Coronavirus Disease 2019 (COVID-19)
CDNA National Guidelines for Public Health Units

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This document summarises recommendations for surveillance, infection control, laboratory testing and contact management for coronavirus disease 2019 (COVID-19). CDNA will review and update these recommendations as required as new information becomes available on COVID-19 and the situation in Australia. These Guidelines will be updated regularly.

Readers should not rely solely on the information contained within these Guidelines. Guideline information is not intended to be a substitute for advice from other relevant sources including, but not limited to, the advice from a public health specialist or other health professional. Clinical judgement and discretion may be required in the interpretation and application of these guidelines.

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Abbreviations and definitions


SARS-CoV-2: Severe acute respiratory syndrome coronavirus 2. The formal name of the coronavirus that causes COVID-19, as determined by the International Committee on Taxonomy of Viruses. Previously, this coronavirus was commonly known as 'novel coronavirus 2019 (2019-nCoV)'. For more information, refer to the International Committee on Taxonomy of Viruses manuscript: (https://www.biorxiv.org/content/10.1101/2020.02.07.937862v1.full.pdf)
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1. Summary

Public health priority

Urgent – public health responses should be initiated as soon as possible.

Case management

All confirmed and probable cases must be isolated until they meet the appropriate release from isolation criteria. Cases should only be managed at home or in other community settings if the home environment permits separation of the case from other household members and following implementation of appropriate infection control measures and risk counselling.

Hospitalised patients should be isolated in a single room, a designated COVID-19 ward or, if symptoms are severe and, where available, in a negative pressure room. Clinical staff should use contact and droplet precautions for routine care of patients with confirmed, probable or suspected COVID-19. Where staff are performing aerosol-generating procedures, they should use contact and airborne precautions.

Contact management

Close contacts of confirmed and probable cases should be advised to quarantine for 14 days following last close contact with the case during the case’s infectious period. Close contacts should be actively monitored for development of fever or respiratory symptoms during this period, where feasible.

2. The disease

Infectious agents

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the infective agent that causes coronavirus disease 2019 (COVID-19). SARS-CoV-2 is a novel coronavirus that was first identified in humans in Wuhan, China, in December 2019. SARS-CoV-2 shares 79.6% sequence identity to SARS-CoV-1 (1).

Coronaviruses are a large family of viruses, some causing illness in people and others that circulate among animals, including camels, cats and bats. Rarely, animal coronaviruses can evolve and infect people and then spread between people. Adaption has led to outbreaks of severe acute respiratory disease due to MERS-CoV and SARS-CoV, but there are also human coronaviruses that cause more mild illness in humans, such as the coronaviruses that cause the common cold.

Reservoir

It is highly likely that the virus has come from an animal source. Genomic analysis suggests that bats appear to be the reservoir of SARS-CoV-2 virus (2), but the intermediate host has not yet been identified (3).
Mode of transmission

Human-to-human transmission of SARS-CoV-2 is via droplets and fomites from an infected person (3).

There is some evidence that COVID-19 infection may lead to intestinal infection and virus can be present in the faeces of infected persons (4). Additionally, airborne transmission of COVID-19 may occur during aerosol-generating procedures. Despite this, current evidence does not support faecal-oral or airborne spread as major drivers in transmission; however, aerosol-generating procedures should be undertaken with appropriate precautions (refer to Aerosol-generating procedures).

Estimates for the basic reproductive number (R₀) of SARS-CoV-2 range from 2–4, with R₀ for confined settings, e.g. cruise ships, at the higher end of this range. Estimates of the effective reproductive number (R_eff) vary from between settings and at different time points are dependent on a range of factors, including, public health interventions such as isolation, quarantine and physical distancing to limit close contact between people (5, 6).

Incubation period

Current estimates suggest a median incubation period of 5 to 6 days, with a range of 1 to 14 days (7). The advice in this guideline uses an upper range of 14 days based upon what is currently known about the incubation period for COVID-19. This advice is supported by the literature (8-10), which is informing reviews of this guideline.

Infectious period

The infectious period of COVID-19 is still being determined; however, there are multiple studies suggesting that pre-symptomatic, and possibly asymptomatic, transmission occurs (11, 12). For example, a Singaporean study of multiple case clusters identified pre-symptomatic transmission occurring 1-3 days before symptom onset (13). A recent study also found that viral loads of throat swabs were highest at the time of symptom onset and decreased quickly within 7 days. The study suggested that viral shedding may occur 2 to 3 days before symptom onset with infectiousness peaking at 0.7 days (95% CI, −0.2–2.0 days) prior to initial symptoms (14). Additionally, a Chinese study found that the viral load in an asymptomatic patient was similar to that of symptomatic patients, suggesting transmission potential of asymptomatic, or minimally symptomatic patients (15). The risk of transmission from symptomatic or pre-symptomatic cases is considered to be higher than from asymptomatic cases (16), as viral RNA shedding is higher at symptom onset (17).

As a precautionary approach, for the purposes of contact tracing, cases are considered to be infectious from 48 hours prior to onset of symptoms. Confirmed and probable cases are considered to pose a risk of onward transmission and require isolation until criteria listed in the release from isolation section have been met.

Clinical presentation and outcome

COVID-19 presents as a mild illness for approximately 80% of cases, with fever and cough being the most commonly reported symptoms. Other symptoms include headache, sore throat, fatigue, shortness of breath, myalgia, anosmia (18), dysgeusia, chills and vomiting. Preliminary evidence suggests that children experience milder clinical symptoms than adults (similar to SARS-CoV and MERS-CoV infections) (19-21). Severe or fatal outcomes occur more frequently in the elderly and those with comorbid conditions (3).
Some individuals remain asymptomatic (21, 22). Asymptomatic case rates are difficult to determine because there is no reason for asymptomatic people to seek medical attention. Some studies estimate that the asymptomatic proportion of cases ranges from 18% to 42% (23, 24).

For confirmed cases reported globally, the case fatality rate is approximately 6.4% (25); however, this is likely an overestimate for the Australian health setting (26). The true case fatality rate for COVID-19 is difficult to estimate due to variable case ascertainment, especially in regards to mild cases, and the impact of health systems on patient outcomes. Mortality of cases is, to a significant extent, determined by individual risk factors and healthcare quality and access. Based on surveillance data notified in Australia as of 28 May 2020, the crude national case fatality rate is 1.4% (103 deaths/7,139 confirmed cases).

**Disease occurrence and public health significance**

Cases of COVID-19 were initially associated with exposure to an animal wet market—located in Wuhan, Hubei Province, China—indicating a probable zoonotic source. Human-to-human transmission of SARS-CoV-2 is well established. As of 28 May 2020, 219 countries/regions have reported cases, numerous countries/regions have reported broader community transmission, and globally there has been over 5,488,000 confirmed cases and 349,000 deaths (25). The situation is rapidly evolving.

The World Health Organization (WHO) declared the outbreak of COVID-19 a Public Health Emergency of International Concern (PHEIC) on 30 January 2020 (27), and declared a pandemic on 12 March 2020 (28).

Australia has implemented measures aimed at slowing the spread of COVID-19 into and within the country, and to prepare healthcare services and laboratories for a targeted response. The Australian Health Sector Emergency Response Plan for Novel Coronavirus (COVID-19) provides an overview of the national approach, the operational plan and guidance for the health sector response.

‘Human coronavirus with pandemic potential’ was added to the Biosecurity (Listed Human Diseases) Determination 2016 as a listed human disease on 21 January 2020, and has been listed temporarily on the National Notifiable Diseases List (NNDL) since 10 February 2020. Processes for permanent listing of COVID-19 on the NNDL are currently underway.

On 18 March 2020, the Australian Government declared a “human biosecurity emergency” under the Biosecurity Act 2015, given the risks COVID-19 poses to human health and the need to control its spread in Australia. The declaration was recommended by the Chief Medical Officer in his capacity as the Director of Human Biosecurity and allows the state and territory Health Ministers to issue targeted, legally enforceable directions and requirements to combat the virus as required.

### 3. Surveillance

There are four main objectives of surveillance for COVID-19:

1. To rapidly identify, isolate and manage cases.
2. To identify, quarantine and provide information to contacts.
3. To rapidly identify and manage clusters and outbreaks.
4. To describe the epidemiology of COVID-19 in Australia to inform public health response including:
   o the progression of the epidemic in time, person and place,
   o transmission dynamics,
   o special risk groups.

4. Communications

Public Health Units (PHU) should, within one working day, notify the central state/territory communicable diseases unit of confirmed cases upon receipt of a notification/report.

As much information regarding the case’s age, sex, comorbidities, place of residence, Indigenous status, date of onset, travel history, laboratory results, clinical status, likely place of acquisition, identification of close contacts and follow-up action taken should be included in the initial report, with additional information being followed up as soon as possible.

Central state/territory communicable diseases units will notify confirmed COVID-19 cases as soon as practicable to the Australian Government Department of Health via both transmission of data to the National Notifiable Diseases Surveillance System (NNDSS) and via email or telephone notification to the National Incident Room.

5. Data management

Initial information on confirmed and probable cases of COVID-19 should be entered onto the jurisdictional notifiable diseases database, for transmission to the NNDSS, within one working day of the notification/report. Enhanced surveillance data should be entered shortly after case follow-up.

6. Case definition

The case definition is based on what is currently known about the clinical and epidemiological profile of cases of COVID-19 presenting in Australia and internationally. Health authorities are constantly monitoring the spectrum of clinical symptoms and nature of illness. Using a 14 day exposure period will cover the duration of the incubation period in the vast majority of cases.
**Confirmed case**

A person who:

i. tests positive to a validated specific SARS-CoV-2 nucleic acid test;

   **OR**

ii. has the virus isolated in cell culture, with PCR confirmation using a validated method;

   **OR**

iii. undergoes a seroconversion to or has a significant rise in SARS-CoV-2 neutralising or IgG antibody level (e.g. four-fold or greater rise in titre).¹

**Probable case**

A person who has detection of SARS-CoV-2 neutralising or IgG antibody¹ AND has had a compatible clinical illness AND meets one or more of the epidemiological criteria outlined in the suspect case definition (see below).

**Suspect case**

*Clinical and public health judgement should be used to determine the need for testing in hospitalised patients and patients who do not meet the clinical or epidemiological criteria.*

A person who meets the following clinical AND epidemiological criteria:

**Clinical Criteria:**

Fever (≥37.5°C)² or history of fever (e.g. night sweats, chills) OR acute respiratory infection (e.g. cough, shortness of breath, sore throat)⁴.

**Epidemiological criteria:**

i. In the 14 days prior to illness onset:
   - Close contact⁵,⁶ (refer to **Contact definition** below) with a confirmed or probable case
   - International or interstate travel
   - Passengers or crew who have travelled on a cruise ship
   - Healthcare, aged or residential care workers and staff with direct patient contact
   - People who have lived in or travelled through a geographically localised area with elevated risk of community transmission, as defined by public health authorities⁷

ii. Hospitalised patients, where no other clinical focus of infection or alternate explanation of the patient’s illness is evident.

**Footnotes:**

¹ Antibody detection must be by a validated assay and included in an external quality assurance program.

² It is recommended that temperature is measured using a tympanic, oral or other thermometer proven to consistently and accurately represent peripheral body temperature.
3 If the person is a close contact of a probable case, at least one person in the chain of transmission must be a confirmed case.

4 Other reported symptoms of COVID-19 include: fatigue, loss of smell, loss of taste, runny nose, muscle pain, joint pain, diarrhoea, nausea/vomiting and loss of appetite. Clinical and public health judgement should be used to determine if individuals with sudden and unexplained onset of one or more of these other symptoms should be considered suspect cases.

5 Testing household contacts of confirmed or probable cases of COVID-19 may not be indicated where resources are constrained. These cases would be considered ‘probable cases’ (refer to definition above).

6 In certain high risk outbreak settings, PHU may consider testing asymptomatic contacts to inform management of the outbreak. For a list of settings, refer to high risk settings.


Enhanced testing

The information in this section reflects the current national recommendations for SARS-CoV-2 testing beyond the suspect case definition. These recommendations will change over time based on a variety of factors, including current epidemiology and testing capacity. It is important to check relevant state and territory health department case definitions and criteria for who should be tested, as these vary according to local epidemiology and circumstances.

Testing beyond the suspect case definition should be undertaken on persons with: fever (≥37.5°C)\(^1\) or history of fever (e.g. night sweats, chills) where no other clinical focus of infection or alternate explanation of the patient’s illness is evident, OR acute respiratory infection (e.g. cough, shortness of breath, sore throat)\(^2\).

\(^1\) It is recommended that temperature is measured using a tympanic, oral or other thermometer proven to consistently and accurately represent peripheral body temperature.

\(^2\) Other reported symptoms of COVID-19 include: fatigue, loss of smell, loss of taste, runny nose, muscle pain, joint pain, diarrhoea, nausea/vomiting and loss of appetite. Testing beyond the suspect case definition may, based on the clinical and public health judgement of the treating clinician, include individuals with sudden and unexplained onset of one or more of these other symptoms.

It is recognised that without any other epidemiological risk factors, the risk of persons having COVID-19 is low. Any asymptomatic persons should stay home until their symptoms have resolved. If symptoms have resolved, persons tested as part of enhanced testing do not need to continue to stay home until their test result is returned. If a person receives a PCR positive test result, they are a confirmed case and must isolate until they meet the appropriate release from isolation criteria.

To mitigate the risk of transmission through donated organs and to ensure transplantation is conducted as safely as possible, all deceased and living donors should be tested for SARS-CoV-2; ideally, recipients would also be tested. For more detailed information, refer to Appendix E.

