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Research paper

# The adequacy of user seal checking for N95 respirators compared to formal fit testing: A multicentred observational study

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ABSTRACT

*Objective:* The objective of this study was to evaluate the adequacy of the user seal check (USC) in predicting N95 respirator fit.
*Design:* This was a prospective, observational study conducted from May to September 2020.
*Setting:* The study setting included three private intensive care units (ICUs) in Victoria, Australia.
*Participants:* ICU staff members in three private ICUs in Melbourne and regional Victoria participated in this study.
*Main outcome measures:* The main outcome measure is the proportion of participants who passed a USC and subsequently failed fit testing of an N95 respirator.
*Intervention:* Three different respirators were available: two N95 respirator brands and CleanSpace HALO® powered air-purifying respirator. Participants were sequentially tested on N95 respirators followed by powered air-purifying respirators until either successful fit testing or failure of all three respirators. The first N95 tested was based on the availability on the day of testing. The primary outcome was failure rate of fit testing on the first N95 respirator type passing a USC.
*Results:* Of 189 participants, 22 failed USC on both respirators, leaving 167 available for the primary outcome. Fifty-one of 167 (30.5%, 95% confidence interval = 23.7–38.1) failed fit testing on the first respirator type used that had passed a USC.
*Conclusion:* USC alone was inadequate in assessing N95 respirator fit and failed to detect inadequate fit in 30% of participants. Mandatory fit testing is essential to ensure adequate respiratory protection against COVID-19 and other airborne pathogens.
**Trial registration** Australian New Zealand Clinical Trials Registry: ACTRN12620001193965


## 1. Introduction

Recommendations for infection prevention following the severe acute respiratory syndrome (SARS) epidemic (2002–2004) highlighted the need for integrated environmental protection, personal protective equipment (PPE), and training.[1] The emergence of SARS-CoV-2 (COVID-19) has reinforced these requirements, especially in light of the high number of healthcare workers who acquired COVID-19.

During 2020 in Victoria, 3572 clinical and 595 nonclinical healthcare workers were infected with COVID-19.[2] It is estimated that during the first wave of COVID-19 infections (23 January-31 May 2020) 29.6% of healthcare worker infections in Australia were acquired within a healthcare setting, increasing to 70.8% during the second wave (1 June to 18 September 2020).[3] During the second wave in Victoria, 77% of medical practitioners and 89% of nurses infected with COVID-19, aquired the disease at work.[4]

It is now recognised that COVID-19 is transmitted via airborne spread; however, early in the pandemic, it was believed to be spread primarily via contact and droplet routes.[5] Protection against airborne disease requires frontline staff to use an air-purifying particulate respirator in the form of an N95 respirator or a powered air-purifying respirator (PAPR).[5]

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A tight seal around the mask is necessary for N95 respirators to function optimally,[6,7,8] with methods for assessing proper fit including the user seal check (USC) and fit testing. Australian standards stipulate annual fit testing for employees in industries where there is exposure to respiratory contaminants, and a USC should then be performed each time a respirator is worn.[9] The USC assesses fit via a visual assessment and detection of gross leakage around the respirator.

Prior to the COVID-19 pandemic, fit testing was not routinely performed in Victorian healthcare settings, with Government guidelines stating if fit testing was not 'reasonably practicable', then a USC with education was a satisfactory alternative.[10] Fit testing only became mandatory in Victoria in August 2020 by which time more than 2500 Victorian healthcare workers had acquired COVID-19 at work. A small number of studies in healthcare workers comparing USC to fit testing indicate up to 40% of USCs may fail to detect an inadequately fitted respirator.[11–16] Thus, reliance on the USC alone may have exposed Victorian healthcare workers to an increased risk of acquiring COVID-19.

Our institution implemented fit testing in the intensive care unit (ICU) in May 2020 at the commencement of the second wave. This study aimed to evaluate the adequacy of the USC compared to qualitative fit testing and thus quantify the potential risk to Victorian healthcare workers relying on USC alone.

