Recommendations for the Performance of Sleep Studies in Australia and New Zealand during Periods of High Community Transmission of COVID-19

Approved by ASA Board 14 February 2022

Executive Summary

SARS-CoV-2, the causative agent of the COVID-19 pandemic, is a highly transmissible respiratory coronavirus, responsible for the widespread prevalence of COVID-19 in communities worldwide and a significant cause of workplace infection of healthcare workers in Australasia since early 2020. In balancing the importance of maintaining patient access to timely diagnostic and treatment sleep studies, with the need to minimise the risk of COVID-19 to staff and patients in sleep laboratories, the Australasian Sleep Association has created a series of recommendations, to assist services in mitigating COVID-19 risk in sleep services. These recommendations assess risks in different scenarios and advise on hazard reduction, aiming to complement overarching government and institutional guidelines on risk mitigation, particularly during periods of high community transmission of COVID-19.

General Recommendations

General recommendations for the performance of sleep studies are presented in the format from the Australian Government publication *Minimising the risk of infectious respiratory disease transmission in the context of COVID-19: The hierarchy of controls. July 2021*[1] which outlines a hierarchy of risk mitigation strategies for COVID-19 transmission based on control measures first adopted by Safe Work Australia. The hierarchy consists of five hazard control measures and lists avoidance and mitigation strategies in decreasing order of effectiveness and reliability.

Individual facilities must comply with their respective state legislation and health department/health service directives. Where the following recommendations differ from such directives, the requirements of the respective state or health service should be followed. Similarly, respective facilities' infection control policies should be followed where there are differences to the following recommendations.

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Category	Control Measures (from Source Document [1])	Recommendations
Elimination	Physically Remove the Hazard	
Reduce opportunities for the virus to enter the facility	Do not admit SARS-CoV-2-positive patients to hospital unless clinically necessary	
	Limit the number of patients or residents going to the facility	
	Proactively detect and prevent entry to the facility of potentially infectious people	*The US Centre for Disease Control (CDC and American Academy of Sleep Medicine (AASM)) recommends screening of patients for symptoms consistent with COVID-19 or exposure to others with COVID-19 prior to entering healthcare facilities. Patients should be advised to reschedule their appointment if they subsequently develop symptoms of COVID-19. Summary of CDC recommendations during COVID-19 | Sleep Medicine (aasm.org)* 1. All patients and attending carers should be screened for <u>symptoms</u> of COVID-19 in the 24 hr period preceding a sleep study. *The CDC advises that screening for asymptomatic or pre-symptomatic COVID infection with PCR or Rapid Antigen Tests <u>might</u> be used, depending on local government policy and testing availability.* 2. Facilities can consider screening of patients before a diagnostic sleep study with Rapid Antigen Tests. Patients should be screened with a Rapid Antigen Test before a positive airway pressure study is performed. (See below).
	Reduce the number of visitors and non-essential staff	3. Adult patients should be advised to attend their sleep study alone. Others including family members or carers should only attend if direct care is required that cannot be provided by laboratory staff. 4. Interpreters, where required, must use appropriate PPE. Alternatively, facilities could explore the use of telephone interpreters to assist in the set up and conduct of a sleep study.
Substitution	Replace the Hazard	
Find other ways to provide care that will reduce the potential for transmission	Plan for alternatives to aerosol-generating procedures.	5. Consider alternative approaches to laboratory diagnostic sleep studies (home studies, simplified diagnosis such as oximetry when appropriate). 6. Consider alternative models of care for treatment sleep studies (such as autotitrating PAP, addition of oximetry modules to devices at home).
Engineering Controls	Isolate people from the hazard	
Use physical barriers and other forms of hazard reduction.	Review and optimise ventilation and air quality including: • Air exchange rates • Airflow and air filtration systems • Temperature • Ambient humidity	7. Services should be aware of air exchange rates in study rooms to calculate the time to rest the room between patients.

