




Pulmonary function testing during SARS-CoV-2: An ANZSRS/TSANZ position statement

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Associate Editor: Chi Chiu Leung; Senior Editors: Paul Reynolds and Philip Bardin

Abstract

The Thoracic Society of Australia and New Zealand (TSANZ) and the Australian and New Zealand Society of Respiratory Science (ANZSRS) commissioned a joint position paper on pulmonary function testing during coronavirus disease 2019 (COVID-19) in July 2021. A working group was formed via an expression of interest to members of both organizations and commenced work in September 2021. A rapid review of the literature was undertaken, with a 'best evidence synthesis' approach taken to answer the research questions formed. This allowed the working group to accept findings of prior relevant reviews or societal document where appropriate. The advice provided is for providers of pulmonary function tests across all settings. The advice is intended to supplement local infection prevention and state, territory or national directives. The working group's key messages reflect a precautionary approach to protect the safety of both healthcare workers (HCWs) and patients in a rapidly changing environment. The decision on strategies employed may vary depending on local transmission and practice environment. The advice is likely to require review as evidence grows and the COVID-19 pandemic evolves. While this position statement was contextualized specifically to the COVID-19 pandemic, the working group strongly advocates that any changes to clinical/laboratory practice, made in the interest of optimizing the safety and well-being of HCWs and patients involved in pulmonary function testing, are carefully considered in light of their potential for ongoing use to reduce transmission of other droplet and/or aerosol borne diseases.

KEYWORDS

aerosol, COVID-19, personal protective equipment, pulmonary function tests, respiratory function tests, SARS-CoV-2, spirometry

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This document has been endorsed by the Thoracic Society of Australia and New Zealand Board on 18 July 2022 and by the Australian and New Zealand Society of Respiratory Science on 19 July 2022. It is due for review on 1 February 2023.

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The key messages from the main text of the document are summarized below. Further details regarding the context and strength of evidence underpinning each message are provided in the main text and Table 1.

Precautionary measures must be taken to mitigate airborne (droplets and aerosols) transmission risk and reduce risks (optimize safety) for *all* people who interact with the pulmonary function testing space (high priority). This includes, but is not limited to, healthcare workers (HCWs), patients, administrative personnel and cleaners.

The working group decided not to stratify risk according to pulmonary function test (PFT) setting (e.g., clinical vs. occupational health) due to (1) cough and forced expiratory manoeuvres (as occurs with PFTs) being activities that produce the greatest amount of aerosol, and cough being a likely occurrence in any setting where PFTs are performed; (2) with high community transmission and prevalence, it is not possible to differentiate risk. That is, patients can be classified into two groups: (a) symptomatic coronavirus disease 2019 (COVID-19) suspected or positive, and close contacts; (b) the population at large which is likely to include pre-symptomatic, asymptomatic and unreported COVID-19-positive cases. Both groups have transmission risks associated with them.

Transmission routes of SARS-CoV-2

- Global and national health advisory organizations recognize that severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is predominantly transmitted via both

droplet and aerosol routes, although other routes of transmission may also contribute to infection.

Effects of PFTs on aerosol generation

- PFTs result in aerosol generation. Additionally, PFTs present an unpredictable risk of cough, which, in itself, results in high levels of aerosol generation. Risk mitigation strategies against aerosol generation should be used for PFTs in all settings.

Risk control strategies to reduce the transmission of SARS-CoV-2 in pulmonary function testing**Transmission factors**

- Factors contributing to risk of transmission of SARS-CoV-2 include activities with forced exhalations (e.g., loud speaking, cough, sneeze, PFTs, exercise), acute symptoms that are associated with increased viral load, distance from index case and duration of exposure, and environmental ventilation.

Risk mitigation strategies using Hierarchy of Controls*Elimination*

- Pulmonary function testing should not be performed in patients who are known to be COVID-19 positive or suspected COVID-19 positive (including those with fever, new acute COVID-19-like symptoms or asymptomatic and awaiting rapid antigen test [RAT] or Polymerase chain reaction (PCR) test results).
- Non-urgent PFTs should be deferred for a minimum of 14 days after exposure to COVID-19 in close household contacts of a positive case. Consider deferring PFTs in those known to have had a recent exposure or other epidemiological risk factors.
- Non-urgent PFTs should be deferred for a minimum of 14 days after the diagnosis of COVID-19 infection (or a minimum of 20 days in patients identified as having 'significant' immunocompromise). In most cases, this will correspond to an additional 7 days after release from isolation (RFI). In those with lingering symptoms, severe infection and/or immunocompromise who may require longer periods of isolation, it is recommended to defer non-urgent PFTs for a minimum of 7 days after eventual RFI.
- Clinically urgent PFTs could be performed immediately after RFI if needed. However, waiting a minimum of 10 days after the diagnosis of infection is preferable.

Substitution

- Consider modifications or substitutions that can be made to test circuits or procedures to reduce aerosol spread and transmission risk.

Isolation

Home-based model of care

- Telehealth spirometry may be a useful tool for maintenance of quality care of chronically ill patient groups and for monitoring in clinical trials. Careful selection of device and subjects is suggested.

Physical barriers between subjects and operators

- Evidence for the reduction of droplet and aerosol transmission by using physical barriers between patient and operator during PFT is limited and much of the literature is that of short communications rather than study data. When used, the impact on ventilation streams should be considered.

Single patient per clinic room/laboratory and physical distancing

- PFTs should be undertaken in a room that is closed to other internal spaces involving only one patient at a time (i.e., PFTs should not be performed in shared spaces).
- The number of people in a room during testing should be minimized to reduce transmission risk.
- Physical distancing and density limits set by local jurisdictional or regulatory bodies must be adhered to throughout the workplace as a minimum.

Inline filters

- Inline filters reduce, but do not eliminate, respirable particle dispersion from PFT breathing circuits. Inline filters meeting PFT specifications should be used in PFT breathing circuits where able.
- Careful consideration is advised to determine the impact of inline filter use on cardiopulmonary exercise test (CPET) parameters.

Use of masks for field walking tests

- Surgical masks should be worn during field walking tests (e.g., 6-min walk tests) unless poorly tolerated by the patient. Interpretation of tests should consider the potential increase in symptoms due to mask wearing.

Cough etiquette

- Cough etiquette in combination with other mitigation measures, such as hand hygiene and mask wearing, may assist with reducing disease transmission.

Engineering controls

Ventilation

- Ventilation is a complex area and expert advice may be required to ensure effective room ventilation.
- A minimum of 12 air changes per hour (ACH) is recommended for rooms where pulmonary function testing is performed.
- Additional strategies, such as air cleaning units, should be employed where the minimum ACH is not met.
- HCWs should be aware of limitations in using CO₂ monitoring to assess ventilation levels.

UV for surface disinfection and in-room air decontamination

- UV radiation 'C' (UVC) units may be useful as an additional control measure for room and/or surface decontamination, but are not suggested for routine use in Australian healthcare facilities presently.

Administrative controls

Cleaning: High-touch and non-disposable equipment

- SARS-CoV-2 RNA has been isolated from inanimate surfaces, but was rarely detected after disinfecting surfaces with appropriate cleaning solution. No direct evidence of fomite transmission has been recorded.
- Disinfecting high-touch surfaces is a simple and effective way to mitigate the risk of possible fomite transmission of SARS-CoV-2 and other transmissible pathogens.
- Non-disposable medical consumable items must be disinfected and/or sterilized in accordance with appropriate standards.

Staff not to attend work while unwell

- HCWs should follow workplace and government public health directives regarding working while unwell and returning to the workplace following illness.

Vaccination

- All HCWs performing pulmonary function testing should have up-to-date vaccination status as per the appropriate current public health directives for HCW.
- While vaccination of both staff and patient may provide some reduction of the risk of viral transmission during PFT measurement, no vaccine is 100% effective, particularly with emerging COVID-19 strains, and the benefits may wane over time.
- Vaccination alone cannot eliminate the risk of viral transmission and vaccination status should not be used to modify personal protective equipment (PPE) choice.

Testing for SARS-CoV-2

- While reverse transcription (RT)-PCR remains the gold standard for the diagnosis of COVID-19, RAT has been accepted as a valuable screening tool in addition to other controls, and targeted testing may be useful for identifying individuals who are likely to be infectious, for whom testing should be deferred.
- A negative RAT does not exclude disease and hence should not be used to inform use of PPE.

Pre-test screening questionnaires

- Pre-screening questionnaires in the days prior to testing, and then again in person at the clinic visit, may add value to other mitigation strategies.
- Screening questionnaires should not be used to decide the level of PPE use.

Changes to operational practices

- Triage of PFT requests and other operational changes may be required during periods of high community

prevalence of COVID-19 to meet logistical and infection prevention and control requirements.

Personal protective controls

- At a minimum, P2 respirators and eye protection should be worn by HCWs in areas where PFTs are performed.
- Training and education in proper selection, limitations and use of PPE, including respirators, is essential.
- All HCWs wearing respirators must be fit tested to ensure good fit and seal.
- Fit checking of respirators with each use is essential.
- Respirators must have regulatory approval.
- All HCWs must be trained in and undertake good hand hygiene practice.
- Gloves and gowns should be worn when the risk of exposure to bodily fluids is anticipated to be likely.

All key messages received 100% consensus from the voting panel.

INTRODUCTION

By the end of 2021, the COVID-19 pandemic had resulted in more than 300 million infections and 5.5 million deaths globally.^{1,2} Australia and New Zealand's initial approach was to strive for elimination through border closures and imposing restrictions around movement, physical distancing and mask wearing. However, the emergence of the Delta and Omicron strains of the SARS-CoV-2 virus in the second half of 2021 with their increased transmissibility rendered the goal of elimination unattainable.³ The National Plan to transition Australia's National COVID-19 Response^{4,5} balances high levels of immunization and targeted mitigation strategies to reduce the likelihood of overwhelming healthcare resources. New Zealand is following a similar strategy.⁵ As restrictions around movement have eased, SARS-CoV-2 infection has spread widely in Australia and New Zealand.

PFTs are valuable tools providing objective measures of pulmonary function that may assist with the diagnosis, clinical management or surgical work up of people with respiratory symptoms or those at risk of respiratory disease. PFTs are performed in a spectrum of healthcare settings including public pulmonary function laboratories attached to public hospitals, private pulmonary function laboratories attached to private hospitals or standalone, and primary and occupational health care. PFTs are also performed in research and education settings. The key diagnostic test for airway diseases, such as asthma and chronic obstructive pulmonary disease (COPD), is spirometry. Spirometry is widely used for monitoring of respiratory disease, but is also an important component of health surveillance where workers are exposed to respiratory hazards. Other tests of pulmonary function include (but are not limited to) lung volumes, diffusing capacity across the lung of carbon monoxide (DLCO), respiratory muscle strength, oscillometry, bronchial provocation and exercise physiology tests.

The World Health Organization (WHO), Centres for Disease Control and Prevention (CDC) (USA) and Australian Health Protection Principal Committee acknowledge that SARS-CoV-2 virus can be transmitted by droplets and aerosols.⁶⁻⁸ In the healthcare setting, patients presenting for PFTs often display respiratory symptoms similar to those associated with COVID-19 infection. The high risk of virus transmission confers safety implications for HCWs who perform PFTs as well as patients and their carers who attend for PFTs. A safe workplace is a fundamental right of all workers⁹ and the Australian Commission on Safety and Quality in Health Care updated the Preventing and Controlling Infection Standard in May 2021 to include a precautionary approach where there is 'emerging or rapidly evolving scientific knowledge around an infection, or aspects of its transmission'.¹⁰ These factors underpinned the importance of rigorously reviewing the logistics and infection control practices of PFT assessment in the context of COVID-19 to ensure appropriate occupational safety for HCW, while aiming to maintain timely access to appropriate testing for patient care. Responses to the conduct of PFTs have been heterogeneous across the many stages of the pandemic.¹¹ Responses include service volume reduction, the introduction of screening measures, increased use of PPE, postponement of specific test procedures or entire PFT services. Each response aimed to strike a satisfactory balance between risk versus benefit; however, determining the right measure for specific contexts was not without challenge. This was particularly notable upon the emergence of the highly transmissible variants (e.g., Omicron) and the proliferation of asymptomatic transmission.

In response, in September 2021, the Boards of the Thoracic Society of Australia and New Zealand (TSANZ) and the Australian and New Zealand Society of Respiratory Science (ANZSRS) prioritized the establishment of a collaborative working group to undertake a rapid review of the literature and propose a practical and reasonable approach for the performance of PFTs during COVID-19 outbreaks in Australia and New Zealand. In line with the vision of the Boards of TSANZ and ANZSRS, the working group terms of reference embodied a 'precautionary approach' that placed high priority on the safety of patients and healthcare professionals. This position acknowledges the following important factors:

1. Precautionary measures must be taken to mitigate airborne (droplets and aerosols) transmission risk and reduce risks (optimize safety) for *all* people who interact with the pulmonary function testing space (high priority). This includes, but is not limited to, HCWs, patients and carers, administrative personnel and cleaners.
2. The public health and clinical landscape as well as the body of relevant evidence have rapidly evolved and continue to do so. It is anticipated that advice contained within this document may also evolve over time.
3. A 'lack of evidence of effect' is not the same as 'evidence of a lack of effect'. Guidance contained within this

document aims to strike a balance that considers both evidence and expert clinical judgement.