## 2. Methods

### 2.1. Study design, setting, and participants

We performed a prospective, observational study in three private, Australian ICUs between May and September 2020.

Two units were located in metropolitan Melbourne: a 26-bed, College of Intensive Care Medicine—accredited teaching unit, and a nine-bed unit. The third ICU was an eight-bed unit located in regional Victoria. The largest ICU provided care to patients with confirmed COVID-19, and the smaller units for suspected COVID-19 patients.

A qualitative fit testing program was introduced as a quality and safety initiative using research methodology. Low-risk ethics approval was granted by the institutional ethics review board (reference EH2020-580).

Fit testing was offered to all ICU staff members. Recruitment for the study continued until adequate numbers were obtained as determined by the prespecified sample size calculation. Fit testing was conducted in the ICU during rostered shifts. Male personnel were required to be clean shaven. Baseline demographics were recorded including sex, role, type of PPE training, recent experience using N95 respirators, and years of critical care experience.

Fit testing was performed by one of four ICU staff members: two nurses and two doctors, all of whom were trained in qualitative fit testing by an occupational hygienist. All four staff members were experienced in N95 respirator use including donning and doffing procedures.

The 3M™ FT-30 qualitative fit test apparatus (Bitter) using Bitrex® (3M Australia, Building A, 1 Rivett Road, North Ryde NSW 2113) was chosen as a readily available, affordable, and validated method. We did not have access to quantitative testing at the commencement of the study. As there were no healthcare-specific regulations regarding fit testing, all testing procedures followed the Occupational Safety and Health Administration (OSHA) Regulation 1910:134.[17]

In summary, fit testing comprised the following steps:

- sensitivity to Bitrex® determined
- respirator donned and USC performed
- semi-occlusive hood placed over head
- nebulised Bitrex® solution introduced into the hood at regular intervals whilst a staff member performed specific activities
- a fail was recorded and the test stopped if the staff member could taste the Bitrex®

In the setting of global supply limitations of PPE, only two brands of N95 respirators were available during the study period: 3M 1860 (3M, St. Paul, Minnesota, USA; North Ryde, NSW, Australia) and Halyard Fluidshield, regular size (Halyard, Alpharetta, Georgia, USA; North Ryde, NSW, Australia). The USC was performed according to the individual respirator manufacturer's instructions (package insert) to detect an air leak around the perimeter of the respirator.

The ICUs involved also had access to a half mask PAPR device, the CleanSpace HALO® (CleanSpace Technology Pty Ltd, NSW, Australia).

Fit testing was performed in a stepwise process as follows.

Step 1: First N95 type—unassisted

Participants were given the respirator most available on the day of testing.

They were instructed to don the respirator as per their usual practice, with no intervention provided by the tester (unassisted donning).

If the participant was satisfied with the seal (as determined by independently performing a USC), they proceeded to a fit test.

Those who failed either the USC or fit test proceeded to Step 2.

Step 2: First N95 type—assisted

The tester provided instruction and assistance with the donning of a new respirator (same brand and size).

If the USC was adequate (assessed by the tester and participant), a fit test was performed.

Those who failed either the USC or fit test proceeded to Step 3.

For the first N95 respirator assessed, two attempts at passing (Step 1 unassisted and Step 2 assisted USC) were offered as per the recommendations of the training occupational hygienist. A participant could pass after an unassisted USC; however, to ensure failure of the fit test was not due to poor donning, failure for the primary outcome was only recorded if participants failed after assisted donning, i.e. failed both Steps 1 and 2.

Step 3: Second N95 type—assisted

The tester assisted the participant to don the alternate N95 respirator.

If they passed the USC, a fit test was performed.

Participants who failed either the USC or fit test then proceeded to Step 4.

For step 3 (second N95 respirator type), the requirement for two attempts at passing was modified due to critical N95 respirator supply limitations mid pandemic and only an assisted fitting was offered, in order to minimise stock wastage.