Jurisdictions may test asymptomatic persons who are quarantined due to international (i.e. ‘returned travellers’) or interstate travel, with results to be received prior to the end of the quarantine period. As more information is becomes available, this recommendation may be strengthened. For further information, see Contact management – returned travellers.

7. Laboratory testing

Persons meeting the suspect case definition should be tested for SARS-CoV-2. Persons meeting the enhanced testing criteria should be tested for SARS-CoV-2. State and territory communicable diseases units can advise on which laboratories can provide SARS-CoV-2 testing; appropriate specimen type, collection and transport; and also facilitate contact management if indicated.

In the context of specimen collection from confirmed, probable, or suspect cases in a clinic or pathology collection centre, when specimen collection is the only procedure required, the following infection prevention and control precautions apply. If clinical examination is required, full contact and droplet precautions should be observed as described in the Coronavirus (COVID-19) guidance on use of personal protective equipment (PPE) in non-inpatient health care settings, during the COVID-19 outbreak (https://www.health.gov.au/resources/publications/coronavirus-covid-19-guidance-on-use-of-personal-protective-equipment-ppe-in-non-inpatient-health-care-settings-during-the-covid-19-outbreak)

Infection prevention and control precautions:

- Perform hand hygiene
- Use gloves, surgical mask and eye protection (safety glasses or face shield).
  - Gloves must be removed, and hand hygiene performed after each patient, and new gloves put on before the next one.
  - Safety glasses and face shields can be worn during consecutive patients’ specimen collections in the same location.
    - If it is labelled as reusable, the face shield can be cleaned with a detergent/disinfectant wipe in between uses.
    - If surgical masks are in short supply, they can be used for periods up to 4 hours during consecutive patients’ specimen collections in the same location.
      - The mask should be discarded if it becomes wet or contaminated and on leaving the room.
      - Take care not to touch the mask while it is on; if the front of the mask is touched, remove and discard it, perform hand hygiene and put on a new one.
- The need for a gown or apron is based on risk assessment:
  - A gown or apron is needed for specimen collection, only if close physical contact with a symptomatic patient or splash/spray of body substances is anticipated.
  - If worn, a gown or apron can be worn for specimen collections from consecutive patients in the same location.
    - It must be changed if it becomes visibly contaminated.
    - It must be removed when leaving the immediate area to avoid contaminating other environments.
For collection of specimens from asymptomatic members of the public being tested for surveillance purposes, standard precautions are required; additional PPE is not required. Perform hand hygiene between individual subjects.

For detailed guidance on the use of PPE in hospitals during the COVID-19 outbreak, refer to Appendix B. For information on circumstances requiring airborne precautions, refer to aerosol-generating procedures.

Routine tests for acute pneumonia/pneumonitis should be performed where indicated, including bacterial cultures, acute and convalescent serology, urinary antigen testing and nucleic acid tests for respiratory pathogens, according to local protocols.

Serology for SARS-CoV-2 can help identify individuals who have developed detectable antibodies as part of an immune response to the virus. Serology does not currently have a role for diagnosis during acute illness but has utility for the diagnosis of past SARS-CoV-2 infection. Collection of serum must be performed under transmission-based precautions if an individual is a suspect COVID-19 case or has proven COVID-19 infection and not yet released from isolation. Collection of serum from proven cases of COVID-19 who have been released from isolation can be performed using standard precautions.

Refer to Appendix A for additional SARS-CoV-2 laboratory testing information.

8. Case management

Response times

On the same day as notification of a confirmed, probable, or suspect case, begin follow up investigation and, where applicable, notify your central state or territory communicable diseases unit.

PHU staff should be available to contribute to the expert assessment of patients under investigation as possible cases on request from hospital clinicians or general practitioners.

Response procedure

Case investigation

The response to a notification will normally be carried out in collaboration with the clinicians managing the case, and be guided by the COVID-19 PHU checklist (Appendix C) and the COVID-19 investigation form (currently pending).

Regardless of who does the follow-up, PHU staff should ensure that action has been taken to:

- Confirm the onset date and symptoms of the illness.
- Confirm results of relevant pathology tests, or recommend that tests be done, including repeat tests where relevant.
- Determine if the diagnosis has been discussed with the case or relevant caregiver before beginning the interview).
- Review both case and contact management.
- Commence or complete contact tracing and determine if the case has attended settings that are at higher risk for infection.
Ensure appropriate infection control guidelines are followed in caring for the case.
Identify the likely source of infection

Note: If interviews with suspect cases are conducted face-to-face, the person conducting the interview must have a thorough understanding of infection control practices and be competent in using appropriate PPE.

**Identification of potential source contacts**

Potential source contacts (or ‘upstream contacts’) are individuals who had contact with the first reported case during the time in which the case was likely to have acquired infection. Where a confirmed case has no identified source of infection, potential source contact tracing of the ‘first reported case’ (or in an outbreak, index case) should be undertaken. The aim is to identify potential unrecognised chains of transmission, and may be particularly useful to identify the source of introduction of disease in a setting where there is potential for rapid transmission (e.g. aged care facilities, correctional facilities, and closed community settings). In such settings, potential source contact tracing should be done for the first reported case or index case.

For most cases, infection is likely to have been acquired 5-7 days prior to the first reported case becoming symptomatic (i.e. the median incubation period of the disease) but may be from anyone who has had contact between 14 days and 24 hours before the first reported case became symptomatic (i.e. the longest and shortest possible incubation periods). These individuals may be unidentified cases and the transmission source for the first reported case. Follow-up should occur for any person who in that period had:

- face-to-face contact with the index case in any setting for greater than 15 minutes cumulative over the course of a week, or
- sharing of a closed space with the index case for a prolonged period (e.g. more than 2 hours).

All potential source contacts should be screened for possible symptoms, have their temperature measured and, where feasible, be tested for SARS-CoV-2 infection with a PCR test; with prioritisation of those at highest risk. If a validated serological assay is available, serological testing should also be considered for potential source contacts who are currently well (noting the limitations of antibody testing and potential lack of availability). In settings where there is potential for rapid transmission, it is likely that contacts will be identified as both close contacts and potential source contacts, and contact status may not be able to be determined.

For potential source contacts who test positive, via PCR or a validated serological assay, clinical and public health judgement should be used to determine if they are infectious; if infectious, they should be managed as any other confirmed case. They should also be assessed to determine if they are likely to be the primary case who infected the first reported case (or index case if an outbreak), a secondary case infected by the first reported case, or represent a separate transmission chain.

Wherever a new case is identified, rapid contact tracing of these cases must also occur.

**Clinical management**

In the absence of pathogen-specific interventions, patient management largely depends on supportive treatment, and vigilance for and treatment of complications.
Further advice on clinical management is available from:

- **National COVID-19 Clinical Evidence Taskforce**: [https://covid19evidence.net.au/](https://covid19evidence.net.au/)
- **Cochrane Library: Coronavirus (COVID-19)**: [https://www.cochranelibrary.com/covid-19](https://www.cochranelibrary.com/covid-19)

**Education**

Cases should be educated about the nature of the illness, importance of isolation and infection control measures that prevent the transmission of COVID-19. PHU staff should provide a COVID-19 factsheet to cases and their household contacts.

**Isolation and restriction**

Depending on clinical indication, cases should either be managed in hospital, at home, or other community settings identified by the PHU. Cases may be managed at home or in a community setting only if:

- a risk assessment is conducted regarding the suitability of the accommodation and living arrangements, including who else is in the home and their vulnerability to severe disease; and
- If it can be assured that the home environment permits separation of the case from other household members; the case and household contacts are counselled about risk, and; appropriate infection control measures are in place.

Healthcare workers and others who come into contact with confirmed, probable, and suspect cases must be protected according to recommended infection control guidelines. Visitors should be restricted to close family members.

If a case is identified through serology, clinical and public health judgement should be used in determining case management and whether or not a case requires isolation. If the case had a clinically compatible illness some time ago, it may not be necessary to isolate and trace close contacts.

A risk assessment should be undertaken for suspect cases who initially test negative for SARS-CoV-2. If there is no alternative diagnosis and a high index of suspicion remains that such cases may have COVID-19, consideration should be given to continued isolation and use of the recommended infection control precautions, pending further testing (refer to Laboratory testing section and Appendix A) and re-assessment. Suspect cases can otherwise discontinue isolation upon receipt of a negative test result, though should stay home until symptoms have resolved. Suspect cases who are close contacts or are required to quarantine for other purposes (e.g. international travel) must continue quarantine for the remainder of the 14 day period, regardless of any negative test results. Refer to Contact management for further information.

In addition to standard precautions, including hand hygiene (5 Moments), recommendations for the use of PPE during clinical care of people with confirmed, probable, or suspected COVID-19 are:

- **Contact and droplet precautions** are recommended for routine care of patients with confirmed, probable, or suspected COVID-19.
- **Contact and airborne precautions** are recommended when performing aerosol-generating procedures. Refer to Appendix B for further information.
Other recommended infection control measures include:

- When a patient with acute respiratory symptoms, and/or who meets the suspect, probable, or confirmed case definition presents to a healthcare setting (GP, hospital ED, or pathology collection centre), the patient should immediately be:
  - given a surgical mask to put on if acute respiratory symptoms are present, AND
  - placed in a single room with the door closed or in a physically separated closed area designated for suspected COVID-19 cases OR
  - directed to a negative pressure room if an aerosol-generating procedure is to be performed (or an isolation room with the door closed if a negative pressure room is not available).
- needs to be transferred out of their isolation room, the patient should wear a “surgical” mask and follow respiratory hygiene and cough etiquette.

For more detailed guidance on the use of PPE in hospitals during the COVID-19 outbreak, refer to Appendix B.


**Release from isolation**

The following information details the circumstances under which confirmed and probable cases can be released from necessary isolation restrictions, as well as when cases are clear to go into high risk settings. Cases can be released from isolation if they meet the appropriate criteria in either point 1, 2, or 3 – whichever is applicable. Cases can go into a high risk setting if they meet the criteria in point 4.

1. **Confirmed cases who are asymptomatic.**

   The case can be released from isolation if at least 10 days have passed since the first positive sample was taken and no symptoms have developed during this period.

2. **Confirmed or probable cases with mild illness who did not require hospitalisation.**

   The case can be released from isolation if they meet all of the following criteria:
   - at least 10 days have passed since the onset of symptoms; and
   - there has been resolution of all symptoms of the acute illness for the previous 72 hours$^{1,2}$

3. **Confirmed or probable cases with more severe illness who have been discharged from hospital.**

   If the case is ready clinically for hospital discharge, but has **not** had two consecutive swabs taken at least 24 hours apart which are negative for SARS-CoV-2 by PCR, then they can be discharged to home isolation.
The case can be released from home isolation if they meet all of the following criteria:

- at least 10 days have passed since hospital discharge; and
- there has been resolution of all symptoms of the acute illness for the previous 72 hours\(^1,2\)

If the case, at or prior to discharge, has had two consecutive swabs taken at least 24 hours apart which are negative for SARS-CoV-2 by PCR, then the case can simultaneously be discharged and released from isolation.

4. Release into high risk setting.

Cases returning to a high risk setting (such as working in a health care setting, living in a residential age care setting or being transferred to another ward in a hospital, see below for a list of high risk settings) can be released from isolation based on the clinical criteria above, but must meet a higher standard and need additional assessment before going into the high risk setting.

Confirmed and probable cases who will be going into a high-risk setting can go into that setting if they meet all the following criteria:

- be at least 10 days after the onset of the acute illness;
- the person has been afebrile for the previous 48 hours;
- resolution of the acute illness for the previous 24 hours\(^1\);
- PCR negative on at least two consecutive respiratory specimens collected at least 24 hours apart at least 7 days after symptom onset\(^3,4\)

\(^1\) Some people may have pre-existing illnesses with chronic respiratory signs or symptoms, such as chronic cough. For these people, the treating medical practitioner should make an assessment as to whether the signs and symptoms of COVID-19 have resolved. If individuals have a persistent post-viral cough with negative test results, they are eligible for release from isolation.

\(^2\) If a case who meets these criteria is additionally swabbed and tests positive, then the case can still be released from isolation based on current evidence from the literature and Australian public health experience that suggests these people are unlikely to be infectious. However, to go into a high risk setting they must meet the clinical and laboratory criteria as above in point 4.

\(^3\) If the patient has a productive cough due to a pre-existing respiratory illness or other ongoing lower respiratory tract disease, then the sputum or other lower respiratory tract specimens must be PCR negative for SARS-CoV-2. Otherwise upper respiratory tract specimens (deep nasal and oropharyngeal swabs) must be PCR negative.

\(^4\) A small proportion of people may have an illness that has completely resolved but their respiratory specimens remain persistently PCR positive. In these circumstances, the decision around release to a high risk setting should be made on a case by case basis after discussion between the treating medical practitioner, the testing laboratory and public health. This may include laboratory interpretation of PCR cycle threshold (Ct) values and/or viral culture where available.

Routine PCR testing post-release from isolation is not recommended unless the person develops new clinical features consistent with COVID-19.
If a case is identified through serology, clinical and public health judgement should be used in determining case management and whether or not a case requires isolation. If the case had a clinically compatible illness some time ago, it may not be necessary to isolate. If isolation is required, the case can be released from isolation when the appropriate criteria (above) are met.

Persons who have been released from isolation should still adhere to hygiene and physical distancing measures, as the extent of acquired immunity is unknown.

