

Particulate face masks for protection against airborne pathogens — one size does not fit all: an observational study

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In the past decade, the world has seen epidemics of severe acute respiratory distress syndrome,¹ multidrug-resistant tuberculosis,² highly pathogenic avian influenza³ and pandemic influenza H1N1 2009.⁴ Transmission of these diseases from patients to health care workers has been described,⁵ in some cases resulting in death.⁶ To avoid such transmission, the use of personal protective equipment (PPE) is recommended,⁷ the most important aspect of which is a P2 respirator (known in the United States as an N95 respirator). This is often referred to in a clinical context as a particulate face mask. These masks filter out airborne infectious particles. Guidelines suggest their use for health care workers caring for patients with pandemic influenza⁸ or suspected or confirmed tuberculosis.⁹

Although a number of previous studies have evaluated characteristics and fit testing of P2 masks,¹⁰⁻¹² they have not included the types of mask commonly stockpiled in Australia.¹³ Australian guidelines recommend that "P2 (N95) respirators should be used within the context of a respiratory protection program that includes fit testing, fit checking and training".¹⁴ Qualitative fit tests rate masks as either pass or fail, based on the wearer detecting a test substance through taste or smell. These tests are generally easy and relatively cheap to perform and do not require specialised personnel or equipment, but give only a subjective measure of the quality of seal of the face mask.¹⁵ In contrast, quantitative tests are costly, but provide an objective measure of the quality of the mask's seal. There is some evidence that the results correlate well between qualitative and quantitative tests.¹⁶

We evaluated three P2 masks that are commonly available in Australia and were available at our hospital. For each of these masks, we aimed to determine the proportion of health care workers who achieved a good fit with the mask, factors that affected fitting, the effect of training, and acceptability of the mask.

Methods

The study was approved by our institutional human research ethics committee. Participants were volunteers drawn from staff involved in clinical care of patients in the 18-bed general intensive care unit of an Australian teaching

ABSTRACT

Objective: To determine the proportion of hospital staff who pass fit tests with each of three commonly used particulate face masks, and factors influencing preference and fit test results.

Design: Observational study.

Setting and participants: 50 healthy hospital staff volunteers in an 18-bed general intensive care unit in an Australian teaching hospital.

Interventions: Participants were administered a questionnaire about mask use and their preferred mask and underwent qualitative fit-testing with each of three different particulate masks: Kimberly–Clark Tecno! FluidShield N95 particulate filter respirator (KC), 3M Flat Fold 9320 particulate respirator and 3M 8822 particulate respirator with exhalation valve. Participants who failed fit-testing were trained in correct mask donning, and fit-testing was repeated.

Main outcome measures: Proportion of participants who passed the fit test for each mask and the effect of training.

Results: The proportion of participants who passed a fit test was low for all three masks tested (KC, 16%; flat fold, 28%; and valved, 34%). Rates improved after training: the first mask tested fitted in 18% of participants pre-training and 40% post-training ($P=0.02$). None of the masks fitted for 28% of participants. There were no significant predictors of fit-test results.

Conclusions: A large proportion of individuals failed a fit test with any given mask, and we were not able to identify any factors that predicted mask fit in individuals. Training on mask use improved the rates of adequate fit. Hospitals should carry a range of P2 masks, and should conduct systematic P2 mask training and fit-testing programs for all staff potentially exposed to airborne pathogens.

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hospital. Exclusion criteria were the presence of facial hair or pregnancy.

After providing written informed consent, participants filled in a questionnaire and underwent fit testing with each of the three masks, in random order, without training.

Those who failed a fit test with any particular mask received training on correct fitting, and the fit test was repeated. Training was conducted using posters and DVDs provided by the masks' manufacturers.

The three masks evaluated were the Kimberly–Clark Tecnol FluidShield N95 particulate filter respirator (KC; Kimberly–Clark, Sydney, NSW), the 3M Flat Fold 9320 particulate respirator (3M flat fold; 3M, Sydney, NSW), and the 3M 8822 particulate respirator with exhalation valve (3M valved; 3M, Sydney, NSW).

Fit testing was performed using 3M Qualitative Taste Fit Testing Kits F10 and F30 (3M, Sydney, NSW), according to the manufacturer's instructions. Participants underwent a sensitivity test while wearing a test hood but no mask, to determine their ability to taste saccharin. If saccharin could not be tasted, then denatonium benzoate was used instead.

Participants then rinsed their mouths with water, waited 10 minutes, and donned the test hood over a mask. A test solution of saccharin (830mg/mL in water) or denatonium benzoate (1.688mg/mL in isotonic saline) was aerosolised into the hood. The participants performed a series of dynamic

manoeuvres (such as talking and walking) over at least 3 minutes. A test was deemed a pass if no taste was detected by the end of the above protocol (mask effective), and a fail if the substance was tasted at any time (mask ineffective).

Continuous variables were compared using the Student *t* test, and proportions were compared using χ^2 tests. A $P < 0.05$ was considered significant. All statistical analyses were performed using Intercooled Stata version 10 (Stata-corp, Tex, USA).

Results

Fifty volunteers participated in the study (Table 1). Of these, 46 (92%) had previously used the KC mask; one of these had also used the 3M flat fold, and another of these, the 3M valved mask. Seven (14%) had been previously trained in the use of any P2 mask.

Preferred masks

The 3M valved was the most preferred mask before testing, and the 3M flat fold afterwards. The preference for the KC dropped significantly after testing (Table 2).

