

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Biosecurity (Listed Human Diseases) Amendment Determination 2020

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The *Biosecurity (Listed Human Diseases) Amendment Determination 2020* adds 'human coronavirus with pandemic potential' as a listed human disease, and therefore enables the application of a range of measures under the *Biosecurity Act 2015*.

Human rights implications

This legislative instrument engages and is consistent with Article 12(1) of the International Covenant on Economic, Social and Cultural Rights by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

This instrument provides the means of protecting public health in Australia through enabling the application of human biosecurity measures to manage the risk of human coronavirus with pandemic potential entering Australian territory, or emerging, establishing, or spreading in Australian territory or a part of Australian territory.

Conclusion

This legislative instrument is compatible with human rights because it promotes the human right to an adequate standard of living and the highest attainable standard of physical and mental health.

Professor Brendan Murphy
Director of Human Biosecurity
Chief Medical Officer
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Biosecurity (Listed Human Diseases) Amendment Determination 2020

I, Professor Brendan Murphy, Director of Human Biosecurity, make the following legislative instrument.

Dated

Professor Brendan Murphy **DRAFT ONLY—NOT FOR SIGNATURE**
Director of Human Biosecurity

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1 Name

This instrument is the *Biosecurity (Listed Human Diseases) Amendment Determination 2020*.

2 Commencement

This instrument commences on the day it is registered.

3 Authority

This instrument is made under subsection 42(1) of the *Biosecurity Act 2015*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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Schedule 1—Amendments

Biosecurity (Listed Human Diseases) Determination 2016

1 Section 4

After “(g) yellow fever”, add

“; (h) human coronavirus with pandemic potential”.

Commented [KM1]: This is drafted this way to remove the full stop after yellow fever, add the semi-colon and paragraph (h)

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**Communicable Diseases Network Australia Committee Meeting
Jurisdictional Executive Group**

Meeting Date: 20 January 2020

Item Number: 2.1

Sponsor: Chair

Speaker: Members

Viral Pneumonia in Wuhan, China

Recommendations

That CDNA Members:

- 1. Discuss** the outbreak of viral pneumonia in Wuhan, China.

Purpose of Paper

To discuss the outbreak of viral pneumonia in Wuhan, China.

Background

Please refer to the attachments to aid the discussion.

Aboriginal and Torres Strait Islander health impact statement

Nil.

Attachments

- Attachment A: Event Update 2 – Viral Pneumonia in China
- Attachment B: International Travel Patterns from Wuhan, China
- Attachment C: Series of National Guidelines – Middle East Respiratory Syndrome Coronavirus
- Attachment D: Case Definition – Middle East Respiratory Syndrome Coronavirus
- Attachment E: Laboratory Case Definition – Middle East Respiratory Syndrome Coronavirus
- Attachment F: World Health Organization Technical Documents for Novel Coronavirus

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FOR OFFICIAL USE ONLY**Contact information**

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Australian Government

Department of Health National Incident Room

Viral Pneumonia - China

Report Details

Report Type	Stakeholder Update
Issued	2020-01-17
Reference	NIR #2238
Update	2

Key Points

Epidemiological Situation

- On the 9th January the World Health Organization reported that Chinese authorities had made a preliminary determination of a novel (or new) coronavirus, identified in a hospitalised person with pneumonia in Wuhan, Hubei Province China¹.
- There are many different coronaviruses that affect humans and animal including for example, coronaviruses that cause the common cold but also more clinical serious conditions such as Severe Acute Respiratory Syndrome (SARS) and Middle Eastern respiratory syndrome (MERS).
- As of 16 January, there have been 43 cases preliminarily diagnosed with novel coronavirus. All cases either live or have recent travel history to Wuhan.
 - Of those 43 cases, 41 have been diagnosed in Wuhan China, one in Thailand, and one in Japan.
 - No additional cases have been detected since 3 January 2020 in China.
- Thai health authorities have reported a confirmed case of the novel coronavirus in a Chinese tourist who is a resident of Wuhan and was unwell prior to travelling to Thailand.²

¹ WHO Statement Regarding Cluster of Pneumonia Cases in Wuhan, China <https://www.who.int/china/news/detail/09-01-2020-who-statement-regarding-cluster-of-pneumonia-cases-in-wuhan-china> - accessed 10 January 2020

² WHO Disease Outbreak News, Novel Coronavirus – Thailand (ex- China) <http://origin.who.int/csr/don/14-january-2020-novel-coronavirus-thailand-ex-china/en/> - accessed 17 January 2020

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- On 16 January, Japan reported a confirmed case of the novel coronavirus in a Chinese national who had recently returned from Wuhan, China.³
- There have been two reported deaths. One in a case with severe underlying medical conditions, and the other a case who was 69 years old.²
- There appears to be a common epidemiological link **in most cases**, where those affected attended (as vendors, traders or customers) a live seafood market. Media is reporting that the market also sold birds, bats, other animals and organs from wildlife.⁴
 - The cases identified in Japan and Thailand claim that they had not visited the Huanan South China Seafood Market.
 - A member of a small family cluster in China did not visit the Huanan South China Seafood Market, but is the wife of a market vendor.
- The source of infection remains under investigation.
- Chinese health authorities have implemented monitoring, control and prevention measures including contact tracing, isolation of cases and public risk communications. The market **has been closed since 1 January 2020** and has undergone environmental sanitation and disinfection.⁴
- There is no evidence of ongoing human to human transmission at this time. Additionally, there has been no reported transmission to health care workers.⁴
- Investigation and laboratory testing in China is ongoing.
- To date, there are no reported cases in Australia.
- Australia has excellent public health laboratory capacity to test for and identify the novel coronavirus and strong public health systems in place should a case be identified in Australia.
- The Department of Health, through the National Incident Room, is closely monitoring this situation in collaboration with the World Health Organisation and the states and territories.

Full detail at [Appendix A](#).