If a recently recovered COVID-19 case becomes a close contact of a confirmed or probable case, they do not need to self-quarantine again. However, the recovered case should not attend high-risk settings (refer to suspect case definition) until 14 days after the last unprotected contact with the confirmed case and should vigilantly self-monitor for symptoms clinically consistent with COVID-19. If symptoms reappear, they should immediately self-isolate and be retested for SARS-CoV-2. If the recently recovered case is a household contact of a currently isolated case, particular care should be taken with regards to consistent hand hygiene. If the recently recovered case needs medical attention, they should follow the processes outlined in Medical care for quarantined individuals. As further evidence becomes available on the duration of immunity, these recommendations may be amended.

Faecal sampling is not recommended as a standard test, however, it may be done for patients with gastrointestinal symptoms. For cases who do have faecal samples tested, and remain persistently PCR positive in these samples after all the release from isolation criteria (above) are met, further or extended precautions and exclusions should be implemented on a case-by-case basis:

- All cases with diarrhoea should be advised not to prepare food for others until 48 hours after symptoms have resolved.
- Cases who have employment that may pose an increased risk of onward transmission (e.g. healthcare workers, restaurant workers and food handlers), should be excluded from work until 48 hours after any symptoms of diarrhoea have resolved.
- Cases with ongoing diarrhoea or faecal incontinence who may have limited capacity to maintain standards of personal hygiene should continue to be isolated until 48 hours after the resolution of these symptoms.

Patients do not require repeat testing until they are PCR negative in faecal samples. It is recommended that people who remained persistently PCR positive in faecal samples use soap and water for hand hygiene. If this is unavailable, alcohol hand gel should be used. Education emphasising the importance of proper hand hygiene should be provided to all cases upon release from isolation.

High risk settings

In the context of the release from isolation criteria and some aspects of testing outlined in the case definition, high-risk settings are defined as:

- Aged care and other residential care facilities
- Healthcare settings
- Military – group residential and other closed settings, such as Navy ships or living in accommodation
- Boarding schools and other group residential settings
- Educational settings where students are present
- Childcare centres
- Correctional facilities
- Detention centres
• Remote industrial sites with accommodation (e.g. mine sites)
• Aboriginal and Torres Strait Islander rural and remote communities, in consultation with the local PHU
• Settings where COVID-19 outbreaks are occurring, in consultation with the local PHU

* In relation to persons going into high risk settings, this includes: persons returning to work in healthcare settings; patients who will be remaining in hospital after release from isolation; and those regularly attending healthcare settings for any other purpose. Persons who need to present to an emergency department or general practice for medical consultations and treatment can do so without meeting these criteria, but should, where feasible, inform staff before arrival if they have recently been released from isolation.

**Aerosol-generating procedures**

Appropriate care should be taken during aerosol-generating procedures. Listed examples of aerosol-generating procedures are available in Appendix B. Collection of upper respiratory specimens is not generally regarded as aerosol-generating, but airborne precautions should be used for collection of specimens from severely symptomatic patients (refer to Laboratory testing section).

P2/N95 respirators should be used only when required. Unless used correctly, i.e. with fit-checking, they are unlikely to protect against airborne pathogen spread.

Airborne precautions should be used routinely for aerosol-generating procedures, such as bronchoscopy, intubation, suctioning etc. in hospital settings. Nebuliser use should be discouraged and alternative administration devices (e.g. spacers) should be used.

The Laboratory testing section provides detailed information on sample collection for SARS-CoV-2.

**Active case finding**

Contacts (refer to Contact management section) should be identified and advised to immediately seek medical advice should they develop symptoms. Contacts or caregivers should be asked to also inform the public health agency if they develop symptoms.

**Definition of COVID-19 death**

A death due to COVID-19 is defined for surveillance purposes as a death resulting from a clinically compatible illness, in a probable or confirmed COVID-19 case, unless there is a clear alternative cause of death that cannot be related to COVID-19 (e.g. trauma). There should be no period of complete recovery from COVID-19 between illness and death.

**9. Environmental evaluation**

Where local transmission of COVID-19 is thought possible, a thorough review of contributing environmental factors should be done. This should include a review of infection control procedures, and opportunities for exposure to respiratory or faecal contamination.

If a case has had occupational exposure to animals it may be appropriate to consult with animal health authorities.
10. Contact management

Identification of contacts

Persons categorised as close contacts (refer to definition of “close contacts” below) of a confirmed or probable case should be followed-up, provided with information, and self-quarantine at home for 14 days following the last close contact with the case whilst infectious. Close contacts should be monitored for the development of symptoms for 14 days after the last exposure to the infectious case (i.e. the maximum incubation period) where feasible to do so.

Contacts of suspect cases should also be considered for contact management if there is likely to be a delay in confirming or excluding COVID-19 in the suspect case, such as delayed testing.

Less frequent active follow-up together with passive surveillance may be necessary if there are large numbers of close contacts to monitor.

Contacts who do not meet the close contact definition but may have had some exposure to the infectious case (e.g. workplaces) should be identified and provided information (refer to Education below), where feasible.

Close contact definition

A close contact is defined as requiring:

- face-to-face contact in any setting with a confirmed or probable case, for greater than 15 minutes cumulative over the course of a week, in the period extending from 48 hours before onset of symptoms in the confirmed or probable case, or
- sharing of a closed space with a confirmed or probable case for a prolonged period (e.g. more than 2 hours) in the period extending from 48 hours before onset of symptoms in the confirmed or probable case.

For the purposes of surveillance, a close contact includes a person meeting any of the following criteria:

- Living in the same household or household-like setting (e.g. in a boarding school or hostel) – referred to as ‘household contacts’.
- Direct contact with the body fluids or laboratory specimens of a case without recommended PPE or failure of PPE.
- A person who spent 2 hours or longer in the same room (such as a GP or ED waiting room; a school classroom; communal room in an aged care facility). Refer to Special situations for further information specific to aged care facilities and schools.
- A person in the same hospital room when an aerosol-generating procedure is undertaken on the case, without recommended PPE.
- Aircraft passengers who were seated in the same row as the case, or in the two rows in front or two rows behind a confirmed or probable COVID-19 case. Contact tracing of people who may have had close contact on long bus or train trips should also be attempted where possible, using similar seating/proximity criteria.
- For aircraft crew exposed to a confirmed or probable case, a case-by-case risk assessment should be conducted by the airline to identify which crew member(s) should be managed as close contacts. Refer to Special situations and Appendix D for further information.
• If an aircraft crewmember is the COVID-19 case, contact tracing efforts should concentrate on passengers seated in the area where the crewmember was working during the flight and all of the other members of the crew. A case by case risk assessment should be conducted to identify which passengers and crew members should be managed as close contacts. Refer to Special situations and Appendix D for further information.

• Close contacts on cruise ships can be difficult to identify, and a case-by-case risk assessment should be conducted to identify which passengers and crew should be managed as close contacts. Refer to Special situations for further information.

Contact needs to have occurred within the period extending 48 hours before onset of symptoms in the case until the case is classified as no longer infectious (refer to Release from isolation).

Note that:
• Healthcare workers and other contacts who have taken recommended infection control precautions, including the use of full PPE, while caring for a symptomatic confirmed or probable COVID-19 cases are not considered to be close contacts.
• Contact tracing is not required for close contacts arriving on international flights on or after 16 March 2020.

**Returned traveller definition**

Returned travellers are defined as those who have undertaken international travel to any country outside Australia in the last 14 days.

**Contact assessment**

All persons identified as having had contact with a confirmed or probable case should be assessed to see if they should be classified as a close contact and should have demographic and epidemiological data collected. Information on close contacts should be managed according to jurisdictional requirements.

All identified contacts who do not meet the close contact definition should be provided with information on their risk (refer to Education below), where feasible.

Identification and assessment of the contacts of suspect cases may be deferred pending the results of initial laboratory testing.

**Close contact testing**

Routine laboratory screening for COVID-19 is not recommended for asymptomatic close contacts; however, in certain high risk outbreak settings, PHU may consider testing asymptomatic contacts to inform management of the outbreak.

**Prophylaxis**

No specific chemoprophylaxis is available for contacts.

**Education**

Close contacts should be counselled about their risk and the symptoms of COVID-19 and provided with a COVID-19 factsheet. They should be advised to self-quarantine. Other contacts not defined as close contacts are not required to quarantine, but may similarly, where feasible, be counselled about their risk and the symptoms of COVID-19 and provided with a COVID-19 factsheet.
**Quarantine and restriction**

**Close contacts**

Asymptomatic close contacts should be advised to self-quarantine at home for 14 days following the last contact with the infectious case, and to monitor their health for 14 days after the last possible contact with a confirmed or probable COVID-19 case.

Where feasible to do so, PHU should conduct active daily monitoring of close contacts for symptoms for 14 days after the last possible contact with a confirmed or probable COVID-19 case.

Self-quarantined close contacts should be advised on the processes for seeking medical care. Refer to Medical care for quarantined individuals.

For the purpose of contact management, swabs are **not** currently indicated during quarantine in well people. A medical clearance from a health care provider is not required for release from quarantine or for other purposes such as returning to work, school or university.

**Returned travellers**

All travellers who have returned from international travel are required to be in mandatory quarantine for 14 days after arrival in Australia. Returned travellers must adhere to jurisdictional quarantine requirements, which may include mandatory hotel quarantine.

In addition, some state and territory governments have travel restrictions for persons arriving from other domestic jurisdictions. Persons may be required to quarantine for 14 days following travel to another state or territory and should check local requirements before travelling.

Quarantined returned travellers should be advised on the processes for seeking medical care, refer to Medical care for quarantined individuals. All returned travellers undertaking quarantine should self-monitor for symptoms and **immediately isolate themselves from others if they become unwell**. This advice should be followed for 14 days after returning to Australia/from interstate.

Jurisdictions may test asymptomatic persons who are quarantined due to being a returned traveller or having undertaken interstate travel. Test results should be received prior to the end of the quarantine period. Testing may occur throughout the quarantine period. Early testing will allow earlier release from case isolation of detected cases than if tested late in the quarantine period.

Specimens for quarantine release testing should be collected as close to the end of the quarantine period as possible, while still allowing enough time for results to be received by day 14 of the individual’s quarantine period. This will usually mean collecting specimens on day 12 but may be earlier depending on a variety of factors including specimen transport and laboratory processing times. If a negative test result is received, the returned traveller may finish quarantine after the 14-day period has transpired. If a positive result is received, the returned traveller should be isolated and managed as per the recommendations for confirmed cases. As more information becomes available, this recommendation may be strengthened.

All returned travellers who have undertaken international travel in the last 14 days **who are unwell** with fever, or with respiratory symptoms (with or without fever) or other symptoms consistent with COVID-19 should be isolated and managed as per the current recommendations for suspect cases.
**Physical distancing**

Physical distancing is an effective measure, but it is recognised that it cannot be practised in all situations. The aim is to generally reduce the potential for transmission. Whilst practising physical distancing, people can travel to work (including by public transport) and carry out normal duties. Physical distancing outside the workplace is aimed at nonessential activities and includes:

- Avoiding crowds and mass gatherings.
- Avoiding small gatherings in enclosed spaces, for example family celebrations.
- Attempting to keep a distance of 1.5 metres between themselves and other people where possible, for example when out and about in public spaces.

Jurisdictions may have public health directions in place to ensure physical distancing is occurring to further support prevention of transmission, depending on the nature of the outbreak at a point in time.

**Quarantine and essential workers**

Quarantined individuals who are regarded as essential workers in a critical infrastructure industry should work from their quarantine space (e.g. home, hotel) and/or implement alternate staffing arrangements wherever possible. Where this is not feasible, an individual risk assessment should be conducted in collaboration with the PHU to identify essential workers who may be permitted to maintain normal work patterns while in quarantine. This should only be considered in circumstances where there is risk of grave damage to Australian national interests and security if the worker is unable to work. If normal work patterns are maintained, the essential worker should vigilantly practise physical distancing, hand and respiratory hygiene, and wear a mask whilst around others at work. Normal quarantine restrictions should be adhered to outside of essential work activities.

**Medical care for quarantined individuals**

If individuals under self-quarantine need to see a doctor for any reason (e.g. fever and respiratory symptoms or other illness/injury), they should telephone their GP or hospital Emergency Department before presenting. Patients with severe symptoms should call 000 and make it clear they are in quarantine or isolation (or otherwise) because of COVID-19. If the patient has symptoms consistent with the COVID-19 case definition, the local PHU should be consulted about the most suitable venue for clinical assessment and specimen collection. Where feasible, patients should don a surgical mask before presenting to any healthcare setting. Contact and droplet precautions are recommended for routine care of patients in quarantine.

**Management of symptomatic contacts**

If fever or respiratory symptoms consistent with the clinical criteria in the suspect case definition develop within the first 14 days following the last contact, the individual should be immediately isolated and managed as per the current recommendations for suspected COVID-19 cases, with urgent testing for COVID-19 undertaken in an environment that minimises the exposure of others.

Ill contacts who are being evaluated for COVID-19 can be appropriately isolated and managed at home or in other community settings identified by PHU, unless their condition is severe enough to require hospitalisation.

Symptomatic close contacts who test negative for SARS-CoV-2 by PCR should be re-tested, given the pre-test probability for COVID-19. Re-testing should occur as soon as possible after a negative result is received, and if still negative, another test may be conducted on day 14 of the quarantine period. They will still need to be monitored for 14 days after their last contact with a confirmed or probable COVID-19 case.
11. Outbreak investigation and management in high-risk settings

This section focuses on the epidemiological investigation and response to an outbreak in a high-risk setting (i.e. a setting where there is potential for rapid transmission). Investigations in these settings differ as a wider range of contacts needs to be considered.

