit Tester, TSI, Shoreview, USA). A smaller sample of 3M 1860, 1870+, 9211+, and Honeywell Sperian N11125 also underwent decontamination and fit testing using the above protocol.	The 3M 8511, 3M 1860, 3M 1870+, 3M 9211+, Kimberly Clark PFR95, and Sperian N1125 respirators all passed both qualitative and quantitative fit testing after 1, 5, and 10 cycles of decontamination which corresponded to 2, 3, and 4 donnings and doffings. One of the 3M 1870s sustained a strap failure after the 5th cycle.

Ultraviolet (UV)			
Golladay, Leslie, Zuelzer, Cassano, Plauny, Daniels, Bearman, Kates (2021)	1860 (3M, St. Paul, USA), Halyard Fluidshield (O&M Halyard Health, Alpharetta, GA)	Respirators were used clinically and collected for UV decontamination ($>1000\text{mJ/cm}^2$ UV radiation per side or respirator) using a mobile UV sanitation unit (Tru-D SmartUVC, LLC, Memphis, USA). Qualitative (saccharin/Bitrex) and quantitative (PortaCount Respirator Fit Tester model 8038 (TSI, Incorporated, Shoreview, MN, USA) fit testing was utilized after use and decontamination.	All 12 participants were able to pass qualitative fit tests after 18 cycles of use and UV decontamination. Respirators were also quantitatively fit tested after 20 cycles of use and decontamination and found to have an average fit factor of 195.
Huber, Goldman, Epstein, Stella, Sakmar (2021)	8210 (3M, St. Paul, USA)	2 respirators were quantitatively fit tested (TSI PortaCount Pro Plus, TSI, Shoreview, USA) and then exposed to either 14 exposure cycles with $5,000\text{mJ/cm}^2$ per side or a single cycle of $20,000\text{mJ/cm}^2$ per side followed by 6 cycles of $10,000\text{mJ/cm}^2$ per side (Lambda 800; Perkin Elmer, Waltham, USA). After each cycle, they were re-fit tested.	Both respirators maintained a fit factor of 200 for exposures less than a total dosage of $50,000\text{mJ/cm}^2$ per side, corresponding to 50 decontamination cycles. The authors did not report when the respirators would have had a fit of less than 100. The authors noted an odor from the UV-treated respirators, but that the odor was reduced when the decontamination took place in nitrogen gas.
Ozog, Parks-Miller, Kohli, Lyons, Narla, Torres, Levesque, Lim, Hamzavi (2020)	1860, 9210, 8210, 9010 (3M, St. Paul, USA), 1512 (Moldex, Culver City, USA), Cardinal Health N95A-S, Cardinal Health USA R/S (Cardinal Health, Dublin, USA)	After an initial fit test (Qualitative, Saccharin), a 1.5J/cm^2 UVGI dose was applied to each side of the respirator. Another fit test was performed. This cycle was repeated until the respirator failed the fit test.	The 3M 1860 model passed 20 cycles. The 3M 9210 and Moldex 1512 models passed 2 cycles. The 3M 8210 and Cardinal Health N95A-S passed 1 cycle each.

