**The adequacy of user seal checking for N95 mask use compared to formal fit testing. A retrospective, multicentre observational study.**

**Dr Helen Cass**

**Dr Diane Kelly**

**Assoc Prof Nerina Harley**

**Assoc Prof Dean McKenzie**

**Ms Gabrielle Hanlon**

**Dr Jonathan Barrett**

**Epworth HealthCare**

1. **Background**

Personal Protective Equipment (PPE) is used in many industries to protect workers against exposure to harmful particulate substances. Air purifying respirators are one of the essential components of PPE, and are available in several designs and varying levels of filtration, indicated by a letter and number, however the nomenclature varies between countries. In Australia, a respirator designated as N95 is intended to filter over 95% of fine airborne particles, which includes oil-free aerosols (dusts & mists) and airborne respiratory pathogens.

In the healthcare setting the use of either a certified N95-Filtering Facepiece Respirator (N95-FFR) or a Powered Air Purifying Respirator (PAPR) (1) is required to provide protection against occupational exposure to substances via droplet and airborne transmission.

The most common is the N95-FFR, which is a disposable, half-facepiece, air-purifying mask that is intended to form a complete seal with the face in order to provide optimum protection (2).

Evidence has shown that face-seal leakage is the main reason a mask’s efficacy is compromised in providing protection against bioaerosols (3,4,5). Factors identified with face-seal leakage include face size, mask size, strap tension and edge shape. It is therefore paramount that adequate training is provided for the correct selection and use of the N95-FFR.

In the USA and Canada formal fit testing has been legislated (4,6). However in Australia there are only recommendations by the National Health and Medical Research Council (NHMRC) that regular users of N95-FFR should undergo annual fit testing (Joint Australian & New Zealand Standards Committee AS/NZS 1715.2009). This can be done using a qualitative test based on taste or a quantitative test using a device that counts the number of particles on both sides of the mask. Either method is acceptable according to the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC), USA (2).

For many industries fit testing is a mandatory requirement for the employee on commencement of employment, and thereafter annually. However a previous study of the healthcare industry across Australia has shown a low uptake of fit testing (7) Therefore it could be inferred that the wearer seal check is being used as the sole means of assessing mask protection.

The wearer seal check has been part of the Occupational Safety and Health Administration respiratory protection program since the 1990’s (8). This is a means of self checking the correct fit by visual assessment and detecting any gross leakage. Training is by various means including printed instructions, non-interactive video, computer based or direct interactive training.

The current novel coronavirus (COVID-19) pandemic has highlighted the importance of safety for healthcare personnel (9) particularly in relation to PPE. To date, there are few studies that have addressed the issue of the wearer seal check being reliable enough to negate the need for fit testing for N95-FFR’s (10-13).

Current practice in Epworth ICUs is the ad-hoc use of one of two brands of disposable N95 masks or the use of a Powered Air Purifying Respirator. Staff receive training in the use of the various masks, and are expected to perform a wearer seal check if using the disposable N95. Fit testing has not previously been performed.

1. **Objectives**

To assess the adequacy of the wearer seal check compared to the reference standard of qualitative fit testing for various models of N95-FFR.

**Outcome Measures**

The primary outcome measure is the proportion of healthcare personnel failing fit testing on first N95 mask type fitted. A failure of fit testing is defined as failing both first attempt (without assistance) and second attempt (with assistance).

Secondary outcome measures:

* Proportion failing first mask without assistance.
* Failure rates for each mask type (Halyard, Apharetta, Georgia, USA; Sydney, Australia and 3M, St. Paul, Minnesota, USA; Sydney, Australia)
* Proportion failing both N95 masks
* Proportion failing both N95 masks and Powered Air Purifying Respirator (PAPR)

1. **Methodology**

[Fit testing of N95](file:///Users/DrHelenCass/Desktop/%0dFit%20testing%20of%20N95) masks will commence in ICU at Epworth Richmond, Freemasons and Geelong as part of a quality and safety initiative being implemented by the ICU directors at each site. Qualitative fit testing will be performed using the 3M FT-30 Qualitative fit test apparatus (Bitter). <https://www.3m.com.au/3M/en_AU/safety-centers-of-expertise-au/respiratory-protection/fit-testing>

Fit testing will be freely offered to all ICU staff who have been trained in using an N95 mask.

Briefly, a light-weight hood with a large clear window will be placed over their head and diluted testing solution nebulized into the hood until the staff member can taste it. They will then remove the hood, wipe their face and lips, take a drink of water and wait 10 minutes

Staff members will then be instructed to don an N95 mask according to their usual practice.

The hood will be put back on, and full-strength testing solution nebulized into the hood as they perform 6 exercises for a minute each: breathing normally, breathing deeply, moving their head side-to-side, moving their head up and down, bending over and talking.

If they cannot taste the solution by the end of the test, the seal of the face mask is deemed intact, and the staff member knows that mask and fit checking process is safe for them.

If staff members can taste the solution at any step, fit testing is deemed to have failed at that point.

The assessor will then assist them to re-apply the mask using a manual and visual fit check, and the taste test will be repeated. If the repeat test also fails then staff are subsequently tested on the alternative N95 mask.

