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N95 Masks to Protect Health Care Workers



Is the New Fast Fit-Test Protocol Cutting Corners?

To the Editor:

The COVID-19 pandemic has highlighted the importance of protecting health care workers (HCWs) from airborne viral transmissions. Airborne personal protective equipment importantly includes at least a well-fitted N95 mask (alternatively elastomer half- or full-mask respirator, or a powered air-purifying respirator). Fit-testing is required to help select the optimal N95 mask and to ensure that the N95 mask worn fits each individual's shape and facial anthropometric dimensions and that there is no

demonstrable leak during simulated workplace exercises.¹ Fit-testing is embedded in respiratory protection programs for HCWs to learn how to correctly don and doff N95 masks.

Quantitative over qualitative fit-testing is preferred, because it is faster and superior in detecting leaks.¹ In the United States, the Occupational Safety and Health Administration (OSHA) defines a set of exercises to be performed during quantitative fit-testing (standard protocol). Recently, OSHA approved a modified fast quantitative fit-test protocol that has also found usage around Australia during the COVID pandemic.^{2,3} Before COVID-19, OSHA estimated an annual saved 100,000 hours of employee time by reducing the fit-test time by 5 min and assuming 1.3 million respirator wearers.^{2,3}

Methods

This audit (GEKO42159) compares the results obtained by two quantitative fit-testing protocols (Table 1): (1) standard (condensation nuclei counter, TSI 8038, PortaCount) of previously reported fit-test results⁴ and (2) modified fast (condensation nuclei counter, TSI 8048, PortaCount) used as part of an institutional mandatory fit-testing program within the Department of Anaesthesia and Pain Management of our tertiary teaching hospital.^{3,5,6} Forty-four HCWs underwent quantitative fit-testing (standard protocol)

during the first audit period (April to August 2020). Of these, 34 underwent additional institutional quantitative fit-testing (modified fast fit-test protocol, February to April 2021). During the two audit periods, different N95 mask selections were available. The main N95 mask available during the first audit was Proshield (TN01; BSN Medical, Mulgrave), and this N95 mask was retested in 19 staff (10 women, 9 men) during the second audit period (available for comparison of both protocols) and not retested in 15 HCWs because of increased availability of other N95 masks during the second audit period at our institution.

Results

No HCW reported significant changes in facial morphology/body habitus between the audit periods. The fit-pass rate was 14 (74%) and 8 (42%) for the modified fast and standard protocols, respectively (Table 2). This resulted in five (26%) false negatives (no leak detected with modified fast but detected with standard protocol) and a sensitivity of 0.5.

Discussion

This audit suggests that the modified fast protocol may be less reliable in detecting leaks than the standard protocol. A limitation of this audit is that both tests were not performed in immediate succession. Although facial morphology may change

over time (reported fit-pass rate decreases <10%/year),¹ the two fit-tests were less than 12 months apart in all HCWs. The two different fit-testing apparatus models used are unlikely to have influenced our results, because according to the manufacturer, the models differ mainly in the software and the applied protocols. Also, the subjects were fit-tested with matching N95 mask types and sizes in both protocols, and a fit-check was performed before each fit-test. Furthermore, at the time of the modified fast protocol, the tested staff likely gained more experience in donning the respirators correctly through repeated training during the ongoing pandemic, which should have led to an increase in fit-pass rate, while the opposite was observed. Another limitation was that we

TABLE 1] Standard and Modified Fast Fit-Testing Protocols for Filtering Facepiece Respirators

Fit-Test Exercise	Standard Protocol	Modified #Fast Protocol
Normal breathing, seconds	60	...
Deep breathing, seconds	60	...
Turning head side-to-side, seconds	60	30
Moving head up-and-down, seconds	60	30
Talking, seconds	60	30
Grimacing, seconds	15	...
Bending over, seconds	60	30
Normal breathing, seconds	60	...
Total time, min	7.2	2.5
Ambient purge, ambient sample, mask sample	Beginning, before every exercise, and at the end	Beginning and end only
Sample time, seconds	40	30

only compared the two fit-test protocols with one N95-mask model in two sizes. The observed relatively low fit-pass rate may be specific to the N95 mask available for testing.⁴ Furthermore, this small audit was not a well-designed controlled study but a “real life” set of observations.

Of note, the modified fast protocol for the filtering facepiece respirators (eg, N95) was tested only in 29 subjects as part of three small supporting studies submitted to OSHA (one study each for full-facepiece, half-mask elastomeric, and filtering facepiece respirators), albeit using 10 N95 mask models, resulting in only 114 tested out of a potential 290 pairs with difficult-to-follow exclusion criteria.^{2,6} Concerns raised during the approval process against the modified protocol were in part caused by the reduced number of exercises (the main determinant of fit¹), the frequency of calibration and sampling duration, and other methodological issues with the submitted studies.²

Deep breathing and grimacing represent realistic workspace situations that may produce temporary leaks, but these were not assessed in the modified fast protocol.²

In this limited audit, we found a significantly reduced sensitivity with the modified fast compared with the standard protocol to detect un-fit N95-masks. Although we showed 43% false negatives, the licensing study showed none. Unfortunately, the original study discloses neither the respirators used nor sufficient details about the participants. Because the reference method has more and longer exercises, it is only logical that there should have been false negatives when using fewer and shorter exercises.

Rapidly addressing our findings with larger studies of greater methodologic rigor is essential. In the meantime, public health experts should carefully consider these findings as they select their approach to fit-testing protocol in hospital-based respiratory protection

TABLE 2] Fit-Test Results Using Modified Fast and Standard Quantitative Fit-Testing Protocols

Mask	Modified Fast Protocol		Standard Protocol		TP	FP	FN	TN	Sensitivity	Specificity
	Passed	Failed	Passed	Failed						
All, N = 19	14 (74%)	5 (26%)	9 (47%)	10 (53%)	5 (26%)	0 (0%)	5 (26%)	9 (47%)	0.50	1.00
Small, n = 7	6 (86%)	1 (14%)	3 (43%)	4 (57%)	1 (14%)	0 (0%)	3 (43%)	3 (43%)	0.25	1.00
Medium, n = 12	8 (67%)	4 (33%)	6 (50%)	6 (50%)	4 (33%)	0 (0%)	2 (17%)	6 (50%)	0.67	1.00

Proshield masks medium TN01-11 or small TN01-12 were used. FN = false negative as no leak detected with modified fast but detected with standard protocol; FP = false positive as leak detected with modified fast but not with standard protocol; TN = true negative, as in no leak detected on either protocol; TP = true positive as leak detected on both protocols.

programs, especially in HCWs with roles that place them at higher risk of airborne exposure.

In conclusion, our audit identified a seemingly significantly reduced sensitivity in detecting N95 mask leaks with the modified compared with the standard fit-testing protocol. Further evaluating the modified fit-test protocol in more rigorous studies will be crucial.

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