Wanner, Ader, Caplan, Padaki, Ravert, Drees (2021)	1870 (3M, St. Paul, USA)	16 participants tested 45 respirators for up to 4 wear cycles. Each wear cycle consisted of 1 clinical shift and 1 round of UV decontamination using the ClorDiSys UVGI Light System (ClorDiSys, Somerville, USA). The respirators were then fit tested (PortaCount 8038 Fit-Tester, TSI, Shoreview, USA)	The mean fit-test failure rate was 29.7% and there was no statistically significant increase in the probability of failure with increased decontamination and reuse cycles. Self-reported hours worn and number of donnings/doffings per shift were not significantly associated with fit failure.
Multiple Methods			
Chen, Ngan, Manson, Maynes, Borschel, Rotstein, Gu (2020)	1860S, 8210, 9210 (3M, St. Paul, USA)	Respirators underwent a quantitative fit test (PortaCount Respirator Fit Tester 8048, TSI, Shoreview, USA) and then were subjected to 1 of 7 decontamination methods (Autoclave (3850E Autoclave, Tuttnauer, Hauppauge, USA), 70% ethanol, forced air dry heat (VWR Forced Air Oven; VWR International, Mississauga, Canada), humid heat (HCSS74W12, Climate Select Heated Holding Cabinet with Humidity, BevLes Company, Inc., Erie, USA), hydrogen peroxide gas plasma (STERRAD 100S Sterilizer, Advanced Sterilization Products, Irvine, USA), hydrogen peroxide vapor (Steris V-PRO maX Low Temperature Sterilization System, Steris Life Sciences, Mentor, USA), UVGI (V 05-1060-R, Atlantic Ultraviolet Corporation, Hauppauge, USA)) for either 1, 3, 5, or 10 cycles before being re-fit tested.	Results were reported as percent leakage. All control respirators demonstrated 0 leakage. For respirator models in the autoclave results for 1 and 3 cycles, respectively, were as follows: 3M 1860 (11.11% - 12.5%), 3M 8210 (14.29% - 0.74%). Using ethanol: 3M 1860 (1.22% - 0.93%). Forced air: all model types showed leakage values of .57% or below after 10 cycles. Humid heat: 3M 8210 (.83% after 10 cycles). HPGP sterrad: 1860S and 8219 (4% - 11.11% after 5 and 10 cycles, respectively), 9210 (14.29% - 6.67% for 5 and 10 cycles, respectively). Steris HPV: .58% was highest value obtained on 1860S. UVGI 1860S highest leakage was .96% after 5 cycles.

Fischer, Morris, van Doremalen, Sarchette, Matson, Bushmaker, Yinda, Seifert, Gamble, Williamson, Judson, de Wit, Lloyd-Smith, Munster (2020)	3M Aura Particulate Respirator 9211+/37193 (3M, St. Paul, USA)	Respirators were worn for 2 hours and subjected to either UV light (260–285 nm) (LEDi2, Houston, USA), 70°C dry heat, 70% ethanol, or VHP (Panasonic MCO-19AIC-PT, Panasonic, Kadoma, Japan). Each cycle was repeated 3 times and fit was evaluated quantitatively.	None of the respirators experienced a considerable reduction in fit after a single decontamination cycle. However, ethanol and heat treatment of respirators significantly decreased fit and the median fit factor fell below 100 after 3 cycles of treatment. UVGI and VHP treated respirators performed similarly to the control respirators for the first 2 cycles, however their fit declined with the number of treatment and wear cycles. The authors did not report statistical significance between for changes in fit. All but 1 of the control respirators maintained fit through 3 wear cycles, with 1 of the 6 respirators experiencing a fit failure after 3 cycles of wear.
Meisenhelder, Anderegg, Preecha, Ngooi, Liao, Xiao, Chu, Cui, Doyle (2020)	Dry heat: 1860, 1870, 8210+ Autoclave: 1870, 8210+ (3M, St. Paul, USA)	Respirators were subjected to either 5 cycles of dry heat at 95 °C for 40 min cycle in a Despatch LAC1-38-8 laboratory convection oven (Illinois Tool Works, Lakeville, USA) or autoclave at 121°C for 20 minutes in a Getinge 533LS steam sterilizer (Getinge, Wayne, USA). Respirators were donned and doffed 5 times and quantitative fit testing was performed using a TSI PortaCount 8038 (TSI, Shoreview, USA).	In the dry heat experiment, all 3 models of respirators passed quantitative fit testing after 5 cycles of wear and treatment. For the respirators that were decontaminated in an autoclave, the 3M 8210+ failed fit testing after the first cycle. The 3M 1870 experienced a decrease in fit, but the fit factor was greater than 100 after 5 cycles.

