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Fit-testing of N95/P2-masks to protect health care workers

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Abstract

- In the context of COVID-19, well fitted respirators e.g. N95/P2-masks are recommended as part of personal protective equipment when performing aerosol generating procedures.
- Fit-checking is recommended prior to donning a respirator. However, fit-checking is unreliable in detecting proper fit.
- Fit-testing is recommended to ensure proper fit of respirators for individual health care worker and is required to comply with respirator standards. However, fit-testing is not performed in all health care settings.
- The small cost of performing fit-testing has to be compared to the welfare of the health care workers as well as potential cost of sick leave or legal costs.

The Coronavirus Disease 2019 (COVID-19) pandemic is caused by the coronavirus SARS-CoV-2 and has many similarities with Severe Acute Respiratory Syndrome (SARS, SARS-CoV-1) and Middle East Respiratory Syndrome (MERS, MERS-CoV). While reported morbidity and mortality from COVID-19 are lower than from SARS and MERS, up to 14% (Italy, Spain) of healthcare workers have been infected (1). During the SARS epidemic, nosocomial infection despite adequate personal protective equipment (PPE) has been reported particularly in healthcare workers who were involved in aerosol generating procedures (2). The use of non-fit-tested N95/P2-masks alongside incorrect donning and doffing of PPE have been stated as possible causes of infection (2). In the context of COVID-19, there is an increased awareness and demand for fit-testing of N95/P2-masks becoming a matter of debate in Australian hospitals between clinicians and administrators (3).

SARS-CoV-2 is highly contagious with transmission routes appearing to be droplet, aerosol and indirect via contact (1, 4). While droplets are large enough to fall to the ground in timely fashion, aerosol particles are small enough to remain airborne for several minutes and transmission may occur at a distant time or space. SARS-CoV-2 remains viable in aerosols for at least three hours (4). When inhaled, aerosol particles pose a particular risk since they can reach the deepest lung regions which is associated with increased disease severity.

Potential hazardous aerosol-generating procedures include tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, bag-valve-mask ventilation, bronchoscopy, ventilation disconnections and nebulisation of drugs (5). During the SARS epidemic, transmission to healthcare workers was estimated to be more than 6.6 times increased in those exposed compared to those not exposed to aerosol-generating procedures with a similar pattern evolving during COVID-19 (6).

Contact and droplet personal protective equipment (PPE) precautions are currently recommended when caring for patients with COVID-19 but additional airborne PPE precaution when performing aerosol-generating procedures (5, 7). International and national recommendations regarding

airborne PPE precautions generally include at least a well fitted N95/P2-mask in addition to goggles or face-shield, impervious gown and gloves (5, 7).

In health care, filtering half facepiece respirator or N95/P2-masks are globally the most frequently used respirators. Crucially, N95/P2-masks may only provide satisfactory airborne protection if they properly fit to the individual's face providing a tight facial seal (8, 9). Any leak decreases airborne protection as unfiltered air is drawn inside the mask. Evidently, in regards to airborne protection, correct respirator fit is far more important than the filtration capacity of the material (10). Inline, surgical masks have a too large leak to provide adequate airborne protection although made of materials with filtration capacity similar to N95/P2-masks (9). Other forms of respirators used by healthcare workers are elastomer half mask respirators (EHMR) and powered air purifying respirators (PAPR) being suitable alternatives when no N95/P2-mask is found to fit the healthcare 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 National Institute for Occupational Safety and Health (NIOSH) standard requires a N95/P2-mask to provide adequate fit to at least 95% of the US population represented by a fit-test panel with defined facial dimensions (11). However, reported initial fit-pass rates for N95/P2-masks vary widely with lower rates in females Asians (34-84%) than in Caucasians (70-90%) (8, 12).

Fit-checking and the ability to detect leak

Fit-checking (user seal-check, self-check), not to be confused with fit-testing, describes a subjective self-check aiming to detect good facial seal through the absence of air leaks using both positive and negative pressure tests (9). Most international and national health agencies advocate fit-checks prior to usage of any respirator as a minimum safety standard to ensure appropriate respiratory protection (5, 9).

Some health officials advocate the elimination of fit-testing due to time and cost and that fit-check is sufficient in determining respirator fit. While a fit-check remains recommended prior to each use

of any respirator in routine practice, studies clearly demonstrate that fit-check does not reliably detect leakage (12–14).

Fit-testing and selection of optimal respirator

Fit-test protocols include defined fit-test exercises to assess protection provided under simulated work conditions (9). 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 of N95/P2-masks by healthcare facilities are frequently guided by comfort, price and market availability during the COVID-19 pandemic rather than fitting characteristics.

Fit-checking prior to fit-testing is recommended as this can increase fit-pass rates in addition to emulating 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 (7). Annual fit-testing is recommended to comply with OSHA and the Australian Standard (AS/NZS1715:2009) as fit-test pass rates decrease over time (9, 11). Additional fit-testing is required prior to using a new respirator model and poses a challenge in times of changing stock during pandemics (11).