4. The most appropriate actions to mitigate the risks of COVID-19 transmission may differ according to local factors. These may include factors such as public health orders, vaccination status, transmission rates, local policy, access to resources and so on. Key findings from this report are intended to supplement local measures.

The statement was written with careful consideration of the highly variable pandemic-related characteristics (e.g., transmission rates, pandemic phases, public health responses, healthcare workforce policies) across various settings of Australia and New Zealand, and aimed to synthesize findings from an evidence-informed (or expert consensus) perspective. The statement is not intended to mandate specific practices for specific settings; rather it aims to establish an evidence-informed foundation to guide safe provision of PFTs and associated decision-making locally in conjunction with local infection prevention and public health directives at any stage of the COVID-19 pandemic.

Practices without access to local infection prevention support may benefit from contacting larger facilities for additional guidance (e.g., TSANZ accredited laboratories). The key findings may confer relevance to future pandemics; however, this was not the focus of the present work.

In this document, the person undergoing the PFT is referred to as the 'patient', noting that not all people undergoing PFTs will be patients (e.g., occupational health, education, research). All people conducting PFTs and in attendance in the workplace as workers where PFTs are performed are referred to as 'healthcare workers' including, but not limited to, clinical scientists, nurses, doctors, physiotherapists, research scientists, administrative officers, cleaners, interpreters and staff in education facilities.

Relevance to primary care, occupational health, independent providers and PFT training providers

Careful consideration was given to the comparability of risks associated with performing PFTs across a variety of settings including public pulmonary function laboratories attached to public hospitals, private pulmonary function laboratories attached to private hospitals or standalone, and primary and occupational health care, as well as in coursework with education facilities or PFT training providers. The working group acknowledged that various screening strategies existed within many workplace settings that might confer benefits for reducing transmission risk in specific cases. However, overwhelmed testing and tracing programmes with the rise of the Omicron variant, escalation of COVID-19 case numbers, emergence of presymptomatic, asymptomatic and unreported positive cases,¹² and high levels of transmission within the community and family groups suggested that employment-

related risk management strategies were unlikely to be sufficiently effective for effective risk stratification on their own. Hence, a decision was made to not attempt to stratify risks according to different settings where PFTs may be conducted (e.g., clinical vs. occupational health).

COVID-19 outbreaks have had a significant impact on the provision of PFTs in primary care settings such as general practice and community health centres, as well as occupational health. The working group agreed that the key messages in this document are as relevant to the primary care sector as they are to other settings. Although many of the PFTs documented herein are not relevant to primary care, pre- and post- bronchodilator spirometry remains an essential component in the management of patients with or being investigated for respiratory disease in general practice, and health surveillance in occupational medicine. Importantly, providing spirometry in these settings requires a 'precautionary approach' and strong consideration of the key messages in this document to ensure the safety of patients and HCWs alike whilst COVID-19 outbreaks continue to occur in Australia and New Zealand.

METHODS

Development of the working group

Society members without relevant conflicts of interest voluntarily self-nominated to be considered for working group membership. The panel strived to achieve equitable representation across Australian and New Zealand states/territories, gender, career stage, professions and different healthcare sectors (tertiary and regional hospitals, public and private health care). The final working group comprised expert respiratory physiologists, respiratory physicians (adult and paediatric), a general practitioner, an occupational medicine physician, academics and a research methodologist. Full details of the working group composition are in Table S1 in the Supporting Information. The working group met one to two times per week throughout the course of the work and maintained regular communication through a shared online workspace and repository.

Review methodology

A rapid review scoping methodology was implemented for all research questions, with the extent of literature appraisal commensurate to the nature of the question and the timeliness of the review goals. The working group adopted a 'best evidence synthesis' approach to answering our research questions with no original meta-analyses planned. This approach allowed the working group to accept findings of prior relevant reviews or societal documents if deemed appropriate for our study aims.

Research questions

The working group developed an initial list of priority research questions in response to the following trigger question: ‘What are the most important issues affecting lung function testing laboratories during the COVID-19 pandemic?’ Initial suggestions were discussed among the working group and refined down to the following list that were ratified by the CEO/Board of TSANZ and ANZSRS:

- Should COVID-19 be considered an aerosol transmissible disease for the purpose of lung function testing?
- What are the effects of lung function tests on aerosol generation?
- What risk mitigation strategies are appropriate to implement in lung function testing settings to reduce SARS-CoV-2 transmission risks?

Literature search

Two complementary search strategies (one specific and one sensitive) were developed by a researcher with methodology expertise (CO) to encompass the broad scope of work. Both incorporated a combination of subject headings and keyword terms applied to title and abstract fields that aligned to the recommended population/concept/context (PCC) framework for scoping reviews.¹³ Search term constructs were tailored according to each of the aims of each strategy and included terms related to SARS-CoV-2 and other airborne transmissible diseases, lung function tests, airborne transmission and potentially relevant interventions. These are described in further detail in Table S2 in the Supporting Information. Searches were implemented in Ovid Medline without date limits up to 9 November 2021 and restricted to English language and humans. The complete list of terms derived for each search strategy is available in Tables S3 and S4 in the Supporting Information. Search yields were exported into Endnote X9 and de-duplicated using default settings. Records were screened on title and abstract by members of the panel to identify potentially relevant studies. All studies that were not excluded were considered resources of potential relevance to the working group and were retained. Additional focused database searches in addition to hand-searching emerging literature (e.g., via journal table of content alerts, personal communications) after November 2021 and review of references within included studies were performed to enrich the final yield.

Assessment of bias of included studies

Quality assessment was undertaken where deemed appropriate, and emphasized factors likely to pertain relevance for healthcare decision-making (rather than solely on risks of bias). Formal risk of bias evaluations were not conducted on

papers included within the review; however, the working group acknowledged prior evaluations of papers (where able to be identified) and planned to use the Critical Appraisal Skills Programme (CASP) suite of quality appraisal tools where required.¹⁴

Work plan

In light of rapid changes in clinical practice, research and public health policy in response to the COVID-19 pandemic, this report was prepared with the understanding that initiatives of potential relevance were likely occurring concurrently. The working group agreed to review, appraise and adopt relevant findings from such works to reduce duplication of effort, where appropriate. We deferred to recommendations from peak authority bodies (e.g., WHO) or government agencies where advice pertained to specific topics of relevance to our scope of work. This included monitoring of findings from Australia’s National COVID-19 Living Clinical Evidence Taskforce even though the topic of ‘Spirometry during COVID’ was listed as ‘out of scope’ as of October 2021.¹⁵ As the present work focused on contextualization of evidence to Australian and New Zealand healthcare settings, differences were expected to occur in comparison with some other published guidance documents. Differences in practices and policies across state, territory and other regional or healthcare jurisdictions were also acknowledged. Findings were intended to be applicable for all providers of PFTs across any relevant setting, in consideration with such local factors.

Evidence synthesis

Research questions were answered using results of the database search and hand-searched resources as the principal basis of evidence synthesis. Where insufficient evidence was available, discussion and expert opinion of working group members was used to formulate preliminary conclusions. The strength of each finding was then rated using an adaptation to the approach used by Australia’s ‘National COVID-19 Living Clinical Evidence Taskforce’ based on Grading of Recommendations, Assessment, Development and Evaluations (GRADE) methodology, as follows:

Level I: Evidence-based (strong)—Supported by multiple studies and/or strong evidence of effect that directly relates to the research question. Benefits would be deemed to outweigh harms for almost everyone and all or nearly all informed patients and HCW would likely want this option;

Level II: Evidence-based (conditional)—Supported by limited studies and/or weak evidence of effect that may not directly answer the research question. Benefits would be deemed to outweigh harms for many but not all patients

and HCW. Most informed patients and HCW would likely want this option;

Level III: Good practice point—These findings represent the guideline panel's view of optimal practice, but are not formally rated. This rating is used when conflicting or inconclusive evidence is available, but it would not be a good use of the panel's limited resources to conduct formal evidence summaries;

Evidence gap—This was used when an evidence-informed answer was unable to be generated and expert panel consensus could not be reached.

Careful attention was directed towards the generation of clinically practical (i.e., interpretable, translatable) findings, particularly with regard to risk mitigation strategies for PFTs. This was achieved using an established occupational health and safety risk control classification system (Hierarchy of Risk Control), with risks evaluated separately according to distinct phases of pulmonary function testing (pre-test, during test, after test). The primary deliverable from the synthesis was a series of clinical practice points. Each statement was reviewed by the full working group and voted upon to determine group consensus. This was defined as a minimum of 50% of voters approving the statement wording (allowing for minor amendments where necessary). The final set of consensus statements were then submitted to the Boards of TSANZ/ANZSRS for final ratification and approval.

RESULTS

The database searches resulted in a total combined yield of 3253 publications after de-duplication. Following screening, 120 studies from the primary database search plus an additional 146 documents from additional sources (e.g., hand-

searching, grey literature) were considered potentially suitable to inform answers to the research questions. Full details of the screening process are provided in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram (Figure 1).

The findings of the review are described in the following text. The outcome of voting to determine consensus of resulting key messages was 100% for all key messages.

Transmission routes of SARS-CoV-2

Obtaining a clear understanding of the transmission route of COVID-19 was agreed as one of the utmost important issues to address for the entire project. However, it was agreed early during working group meetings that it was both beyond the scope of our terms of reference as well as the authority of TSANZ/ANZSRS to seek a specific answer to this issue. The question was therefore amended to become a societal position that would be accepted in order to underpin the remainder of the project agenda.

Compelling evidence emerged during the course of the working group regarding the transmission pathways of COVID-19, and it was agreed that the position of the WHO would be accepted in its entirety. The following is an excerpt transcription from WHO as of 30 April 2021⁶:

'The virus can spread from an infected person's mouth or nose in small liquid particles when they cough, sneeze, speak, sing or breathe. These particles range from larger respiratory droplets to smaller aerosols. Current evidence suggests that the virus spreads mainly between people who are in close contact with each other, typically within 1 metre (short-range). A

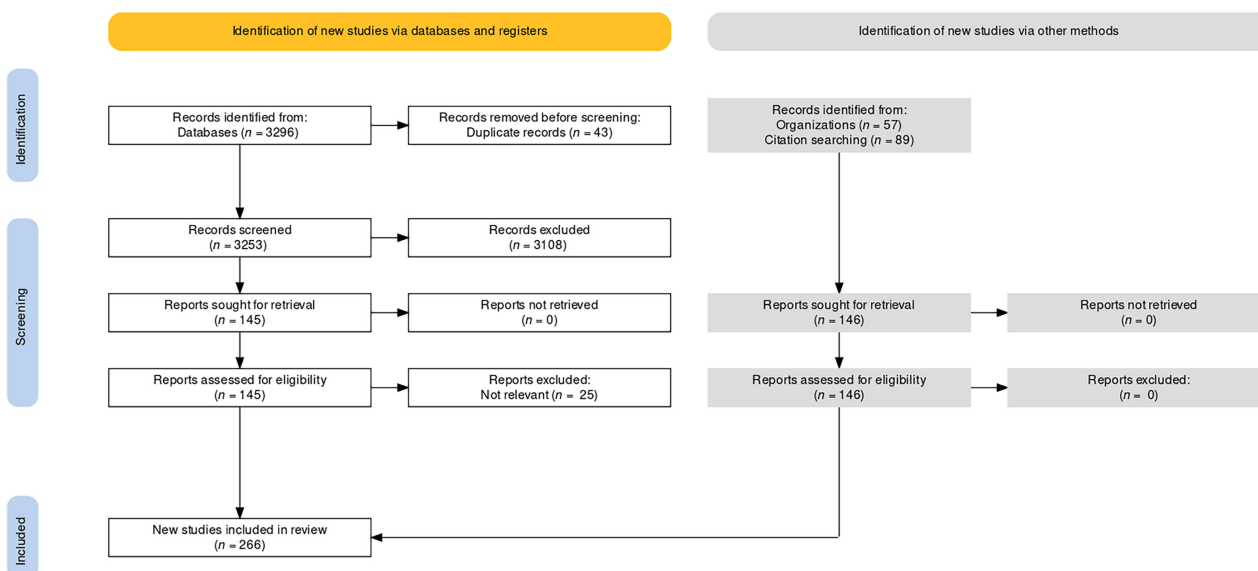


FIGURE 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram of included studies

person can be infected when aerosols or droplets containing the virus are inhaled or come directly into contact with the eyes, nose or mouth. The virus can also spread in poorly ventilated and/or crowded indoor settings, where people tend to spend longer periods of time. This is because aerosols remain suspended in the air or travel farther than 1 metre (long-range). People may also become infected by touching surfaces that have been contaminated by the virus when touching their eyes, nose or mouth without cleaning their hands'.