A high-risk setting is defined as a setting where there is evidence of a risk for rapid spread and ongoing chains of infection. These include but are not limited to:

- Places where people reside in groups.
- Workplace settings where previous outbreaks have shown large scale amplification.

Note that some of these settings have specific guidance documents. Examples of these settings are provided below.

Within these settings, for the purposes of investigation, an outbreak is defined as:

- A single confirmed case of COVID-19 in a resident, staff member or frequent attendee of a high-risk setting.

This definition does not include a single case in an infrequent visitor of the setting. A determination of whether someone is a frequent or infrequent visitor may be based on frequency of visits, time spent in the setting, and number of contacts within the setting.

Due to the importance of undertaking early action to minimise transmission within a high-risk setting, PHU should consider advising that the facility should implement some of these actions (see ‘steps in investigation’ below) where an outbreak is suspected, whilst awaiting laboratory confirmation.

When an index case of COVID-19 is identified who likely acquired their infection within the setting (i.e. the case has not left the setting within the previous 14 days), then it is likely that there are already other transmission chains.

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Index case is the first case reported to a health agency that is part of an outbreak. The primary case is the first case that occurred in the outbreak.
Further details about the steps

High-risk settings – steps in investigation

There are several initial steps that public health unit staff need to take when responding to an outbreak of COVID-19 in high-risk settings. Further details for each step are provided below.

1. Define the setting.
2. Confirm and declare a COVID-19 outbreak with one confirmed case.
3. Identify those most at risk of severe disease.
4. Arrange diagnostic testing for COVID-19 for all members of the setting. If available, consider additional serological tests. If other members of the setting are symptomatic, test these individuals for other respiratory pathogens such as influenza as well as COVID-19.
5. Ensure that the facility managers have notified ALL staff, residents (where applicable) and visitors as relevant, that cases of COVID-19 have occurred in the setting.
6. Advise staff about enhanced implementation of infection control measures. Determine if staff have worked at any other aged care facility or provided in home care in the last 14 days.
7. Collate information onto a line list that describes people infected in terms of time, place and person.
8. In a residential facility, ensure the staff form an outbreak management team that meets within hours of the identification of a case. The team should not be part of day-to-day facility management.
9. Identify and inform relevant internal and external stakeholders.
10. Isolate and treat individuals who test positive. Quarantine, as best as possible, those individuals who test negative and monitor for illness – persons in this group are considered to be susceptible or incubating.
11. Where feasible, commence a program of repeat tests for those (who may be) susceptible or incubating who are in quarantine. This will identify those who are pre-symptomatic to enable rapid removal from the environment.
12. Identify suitable sites where individuals may be cohorted together into either: isolation of the sick OR quarantine the exposed.

1. Define the setting

High-risk settings are defined as a setting where there is evidence of a risk for rapid spread and ongoing chains of infection. These include but are not limited to:

- Places where people reside in groups, e.g.
  - Residential settings such as aged care facilities, military residential groups, residential, boarding schools, boarding houses, homeless shelters, correctional facilities, remote industrial sites with accommodation, migrant workers accommodation, remote communities.
- Workplace settings where previous outbreaks have shown large scale amplification e.g.
  - Abattoirs.

Consider if a smaller defined setting is appropriate.

The context and parameters of the outbreak may enable the definition of the setting to be a defined section of a facility. However, experiences in outbreaks in Australia indicate that at the early stage a broad definition of the setting should be used where possible; this can be scaled back later after further investigation and/or testing.
Any determination of how to define the parameters should consider any movement of staff or residents to other areas (e.g. other wards or blocks), and the potential for cases to have spread to the wider community, e.g:

- A single block of a prison or single unit in a military base
- A dormitory in a boarding school that is well separated from others

In the setting of an aged care facility, a wide definition of the setting is required at the outset because experience of transmission in these facilities is that it has been widespread and the population in the community is at risk of severe disease.

If a smaller setting is defined, the following steps should be instituted for the smaller setting. The decision to define the whole setting versus part of the setting should take into account the size of the community, availability of laboratory testing facilities and contact patterns within the community, including staffing patterns.

2. **Confirm and declare an outbreak investigation**

An outbreak is declared for a single confirmed case of COVID-19 in a resident, staff member or frequent attendee at the setting.

The rationale for one case being considered an outbreak is to stimulate wider immediate investigation than what may occur through routine case and contact follow-up.

Note that an outbreak is not declared if the single case is an infrequent visitor. A determination of whether someone is a frequent or infrequent visitor may be based on frequency of visits, time spent at the setting, and number of contacts within the setting.

3. **Identify those most at risk of severe disease**


4. **Arrange testing for all members of the setting for SARS-CoV-2 and other respiratory pathogens**.

When an index case of COVID-19 is identified who is likely to have acquired his/her infection within that setting (i.e. the case has not left the setting within the previous 14 days, or has had minimal or no contact with others outside of the setting), then it is likely that there are already other transmission chains within the setting. Testing widely should help identify those who may be shedding virus.

Consider if serological tests are available to identify persons previously infected. Note the evidence at the time about whether this indicates the person is immune or considered still susceptible.

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2 Index case is the first case reported to a health agency that is part of an outbreak. The primary case is the first case that occurred in the outbreak.
5. Ensure that the facility managers notify ALL staff, residents (where applicable) and visitors (if relevant), to the persons in the setting that a case of COVID-19 has occurred in the setting.

Messaging needs to be clear that there is only one case (if applicable), but to be cautious, all members of the setting are being tested. The facility needs to take a strong leadership role with support from the PHU staff. The Australian Government Department of Health state office (https://www.health.gov.au/about-us/contact-us/state-and-territory-offices) should be engaged at the start of the outbreak, along with the Aged Care Safety and Quality Commission (https://www.agedcarequality.gov.au/).

6. Advise staff about enhanced implementation of infection prevention and control measures and develop a process for ongoing IPC observation.

Enhanced infection prevention and control measures are detailed in the Infection Control Expert Group's COVID-19 Infection Prevention and Control for Residential Care Facilities (https://www.health.gov.au/sites/default/files/documents/2020/05/coronavirus-covid-19-guidelines-for-infection-prevention-and-control-in-residential-care-facilities_0.pdf). While the advice in these guidelines is tailored specifically to the setting of a residential care facility, the principles and actions can be applied to any setting where there is potential for rapid transmission.

Ensure all staff have completed infection control training, in person or online (COVID-19training.gov.au). Ensure that the facility appoints an IPC audit officer and that this person attends the site daily until the outbreak is over. This person's role should be observing day-to-day practices and providing advice to staff where needed. The IPC audit officer should report daily to the outbreak management team.

7. Collate information.

Collate information onto a line list that describes people infected in terms of time, place and person. If available, a map of the facility (such as are used to identify evacuation points) may be useful to identify case locations. Seek staff rosters for employees who have been nearer the index case. Consider diagrams for chain of infection.

8. In a residential facility, ensure the staff form an outbreak management team that meet within hours of the identification of a case. The team should not be part of day-to-day facility management.

Guidelines about who should be members of this team can be found in the https://www.health.gov.au/resources/publications/coronavirus-covid-19-guidelines-for-outbreaks-in-residential-care-facilities

9. Identify and ensure the staff inform relevant internal and external stakeholders.

Because of the extended testing strategy in this outbreak investigation, messaging to other stakeholders such as families in a boarding school or aged care facility is important. Other agencies involved in the oversight of the facility should also be identified.

10. Isolate and treat individuals who test positive. Quarantine, as best as possible, those individuals who test negative and monitor for illness.

Individuals in the quarantine group are considered to be either susceptible or incubating.
11. Where feasible, commence a program of repeat tests for those in quarantine (susceptible or incubating persons).

This will identify those who are pre-symptomatic to enable rapid removal from the environment. Refer to Table 1.

a. With each round of testing, those who are PCR positive can be removed to positive cohort isolation wherever possible
b. In subsequent rounds, only those who are PCR negative (i.e. those who are susceptible) should be tested.
c. Symptom screening should be conducted daily, for the negative (quarantined) cohort.

12. Identify suitable sites where individuals may be cohorted together into either: isolation of the sick OR quarantine of those exposed.

In residential settings, cohort methods of quarantine and isolation, based on symptoms and/or PCR test results, provides residents and staff with a higher level of independence within the setting, and removes barriers to care and support that are presented when individual isolation occurs. It is an important disease control intervention to manage outbreaks.

Furthermore, cohort-based quarantine and isolation for PCR positive residents reduces the amount of single use PPE required. Where possible, closed settings may consider proactive cohorting of staff and residents as an outbreak prevention measure to ensure that if there is an outbreak, it will be limited to a sub-group of residents.

Staff working at a facility with an outbreak should only work within one of the cohorts and not move between those with the disease and those in quarantine. They should not attend work at a different facility (e.g. another aged care setting, university residence) for the duration of the outbreak. Staff should be regularly screened for symptoms in addition to participating in whole of setting testing.

Table 1. Testing and ongoing actions for the individuals in the defined setting.

<table>
<thead>
<tr>
<th>Recommended testing and action</th>
<th>Testing overview</th>
<th>Repeat Testing Days (where feasible)</th>
<th>Date for quarantine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Following testing and action</td>
<td>Test all members of the setting via PCR</td>
<td>Whom to test</td>
<td>Date for quarantine</td>
</tr>
<tr>
<td>Isolate positive persons (may designate an area to cohort positive cases)</td>
<td>Isolate positive persons (may designate an area to cohort positive cases)</td>
<td>Re-test PCR negative cohort where feasible (e.g. 72 hourly)</td>
<td>14 day quarantine starts from date that the quarantine cohort are PCR negative</td>
</tr>
<tr>
<td>Quarantine cohort of negative community members (an off-site quarantine site may suit depending on the setting)</td>
<td>Quarantine cohort of negative community members &amp; screen for symptoms</td>
<td>A subset of the quarantined cohort may be re-tested if appropriate.</td>
<td>If any of the quarantined cohort are positive: 1. Recommence 14-day quarantine period 2. Consider retesting every 72 hours until no new PCR positive tests.</td>
</tr>
</tbody>
</table>
**Release from isolation**

Release from isolation for cases should be according to the appropriate release from isolation criteria. If the setting involves older Australians, it may be difficult to determine when the person is symptom free because of comorbidity. If it is difficult to identify symptom free days, two negative PCR swabs 24 hours apart indicate the case can be released from isolation.

**Consideration of source of introduction of disease (upstream investigation)**

This seeks to identify other chains of transmission in the community that may be unrecognised. For further information, see identification of potential source ('upstream') contacts.

**Staff**

Staff working in a facility or community where an outbreak is occurring should not attend work at a different facility (e.g. another aged care setting, university residence) until the outbreak is declared over. Staff should be regularly screened for symptoms and/or tested during an outbreak. PHU should consider this for all staff, including anyone who works on site (e.g. cleaners, visiting staff, contractors, etc.).

All staff should self-monitor for signs and symptoms of acute respiratory illness and self-exclude from work if unwell, even if appropriate PPE has been used.

The setting should maintain a register for all staff and visitors to check for symptoms and the occurrence of fever at the beginning of every shift, in addition to regular visitor register protocols.

Once isolation of infected persons is in place, to further reduce the risk of transmission, specific staff should be allocated to support/care for PCR positive isolated residents. The facility should ensure that staff members:

- Do not move between their allocated room/section and other areas of the facility or care for other residents.
- Follow guidelines for infection prevention and control and correct use of PPE.

**Declare that the outbreak is over**

Repeat testing allows for close observation of the outbreak and clarity regarding when it can be declared over. In most circumstances, an outbreak can be declared as over 14 days post isolation of the last case.

Once the outbreak is over, PHU should ensure that cluster reports are provided to relevant stakeholders and that data is summarised appropriately.

12. **Special risk settings**

**Healthcare workers**

All healthcare workers should observe usual infection prevention and control practices in the workplace. This includes healthcare workers and other staff in any setting who have direct patient contact.

Healthcare workers with influenza-like illness should not work while they are symptomatic. They should be tested for SARS-CoV-2 and undergo isolation pending results. Healthcare workers who are defined as close contacts should be treated as such (refer to section 6. Contact Management).
In settings where the loss of the healthcare worker will have a significant impact on health services, an individual risk assessment should be conducted in collaboration with the PHU.

Quarantined healthcare worker close contacts should be advised on the processes for seeking medical care. Refer to Medical care for quarantined individuals.

PHU may assist infection control units of health facilities to identify and monitor healthcare worker close contacts.

It is recognised that clinical work restrictions on close contacts who are healthcare workers may place strain on individuals and on the delivery of health services. This underlines the importance of ensuring healthcare workers implement appropriate infection control precautions when assessing and managing confirmed, probable, and suspect COVID-19 cases.

**Staff (including Healthcare workers) who have direct patient contact in a hospital or residential/aged care facility.**

Healthcare workers and other staff with close patient contact who work in hospitals or residential/aged care facilities should take additional precautions because they come into contact with a high caseload of potentially vulnerable patients.

**Aboriginal and Torres Strait Islander Communities**

CDNA will continue to monitor the emerging evidence around COVID-19 transmission risks in healthcare settings and Aboriginal and Torres Strait Islander communities and revise these recommendations as needed. For further information, refer to the CDNA Interim National Guidance for remote Aboriginal and Torres Strait Islander communities for COVID-19 (https://www.health.gov.au/resources/publications/cdna-interim-national-guidance-for-remote-aboriginal-and-torres-strait-islander-communities-for-covid-19).