Viscusi, Bergman, Novak, Faulkner, Palmiero, Powell, Shaffer (2011)	3M 8000, 3M 8210, 3M 1860, 3M 1870 (3M, St. Paul, USA), Moldex 2200 (Moldex, Culver City, USA), Kimberly Clark PFR95-270 (Kimberly-Clark, Irving, USA)	10 subjects underwent testing with 6 of the respirator types with 3 different decontamination methods and a control. Respirators were decontaminated using UVGI (Sterilgard III laminar flow cabinet (The Baker Company, Sanford, USA) fitted with a 40W UV-C bulb, Intensity 1.8 mW/cm ²), moist heat incubation (Caron Model 6010 laboratory incubator (Caron, Marietta, USA)), or microwave-generated steam (Sharp Model R-305KS (Sharp Electronics, Mahwah, USA)). They were then donned 5 times and fit tested quantitatively (TSI Portacount Plus, TSI, Shoreview, USA)	For 2 of 6 FFR models (3M 8210 and Moldex 2200), 80% and 70% of wearers experienced a significant decrease in fit with exposure to moist heat incubation. The median decrease in fit factor was 29 and 59 for the 3M 8210 and Moldex 2200 respectively. However, 70% of subjects still maintained passing fit factors for both models and the average fit factors were 122 and 119, respectively. There was no significant decrease in fit for the other models or decontamination methods. The authors also note that 92.5% of fit values were >50, and that even though the respirators may not meet fit test requirements, they still provide a much better fit than surgical masks.
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Continuous Use

Of the studies identified in the review, only one attempted to study true continuous use, as opposed to limited reuse, finding that 88% percent of participants passed fit testing after 2-12 hours (Rivard et al., 2021). Of the 12% who failed repeat fit testing, failure occurred after 3-10 hours of use. Failure of the initial fit test was associated with respirators used longer than two days. However, if initial fit testing was passed, respirators were not more likely to fail subsequent fit tests, compared to respirators worn for two days.

Even with continuous reuse, the CDC permits removal of the respirator when necessary (up to a total of five donnings), so true continuous use is difficult to study (National Center for Immunization and Respiratory Diseases (NCIRD), 2021). As such, although participants were instructed to participate in a fit test before doffing their respirator for breaks or nourishment, the authors did not record the number of times the respirators were donned and doffed, a major limitation of the study.

Limited Reuse without Decontamination

Donning and doffing respirators can lead to degradation in their ability to function, resulting in diminished ability of reused respirators to pass a fit test. However, the rate at which fit failure occurs can be highly variable based on the number of donnings (Bergman et al., 2012; Degesys et al., 2020; Jung et al., 2021; Vuma et al., 2019), the hours worn with each use (Degesys et al., 2020; Jung et al., 2021), and the individual N95 model type (Degesys et al., 2020). Because of these factors, there is not a clear consensus as to how many reuses per respirator are acceptable. Bergman et al. (2012) concluded that no more than five donnings should be performed to maintain a risk of respirator failure below five percent. However, this study only included repeated donning/doffings and did not include extended wear time or use in the clinical setting.

In a study utilizing respirators worn in a healthcare setting, Fabre et al. (2021) concluded that up to 23 donnings can be performed while maintaining the same failure rate of less than five percent. However, the data was limited as participants wore the respirators clinically and self-reported their number of donnings and doffings (Fabre et al., 2021). Additionally, this paper excluded respirators from their primary analysis that failed either a seal check or qualitative fit test but were verified quantitatively for failure. When these unverified failures were included, the >95% pass rate decreased from 23 donnings to 16 donnings. At 40 donnings, the failure rates for quantitatively verified failures and total failures were 82% and 87% respectively.

In general, studies show that respirators' fit factors do tend to decrease with an increased number of donnings (Bergman et al., 2012; Degesys et al., 2020; Jung et al., 2021; Vuma et al., 2019). Vuma et al. (2019) found that both the average and median fit factors were lower after six donnings than the first donning, while Bergman et al. (2012) found that fit factors for half of the models tested were significantly reduced after 10 donnings, with all models experiencing a statistically significant reduction in fit factor after 15 donnings. However, Bergman et al. (2012) also found that the majority of N95s (55%-65%, depending on model) still had passing fit factors on the 20th donning, demonstrating that all respirators do not fail at the same rate.