The CDC and Australian Health Protection Principal Committee also acknowledge that SARS-CoV-2 virus can be transmitted by both droplets and aerosols.^{7,8}

Key message

- Global and national health advisory organizations recognize that SARS-CoV-2 is predominantly transmitted via both droplet and aerosol routes, although other routes of transmission may also contribute to infection.

(Evidence level I; key message agreement 12/12 [100%])

Effects of PFTs on aerosol generation

In all expiratory activities (including but not limited to breathing, speaking, sneezing, coughing), people produce a myriad of respiratory particles across a spectrum that includes aerosols and droplets, all of which are capable of transmitting infection.¹⁶

While WHO has defined specific medical procedures as being high risk for airborne transmission (positive pressure ventilation, tracheal intubation, airway suctioning, nebulizer treatment and bronchoscopy),¹⁷ other activities, such as loud talking, coughing, forced exhalation and exercise, produce much higher loads of aerosols.^{18–23} For example, Wilson et al.¹⁸ showed that, compared to quiet breathing, high-flow nasal oxygen and positive pressure non-invasive ventilation increased small particles counts up to 2.3- and 7.8-fold, respectively, and exertional expiratory activities such as speaking, forced exhalations (as seen with forced vital capacity manoeuvres) and coughing increased particle counts by 34.6-, 227.6- and 370.8-fold, respectively. In a study comparing tracheal intubation, tracheal extubation and volitional cough, Brown et al.¹⁹ found the average concentration of aerosol generated for tracheal intubation and extubation was much lower

compared to volitional cough (500- and 35-fold, lower, respectively).

As well as considering pulmonary function manoeuvres as an aerosol-generating procedure (AGP) by nature of the type of respiratory efforts made, they also may result in significant aerosol-generating behaviours by provoking cough. In a re-analysed dataset, Greening et al.²⁴ showed in a healthy population that, compared to tidal breathing, three different breathing manoeuvres generated increased small particle mass (forced expiratory volume [+150%], slow vital capacity [SVC] following inhalation from residual volume [+470%] and cough at total lung capacity [+640%]). Interestingly, no significant difference between tidal breathing and SVC following inhalation from functional residual capacity was seen. The AERATOR study,²⁵ which measured small particle generation from quiet breathing, speaking, voluntary cough, unfiltered peak flow, filtered peak flow and filtered forced expiratory volume in 1 s (FEV₁), showed highest particle generation for voluntary cough for both healthy volunteers and patients followed by unfiltered peak flow measurement. An order of magnitude fall in measured small particles was observed when an inline filter was added to the peak flow meter in both healthy volunteers and patients. Spirometry performed with an inline filter reduced respirable particle emission to the environment. Garzona-Navas et al.²⁶ showed increasing aerosol concentration with increasing exercise intensity in healthy individuals. The same group, in a similar study in healthy individuals, showed significant aerosol generation with exercise, with larger particles (0.3–10 µm) rising significantly from exercise at 50% of predicted heart rate (HR) and smaller particles (0.02–1 µm) rising significantly from exercise at 75% of predicted HR and continuing during active recovery.²⁷

Review of the literature showed cough to be a consistent producer of large numbers of respiratory particles. PFTs can induce coughing in patients irrespective of previous cough history. In a study that assessed cough in 122 patients attending for pulmonary function, approximately 52% of patients spontaneously coughed following spirometry manoeuvres.²⁸ Lower levels of cough were seen for gas transfer and lung volumes. Although higher levels of cough were seen in those with pre-existing cough compared to those with no pre-existing cough, it was not possible to predict cough based on patient's cough history. Higher incidences of cough are seen during bronchoprovocation testing with a clinical trial finding cough in 85.3% of subjects undergoing mannitol challenge and 73.5% of subjects undergoing hypertonic saline challenge.²⁹ In fact, studies suggest that counting cough during mannitol challenge may be useful for identifying asthma and chronic cough.^{30,31} Cough has also shown to be induced during eucapnic voluntary hyperpnoea tests in patients with asthma.³² Inline filters have been demonstrated to be effective in reducing aerosol emission (refer

to risk mitigation strategies); however, they are unable to decrease aerosol emission from cough that occurs when the patient is off the mouthpiece.

Key message

- PFTs result in aerosol generation. Additionally, PFTs present an unpredictable risk of cough, which, in itself, results in high levels of aerosol generation. Risk mitigation strategies against aerosol generation should be used for PFTs in all settings.

(Evidence level I; key message agreement 12/12 [100%])

Risk control strategies to reduce the transmission of SARS-CoV-2 in pulmonary function testing

Transmission factors

In order to be able to assess the evidence and make recommendations on risk mitigation factors, the working group first needed to understand the risk factors for transmission of SARS-CoV-2 during clinical procedures. An editorial by Klompas et al.³³ summarizes four transmission risk factors for consideration:

- activities that result in forced exhalation including cough,
- symptoms and disease burden,
- distance and
- duration of contact.

Many PFTs, including spirometry, contain forced exhalations as part of the procedure and may also induce cough. As reported in the previous section, PFTs result in aerosol generation.

The likelihood of active infection and increased viral load is higher in symptomatic individuals compared to asymptomatic individuals. Symptomatic individuals, through coughing, sneezing and laboured breathing, are more likely to emit virus into air around them.³³ In clinical settings, patients attending for PFTs often present with respiratory symptoms and it can be difficult to distinguish acute from chronic symptoms.

Respiratory particles will be most dense closest to the source. As distance from the source increases, droplets fall, and aerosols diffuse and are diluted in the room air. A review article by Bahl et al.³⁴ concluded that horizontal particles may travel more than 2 m and, in some cases, up to 8 m. However, Chu et al.³⁵ showed, in a systematic review and meta-analysis, an 82% reduction in risk of transmission

of coronavirus with a physical distance of 1 m in healthcare and community settings, with each additional metre of separation more than halving the risk of transmission up to 3 m. The vast majority of PFT assessments require the HCW to be within 1 m of the patient.

The longer the duration of exposure to pathogen-laden droplets or aerosols, the higher the risk of infection. Both WHO³⁶ and CDC³⁷ identify 15 min of close exposure cumulatively over 24 h as a significant close contact duration. However, the 15-min threshold is arbitrary and anecdotal evidence of fleeting contact resulting in transmission of SARS-CoV-2 virus has been reported in the media and elsewhere.³⁸ PFTs require the HCW to have direct patient contact for a minimum of 15 min and up to 120 min depending on tests ordered.

In addition to the factors described by Klompas et al.,³³ the working group also considered ventilation and fomite transmission.

Ventilation

Distance and duration of droplet and aerosol spread are impacted by the level of ventilation. The level of ventilation contributes to the rate of dilution and dispersion of aerosols in the environment.³⁹ A number of studies have shown increased incidence of transmission of SARS-CoV-2 virus where exposed individuals who later tested PCR positive were more likely to have been in an enclosed environment with lower levels of ventilation.^{40–42}

Fomites

Fomite transmission of SARS-CoV-2 virus, while possible, is currently thought to be trivial compared to aerosol or droplet transmission.^{43,44}

Key message

- Factors contributing to risk of transmission of SARS-CoV-2 include activities with forced exhalations (eg., loud speaking, cough, sneeze, PFTs, exercise), acute symptoms that are associated with increased viral load, distance from index case and duration of exposure, and environmental ventilation.

(Evidence level I; key message agreement 12/12 [100%])

Risk mitigation strategies

Responsibility for risk management may occur at institutional, management or worker level. Employers are vicariously liable for the conduct of their employees and should

implement strategies to attain compliance with public health directives and the delivery of safe workplaces for HCW, patients and visitors to their facilities. While workplaces are required to provide a safe work environment through elimination of risks as is reasonably practicable, workers must take reasonable care for their own health and safety and the safety of others who may be affected by the worker's actions. This is done by workers complying with workplace policies and procedures to comply with occupational health and safety regulations.^{45–47}

The working group utilized the Hierarchy of Risk Control, a standard occupational health and safety risk control tool, to group controls to mitigate the risk against transmission of SARS-CoV-2 where PFTs are performed. Further information regarding the Hierarchy of Risk Controls can be found in guidance documentation from Work Safe Australia.⁴⁸ Table 1 summarizes the controls reviewed and includes the working group's consensus of the evidence level for the control and the direction of effect of the control on reducing SARS-CoV-2 transmission. Each control was assessed independent to other controls. Figure S1 in the Supporting Information shows where controls may be used in the PFT workflow. Further details about the controls are described in the main text in the following sections.

Hierarchy of Controls—Risk mitigation for exposure to SARS-CoV-2 during pulmonary function testing

Elimination

A CDC summary⁴⁹ and recent reviews^{50,51} report that while persistent detectable SARS-CoV-2 RNA on PCR testing is seen in some patients who have recovered from COVID-19 infection, replication-competent virus has rarely been recovered. Furthermore, infectivity is unlikely after 10 days from diagnosis in mild to moderate infection and after 20 days in those with severe infection and/or an immunocompromised state. This is also supported by an early analysis of the Omicron variant.⁵²

The working group's recommendations are based on the available consensus evidence around potential transmission risks at the time of writing, rather than the evolving isolation requirements in different jurisdictions over time. However, if appropriately applied, the timing of RFI may assist in determining safe timing for PFTs in the setting of recent COVID-19 infection or exposure. RFI decisions may be based on public health directives or local infection control advice and are designed to reduce transmission risk in the community. It is often acknowledged that further precautions may be relevant in high-risk environments. Given the potential complexities of RFI decisions in some individuals (particularly in those with severe illness or immunocompromise), it is recommended that deferring non-urgent PFTs for an additional 7 days after RFI would ensure appropriate transmission risks are further minimized in this high-risk setting.

For the purpose of these recommendations, the working group considered 'clinically urgent' PFTs those that directly impact diagnosis and immediate management of patients. PFTs that are performed for non-urgent diagnosis and management and to monitor disease state are considered 'clinically non-urgent'. Table 2 summarizes suggested wait times.

Defer PFTs in those with known or suspected SARS-CoV-2 infection. PFTs should not be performed in patients who are known to be COVID-19 positive on a recent RAT or PCR test (see below for PFT timing post COVID-19 infection). PFTs should not be performed in patients who are suspected to have COVID-19 infection based on symptoms (e.g., febrile, new acute respiratory or COVID-19-like symptoms where another cause for symptoms is not readily identifiable), awaiting COVID-19 test results (defer until result is known) or are quarantined or in isolation as per local public health directives (e.g., close contacts or other public health determined epidemiological risk factors).

PFTs after close contact with a COVID-19-positive case. Clinically non-urgent PFTs should be deferred until at least 14 days after the initial exposure date where the patient is a close contact of a positive case. This is consistent with the current Australian COVID-19 Test and Isolate National Protocols⁵⁴ that state close contacts should 'avoid visiting high-risk settings for at least 14 days following exposure to the person with COVID-19'. At the time of writing, different Australian states and territories have different requirements for household contacts, with some no longer requiring contacts to isolate but still advising precautions including avoidance of high-risk settings and mask use indoors. In New Zealand, current household contact self-isolation requirements are for 7 days after initial exposure, and non-essential PFTs should similarly be deferred until at least 14 days after exposure.⁵⁵

If deemed clinically urgent, PFTs may be performed immediately upon release from any applicable quarantine. It is preferable, however, to wait ≥ 10 days after exposure. Consideration of RAT or PCR testing immediately prior to performing PFTs may assist in deferring any newly positive cases that are identified in these circumstances.