**Key drivers of increased risk of transmission and severity**

- **Mobility:** Aboriginal and Torres Strait Islander peoples are highly mobile, with frequent travel often linked to family and cultural connections and community events involving long distances between cities, towns, and communities. In addition, remote communities have a high flow of visitors (e.g. tourists, fly-in fly-out clinicians and other workers). This increases the risk of transmission even in generally isolated communities.
- **Remoteness:** A fifth of the Aboriginal and Torres Strait Islander population lives in remote and very remote areas. There is often reduced access health services, these are usually at capacity in normal circumstances and are often reliant on temporary staff. Limited transport options may further inhibit presentations and delay laboratory testing.
- **Barriers to access:** Unwell people may present late in disease progression for many reasons including lack of availability of services, institutional racism, and mistrust of mainstream health services.
- **Overcrowding:** Many Aboriginal and Torres Strait Islander communities have insufficient housing infrastructure, which results in people living in overcrowded conditions. This facilitates disease transmission and makes it difficult for cases and contacts to maintain physical distance measures and self-quarantine.
- **Burden of disease:** Aboriginal and Torres Strait Islander people experience a burden of disease 2.3 times the rate of other Australians. This may increase the risk of severe disease from SARS-CoV-2.
**Key response strategies**

- **Shared decision-making and governance:** Throughout all phases, COVID-19 response work should be collaborative to ensure local community leaders are central to the response. Further risk reduction strategies and public health responses should be co-developed, and co-designed, enabling Aboriginal and Torres Strait Islander people to contribute and fully participate in shared decision-making.

- **Social and cultural determinants of health:** Public health strategies should be considered within the context of a holistic approach that prioritises the safety and well-being of individuals, families and communities while acknowledging the centrality of culture, and the addressing racism, intergenerational trauma and other social determinants of health.

- **Community control:** The Aboriginal Community Controlled Health Services (ACCHS) sector provides a comprehensive model of culturally safe care with structured support and governance systems. The network of ACCHS and peak bodies should be included in the response as a fundamental mechanism of engagement and communication.

- **Appropriate communication with the community:** Each community action plan should contain recommendations for communication within the community. These should be implemented as agreed by community-controlled organisations. Messages should be strengths-based and encompass Aboriginal ways of living, including family-centred approaches during both prevention and control phases. They should address factors that may contribute to risk such as social determinants of health, including living arrangements and accessibility to services.

- **Clinical Communication:** Public health officers should immediately alert other health services in the region and the regional town that there is a suspect case (if this is thought likely to be confirmed) or if there is a confirmed case. This should include services in other jurisdictions if there is regular travel between these communities.

- **Education of confirmed and suspect cases:** Suspect cases should be offered education on why isolation is required to protect others and how this can be done within a household as well as social and cultural support. This should be ongoing if the case is confirmed. All contacts should be provided with an explanation of COVID-19, ample opportunity to ask questions; informed about the community response plan including quarantine options and why it is important that they quarantine themselves to protect others.

- **Flexible and responsive models of care:** Consider flexible health service delivery and healthcare models (e.g. pandemic assessment centres, flexible ACCHSs clinic hours/location with additional staffing, and home visits). Consider employing the use of point of care influenza tests, where available, to help determine whether influenza is implicated in presentations in the community.

- **Isolation and quarantine:** Families should feel empowered and be part of decision-making around quarantine. This can be achieved through exploring with families what quarantine looks like, working through how it might impact on the family and their way of living, and identifying ways around it. Family members will want to visit unwell people in hospital. It should be made clear that there are other ways to be with sick family members in hospital, maintain communication with families and communities in lieu of gatherings (e.g. staying socially connected through the internet and video calling).
**Aged care facilities**

Aged care facilities are high-risk settings for infectious disease outbreaks. This is because there is often high density living with extensive close physical contact between staff and residents during the provision of care. Residents are at increased risk of severe illness and death due to their age and presence of co-morbid conditions. There are often many visitors, volunteers and staff moving between the community and facilities, which can promote the spread of infectious diseases.

Residents of aged care facilities who require testing for SARS-CoV-2 should be tested on site, where feasible.

**Preventative measures**

In addition to usual preventative protocols, aged care facilities should ensure that high rates of influenza vaccination are maintained amongst all occupants and staff. Messaging to discourage unwell visitors from visiting facilities and occupants should be reinforced, and care should be taken to ensure unwell staff and volunteers know not to present to work while symptomatic with any infectious condition. Visitors, residents and staff should be encouraged to increase their frequency of hand hygiene (with soap and water or using alcohol hand rub), surface cleaning, and to use correct cough/sneeze etiquette.

**Outbreaks**

The vast majority of aged care facilities should have frameworks and protocols for testing and isolation in the event of respiratory disease outbreaks.


**Correctional and detention facilities**

Correctional and detention facilities are likely to be at increased risk for significant transmission of COVID-19. This is due to high-density shared living arrangements where inmates are often located in close proximity and logistical and practical difficulties involved in implementing physical distancing. Visitors, inmates and staff moving between the facility and the community, and inmate transfers between facilities, represent potential routes of introducing infection into correctional and detention facilities.

**Preventive measures**

Consider zoning or cohorting of staff, inmates and essential prison services (e.g. food service, laundry, cleaning) so that if a case occurs, the number of close contacts is a fraction of the people in the facility, not everyone. Correctional and detention facilities should educate staff, inmates and visitors to inform their behaviour and promote preventive measures. Staff, inmates and visitors should be encouraged to self-screen for symptoms, practise good personal hygiene, and practise physical distancing where possible. If staff or visitors are unwell, they should not enter the facility, and facilities should consider the use of a screening tool for visitors and/or staff. If inmates are unwell with COVID-19 symptoms, SARS-CoV-2 testing should be arranged. Unwell inmates should be kept separate from others until results are available and/or symptoms have resolved. Facilities should undertake regular environmental cleaning and should ensure hygiene supplies such as soap are readily available for inmates and staff. Precautions should be taken when transferring inmates between facilities and when admitting new inmates to a facility, with screening processes in place.
Early detection, testing and isolation of symptomatic inmates is essential. For more information, refer to section 3.2 of the *CDNA National Guidelines for the Prevention, Control and Public Health Management of COVID-19 Outbreaks in Correctional and Detention Facilities in Australia*.

**Outbreaks**

Correctional and detention facilities may already have frameworks and protocols in place for testing and isolation in the event of a disease outbreak. Correctional and detention facilities should prepare for and manage outbreaks of COVID-19 with close reference to the *CDNA National Guidelines for the Prevention, Control and Public Health Management of COVID-19 Outbreaks in Correctional and Detention Facilities in Australia*.

### 13. Special situations

**Cruise ships**

**Risk assessment and identification of contacts**

Cruise ships represent a high-risk setting for outbreaks of COVID-19. All persons travelling on cruise ships, regardless of whether cases of COVID-19 have occurred, should be quarantined for 14 days following disembarkation.

**Hospital transfer of confirmed, probable or suspect cases**

If confirmed, probable or suspect cases on board require transfer to a hospital, the Commonwealth Biosecurity Officer will notify the port authority to provide access for medical transport. The jurisdictional Human Biosecurity Officer will then coordinate transfer of the person to an appropriate medical facility for further management, via the most appropriate means that adheres to necessary precautions.

**Quarantine for passengers and crew after arrival at a seaport**

All returned travellers should quarantine. Returned international travellers, including cruise ship passengers and crew, must adhere to jurisdictional quarantine requirements. States and territories should ensure effective quarantine of returned international travellers, which may include hotel-based quarantine. Matters of quarantine should be addressed jurisdictionally. It is important that appropriate PPE precautions are employed during any travel following disembarkation.

**Disembarking and embarking**

After all confirmed, probable and suspect cases have been managed appropriately and the Human Biosecurity Officer has determined that no other passengers or crew have symptoms consistent with COVID-19, remaining passengers and crew will be allowed to disembark. The vessel may be permitted to commence embarking once it is certain there is no risk of ongoing transmission.
Air crew

Risk assessment and identification of contacts

Decisions regarding the contact classification of cabin crews can be difficult to determine. On an aircraft with one or more confirmed or probable cases of COVID-19, a case-by-case risk assessment should be conducted by the airline in conjunction with the PHU to identify which crew should be managed as close contacts.

Considerations for conducting a risk assessment should include:

- Proximity of crew to confirmed or probable case
- Duration of exposure to confirmed or probable case
- Size of the compartment in which the crew member and confirmed or probable case interacted
- Precautions taken, including PPE worn, when in close proximity to the confirmed or probable case

When the case is in a crew member, similar principles can be applied to identify passengers and crew who should be managed as close contacts.

Where it has been determined that a crewmember is a close contact, the airline is responsible for notifying the relevant state/territory public health authority to facilitate management of the close contact.

For further information, refer to Appendix D: Risk assessment and identification of close contacts in aircrew.

Schools

The best way to prevent transmission of COVID-19 in schools is through the promotion of correct hand hygiene habits and cough/sneeze etiquette. Children or staff with respiratory symptoms should not attend school while symptomatic. If a child or staff member becomes ill with respiratory symptoms, they should be isolated from other students and sent home as soon as possible.

Contact tracing or management of school outbreaks may require temporary full or partial school closures; however, closures are not generally recommended as a reactive measure on public health grounds.
14. References

20. Xia W, Shao J, Guo Y, Peng X, Li Z, Hu D. Clinical and CT features in pediatric patients with COVID-19 infection: Different points from adults.n/a(n/a).

15. Appendices

Appendix A: PHLN guidance on laboratory testing for SARS-CoV-2
Appendix B: Guidance on the use of personal protective equipment (PPE) in hospitals during the COVID-19 outbreak
Appendix C: PHU checklist
Appendix D: Risk assessment and identification of close contacts in aircrew
Appendix E: Information for donor and transplant professionals
Appendix A: SARS-CoV-2 Laboratory testing information

Laboratory testing for SARS-CoV-2 continues to evolve rapidly with the accumulation of clinical data, and as reagents and protocols are refined.

The aim of testing is to, if clinically appropriate, exclude common respiratory viruses using local hospital and community nucleic acid testing capacity, and to simultaneously refer onward to a laboratory with capacity to test for SARS-CoV-2. As co-infection is possible, initial testing protocols should include testing for SARS-CoV-2 in patients with epidemiological risk, even where another infection is shown to be present.

Samples for testing

(i) upper respiratory tract samples  
(ii) lower respiratory tract sample if the lower tract is involved  
(iii) serum (to be stored pending serology availability)

Upper respiratory tract samples

1. Deep nasal and oropharyngeal swab: may be dacron or rayon, although flocked is preferred
   - oropharyngeal (throat): swab the tonsillar beds and the back of the throat, avoiding the tongue
   - deep nasal:
     - Using a pencil grip and while gently rotating the swab, insert the tip 2–3 cm (or until resistance is met), into the nostril, parallel to the palate, to absorb mucoid secretion.
     - Rotate the swab several times against the nasal wall.
     - Withdraw the swab and repeat the process in the other nostril. To conserve swabs the same swab that has been used to sample the oropharynx should be utilised for nasal sampling.
   - place the swab(s) back into the accompanying transport medium

Sampling both sites, deep nasal and oropharynx, is recommended to optimise the chances of virus detection. The swab(s) should be placed in transport medium, which may be viral transport medium (VTM) or Liquid Amies.

If SARS-CoV-2 testing is to be undertaken in a different laboratory to testing for other respiratory viruses, then the original swab and remaining eluate should be forwarded for SARS-CoV-2 testing.

2. Nasal wash/aspirates
   - collect 2-3 mL into a sterile, leak-proof, screw-top dry sterile container

   A nasal wash or aspirate, if available, may be substituted for the deep nasal swab sample described above.

3. Self-collected deep nasal and oropharyngeal swab using a single swab
   - Clear instructions should be provided to the patient. A self-collected combined deep nasal, oropharyngeal swab can be used that accesses the throat, and then a deep nasal swab inserted as far as comfortably possible into the depth of the nasal cavity. The process is then repeated in the second nostril. The swab is then placed into viral transport medium (VTM) or Liquid Amies.
• This broadens the use of swabs available, reduces infection risk to the health care worker providing the collection and also reduces the requirements for Personal Protective Equipment. PHLN has reviewed data that suggests this has been determined to be equivalent to combined nasal/nasopharyngeal and throat swabs in detecting coronavirus.
• To maximise control of the collection process, it is recommended that the self-collect process be undertaken with medical oversight.
• It is recommended that laboratories validate their ability to obtain equivalent viral loads and monitor positivity rates using these self-collection kits compared to other methods of collection.
• A self-collected sample should be clearly identified as such on the report.

**Lower respiratory tract samples**

1. Sputum
   • patient should rinse his/her mouth with water before collection
   • expectorate deep cough sputum directly into a sterile, leak-proof, screw-top dry sterile container

2. Bronchoalveolar lavage, tracheal aspirate, pleural fluid
   • collect 2-3 mL into a sterile, leak-proof, screw-top sputum collection cup or dry sterile container

As lower respiratory tract specimens contain the highest viral loads in SARS-CoV and MERS-CoV, it is advised that lower respiratory tract specimens should be collected for SARS-CoV-2 testing where possible. Initial experience in testing for SARS-CoV-2 seems to be consistent with this prior experience. Repeat testing (especially of lower respiratory tract specimens) in clinically compatible cases should be performed if initial results are negative and there remains a high index of suspicion of infection.

