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Can homemade fit testing solutions be as effective as commercial products?

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Abstract. *Background:* Fit testing is used to determine whether a N95 mask will provide respiratory protection for the wearer by preventing inhalation of airborne transmitted microorganisms. National guidelines recommend that healthcare workers (HCW) who use N95 masks require fit testing. Quantitative fit testing requires the purchasing and use of fit testing solutions and associated equipment. In high volume, these solutions are expensive and may not be readily available, as was seen in the 2009 H1N1 influenza pandemic. The aim of this study was to determine how a homemade solution compared against a commercially available product and a placebo.

Methods: A fit test was performed on the same person, on three separate occasions, using three different solutions – commercial (45% sodium saccharin), homemade (to be disclosed) and placebo (water). The solution was double blinded and solutions were chosen and administered in a random order.

Results: A total of 48 people participated in this study. At the threshold testing stage, 8.3% did not taste any solution, 16.7% of people could taste the placebo, 89.6% could taste the commercial solution and 91.7% could taste the homemade solution. All persons who could taste the commercial solution could taste homemade solution.

Conclusion: The findings of our study suggest that fit testing solutions could be made locally with a similar effect to that of commercial products, that quantitative fit testing is unreliable and that serious consideration should be given to the role of quantitative fit testing in future guidelines and standards. We recommend that this study be conducted on a larger scale to support our findings.

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Introduction

Recent outbreaks of respiratory tract infectious diseases have brought greater attention to the need for respiratory protection for healthcare workers.^{1–3} When there is a high probability of airborne transmission of an infectious agent, sound scientific principles support the use of P2 respirators to attempt to prevent transmission.⁴ The current Australian National Health and Medical Council (NHRMC) guidelines recommend that ‘in order for a P2 respirator to offer the maximum desired protection it is essential that the wearer is properly fitted and trained in its safe use’.⁴ The terms ‘properly fitted’ and ‘trained’ are further expanded upon in the NHMRC guidelines that describe two procedures: a ‘fit check’ and a ‘fit test’. ‘Fit

check’ is the term used to describe the process by which healthcare workers self check the fit of their respirator to ensure the respirator is sealed over the bridge of the nose and mouth and that there are no gaps between the respirator and the face.⁴ ‘Fit test’ is the term used to describe a procedure identifying which size and style of P2 respirator is suitable for an individual and ensuring that it is worn correctly.

There are two methods used to undertake fit testing: qualitative and quantitative. Quantitative fit testing methods are considered the gold standard method and measure leakage into the respirator.⁵ Methods for quantitative fit testing are described in AS/NZS 1715:2009 and require the use of specialised equipment by a trained operator. The qualitative fit

Implications

- There is a potential to make fit testing solutions locally, with efficacy equal to that of commercial products.
- A practical option for making a fit testing solution is provided, in the event that a commercial product is unavailable.
- The usefulness of qualitative fit testing is questionable.

testing procedure is most commonly used in healthcare settings and is a pass/fail test to assess respirator fit, based on an individual's response to a test agent. Qualitative fit testings require the purchase and use of fit testing solutions and associated equipment. Although fast and simple to do, qualitative fit tests have the limitation of being influenced by the wearer. If used in high volume, the solutions used in qualitative fit testing are expensive and may not be readily available, as was our experience in Tasmania during the 2009 H1N1 influenza pandemic. The aim of this study is to determine, when undertaking qualitative fit testing, if there is any difference in performance between a commercially available fit testing solution, a fit testing solution made locally and a placebo.

Methods

Study design

This was a single-site, blinded crossover study conducted in Tasmania, Australia.

Study setting and timeframe

The study took place within the Population Health Department of the Department of Health and Human Service (DHHS) in Hobart, Australia, from January 2010 to September 2011.