Response Actions

China

National authorities have reported the following response measures:

- One hundred and twenty-one close contacts have been identified and are under medical observation;
- Pathogen identification and the tracing of the cause is ongoing;
- Wuhan Municipal Health Commission carried out active case finding, and retrospective investigations have been completed;
- Environmental sanitation and further hygiene investigations are under way.⁴

Australia

- The National Incident Room is actively monitoring this outbreak.
- No specific measures are recommended for travellers to Australia at this time. This is consistent with the recommendations of the WHO under the IHR.⁴

³ WHO Disease Outbreak News Novel Coronavirus – Japan (ex-China) <https://www.who.int/csr/don/16-january-2020-novel-coronavirus-japan-ex-china/en/> - accessed 17 January 2020

⁴ WHO Disease Outbreak News, Pneumonia of unknown cause - China https://www.who.int/csr/don/05-january-2020-pneumonia-of-unknown-cause-china/en/?fbclid=IwAR3dxY_pgmycpud1lsir4DxYblsDnum1WGGnoFf_lsyR4PBQQLrC4F1_oww - accessed 10 January 2020

FOR OFFICIAL USE ONLY**Thailand**

National authorities have reported the following response measures:

- Screening of travellers from Wuhan at airports;
- Activated enhanced surveillance at public and private hospitals;
- Monitoring identified contacts, including 40 high-risk and 142 low-risk contacts.
- Risk information accessible to the public including a hotline for people returning from the Wuhan with related symptoms.²

Full detail at [Appendix B](#).

Risk

More comprehensive information is required to understand the current status and epidemiology of the outbreak, and the clinical picture. Further investigations are also required to confirm the source, modes of transmission, extent of infection and any effective medical countermeasures.

Chinese authorities have noted, while the virus in question can cause severe illness in some patients, it does not transmit readily between people.

Australia has excellent public health laboratory capacity to test for and identify viral and bacterial agents and strong public health systems and border measures to detect and manage ill travellers.

Planned Action

Australian National Focal Point (Health)

- The National Incident Room will continue to review any available information on the outbreak and will update advice as and when required.
- **Assessment to the risk to Australia and Australians is ongoing.**
- **Information and advice on this outbreak will be published on the Department of Health website shortly.**

Authorised By

Celia Street, FAS Office of Health Protection

Distribution

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Further Information

This report is issued by the Australian National Focal Point (NFP). The Australian NFP is located in the Office of Health Protection at the Australian Government Department of Health and its activities are supported 24/7 by the National Incident Room. The Australian NFP is established under the *National Health Security Act 2007*.

For more information on the event(s) in this report, contact the NFP at health.ops@health.gov.au or +61 (2) 6289 3030.

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Appendix A

Appendix A: Epidemiological Situation

Situation

- On 31 December 2019, the WHO China Country Office was informed of cases of pneumonia of unknown aetiology (unknown cause) detected in Wuhan City, Hubei Province of China. As of 3 January 2020, a total of 44 patients with pneumonia of unknown aetiology have been reported to WHO by the national authorities in China. Of the 44 cases reported, 11 were severely ill, while the remaining 33 patients are in stable condition.⁴
- Chinese national authorities report that all patients were isolated and received treatment in Wuhan medical institutions.⁴
- China has strong public health capacities and resources to respond and manage respiratory disease outbreaks.¹
- Preliminary identification of a novel virus in a short period of time is a notable achievement and demonstrates China's increased capacity to manage new outbreaks and share information.¹
- In addition to treating the patients in care and isolating new cases as they may be identified, public health officials remain focused on continued contact tracing, conducting environmental assessments at the seafood market, and investigations to confirm the identity of the pathogen causing the outbreak.¹
- High volumes of Chinese nationals undertaking international travel during the upcoming Lunar New Year season has prompted some Asian countries such as Singapore, Hong Kong, South Korea, Thailand and Taiwan to implement increased border surveillance.⁵

Background

- Human coronaviruses are common throughout the world.
- Coronaviruses are a large family of viruses with some causing less-severe disease, such as the common cold, and others more severe disease such as MERS and SARS. Some transmit easily from person to person, while others do not. According to Chinese authorities, the virus in question can cause severe illness in some patients and does not transmit readily between people.¹
- It is the potential clinical severity of MERS-CoV and SARS-CoV has led to intensified global interest and the heightened concerns around disease transmission.

⁵ China's new virus looms over Lunar New Year travel <https://asia.nikkei.com/Spotlight/Society/China-s-new-virus-looms-over-Lunar-New-Year-travel> - accessed 10 January 2020

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Appendix B

Appendix B: Response Actions

China

- China has a Physical Containment Level 4 Laboratory, based in Wuhan, where laboratory testing is being undertaken.

Thailand

- Screening travellers from Wuhan city commenced on 3 January 2020 at Suvarnabhumi Airport, Don Mueang, Phuket and Chiang Mai airports.
- The Ministry of Public Health of Thailand has international-standard diagnosis and medical care, and is closely coordinating with WHO and related departments for the potential response measures.

Border Measures in Australia

- Australia has well established processes in place for screening of ill travellers arriving at our international air and sea ports.
- No international travellers suspected of having coronavirus have been identified at Australian borders.
- No specific measures are recommended for travellers to Australia at this time. This is consistent with the recommendations of the WHO under the IHR.
- Border agencies have been advised to follow existing processes for screening ill travellers arriving at Australia's international air and seaports. This includes identification of ill travellers, isolation and referral to Human Biosecurity Officers where indicated.
- This novel coronavirus is not an LHD under the *Biosecurity Act 2015*, however should it become necessary, a disease can be determined as an LHD very quickly.

Laboratory Testing in Australia

- The preliminary determination of a novel coronavirus assists with disease detection and response.¹
- Through the Victoria Infectious Diseases Reference Laboratory, Pathwest (WA), Queensland Health Forensic and Scientific Services and the Institute for Clinical Pathology and Medical Research (NSW) there is good capability to test for the novel coronavirus.

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Article Type: Rapid Communication

Title: Pneumonia of Unknown Etiology in Wuhan, China: Potential for International Spread Via Commercial Air Travel

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Keywords: SARS; Air Travel; Coronavirus; Pneumonia; Outbreak; Zoonosis

Word count: 659

Tables: 1

Figures: 0

Highlight: There is currently an outbreak of a pneumonia of unknown etiology in Wuhan, China.

While there are still several unanswered questions, we evaluate the potential for international dissemination of this disease via commercial air travel should the outbreak continue.