Category	Control Measures (from Source Document [1])	Recommendations
	Use negative pressure rooms for suspected or confirmed COVID	8. Patients with suspected or confirmed COVID should not have laboratory sleep studies until they are non-infectious (as defined by government policy).
	Consider safe, temporary barriers to direct people into chosen areas	9. Services should have means of controlling patient flow through their facilities to reduce the risk of viral transmission. For example, dedicated "in" and "out" routes should be used where possible.
	Redesign work areas to limit number of workers at workstations	10. Facilities should consider alternative working arrangements for staff including staggered shifts or working from home arrangements. 11. Facilities must ensure that the work environment allows adequate physical distancing between staff members. 12. Avoid close contact between staff away from the workstation. For example, staff tea-rooms must not be used if physical distancing is not possible. 13. During times of very high community transmission consider separating staff to teams working in different areas or at different times.
	Place physical barriers such as glass or plastic screens in reception areas where physical distancing is difficult to maintain.	*There are limited data on the effectiveness of screens and barriers at reducing transmission of infection. Physical barriers probably reduce exposure to larger aerosols and droplets but are unlikely to reduce exposure to smaller aerosols and may increase aerosol transmission due to effects on airflow patterns.* [2] 14. Services should consider the need for physical barriers depending on the physical layout, airflow patterns and the type of interactions within the environment.
Administrative Controls	Change the Way People Work	
Effective and consistent implementation of policies and protocols	Set up clear lines of governance. Assign a lead with overall responsibility for: • Task analysis • Risk assessments • Ventilation assessments/monitoring air quality • Infection control strategies • Promoting hand hygiene.	15. Services must clearly designate a senior staff member responsible for overall risk assessment, developing/initiating infection control procedures consistent with national and regional legislative requirements and maintaining up to date knowledge in current expert guidelines.
	Ensure evidence-based infection control policies are in line with national guidance.	
	Ensure staff training and competency in precautions	16. All staff working within clinical areas must be competent in infection control techniques
	Encourage staff not to attend if unwell	17. Services must reinforce to all staff not to attend work even if mildly unwell.
	Discourage staff from working across multiple facilities	18. Services should actively discourage working across multiple facilities and, in the care of services with satellite sites, should roster staff accordingly to avoid working across different sites.
	Consider surveillance testing of asymptomatic staff	
Minimise opportunities for infection transmission	Reduce opportunities for transmission between staff by promoting use of telehealth technology for staff meetings	19. Staff educational and business meetings should utilise videoconferencing technology to avoid groups in single rooms. Where in-person meetings are essential, all participants must exercise appropriate physical distancing and utilise appropriate PPE.
	Ensure patients and support people comply with hand hygiene and PPE requirements.	20. Services should actively promote basic hygiene and, where appropriate, PPE use to patients in instructions to patients before undergoing sleep studies. Visual reinforcement of these techniques, such as posters, should also be prominently displayed within the facility.