**Serology**

Serum should be collected during the acute phase of the illness (preferably within the first 7 days of symptom onset), stored, and tested in parallel with convalescent sera collected 2 or more weeks after the onset of illness. If no acute sample was collected, sera collected 14 or more days after symptom onset may be tested.

**Specimen handling in the laboratory**

**Microbiology Laboratory**

Laboratory staff should handle specimens under PC2 conditions in accordance with AS/NZS 2243.3:2010 Safety in Laboratories Part 3: Microbiological Safety and Containment. Specimens should be transported in accordance with current regulatory requirements as diagnostic samples for testing.
**Point of care testing outside a PC2 facility**

PHLN members considered the guidance from [WHO on laboratory biosafety](https://www.who.int/publications-detail/laboratory-biosafety-guidance-related-to-coronavirus-disease-2019-(covid-19) and notes the highlighted recommendations which refer to laboratory-based work:

- All procedures must be performed based on risk assessment and only by personnel with demonstrated capability, in strict observance of any relevant protocols at all times.

Diagnostic testing steps for specimens conducted outside of a PC2 facility (such as rapid respiratory testing performed at, or near, the point of care) should be assessed to determine if aerosol generation may occur, to inform which Transmission-based Precautions should be applied, to provide a barrier between the specimen and personnel during specimen manipulation. If local community transmission is established, consideration should be given to implementing airborne precautions. Staff undertaking point of care testing should be adequately trained and assessed in the appropriate use of PPE. Testing should be done in a well ventilated room, preferably with an external exhaust fan. Testing in non NATA/RCPA accredited medical pathology facilities should also adhere to the current NPAAC regulatory framework with respect to point of care tests.

**Clinical Pathology**

Non-respiratory specimens (blood, urine, and stool) are known to contain virus. Standard precautions should be used for non-microbial pathology testing (such as routine biochemistry and haematology). Where possible auto-analysers should be used according to standard practices and/or local protocols. There is evidence that capping and uncapping of samples is not a high risk aerosol generating procedure.

**Respiratory Virus Diagnostic Testing**

Nucleic acid testing of the upper or lower respiratory tract samples is performed for influenza and other common respiratory viruses using standard protocols and methods of the hospital or community laboratory.

Standard protocols of the testing laboratory for respiratory sample processing should be used. This is expected to consist of PC2 laboratory practices, and use of a Class II Biosafety cabinet for aerosol-generating procedures (such as centrifuging without sealed carriers, vortexing). Viral culture can only be undertaken in an accredited laboratory that has a PC3 facility.

The residue (original swab and remaining eluate) of the upper tract sample is forwarded together with the lower tract sample and the serum to the reference laboratory with SARS-CoV-2 testing capacity requesting SARS-CoV-2 testing.

Clinical liaison with jurisdictional public health officers is essential to coordinate referral and testing.

Standard protocols should be used for sample packaging and transport as diagnostic samples for testing (i.e. Category B).
**SARS-CoV-2 specific testing**

*Nucleic acid testing*

Nucleic acid testing (NAT) using real time polymerase chain reaction (RT-PCR) is the method of choice for detection of SARS-CoV-2. Specific diagnostic test approaches for SARS-CoV-2 will be described here only in broad terms. There is significant variation in PCR assays employed by different PHLN member laboratories and non PHLN laboratories performing these tests, and test algorithms are likely to be further refined over time. Commercial assays are becoming available from March 2020 and evaluation of these, or reference to another laboratory evaluation, needs to be performed prior to introduction.

Specific Real Time PCR primer sets to detect SARS-CoV-2 are available. Some PHLN member laboratories have designed their own, and some have implemented primer sets recommended to the World Health Organization (WHO) by leading international coronavirus reference laboratories (available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance). The majority of PHLN testing capacity now employs relatively swift RT-PCR assays for screening, with a laboratory turnaround time of several hours. Confirmation of positives is being done either with RT-PCR assays detecting a different target gene, or broadly reactive PCR tests with sequencing of amplicons (see below).

Well pedigreed PCR primer sets, probes and protocols are available from the WHO/ European Viral Archive (EVAg) (available at https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf?sfvrsn=a9ef618c_2).

Many PCR assays, including those available through WHO will also detect other zoonotic coronaviruses such as SARS-CoV, sometimes with a recognisable shift in the cycle threshold value (Ct) compared to the SARS-CoV-2 target, but not commonly circulating coronaviruses usually detected by commercial assays (e.g. NL63, 229E strains).

Several Australian PHLN reference laboratories began diagnostic testing for the current outbreak using PCR assays capable of detecting a wide range of coronaviruses, including zoonotic and novel pathogens. A number of these were mapped against the promulgated nucleic acid sequence of SARS-CoV-2 from Wuhan, China (GenBank accession MN908947, December 2019) early in the course of the outbreak. Nucleic acid sequencing of amplicons from positive tests is used to identify the coronavirus in this approach. These assays have relatively long turnaround times and have largely been replaced by RT-PCR other than as a confirmatory test in some laboratories.

Complementary DNA (cDNA) synthesized from the VIDRL SARS-CoV-2 has now been made available to all PHLN member laboratories as a test positive control. Synthetic positive control material in the form of nucleic acid templates is also available through WHO/ European Viral Archive (EVAg).

There is variable use of one or two viral targets for SARS-CoV-2 testing. Confirmatory testing using an alternative target, at least in the early stages, for positive samples, is recommended if using a single target.

Testing algorithms are likely to be revised pending further information about the virus, and the number of specimens received in the laboratory for testing.

Viral culture should not be performed for routine diagnosis, and should only be attempted in reference laboratories with appropriate experience and containment facilities. Currently where attempted this is being done at Physical Containment Level 3 (PC3), consistent with current recommendations for SARS-CoV, pending specific SARS-CoV-2 international recommendations.
The Royal College of Pathologists of Australasia Quality Assurance Program (RCPAQAP), with Australian Government support, performed the first SARS-CoV-2 specific QAP, which closed on 11th March 2020, and involved 16 public and private laboratories in all Australian states and in New Zealand. This proficiency testing program (PTP) supplemented previous SARS-CoV, MERS-CoV and other coronaviruses PTP. A second, more detailed PTP is planned to be performed by the RCPA QAP in mid-2020. The second PTP is planned for distribution to a wider range of laboratories, once testing has been extended to more laboratories.

Randox Laboratories and Quality Control for Molecular Diagnostics (QCMD) have announced a pilot EQA scheme for coronaviruses which will include inactivated SARS-CoV-2.

**Serology**

Serology does not currently have a role in the diagnosis of COVID-19 during the acute illness but can be helpful for the diagnosis of past cases, such as for public health follow up of suspected cases who either did not undergo NAT during the acute illness or were NAT negative. Serology will also be important for broad-based surveillance, vaccine efficacy and research activities.

Serology for the determination of past COVID-19 is performed using either in-house methodology or commercially manufactured kits. The SARS-CoV-2 antigens are the four structural proteins: the spike, membrane, envelope and nucleocapsid proteins. Antibody tests to date have used either whole virion or the complete or certain domains of the spike protein and the nucleocapsid protein. The nucleoprotein is the most abundant viral protein whereas the spike protein is the most diverse across the coronaviruses, and therefore the most specific for SARS-CoV-2. The temporal pattern of antibody expression has not been fully elucidated and the persistence of the antibody isotypes is currently unknown. Early evidence suggests that IgM, IgA, IgG and neutralising antibodies become detectable between one and two weeks after illness onset in the majority of cases but some NAT-confirmed COVID-19 cases have not shown seroconversion.

It is recommended that antibody detection be performed using a validated assay meeting acceptable and documented performance standards. Laboratory-based antibody assays available or in development include neutralization assays, enzyme-linked immunosorbent assays, microsphere immunoassays and immunofluorescence assays. A number of point-of-care serological tests have been approved by the Therapeutic Goods Administration subject to conditions, including restrictions on who can obtain them. See ‘Public Health Laboratory Network Statement on Point-of-Care Serology Testing for SARS-CoV-2 (the virus that causes COVID-19)’ for more information. No SARS-CoV-2 western blot assay or SARS-CoV-2 antigen test is currently available.

A seroconversion, or significant rise (e.g. four-fold or greater titre rise) in either neutralising or IgG antibody level is definitive laboratory evidence of SARS-CoV-2 infection whereas detection of neutralising or IgG antibody in a single specimen from a person meeting clinical criteria for COVID-19 is suggestive evidence of SARS-CoV-2 infection. The role of serology for the diagnosis of COVID-19 will be reviewed as more information on the serological response to SARS-CoV-2 becomes available.

The role of serology in determining immunity to SARS-CoV-2 is currently unclear. The development of neutralising antibodies to the spike protein, the virus receptor responsible for host cell entry, has been shown but the correlation of antibodies detected using different methods with virus neutralisation is not known. Further, more studies are needed to determine whether the development of neutralising antibodies to SARS-CoV-2 is indicative of protection from reinfection.
Further Information

The Department of Health has produced a series of resources on COVID-19 for health professionals, including pathology providers and healthcare managers, these may be accessed here: (https://www.health.gov.au/resources/collections/coronavirus-covid-19-resources-for-health-professionals-including-aged-care-providers-pathology-providers-and-healthcare-managers)
Appendix B: Guidance on the use of personal protective equipment (PPE) in hospitals during the COVID-19 outbreak.

Background

This guidance was developed by the Infection Control Expert Group (ICEG) and endorsed by the Australian Health Protection Principal Committee (AHPPC) to provide guidance on the use of personal protective equipment (PPE) in hospital settings during the COVID-19 outbreak.

These recommendations are based on current evidence, current status of COVID-19 in Australia, risk assessment and expert advice. This guidance will be updated as new information becomes available or the epidemiology changes significantly.

This guidance is intended for health care workers in hospital settings including emergency department (ED), intensive care unit (ICU), operating suite, surgery, general medical and surgical wards and obstetrics. The same principles apply to general and neonatal paediatrics, but detailed discussion of their application in paediatric practice is outside the scope of this document.

Refer to above for current case definitions and testing criteria.

Guidance on the use of personal protective equipment (PPE) in non-inpatient healthcare settings during the COVID-19 outbreak is available here.

Further information on the use of masks and respirators in the context of COVID-19 is available here.

NOTE: For clinical care of patients who are NOT potential or confirmed COVID-19 cases, standard infection prevention and control precautions – including use of PPE if required – should be observed i.e. business as usual.

CURRENT EVIDENCE

Evidence relating to transmission of COVID-19 in hospitals is variable, sometimes contradictory and cannot always be extrapolated to the Australian context. Many uncertainties remain. The following advice is based on the best available evidence and the current epidemiology of COVID-19 in Australia, where community transmission is minimal, except in limited geographic areas.

- Asymptomatic COVID-19 has been observed and can occur at any age. Its incidence and role in transmission is not yet known. High rates of asymptomatic infection have been reported during outbreaks in closed settings e.g. cruise ships, aged care facilities, or in the context of high community prevalence. Presymptomatic transmission is well documented; the duration of infectivity before the onset of symptoms is uncertain but limited evidence suggests it can be up to 48 hours. The relationships between viral RNA load and infectivity or disease stage are uncertain:
  - The presence of viral RNA does not necessarily indicate viable/infectious virus
  - Viral RNA load at different stages of disease varies. It has been reported to be relatively high in the early stage, even when symptoms are mild, but to decrease in later stages of disease. It has also been reported to increase with late deterioration.

- There is limited and sometimes contradictory evidence about the mode of transmission of COVID-19 and its relevance to the type of respiratory protection required in different settings:
  - Respiratory droplets produced by breathing, talking and coughing contain particles of varied sizes.
- large droplets (>10 micron) settle on surfaces close to the source patient
- small particles (<10 micron) can remain suspended and travel long distances
  - Clinical and epidemiological evidence suggest that, like most respiratory viral infections, COVID-19 is predominantly transmitted by large droplets.
  - Airborne transmission is believed, by most authorities, to be rare.
    - The quantity of virus contained in small particles (<10 micron) is significantly less than in large droplets and viability is rapidly lost by desiccation.
    - The transmission dynamics of COVID-19 differ significantly from those of the few infectious diseases for which airborne transmission is recognised e.g. TB, measles, varicella, for which reproductive numbers are much higher.
    - Some high risk aerosol-generating procedures are likely to increase the risk of COVID-19 transmission.

**CURRENT STATUS OF COVID-19 IN AUSTRALIA**

- By international standards, Australia has a high (and increasing) rate of testing and a very low percentage of positive results – currently (mid-May 2020) <1%.
- More than 60% of total cases in Australia (to mid-May 2020) have been acquired overseas.
- The number of cases and deaths from COVID-19 in Australia are in marked contrast to those in many parts of Europe, the United Kingdom and North America.
- Since the introduction of travel restrictions and physical distancing measures, the daily number of new infections in Australia has fallen dramatically.
- Community transmission is modest and limited to a few localised sites.
- The case fatality rate in Australia, overall, is <2% and the median age of death is 80 years.
- Limited data are available about COVID-19 cases in healthcare workers. Of those for which information is available, a significant proportion were not occupationally-acquired.

These data indicate that current containment measures in community and health care settings in Australia are effective, if consistently observed.

**General guidance on procedures performed on patients who are NOT suspected or confirmed cases of COVID-19**

During the COVID-19 outbreak, PPE for the care of patients who are NOT confirmed or potential cases of COVID-19 should be used in accordance with the *Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019)*[^1].

**Standard precautions** are required for all patients regardless of known COVID-19 status, including hand hygiene and risk assessment to determine the level of PPE required, if any.