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On December 30, 2019, a report of a cluster of pneumonia of unknown etiology was published on ProMED-mail, possibly related to contact with a seafood market in Wuhan, China.¹ Hospitals in the region held an emergency symposium, and support from federal agencies is reportedly helping to determine the source of infection and causative organism. The seafood market has since been closed, but purportedly sold a variety of live animal species. On January 5, 2020, the World Health Organization (WHO) published a document outlining their request for more information from Chinese public health authorities, and detailed 44 patients had “pneumonia of unknown etiology”, with 121 close contacts under surveillance (www.who.int/csr/don/05-january-2020-pneumonia-of-unknown-cause-china/en/). The WHO reported that 11 patients were severely ill, and many affected individuals had contact with the Huanan Seafood market. Some patients were reported to have fever, dyspnea, and pulmonary infiltrates on chest radiography. At the time of publication, limited information has been produced directly by Chinese public health authorities, however media reports documenting interviews with such authorities have stated that the etiology is not yet identified, that there are now 59 affected patients, and that Severe Acute Respiratory Syndrome (SARS), the Middle East Respiratory Syndrome (MERS), avian influenza, and several other common respiratory pathogens have been ruled out (<http://news.hebei.com.cn/system/2020/01/05/100154729.shtml>). On January 8, 2020, news outlets and ProMED-mail reported that genetic sequencing demonstrated a novel coronavirus as the potential causative organism.² Given the recent history of zoonotic transmission of a coronavirus emerging from a live-animal market in China in 2002, and the potential for novel pathogens to rapidly spread globally via commercial air travel,^{3,4} we sought to evaluate international travel patterns from Wuhan, China in order to anticipate patterns of disease dispersion should this outbreak evolve.

We evaluated 2018 travel data generated from the International Air Transport Association (IATA) to quantify passenger volumes originating from the international airport in Wuhan, China, between January through March, inclusive. IATA data accounts for approximately 90% of passenger travel itineraries on commercial flights, excluding transportation via unscheduled charter flights (the remainder is modelled using market intelligence). These data represent direct origin (Wuhan) to destination trips, and indirect trips that originated in Wuhan, but had connecting flights to a final destination. We also report Infectious Disease Vulnerability Index (IDVI) scores for countries receiving significant numbers of travellers from Wuhan.⁵ The IDVI score is a validated tool to estimate a country's capacity to prepare for and manage infectious disease threats. A score is based on metrics from seven domains; demographic, health care, public health, disease dynamics, political (domestic), political (international), and economic. Countries are scored between 0-1, with higher scores representing greater capacity to respond to outbreaks.⁵

Table 1 outlines the top 20 destination cities with passengers arriving from Wuhan; Bangkok, Hong Kong, Tokyo, and Taipei received the largest volumes with 41 080, 23 707, 20 001, and 17 645 arrivals between January and March, respectively. The IDVI for these leading destinations all exceed 0.65. Sydney and Victoria, Australia, and Dubai, UAE are the only three cities in the top 20 destinations that are outside of Asia. Bali, Indonesia has the lowest IDVI score (0.563) in the top 20 destination cities.

At the time of publication, much is still unknown about this etiology of this respiratory syndrome. Enhanced surveillance at airports has been enacted in several Asian cities. There are now reports of respiratory illnesses in travellers from Wuhan under investigation in Singapore, Hong Kong, and Seoul, however to date these illnesses are not confirmed to be related to the Wuhan outbreak. Public health agencies around the world are reminding frontline healthcare providers to be vigilant for potential imported cases, however this may be complicated in the northern hemisphere by high levels of influenza-like illnesses at this time of year. To our knowledge, no advisories against travel to Wuhan have been issued. Fortunately, most countries receiving the largest volumes of passengers from Wuhan, China appear to have high IDVI scores, corresponding to relatively strong public health and healthcare capacity.

Seventeen years after the global SARS epidemic, the current outbreak in Wuhan, China serves as a reminder of how rapidly novel pathogens can appear and spread with potentially serious global consequences. Although it is unclear what the current burden of disease is or the potential for human-to-human transmission, major Asian hubs are the most probable sites of exportation should this epidemic continue, and public health officials are already on alert in those locations.

Author contributions:

IIB, KK, AW conceived the idea

AW, ATB, CH conducted data analysis

IIB, KK, AW, ATB, MK interpreted data and contributed to writing

Conflict of interest/disclosure

KK is the founder of BlueDot, a social enterprise that develops digital technologies for public health. KK, AW, ATB, and CH are employed at BlueDot. IIB has consulted for BlueDot. MK has no conflicts of interest to declare.

References

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4. Poutanen S. M., Low D. E., Henry B., et al. Identification of severe acute respiratory syndrome in Canada. *N Engl J Med.* 2003; 348: 1995-2005.
5. Moore M, Gelfeld B, Okunogbe A, Paul C.
Identifying Future Disease Hot Spots: Infectious Disease Vulnerability Index. *Rand Health Q.* 2017; 6: 5.

Table 1: Top 20 passenger destination cities from Wuhan, China, January to March, 2018, and corresponding Infectious Disease Vulnerability Index (IDVI) of destination countries

DESTINATION CITY	POPULATION* (IN MILLIONS)	DESTINATION PROVINCE	DESTINATION COUNTRY	IDVI	DIRECT VOLUME**	TOTAL VOLUME**
BANGKOK	8.28	Bangkok Metropolis	Thailand	0.711	38,457	41,080
HONG KONG	7.39	Hong Kong Special Administrative Region (SAR)	Hong Kong (SAR)	0.664*	23,608	23,707
TOKYO	9.27	Tokyo	Japan	0.926	18,581	20,001
TAIPEI	2.62	Taipei	Taiwan	0.710	15,086	17,645
PHUKET	0.39	Phuket	Thailand	0.711	14,097	16,656
SEOUL	9.78	Seoul	Korea (South)	0.879	11,771	13,727
SINGAPORE	5.61	Singapore	Singapore	0.878	8,599	13,123
KOTA KINABALU	0.25	Sabah	Malaysia	0.761	12,340	12,661
MACAU	0.62	Macau Special Administrative Region (SAR)	Macao (SAR)	0.664*	10,918	10,932
DENPASAR BALI	0.79	Bali	Indonesia	0.563	7,759	9,065
SYDNEY	5.23	New South Wales	Australia	0.913	5,093	8,431
DUBAI	3.14	Dubai	United Arab Emirates	0.765	6,389	7,389
KUALA LUMPUR	1.81	WP Kuala Lumpur	Malaysia	0.761	2,393	6,822
KAOHSIUNG	2.77	Kaohsiung City	Taiwan	0.710	6,373	6,617
OSAKA	2.69	Osaka	Japan	0.926	3,062	5,745
KRABI	0.46	Krabi	Thailand	0.711	5,012	5,718
MELBOURNE	4.94	Victoria	Australia	0.913	0	5,648
SURAT THANI	0.13	Surat Thani	Thailand	0.711	5,044	5,624
CHIANG MAI	0.13	Chiang Mai	Thailand	0.711	4,354	5,293
PENANG	1.77	Pulau Pinang	Malaysia	0.761	4,436	5,059