PFTs after COVID-19 infection. COVID-19 clearance criteria have been variably defined for immunocompetent people as after 7–14 days from symptom onset (or positive PCR swab or RAT result) in mild and asymptomatic cases. Clearance criteria for those with severe illness, and, or persistent symptoms, as well as those who are immunocompromised have been variably defined as occurring up to 20 days after symptom onset (provided that fever has resolved and symptoms have improved).^{49,55–57} These definitions have evolved in different jurisdictions over time. The shorter duration of clearance after 7 days (and ongoing review of isolation requirements for household contacts) has been increasingly suggested and adopted at least partially for pragmatic

TABLE 1 Effectiveness of potential controls for reducing exposure to SARS-CoV-2 transmission during pulmonary function tests

Control type	Evidence level	Control ^a	Pre-test Future/immediate exposure risk	During test Immediate exposure risk	Post-test Subsequent exposure risk
Eliminate risk	I	Deferment/postponement/cancellation due to CONFIRMED SARS-CoV-2 infection	↓↓	↓↓	↓↓
	I	Deferment/postponement/cancellation due to SUSPECTED high risk (e.g., symptoms, epidemiological factors) SARS-CoV-2 infection	↓↓	↓↓	↓↓
Substitute	III	Minimum tests to inform clinical decision-making (reduce the duration of contact)	N/A	↓	N/A
		Substitution/modification of test (effect will depend on the test) (see Table 4)			
Isolate	I	Use of inline filters where available ^b	N/A	↓↓	↓↓
	I	Patient use of masks during assessments where able	N/A	↓↓	↓↓
	I	Physical distancing (>1 m) of all persons (as able)	↓	↓↓	↓
	II	Home-based model of care (where available/appropriate)	↓↓	↓↓	↓↓
	III	Density limits in waiting rooms, testing areas	↓	↓	↓
	III	Single patient per clinic room/laboratory	N/A	↓	↓
	III	Cough etiquette	N/A	-	-
	EvG	Physical barrier between operator and patient during testing	N/A	↓	N/A
Engineering	I	Ventilation (see Table 5)	↓↓	↓↓	↓↓
	II	UV lights for decontamination of room/surfaces	-	-	↓
Administrative	I	High-touch cleaning	↓	-	↓
	I	Cleaning non-disposable equipment between patients	N/A	N/A	↓
	I	HCWs not to attend work when unwell	↓↓	↓↓	↓↓
	I	COVID-19 vaccinated HCW ^c	↓↓	↓↓	↓↓
	I	COVID-19 vaccinated patients ^d	↓↓	↓↓	↓↓
	I	Confirmed negative PCR test (if available)	↓↓	↓↓	↓↓
	I	Confirmed negative supervised rapid antigen test (if available)	↓	↓	↓
	III	Use of pre-test screening questionnaires	↓	↓	↓
III	Triage of referrals for operational reasons/reducing exposure	N/A	N/A	N/A	
Personal protective	I	Hand hygiene (HCW and patients)	↓↓	↓↓	↓↓
	II	Appropriate personal protective equipment (HCW and patients)	↓↓	↓↓	↓↓
Key			Strength of evidence for controls to reduce SARS-CoV-2 transmission		
			Refer to main text for explanation of evidence levels		
Level I			Evidence based (strong)		
Level II			Evidenced based (conditional)		
Level III			Good practice (inconclusive evidence/expert advice)		
EvG			Evidence gap (absence of evidence)		

Note: Direction of effect of control on exposure risk: N/A, not applicable; -, no effect; ↓, small decrease; ↓↓, large decrease.

Abbreviations: COVID-19, coronavirus disease 2019; EvG, Evidence Gap; HCW, healthcare worker; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

^aEach control has been assessed independent of other controls.

^bEvidence varies for test type. See main text for details.

^cCondition of employment/mandatory for all healthcare settings in most Australian and New Zealand jurisdictions.

^dAdditional controls may be required for patients who are unvaccinated or not fully vaccinated to reduce risk to self and others.

TABLE 2 Summary of recommendations for determining the timing of PFTs post COVID-19 infection or exposure

COVID-19 status	Immune status	Minimum RFI ^a	Timing of PFTs	
			Clinically urgent	Not clinically urgent
Close contact	Not applicable	0–7 days ^b	After RFI, but ≥ 10 days after contact is preferable	Minimum of 14 days after exposure
Recent positive	Immunocompetent	7 days	After RFI, but ≥ 10 days after diagnosis is preferable	Minimum of 14 days after diagnosis Or ≥ 7 days after RFI
	‘Significantly’ immunocompromised ^d	7 to ≥ 20 days ^c	After RFI, but ≥ 14 days after diagnosis is preferable	Minimum of 20 days after diagnosis or ≥ 7 days after RFI ^c
	‘Mildly’ immunocompromised ^c	7 to ≥ 20 days ^e	After RFI, but ≥ 10 days after diagnosis is preferable	Minimum of 14 days after diagnosis or ≥ 7 days after RFI ^c

Abbreviations: COVID-19, coronavirus disease 2019; PFTs, pulmonary function tests; RAT, rapid antigen test; RFI, release from isolation.

^aRFI criteria is determined by local public health/infection prevention advice and should ensure there has been resolution of fever and improved or resolved symptoms and may include other assessments or COVID-19 testing (current at 2 May 2022).

^bDifferent jurisdictions have different requirements (2 May 2022).

^c‘Mildly’ immunocompromised persons may include, but are not limited to, patients on corticosteroids prednisolone < 20 mg/day; methotrexate, azathioprine, 6-mercaptopurine; asymptomatic HIV with CD4 count > 200 .

^d‘Significantly’ immunocompromised persons may include, but are not limited to, solid organ and bone marrow transplant recipients; active haem/solid malignancy on chemotherapy; active HIV/AIDS with CD4 < 200 ; and patients receiving significant immunosuppressive treatments that would affect immune responses (e.g., B-cell-depleting therapies such as rituximab)—prolonged corticosteroids (i.e., prednisolone ≥ 20 mg/day).

^eSome jurisdictions have considered waiting ≥ 20 days after the onset of infection or performing a RAT or PCR test immediately prior to attendance at a high-risk setting.^{49,53}

reasons as COVID-19 infections move towards a recurrent outbreak phase.^{56,57}

PFTs after COVID-19 infection in immunocompetent patients: In immunocompetent patients recovering from COVID-19 infection, PFTs should not be performed prior to RFI and clearance from active COVID-19 infection as defined by local public health/infection prevention criteria.

Non-urgent PFTs should be deferred for a minimum of 14 days after diagnosis. At the time of writing, this corresponds to an additional 7 days after release from the minimum isolation requirements, as per the current Australian COVID-19 Test and Isolate National Protocols⁵⁴ and the self-isolation requirements in New Zealand.⁵⁵ Some patients with slowly resolving symptoms or with more significant illness may have required a longer period of isolation prior to clearance and waiting to perform PFTs 7 days after RFI is suggested.

If deemed clinically urgent, PFTs may be performed immediately upon RFI. It is preferable, however, to wait ≥ 10 days after test positive date.

PFTs after COVID-19 infection in immunocompromised patients: ‘Significantly’ immunocompromised individuals (see Table 2 footnotes) with COVID-19 infection may require a longer period in isolation as they may have a reduced ability to effectively clear SARS-CoV-2 and have a prolonged infectious period.⁵⁷ They are likely to have had additional specialist evaluation and testing to determine the appropriate timing of RFI (which may be ≥ 20 days), particularly in those who are hospitalized with more severe illness.⁴⁹ Waiting to perform non-urgent PFTs for a minimum of 7 days after RFI is advised.

Some patients recovering from COVID-19 infection in the community may be ‘mildly’ immunocompromised or on low-level immunosuppression (see Table 2 footnotes). Many are expected to have a normal immune response to vaccination and most viral infections and may be released from isolation after 7–14 days provided they meet any symptom recovery and testing requirements.

Some jurisdictions have suggested considering additional waiting time and/or COVID-19 testing prior to community-based immunocompromised patients entering a ‘high-risk’ setting after COVID-19 infection, such as waiting ≥ 20 days after the onset of infection or performing a RAT or PCR test immediately prior to attendance.^{49,53} It is noted, however, that positive test results may be difficult to interpret at times, and more complex testing and clinical decision-making may be required for some individuals, potentially involving local institutional COVID-19 clearance expertise, if available.

Scheduling of patients recently cleared from COVID-19 infection to separate them from other potentially immunocompromised patients or at the end of lists may be considered where time-sensitive PFTs are required to inform clinical decision-making.

Key messages

- Pulmonary function testing should not be performed in patients who are known to be COVID-19 positive or suspected COVID-19 positive (including those with fever, new acute COVID-

19-like symptoms or asymptomatic and awaiting RAT or PCR test results).

- Non-urgent PFTs should be deferred for a minimum of 14 days after exposure to COVID-19 in close household contacts of a positive case. Consider deferring PFTs in those known to have had a recent exposure or other epidemiological risk factors.
- Non-urgent PFTs should be deferred for a minimum of 14 days after the diagnosis of COVID-19 infection (or a minimum of 20 days in patients identified as having ‘significant’ immunocompromise). In most cases, this will correspond to an additional 7 days after RFI. In those with lingering symptoms, severe infection and/or immunocompromise who may require longer periods of isolation, it is recommended to defer non-urgent PFTs for a minimum of 7 days after eventual RFI.
- Clinically urgent PFTs could be performed immediately after RFI if needed. However, waiting a minimum of 10 days after diagnosis of infection is preferable.

(Evidence level I; key message agreement 12/12 [100%])

Substitution

It may be possible to substitute or modify tests to reduce aerosol generation and transmission risk. The working group notes that many of the controls in this section are modifications rather than substitutions of tests, but agreed that documentation of the modifications was best placed in this section. Table 3 provides some examples of potential substitutions or modifications of PFTs. Many of the modifications are discussed in more detail later in the document.

In situations of high community prevalence, reducing test types to the minimum required to inform clinical decision-making may assist with limiting potential exposure by reducing test duration. For example, in a patient with interstitial lung disease (ILD) with new onset of shortness of breath (and COVID-19 has been ruled out), performing baseline spirometry and DLCO only, instead of pre- and post-bronchodilator spirometry, DLCO and lung volumes, may be an option.

Some PFT assessments include the administration of bronchodilator medications. In such circumstances, this should be performed via metered dose inhaler and spacer. Use of nebulizers (i.e., jet, mesh or ultrasonic) increases aerosol emission to the local environment and should be avoided where possible. If nebulization is deemed necessary for bronchodilator assessment, strong emphasis should be placed on other hierarchy of control factors such as isolation

measures, engineering controls and PPE (see below). Use of breath-activated nebulizers and/or use of non-vented mouthpieces with filters on exhalation ports should also be considered to reduce aerosol emission to the environment.

Key message

- Consider modifications or substitutions that can be made to test circuits or procedures to reduce aerosol spread and transmission risk.

(Evidence level will depend on substitution or modification; key message agreement 12/12 [100%])

Isolation

Home-based model of care. Through the COVID-19 pandemic, telehealth consultations have become an important tool in the assessment and management of patients. Home spirometry administered via a telehealth consultation can be a useful tool for clinical management patients with known chronic respiratory disease and for research. Telehealth-supervised spirometry has been shown to be particularly useful in the assessment and monitoring of people with cystic fibrosis,^{58–60} but has also been found to be useful in other disease groups.^{61,62} As performance of remotely supervised spirometry testing separates HCWs from patients, transmission risk to HCWs and other patients is effectively eliminated.

Home spirometers may vary in quality and accuracy to clinic spirometers and careful evaluation of home spirometers prior to bulk purchase is warranted. Paynter et al.⁶³ re-analysed data from a longitudinal study of patients with cystic fibrosis comparing home and clinic spirometry. They showed mean cross-sectional differences between home and clinic devices of 2% of predicted FEV₁ (home device lower), with big differences in precision between modalities. However, longitudinal change between home and clinic spirometry was not qualitatively impacted. In an unpublished report (Brigitte Borg 12/01/2022, with permission), three out of four home spirometers assessed did not meet accuracy specifications for spirometers.⁶⁴

It is also worthwhile considering selection criteria for patients. In addition to standard telehealth eligibility criteria, other considerations, such as access to appropriate technology for measuring spirometry in parallel with telehealth consultation, previous demonstration of acceptable test performance (grade A or B as per Graham et al.⁶⁵) and no history of previous adverse event when performing spirometry (patient safety), should be taken into account.

HCWs conducting PFT via telehealth must be competent in the principles and practice of spirometry.

Currently, while telehealth consultations are billable under the Australian Medicare Benefit Schedule, no such provision exists for diagnostic tests such as spirometry.

TABLE 3 Examples of potential substitutions or modifications of pulmonary function tests

Procedure type	Procedure	Substitute	Modification
Quiet breathing, close contact	ABG		Patient to wear surgical mask
	Skin prick test		
	Measure height and weight		
	Finger prick haemoglobin measurement		
Tidal breathing range tests	Hypoxic altitude simulation		Add inline filter: consider impact of dead space in circuit on tidal volume, respiratory rate and exhaled gas concentrations
	Shunt		
	Multiple breath nitrogen washout		
	Bronchodilator administration via nebulizer	Use MDI and spacer	Use breath-activated nebulizers ± non-vented mouthpiece and filter on exhalation port
Vital capacity range tests	DLCO	ABG (patient can wear mask)	Inline filters
	Static lung volumes	Lung CT calculation of total lung volume (where CT being performed as part of assessment. Consider radiation exposure)	
	FeNO	Offline sampling of exhaled breath	
FVC tests	FVC, PEF	SVC where only capacity is required	Inline filters
Higher risk of cough	BPT: mannitol, methacholine, EVH, hypertonic saline	Good clinical history, empirical trial of respiratory medications, FeNO where high suspicion of eosinophilic asthma	Teach cough etiquette prior to commencement of test
	Airway clearance therapy assessments: hypertonic saline, mannitol		Filters on exhalation port of nebulizers Inline filter on EVH circuit
High ventilation tests	CPET		Use of inline filters in exercise breathing circuits
	6MWT		Use of surgical masks for exercise assessments not requiring sampling of exhaled breath
	Step test		
	EVH		
	Exercise-induced laryngeal obstruction assessment		

Abbreviations: 6MWT, 6-min walk test; ABG, arterial blood gas; BPT, bronchial provocation test; CPET, cardiopulmonary exercise test; CT, computed tomography; DLCO, diffusing capacity across the lung of carbon monoxide; EVH, eucapnic voluntary hyperpnoea; FeNO, fraction of exhaled nitric oxide; FVC, forced vital capacity; MDI, metered dose inhaler; PEF, peak expiratory flow; SVC, slow vital capacity.