Fit testing

The 50 participants underwent a total of 150 fit tests, one test each for each of the three types of mask. Considering all fit tests together (pre- and post-training), 14 participants (28%) found that none of the masks fitted. Of the 36 who passed a fit test with any mask, 18 passed with only one type of mask, eight with two types, and 10 with all three types.

All three masks had low rates of fitting, with the KC having the lowest at 16% (Table 3). Training significantly improved the rate of successful fit tests for both the 3M masks but not the KC mask (Table 3).

Table 1. Occupation and age of participants

	≤ 29 years	30–39 years	40–49 years	≥ 50 years	Total
Doctor	4	3	3	3	10
Nurse	15	5	3	2	25
Medical student	4	1	0	1	6
Other*	1	5	2	1	9

* Included patient care assistants, physiotherapists, pharmacists and laboratory staff.

Table 2. Preferred masks before and after testing and reasons for stated preference

	Before testing (<i>n</i> =50)			After testing (<i>n</i> =50)		
	KC	3M flat fold	3M valved	KC	3M flat fold	3M valved
No. who nominated mask as preferred option	21 (42%)	6 (12%)	22 (44%)	5 (10%)	24 (48%)	20 (40%)
Reasons for preference*						
Familiarity	21	0	3	2	2	0
Shape	1	4	6	1	3	7
Best predicted fit	0	5	13	1	9	10
Brand	0	0	0	0	0	1
Extra features	0	0	7 [†]	0	0	2
Good fit	–	–	–	5	13	15
Comfortable to wear	–	–	–	3	10	9

KC = Kimberly–Clark Tecnol FluidShield N95 particulate filter respirator. 3M flat fold = 3M Flat Fold 9320 particulate respirator. 3M valved = 3M 8822 particulate respirator with exhalation valve.

* Reasons were not mutually exclusive: participants could tick as many features as they considered relevant. † All cited the exhalation valve.

Table 3. Number of participants (%) who passed a fit test with each mask, before and after training

	Pre-training (n = 50)	Total (pre-+ post-training) (n = 50)	P
KC	8 (16%)	14 (28%)	0.15
3M flat fold	14 (28%)	24 (48%)	0.04
3M valved	17 (34%)	27 (54%)	0.04
First mask tested	9 (18%)	20 (40%)	0.02

KC = Kimberly-Clark Tecnol FluidShield N95 particulate filter respirator.
 3M flat fold = 3M Flat Fold 9320 particulate respirator.
 3M valved = 3M 8822 particulate respirator with exhalation valve.

To evaluate the effect of training overall and to eliminate the effect of learning contamination and mask type, we considered only the first mask fitted for each participant. The first mask fitted was equally distributed among the three mask types. The proportion of participants who achieved a fit with the first mask increased significantly from 9/50 (18%) before training to 20/50 (40%) after training ($P=0.02$).

Predictors of fit test results

On univariate logistic regression analysis, none of the variables tested — sex, age, head circumference, occupation and order of mask testing — were significant predictors of failure to fit any of the three masks. Moreover, there was no difference in the mean head circumference (SD) of those who did not achieve a fit with any mask (56.3 [2.4] cm) compared with those who achieved a fit with at least one mask (56.6 [1.7] cm) ($P=0.60$).

Discussion

We found unexpectedly high failure rates for three common P2 masks. We also found that a large proportion (28%) of health care workers were unable to pass a fit test with any of the three masks, even after training. It is concerning that almost a third of our sample, all of whom work in a clinical setting and are required to wear these masks, could not fit any of the three masks easily accessible in Australia. This, along with the fact that there were no significant predictors of fit-test failure, reinforces the need for hospitals to conduct systematic fit-testing programs for all staff who may be exposed to airborne pathogens. Furthermore, while training had a less marked effect than one might predict, it did significantly improve the chance of a successful fit test with a given mask. Thus, training of relevant staff in the use of P2 masks should be a routine part of hospital infection control and prevention activities.

The considerable failure rate with all three masks suggests that hospitals should stock more than three types of P2 mask. Although our data did not show this, it is likely that a significant minority of individuals will not be fitted by commonly used masks because of facial characteristics, such as face size and shape.^{12,17} We could find no factors that would allow individuals to select an appropriate mask without undergoing fit testing. It was particularly worrying that the KC mask, which is the type generally used in our hospital, fitted the fewest participants, with or without training. Many participants initially chose this mask as their preferred one, citing familiarity, but changed their minds when a fit was not achieved.

This study has several limitations. Qualitative fit testing is a participative process, relying on an individual's perception of taste. As each individual was aware which mask was being tested, it is conceivable that their attitude towards the mask may have influenced their taste threshold and thus the result of the test. However, qualitative testing is widely available and more practical for small to medium-sized hospitals than quantitative testing, which requires a large initial financial outlay. Thus, the way in which we performed our study provides good generalisability to many Australian health care settings. Testing the three masks sequentially may have contaminated the results of later tests because of a learning effect. However, this is unlikely to be the case, as we endeavoured to exclude this bias by testing the masks in random order in each individual.

In conclusion, we found that a large proportion of health care workers failed a fit test with any given mask, but there were no factors that predicted mask fit in individuals. Training on using a mask improved the rates of adequate fit. These findings strongly support the recommendation that all acute hospitals should undertake P2 mask fit-testing and training programs for all clinical staff. Given that, despite a choice of three masks, a fit was not achieved in all individuals, a variety of masks (at least five types) should be made available to individuals who work in hospitals where they may be exposed to airborne transmission of pathogens.

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