Step 4: PAPR (CleanSpace Halo half-mask)

Participants who failed fitting of both brands of N95 respirator proceeded to assisted donning and fit testing of the PAPR (negative pressure mode, motor off) using either the same qualitative method or quantitative testing using a PortaCount 8040 (TSI Incorporated, Shoreview, Minnesota, USA).

For quantitative testing, a fit factor of $\geq$100 was recorded as a pass.[17]

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### 2.2. Primary outcome

The primary outcome was the proportion of participants who passed a USC and subsequently failed fit testing.

The primary outcome was only recorded for the first N95 respirator type used that passed a USC to avoid participants being counted twice.

### 2.3. Secondary outcomes

- Proportion of participants who failed fit testing on the first N95 respirator without assistance (Step 1).
- Failure rates for each N95 respirator type.
- Proportion of participants who failed both N95 respirator types.
- Proportion of participants who failed both N95 respirator and PAPR.

### 2.4. Statistical analysis

The study was designed to estimate the failure rate with a precision or half-width of the corresponding exact binomial 95% confidence intervals (CIs) of no greater than 7.5% and was undertaken using Stata 16 (Stata Corporation, College Station, Texas, 2019). The failure rate was expected to range from 0% to 20%.[14]

A sample size of 150 was determined to allow a precision of ±7.5% for any overall error rate from 0% to 20%, e.g., a 95% CI no wider than ±7.5%.[18,19]

The primary outcome of the number of failures was estimated using exact (Clopper–Pearson) binomial 95% CIs.[20] The positive predictive value, in this case the percentage of passes on USC that also passed on the fit test, was calculated at each step of the fit testing process.

Failures are reported as frequencies and percentages, and dimensional variables are reported as means and standard deviations or, in the presence of skewness, medians and interquartile ranges.

Failure rates were regressed on six baseline variables: sex, occupation, type of training, N95 respirator type (Halyard and 3M), prior N95 respirator use, and critical care experience, employing binary logistic regression on each variable separately and combined (multivariable). Ninety-five percent CIs were reported throughout. The level of statistical significance was set at 0.05, two-tailed.

Statistical analyses were performed using Stata 16 (Stata Corporation, College Station, Texas, 2019). Each participant appeared only once in all inferential analyses.

## 3. Results

There were 189 participants, with 128 (68.3%) being female. There were 47 (24.9%) doctors, 128 (67.7%) nurses, 10 (5.3%) allied health professionals, and 4 (2.1%) support staff members.

The median experience in critical care was 10 (25th to 75th percentile = 4–15) years, and a median of 20 (10–30) N95 respirators per participant had been used in the previous 3 months; 91 (48.1%) had previously used Halyard Fluidshield, and 13 (6.9%) had used the 3M1860; 72 (38.1%) had experience of both respirators, and 13 (6.9%) had used neither.

Prior PPE training incorporating respirator donning had been delivered via demonstration and hands-on practice in 168 (88.9%) and via demonstration only in 21 (11.1%).

The flow of participants in relation to the primary outcome is shown in Fig. 1a. The 80 participants who failed fit testing and the 21 who failed the USC at Step 1 proceeded to a second attempt on the same respirator at Step 2. After passing the USC, 41 of these failed fit testing and 43 failed the USC; these 84 participants proceeded to Step 3, and 10 of these failed fit testing, giving a total of 51 failed fit tests. By the end of Step 3, 22 participants had failed USC on both respirators, leaving 167 participants available to compare USC versus fit test for the primary outcome.

The primary outcome, the proportion of participants who passed a USC and subsequently failed fit testing, was observed in 51 of 167 (30.5%, 95% CI = 23.7–38.1%).

Fit testing failure rates with each respirator were 18/60 (30.0%) for 3M and 33/107 (30.8%) for Halyard.

