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The efficacy of continuous use disposable N95 masks in clinical practice in the emergency department

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ABSTRACT

During the SARS-CoV-2 pandemic, many emergency departments (EDs) initiated continuous use of N95 disposable respirators (N95s) rather than discarding them after each use to conserve respirators. This study investigates the efficacy of wearing disposable N95s continuously during clinical work.

Methods: This is a prospective cohort study of ED staff required to wear N95s continuously throughout their shifts. Subjects were doctors, nurses, and technicians who were previously fitted for their assigned N95 by employee health. Subjects were fit tested periodically throughout their shifts. Investigators filled out a questionnaire for each subject noting the hours of continuous N95 wear. Data were analyzed using descriptive statistics.

Results: One hundred thirteen N95s were evaluated, with 23 failures at first testing. These were not retested. Twenty-seven N95s passed at the start of a shift and did not have repeat testing during the course of the shift. These were excluded from further analysis. Seventeen N95s passed testing after several hours of continuous wear, but only had a single fit test done partway or at the end of a shift. These were assumed to have passed if tested at shift start, and were assigned as "passes" for continuous use. Forty-six N95s had an initial pass and were evaluated for continuous use, of which 6 subsequently failed later in the shift, giving a fail rate with continuous use of 9.5%.

Conclusion: Continuous use of disposable N95s throughout an ED shift is reasonable during a PPE shortage if wearers are assured of fit at the start of their shift.

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1. Introduction

Previous disease outbreaks of the 21st century reveal that the United States's (US) supplies of personal protective equipment (PPE) are insufficient to meet demand during times of public health crisis [1]. The SARS-CoV-2 (COVID-19) pandemic of 2020 has unique characteristics that have resulted in even more widespread shortages than previous outbreaks. COVID-19 is a novel pathogen without rapid, reliable, and widely available methods of diagnostic testing, vaccines, or treatment regimens. The widespread transmission of COVID-19 across the globe disrupted supply chains of PPE while also increasing demand. During the 2009 H1N1 pandemic in the US, N95 filtering facepiece respirator (hereafter referred to as N95s) use increased by 51% [2]. It is unclear how much use has increased during the current COVID-19 pandemic, but it is likely multiple orders of magnitude higher. In standard use, most N95s used in healthcare are designed to be used once during a single clinical encounter. Due to widespread shortages, rationing and preservation of N95s are considered paramount. The US Center for Disease

Control (CDC) published guidelines for both extended use and reuse of N95s to extend the supply of these vital pieces of PPE [3]. Extended use is defined as the use of the same N95 over multiple patient encounters, without donning or doffing between patients, while reuse is the reapplication of the N95 multiple times per day or over multiple consecutive days. Limited data exists regarding the safety and efficacy of N95 reuse, including two small experimental studies which found that N95s have increased failures after repeated donnings and doffings [4,5]. This suggests that extended use of N95s might be superior to reuse because of limiting donning/doffing, but failure of N95s over time after successful application has not been studied. We sought to determine the failure rate of disposable N95s during extended use over multiple days in an Emergency Department (ED).

2. Materials and methods

2.1. Study design

This was an anonymous, cross-sectional study of health care workers (HCWs) required to use disposable N95s in an extended fashion during clinical duties in the ED. The study was IRB exempt.

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2.2. Study setting and population

The study was conducted from April 1 through June 15, 2020 at a community-based level I trauma center with an annual census of 55K. Study subjects (hereafter referred to as HCWs) were physicians (residents and attendings), nurses, medical technicians, and radiology technicians who had already been fit tested by the study site and assigned an appropriately sized N95 as per OSHA mandate. HCWs were enrolled if an investigator trained in OSHA fit testing was available (convenience sample). HCWs were excluded if they had either not been institutionally fit tested or had failed their fit tests, if there was no N95 available (due to supply shortages), if they chose to bring their own PPE, or if they refused participation. During the study period, HCWs were required to wear N95s for the duration of their clinical shifts, which varied from 8 to 12 h, with removal only when necessary. The hospital policy for mask use reflects CDC guidelines that disposable N95s should be reused for 5 days in the absence of gross contamination. This policy had been in place since the onset of the pandemic.

2.3. Study protocol and measurements

Study N95s were supplied by the hospital. Mask types included were the following: 3M 1860, 3M 8210, 3M Aura 1870, Kimberly-Clark 46,727, Milwaukee 50-73-4010, and Honeywell H801.

