



Supporting Information

Supplementary results

**This appendix was part of the submitted manuscript and has been peer reviewed.
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Appendix to: Ng I, Kave B, Begg F, et al. N95 respirators: quantitative fit test pass rates and usability and comfort assessment by health care workers. *Med J Aust* 2022; doi: 10.5694/mja2.51585.

1. Characteristics of the N95 respirators used in our study

	1860 (3M)	1860(S) (3M)	DE2322 (BYD)	Proshield (BSN)	Fluidshield (Halyard)	Aura 9320A+ (3M)
Type	Semi-rigid cup	Semi-rigid cup	Vertical flat fold cup	Duckbill	Duckbill	3-panel flat fold
Inhalation resistance	NA	NA	11.2 mmH ₂ O ³	NA	10.1 mmH ₂ O ⁸	≤ 120 Pa ^{10,11}
Exhalation resistance	NA	NA	10.8 mmH ₂ O ³	NA	9.4 mmH ₂ O ⁸	≤ 120 Pa ^{10,11}
>99% bacterial filtration efficiency	Pass ¹	Pass ¹	Pass ⁴	Pass ⁶	Pass ⁸	NA
>95% particle filtration efficiency	Pass ¹	Pass ¹	Pass ³	Pass ¹	Pass ⁹	Pass ^{10,12}
Fluid resistance level	2 ²	1 ²	3 ⁵	3 ⁷	3 ¹	2 ¹³

NA = not applicable.

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3M 1860, 3M 1860S



BYD DE2322



BSN Proshield 72509 TN01-11 Medium; Halyard Fluidshield 46727



3M Aura 9320A+

2. Development and validation process of the usability and comfort assessment survey

There is currently lack of information about respirator performance, and there is no validated evaluation tool available to assess usability and comfort of respirators. Therefore, we were required to design the assessment tool for this study.

The development process involved the followings:

- Review of literature:

Our survey instrument was largely based on project BREATHE criteria ¹, together with other peer reviewed journal articles.²⁻⁸

- Subject matter experts:

Using a participatory action research framework, eight experienced, hospital-based health practitioners assisted in developing the survey instrument. The group included nurses, anaesthetists, occupational therapists, wound care nurses and infection prevention experts. All of the members were experienced in the use of respiratory protective equipment, and had previously completed quantitative fit testing. They were either managers or members of the Respiratory Protection Program, with expertise in the selection, use, training, and managing problems or complications related to respiratory protective equipment.

- Identification of domains/items:

- The following areas were identified to be important, based on Project BREATHE recommendation ¹:

- i. Safe and effective use: safe donning, safe doffing, user seal check, accuracy with workplace protection, and barrier from blood/fluid penetration.
- ii. Use integration with occupational activities: compatibility with other equipment, vision, communication (both hearing and speaking), and transparency of respirator.
- iii. Comfort and tolerability (no major medical or psychological issues): allergy, breathing resistance (work of breathing), claustrophobia and anxiety.
- iv. Comfort and tolerability with extended or repeated use: pressure (especially nose, cheek, ears and chin), skin irritation, weight of respirator, heat, humidity and odour.

- Deductive process:

We excluded items that were already under current NIOSH/FDA Surgical N95 assessment requirement, such as level of blood and body fluid resistance, equipment compatibility, breathing resistance and allergenicity.⁹ We also excluded items that

required specific testing, such as speech intelligibility, heat and humidity measurement.¹⁰ All the respirators used in this study were half-facepiece, light-weight (6-11g), and not transparent, we therefore excluded the following items: vision, weight and transparency of respirator.

- Based on the above deductive method, we were left with three questions for usability: ease of use when donning and doffing, user-seal check success and seal of mask; and three questions for comfort: skin irritation, anxiety limiting use and specific pressure areas.
- Three additional questions were included for comfort assessment, based on previous study findings and our healthcare workers' experience/feedback:
 - i. Firmness of fit - discomfort was often found to be associated with tight-fitting respirator models.⁴
 - ii. Breathability - although breathing resistance could be objectively measured, we believed that there was a subjective component of breathability. Many studies also included the question of impact on breathability in their comfort assessment.^{2,7}
 - iii. Eye irritation - there have been increasing reports of face-mask associated ocular irritation and dryness.¹¹
- The wording for each question, and the response categories and scales were developed by the consensus of the group.
- A pilot testing was run within the perioperative service at our institution with the introduction of a new N95 respirator. This was to ensure interpretability of the questions. We received 44 responses. Free text responses were also available and results were analysed to check whether any further items need to be added. Questions were modified accordingly based on the responses.