The overall wear time of an individual respirator may also be an important factor in the rate of failure among those with limited reuse. In one study utilizing healthcare workers (Nakamoto et al., 2021), 85.4% of respirators were able to pass a fit test after being worn for approximately two hours once per week for a total of four donnings. A similar non-clinical study (Fischer et al., 2020) demonstrated that of respirators worn for two hours and donned a total of three times, 83.3% did not experience any fit failures. In another study (Jung et al., 2021), increased wear time was correlated with increases in fit failure.

However, this may be confounded by subsequent increase in the number of donnings/doffings with increased wear time (Jung et al., 2021).

The specific N95 model may affect the capacity for limited reuse, as some studies found varying fit failure rates between differing styles. One study (Degesys et al., 2020) based on self-reported use and reuse by healthcare workers determined that fit failure rate was 70.6% for duckbill style respirators (Kimberly-Clark 46727 and Halyard 46867 respirators) compared to 27.5% for dome-shaped respirators (3M 1860), suggesting that duckbill style respirators may fail at a faster rate. In contrast, another study (Vuma et al., 2019) reported no differences in fit failure in some of the same models (3M 1680 and Kimberly Clark 468727), however, this study only involved six donnings and no clinical usage. Nakamoto et al. (2021) found no difference between duckbill-shaped (HPR-R/HPR-S), dome-shaped (Hi-Luck 350), and three-panel flat-fold respirators (9211) worn by healthcare workers over three reuses. Fabre et al. (2021) found no difference in fit failure rates between 3M 1860 (dome-shaped) and 1870 respirators (three-panel flat-fold) after up to 40 reuses based on self-reported length of wear and number of donnings.

The ability to pass a fit test is determined by not only the integrity of the respirator itself, but also the user's ability to don it properly. Despite training on proper donning technique, studies (Jung et al., 2021; Vuma et al., 2019) demonstrated that anywhere from 50-100% of users who failed a quantitative fit test were able to pass a subsequent test, suggesting that the failure may have been due to improper donning rather than a failure of the respirator itself. Several studies either allowed participants to re-attempt the fit test after failing (Jung et al., 2021) or saw an increase in pass rate after an initial fit test (Duncan et al., 2020; Vuma et al., 2019), suggesting that a participant's familiarity with the respirator may play a role in early trial fit rates. This hypothesis was also discussed by Anderegg et al. (2020a), which reported higher quantitative fit factors with re-use during consecutive donnings. Other factors that may lead to inability to reuse a respirator beyond fit failure include breakdown of other parts of the respirators, including strap failure (Duncan et al., 2020).

Reuse with Decontamination

Reuse with decontamination comprised the majority of articles in this review. The 3M Company (St. Paul, USA), the manufacturer of the most commonly tested respirators, does not recommend decontamination of their respirators as they were not designed for this purpose (3M, 2021). Additionally, as of June 2021, the Food and Drug Administration has revoked the emergency use authorizations for decontamination systems as respirator availability has increased (United States Food and Drug Administration, 2021). However, many studies have attempted to assess the effectiveness of various decontamination methods to inactivate pathogens without compromising the respirators' integrity, which could prove useful if the healthcare system returns to crisis capacity. Decontamination can affect the respirator's filtration ability, damage the seal, or destroy other respirator components, such as ear loops or nose pieces. For example, even when fit could be maintained after decontamination, strap failure occurred in some respirators, leading to inability to reuse them (Derr et al., 2020; Massey et al., 2021; Viscusi et al., 2011). Additionally, lab-based testing of respirator decontamination methods may not adequately reflect respirator use in the real-world clinical environment.