Participants

Eligible participants were adult volunteers aged 18 or over who worked for the Tasmanian DHHS. Information regarding the study was advertised in various locations with the DHHS and participants subsequently nominated themselves. Patients with a known reaction to any products contained in the fit testing solutions were excluded from the study. Persons who had eaten, drunk any fluids or smoked 30 min before participating in the trial were excluded until 30 min had passed.

Interventions

Three different fit testing solutions, a commercial product, a homemade product and a placebo (water) were decanted into identical-appearing bottles by an infectious diseases pharmacist at the Royal Hobart Hospital, Tasmania. All solutions appeared identical. All other researchers involved in

this study were blinded to the contents of each bottle by the pharmacist.

Solution preparation

Homemade product

The homemade solution was developed by using artificial sweetener containing saccharine which was dissolved in sterile water. This product was made to the same concentration as the commercially available product. More specifically, to make the homemade solution, 830 mg of sodium saccharine was dissolved in 100 mL of distilled water. To make a threshold solution, another 100 mL of distilled water was added to 1 mL of the fit testing solution. A 'threshold' solution is a diluted fit testing solution.

Commercial product

The commercially available fit testing solution contained 45% sodium saccharin and 95% water, whilst the threshold fit test solution contained <1.0% sodium saccharin and 99% water.

Placebo

The placebo was sterile water.

Testing procedure

The fit testing procedure was performed in accordance with the manufacturer's instructions for the commercial products, the Tasmanian Department of Health and Human Services and the United States Occupation Health and Safety Administration.^{6,7} To begin the intervention, a fit testing solution was chosen randomly by the researcher from the three available groups of solutions (i.e. commercial, homemade or placebo). A threshold test was then performed on the participant who was also blinded to the solution used. A threshold test determines the participants' ability to taste a weak solution of the challenge agent.⁸ This procedure involved spraying the threshold solution into a hood worn by the participant until the solution could be tasted or until 30 sprays were administered. Participants were asked if they could taste anything throughout the procedure. The threshold number (number of sprays) was recorded. If the participant could taste the solution, they were deemed to have passed the threshold test. If the participant could not taste the solution, they were deemed to have failed.

For those participants who passed the threshold testing stage a P2 (N95) respirator was donned by the participant and a fit check and fit test was performed. The fit test used the full strength solution to verify that the wearer could achieve an acceptable facial fit with the respirator. The testing at this stage involved another three steps:

- (1) The researcher chose a fit testing solution at random
- (2) The fit testing procedure was performed (Table 1)
- (3) A record was made of whether the person tasted (failed) or did not taste (passed) the test

Once the fit testing procedure was completed and 15 min was allowed to elapse (or until the participant could not taste

Table 1. Fit testing procedure

A hood was placed on the participant. Subjects were taken through the following exercise whilst simultaneously carrying out the tester's instructions

Participant and task [^]	Researcher
1. Breathe normally.	1. Press nebuliser by half the threshold amount every 30 s (i.e. threshold = 10; press nebuliser 5 times).
2. Breathe deeply through mouth.	2. Press nebuliser by half the threshold amount every 30 s.
3. Turn head to left and right; pause to breathe at each side.	3. Press nebuliser by half the threshold amount every 30 s.
4. Move head up and down; pause to breathe at each angle.	4. Press nebuliser by half the threshold amount every 30 s.
5. Read out aloud the 'Rainbow Passage' (provided below).	5. Press nebuliser by half the threshold amount every 30 s.
6. Breathe normally.	6. Press nebuliser by half the threshold amount every 30 s.

[^]Tasks below completed in 60 s.

the solution), another threshold and fit testing procedure was performed on the same person, using a solution from one of the remaining two solution groups. Threshold and fit testing was performed using these solutions as described earlier. Once this was completed, the process was repeated for the remaining solution group. The test concluded when each participant had had a threshold and fit testing procedure conducted using solutions from all three groups (homemade, commercial, placebo). Fig. 1 summarises this process. Three different researchers over the study period conducted the fit testing, however a documented procedure was used to limit practice variation.