Category	Control Measures (from Source Document [1])	Recommendations
	Educate patients on safe mask use and disposal	21. Services should provide verbal instructions to patients about safe mask use reinforced by visual aids such as posters. Patients must be advised on appropriate handling and disposal of masks during the period in the sleep laboratory.
	Ensure patients remain in their allocated room and practice physical distancing.	22. Patients undergoing sleep studies should not mingle with other patients to reduce the risk of cross transmission. Where possible, patients should remain within the study room for the duration of the study period.
	Manage workspaces to reduce respiratory transmission by adopting measures that improve physical distancing eg floor markings, spaced sitting, maximum room occupancy signs.	23. Facilities must clearly display reminders on safe occupancy levels and distancing for both patients and staff.
	Ensure sufficient hand hygiene products and facilities available.	24. Services must have readily accessible and highly visible access to hand hygiene products for both staff and patients.
	Set up a plan to manage a facility outbreak.	
	Use standardised infection control signage.	
Maintain staff wellbeing	Have enough staff to avoid excessive workloads and ensure that staff can take regular breaks.	25. Services must actively monitor staff workloads and both the impact of increased duties due to COVID and reduced staffing levels due to illness, quarantine or redeployment to other frontline services. Staff should not be expected to work additional shifts to maintain service activity.
	Assess staff vulnerability to COVID-19 infection and redeploy if needed.	26. Services must identify staff who are more vulnerable to acquiring COVID-19 or more vulnerable for severe disease. Individual strategies must be developed for each staff member to manage these risks.
	Develop a policy to manage staff who become unwell in the workplace	27. An accessible and clear policy must be developed to manage staff who develop symptoms/illness including a clear pathway for testing and clear instructions on when return to work would be appropriate.
	Ensure all staff are vaccinated.	28. All staff within the service, including support staff, must be vaccinated in accordance with Commonwealth or State recommendations unless there are recognised medical contraindications to vaccination. In this case, redeployment to other areas should be considered.
	Provide an employee assistance program that provides psychological support.	29. Facilities must be familiar with available employee assistance programs/counselling services either within the overarching organisation or in the community.
Personal Protective Equipment	Protect the Worker	
Review PPE policies and guidelines	Train staff in PPE usage including donning and doffing competency.	30. All staff must be trained and have competency maintained in PPE procedures including donning and doffing.
	Have PPE available at the point of use.	31. Appropriate PPE must be available within the sleep laboratory to meet the infection control requirements.
Set up a respiratory protection program	Fit test staff who require a particulate filter (N95) respirator.	*The National COVID-19 Clinical Evidence Taskforce [3,4] recommends wearing of a face mask and specifically a N95-type respirator and eye protection where there is prevalent community transmission, there is close or extended face-to-face exposure, the physical environment is in an enclosed space or with respiratory procedures which may result in aerosolization or particles. The taskforce also recommends mask fit testing and perform a seal check each time the mask is applied. The US Centers for Disease Control (CDC) [5] also recommends use of a N95-type respirator and eye protection during aerosol-generating procedures when there is community transmission of COVID-19. The CDC recommends annual mask fit testing.*
	Train staff to perform a fit (seal) check each time a N95 respirator is used.	
	Emphasise the importance of eye protection.	

Category	Control Measures (from Source Document [1])	Recommendations
		32. The ASA recommends PPE including N95-type respirators and eye protection be used during all patient encounters at this time (February 2022) considering the high community transmission of COVID-19 and the close, often prolonged face-to face exposures which occur during a sleep study.
	Consider use of a powered air purifying respirator Ensure staff are trained and competent to use air purifying equipment if available.	*The CDC recommends "exploring options to improve indoor air quality in all shared spaces…and to consider the addition of portable solutions to augment air quality."(Infection Control: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) | CDC)* 33. *There is emerging evidence that use of PPE including with N95-type respirator and the addition of improved ventilation with a High Efficiency Particulate Air (HEPA) filter significantly reduces skin contamination with aerosolised virus, compared to use of PPE alone.* [2] *HEPA filtration can either be applied at "point of emission" (e.g. inside a hood with the patient) or more practically, in the room itself .* [6,7] *The minimal effective filtration rate is unknown and varies according to room size. Higher filtration rates are noisier. Machine choice therefore will vary according to a balance of filtration rate, room size and machine noise.* Sleep services should understand the ventilation systems in use in sleep study rooms and consider the addition of portable HEPA filters, particularly for PAP studies. The choice of HEPA filter will depend on a balance between filtration rate, room size and machine noise.

Laboratory Positive Airway Pressure Sleep Studies

CPAP and bilevel ventilation are regarded as "aerosol-generating procedures". Virus transmission can occur by either droplet formation (larger particles that deposit closer to the source) or aerosols (small droplets that remain suspended in the air longer). There are both benchtop and clinical data supporting the potential for transmission of infectious particles with noninvasive ventilation first described at the time of the SARS epidemic almost 20 years ago. [8] As a result, many sleep laboratories in Australasia and across the world have suspended sleep studies involving positive airway pressure therapy. The concern arises from the design of CPAP circuits. CPAP circuits in common use are single limb circuits with venting of air directly into the environment from an expiratory port or vent in or near the mask. The flow rate of air vented from the circuit is dependent of the pressure setting of the device and the mask fit. An Australian study has shown that unintended mask leak at levels equivalent to the leak from a standard vented masks is a source of viral environmental contamination. [7] Despite the risk of increased environmental contamination with infectious particles, CPAP is recommended in the acute treatment for hypoxaemic respiratory failure due to COVID-19 pneumonitis, where non-vented masks and expiratory viral filters are used.