**Cough etiquette and respiratory hygiene** must be observed at all times.

**Physical distancing during the COVID-19 outbreak:** healthcare staff should stay at least 1.5m away from other people including:

- patients, except when unavoidable, e.g. during physical examination/care AND

members of the public, hospital visitors and other staff e.g. in wards, clinics and nonclinical areas e.g. during meetings, in offices and shared workplaces and during tea breaks etc.

Aerosol-generating procedures (AGPs) performed on non-COVID-19 patients.

- Given the current low prevalence of COVID-19 in Australia, standard precautions, in addition to PPE appropriate for the procedure and setting (e.g. operating theatre), are adequate for the performance of AGPs on patients who are not suspected or confirmed cases of COVID-19. A surgical mask, gown, gloves, eye protection (and head covering if required as regular theatre attire) would typically be worn. A P2 or N95 respirator is not required in this context.

NOTE: For AGPs performed on patients who are NOT suspected or confirmed cases of COVID-19, P2 respirators are not required, i.e., a surgical mask is appropriate.

General guidance on procedures performed on patients who ARE potential or confirmed COVID-19 cases.

Care of patients with acute respiratory symptoms or potential or confirmed COVID-19

- Standard precautions, cough etiquette and physical distancing apply, as for all patients
- Patients with acute respiratory symptoms should be asked to wear a surgical mask upon presentation to hospital
- Patients should be placed in a single room with the door closed or in a physically separated closed area designated for suspected COVID-19 cases
- The minimum requirement for an AGP on a patient with suspected or confirmed COVID-19 is a single room with the door closed or a space at least 3m from other patients, designated for the purpose. However, if possible, a high risk AGP (see page 6) should be performed in a negative pressure room or well-ventilated operating or procedure room.

If transfer outside of the room or designated area is necessary, the patient should wear a surgical mask during transfer and practice respiratory hygiene and cough etiquette.

Environmental hygiene

- In addition to routine cleaning, frequently touched surfaces should be cleaned frequently, preferably after each use, or whenever visibly soiled, with detergent/disinfectant wipes or a detergent product, using disposable or laundry safe cloth

Advice on Environmental cleaning and disinfection for health and residential care facilities is available on the Department of Health website.

Transmission-based precautions

- Contact and droplet precautions should be used for the routine care of patients with confirmed or potential COVID-19. Contact, droplet and airborne precautions should be used when performing AGPs on these patients.

NOTE: Previous advice to use airborne precautions for care of patients with severe coughing has been withdrawn because:

- viral load does not necessarily correlate with the stage or severity of COVID-19
- coughing predominantly generates droplets
- surgical masks used by patient and healthcare worker provide adequate protection
Transmission of COVID-19

There is strong clinical and epidemiological evidence that the predominant mode of spread of COVID-19 is via respiratory droplets (produced during speaking, coughing, sneezing etc.):

- **Directly** during close face-to-face contact (within ~1.5 m) by exposure of the face (and then mucosae of mouth, nose or eyes) OR
- **Indirectly** by touching surfaces or fomites contaminated by respiratory droplets and then touching the face

Contact and droplet precautions; PPE for use in routine care of patients with confirmed or potential COVID-19

The following PPE should be put on before entering the patient's room:

- Long-sleeved, preferably fluid-resistant, gown or apron
  - a cloth gown or apron is adequate when direct physical contact is minimal and/or the risk of splash is low (e.g. specimen collection, observations, medication delivery)
- Surgical mask. Varying levels (1,2,3) of fluid resistant surgical masks are available. When the likelihood of exposure to body fluid is low, in routine care, a level 1 surgical mask is appropriate. Level 2 or 3 masks should be used when there is a risk of blood or body fluid exposure and in the operating theatre.
- Eye protection: face shield, wrap-around safety glasses, visor or goggles
- Disposable non-sterile gloves when in direct contact with patient (use hand hygiene before donning and after removing gloves)

Use of boots or shoe covers is not recommended unless gross contamination is anticipated or required as standard attire in operating theatre or trauma room.

Long hair should be securely tied back.

A head covering is not required except as part of standard operating theatre attire or when performing a sterile/aseptic procedure (e.g. central line insertion).

Care should be taken to avoid self-contamination when removing PPE.

The principle is to avoid contamination of clothing, skin or mucous membranes (including the eyes) with potentially contaminated PPE. Do not touch the front of the gown, eye protection or mask and perform hand hygiene between steps. The following sequence is recommended and safe but alternative sequences can be performed safely.

- Remove gloves without touching the outside of the glove and perform hand hygiene
- Remove gown/apron, without touching the front of the gown, by folding it so that the external (exposed) side is inside; perform hand hygiene
- Remove eye protection and mask outside the patient's room and perform hand hygiene.

Unsoiled PPE can be discarded into general waste; if visibly soiled e.g. with blood or faeces, PPE should be disposed of as clinical/infectious waste. (Note: local jurisdictional regulations for waste disposal should be followed).

Only PPE marked as reusable should be reused after decontamination and reprocessing according to the manufacturer's instructions. All other PPE must be disposed of after use.
Contact and airborne precautions: use of PPE during AGPs for patients with confirmed or potential COVID-19

The only modification for airborne precautions, is the requirement for use of a particle filter (P2/N95) respirator or equivalent instead of a surgical mask – all other components of standard, contact and droplet precautions remain the same.

Principles of use of P2/N95 respirators in COVID-19

- P2/N95 respirators should be used only in the context of AGPs
- Health care professionals who use P2/N95 respirators should be trained in their correct use, including how to perform fit-checking and safe removal
- Unless P2/N95 respirators are used correctly, protection against airborne pathogen transmission will be compromised

Fit-checking is the minimum standard for each occasion of use of a P2/N95 respirator.

- An airtight protective seal is difficult to achieve in the presence of facial hair that underlies the edge of the respirator. If this is the case, facial hair should be removed or an alternative type of respiratory – e.g. powered air-purifying respiratory (PAPR) – considered (see below)
- If available, a range of types and sizes of P2/N95 respirators may need to be fit-checked to find one that achieves a protective seal (i.e. passes fit-check). If a suitable P2/N95 respirator cannot be found an alternative - e.g. PAPR - should be considered.

Fit-testing is defined in the Australian/New Zealand Standard 1715 2009 as a validated method for matching P2/N95 respirators with an individual’s facial shape, but has not been widely applied in Australia. Despite increased awareness and demand, in the context of COVID-19, fit-testing of all healthcare professionals, who may need to use P2/N95 respirators, will be difficult due to limited supplies and range of types/sizes available.

NOTE: Fit-testing does not guarantee that a respirator will not leak, particularly if a different type or size is used – this reinforces the need to fit-check each time a respirator is used.

Transmission-based precautions, as outlined – including appropriate use of P2/N95 respirators – will provide high level protection of health care workers caring for patients with suspected or confirmed COVID-19.

Powered air-purifying respirators (PAPR)

- PAPRs are a possible alternative to P2/N95 respirators in selected circumstances
- A number of different types of relatively lightweight, comfortable PAPRs is available
- The use of a PAPR may not provide any additional protection compared to a well sealed P2/N95 respirator
- PAPRs should only be used by healthcare professionals trained in their use, including safe removal in correct sequence; respirator is last item of PPE to be removed
- PAPRs should be used according to the manufacturer’s instructions
- If a health care professional is required to remain in the patient’s room continuously for a long period to perform multiple AGPs e.g. more than one hour, the use of a PAPR may be considered for additional comfort and visibility
- PAPRs used during sterile procedures should be suitable for use to maintain sterile field
- PAPRs designed for use in settings outside of healthcare are not recommended
- Manufacturer’s instructions for reprocessing of reusable PAPR components and management of filters should strictly be followed
Care is required with removal of a PAPR, which is associated with a risk of self-contamination. Only PPE marked as reusable should be reused after decontamination and reprocessing according to the manufacturer’s instructions. All other PPE must be disposed of after use.

**Aerosol-generating procedures**

Some AGPs performed during the care of patients with suspected or confirmed COVID-19 may be associated with an increased risk of transmission. The following examples are illustrative of a range of AGPs.

**Instrumentation or surgical procedures on the respiratory tract including:**

- Insertion or removal of endotracheal tube and related procedures e.g. manual ventilation and open suctioning of the respiratory tract
- Bronchoscopy and upper airway procedures that involve open suctioning
- Tracheotomy/tracheostomy (insertion, removal, open suctioning)
- Ear-nose-throat, faciomaxillary or transphenoidal surgery; thoracic surgery involving the lung
- Post-mortem procedures involving high speed devices on the respiratory tract
- Intentional or inadvertent disconnection/reconnection of closed ventilator circuit

**Other procedures that can generate respiratory aerosols**

- Manual or non-invasive ventilation (NIV): bi-level positive airway pressure ventilation (biPAP); continuous positive airway pressure ventilation (CPAP)
- Collection of induced sputum
- High flow nasal oxygen
- Upper gastrointestinal instrumentation that involves open suctioning of URT
- Some dental procedures e.g. involving high speed drilling

**Cardiopulmonary resuscitation (CPR) is a special circumstance:**

- Because it is an emergency, life-saving procedure, special consideration is warranted for cardiopulmonary resuscitation (CPR).
- A systematic review of AGPs showed that CPR was a high risk procedure, associated with an increased risk of transmission of SARS.
- However, neither chest compression nor defibrillation, alone, was associated with increased risk unless accompanied by intubation.
- In the context of a low rate of community transmission of COVID-19, chest compression and defibrillation are unlikely to pose a risk to first responders or bystanders who commence CPR without knowledge of the subject’s COVID-19 status.
- A healthcare worker using contact and droplet precautions can safely commence chest compression or defibrillation of a patient with potential or confirmed COVID-19, until another clinician arrives, using airborne precautions, to manage the airway

**Use of PPE in specific hospital settings**

**Intensive care unit (ICU)**

Because most ICU patients require or are likely to require AGPs, P2/N95 respirators are often used routinely in ICUs.

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However the risk of airborne transmission is minimal once the patient is intubated with a closed ventilator circuit. In this situation contact and droplet precautions are appropriate.

- **Contact and airborne precautions** should be used for care of COVID-19 patients in ICU requiring AGPs
  - The use of P2/N95 respirators is recommended for AGPs, in the ICU.
  - If a healthcare professional is required to remain in an ICU patient’s room for a long period (e.g. more than one hour) to perform multiple AGPs, the use of a PAPR may be considered, as an alternative, for greater comfort and visibility.

ICU staff caring for patients with COVID-19 (or any other potentially serious infectious disease) should be trained in the correct use of PPE, including the use of P2/N95 respirators and PAPRs, by an infection prevention and control professional or other suitably qualified educator.

**Wards, including care of critically ill patients outside of the ICU setting**

- **Contact and droplet precautions** should be used for care of COVID-19 patients in general wards.
- **Contact and airborne precautions** should be used for care of COVID-19 patients in general wards, when performing an AGP
  - AGPs should be performed in a negative pressure room (or a standard isolation room with door closed).
  - The number of persons present in the room should be minimised.

**Emergency departments**

- **Contact and droplet precautions** should be used for routine care of COVID-19 patients in the emergency department.
- **Contact and airborne precautions** should be used for care of COVID-19 patients when performing an AGP (e.g. passage of an endotracheal tube)
  - AGPs should be performed in a negative pressure room, where possible (or a standard isolation room with door closed).
  - The number of persons present in the room should be minimised.

**Operating suite**

NOTE: For procedures performed on patients in an operating suite who are NOT confirmed or potential cases of COVID-19, the usual surgical PPE for the clinical circumstances should be used, i.e., surgical mask, theatre cap, gown, gloves, eye protection.

Routine infection prevention and control principles should be strictly adhered to during elective surgery, including avoidance of unnecessary entry and exit from the operating theatre during surgery.

The number of people in the theatre should be limited to those required for clinical or educational purposes.

- Surgical procedures for patients with suspected or confirmed COVID-19 should be performed only in an emergency.

Separate guidelines are available for use of PPE by anaesthetic and surgical staff caring for patients with confirmed or potential COVID-19 in the operating suite, during different types of surgery or procedures.

The same general principles apply as outlined above:
• **Standard precautions** apply to the care of all patients, including use of PPE based on risk assessment
• **Contact and droplet** precautions for anaesthetic or surgical procedures not involving AGPs in patients with suspected/confirmed COVID-19
• **Contact, droplet and airborne** precautions for anaesthetic or surgical procedures involving AGPs with suspected/confirmed COVID-19

**Labour ward**

For care of a pregnant woman, with suspected or confirmed COVID-19, during labour:

• The woman should be asked to wear a surgical mask, if tolerated
• **Contact and droplet precautions** should be observed by labour ward staff, in addition to standard precautions
• **Contact, droplet and airborne precautions** should be used in the later stages of labour if an AGP, such as intubation, ventilation or high flow nasal oxygen of mother or baby is required.
• The woman’s partner or other support person (one only) may attend the delivery even if s/he is in quarantine\(^6\). Precautions required to protect labour ward staff include:
  o On entering the hospital, the partner/support person should: perform hand hygiene and put on surgical mask (to protect staff); in the labour ward put on a gown (to protect clothes from blood/liquor)
  o On leaving the labour ward, the partner/support person should remove gown and perform hand hygiene; perform hand hygiene and remove mask (if not in quarantine) when leaving premises
  o If the partner is in quarantine as a close contact, s/he should observe precautions as instructed by the PHU and wear a mask until reaching home.
  o **A person with acute respiratory or other symptoms consistent with COVID-19 should not attend the delivery.**

**Where can I get more information?**

For the latest advice, information and resources go to the Department of Health website www.health.gov.au

Call the National Coronavirus Health Information Line on 1800 020 080. The line operates 24 hours a day, seven days a week. If you require translating or interpreting services, call 131 450.