*2018 estimates (United Nations)

**IDVI value estimated for China

***IATA data between January through March, 2018, inclusive

Middle East Respiratory Syndrome Coronavirus (MERS-CoV)

CDNA NATIONAL GUIDELINES FOR PUBLIC HEALTH UNITS

Revision history			
Version	Date	Revised by	Changes
1.0	15 Oct 2014	Developed by MERS-CoV SoNG working group	Original
1.1	24 July 2015	MERS-CoV SoNG Working Group	Presenting symptoms; contact management and case definitions updated to address revised evidence following outbreak in Republic of South Korea. Further minor update approved by AHPPC Chair 7 September 2015 to include WHO recommendations on the testing of asymptomatic close contacts in the context of a hospital outbreak.

The Series of National Guidelines ('the Guidelines') have been developed by the Communicable Diseases Network Australia (CDNA) and noted by the Australian Health Protection Principal Committee (AHPPC). Their purpose is to provide nationally consistent guidance to public health units (PHUs) in responding to a notifiable disease event.

These guidelines capture the knowledge of experienced professionals, and provide guidance on best practice based upon the best available evidence at the time of completion.

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 health professional. Clinical judgement and discretion may be required in the interpretation and application of these guidelines.

The membership of the CDNA and the AHPPC, and the Commonwealth of Australia as represented by the Department of Health ('the Commonwealth'), do not warrant or represent that the information contained in the Guidelines is accurate, current or complete. The CDNA, the AHPPC and the Commonwealth do not accept any legal liability or responsibility for any loss, damages, costs or expenses incurred by the use of, or reliance on, or interpretation of, the information contained in the guidelines.

Endorsed by CDNA: 24 July 2015
 Noted by AHPPC: 14 August 2015
 Released by Health: 7 September 2015

Middle East Respiratory Syndrome Coronavirus (MERS-CoV)

CDNA NATIONAL GUIDELINES FOR PUBLIC HEALTH UNITS

1. Summary

Public health priority

Urgent.

Advice should be sought, where applicable, from the relevant state or territory central communicable diseases agency on the process for reporting of suspected, probable and confirmed MERS-CoV cases. MERS-CoV infection is a nationally notifiable disease.

Case management

Isolate suspected, probable and confirmed cases in a single room with negative pressure air-handling and an ensuite bathroom (if available) and use standard and transmission-based precautions (contact and airborne).

Contact management

Close contacts of probable and confirmed cases are subject to some work and travel restrictions and should be actively monitored for development of fever and respiratory symptoms in the 14 days following the last contact, while casual contacts are subject to self-monitoring only.

2. The disease

Infectious agents

The Middle East respiratory syndrome coronavirus (MERS-CoV).

Coronaviruses are a large and diverse family of viruses that include viruses that are known to cause illness in humans (including the common cold) and animals.

Reservoir

It is likely that the virus has come from an animal source. MERS-CoV has been detected in camels in several Middle East countries with human cases of MERS-CoV infection. Additionally, serological evidence of camel exposure to MERS-CoV or a closely related virus has been found in camels over a wide area of northern Africa and the Middle East. It is suspected, but not confirmed, that infected camels may be the source of the virus for some human cases. There are also limited reports of MERS-CoV being detected in bats.

More information is needed to identify the possible role that camels, bats, and other animals may play in the transmission of MERS-CoV. MERS-CoV is genetically distinct from SARS-CoV, and appears to behave differently, being less transmissible but with a higher mortality rate. However, the full spectrum of illness remains unclear.

Mode of transmission

The mode or modes of transmission of MERS-CoV are not fully known.

There have been some cases with a strong history of exposure to camels or camel products (e.g. milk), including at least one cluster where the camels also tested positive. However, there have been many sporadic cases with no history of prior exposure to camels or other animals.

There have been multiple clusters of cases in which human-to-human transmission has occurred. These clusters have been observed in health-care facilities, among family members and between co-workers. However, the mechanism by which transmission occurred in these instances, whether respiratory (e.g. coughing, sneezing) or direct physical contact with the patient or via fomites after contamination of the environment by the patient, is unknown.

Infection control recommendations for managing suspected, probable and confirmed cases are consistent with those recommended for SARS-CoV and pandemic influenza. As further information becomes available, these recommendations will be re-evaluated and updated as needed.

Incubation period

From 2 to 14 days; most commonly 5 days.

Infectious period

The duration of infectivity for MERS-CoV infection is unknown. Standard precautions should be applied throughout any admission; additional isolation precautions should be continued until at least 24 hours after the resolution of symptoms.

Given that little information is currently available on viral shedding and the potential for transmission of MERS-CoV, testing to detect the virus may be necessary to inform decision-making on infectiousness. Patient information (e.g. age, immune status and medication) should also be considered.

Clinical presentation and outcome

Clinical presentation ranges from asymptomatic to severe pneumonia with acute respiratory distress syndrome and multi-organ failure. Nearly all symptomatic patients have presented with fever. Respiratory symptoms are common and gastrointestinal symptoms are less commonly reported.