The rainbow passage referred to in Table 1 is as follows:

'When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colours. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond his reach, his friends say he is looking for the pot of gold at the end of the rainbow.'⁷

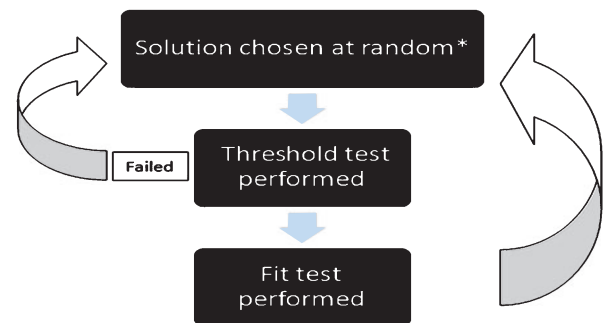
For each fit test and solution used, a record was made as to whether the participant tasted the solution (failed) or did not taste the solution (passed). Once the testing of a participant was complete, the fit testing equipment and hood were cleaned with warm water and neutral detergent.

Data analysis

A data collection sheet was developed to record outcomes from each participant and solution. This information was subsequently entered into a database (SPSS Version 20.0, IBM Corporation, New York, USA). Data collected were gender, fit testing solution code, threshold level and pass/fail, pass/fail of the fit testing procedure, and type of respirator used. Once the data was entered into SPSS, the solutions used in the study were unblinded by the pharmacist.

Ethics

Verbal consent from each participant was obtained before the commencement of the study and an information sheet was



*Solution chosen from one of the three groups of blinded solutions (placebo, homemade or commercial).

Fig. 1. Summary of the fit testing process.

provided. Ethics approval for this study was granted by the Tasmanian Human Research Ethics Committee (approval number H0010996) and the provision of verbal consent deemed appropriate. The study was conducted in accordance with the protocol described and approved by the ethics committee.

Results

There were 48 people in this study. Thirty-seven (77%) of participants were female. All participants used a Kimberley Clark P2 (N95) respirator. At the threshold testing stage, four participants (8.3%) did not taste any solution. They did not proceed onto the next stage of fit testing.

Of the remaining participants, at the threshold testing stage, eight (16.7%) people could taste the placebo, 43 (89.6%) could taste the commercial solution, and 44 (91.7%) could taste the homemade solution. All persons who could taste the commercial solution could taste the homemade solution.

Of all who passed the threshold testing stage and who were subsequently fit tested, 40 (91%) passed the fit test. Of the four persons who failed the fit test, three could taste both the homemade and commercial solution. One person could taste the commercial product but passed using the homemade product.

Discussion

The purpose of this study was to examine the efficacy of the solutions used in qualitative fit testing. There are two main points of interest from this study, which could lead to further debate and discussion. First, 17% of participants could taste the placebo. Second, the commercial product and the homemade product performed almost identically at both the threshold and fit testing stages of this procedure. The first point of interest relates to the broader issue of the efficacy of qualitative fit testing and it is not the purpose of this paper to explore this. This issue, coupled with decisions around which respirator to use in a given situation are debated elsewhere.^{9–12}

Findings from this study suggest that it is possible to make a homemade fit testing solution simply by using readily available artificial sweeteners. Such a finding needs to be replicated in larger size studies, using different research designs and different masks. Nonetheless, this study tests a novel process of using homemade fit testing solutions. Furthermore, should another pandemic occur and fit testing solutions become unavailable when qualitative fit testing is required, we provide an alternative that appears to be comparable to a commercially available product.

This study has several implications for practice and policy. We provide a practical option for making a fit testing solution, should a commercial product be unavailable or deemed too expensive. With respect to policy, our study casts considerable doubt over the usefulness of qualitative fit testing in general, given the significant percentage of participants who claimed to taste the placebo.