Many different decontamination methods have been studied with varying results. Studies demonstrated that moist heat techniques, including autoclave and steam, contributed to degradation of respirator quality. Massey et al. (2021) found that respirators subjected to moist heat after a single donning passed quantitative fit testing after up to 10 cycles, which was comparable to testing data released by 3M in a technical bulletin (3M, 2021). Anderegg et al. (2020a) reported that respirators treated with moist heat passed fit testing after five cycles with up to eight donning/doffings but noted damage to the respirators and fit factors that were lower than the corresponding controls. They also found differences between various models of respirators. Other studies found more detrimental effects of heat

on respirator fit. In one study (Viscusi et al., 2011), moist heat treatment led to a significant decrease in fit in two of six different models. Another study (Meisenhelder et al., 2020) reported that the 3M 8210+ failed fit testing after one cycle of five donnings/doffings and treatment with autoclave, while the 3M 1870 experienced a decrease in fit but maintained a fit factor greater than 100 after 25 total donnings/doffings. In yet another study (Czubryt et al., 2020), 14.2% of the Aearo 1054S respirators donned twice and treated with steam experienced a fit factor less than 100. However, this study was the only among those involving moist heat in which participants wore a respirator for an extended period of time (2-8 hours). It also was unique in that it involved re-fit testing the respirator on a different user, one of only two studies to do so (Czubryt et al., 2020; Levine et al., 2021).

For those respirators treated with dry heat, Meisenhelder et al. (2020) reported that all models tested were able to maintain fit up to five cycles with five donnings/doffings, and Massey et al. (2021) demonstrate that the fit is retained for 10 cycles with a single donning/doffing. Loh et al. (2020) reported a 5% failure rate for respirators treated with 85° C dry heat, but noted a decrease in fit factors after treatment, even among those who passed fit testing. Notably, none of the studies of dry heat treatment involved extended wear time or clinical usage.

The ability of respirators treated with Ultraviolet Germicidal Irradiation (UVGI) decontamination to pass qualitative fit testing was largely dependent on the model (Ozog et al., 2020). The 3M 1860 (dome-shaped) respirators passed 20 cycles of decontamination, while the 3M 9210 (three-panel flat-fold shaped), Moldex 1512 (dome-shaped) model, 3M 8210 (dome-shaped), and Cardinal Health N95A-S (dome-shaped) respirators passed only 1-2 cycles (Ozog et al., 2020). This was tested in the lab with a single fit test after each decontamination cycle.

Wanner et al. (2021) found that after four cycles of a clinical shift and UV decontamination, 3M 1870 respirators experienced nearly a 30% failure rate, with the probability of failure increasing with reuse. This is in contrast to lab-based studies of various 3M respirators demonstrating that respirators exposed to UV decontamination can pass fit testing for up to 10-50 cycles without donning and doffing (3M, 2021; Huber et al., 2021). In contrast, another study (Golladay et al., 2021) involving real-world healthcare workers demonstrated that 100% of 3M 1860 respirators were able to pass fit testing after up to 18 cycles of a shift of clinical wear and UV sanitation. Likewise, Viscusi et al. (2011) demonstrated that there was no significant decrease in fit for those treated with UV for 5 donnings without wear time.

All respirators decontaminated with vaporized hydrogen peroxide (VHP) were able to pass fit testing up to 3-15 decontamination cycles, with the exception of the Halyard 46727, of which 66% failed after two cycles of testing (Jatta et al., 2021; Levine et al., 2021). Derr et al. (2020) found that respirators subjected to aerosolized hydrogen peroxide (aHP) decontamination were able to maintain fit for up to 10 cycles with four total donnings/doffings. These studies are consistent with results of previous tests that demonstrated that respirators treated with hydrogen peroxide are able to maintain fit up to 10-20 cycles without donning/doffing (3M, 2021). However, real-world data in which healthcare workers wore an N95 for approximately four hour periods during their shifts demonstrated that the median number of cycles before failure was only two cycles (Lieu et al., 2020). This was highly dependent on the model, with 66% of 3M 1860 respirators failing fit testing after their first cycle compared to 22% of the 3M 1870+, 22% of the Moldex models, and 0% of the ProGear 88020 (Lieu et al., 2020). Another study (Maranhao et al., 2020) showed that fit failure in respirators treated with VHP was associated with the number of times the respirator was decontaminated but not the number of donnings/doffings. Levine et al. (2021) conducted fit testing on a single user after VHP decontamination, but also re-tested respirators which failed fit testing on their first wearer on a second participant, finding no significant difference in fit between respirators which passed fit testing on the first donning and those redonned by a second user.