Key message

- Telehealth spirometry may be a useful tool for maintenance of quality care of chronically ill patient groups and for monitoring in clinical trials. Careful selection of device and subjects is suggested.

(Evidence level II; key message agreement 12/12 [100%])

Physical barriers between subjects and operators. Several international governing bodies have made recommendations on the use of a physical barrier such as Perspex between the operator and patient during PFTs,^{66–68} but literature on the efficacy of reducing transmission is conflicting. A review by Wang et al.⁶⁹ notes that the use of Perspex as a barrier can impede airflow and trap higher concentrations of aerosols in the breathing zone, therefore increasing the risk of transmission. While this study does

not elaborate how airflow is impeded, other research has shown that barrier size and placement can interfere with air movement and ventilation systems.⁷⁰ In contrast, a laboratory study that measured efficiency of transparent barriers for customer-facing industries found at least 71% reduction in particle transmission (71%–93%) when the barrier is at least 9 cm above the cough height.⁷¹ In the setting of AGPs, Price et al.⁷¹ reviewed research on the use of barriers and found that much of the available literature were short letters and commentaries to validate devices rather than laboratory studies. In the studies that did measure particle reduction of aerosols and droplet, contamination was based on visual representations only.

Key message

- Evidence for the reduction of droplet and aerosol transmission by using physical barriers between patient and operator during PFT is limited and much of the literature is that of short communications rather than study data. When used, the

impact on ventilation streams should be considered.

(Evidence gap; key message agreement 12/12 [100%])

Single patient per clinic room/laboratory and physical distancing. The TSANZ Respiratory Function Laboratory Accreditation standards require that PFTs are performed in fully enclosed rooms (i.e., they can be separated from other internal spaces by closing a door) with adequate ventilation and that only one patient at a time is tested per room.⁷² The standard is for two purposes: patient privacy and infection transmission risk.

Specific to COVID-19, guidance from organizations in the United States, Canada and Argentina recommends that only the patient and the HCW conducting the test be present in the room during testing.⁷³⁻⁷⁵ It may be necessary in some circumstances for additional persons to be present (parents, interpreters, carers and additional HCWs). In such cases, people should be screened and wear a face mask at all times. This advice was deemed to confer appropriate relevance to the Australian and New Zealand settings. The working group therefore elected to adopt this position without change.

While in the room, HCWs should, where possible, remain greater than 1 m from the patient.³⁵

Additionally, practices providing PFTs must comply with local jurisdictional or regulatory bodies physical distancing and density limits for staff and visitors within clinical spaces, waiting rooms, offices and breakrooms as a minimum (see *Transmission factors*).

Key messages

- PFTs should be undertaken in a room that is closed to other internal spaces involving only one patient at a time (i.e., PFTs should not be performed in shared spaces) (Evidence level III).
- The number of people in a room during testing should be minimized to reduce transmission risk (Evidence level III).
- Physical distancing (Evidence level I) and density limits (Evidence level III) set by local jurisdictional or regulatory bodies must be adhered to throughout the workplace as a minimum.

(Key message agreement 12/12 [100%])

Inline filters. Tests other than CPETs: Use of antibacterial/antiviral filters in breathing circuits is a standard practice for PFT laboratories in Australia and New Zealand, and should be used in all settings where PFTs are performed to prevent contamination of equipment and cross-infection of

patients.^{65,76-78} In the context of COVID-19, use of inline filters in PFT breathing circuits has been recommended as a minimum risk mitigation strategy by all respiratory governing body advice that was reviewed^{67,68,74,75,79-85} and within the literature on PFTs in the COVID-19 pandemic.^{66,73,82,86-89}

Although inline filters can impact negatively on measured FEV₁ and peak expiratory flow, this has been found to be clinically insignificant and within intra-test variability when inline filters meeting specifications for use in PFT breathing circuits are used.^{76,77} Specifications for measurement devices need to be maintained with the inclusion of inline filters.⁷⁶ For inline filters to be effective in PFT circuits, they need to be highly efficient (>99%) across flows up to 840 L/min, the upper limit for the flow range required for spirometers.⁶⁴ Efficiency may vary between bacterial and viral particles.

Placement of inline filters in the breathing circuit is important. A filter at the proximal end of the circuit (between the patient and equipment) protects the equipment from higher levels of contamination and reduces aerosol dispersion to the environment, while a filter at the distal end of a circuit (at exhalation port) does not prevent circuit contamination, but reduces aerosol dispersion to the environment. The position of the filter in the breathing circuit may also affect PFT device performance. Consultation with manufacturers or their agents to confirm compatibility and placement of filter in breathing circuit to ensure accuracy of results is advised. Calibration of devices when using inline filters should be performed with consideration of the American Thoracic Society/European Respiratory Society standards,⁶⁵ manufacturers' advice and internal evaluations.

In the context of aerosol emission to the environment, the AERATOR study showed a significant reduction, but not elimination, of aerosol emission to the environment comparing unfiltered peak flow to filtered peak flow in volunteers and patients.²⁵ Another study²² showed increased respirable particle levels immediately adjacent to the exhalation port of the device with a commonly used filter in the circuit compared to ambient levels, suggesting filters do not eliminate respirable particle dispersion to the immediate environment. A third study supports this finding.⁹⁰

Inline filters and CPET: CPET involves increased minute ventilation due to both increased respiratory rate and increased tidal volumes, with corresponding increases in the concentration of airborne (droplets and aerosols) particles within testing rooms.²⁶ Some laboratories use inline filters during CPET. However, a recent international consensus statement⁵⁰ recommended 'extreme caution' in the use of inline filters because of concerns that the increased minute ventilation and associated increased water vapour would saturate the filter. They posited that this could increase expiratory resistance thereby reducing maximal exercise capacity and increasing dyspnoea. The current evidence is limited to studies of very low numbers, with two studies showing that filters placed distal to the sampling line alter CPET

parameters,^{91,92} whereas one study ($n = 2$) using an inline filter proximal to the sampling line showed no effect on CPET parameters.⁹³ None of the studies included patients with respiratory or cardiac disease. Before implementing inline filters for CPET, it is advised that practices consult vendors for advice on use of inline filters proximal or distal to the sampling port and other technical considerations, as well as performing their own intra-laboratory comparisons. Given the high clinical utility of CPET, individual laboratories should weigh the benefits of safely providing CPET services with the use of inline filters against the potential effect on exercise capacity, dyspnoea and other CPET parameters. Use of additional control measures may be of benefit. For example, high-efficiency particulate arrestance (HEPA) filtration has been shown to substantially reduce particle numbers during CPET and almost halve the time required for aerosol clearance.²⁶

Key messages

- Inline filters reduce, but do not eliminate, respirable particle dispersion from PFT breathing circuits. Inline filters meeting PFT specifications should be used in PFT breathing circuits where able.
- Careful consideration is advised to determine the impact of inline filter use on CPET parameters.

(Evidence level I; key message agreement 12/12 [100%])

Use of masks for field walking tests. Several studies support the use of surgical masks during field walking tests⁹⁴ demonstrating minimal or no effect on 6-min walk distance, HR or oxygen saturation in patients with COPD and ILD.^{95,96} These findings can likely be extrapolated to other exercise tests such as the incremental and endurance shuttle walk tests and sit-to-stand tests based on findings from healthy participants.^{97–99} There may be individuals in whom mask wearing disproportionately exaggerates dyspnoea due to individual psychophysiological perceptions of loads¹⁰⁰; however, identifying such people is challenging.

Key message

- Surgical masks should be worn during field walking tests (eg., 6-min walk tests) unless poorly tolerated by the patient. Interpretation of tests should consider the potential increase in symptoms due to mask wearing.

(Evidence level I; key message agreement 12/12 [100%])

Cough etiquette. Cough is the highest generator of respirable particles across both breathing manoeuvres and procedures considered to be aerosol generating (see section *Effects of PFTs on aerosol generation*). Cough etiquette, also known as respiratory hygiene, describes techniques of covering the mouth when coughing or sneezing. The two commonly promoted methods are: covering the mouth and nose with a tissue to cough or sneeze, then disposing of the tissue and washing hands; and coughing or sneezing into the elbow, or sleeve or mask (not the hands). Health organizations and government health departments widely promote cough etiquette as a mitigation tool to reduce the transmission of respiratory illness by reducing respiratory particle emission into the environment through sneeze or cough.^{101–106} Although there is little direct evidence to support cough etiquette as a mitigation method for reducing emissions of respiratory particles,^{107,108} indirect evidence suggests cough etiquette may reduce disease transmission, particularly when combined with other practices such as hand hygiene and mask wearing.^{109,110} Further indirect evidence suggests that mask use by patients when coughing between PFT manoeuvres may be useful in reducing respiratory particle emission.¹¹¹ Hand hygiene (see *Personal protective controls*) is a particularly important component in cough etiquette: post cough/sneeze if using tissues; prior to application of clean masks; and prior to and following removal of soiled masks.

Key message

- Cough etiquette in combination with other mitigation measures, such as hand hygiene and mask wearing, may assist with reducing disease transmission.

(Evidence level III; key message agreement 12/12 [100%])

Engineering controls

Ventilation. Ventilation is a complex area and expert advice (e.g., ventilation specialist, occupational hygienist) may be required to ensure effective room ventilation.

HVAC systems: The advice in this section relates to systems that are incorporated into the building structure and are able to both supply conditioned air to the room as well as remove air either to the outside of the building or to be filtered/decontaminated. Air conditioning units such as split systems or heat pumps will only heat or cool the supplied air; however, they will not improve the overall ventilation of the room. It is beyond the scope of this document to detail the different types of heating ventilation and air

TABLE 4 Summary of recommendations for HVAC system settings

Organization	Setting	Pressure relationship to adjacent areas	Minimum outdoor ACH ^a	Minimum total ACH ^b	Air exhausted to outdoors	Relative humidity (%)	Temperature (°C)
United States Department of Veterans Affairs	Pulmonary function laboratory	Neutral	2	8	Yes	20–60	21–24
United States Department of Veterans Affairs ¹¹⁴	Exercise testing laboratory	Neutral	2	10	Yes	20–60	21–24
World Health Organization ³⁹	Healthcare settings including COVID-19 treatment and quarantine	Negative	-	Six but 12 for AGP	Yes	-	-
American Institute of Architects Academy of Architecture for Health ¹¹⁵	Bronchoscopy, sputum induction, pentamidine nebulization	Negative	2	12	Yes	-	20–23
Victorian Health and Human Services Building Authority ¹¹⁶	Inpatient room	Neutral	2	Six (volume is calculated using room height of 1.83 m)	No restriction	Uncontrolled	21–24
New South Wales Ministry of Health + Victoria Health Engineering Service Guidelines ^{116,117}	Bronchoscopy, sputum induction, pentamidine nebulization	Negative	3	12	Yes	35–60	20–23

Abbreviations: ACH, air changes per hour; AGP, aerosol-generating procedure; COVID-19, coronavirus disease 2019; HVAC, heating ventilation and air conditioning.

^aMinimum number of ACH that are made up of fresh air from outside the building, that is, not recirculated or filtered air.

^bMinimum total number of ACH; this includes the minimum recommended outside air changes.

conditioning (HVAC) systems; therefore, it is recommended that either the facilities management of the local institution or specialist HVAC engineers are consulted to determine the exact specifications of any system present in areas where testing is performed.

HVAC systems are used to supply clean air to a room, contain contaminated air and move it outside or dilute the air in a room with fresh or filtered air (e.g., having been passed through a HEPA filter). HVAC systems can also incorporate UV germicidal irradiation rather than filtration as a means of decontaminating air as it moves through ducting and may be advantageous in comparison to HEPA filtering as it does not increase resistance to airflow in the system resulting in energy savings.¹¹²

Room ACH is calculated as the ventilation airflow (m³/h) divided by the room volume. Engagement of HVAC engineers will likely be required to measure ACH as specialist equipment is required to measure flow from supply and exhaust ducts. The number of room ACH is probably the most important metric in relation to HVAC performance as this determines how quickly airborne pathogens will be removed from a room. For example, it takes 138 min to achieve 99% removal of airborne contaminants with 2 ACH, this drops to 23 min with 12 ACH.¹¹³

HVAC systems allow the temperature and humidity of the rooms to be controlled, which is an important factor in infection prevention. Evidence suggests that controlling

relative humidity reduces transmission of airborne infectious organisms, including some strains of influenza, with optimal relative humidity set around 50%.¹¹²

There is little specific advice available on the level of ventilation required for rooms where pulmonary function testing is performed (e.g., advocating ‘adequate’ ventilation without further detail). A summary of recommendations from various groups is given in Table 4.

Based on data presented in Table 4 and the airborne nature of SARS-CoV-2 spread, the working group’s precautionary approach means that a minimum of 12 ACH is recommended in rooms where pulmonary function testing is performed. Additional desirable features are negative pressure with respect to surrounding spaces, a minimum of 2 ACH of outdoor air, relative humidity of 20%–60% and temperature of 21–24°C.