The study only examined one type of P2 (N95) respirator. It is possible that participants would have had a different result if they wore a different respirator. Furthermore, there were three different persons who conducted the fit tests and we could not control for potential operator variation.

Conclusion

The findings of our study suggest that fit testing solutions could be made locally and be equally effective as commercial products. A homemade fit testing solution can be made by dissolving 830 mg of sodium saccharine into 100 mL of distilled water.

Conflicts of interest

One of the authors has an editorial affiliation with *Healthcare Infection*. This author played no part in the peer review process. The review process was double blinded and this

author played no role in the editorial decision making whatsoever. All other authors have no conflicts to declare.

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References

1. Seto WH, Tsang D, Yung RW, Ching TY, Ng TK, Ho M, *et al.* Effectiveness of precautions against droplets and contact in prevention of nosocomial transmission of severe acute respiratory syndrome (SARS). *Lancet* 2003; 361(9368): 1519–20. doi:10.1016/S0140-6736(03)13168-6
2. Webster R, Peiris M, Chen H, Guan Y. H5N1 Outbreaks and Enzootic Influenza. *Emerg Infect Dis* 2006; 12(1): 3–8. doi:10.3201/eid1201.051024
3. Bearden A, Friedrich TC, Goldberg TL, Byrne B, Spiegel C, Schult P, *et al.* An outbreak of the 2009 influenza A (H1N1) virus in a children's hospital. *Influenza Other Respir Viruses* 2012; 6(5): 374–9. doi:10.1111/j.1750-2659.2011.00322.x
4. National Health and Medical Research Council. Australian Guidelines for the Prevention and Control of Infection in Healthcare. Canberra: National Health and Medical Research Council; 2010. Available from: <http://www.nhmrc.gov.au/node/30290> [verified September 2012]
5. Lam SC, Lee JKL, Yau SY, Charm CYC. Sensitivity and specificity of the user-seal-check in determining the fit of N95 respirators. *J Hosp Infect* 2011; 77(3): 252–6. doi:10.1016/j.jhin.2010.09.034
6. Department of Health & Human Services Tasmania. Infection Control Advice Fit Testing of P2 (N95) masks. Hobart, Tas.: Department of Health & Human Services Tasmania; 2009.
7. Occupational Safety and Health Administration. Personal Protective Equipment. Fit testing. Washington, DC: Occupational Safety and Health Administration; 2010.
8. Kimberly-Clark Professional. Qualitative Fit Testing Instructions. For KIMBERLY-CLARK* TECNOL* PFR95* N95 Particulate Filter Respirators and Surgical Masks. Kimberly-Clark Professional; 2006. Available from: http://www.kcprofessional.com/us/download/product%20literature/KCPI_0356_fit_test%20.pdf [verified June 2012]
9. Hannum D, Cysan K, Jones L, Stewart M, Morris S, Markowitz SM, *et al.* The effect of respirator training on the ability of healthcare workers to pass a qualitative fit test. *Infect Control Hosp Epidemiol* 1996; 17(10): 636–40. doi:10.1086/647195
10. Lee MCMD, Takaya SM, Long RM, Joffe AMMD. Respirator-fit testing: does it ensure the protection of healthcare workers against respirable particles carrying pathogens? *Infect Control Hosp Epidemiol* 2008; 29(12): 1149–56. doi:10.1086/591860
11. Au SSW, Gomersall CD, Leung P, Li PTY. A randomised controlled pilot study to compare filtration factor of a novel non-fit-tested high-efficiency particulate air (HEPA) filtering facemask with a fit-tested N95 mask. *J Hosp Infect* 2010; 76(1): 23–5. doi:10.1016/j.jhin.2010.01.017
12. Kelly L, Clark K. The effectiveness of training and taste testing when using respirator masks. *J Hosp Infect* 2004; 58(3): 240–1. doi:10.1016/j.jhin.2004.07.009