The telephone number of your state or territory public health authority is available on the coronavirus page on the Department of Health website www.health.gov.au/state-territory-contacts

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\(^6\) Quarantine is required for someone who has had close contact with a potential or confirmed case, recent overseas travel or other exposure in the last 14 days but who remains asymptomatic.
Appendix C: PHU checklist

*Using the appropriate jurisdictional investigation form or program, contact the patient or their doctor to:*

- Confirm the onset date and symptoms of the illness.
- Confirm results of relevant pathology tests, or recommend that tests be done, including repeat tests where relevant.
- Where applicable and feasible, seek the doctor’s permission to contact the case or relevant care-giver.
- Review case management including:
  - infection control measures being used in caring for the case, and
  - home isolation procedures are being followed.
- Ensure appropriate infection control measures are followed in caring for the case.

*Interview the case or care-giver to complete exposure and contact history and other details*

- Complete the exposure history and other sections of the relevant jurisdictional investigation form.
- Identify close contacts according to the contact definition.
- Identify the likely source of infection.
- Determine if the case has attended settings that are at higher risk for infection.

*Follow-up case’s contacts to:*

- Assess risk of COVID-19 transmission and identify any close contacts.
- Determine current symptoms, if any, and manage as a suspect case if present.
- Explain symptoms, advise on active daily monitoring of symptoms by public health unit (close contacts) where feasible and need to immediately report any new symptoms.
- Explain to all close contacts the need for quarantine.
- Provide state based factsheets as appropriate.
- Arrange PCR and serological testing if available and contact is symptomatic, and follow local policy for testing in an outbreak setting. Seek protocol on this from the reference laboratory or central communicable disease agency where necessary.
- For cases in schools, aged care facilities, correctional and detention facilities, and Aboriginal and Torres Strait Islander communities, relevant guidelines should be followed. Refer to Special risk settings and Special situations for links to guidelines.

*Notify central jurisdictional communicable disease control agency, if they do not already know*

*Central communicable disease control agency to notify Commonwealth Department of Health Office of Health Protection*

*Consider need for media release and designate a media spokesperson.*
Appendix D: Risk assessment and identification of close contacts in aircrew

These recommendations are intended to assist airlines undertaking risk assessments in consultation with PHUs to identify which air crew are close contacts of a confirmed or probable COVID-19 case. The recommendations relate to the specific circumstance where an ill passenger or crew member has travelled on a flight and potentially exposed other passengers and crew. It is important to note that an infected person may be infectious up to 48 hours prior to onset of symptoms and while symptomatic. Any risk assessment needs to consider that a person may appear well, but still be infectious. This risk assessment is directed at identifying air crew close contacts. Contact management among passengers is the responsibility of public health units.

General principles

- Case-by-case risk assessments should be conducted by the airline in consultation with PHUs to identify close contacts among aircrew where one or more confirmed or probable cases of COVID-19 were present on a flight.
- Risk assessments for air crew should be consistent with criteria for being a close contact:
  - Face-to-face contact in any setting with a confirmed or probable case, for greater than 15 minutes cumulative over the course of a week, in the period extending from 48 hours before onset of symptoms in the confirmed or probable case;
  - Sharing of a closed space (i.e. the same air craft section) with a confirmed or probable case for a prolonged period (more than 2 hours) in the period extending from 48 hours before onset of symptoms in the confirmed or probable case; or
  - Direct contact with the body fluids (e.g. used tissues) of a confirmed or probable case in the absence of wearing recommended PPE or if there was a failure of PPE.
- Risk assessments should be conducted in consultation with the relevant public health unit, particularly where the exposures are unclear or complex.

Considerations for conducting risk assessments

For aircraft crew exposed to a confirmed or probable case, a case-by-case risk assessment should be conducted by the airline to identify which crew member(s) should be managed as close contacts.

Considerations for conducting a risk assessment should include:

1. Proximity of crew to confirmed or probable case  
   Crew who have had face-to-face contact with an infected passenger for greater than 15 minutes cumulative during the course of the flight should be considered close contacts.

2. Duration of exposure to confirmed or probable case  
   Crew who provided prolonged periods of in-flight service in the section of the aircraft where the infected passenger was seated should be considered close contacts.
3. Size of the compartment in which the crew and confirmed or probable case interacted
   Subject to considerations about aircraft design and airflow patterns, crew who provided in-flight service for greater than 15 minutes cumulative in confined sections (e.g. first or business class) where the infected passenger was seated should be considered close contacts.

4. Precautions taken, including PPE worn, when in close proximity to the confirmed or probable case
   Crew who were involved in looking after an infected passenger (e.g. providing first aid) who was ill without wearing appropriate PPE should be considered close contacts.

   Cockpit crew who did not walk through cabins or come close to the infected passenger(s) or crew member(s) are not considered to be close contacts.

   Where the confirmed or probable COVID-19 case is an aircraft crew member, all associated crew should be considered close contacts. In this circumstance, public health units will concentrate contact tracing efforts on passengers seated in the area where the crew member worked during the flight along with other members of the crew. The same general principles and considerations detailed above can be adapted to identify close contacts in these circumstances.

   If an airline becomes aware that a crew member or passenger is a close contact of a confirmed or probable case, they should notify the local public health unit to facilitate management of the close contact/s.
Appendix E: Organ donation and transplantation

Testing of deceased and living donors and transplant recipients

Viral safety of donated tissue and organs remains a concern as there is significant uncertainty about viraemia during the COVID-19 incubation period; during an asymptomatic course of infection; or after symptom resolution (29-32).

There is currently no licensed test for the screening of blood, plasma or cell and tissue donations. Laboratory screening of blood, plasma, cells and tissues is currently not recommended. This is because transmission of COVID-19 through donated tissues and organs has not been reported; and levels of detected RNA in plasma coinciding with clinical symptoms are very low (29). SARS-CoV-2 testing is rapidly evolving and these recommendations will be subject to ongoing review.

To mitigate the risk of transmission through donated organs and to ensure transplantation is conducted as safely as possible, all deceased and living donors should be tested for SARS-CoV-2 with negative results obtained prior to transplantation proceeding; ideally, the same principles would be applied to recipients. Donation should not proceed from deceased individuals in whom there is a clinical suspicion of COVID-19. All deceased donors should be routinely tested to exclude COVID-19, although transplant teams should have the discretion to proceed prior to test results being available in time constrained circumstances. The practice of routine testing of potential recipients of deceased donor organs should be determined by the local transplant unit in consultation with infectious disease clinicians. When testing has been performed and the potential recipient is deemed to be at low risk on epidemiological and clinical grounds, the decision to proceed to transplantation prior to test results being available in time constrained circumstances should be at the discretion of the transplant team.

Processing of respiratory samples from donors (including all unrelated haemopoietic stem cell donors) and recipients should be prioritised in order to enable expedited retrieval and transplantation processes. Increasing availability of rapid testing may expedite testing timeframes to support time criticalities for deceased donor testing.

Asymptomatic donors and recipients without any other epidemiological risk factors are not classified as suspect cases and do not need to be quarantined or isolated following testing, unless a positive test result is received.

For collection of specimens from asymptomatic members of the public being tested for surveillance (i.e. enhanced testing) purposes, standard precautions are required; additional PPE is not required. During the COVID-19 outbreak, PPE for the care of patients who are not suspected or confirmed cases of COVID-19 should be used in line with the Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019). (https://www.nhmrc.gov.au/about-us/publications.australian-guidelines-prevention-and-control-infection-healthcare-2019#block-views-block-file-attachments-content-block-1). These guidelines should also be considered together with the COVID-19 specific advice from the Infection Control Expert Group on the use of PPE for inpatient care https://www.health.gov.au/resources/publications/guidance-on-the-use-of-personal-protective-equipment-ppe-in-hospitals-during-the-covid-19-outbreak
Interstate travel for tissue and organ retrieval and transplantation teams

To protect the health and safety of all involved in organ retrieval and transplantation during the COVID-19 pandemic, where possible, local teams should conduct surgical retrieval of organs within the donor hospital. Where this is not possible, organ and tissue retrieval and transplantation teams should not be restricted from interstate travel for the purpose of tissue and organ procurement or delivery.

Persons who have travelled interstate for organ and tissue retrieval and transplantation purposes should not be subject to quarantine measures, but should vigilantly self-monitor for symptoms for 14 days following their return and immediately isolate if they become unwell. These persons must continue to adhere to physical distancing measures, hand hygiene, respiratory hygiene and cough etiquette during and after travel.

Information for donation and transplant professionals

Knowledge about COVID-19 is rapidly evolving with advice and publications regarding the disease continually being updated. The guidance in this appendix will evolve due to changing circumstances, e.g. community prevalence of viral infection, viral test accessibility, and intensive care unit and hospital capacity.

Clinicians within the organ donation and transplantation sector should ensure that information utilised is in its most up to date form.

The donor risk assessment interview includes questions about travel and occupation (healthcare workers with direct patient contact) that is relevant to assessing epidemiological risk for COVID-19. In addition, it should be ascertained whether the donor has ever been tested or diagnosed with COVID-19, or has been in close contact with a person known to have confirmed, probable, or suspected COVID-19.

Routine testing of recipients prior to transplantation

Ideally, routine testing of organ recipients for SARS-CoV-2 will be undertaken, preferably within 48 hours of transplantation for recipients of living donor organs, and shortly prior to transplantation for recipients of deceased donor organs, if possible. Samples collected should include:

- Nose and throat swab (PCR test)
- Blood (for retrospective serology testing)

Testing of recipients is based on potential impact of COVID-19 during a highly-immunosuppressed post-transplantation phase. For intended recipients of living donor organs a negative result should be obtained prior to proceeding. For recipients of deceased donor organs, where possible obtain the PCR results prior to proceeding with transplantation although this should be at the discretion of the transplant team in time constrained circumstances.

Recipients (or their delegates) should be questioned to ascertain epidemiological risk and clinical features for COVID-19 prior to proceeding with transplantation. Where there is suspicion for recipient COVID-19 infection negative PCR results should be obtained prior to proceeding with transplantation. Careful consideration should be given to recipients who are at epidemiological risk and may be in the incubation period of COVID-19 where PCR tests may be negative.
**Routine testing of living donors**

It is recommended that routine testing of living donors (generally kidney donation) is undertaken for SARS-CoV-2 (virus causing COVID-19), preferably within the 48 hours prior to donation. Samples collected should include:

- Combined deep nasal and throat swab (PCR test), and
- Blood (for retrospective serology testing)

Obtain the PCR results prior to proceeding with donation.

**Routine testing of deceased donors**

Routine COVID-19 (SARS-CoV-2) virus testing should be undertaken in all deceased donors, before proceeding with donation in certain cases as described below, and generally within 72 hours of donation for all other cases. Samples collected should include:

- Combined nose and throat swab (PCR test), and
- Lower respiratory tract specimen, preferably endotracheal aspirate* (PCR test), and
- Blood (serology clotted) tube (for retrospective serology testing)

*Undertake endotracheal aspirate only if it can be done safely, as per local ICU policies. If it is not possible to collect a lower respiratory tract specimen, then a stool PCR (rectal swab) may be undertaken; SARS-COV-2 RNA may be detectable in stool for a longer duration than in respiratory tract specimens. Broncho-alveolar lavage is not currently recommended owing to the higher risk of aerosol generation and the need to conserve ICU bronchoscopes.

Where possible obtain the PCR results prior to proceeding with donation.

**Decision to proceed with donation and transplantation**

- Where possible obtain COVID-19 (SARS-CoV-2) PCR results prior to proceeding with donation.
- Donors in whom COVID-19 is NOT suspected, probable or confirmed – donation can proceed without prospective PCR test results being available, noting that access to timely PCR testing is currently variable.
- In a suspect case of COVID-19 only proceed to organ retrieval and transplantation once negative PCR test results are received (donation workup can continue until this time).
- If a potential living donor has ARI symptoms, donation should be delayed until symptoms have resolved even if the test is negative. Only in time critical circumstances, and where the transplantation team has appropriately considered epidemiological and clinical risks, should transplantation proceed prior to resolution of ARI symptoms.

A **suspect case** is a patient satisfying epidemiological **AND** clinical criteria, as described in the [case definition](https://www.who.int/docs/default-source/coronaviruse/who-china-joint-mission-on-covid-19-final-report.pdf).
If it is not possible to obtain PCR test results, do not proceed in a suspect case.

NOTE: COVID-19 tests may be negative in the incubation period of up to 14 days. Diagnostic sensitivity is improved by testing lower respiratory tract samples in addition to upper respiratory tract samples.

Obtain advice from an **Infectious Disease physician** where PCR tests are negative, there is a strong clinical suspicion of COVID-19 infection, and no other cause is identified.

- **Exclude as deceased donors:**
  - If **confirmed COVID-19 positive** – do not work up for donation if known infection; stand down case if positive result obtained as part of donor workup.
  - If **probable case of COVID-19**
    - If **COVID-19 is suspected due to presence of severe bilateral community-acquired pneumonia** and no other cause is identified (irrespective of COVID-19 PCR test results).
    - If the donor suffered unexplained respiratory failure leading to death (33).
  - If prior infection, it may be safe to proceed to donation although information is limited at present. Consider only after discussion with an Infectious Disease physician and when the need for transplantation is urgent.