Typically, the disease starts with fever and cough. Other common symptoms are myalgia and chills. Sore throat, arthralgia, dyspnoea, nausea, vomiting and diarrhoea are less commonly present. In the 2015 South Korean outbreak pneumonia was present in a minority of patients at initial presentation, but it is unclear whether early testing of contacts with, at the time, milder clinical manifestations of MERS-CoV infection may have influenced the reported spectrum of illness.

Patients who develop pneumonia or pneumonitis often require mechanical ventilation and other organ support. The case fatality rate for confirmed cases is estimated at 30-40 percent, but this may decrease when the spectrum of disease is better understood, as suggested by lower case fatality observed in the South Korean outbreak.

Persons at increased risk of disease

The age distribution of reported cases is skewed heavily to the middle-aged and elderly. Cases who are elderly, immunocompromised or with co-morbidities have an increased case fatality rate[1].

Disease occurrence and public health significance

As of June 2015 there have been no confirmed MERS-CoV cases reported in Australia.

Countries that have reported cases in the Middle East include Iran, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia (KSA), United Arab Emirates (UAE) and Yemen, with Saudi Arabia and UAE being most affected.

Persons who acquired MERS-CoV in Middle Eastern countries have exported the infection to many other countries, which has resulted in health facility outbreaks in France, the United Kingdom, and most notably South Korea. For a full list of countries where MERS-CoV cases have been detected see the World Health Organization (WHO) coronavirus infection website [1].

WHO expects that additional cases of MERS-CoV infection will be reported from the Middle East, and that it is likely that cases will continue to be exported to other countries by tourists, travellers, guest workers or pilgrims who might acquire infection following exposure to human cases (possibly in a health care setting), or possibly from camels or other unknown animal sources (for example, while visiting farms or markets).

Until more is understood about the mode of transmission and risk factors for infection, it is expected that sporadic cases will continue to occur, with potential for limited transmission within households and healthcare settings.

3. Routine prevention activities

It is recommended that people with significant medical conditions such as diabetes, renal disease and chronic lung disease who are intending to travel to the Middle East – including those undertaking the Hajj or Umrah - consult a doctor prior to travel.

People travelling in countries affected by MERS-CoV should maintain good hygiene practices, avoid contact with animals, especially camels, and refrain from consuming unpasteurised milk or undercooked meat.

Travellers to the Middle East and travel organisations should be advised of general travel health precautions which will lower the risk of infection in general, including respiratory viruses and traveller's diarrhoea. Specific emphasis should be placed on:

- hand hygiene and respiratory hygiene
- adhering to good food-safety practices,
- maintaining good personal hygiene.

Travel advice for Australians is available at the Australian Department of Health MERS-CoV web page [2]. Travellers should check if there are any travel restrictions in place prior to travel.

4. Surveillance objectives

- To rapidly identify, isolate and treat cases, and prevent transmission to their contacts
- To identify and provide information to contacts and ensure that they are isolated rapidly should symptoms occur

- To describe the epidemiology of MERS-CoV infection in Australia, including identifying risk factors for transmission.

5. Data management

Probable and confirmed cases of MERS-CoV infection should be entered onto the notifiable diseases database within one working day of notification/report. Data for suspected cases should be maintained according to jurisdictional protocols.

6. Communications

Where applicable, public health units should immediately notify the central state/territory communicable diseases agency of suspected, probable and confirmed cases once notifications/reports are received. Provide the case's age, sex, place of residence, indigenous status, date of onset, travel history, laboratory results, clinical status, likely place of acquisition, and follow-up action taken.

State/territory communicable disease agencies should immediately notify probable and confirmed MERS-CoV cases to the National Incident Room.

7. Case definition

The criteria for a suspected case of MERS-CoV are to be used to direct testing and initial infection control and public health actions. Suspected cases will ultimately be reclassified as either having a diagnosis of MERS-CoV excluded, or meeting the criteria for a probable or confirmed case. The criteria for probable and confirmed cases of MERS-CoV define those cases that are to be reported to the National Notifiable Diseases Surveillance System.

Suspected case¹

Knowledge and understanding of MERS-CoV infection continues to expand. The following criteria are based on case series reported from recent outbreaks and represent combinations of symptoms and epidemiological criteria in which MERS-CoV testing is strongly recommended.

Atypical presentations occur, and clinical and public health judgement should also be used to determine the need for testing in patients who do not meet the criteria below.

Testing and initial infection control and public health actions for MERS-CoV should be undertaken for persons with:

- A. Fever AND pneumonia or pneumonitis or acute respiratory distress syndrome (ARDS) AND
 - o history of travel from or residence in affected countries in the Middle East² within 14 days before symptom onset, OR

¹ Check for updates on the [Australian Department of Health MERS-CoV website](http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-mers-cov.htm) (<http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-mers-cov.htm>).

- o contact³ (within the incubation period of 14 days) with a symptomatic traveller who developed fever and acute respiratory illness of unknown aetiology within 14 days after travelling from affected countries in the Middle East, OR
- o contact (within the incubation period of 14 days) with a symptomatic traveller who developed fever and acute respiratory illness of unknown aetiology within 14 days after travelling from a region with a known MERS-CoV outbreak at that time⁴,

OR

B. Fever AND symptoms of respiratory illness (e.g., cough, shortness of breath) AND

- o being in a healthcare facility (as a patient, worker, or visitor) in a country or territory in which recent healthcare-associated cases of MERS have been identified⁴ within 14 days before symptom onset, OR
- o being in contact with camels or raw camel products within affected countries in the Middle East within 14 days before symptom onset.

OR

C. Fever OR acute symptoms compatible with MERS-CoV AND onset within 14 days after contact with a probable or confirmed MERS-CoV case while the case was ill.

OR

D. Testing and initial infection control and public health actions for MERS-CoV should also be considered, in consultation with the public health unit, where there is a cluster of patients with severe acute respiratory illness of unknown aetiology following routine microbiological investigation, particularly where the cluster includes health care workers.

² Affected countries in the Middle East include Iran, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia (KSA), United Arab Emirates (UAE) and Yemen

³ See section 11: Definition of contact

⁴ See the World Health Organization (WHO) coronavirus infection website [1] for list of countries currently experiencing a MERS outbreak

Probable case

- A person with an acute respiratory infection with clinical, radiological, or histopathological evidence of pulmonary parenchymal disease (e.g. pneumonia or pneumonitis or Acute Respiratory Distress Syndrome (ARDS)); AND

No possibility of laboratory confirmation for MERS-CoV because the patient or samples are not available for testing; AND

Close contact with a laboratory-confirmed case (see the Contact Management section below for guidance on identifying close contacts).