Fig. 1a does not show subsequent testing of the 41 participants who failed at Step 2 as the primary outcome only related to the first respirator donned which passed a USC. Fig. 1b shows the completion of testing for all 189 participants until either successful fitting or failure of all three respirators.

Table 1 shows the comparison of baseline variables for the primary outcome cohort. Both individual (one regression per variable) and multivariable logistic regression (variables entered simultaneously) demonstrated no statistically significant association with fit test failure for any of the baseline variables (95% CIs included a value of 1, expected under the null hypothesis).

Fig. 2 summarises the results of all testing from Step 1 to Step 4. The bar graph shows the three potential outcomes for each step: fail USC (do not proceed to fit testing), fail fit testing, or pass fit testing. The line summarises the cumulative pass rate as participants progressed through each step until successfully fitted. Eleven participants were lost to follow-up after Step 3 and hence were not fit tested on the PAPR.

The proportion who passed a fit test increased from 88/189 (46.6%, 95% CI = 39.3–53.9%) on unassisted fitting to 105/189 (55.6%, 95% CI = 48.2–62.8%) after the provision of assistance on the first respirator type worn. This further increased to 131/189 (69.3%, 95% CI = 62.2–75.8%) with access to the second respirator type (Step 3). Fifty-eight of 189 (30.7%, 95% CI = 24.2–37.8%) failed on both N95 respirator types, and 47 proceeded to fit testing on CleanSpace HALO® PAPR, with 100% of these passing fit testing at Step 4.

The positive predictive value at Step 1 was 60.13% (88 passed fit testing out of 168 that passed USC testing, 95% CI = 44.6%–60.1%). The positive predictive value decreased to 17/58 (29.3%, 95% CI = 18.1–42.7%) at Step 2 and then increased to 11/21 (52.4%, 95% CI = 29.8–74.3%) at Step 3.

## 4. Discussion

The USC failed to detect an unsafe fit, as determined by fit testing, in three out of 10 ICU staff members. This was consistent across respirator types, sex, occupation, experience, and training. These results quantify the potential risks to Victorian healthcare workers who adhered to contemporary guidelines in which the USC alone was considered adequate to determine a proper fitting respirator. Fit testing did not become mandatory in Victorian hospitals until August 2020.[21]

Our primary outcome result was consistent with that of previous research directly comparing USC to fit testing in health care[11–16,22]; however, the overall failure rate on the first respirator assessed was higher than observed in mature fit testing programs.[23] This likely reflects the limited choice of respirators available, in particular the lack of smaller sizes for females, which is in keeping with previous studies highlighting higher failure rates in female healthcare workers.[24,25] Although the practice of using respirators regardless of size or facial characteristics is not typical of experienced fit testing programs, it accurately reflects Victorian practice at the time of the study.

The provision of expert assistance with fitting improved success rates by 10% on the first N95 respirator tested (Step1 to Step 2), highlighting the potential importance of assisted donning. However, even with this assistance, a large proportion of ICU staff members were unable to be successfully fitted with access to only