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 (saccharine) under predefined exercises. Qualitative fit-testing is relatively easy to perform on a departmental level due to the minimal equipment cost. The main determinant of cost is time required to perform the test which is slightly more compared to quantitative fit-testing (15, 16). A major drawback is the subjective nature as the qualitative fit-test relies on the testee to indicate absence/presence of taste. Healthcare worker with claustrophobia may not tolerate the test hood. In addition, some healthcare worker with increased anxiety may intentionally or unintentionally fail the fit-test (indicate leak) especially during pandemics (16). As the test hood is reused, infection control considerations especially during a pandemic are 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 of the respirator with a value >100 required by NIOSH to indicate sufficient fit (no leak) (17). Evidently, the fit-factor cannot differentiate between particle penetration through the respirator (material) and face seal leakage (design) but face seal leakage is by far the greater influence of the fit-factor since the filter characteristics are strictly prescribed (17).

The ambient particle counting method is the most commonly used quantitative method by hospital respiratory protection programs (17). It requires a device that counts particles of a predefined particle size typically inside and outside the mask. It requires the piercing of the mask in order to insert a sampling tube that is airtight sealed off. Hence, the tested mask cannot be reused, which is a disadvantage in times of extreme respirator shortages. Quantitative fit-testing is superior in detecting leak compared with qualitative fit-testing and therefore should be the preferred fit-testing method (15, 16).

Legislation and current practice

When using respirators, fit-testing is considered the gold standard and many countries have recommendations or legislative requirements to perform this routinely but there are large variances in the actual performance of these interventions between countries and between health services within a country (5, 7, 9). Fit-testing has been mandatory in the US since 1972 with nearly all health care providers being compliant (11, 17).

The Australian Standard AS/NZS-1715:2009 recommends annual fit-testing and that healthcare facilities should ensure that they have a respiratory protection program that regularly evaluates the risk to which healthcare workers are exposed and determines which healthcare workers are required to undertake fit-testing (9). In addition, the Australian Guidelines for the Prevention and Control of Infections in Healthcare (National Health and Medical Research Council, 2019) state that in order for N95/P2-masks to offer maximum desired protection it is essential that the wearer is

properly fitted and trained in its safe use (9). The Australian Department of Health recommends fit-testing as the gold standard when using N95/P2-respirators but recognizes that fit-testing 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 (7). Health Departments of South Australia, New South Wales, Queensland and Western Australia recommend fit-testing of healthcare workers that require wearing N95/P2-mask in high-risk areas (3, 18, 19) (20). WorkSafe Victoria also recommends fit-testing of healthcare workers and the Department of Health and Human Services, Victoria states that fit-testing should be considered if readily available (21, 22). So far, however, South Australia is the only Australian State/Territory to have implemented a state wide fit-testing program for healthcare workers (18).

Financial and logistical considerations of implementing a fit-testing program

Adopting fit-testing into a respiratory protection program poses a financial and logistic challenge (8). As the cost of fit-testing depends largely on the time required to perform fit-testing, efficient organization may help reduce cost. Respiratory protection programs should identify and preferentially fit-test healthcare workers with the greatest risk of performing aerosol-generating procedures (9, 18). Online learning reduces up-front learning time (12). Private companies offer quantitative fit-testing between $50-$100 per person. While this cost may appear high, it is on-par with other in-person mandatory training and relatively low when compared with potential sick leave or legal costs in case of nosocomial infection. Fit-testing also provides an opportunity to ensure that the healthcare worker is properly trained in correct usage of the respirator which in itself improves protection of the healthcare worker 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/P2-mask selection in regards to initial fit pass rates (8). Hospital respiratory protection programs need to have a pre-defined plan for healthcare worker who do not pass a fit-test. Ideally, different N95/P2-mask shapes and sizes are available. Only very few healthcare workers will fail standard N95/P2-masks and sizes (<5%) (8). Alternatively, EHMR or PAPR may be an option. If all available respirators fail, then the healthcare 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/P2-masks with inadequate fit

One cluster randomised study attempted to compare non-fitted with fitted N95/P2-masks but was unable to draw any conclusions due to unusually high fit-pass rates without any difference between the groups (23). Whether using fit-checked N95/P2-masks as opposed to fit-tested N95/P2-masks is sufficient in regards to protect healthcare workers exposed to aerosol-generating procedures from nosocomial COVID-19 transmission remains unknown and has to be assessed in relation to room ventilation (negative pressure) (24). Mathematical modelling suggests that the risk of airborne transmission of tuberculosis decreases exponentially with increasing room ventilation and/or protection factor of the respirator used (24). Additionally, the relative contribution of a given respirator decreases with increased room ventilation rates and decreased amount of aerosol / viral concentrations. Low amount of aerosol / viral concentration may explain why droplet precaution appeared to provide adequate protection for healthcare workers caring for SARS patients that didn't involve aerosol-generating procedures (2). However, the use of non-fitted N95/P2-masks and inadequate room ventilation in addition to incorrect or inconsistent PPE have been implicated in SARS transmissions to healthcare workers despite adequate PPE (2).

Conclusions

Healthcare 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 as without adequate fit the degree of airborne protection provided by respirator is significantly reduced. The COVID-19 pandemic has brought to light deficiencies of some Australian healthcare facilities to protect their healthcare workers to the appropriate national standard.

Fit-checking is recommended every time a healthcare worker dons a respirator. In contrast to some opinions, fit-checking is unreliable in detecting adequate fit or leak. 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 healthcare workers who are exposed to aerosol-generating procedures.

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