Fit testing of N95 or P2 masks to protect health care workers

Fit testing of respirators is recommended to ensure proper fit for individual health care workers and is required to comply with respirator standards

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Coronavirus disease 2019 (COVID-19) is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and has many similarities to severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). While reported morbidity and mortality from COVID-19 are lower than from SARS and MERS, many health care workers have been infected (up to 15% of health care workers in Victoria).[1] During the 2003 SARS epidemic, nosocomial infection despite adequate personal protective equipment (PPE) was reported particularly in health care workers who were involved in aerosol-generating procedures.[2] The use of non-fit tested particulate respirators (N95 or P2 masks) alongside incorrect donning and doffing of PPE has been stated as a possible cause of infection.[2] In the context of the COVID-19 pandemic, there is an increased awareness and demand for fit testing of N95 or P2 masks in Australian hospitals.[3]

COVID-19 is highly contagious, with transmission appearing to occur through respiratory droplets, aerosols and direct and indirect contact.[4,5] While droplets are large enough to fall to the ground in a timely fashion, aerosol particles are small enough to remain airborne for several minutes and transmission may occur at a distant time or place. SARS-CoV-2 remains viable in aerosols for at least 3 hours.[5] When inhaled, aerosol particles pose a particular risk as they can reach the deepest lung regions, which is associated with increased disease severity.

Potentially hazardous aerosol-generating procedures include tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, bag–valve–mask ventilation, bronchoscopy, ventilation disconnections, and nebulisation of drugs.[6] During the 2003 SARS epidemic, transmission to health care workers was estimated to increase more than 6.6 times in those exposed to aerosol-generating procedures compared with those not exposed; a similar pattern has evolved during the COVID-19 pandemic.[7]

Contact and droplet PPE precautions are currently recommended when caring for patients with COVID-19 but additional airborne PPE precaution is required when performing aerosol-generating procedures.[6,8] International and national recommendations regarding airborne PPE precautions generally include at least a well fitted N95 or P2 mask in addition to goggles or face-shield, impervious gown and gloves.[6,8]

In health care, filtering half facepiece respirators and N95 or P2 masks are globally the most frequently used respirators. Crucially, such masks may only provide satisfactory airborne protection if they properly fit

the individual's face to provide a tight facial seal.[9,10] Any leak decreases airborne protection as unfiltered air is drawn inside the mask. Evidently, for airborne protection, correct respirator fit is far more important than the filtration capacity of the material.[11] Surgical masks, although made of materials with filtration capacity similar to that of N95 or P2 masks, have too much leakage to provide adequate airborne protection.[10] Other forms of respirators used by health care workers are elastomeric half-mask respirators and powered air purifying respirators; these are suitable alternatives when no N95 or P2 mask is found to fit the health care worker or when availability is limited.

Quality of fit (absence of leak) depends largely on the shape and size of the respirator in relation to the wearer's facial anthropometric dimensions. The United States National Institute for Occupational Safety and Health standard requires an N95 mask to provide adequate fit to at least 95% of the US population represented by a fit test panel with defined facial dimensions.[12] However, reported initial fit test pass rates for N95 or P2 masks vary widely, with lower rates among female Asians (34–84%) compared with white people (70–90%).[9,13]

Fit checking and the ability to detect leaks

Fit checking (user seal-check, self-check), not to be confused with fit testing, describes a subjective self-check to detect good facial seal through the absence of air leaks using both positive and negative pressure tests.[10] Most international and national health agencies advocate fit checks before use of any respirator as a minimum safety standard to ensure appropriate respiratory protection.[6,10]

Due to time and cost, some health officials advocate the elimination of fit testing and consider that fit checking is sufficient in determining respirator fit.

While a fit check remains recommended before each use of any respirator in routine practice, studies clearly demonstrate that fit checking does not reliably detect leakage.[13–15]

Fit testing and selection of optimal respirator

Fit test protocols include defined exercises to assess protection provided under simulated work conditions.[10] Fit testing should form part of hospital respiratory protection programs, as passing a fit test improves the physical protection afforded to the wearer by a particular respirator. However, the selection of brand and model by health care facilities is frequently guided by comfort, price and market availability during the COVID-19 pandemic rather than fitting characteristics.

Fit checking before testing is recommended as this can increase pass rates as well as emulate everyday clinical practice. Conversely, passing a fit test on a given respirator does not guarantee fit while providing clinical service, and fit checking is still required before each use.[8] As pass rates decrease over time, annual fit testing is recommended to comply with US Occupational Safety and Health Administration requirements and Australian and New Zealand Standard AS/NZS 1715:2009.[10,12] Additional fit testing is required before using a new respirator model and poses a challenge in times of changing stock during pandemics.[12]

Qualitative fit testing uses aerosolised test agents and determines mask fitness by the inability of the respirator wearer to taste (not smell) the test agents — bitter (denatonium benzoate) or sweet (saccharin) — under predefined exercises. Qualitative fit testing is relatively easy to perform on a departmental level owing to the minimal equipment cost. The main determinant of cost is time required to perform the test, which is slightly longer than that for quantitative fit testing.[16,17] A major drawback of qualitative fit testing is the subjective nature of relying on the testee to indicate absence or presence of taste. Health care workers with claustrophobia may not tolerate the test hood. In addition, some health care workers with increased anxiety may intentionally or unintentionally fail the fit test (ie, indicate leakage), especially during a pandemic.[17] As the test hood is reused, infection control considerations during a pandemic are particularly important.