WHO provides strategies to employ should a current HVAC system fall short of the ideal standards³⁹:

1. Investigate ways to increase the ventilation rate of the current system, for example, increase fan speeds or disable secondary controls that change air supply based on CO₂ levels or temperature
2. Use natural sources of ventilation, for example, opening windows to supplement ventilation. Care would however need to be taken to avoid large fluctuations in temperature or humidity that may affect PFT measurement devices.

3. Use portable HEPA filtration devices (see *Air cleaning units* below) to bridge the gap between measured ACH from the HVAC system and target ACH.
4. Increase the percentage of outdoor air supplied by the HVAC system if it has a recirculation mode.
5. Reduce the occupancy of the room. As well as ACH, WHO also provides guidance on ventilation rates in L/s/patient (160 L/s/patient with AGP). Reducing occupancy of the room increases ventilation rates with no change in system performance.
6. Consider leaving the room unoccupied post-test to allow clearance of potentially contaminated air. Room clearance at various ACH rates can be found on the CDC website¹¹³ and can be used to determine appropriate stand-down times. Caveats such as the assumption of perfect mixing of the air should be noted.

Non-HVAC ventilation/natural ventilation: Buildings that are not mechanically ventilated (no HVAC system) may use natural forces (wind, thermal differences) to move air through their structure. Natural ventilation requires incorporation of purpose-built features, such as windows, doors, solar chimneys, wind towers or trickle ventilators, into the building design and is often dependant on climate and human behaviour for correct function. Natural ventilation methods can provide very high levels of ventilation at low cost; however, they can be affected by changes in driving forces (e.g., outside temperature and wind direction), can be difficult to control and may vary in levels of airflow available. Of note, air cleaning filters cannot be incorporated within the system and normal operation will be affected by factors such as the opening and closing of windows or doors.

WHO provides recommendations on levels of ventilation for naturally ventilated healthcare facilities.¹¹⁸ Natural ventilation is measured as airflow *per person*, with minimum ventilation requirements for a room defined as 160 L/s/person (averaged per hour) where AGPs are performed and 60 L/s/person (averaged per hour) for general wards and outpatient departments.

The ventilation rate (flow) of a room can be estimated by the formula below or can be measured by a professional to ensure compliance.

$$\text{Ventilation rate (L/s)} = k \times \text{wind speed (m/s)} \\ \times \text{smallest opening area (m}^2\text{)} \\ \times 1000 \text{ (L/m}^3\text{)}$$

Where:

- $k = 0.05$ in the case of single-sided ventilation or 0.65 in the case of cross ventilation
- In the case of mosquito net presence: ventilation rate $\times 0.5$
- Wind speed: the wind speed refers to the value at the building height at a site sufficiently away from the building without any obstructions (e.g., at an airport)

Where a naturally ventilated room does not meet minimum requirements, the following strategies may be employed:

- Assess current building openings and consider modification of dimensions of windows or doors. Investigate the possibility of new openings.
- If increased ventilation is not possible, look to reduce occupancy to improve airflow/patient rates as discussed above.
- Make use of portable HEPA filtration devices to improve overall ACH.
- Installation of wall or window extractor fans. These may create a negative pressure in the testing room with respect to corridors outside to minimize escape of contaminated air.
- Consider leaving the room unoccupied post-test to allow clearance of potentially contaminated air (refer to point 6 above for further details).

Air cleaning units: Standalone air cleaning units can be used in situations where an HVAC system is not available or where the ACH of the current installation does not meet the requirement.³⁹ Standalone units use HEPA (or other high-grade filters), UV-C (see also *UV for surface disinfection and in-room air decontamination*) or other emerging technologies to remove viruses and other microorganisms from the air. Current evidence of health benefits for emerging technologies such as ionizers or UV with photocatalytic oxidation is limited and may in fact be harmful due to potential ozone generation.¹¹⁹ Choice of unit should ensure that the amount of air being cleaned meets the required ACH for the room, which requires knowledge of room volume and clean air delivery rate of the unit. Air cleaners should be operated continuously with attention paid to positioning close to the patient to provide the maximum treatment of potentially contaminated air. Room airflow direction should also be taken into consideration for placement of the unit; for example, the unit should ideally be placed away from sources of clean air (e.g., windows or doors) and closer to where the air may be less clean to maximize effectiveness.¹¹⁹

CO₂ monitoring. Measurement of CO₂ is a low-cost tool which uses the background CO₂ levels generated by human exhalation to monitor the environment.¹²⁰ In the absence of other mitigation strategies (e.g., HEPA filtration), CO₂ monitoring may be used as a proxy to monitor ventilation. A CO₂ level of less than 800 ppm with a suggested acceptable upper range of 1000 ppm indicates adequate ventilation.^{121–123} Limitations of CO₂ monitoring include:

- measurements are only valid when a room is occupied,
- there are few evidence-based recommendations for acceptable CO₂ levels,

- it is unlikely any single CO₂ cutoff is equally applicable across all environments and^{120,124}
- CO₂ monitoring cannot be used to evaluate the adequacy of other mitigation strategies. For example, HEPA filtration devices are not designed to remove CO₂ from the environment.¹²³

Key messages

- Ventilation is a complex area and expert advice may be required to ensure effective room ventilation.
- A minimum of 12 ACH is recommended for rooms where pulmonary function testing is performed.
- Additional strategies, such as air cleaning units, should be employed where the minimum ACH is not met.
- HCWs should be aware of limitations in using CO₂ monitoring to assess ventilation levels.
(Evidence level I; key message agreement 12/12 [100%])

Key message

- UVC units may be useful as an additional control measure for room and/or surface decontamination, but are not suggested for routine use in Australian healthcare facilities presently.
(Evidence level II; key message agreement 12/12 [100%])

UV for surface disinfection and in-room air decontamination. UVC (200–280 nm) can be useful for surface disinfection or whole room decontamination. UVC has been shown to be effective at inactivating a number of pathogens as well as SARS-CoV-2¹²⁵; however, care should be taken in its use as exposure to UVC can be dangerous, particularly affecting the eyes and skin.^{126,127} UVC can irradiate objects directly as well as areas in shadow by way of reflection; however, care needs to be taken to ensure that an adequate dosage of UVC reaches non-line of sight areas to ensure decontamination. Dosage is dependent on length of exposure, intensity of the source of UVC (usually a lamp) and distance from source to surface.¹²⁸

UVC can also be used in-room where the upper air is exposed to the UV allowing decontamination while the rest of the room is shielded. Two drawbacks to this method are that the intensity of UV used must be lower than can be deployed in HVAC system ducts and that units must be mounted at more than 2 metres above the floor. It is suggested that these systems are less effective than good ventilation and may not be required if there are greater than 6 ACH.¹¹²

The Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019) do not recommend routine use of UVC disinfection in healthcare facilities, but note that it may be considered in high-risk settings and during outbreaks when other options for disinfection have been exhausted.

Administrative controls

Cleaning: High-touch and non-disposable equipment. Infection prevention and control is an essential component of providing safe, quality care for patients as well as providing a safe working environment for HCW. Healthcare-associated infections are not isolated to hospitals, but may impact office-based practices also. The Australian Guidelines for the Prevention and Control of Infection in Healthcare 2019¹²⁹ provide evidence-based recommendations for essential aspects of preventing and controlling infection. Included in the guidelines are practice statements and recommendations on the routine management of the physical environment. Frequent cleaning and disinfection (where required) of high-touch surfaces and cleaning and/or disinfection of shared patient equipment between use are two such practice statements.

A recent review by Kampf et al.⁴⁴ found inconsistent detection of SARS-CoV-2 RNA on inanimate surfaces in hospital settings (0%–75% intensive care unit surfaces; 1.4%–100% isolation rooms; 0%–61% general wards). The authors noted however that detection of viral RNA does not reflect viral viability or infectivity. Following disinfection, viral RNA was mostly undetectable on surfaces. The authors also noted although indirect transmission of SARS-CoV-2 is assumed to be possible, no direct evidence supporting transmission via fomites has been found. This is supported by a similar review.⁴³ In a separate paper by Kampf et al.,¹³⁰ SARS-CoV-2 virus was effectively inactivated by surface disinfection with 62%–71% ethanol, <0.5% hydrogen peroxide or 500 pm (>0.1%) sodium hypochlorite within 1 min.

Routine cleaning of high-touch surfaces, such as scales, stadiometer, desk, chairs, keyboards and testing equipment, with appropriate detergent and disinfectant is recommended between patients.^{10,73,84,85,131,132} In Australia, Therapeutic Goods Australia (TGA) approved hospital-grade disinfectants must be used.¹⁰

Single-use consumables (nose clips, mouthpieces, spacers) should be used where available to reduce contamination¹³² and non-disposable items should be disinfected and sterilized in line with appropriate standards.¹²⁹

It may be helpful to consider minimizing furniture and other equipment in the room to minimize cleaning.

Key messages

- SARS-CoV-2 RNA has been isolated from inanimate surfaces, but was rarely detected after disinfecting surfaces with appropriate cleaning solution. No direct evidence of fomite transmission has been recorded.
- Disinfecting high-touch surfaces is a simple and effective way to mitigate the risk of possible fomite transmission of SARS-CoV-2 and other transmissible pathogens.
- Non-disposable medical consumable items must be disinfected and/or sterilized in accordance with appropriate standards.

(Evidence level I; key message agreement 12/12 [100%])

Staff not to attend work while unwell. Results from several studies show that HCWs and others frequently present when unwell.^{133–137} HCWs attending work while sick may increase the risk of transmission of communicable illnesses to vulnerable, high-risk patients in healthcare facilities as well as to their colleagues.^{138–140} Public health directives during the COVID-19 pandemic have sought to reduce presenteeism by requiring people with acute respiratory or COVID-19-like symptoms to be tested for COVID-19 and isolate while awaiting results, with further instructions based on findings. Some workplaces have implemented additional return to the workplace criteria for unwell HCW including improving or resolution of symptoms. Employers are vicariously liable for the conduct of their employees and should facilitate adherence with public health directives to ascertain safety of HCWs, patients and visitors attending their facilities.

Key message

- HCWs should follow workplace and government public health directives regarding working while unwell and returning to the workplace following illness.

(Evidence level I; key message agreement 12/12 [100%])

Vaccination. Along with the well-established evidence that COVID-19 vaccines provide strong protection in reducing infection overall, preventing serious illness, hospitalization and death, there is also some evidence that vaccination reduces viral transmission.^{141,142} This may be related to reduced viral load in vaccinated subjects; however, this reduced transmission appears to depend on the COVID-19

variant.¹⁴³ A surveillance study of frontline workers (including HCW) reported that over a 4-month period (early 2021), 204 of 3975 individuals (5%) tested positive for COVID-19. Of the HCWs who tested positive to COVID-19, five of 204 were double-dose and 11 of 204 were single-dose vaccinated.¹⁴⁴ They calculated an adjusted vaccine effectiveness of 91% with full vaccination and 81% with partial vaccination. They also found that viral load and the duration of illness were lower in vaccinated cases.¹⁴⁴ A recent US study reported a fall in vaccine effectiveness against the Delta variant to around 74%, but effectiveness against hospitalization remained fairly high.¹⁴⁵ An early report of vaccine effectiveness in the Omicron variant demonstrates mRNA vaccine effectiveness of 70%,¹⁴⁶ with current advice recommending a third dose of vaccine to improve this.¹⁴⁷

Staff vaccination: New Zealand and the majority of Australian State and Territory Governments are mandating up-to-date vaccination status for HCWs as a condition of employment to protect them from the risk of infection and serious illness and to reduce their risk of transmitting the virus to others in a health care or high-risk setting.

Patient vaccination: While clarifying a patient's vaccination status prior to PFT may provide some further information regarding COVID-19 transmission risk mitigation, even in up-to-date vaccinated patients, factors such as the timing of vaccination, the presence of any immunodeficiency and changing viral strains may influence the magnitude of this effect. Vaccination alone cannot eliminate the risk of viral transmission; hence, other risk mitigation strategies need to be in place.

Key messages

- All HCWs performing pulmonary function testing should have up-to-date vaccination status as per the appropriate current public health directives for HCW.
- While vaccination of both staff and patient may provide some reduction of the risk of viral transmission during PFT measurement, no vaccine is 100% effective, particularly with emerging COVID-19 strains, and the benefits may wane over time.
- Vaccination alone cannot eliminate the risk of viral transmission and vaccination status should not be used to modify PPE choice.

(Evidence level I; key message agreement 12/12 [100%])

Testing for SARS-CoV-2. Reverse transcription polymerase chain reaction (RT-PCR) is a laboratory technique that detects specific viral fragments and is considered to be the 'gold standard' for the diagnosis of COVID-19. The test is only performed in laboratory facilities. Routinely, results are

available within about 24 h, but longer durations (up to 4–5 days) have been seen during outbreaks with high levels of community testing. Viral fragments may be detected for some time following infection, resulting in positive PCR tests, although the individual may no longer be infectious.