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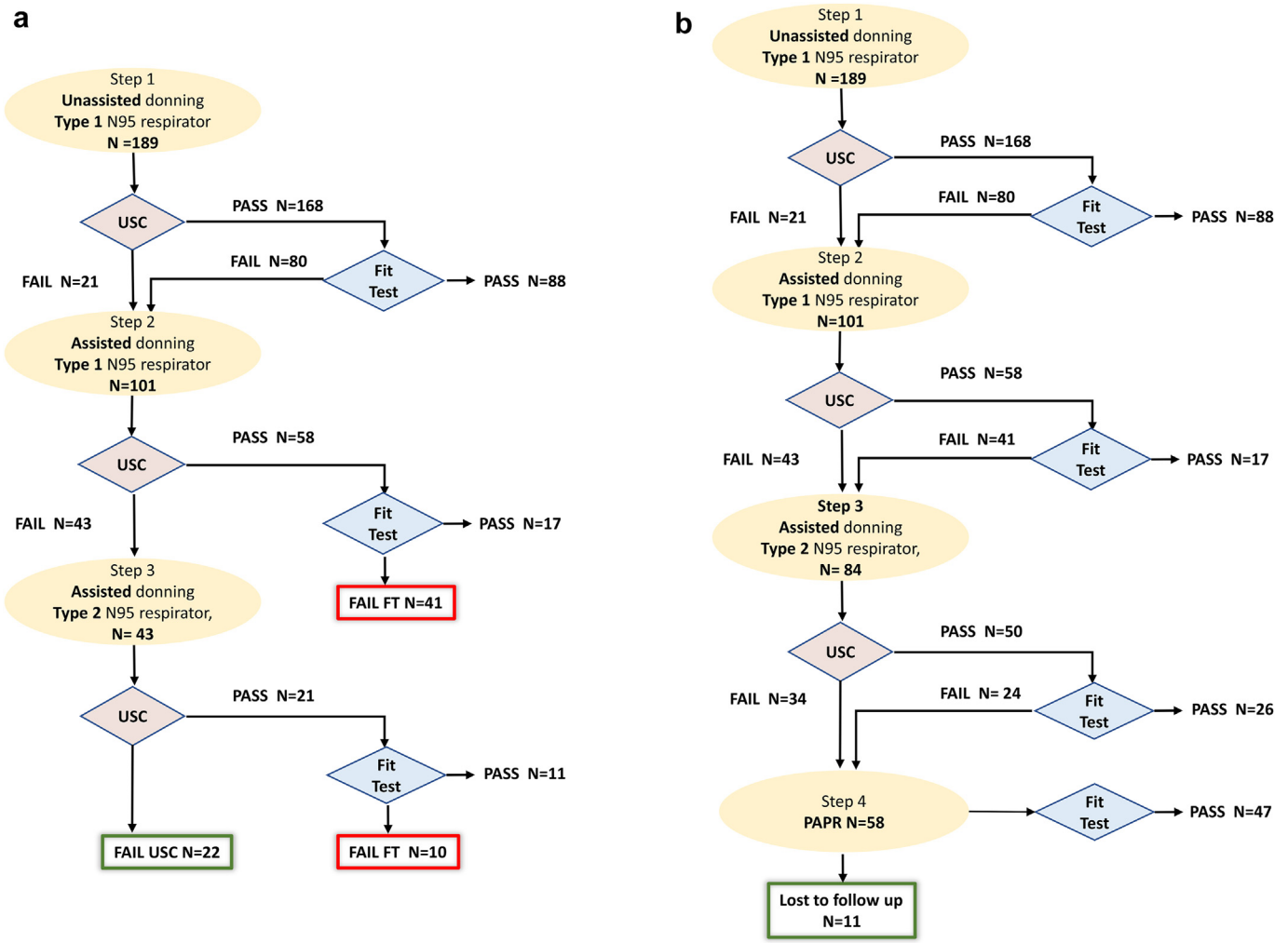


**Figure 1.** (a) Participant flow until primary outcome. (b) Participant flow until passed test. FT, fit test; USC, user seal check.