Quantitative fit testing provides an objective measure of respirator fit. A fit factor is calculated as the ratio of substance concentration outside to inside the respirator, with a value > 100 required by the US National Institute for Occupational Safety and Health to indicate sufficient fit (ie, no leak).[18] Evidently, the fit factor cannot differentiate between particle penetration through the respirator (material) and face seal leakage (design). However, because the filter characteristics are strictly prescribed, face seal leakage is by far the greater influence on the fit factor.[18]

Ambient particle counting is the quantitative method most commonly used by hospital respiratory protection programs.[18] It requires a device that counts particles of a predefined particle size, typically inside and outside the mask, and involves the piercing of the mask in order to insert a sampling tube that is sealed airtight. The tested mask cannot be reused, which is a disadvantage in times of extreme respirator shortages. Quantitative fit testing is superior in detecting leakage compared with qualitative fit testing and should therefore be the preferred fit testing method.[16,17]

Legislation and current practice

Many countries have recommendations or legislative requirements to routinely fit test respirators, but there are large variances in the actual performance of these interventions between countries and between health services within countries.[6,8,10] Fit testing has been mandatory in the US since 1972, with nearly all health care providers being compliant.[12,18]

AS/NZS 1715:2009 recommends annual fit testing and that health care facilities should ensure they have a respiratory protection program that regularly evaluates the risk to which health care workers are exposed and determines which health care workers are required to undertake fit testing.[10] In addition, the Australian Guidelines for the Prevention and Control of Infections in Healthcare state that in order for P2 or N95 masks to offer maximum desired protection it is essential that the wearer is properly fitted and trained in their safe use.[10] The Australian Department of Health recommends fit testing when using P2 or N95 respirators but recognises that it has not been widely applied in Australia and will be difficult to implement during the pandemic due to limited supplies and range of types and sizes of available respirators.[8] The health departments of South Australia, New South Wales, Queensland and Western Australia recommend fit testing for health care workers in high risk areas who require N95 or P2 masks.[3,19–21] WorkSafe Victoria also recommends fit testing of health care workers and the Victorian Department of Health and Human Services states that fit testing should be considered if readily available.[22,23] So far, however, South Australia is the only Australian jurisdiction to have implemented a state-wide fit testing program for health care workers.[19]

Financial and logistic considerations of implementing a fit testing program

Adopting fit testing into a respiratory protection program poses a financial and logistic challenge.[9] As the cost of fit testing depends largely on the time required to perform the testing, efficient organisation may help reduce cost. Respiratory protection programs should identify and preferentially fit test health care workers at greatest risk of performing aerosol-generating procedures.[10,19] Online learning reduces up-front learning time.[13] Private companies offer quantitative fit testing at between $50 and $100 per person. While this cost may appear high, it is similar to that of other in-person mandatory training and is relatively low when compared with potential sick leave or legal costs in cases of nosocomial infection. Fit testing also provides an opportunity to ensure that health care workers are properly trained in correct usage of the respirator, which in itself improves protection in routine clinical practice.

Fit testing is best performed by dedicated staff trained in occupational health and safety. Staff experience has been shown to improve N95 or P2 mask selection in terms of initial fit pass rates.[9] Hospital respiratory protection programs need a predefined plan for health care workers who do not pass a fit test. Ideally, different mask shapes and sizes are available. When this is the case, very few health care workers will fail testing of standard N95 or P2 masks and sizes (< 5%).[9] Alternatively, elastomer half mask respirators or powered air purifying respirators may be an option. If all available respirators fail, then the health care worker is best considered unfit to work in hospital areas that potentially care for patients with COVID-19 and perform aerosol-generating procedures.

Risk to health care workers using N95 or P2 masks with inadequate fit

A cluster randomised study attempted to compare non-fitted with fitted N95 masks but was unable to draw any conclusions due to unusually high fit test pass rates without any difference between the groups.[24] Whether using fit checked rather than fit tested respirators is sufficient to protect health care workers exposed to aerosol-generating procedures from nosocomial COVID-19 transmission remains unknown and must be assessed in relation to room ventilation (negative pressure). Mathematical modelling suggests that the risk of airborne transmission of tuberculosis decreases exponentially with increasing room ventilation and the protection factor of the respirator used.[25] Additionally, the relative contribution of a given respirator decreases with increased room ventilation rates and decreased amount of aerosol viral concentrations.[25] Low aerosol viral concentrations may explain why droplet precautions appeared to provide adequate protection for health care workers caring for SARS patients without using aerosol-generating procedures.[2] However, the use of non-fitted N95 masks and inadequate room ventilation in addition to incorrect or inconsistent PPE use have been implicated in SARS transmissions to health care workers despite adequate PPE.[2]

Conclusion

Health care workers exposed to aerosol-generating procedures are particularly at risk for transmission of SARS-CoV-2 and other respiratory viruses. International and national bodies recommend fit testing to ensure proper fit of respirators because without adequate fit, the degree of airborne protection provided by respirators is significantly reduced. The COVID-19 pandemic has brought to light the failure of some Australian health care facilities to protect their health care workers to the appropriate national standard.

Fit checking is recommended every time a health care worker dons a respirator. Contrary to some opinions, fit checking is unreliable in detecting adequate fit or leakage. In clinical practice, the requirement for fit testing appears particularly important in the absence of negative pressure rooms for the performance of aerosol-generating procedures in infected patients. Respiratory protection programs should preferentially fit test health care workers who are exposed to aerosol-generating procedures.

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