Seal Checks

To help detect fit failure, the CDC recommends performing a seal check, which involves the wearer forcefully inhaling and exhaling while feeling for pressure differences in the respirator that would indicate a seal (Centers for Disease Control and Prevention, 2018). However, studies have shown that seal checks have low sensitivity for detecting a poor fit, with Fabre et al. (2021) and Lieu et al. (2020) finding that seal checks failed to identify respirators that failed subsequent fit testing in 69% and 77.8% of cases respectively. These results were consistent with Danyluk et al. (2011), who identified qualitative fit test failure rates as high as 22% and quantitative fit failure rates as high as 30% for users who had passed a seal check. More concerning was the fact that “experienced” respirator users were no more likely to detect failure than wearers who had never been previously fitted (Danyluk et al., 2011). In a similar study, Lam et al. (2011) calculated the sensitivity of the seal check for detecting failure, finding only 15.2% and 23.0% for the 3M 1860 and 3M 1862, respectively.

Recognizing the limits of the seal check, the CDC recommends performing an abbreviated qualitative fit test, known as a qualitative fit performance evaluation, if respirators are to be reused more than 5 times during crisis standards (Centers for Disease Control and Prevention: National Center for Immunization and Respiratory Diseases, 2020). This evaluation has a reported sensitivity of 92% for detecting fit failure (Nelson et al., 2003). Additionally, Vuma et al. (2019) and Jung et al. (2021) have found that wearers are often able to adjust their respirator after a fit failure to pass a subsequent fit test, potentially as a result of improper doffing. Therefore, use of a qualitative fit performance evaluation could also be used not just to detect fit failure, but to provide feedback to the wearer and thus further extend the life of the respirator. Unlike a seal check, which is much easier to perform, qualitative fit performance evaluations require a scented agent, a test hood, and take almost two minutes to perform.

Seal checks require the user to touch the front of the respirator, which is presumably the most contaminated part. This highlights another concern with respirator reuse, self-contamination, as the wearer may be exposed to contamination during both donning and doffing. Brady et al. (2017) explored the potential for exposure from respirators that were inoculated with bacteriophage MS2 and fluorescein to simulate contamination by droplet, or droplet nuclei, respectively. They determined that for droplet-contaminated respirators, improper doffing and reuse led to almost twice the transfer efficiency of MS2 and almost four times the transfer intensity of fluorescein compared to improper doffing or reuse, alone (Brady et al., 2017).

Unfortunately, improper doffing is a common occurrence in healthcare. In one study evaluating PPE doffing practices of healthcare workers, errors in the doffing sequence, technique, or PPE selection were witnessed in 90% of observed doffing sessions. Although the doffing of gowns had the highest rate of error, healthcare workers incorrectly touched the potentially contaminated front portion of the masks in 26% of doffing sessions (Brady et al., 2017).

Need for Further Research

In addition to the influences of different decontamination methods and the variable durability of different models of respirators, it is important for studies to account for differences among respirator users. For example, although females make up a majority of healthcare staff (Kursumovic et al., 2020), respirators in general have been modeled for the larger faces of white males, potentially resulting in decreased protection for female and ethnically diverse staff (*Trade Unions Congress*, 2017). One study (Ascott et al., 2021) quantified this fit failure difference, finding that females were almost twice as likely as males (18.2% failure rate in females, 9.7% failure rate in males, $p < 0.01$) to fail FFP3 respirator fit testing. Another study (Maranhao et al., 2020) also found a significantly higher fit failure rate among females than males (67% vs. 29%). However, other studies (Vuma et al., 2019) have found similar fit failure rates among males and females. Although there is no consensus, young female healthcare staff have double

the COVID-19-related mortality rate compared to their age-matched female peers in the general population, making proper fit among this population especially important. Similarly, healthcare workers from ethnic minority groups both have higher fit testing failure rates and higher morbidity and mortality risks from COVID-19 (*British Medical Association*, 2021).