HCW recorded how long they had been wearing their N95s, rounded to the nearest hour. Since HCWs were using masks for multiple days in a row, the age of the masks in days was also recorded. HCWs then underwent qualitative fit testing using a standardized hood and 3M FT-32 bitter testing solution (Bitrex). HCWs performed standard maneuvers during fit testing, including open-mouthed breathing, head rotation and tilting, and speaking. The HCWs underwent repeat fit testing throughout the course of their shifts, and the total length of time on shift was recorded for each new fit test. The fit tests were performed by investigators who completed standardized OSHA training in fit test performance. If the HCW tasted the bitter solution during testing, he/she was considered to have failed the test and the N95 was discarded and replaced. N95s were determined to have passed fit testing over the course of continuous use if they passed at the start of a shift and then had a repeat fit test with a pass later in the shift, or if the N95 was not tested at the start of the shift but passed a fit test at least 2 h into the shift (making the a priori assumption that a N95 that passes several hours into a shift would have passed at the start of the shift). N95s that underwent fit testing at the start of a shift and passed but were not retested later in the shift were excluded from further analysis, as they were not considered to have undergone extended use.

HCW type (e.g. nurse vs. physician) and further demographic data were not recorded. Because of the large and changing variety of N95 types utilized in clinical practice due to limited supplies, specific N95 brand was not recorded for subgroup analysis. As subjects were working clinically, no attempt was made to modify their on-shift behavior regarding taking breaks or donning/doffing for nourishment or hydration. Subjects were aware that they were to undergo extended use fit testing prior to taking breaks, however subjects were not queried as to the number of times they had donned and doffed during the course of the shift, as this data was suspected to be unreliable based on observation.

2.4. Data analysis and handling

The results of all fit testing performed on any given individual was recorded on a single standardized data collection sheet which was anonymized at the end of the shift. A single investigator extracted data from collection sheets and entered it into a standardized Excel spreadsheet (Microsoft 2020). Data were analyzed using descriptive statistics, Fisher Exact, and Chi Square with MedCalc (©1993–2013, Ostend, Belgium) and VassarStats.net (©Richard Lowry 1998–2018).

3. Results

One-hundred thirty HCWs underwent fit testing per study protocol. Two HCWs enrolled who hadn't been previously fit tested by the institution, and 1 HCW was wearing a N95 that was not sized appropriately because of lack of supply. These 3 HCW were excluded from further analysis. Thirty HCWs passed fit testing at the beginning of their shifts (initial fit test), but did not undergo further testing. These were excluded from further analysis (Fig. 1). Twenty-seven HCWs failed their fit tests the first time they were tested on their shifts. For 15 HCWs, this was at the start of their shifts. The remaining 12 did not undergo fit testing at the start of their shifts, but underwent fit testing between 2 and 6 h after their shifts had started and failed (delayed fit test, Fig. 1). Nineteen HCWs were not fit tested at the start of their shifts, but underwent fit testing between 2 and 12 h after the start of the shift and passed their fit tests (delayed fit test, Fig. 1). It is assumed for the purposes of this protocol that they would have passed their fit tests had they been tested at the start of the shift. Fifty-one HCWs underwent 2–4 fit tests during the course of their shifts, all of whom passed on the initial test. Of these, 6 subsequently failed their fit tests between 3 and 10 h of continuous use. The remaining 45 continued to pass on repeat testing. These tests were performed from 2 to 12 h of continuous use. The time between start of shift and fit testing is shown in Fig. 2.

N95s in use beyond 2 days (e.g. masks which had been reused) were more likely to fail fit tests on initial testing when compared to N95s that were 1 or 2 days old (Fisher exact, $p < 0.0001$). However, when older N95s passed on initial fit testing, rates of later failure were similar for those in use for 2 days versus those in use beyond 3 days (Fisher exact $p = 0.39$) (Fig. 3).

4. Discussion

Our data demonstrate that N95s used by HCWs in this study performed well over the course of multiple consecutive hours, with 45 of 51 HCWs (88%) passing their repetitive fit tests, and 19 passing their fit tests after at least 2 h on shift. To the best of our knowledge, this is the first study on the performance of extended use of N95s. Researchers in other studies have focused on the effect of multiple donnings and doffings on N95 fit, although it is unclear if this is an adequate surrogate for extended use, during which a mask is meant to be left in place for multiple hours unless it must be removed [4–6]. A study by Grinshpun found that N95 failure is a result of loss of face seal rather than loss of filtering capacity of respirator materials [7]. They also found that 70% of total variability of face seal failure was associated with subject characteristics such as breathing rate and movement of the body and the face, and only 30% was due to actual donning and doffing [7]. Their study was small, but suggests that focus on donning and doffing practices does not adequately address potential sources of N95 failure. N95 failure over time may be related to the activities performed during use, or due to N95 moisture from breathing or sweating during clinical activities. HCWs perform multiple tasks which are only simulated for a few minutes during fit testing. Because these tasks may be variable across HCW roles, it would be beneficial to study rates of N95 failure by HCW type to better understand occupational risks.