If staff fail on both N95 masks then the test will be repeated with a PAPR.

By the end of the testing, staff should know what type/brand of respirator is suitable for them.

This prospective study plans to utilize the data routinely collected during fit testing and anlayse in de-identified form to address the study question and inform the design of future larger studies.

1. **Recruitment**

All staff potentially caring for a patient with suspected or proven COVID-19 at Epworth Richmond, Freemasons and Geelong ICUs will be encouraged to participate in fit testing. Testing will be offered according to the fit testers’ availability, and the staff on those shifts invited to participate.

Data routinely collected for all fit tests includes the staff member’s identifiers, the details of the masks tested and the success or failure of each test.

This study would use only the routinely collected data after the removal of all identifying information. No additional data points or interventions are required.

1. **Privacy, storage and disposal of data**

All data obtained as part of this study will be kept in a locked cabinet in the Epworth Richmond ICU research office.

Electronic data will only contain de-identified data, all electronic files will be password protected and will be stored on a secure server at Epworth HealthCare. Only the investigators listed on this study protocol will have access to the password protected study files.

At the time of data collection, the data will be collected in electronic re-identifiable form, to allow data cleaning. Once data cleaning is complete the data will be de-identified, for statistical analysis.

Data will be kept for 7 years after completion of the study, at which time it will be disposed of according to the Epworth confidential waste disposal guidelines. Electronic data will be deleted.

1. **Data use and analysis**

The primary endpoint, number of mask-fitting failures as defined in sections 3 and 4, will be assessed as the proportion of staff members experiencing failures, accompanied by 95% confidence interval. The latter will be estimated using the exact binomial (Clopper-Pearson) method (14). A sample size for planning analysis (15) was undertaken by Epworth HealthCare biostatistician A/Prof Dean McKenzie, employing Stata 16 (Stata Corporation, College Station, Texas, 2019). Precision or half-width of the corresponding exact binomial 95% confidence intervals was defined as 7.5%. The failure rate is expected to range from zero to 20%, a study of 204 nursing students observing a failure rate of 18.6% in quantitative fit testing of two 3M N95 masks (11).

A sample size of at least 150 healthcare workers would allow a precision of 7.5% for any error rate from zero to 20%. This number is considered to be very feasible as there are in excess of 250 staff across the three ICUs.

The lower and upper limits of exact binomial 95% confidence interval for a range of possible failure rates, for a sample size of 150, is shown below. For a point estimate of zero failures, for example, the 95% confidence interval would be 0% to 2.4%., (16). For a point estimate of 20% failures, the 95% confidence interval would be 13.9% to 27.3%. In both cases, the 95% confidence interval is no wider than the point estimate plus or minus 7.5%.

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| --- | --- | --- |
| number of errors (out of 150) | % | 95% CI |
| 0 | 0.0 | 0.0 to 2.4 |
| 2 | 1.3 | 0.2 to 4.7 |
| 5 | 3.3 | 1.1 to 7.6 |
| 10 | 6.7 | 3.2 to 11.9 |
| 15 | 10.0 | 5.7 to 16.0 |
| 25 | 16.7 | 8.3 to 19.8 |
| 30 | 20.0 | 13.9 to 27.3 |

As described above, the primary outcome of number of failures in fitting masks will be estimated using exact binomial 95% confidence intervals. Failures will be reported as frequencies and percentages, dimensional variables such as age will be reported as means and standard deviations or, in the presence of skewness, medians and interquartile ranges (the difference between the 25th and 75th percentiles). Appropriate statistical graphics such as bar charts and box plots will be presented.

Overall failures and proportion failing first mask fitting will be compared on clinically relevant variables such as mask type (Halyard and 3M), gender , staff (doctor, nurse), recency of prior mask use, type of training will be analysed using Poisson regression with robust standard errors in order to generate relative risks (17). Analysis of number of attempts at mask fitting before eventual passing or failing will be analysed using appropriate methods for count data such as negative binomial regression (18). Possible clustering due to different types of masks fitted on the same person will be taken into account using generalized estimating equation (GEE) or mixed methods / multilevel regression (19).

A commonly suggested ‘rule of thumb’ in ascertaining the number of variables into regression models for binary data is at least 10 events per variable, where events are defined as the less frequent binary outcome (20) As the error rate is expected to be less than or equal to 20% of 150 or 30 staff members, a maximum of three predictor variables or potential confounders could therefore be entered into regression models. The comparison of the performance of potential predictors of failure such as mask type, with and without potential confounders such as gender, will inform larger studies.

All statistical analyses will be conducted by, or under the direct supervision of, Epworth HealthCare biostatistician(s), using standard professional statistical software such as Stata 16 (Stata Corporation, College Station, Texas, 2019) or higher. The level of statistical significance will be set at 0.05, 2-tailed in all analyses. 95% confidence intervals will be calculated throughout. No interim analysis is planned.

1. **Risks & Ethical Issues**

This quality improvement study involves the use of data already being collected as part of a clinical quality improvement initiative with the use of de-identified data only for a directly related secondary purpose i.e. to determine the adequacy of wearer seal checking compared to formal fit testing. As such it is a low-risk observational study and waiver of consent is sought as a quality improvement project.

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