Some facilities may have access to rapid PCR testing devices utilizing RT loop-mediated isothermal amplification (RT-LAMP) technology, with sensitivity close to PCR. Throughput is limited, but results can be available in 1–2 h. These devices have been deployed to more remote locations in Australia, and may also be available in some local pathology laboratories. This may be an option in some healthcare settings where testing is required urgently.

Lateral flow RATs are now readily available. Testing is undertaken at the point of care, and results are available after 15 min. RATs are not as sensitive as PCR, resulting in a narrower window for detecting the virus than PCR testing. RAT will detect virus when the patient is shedding most virus, that is, when they are at their most infectious.¹⁴⁸ However, a negative RAT does not exclude disease and hence should not be used to inform use of PPE.

Historically, public health authorities have insisted upon PCR testing to confirm COVID-19 infections. Where RAT testing was undertaken, it was a requirement that the results be confirmed by PCR testing. However, PCR testing capability was overwhelmed with the rapid spread of the Omicron variant and, with a high pre-test probability, the Australian Commonwealth Health Department recommended changes to testing.⁵⁴ Where an individual has symptoms consistent with COVID-19, then a positive RAT test is considered sufficient to confirm the diagnosis. A number of Australian jurisdictions have already adopted this approach.¹⁴⁹

Whilst all patients for PFTs should be questioned to identify and exclude those with active COVID-19 infection, in practice, those with relatively mild symptoms may nonetheless be present. In such cases, RAT may prove useful in identifying those who have COVID-19 infection. Testing may also prove useful in patients with chronic respiratory disease, where it might be difficult to otherwise distinguish between chronic symptoms and those of acute COVID-19 infection. Furthermore, there may be a role for RAT prior to some specific tests, such as CPET and bronchial provocation tests, where the generation of aerosols is greatest and/or inline filters may not be in use.

Key message

- While RT-PCR remains the gold standard for the diagnosis of COVID-19, RAT has been accepted as a valuable screening tool in addition to other controls, and targeted testing may be useful for identifying individuals who are likely to be infectious, for whom testing should be deferred. A negative RAT does not exclude disease and hence should not be used to inform use of PPE.

(Evidence level I; key message agreement 12/12 [100%])

Pre-test screening questionnaires. Questionnaires for pre-screening patients prior to appointment for (i) COVID-19 symptoms and recent COVID-19 infection, (ii) exposure history (including travel history) and (iii) vaccination status have been recommended by worldwide authorities.^{150–154} Questionnaires may be useful tools for identifying patients who are experiencing mild COVID-19 symptoms, have had a recent exposure or have recently had COVID-19 infection. A pre-screening questionnaire is however unlikely to prevent all potential COVID-19 exposures in the clinic in light of the variable nature of COVID-19 and the prevalence of asymptomatic infections.¹⁵⁵ Questionnaires may have useful positive predictive value (identifying symptomatic suspected patients), but will miss asymptomatic infection. Furthermore, patients may modify the truth of their symptoms or travel history to gain access to medical appointments.

While clarifying a patient's vaccination status prior to PFT may provide some further information regarding COVID-19 transmission risk and need for additional controls, vaccination alone cannot eliminate the risk of viral transmission (see also section *Vaccination* earlier in document).

Administration of questionnaires via telephone or email in the days (~72 h) prior to the clinic visit may be useful in identifying new symptoms or recent COVID-19 infection or exposure as a close contact (and allowing for rescheduling of the appointment). Scheduling of patients recently cleared from COVID-19 infection to separate them from other potentially immunocompromised patients or at the end of lists may be worthwhile. Repeating the questionnaire at the time of appointment will assist with collecting recent symptom and exposure information.

Key message

- Pre-screening questionnaires in the days prior to testing, and then again in person at the clinic visit, may add value to other mitigation strategies. Screening questionnaires should not be used to decide the level of PPE use.

(Evidence level III; key message agreement 12/12 [100%])

Changes to operational practices. During times of increased community prevalence of COVID-19, PFT capacity may be reduced for a number of logistical and infection prevention reasons including but not limited to reduced workforce due to furlough or redeployment of HCW, government

TABLE 5 Example of potential PFT triaging categories (after excluding current COVID-19)

Category	Timing	Examples
Clinically urgent	Tests that are required <i>within days/weeks</i> to allow urgent assessment or treatment to be undertaken Note: The TSANZ Laboratory Accreditation definition of urgent (test within two working days) differs to the definition provided in this COVID-19 guidance ⁷²	Assessment for lung resection suitability or other urgent pre-operative assessment Urgent diagnostic evaluation of respiratory symptoms Urgent evaluation of deterioration in known acute or chronic respiratory disease. Baseline assessment prior to commencement of drugs with potential pulmonary toxicity Baseline assessment prior to commencing work with a significant occupational asthma risk
Clinically essential	Tests that are required for imminent clinical evaluation, usually <i>within weeks/months</i>	Diagnostic evaluation of patients presenting with symptoms indicative of respiratory pathology Evaluation of the response to a change in treatment or intervention Evaluation of deteriorating respiratory symptoms or rapidly progressive disease Assessment and early follow-up for lung transplant or other significant intervention. Other transplant assessment and follow-up protocols (e.g., heart, bone marrow, stem cell, liver) Monitoring for pulmonary complications of treatments with potential pulmonary toxicity (e.g., chemotherapy agents)
Routine surveillance/monitoring/assessment	While exact date of testing may not be critical, it is suggested to perform testing <i>within 6 months of the requested time frame</i> Priority should be given to those with demonstrated disease who are being monitored for deterioration, over healthy subjects who are being monitored routinely	Monitoring for deterioration in known progressive lung disease (e.g., ILD, COPD) Monitoring for progression in known occupational lung disease Screening for occupational or other respiratory disease in asymptomatic cases To assist with confirming a clinical diagnosis in a currently stable patient

Abbreviations: COPD, chronic obstructive pulmonary disease; COVID-19, coronavirus disease 2019; ILD, interstitial lung disease; PFT, pulmonary function test; TSANZ, Thoracic Society of Australia and New Zealand.

directives to reduce non-urgent activity, maintaining density and distancing requirements and resting rooms between tests where ventilation is inadequate. While it may be possible in some settings to increase the hours of operation, access additional space or modify the PFT types performed to meet logistical and infection prevention requirements, triage of PFTs may be necessary.

Triaging PFT requests ensures that higher priority testing is expedited and more routine testing is deferred to more suitable periods (e.g., lower community prevalence, increased testing capability). In secondary and tertiary care settings, triaging of referrals can be time consuming and complex. Adequate clinical notes on PFT referrals, including the referrer's opinion of perceived urgency, may assist with expediting processing. In other settings, such as primary care, HCWs may need to allocate time to review clinical files and determine priority of patient testing.

Spirometry plays an integral role in evidence-based diagnostic and treatment pathways for respiratory disease in a variety of settings including hospital, specialist and primary care, and occupational health.^{156,157} Its use as part of robust assessment processes should not be altered based on infection control and prevention measures; however, testing should only be performed in the presence of a clear clinical indication.⁶⁷ Determining precise definitions of clinical suitability can be challenging. Table 5 outlines broad categories

that may assist with triaging and prioritization, with accompanying clinical case examples. Other similar guidelines offer other examples for triaging PFTs.^{50,74,86,89} Categorization of patients may change over time. For example, a patient identified with an occupational related lung disease undergoing surveillance testing may require 'clinically essential testing' if new or worsening symptoms occur.

Descriptors of urgency may also be dependent upon the clinical setting. For example, in primary care, commonly encountered priority cases might include patients:

- with a provisional diagnosis but poor response to treatment;
- with suspected (but unconfirmed) airways disease;
- with unexplained breathlessness; and/or
- who have commenced treatment for a presumptive diagnosis but require diagnosis confirmation.

Key message

- Triage of PFT requests and other operational changes may be required during periods of high community prevalence of COVID-19 to meet logistical and infection prevention and control requirements.

(Evidence level III; key message agreement 12/12 [100%])

Personal protective controls

Personal protective controls, such as hand hygiene and use of PPE, are not only equipment dependent, but also depend on compliance and correct application of controls. Training and education in hand hygiene, the proper selection, limitations and use of PPE (including fit testing of respirators) and optimization of compliance through risk management systems is essential.

Hand hygiene. Hand hygiene is the cornerstone of effective infection prevention and control. Hands are known to cause cross-transmission of microbial pathogens in health care.^{158,159} WHO has highlighted the need for good hand hygiene in health care, as it is shown to decrease pathogens on the hand.¹⁶⁰ High levels of hand hygiene compliance are required for effective infection prevention and control, hence good clinical practice includes education and monitoring of adherence to good hand hygiene practice. Hand Hygiene Australia (www.hha.org.au) commenced a nationwide campaign (National Hand Hygiene Initiative) in 2009, which was shown to significantly improve compliance of good hand hygiene practice.¹⁶¹ Detailed information regarding good hand hygiene practice is available from the Australian Commission on Safety and Quality in Healthcare, and the Health Quality and Safety Commission New Zealand.¹⁶²⁻¹⁶⁴

Eyewear. Eyewear which includes goggles and face shields form an important part of standard infection prevention precautions. Eyewear is used to protect the HCW from splashes and sprays from blood or other body substances, but can also reduce pathogen exposure to mucous membranes (mouth, nose and eyes) and where skin integrity is compromised (e.g., acne and dermatitis).¹²⁹

Whilst more robust trials are required to determine the effectiveness of eye protection, the current observational evidence suggests a protective effect when eye protection is used in conjunction with masks.¹⁶⁵ The Australian National COVID-19 Clinical Evidence Taskforce found insufficient evidence to develop evidence-based recommendations about eye protection; however, they made consensus recommendations for using eyewear when undertaking direct care of patients with COVID-19, suspected of having COVID-19 or asymptomatic with other risk factors for COVID-19.¹⁵

The working group took a precautionary approach in light of the evidence gap reported by National COVID-19 Clinical Evidence Taskforce, droplet and aerosol generation resulting from PFTs (manoeuvre or associated cough) and the close proximity of HCW to patients, and suggest use of eyewear while performing PFTs.

Gowns and gloves. Gowns (including aprons) and gloves are used to protect HCWs from contaminations to skin, uniforms or other clothing. The type of gown (or apron) and gloves worn should be determined based on the degree of risk. It is recommended that in a clinical setting a fluid impervious gown (or apron) should be used, whilst non-sterile gloves are adequate against exposure to blood or other body substances (e.g., droplets from cough, sputum) and are an essential part of standard infection prevention precautions. Whilst direct empirical evidence is limited, there is a strong theoretical rationale for the use of gowns and gloves of which the benefits of their use outweigh any undesirable effects.¹²⁹ Gloves do not replace the need for hand hygiene. There is a risk of cross-contamination via contaminated gloved hands if used inappropriately and use should be limited to possible contact with bodily fluids.¹⁶⁶

The National COVID-19 Clinical Evidence Taskforce provides no recommendations on use of gloves and gowns in minimizing SARS-CoV-2.

Masks/respirators. Face masks (face coverings that cover the nose and mouth to protect mucous membranes) have been widely promoted as a way of mitigating SARS-CoV-2 transmission in community settings during the COVID-19 pandemic. The protective factor of face masks varies according to the adequacy of mask fit, the materials used and whether the wearer carries the infection or is protecting against infection.^{167,168}

In healthcare settings, surgical masks are used for droplet precautions to mitigate the risk against respiratory droplet transmissible diseases,¹²⁹ but are not intended to protect the wearer from infectious aerosols. P2 (N95) respirators are recommended for use to mitigate the risk against aerosol transmissible diseases.¹²⁹

The evidence for use of P2 (N95) respirators to reduce transmission for aerosol transmissible infections is limited. A study in hospital-based HCWs found continuous use of N95 respirators in HCW compared to surgical mask use or targeted intermittent use of N95 respirators during high-risk procedures or barrier nursing resulted in lower levels of respiratory illness and lower rates of bacterial colonization in HCWs.¹⁶⁹ A couple of reviews suggest facemask use may result in a reduction of risk of SARS-CoV-2 or other coronavirus infection, with N95 respirators or equivalent having stronger associations than surgical masks in one study.^{35,170} Conversely, a more recent review comparing the effectiveness of P2 respirators and surgical masks in preventing SARS-CoV-2 infection found insufficient epidemiological evidence to reach a conclusion.¹⁷¹ Similarly, the Australian National COVID-19 Clinical Evidence Taskforce found limited epidemiological evidence around the effectiveness of various types of face masks/respirators in protecting HCW from COVID-19 or similar viruses.¹⁵

Despite the limited direct evidence, the Australian National COVID-19 Clinical Evidence Taskforce do recommend the use of P2 masks for HCWs where there is a likely high risk of transmission of SARS-CoV-2.