There are no direct data addressing the risk of environmental contamination and nosocomial infection in the context of a PAP sleep study. It is difficult to extrapolate data from studies of CPAP therapy in COVID-19 pneumonitis due to the widespread use of non-vented interfaces and expiratory microbial filters. A recent UK small, multicentre study [9] in hypoxaemic respiratory failure due to SARS-Cov-2 virus demonstrated that CPAP did not increase air or surface contamination compared to high flow nasal oxygen (HFNO) or standard oxygen therapy. However, the CPAP circuits in this study used filters between the mask and expiratory vent and not conventional (vented) masks which are the standard of practice in the sleep laboratory. These results are consistent with studies in healthy individuals [10-12] that demonstrated no significant increase in environmental contamination with positive airway pressure therapy. However, again, these studies do not reflect the real-world sleep laboratory practice. Most of these studies used non-vented masks and expiratory microbial filters and the one study [12] where expiratory filters were not used was conducted in a negative pressure room with HEPA filtration. At this time, the risk to the healthcare worker from environmental contamination during a laboratory PAP sleep study is unknown.

Recommendations

34. Alternative approaches to both treatment initiation and treatment effectiveness studies should be considered during high community COVID-19 transmission before performing a laboratory positive airway pressure sleep study, including home APAP trials, home fixed pressure assessment (with analysis of device derived data) and home oximetry.
35. Services should consider resumption of laboratory positive airway pressure studies where unattended options are not suitable and adequate staff numbers and expertise is available.
36. All patients must be screened for symptoms of or exposure to COVID-19 in the 24 hours before the study and must have a negative COVID-19 test (Rapid Antigen Test or PCR) in the 48 hours before the study to screen for asymptomatic or pre-symptomatic COVID-19.
37. All laboratory staff must utilise adequate PPE including N95-type respirators and eye protection.
38. Laboratory studies must consider the aerosolisation potential of the circuits and interfaces used. Services could consider utilising circuits with both inspiratory (between device and tubing) and expiratory (between non-vented mask and expiratory port) bacterial filters during periods of high

COVID-19 community transmission but must take into account the effect of increased deadspace and/or increased circuit resistance on the individual patient.

39. The service must understand the ventilation systems of the study room, especially the air exchange rates, and use this to determine the period when PPE is required by staff and before other patients can enter the room (Table 1). Where possible, the ventilation to the study room should be engineered to at least 12 air changes per hour. [13] Confirmation of adequate room ventilation may be assessed with the use of non-dispersive infrared CO_2 monitors, aiming for a consistent CO_2 level below 800ppm. [14] Where this cannot be achieved, the service should consider the use of a portable air cleaner with HEPA filtration to filter the volume of air in the room required to compensate for lower the room air exchange rate. [6,13]

TABLE 1. Air changes/hour (ACH) and time required for airborne-contaminant removal efficiencies of 99% and 99.9%

ACH	Time (min) required for removal efficiency of 99%	Time (min) required for removal efficiency of 99.9%
2*†	138	207
4	69	104
6	**46**	**69**
8	35	52
10	28	41
12	23	35
15	**18**	**28**
20	14	21
50	6	8

Sources: CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care facilities. MMWR 1994;43(No. RR-13).