Confirmed case

- A confirmed case requires laboratory definitive evidence of infection with MERS-CoV.

Laboratory definitive evidence

- Detection of MERS coronavirus by polymerase chain reaction (PCR) in a public health reference laboratory using the testing algorithm described in Appendix 3 and summarised below.

Notes:

- (1) Transiting through an international airport (<24 hours stay, remaining within the airport) in the Middle East is not considered to be risk factor for infection.
- (2) Laboratory definitive evidence. To consider a case as laboratory-confirmed, one of the following conditions must be met:
 - o A positive PCR result for at least two different specific targets on the MERS-CoV genome.
 - o One positive PCR result for a specific target on the MERS-CoV genome and an additional different PCR product sequenced, confirming identity to known sequences of MERS-CoV.

See the Laboratory testing section and Appendix 3 for additional MERS-CoV laboratory testing information.

8. Laboratory testing

Patients to be considered for MERS-CoV testing are described under the suspected case definition (above). Where applicable, consult with your state/territory communicable diseases agency to seek advice on which laboratories can provide MERS-CoV testing; appropriate specimen type, collection and transport; and also to facilitate contact management if indicated.

Transmission-based contact and airborne precautions must be used when collecting respiratory specimens [3]. These include:

- Contact precautions, including close attention to hand hygiene
- Airborne transmission precautions, including routine use of a P2 mask/respirator, disposable gown, gloves, and eye protection
- Collection in a room with negative pressure air-handling where available.

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

Serology, if available, may be useful in cases where MERS-CoV is strongly suspected but non-confirmed with PCR but requires paired acute and convalescent sera – seek expert clinical microbiology advice. Serology is also useful to estimate secondary infection rates in asymptomatic cases following exposure to MERS-CoV.

See Appendix 3 for additional MERS-CoV laboratory testing information.

9. Case management

Response times

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

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 MERS-CoV public health unit checklist (Appendix 2) and the MERS-CoV Investigation Form (Appendix 4).

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
- Seek the treating doctor's permission to contact the case or relevant care-giver
- Determine if the diagnosis has been discussed with the case or relevant care-giver before beginning the interview
- Review case and contact management
- Ensure appropriate infection control guidelines are followed in caring for the case
- Identify the likely source of infection.

Note: If interviews with suspected 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.

Wherever possible, cases should be managed in hospital. If clinically indicated, cases may be managed at home only if it can be ensured that the case and household contacts are counselled about risk and that appropriate infection control measures are in place.

Case treatment

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 WHO [4].

Education

Provide MERS-CoV Fact Sheets (Appendix 1) to cases and their close contacts. Ensure that they are aware of the signs and symptoms of MERS-CoV, the requirements of isolation, contact details of the PHU and the infection control practices that can prevent the transmission of MERS-CoV.

Isolation and restriction

Cases must be isolated in an appropriate health facility, unless alternative arrangements are recommended on expert advice. Healthcare workers and others who come into contact with suspected, probable and confirmed cases must be protected according to recommended infection control guidelines. Visitors should be restricted to close family members.

A risk assessment should be undertaken for suspected cases who initially test negative for MERS-CoV. If there is no alternative diagnosis and a high index of suspicion remains that such cases may have MERS-CoV infection, consider continued isolation and use of the recommended infection control precautions, pending further testing (see Laboratory testing section and Appendix 3) and re-assessment.

Given the severity of reported infections, the evidence of limited person-to-person transmission, and gaps in knowledge of transmission pathways, the recommendations on isolation and PPE for management of suspected, probable and confirmed cases take a deliberately cautious approach.

Infection control measures should be those applicable to control the transmission of pathogens that can be spread by the airborne route. These measures are detailed in the [Interim infection prevention and control advice for acute care hospitals relating to suspected Middle Eastern respiratory syndrome coronavirus \(MERS-CoV\) infections](http://www.health.gov.au/mers-coronavirus). (<http://www.health.gov.au/mers-coronavirus>) [3].

In summary, transmission-based precautions for suspected, probable and confirmed cases should include:

- Placement of cases in a negative pressure room with an ensuite bathroom, if available, or in a single room from which the air does not circulate to other areas
- Airborne transmission precautions, including routine use of a P2 respirator (or N95 mask), long sleeved disposable gown, gloves, and eye protection when entering a patient care area
- Contact precautions, including close attention to hand hygiene
- If transfer of the confirmed or probable case outside the negative pressure room is necessary, ask the patient to wear a single use “surgical” face mask while they are being transferred and to follow respiratory hygiene and cough etiquette.

Active case finding

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

10. Environmental evaluation

Where local transmission of MERS-CoV 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.

11. Contact management

As there remain gaps in the understanding of infectivity of MERS-CoV cases and transmission modes the definition of contacts is based on observations of people

infected in large outbreaks, particularly the outbreak in South Korea. The definition of contacts and recommended control measures are subject to review as more information on MERS-CoV becomes available.

Identification of contacts

All persons categorised as a contact (see definitions of “close contacts” and “casual contacts” following) of probable and confirmed cases should be followed-up, and monitored for the development of symptoms for 14 days after the last exposure to the case (i.e. the maximum incubation period).

Contacts of suspected cases should also be considered for contact management if there is likely to be a delay in confirming or excluding MERS CoV infection in the suspected case, such as delayed testing.

Close Contact definition

A close contact is defined as requiring greater than 15 minutes face-to-face contact with a symptomatic probable or confirmed case in any setting, or the sharing of a closed space with a symptomatic probable or confirmed case for a prolonged period (e.g. more than 2 hours).

Hence, close contacts may include:

- A healthcare worker or family member providing direct patient care to, or who were within close vicinity of an aerosol generating procedure performed on, or a laboratory worker who performed tests on specimens from, a confirmed or probable case, without recommended infection control precautions, including not using full personal protective equipment (PPE).
- OR, a healthcare worker, patient or visitor who shared the same closed space for a prolonged time (e.g. more than 2 hours), and without recommended infection control precautions, including not using full personal protective equipment (PPE).
- OR, people who resided in the same household or household-like setting (e.g. dormitory room in a boarding school).