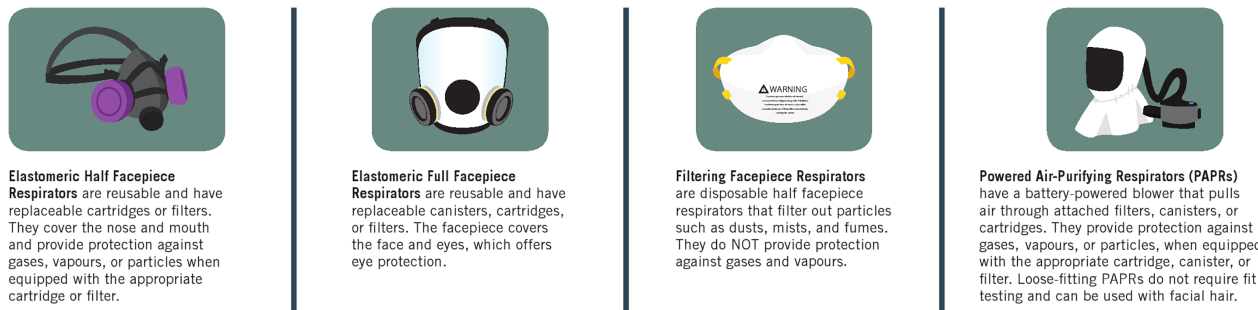


FIGURE 2 Types of respiratory protection (reproduced with permission¹⁷³)

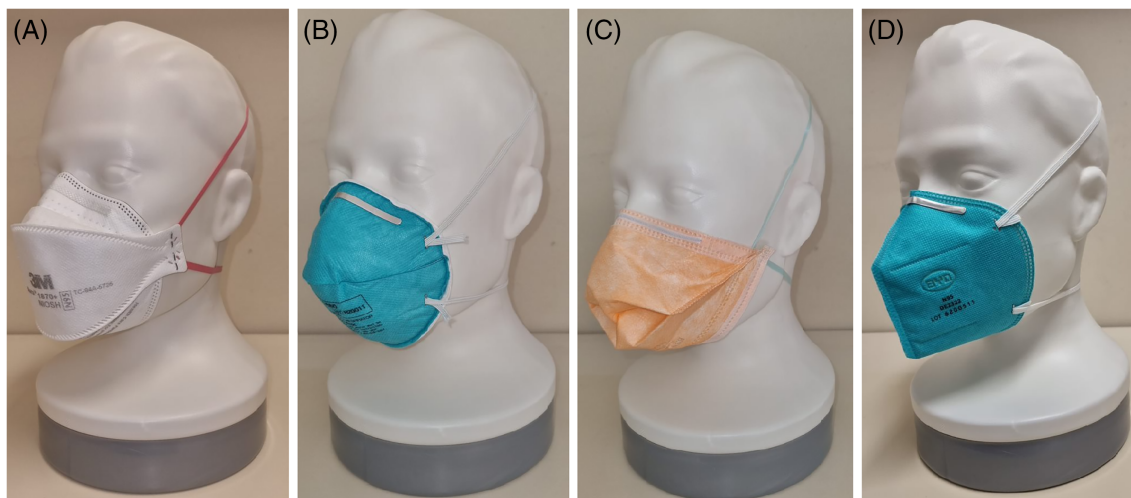


FIGURE 3 Different styles of disposable filtering face piece respirators. Styles shown above: (A) tri-fold, (B) cup, (C) duckbill and (D) flatfold

In coming to a recommendation on mask or respirator use for HCWs performing PFTs, the working group took a precautionary approach. Based on the limited evidence available, acceptance of the WHO and CDC position that SARS-CoV-2 is transmitted via droplets and aerosols, the evidence for increased aerosol generation resulting from PFTs (manoeuvres and associated cough) and the recommendations of the National COVID-19 Clinical Evidence Taskforce, it is recommended that, at a minimum, P2 respirators should be worn by HCW in areas where PFTs are being performed. This recommendation is consistent with other professional body advice and a recent international consensus document.^{50,73,74,84}

Respirators: Particulate filter respirators (respirators) are specifically designed to be tight-fitting to ensure all inhaled air passes through the filter. To be designated as respirators, they must meet the Australian and New Zealand Standard for respiratory protective devices (AS/NZS 1716:2012)^{*} which includes being secured via a head harness (i.e., not via ear loops) as their performance is determined by the ability to maintain a good seal between the respirator and face.¹⁷²

Although various types of respiratory protection are available for filtering particulates, gases and vapours (Figure 2), disposable filtering facepiece respirators (disposable respirators) are predominantly used in health care in Australia and New Zealand. Disposable respirators overcome challenges associated with reprocessing reusable items and are easily applied and removed. Various types of disposable respirators are available (cost range approximately AUD\$4–10) and are shown in Figure 3.

The Australian and New Zealand Standard (AS/NZS 1716:2012; see footnote^{*})¹⁷⁴ identifies the filtration level of disposable respirators with the prefix P followed by a number for the level of filtration for respirable particulates (e.g., P2 ≥ 94% efficiency to particles down to 0.3 μm). The Australian standard for single-use face masks in health care (AS 4381:2015) identifies the level of fluid resistance, the higher the number the higher the resistance to fluid penetration.¹⁷⁴

In Australia and New Zealand, P2 disposable respirators are recommended for HCW when working in high-risk areas.¹⁷⁵ Other respirators, such as an P3/N99 (99% filtration efficiency), Elastomeric (full or half) face piece respirators or powered air-purifying respirators, offer higher filtration efficiencies and may be appropriate for use in some settings.

^{*}AS/NZS 1715 and 1716 are in transition to AS ISO 16972 and AS ISO 16975 at the time of writing.

TABLE 6 Jurisdictional standards and markings for disposable respirator

Product type/class	Jurisdiction	Relevant standard	Relevant markings
P2	Australia and New Zealand	AS/NZS 1716:2012	Manufacturer's name, trade name or mark Filter class (e.g., P1 or P2) Reference to the standard AS/NZS:1716
N95	United States	NIOSH-42CFR84	Manufacturer's name or trademark The NIOSH name or NIOSH logo Filter class (e.g., N95) Model number NIOSH approval number—starting with TC-
FFP2	Europe	EN 149-2001	Manufacturer's name or logo Reference the standard EN149:2001 Manufacturer model number Filtering class (e.g., FFP2) NR if non-reusable European certification mark CE The notified body is responsible for the certification
KN95 ^a	China	GB 2626-2019	Manufacturer's name or trademark Reference the standard GB2626-2019 Filter class (e.g., KN95)

Abbreviations: AS/NZS, Australian/New Zealand Standard; CE, Conformité Européenne (CE) Mark; NIOSH, National Institute for Occupational Safety and Health; NR, non-reusable; TC, testing and certification (TC) approval number.

^aNot currently recommended for use in Australia and New Zealand.

When sourcing a P2 disposable respirator, they should meet the Australian and New Zealand Standard (AS/NZS 1716:2012) for respiratory protection. With the worldwide demand for respirators causing shortages, disposable respirators which meet other similar standards may be adopted, these include N95 (United States) and FFP2 (Europe) as they all offer similar protection with efficiencies $\geq 94\%$ – 95% . Although KN95 (China) also state efficiencies $\geq 94\%$ – 95% , they are not recommended for use in Australian or New Zealand workplaces.¹⁷²

Authentic disposable respirators are required to be marked with the standard to which they conform—beware of counterfeits.^{172,176–178} For a P2 disposable respirator, this should include manufacturer's name, the filter classification (i.e., P2) and the standard (i.e., AS/NZS 1716). For disposable respirators meeting the similar standards, they should also include similar information (see Table 6).

Careful inspection of specific respirator features is recommended as some adaptations may affect suitability for specific healthcare contexts. For example, respirators with exhalation valves can reduce expiratory resistance to promote better user comfort. This feature retains protective effectiveness to the wearer but does not offer protection against expired particles. Such respirator features should therefore not be used in healthcare settings by people with suspected or confirmed COVID-19.

For respiratory protection, respirator fit testing to ensure good face seal is mandatory (see *Respiratory protection programme* below). Furthermore, instruction in their use and fit checking prior to each use is essential.

Respiratory protection programme: The Australian and New Zealand standard Selection, Use and Maintenance of Respiratory Protective Equipment (AS/NZS 1715:2009; see footnote*) mandates fit testing of HCWs using respirators.¹⁷⁹ Despite this, the importance of a robust respiratory

protection programme (RPP) for HCWs has really only become apparent with the onset of the COVID-19 pandemic.

An RPP should include a medical evaluation and education/training in identifying hazards, the various types of respiratory PPE, the importance of selecting proper fitting PPE and demonstration of how PPE is applied and removed. It is important that HCWs also understand the limitations of PPE.¹⁸⁰ Education should include the impact of facial hair and heavy make-up on mask seal effectiveness. HCWs should receive ongoing training and assessment for competency in respirator use.

Fit testing of respirators is a mandatory component of the RPP and is used to ensure that an adequate face seal is achieved and the wearer is properly fitted.^{129,179,181} Access to testing may be difficult due to the need for specialist equipment, trained operators and extensive resources. This does not however diminish the need for all HCWs using respirators to be fit tested. Fit testing respirators can be performed using qualitative and quantitative methods. The quantitative fit test method is most commonly used and is performed according to recognized standards.^{179,182} Testing multiple respirators is advisable to mitigate the risk of supply chain issues and to ensure comfort, personal preference and the ability to rotate respirators to minimize pressure injuries. Repeat fit testing must be performed periodically to review fit in case of significant changes to wearer's facial characteristics (e.g., body weight changes).¹²⁹

User fit-checks are self-tests that aim to ensure a good respirator seal without evidence of leaks.¹²⁹ As there is no guarantee that a respirator will not leak, HCWs must perform self-fit checks with each respirator application. This is regardless of whether a specific mask has been previously approved for an individual's use via fit testing.¹⁸³ The

*AS/NZS 1715 and 1716 are in transition to AS ISO 16972 and AS ISO 16975 at time of writing.

Australian Guidelines for the Prevention and Control of Infection in Healthcare state no clinical activity should be undertaken until a satisfactory fit has been achieved.¹²⁹

Key messages

- At a minimum, P2 respirators and eye protection should be worn by HCWs in areas where PFTs are performed.
- Training and education in proper selection, limitations and use of PPE, including respirators, is essential.
- All HCWs wearing respirators must be fit tested to ensure good fit and seal.
- Fit checking of respirators with each use is essential.
- Respirators must have regulatory approval.
- All HCWs must be trained in and undertake good hand hygiene practice.
- Gloves and gowns should be worn when the risk of exposure to bodily fluids is anticipated to be likely.

(Evidence level II; key message agreement 12/12 [100%])

CONCLUSION

PFTs form an essential component of clinical management and decision-making across many clinical settings. The COVID-19 pandemic has brought to light the exposure risk for HCWs, patients and visitors interacting with the pulmonary function testing space with respect to droplet and aerosol transmissible disease. With suitable controls in place, pulmonary function testing should be able to be performed safely while SARS-CoV-2 is active in the community. It is possible that some permanent changes in pulmonary function testing practices (e.g., ventilation controls) may occur as a result of the COVID-19 pandemic. While this position statement has been contextualized to the SARS-CoV-2 pandemic, the working group strongly advocates that any changes to clinical/laboratory practice made in the interest of optimizing the safety and well-being of HCWs and patients involved in pulmonary function testing are carefully considered in light of their likely suitability for ongoing use to reduce the potential transmission of other airborne (droplet and aerosol) diseases. The working group acknowledge this potential for future application was, however, beyond the mandate of the present position statement.

ACKNOWLEDGEMENT

Open access publishing facilitated by Monash University, as part of the Wiley - Monash University agreement via the Council of Australian University Librarians.

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CONFLICTS OF INTEREST

Brigitte M. Borg is a current TSANZ Victorian Branch Executive Member. Christian Osadnik reports grant funding from RACGP, Rebecca L Cooper Medical Research Foundation, PRF Pat Cosh Trust Fund and GSK Australia, as well as speaker fees from Novartis Australia, all unrelated to the present work. Keith Adam reports payment for expert

testimony unrelated to this work. Vanda Glavas reports funding from Respiratory SA unrelated to this work and is the current ANZSRS Regional Chair SA/NT. Kerry Hancock reports personal fees from Chandlers Hill Surgery and Spirometry Learning Australia outside the submitted work; personal fees and non-financial support from Astra Zeneca, GSK, Novartis, Chiesi, Boehringer Ingelheim, Novartis and Cipla outside the submitted work; personal fees from Asthma Australia, National Asthma Council, Lung Foundation Australia and Optimum Patient Care Australia outside the submitted work; and royalties from Medicine Today Pty Ltd outside the submitted work. Celia J. Lanteri reports receiving speaker fees from Astra Zeneca, Boehringer Ingelheim and GSK for educational presentations unrelated to this work. Ewan G. Morris is a current Clinical Physiologists Registration Board (NZ) board member. Elena K. Schneider-Futschik reports funding from NHMRC, Cystic Fibrosis Australia and TSANZ unrelated to this work. The other authors have nothing to disclose.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analysed in this study.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Borg BM, Osadnik C, Adam K, Chapman DG, Farrow CE, Glavas V, et al. Pulmonary function testing during SARS-CoV-2: An ANZSRS/TSANZ position statement. *Respirology.* 2022;27(9):688–719. <https://doi.org/10.1111/resp.14340>