**Table 1**
Baseline variables for primary outcome.

| | Total, **n = 167** | Fail, **n = 51** | Pass, **n = 116** | OR (95% CI) **(univariate)** | OR (95% CI) **(multivariable)** |
|---|---|---|---|---|---|
| **Sex** | | | | | |
| Male | 57 (34.1) | 16 (31.4) | 41 (35.3) | | |
| Female | 110 (65.9) | 35 (68.6) | 75 (64.7) | 1.19 (0.59–2.42) | 1.41 (0.63–3.12) |
| **Occupation** | | | | | |
| Nurse, allied health & support staff | 123 (73.7) | 36 (70.6) | 87 (75.0) | | |
| Doctor | 44 (26.3) | 15 (29.4) | 29 (25.0) | 1.25 (0.60–2.61) | 1.41 (0.61–3.29) |
| **PPE training** | | | | | |
| Demonstration only | 18 (10.8) | 6 (11.8) | 12 (10.3) | | |
| Hands on | 149 (89.2) | 45 (88.2) | 104 (89.7) | 0.87 (0.31–2.45) | 0.86 (0.30–2.48) |
| **Respirator worn for primary outcome** | | | | | |
| 3M | 60 (35.9) | 18 (35.3) | 42 (36.2) | | |
| Halyard | 107 (64.1) | 33 (64.7) | 74 (63.8) | 1.04 (0.52–2.07) | 1.02 (0.51–2.07) |
| **Number of N95 respirators worn** | | | | | |
| ≤10 | 62 (37.1) | 18 (35.3) | 44 (37.9) | | (reference category) |
| 11-25 | 50 (29.9) | 17 (33.3) | 33 (28.4) | 1.26 (0.56–2.81) | 1.31 (0.58–2.99) |
| >25 | 55 (32.9) | 16 (31.4) | 39 (33.6) | 1.00 (0.45–2.23) | 1.03 (0.46–2.32) |
| **Years of critical care experience**[a] | **n = 166** | **n = 51** | **n = 115** | | |
| ≤5 | 58 (34.9) | 19 (37.3) | 39 (33.9) | | (reference category) |
| 6-14 | 58 (34.9) | 17 (33.3) | 41 (35.7) | 0.85 (0.39–1.87) | 0.85 (0.38–1.90) |
| 15+ | 50 (30.1) | 15 (29.4) | 35 (30.4) | 0.88 (0.39–1.99 | 0.86 (0.37–1.97) |

CI, confidence interval; OR, odds ratio.
[a] One data point missing.

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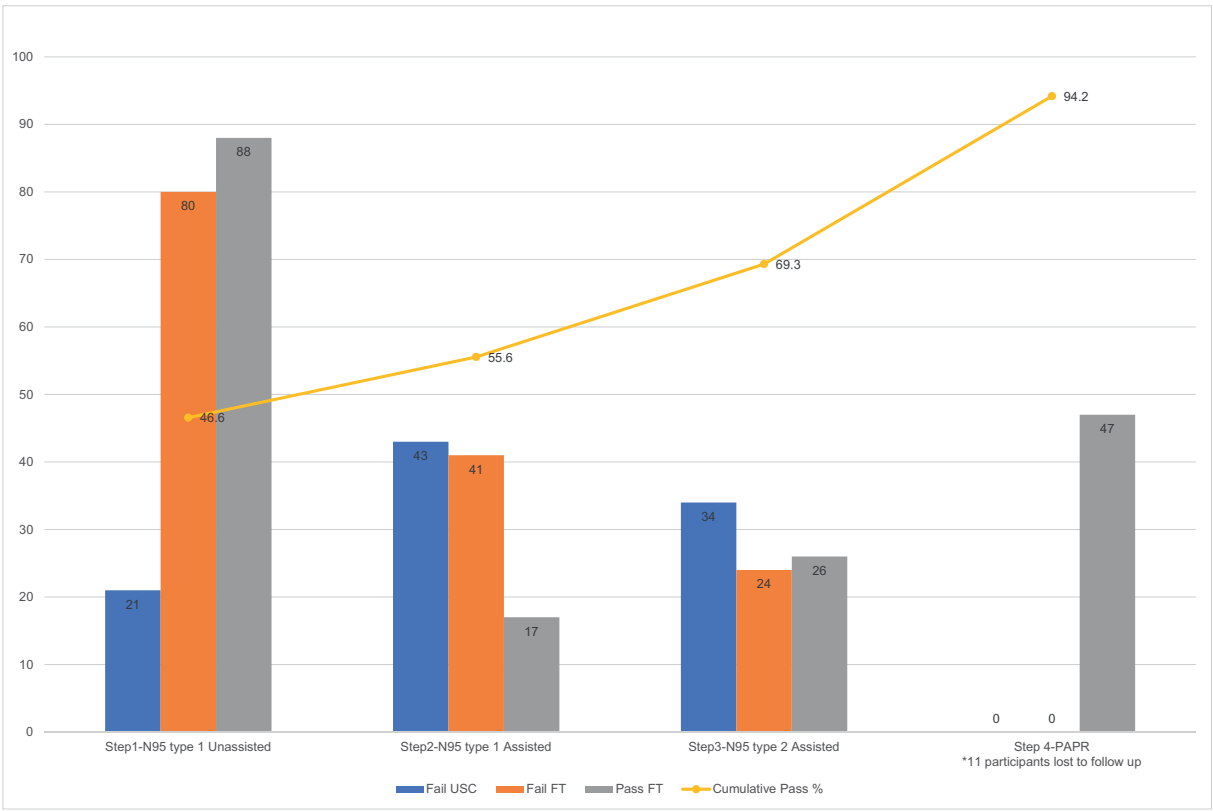