Contact tracing by public health units should prioritise identifying close contacts particularly healthcare workers, and other close contacts who may be at higher risk of severe disease, including the elderly and those with significant co-morbidities.

- Casual contact definition
- Casual contact is defined as any person having less than 15 minutes face-to-face contact with a symptomatic probable or confirmed case in any setting, or sharing a closed space with a symptomatic probable or confirmed case for less than 2 hours. This will include healthcare workers, other patients, or visitors who were in the same closed healthcare space as a case, but for shorter periods than those required for a close contact. Other closed settings might include schools or offices.

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 probable or confirmed MERS-CoV case are not considered to be close contacts. However, these people should be advised to self-monitor and if they

develop symptoms consistent with MERS-CoV infection they should isolate themselves and notify their public health unit or staff health unit so they can be tested and managed as a suspected MERS-CoV case (see recommendations below under *Management of symptomatic contacts*).

Other casual contacts may include:

- Extended family groups e.g. in an Aboriginal community.
- Aircraft passengers who were seated in the same row as the case, or in the two rows in front or two rows behind a symptomatic probable or confirmed MERS-CoV case. It is noted that to date no instances of transmission on airlines have been identified. 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.
- All crew-members on an aircraft who worked in the same cabin area as a symptomatic probable or confirmed case of MERS-CoV. If a crew member is the symptomatic MERS-CoV case, contact tracing efforts should concentrate on passengers seated in the area where the crew member was working during the flight and all of the other members of the crew.

Where resources permit, more active contact tracing may be extended to other persons who have had casual contact (as defined above), particularly in school, office, or other closed settings. In these circumstances, the size of the room/space and degree of separation of the case from others should be considered in identifying contacts.

Contact assessment

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

Identification and assessment of the contacts of suspected cases may be deferred pending the results of initial laboratory testing. However, contact tracing should be considered if MERS-CoV infection remains high on the list of differential diagnoses, even if initial laboratory results are negative or are pending.

Contact testing

Routine laboratory screening for MERS-CoV infection is not recommended for asymptomatic contacts. One exception is in the setting of a hospital outbreak, where WHO recommends RT-PCR testing of nose/throat swabs of asymptomatic close contacts be considered, if feasible. RT-PCR-positive asymptomatic close contacts in this setting should be isolated, monitored closely for symptoms and only released from isolation following two negative RT-PCR tests separated by 24 hours.²

Serological testing of contacts may be useful if available, in order to help determine the secondary infection-attack rate and the proportion of infections that are asymptomatic. Contacts who agree to be tested should be advised that serological

² WHO recommends that if feasible, and in the context of a hospital outbreak, all close contacts of a confirmed case of MERS should be tested for the presence of the virus. See: http://apps.who.int/iris/bitstream/10665/180973/1/WHO_MERS_IPC_15.2_eng.pdf?ua=1.

testing will not be done immediately and is not being conducted for contact management purposes.

Consent should be sought from household and healthcare worker close contacts for the collection of the following samples:

- A baseline serum sample, ideally within 7 days of exposure, to be stored and tested in parallel with a convalescent sample.
- A convalescent serum sample at least 21 days after the baseline sample was collected. If more than 21 days have passed since the last exposure, only a single serum sample is required.

The collection of nasopharyngeal (NP) swabs from asymptomatic contacts for MERS-CoV PCR is not recommended. There is little information available currently to reliably inform the timing of testing or the interpretation of negative test results in this setting.

Serial PCR testing of NP swabs from asymptomatic close contacts to detect MERS-CoV viral shedding may be conducted as part of ethics-approved research studies.

Prophylaxis

No specific chemoprophylaxis is available for contacts.

Education

Contacts should be counselled about their risk and the symptoms of MERS-CoV and provided with a MERS-CoV Fact Sheet (Appendix 1). They should be advised to self-isolate if they develop symptoms, and to immediately notify their public health unit and, if appropriate, their facility infection control unit (i.e. for healthcare workers).

Quarantine and restriction

Close contacts

Home quarantine of asymptomatic close contacts is not routinely recommended, but people identified as close contacts are advised to monitor their health for 14 days after the last possible contact with a symptomatic probable or confirmed MERS-CoV case.

Public health units should conduct active daily monitoring of close contacts for symptoms for 14 days after the last possible contact with a symptomatic probable or confirmed MERS-CoV case.

Close contacts should also be advised to immediately telephone the public health unit to arrange medical assessment if they develop symptoms such as fever, respiratory symptoms (including coughing and shortness of breath), headache, muscle pain or diarrhoea.

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

Close contacts should also be advised to not travel internationally for 14 days after the last close contact with a probable or confirmed case of MERS-CoV, and any travel within Australia during this period should be subject to discussion with public health authorities.

Close contacts should be excluded from schools and sensitive occupations or settings such as health care, aged care, or child care during the 14 days after last unprotected contact with a case.

Casual contacts

Casual contacts should monitor their health for 14 days and report any symptoms immediately to the local public health unit. There are no restrictions on movements; however casual contacts should be advised to contact the public health unit if they develop symptoms.

Healthcare worker close contacts

Healthcare worker close contacts (i.e. persons exposed while unprotected, as described in the Contact definition section) should not undertake work in a healthcare setting for 14 days following the last possible contact with the case. Home quarantine is not routinely recommended during this period if these individuals remain asymptomatic, but some restrictions may be recommended based on a risk assessment of the particular circumstances.

Depending on arrangements in the jurisdiction, public health units may assist infection control units of health facilities to identify and monitor healthcare worker close contacts.

It is recognised that clinical work restrictions on healthcare worker close contacts may place strain on individuals and on health services. This underlines the importance of ensuring healthcare workers implement appropriate infection control precautions when assessing and managing suspected, probable and confirmed MERS-CoV cases.

These recommendations are based on reports from large health facility-based MERS-CoV outbreaks in the Middle East and South Korea which have involved nosocomial transmission of MERS-CoV to both patients and healthcare workers. CDNA will continue to monitor the emerging evidence around MERS-CoV transmission risks in healthcare settings and revise these recommendations as needed.