Consistent with other studies, N95s in our study were more likely to fail with reuse over multiple days. However, we did not find that rates of failure with extended use were different in those using newer N95s compared to those wearing older ones if the N95 passed initial fit testing at the start of the shift (Fig. 3). This suggests that, rather than throwing away an older N95, it may be reasonable to perform a fit test at the start of a shift to determine performance.

It is important to bear in mind that N95 fit test failure may not directly correlate to HCW risk. Qualitative fit testing is very sensitive, but may label masks as “failures” at particle concentrations deemed acceptable by the quantitative method [8]. Additionally, the minimum

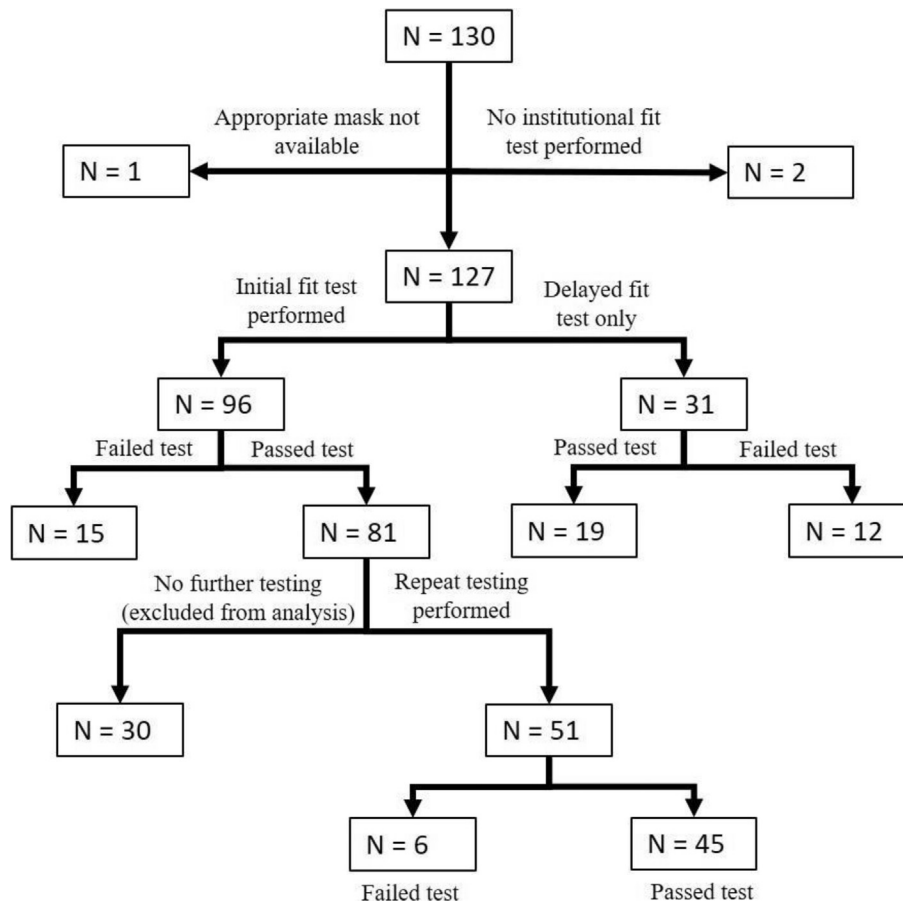


Fig. 1. Flow diagram of study subjects.

infectious dose of COVID-19 is unknown and failed N95s still offer droplet protection to the wearer. Current estimates of asymptomatic infections are 40–45%, but because our institution only tests symptomatic individuals, we cannot speculate as to the risk to HCWs from wearing failed N95s [9].