Cleaning and Disinfection of Positive Airway Pressure Devices

The CDC recommends that the routine cleaning and disinfection procedures for respiratory devices (pre-cleaning of surfaces with detergents then applying hospital grade disinfectant to surfaces for the appropriate contact period in accordance with the manufacturer's instructions) are appropriate with COVID-19 even in areas where aerosol-generating procedures are performed. This is also the recommendation of the World Health Organisation (WHO) who developed a specific procedure for the cleaning and disinfection of CPAP and bilevel devices (see Figure 1). [15]

Figure 1. Care, cleaning and disinfection of BiPAP/CPAP devices.

Checklists for care, cleaning, disinfection and sterilization of respiratory devices (who.int)

BETWEEN PATIENTS

After each patient use, the BiPAP/CPAP must be cleaned, disinfected, and stored appropriately in a clean environment before use on another patient

	Task	Description
1.	Perform risk assessment prior to entering the room	Consider the patient care tasks that will need to be performed or additional risks during disconnection of the device.
2.	Perform hand hygiene	
3.	Don appropriate personal protective equipment (PPE)	PPE worn during disinfectant preparation should include surgical mask/ respirator, goggles or face shield, long-sleeved fluid resistant gown or gown + apron, rubber gloves, and boots or closed work shoes.
4.	Disconnect the device.	Turn off the device and disconnect from the patient, oxygen source and the power.
5.	Dispose of single use tubing, interface and filters in designated waste containers	If patient is being permanently disconnected from BiPAP/CPAP device, dispose of single use tubing, interface, and exhalation valve filters in designated infectious material/biohazardous waste container.
6.	Move the device to a well-ventilated area for cleaning	Move the BiPAP/CPAP device away from patients and other equipment to a designated well-ventilated space where cleaning and disinfection of the device can be performed.
7.	Change gloves	**Discard gloves** in appropriate waste container, perform hand hygiene, and don new gloves.
8.	Wash humidifier	Wash the humidifier in warm water using a mild detergent. Rinse the humidifier thoroughly and allow to air dry completely.
9.	Wipe with detergent and clean water from top-to-bottom with detergent (Cleaning)	Wipe the exterior of the device from top to bottom weekly and between patients with a damp cloth or disposable wipe soaked in detergent and clean water and then wipe off any remaining detergent residue with a dry lint-free cloth. Use mechanical action (scrubbing) and brushing, if necessary, along the edges and joints to remove visible dirt deposits and calcifications.
10.	Prepare disinfectant solutions	Should always be performed before use, in well-ventilated areas away from patients.
11.	Wipe with disinfectant	Prepare a fresh cloth or disposable wipe soaked in a compatible disinfectant. Wipe the device from top to bottom, ensuring surfaces of sensors/cables are wiped while avoiding contact with electrical connectors. **0.1% sodium hypochlorite (1000 ppm)** should only be used according to the manufacturer's instructions if device is known to withstand use of chlorine-based agents and no ammonia-based cleaning agents or acidic body fluids (e.g. urine) are present on the device. Do not use different disinfectant formulations during the same disinfection step, this may produce toxic fumes.
12.	Remove PPE- wash hands	Doff and discard PPE and perform hand hygiene.
13.	Store clean BiPAP /CPAP and disinfect before new use	Ensure cleaned BiPAP/CPAP device is stored in an area where there is low risk of contamination between uses, or that at least 1 minute of contact time has elapsed after the application of the chosen disinfectant (or as specified by the manufacturer) before ventilator device is used on a patient.

The CDC recommends single-patient use only consumables where possible (including disposable tubing and interfaces).

Recommendations

40. Single-patient use circuits and other consumables should be used wherever possible.

41. Routine cleaning and disinfection processes are sufficient for multi-patient use equipment and positive airway pressure devices even with confirmed COVID-19 infections. Special or more intensive equipment cleaning protocols are not required.
42. Refer to the manufacturer's guide for disinfection agents suitable for the specific positive airway pressure device.
43. Staff performing the cleaning and disinfection of equipment must wear appropriate PPE including N95-type masks and eye protection.
44. The WHO checklist for care, cleaning and disinfection of BiPAP/CPAP devices is recommended. Checklists for care, cleaning, disinfection and sterilization of respiratory devices (who.int)

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