**Figure 2.** Fit test outcomes steps 1 to 4. FT, fit test; USC, user seal check.

two standard size N95 respirators. The addition of half-mask PAPR (CleanSpace HALO®) enabled successful fitting of those failing both N95 respirators, showing the potential utility of this device, especially in the setting of N95 respirator supply limitations.

A strength of the study is that it reflects the practices of frontline staff in Melbourne during the 2020 COVID-19 pandemic. Fit testing had not been incorporated into the hospital's respiratory protection program and could only be facilitated in the context of a pilot research project. Our results highlight the potential risk of ad hoc N95 respirator use as opposed to careful validated assessment of fit, based on fit testing. The study's completion also demonstrates the feasibility of implementing fit testing during a pandemic and active regional outbreak.

Some limitations should be noted. The inclusion of only three private hospitals and the availability of only two different N95 respirator types limit the generalisability to other healthcare settings with differing populations and respirator combinations. Selection of the first respirator used was not randomised, and this may have biased our results, particularly in any comparisons between N95 respirator types. In addition, data on facial characteristics that have previously been shown to influence respirator fit were not collected.[26,27] Tester experience and training have also been shown to contribute to failure rates[21,28] and may have impacted our results within a newly established fit testing program.

The use of qualitative fit testing is also a potential limitation of the study. Quantitative fit testing is generally considered to be more reliable and is now the preferred method within Victoria[29]; however, suitable quantitative testing equipment was not available at the time of the study. Qualitative testing remains an internationally validated method, and although it is more subjective,[6] the advantages of availability and cost made it a suitable choice for this study.[17,30]

Our study raises questions about the optimal use of fit testing and PPE for the future protection of healthcare workers from airborne pathogens. Limiting exposure can be considered in the context of a hierarchy of controls with elimination as the most effective and PPE as the least effective.[31] Nevertheless, for clinicians in close proximity to COVID-19 patients, optimal PPE for airborne pathogens allows them to provide therapies such as intubation, high-flow oxygen, and noninvasive ventilation without an increased risk of acquiring COVID-19.[32]

In conclusion, USC alone was inadequate in assessing N95 respirator fit and failed to detect inadequate fit in 30% of participants. Mandatory fit testing is essential to ensure adequate respiratory protection against COVID-19 and other airborne pathogens.

## Conflict of interest

None.

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## CRediT authorship contribution statement

Helen Cass: Conceptualissation; Investigation; Methodology; Project administration; Writing -original draft, review & editing. Gabrielle Hanlon: Conceptualisation; Data curation; Methodology; Project administration; Writing - review & edit. Dean McKenzie: Formal analysis; Software; Writing - original draft, review & editing. Nerina Harley: Conceptualisation; Writing – Review & editing. Diane Kelly: Conceptualisation; Writing – Review & editing. Jonathan Barrett: Conceptualisation; Data curation; Methodology; Supervision; Project administration; Formal analysis; Writing – original draft, review & editing

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