5. Limitations

Our study has several limitations. Because of the wide variety of hospital-approved N95s, there were small numbers of any individual kind of N95, precluding any conclusions regarding rate of failure in

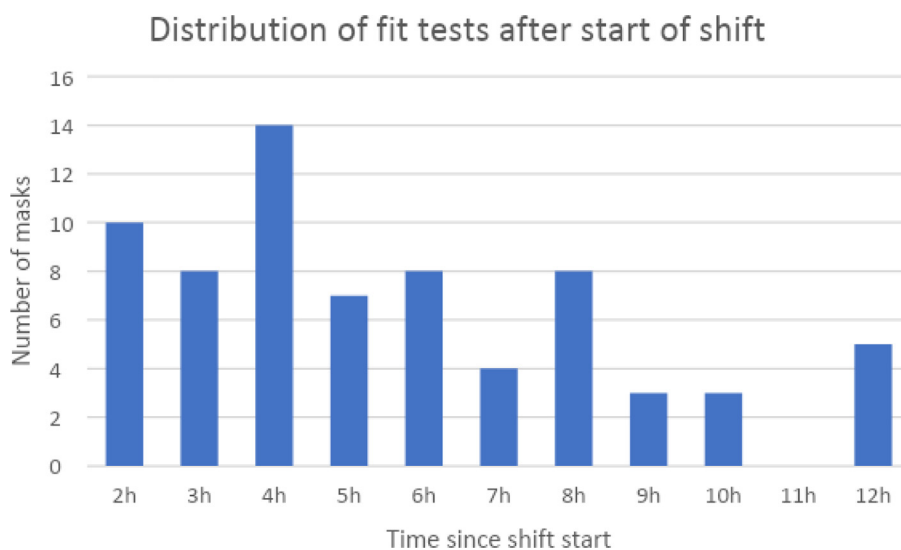


Fig. 2. Distribution of time since beginning of shift to the time of last fit test for any given mask. This figure excludes masks that only had an initial fit test at shift start and those that had a single delayed fit test that resulted in failure.

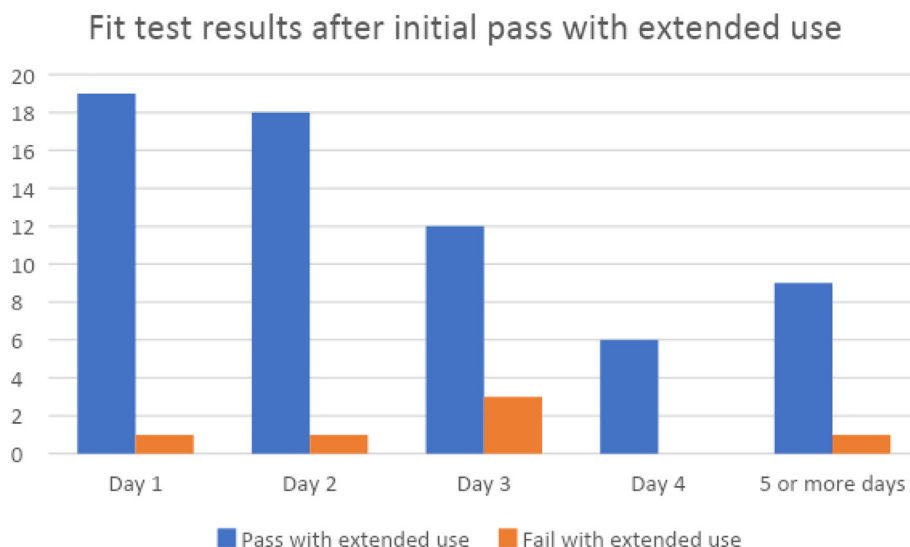


Fig. 3. Incidence of failure after initial fit test pass on masks, distributed by day of mask reuse.

different styles or brands of masks. We also did not attempt to control for subject on-shift behavior, including role related activities (such as performing CPR, transporting, or moving patients, which may affect fit) or donning and doffing events. Our design did not take into account face size/ shape, although we attempted to mitigate this by only testing N95s in which a given individual had been previously tested by hospital representatives and approved for use. We relied on self-reported data for number of hours of N95 usage, and although we feel subjects are unlikely to miscount the number of hours in their shifts, it is possible that error was introduced. Finally, this is a single center study among emergency department HCWs, and may not be generalizable to other medical centers or practice settings.

6. Conclusions

Our study provides preliminary data that disposable N95s may be safely used in an extended capacity if they have passed fit testing at the start of use. Further studies should validate these results and address additional factors beyond donning and doffing that contribute to N95 failure with reuse and extended use.

Declaration of Competing Interest

There are no conflicts of interest for any of the investigators.

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