Methods to Improve Fit

To address these fit failure concerns, several attempts have been made to improve respirator fit across diverse facial geometry. These innovative solutions include the use of adhesive along the edges of a 3M (1860, 1860s) respirator designed to help it adhere to the wearer's face. Researchers found that this modified adhesive respirator passed a fit test in 68% of participants who initially failed a first-choice respirator testing (Wardhan et al., 2020). Additionally, the use of a 3D printed frame for a respirator has been evaluated with promising results (Stemen et al., 2021). Initial studies have shown an average of an additional 41% fit passing rate with the addition of a 3D printed frame across various respirator models and individuals (McAvoy et al., 2020). While finding ways to improve fit testing is still an active area of research demanded by a pandemic, these proposed solutions to fit issues may lead to respirators that more safely protect the diverse healthcare workforce.

Defining Acceptability

It is important to acknowledge that continuous use and reuse are recommended for contingency and crisis capacities, respectively, but not for routine use. As such, the standards for what is acceptable during crisis standards differs significantly from what is acceptable during conventional capacity. When defining acceptability of fit, a fit factor of greater than or equal to 100 has been previously used in qualitative fit tests, in line with OSHA recommendations (Occupational Safety and Health Administration, 2009). Zhuang et al. (2017) further investigated this criterion and determined that if a respirator passes one of two attempts, the user will likely be provided adequate protection (Zhuang et al., 2017). Therefore, an individual respirator may still provide adequate protection even if it doesn't pass every fit test with a fit factor greater or equal to 100.

Acceptable fit factors are generally ten times the assigned protection factor (APF), which is the level of respiratory protection a respirator should provide to the wearer 95% of the time. Of the studies identified in this review that reported fit failures, fit was usually still well above the APF, such as in Viscusi et al. (2011), in which 92.5% of respirators tested had fit factors greater than 50. Therefore, a respirator which has a fit factor less than 100 would likely still offer a better fit than a surgical mask, which Oberg and Brosseau (2008) determined had fit factors of under 10, and may still provide ample protection to the wearer in some situations. However, in May 2021, the CDC directed healthcare facilities to return to conventional capacities and cease reuse and decontamination due to an increase in respirator supply and lack of data as to the "long term stability" of respirators that have been decontaminated (Centers for Disease Control and Prevention: National Center for Immunization and Respiratory Diseases, 2020). Likewise, the FDA subsequently revoked all EUAs for N95 decontamination, effective June 30th, 2021 (United States Food and Drug Administration, 2021).

CONCLUSIONS

Based on the available data, this literature review was unable to establish a consensus about the amount of time a respirator can be worn or the number of uses before fit failure will occur. Variations in reuses before fit failure between different N95 models suggest that a comprehensive recommendation of greater than one reuse or a specific amount of wear time across different models is unlikely. Instead, adequate data could be utilized to support the number of reuses for a specific model respirator using a specific decontamination technology, if applicable. To create these standards, structured testing in a

clinical environment with diverse participants will be crucial to establishing reuse standards for individual respirators. Additionally, surveillance studies will be needed to ensure that any reuse policies are safe and do not put healthcare workers at a greater risk than their peers who can dispose of their respirators after a single use, as designed. The need for surveillance and real-world studies is particularly important as respirators of the same model often failed at very different numbers of donnings/doffings. Lastly, although there are promising studies exploring methods to improve respirator fit, the wide variation in fit failure and poor sensitivity of seal checks supports the CDC recommendation of a qualitative fit performance evaluation with respirator reuse.

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