Validation process

We established face validity and content validity by conducting a thorough literature review and forming a subject matter expert group. As discussed above, the appropriateness of the contents for each measure was determined by expert judgements, based on previous similar studies, current regulation requirement, a deductive process and feedback from a pilot run. Construct validity (both convergent and discriminant validity) was difficult to verify because there were no accepted alternative measurement tools. We measured the correlation between individual item and the overall score for each domain, and found at least moderate agreement. The overall assessment was

strongly correlated with seal rating ($\rho=0.7$, $p<0.001$); and moderately correlated with seal check ($\rho=-0.4$, $p<0.001$) and ease of use ($\rho=-0.3$, $p<0.001$). The overall comfort rating was strongly correlated with firmness of fit ($\rho=0.5$, $p<0.001$) and breathability ($\rho=0.6$, $p<0.001$).

As pointed out by Gosch⁹ and Shaffer⁸, assessment of comfort and usability is almost entirely subjective, and the factors affecting these two domains are not well defined. An alternative method of validation may be required; e.g. validating laboratory-based test methods against clinical outcomes.

References

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3. Post fit-testing follow up usability and comfort assessment

Post fit-testing follow up usability and comfort assessment

After the fit testing, you now learn which type and what size of the N95 mask fit you properly. We would like to know what your experience is when wearing them. Please fill in the questions below for each of the mask that fitted you from the fit test.

Mask Type: _____

What is the type of the N95 mask?

- Semi-rigid Cup: 3M 1860
- Flat Fold Cup: BYD
- Duckbill: BSN Proshield,
- 3-panel flat-fold: 3M Aura
- Duckbill: Halyard Fluidshield
- Other
-

Please specify

What is your preferred size when using this type of N95 mask?

- Regular
- Small
- N/A

How many of this type of N95 mask have you used over the past week ?

- 0
- 1
- 2-5
- 6-10
- 11-15
- >15

What is the usual duration of wear in hours before doffing this N95 mask?

- 0
- 1
- 2
- 3
- 4
- >4

Please specify

How would you rate the seal of the mask?

- poor
- adequate
- good
- very good
- excellent

Do you think you passed the user-seal check when wearing the mask?

- Every single time
- Most of the time
- Sometimes
- Rarely
- Never

How would you describe the ease of use when donning and doffing?

- easy
- somewhat difficult
- difficult

How would you describe the firmness of fit on the face?

- too tight
- about right
- too loose

How would you describe the breathability?

- poor
- average
- good

Have you ever had any of the following problems with this type of N95 mask?

	Yes	No
Eye irritation	<input type="radio"/>	<input type="radio"/>
Skin irritation or rash limiting the duration of use or requiring special skin care	<input type="radio"/>	<input type="radio"/>
Anxiety limiting the duration of wear	<input type="radio"/>	<input type="radio"/>

Significant pressure areas that have limited your duration of use of the mask

	Yes	No
Nose	<input type="radio"/>	<input type="radio"/>
Cheeks	<input type="radio"/>	<input type="radio"/>
Ears	<input type="radio"/>	<input type="radio"/>
Chin	<input type="radio"/>	<input type="radio"/>
Other	<input type="radio"/>	<input type="radio"/>

Please specify

How would rate the overall comfort (Feel) of the mask?

- poor
- adequate
- good
- very good
- excellent

What is your overall assessment of this type of N95 mask?

- poor
- adequate
- good
- very good
- excellent

Please add any other free text comments about this type of N95 mask

4. Free text comments by 89 of 378 participants who completed the usability and comfort survey, by N95 respirator type, with examples*

	Semi-rigid cup type¹	Flat-fold cup type²	Duckbill³	Three-panel flat-fold⁴
All comments	28	4	33	24
Positive comments	9 <i>"Most secure", "Good seal", "Effective"</i>	0	5 <i>"I feel safe", "Very comfortable"</i>	9 <i>"Felt very good", "Very confident with use", "Most comfortable"</i>
Negative comments	20 <i>"Extreme pressure", "Uncomfortable", "Painful", "Rash/irritation"</i>	4 <i>"Not preferred mask", "Don't fit very well"</i>	16 <i>"Hard to breathe", "Feels light", "Donning and doffing can be difficult"</i>	5 <i>"Smell", "Toxic scent", "Fiddly to put on in a hurry"</i>
Neutral comments	2 <i>"Unable to answer...as only worn for the fit test"</i>	0	9 <i>"I don't use N95 all the time", "Fit test was excellent"</i>	8 <i>"Haven't used", "Only mask that I passed"</i>
Logistic problems	3 <i>"Difficult in obtaining"</i>	0	3 <i>"Small duckbills are not readily available"</i>	5 <i>"Least amount of access", "Difficult to get"</i>

* Individual respondents could provide comments classified as falling into different categories.

1. Semi-rigid cup type respirator: 3M™ 1860 or 1860S; 2. Flat-fold cup type: BYD N95 respirator; 3. Duckbill type: BSN Medical ProShield® N-95 masks or Halyard Fluidshield N95 masks; 4. Three-panel flat-fold type: 3M™ Aura™ 9320A+.