Management of symptomatic contacts

If fever, respiratory symptoms, or other symptoms consistent with MERS-CoV infection 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 MERS-CoV cases, with urgent testing for MERS-CoV infection undertaken in an environment which minimises the risk of exposure to others.

Ill contacts who are being evaluated for MERS-CoV infection can be appropriately isolated and managed at home, unless their condition is severe enough to require hospitalisation.

Symptomatic contacts who test negative for MERS-CoV by PCR will still need to be monitored for 14 days after their last contact with a probable or confirmed MERS-CoV case and may require re-testing. There have been a number of reports of MERS-CoV cases who initially tested negative for MERS-CoV by PCR.

12. Special situations

Outbreaks in healthcare facilities

If one or more probable or confirmed MERS-CoV cases are identified in a healthcare facility, an outbreak management team should be convened, including a senior facility manager, an infection control practitioner and appropriate clinical staff, in consultation with PHU staff as required. Control measures may include:

- active case finding, assessment and care
- isolation and/or cohorting
- work restriction for healthcare workers who have had close contact (i.e. unprotected exposure) with a confirmed or probable case
- distribution of fact sheets and other information
- epidemiological studies to determine risks for infection.

Outbreaks in residential care facilities or other residential institutions (e.g. prisons or boarding schools)

There have been few if any reports of MERS-CoV outbreaks in institutions other than in healthcare facilities, and transmission within households appears to be uncommon. Nevertheless, it is assumed that fellow residents in an institution will be at greater risk of infection if there has been a confirmed case living at the institution while infectious.

If one or more probable or confirmed MERS-CoV cases are identified in a residential care facility or institution, an outbreak management team should be convened, in consultation with PHU staff.

13. References and additional sources of information

References:

- [1] [World Health Organization \(WHO\). Coronavirus infections.](http://www.who.int/csr/disease/coronavirus_infections/en/)
(http://www.who.int/csr/disease/coronavirus_infections/en/)
- [2] Australian Department of Health. [MERS coronavirus web page.](http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-mers-cov.htm)
(<http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-mers-cov.htm>).
- [3] [Interim infection prevention and control advice for acute care hospitals relating to suspected Middle Eastern respiratory syndrome coronavirus \(MERS-CoV\) infections](http://www.health.gov.au/internet/main/publishing.nsf/Content/18EA5D58FA62A556CA257BF0001A8E1F/$File/interim-infection-prevention.pdf)
([http://www.health.gov.au/internet/main/publishing.nsf/Content/18EA5D58FA62A556CA257BF0001A8E1F/\\$File/interim-infection-prevention.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/18EA5D58FA62A556CA257BF0001A8E1F/$File/interim-infection-prevention.pdf))
- [4] World Health Organization (WHO). [Interim Guidance Document - Clinical management of severe acute respiratory infections when novel coronavirus is suspected.](http://www.who.int/csr/disease/coronavirus_infections/InterimGuidance_ClinicalManagement_NovelCoronavirus_11Feb13u.pdf)
(http://www.who.int/csr/disease/coronavirus_infections/InterimGuidance_ClinicalManagement_NovelCoronavirus_11Feb13u.pdf).

Additional resources:

[WHO FAQs on MERS-CoV](http://www.who.int/csr/disease/coronavirus_infections/faq/en/): (http://www.who.int/csr/disease/coronavirus_infections/faq/en/)

[WHO MERS-CoV summary and literature updates](http://www.who.int/csr/disease/coronavirus_infections/archive_updates/en/):

(http://www.who.int/csr/disease/coronavirus_infections/archive_updates/en/)

[WHO Update on MERS-CoV transmission from animals to humans, and interim recommendations for at-risk groups \(13 June 2014\)](http://www.who.int/csr/disease/coronavirus_infections/MERS_CoV_RA_20140613.pdf):

(http://www.who.int/csr/disease/coronavirus_infections/MERS_CoV_RA_20140613.pdf)

[WHO updated travel advice on MERS-CoV for Pilgrimages \(3 June 2014\)](http://www.who.int/ith/updates/20140603/en/):

(<http://www.who.int/ith/updates/20140603/en/>)

[US CDC Middle East respiratory syndrome website](http://www.cdc.gov/coronavirus/mers/index.html):

(<http://www.cdc.gov/coronavirus/mers/index.html>)

[ECDC Coronavirus website](http://ecdc.europa.eu/en/healthtopics/coronavirus-infections/Pages/index.aspx) (<http://ecdc.europa.eu/en/healthtopics/coronavirus-infections/Pages/index.aspx>)

[Public Health England Middle East respiratory syndrome coronavirus website](http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/MERSCoV/):

(<http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/MERSCoV/>)

14. Appendices

- Appendix 1. MERS-CoV Factsheet
- Appendix 2. MERS-CoV PHU checklist
- Appendix 3. MERS-CoV laboratory testing information
- Appendix 4. MERS-CoV case investigation form

15. Jurisdiction specific issues

Links to Australian state and territory public health legislation, and the Commonwealth Quarantine Act and amendments are available at:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-state-legislation-links.htm>

Appendix 1: Middle East Respiratory Syndrome (MERS) Factsheet

What is Middle East Respiratory Syndrome (MERS)?

Middle East Respiratory Syndrome (MERS) is a viral illness caused by a novel coronavirus, Middle East respiratory Syndrome Coronavirus (MERS-CoV) that was first identified in Saudi Arabia in 2012. Coronaviruses are a large family of viruses that cause diseases ranging from the common cold to Severe Acute Respiratory Syndrome (SARS).

All recognised cases of MERS-CoV infection (people who have the disease) have to date lived in or travelled to countries in the Middle East, or have had close contact, such as caring for or living with, people who acquired the infection in the Middle East. However, there is no evidence of sustained spread of the disease within the community.

There is a risk of MERS-CoV in the following Middle Eastern countries:

- Jordan, Kuwait, Oman, Qatar, Saudi Arabia, the United Arab Emirates (UAE), Yemen, Lebanon and Iran.

People who caught the infection in the Middle East have travelled to a number of countries outside the Middle East and subsequently developed the disease. There have been no cases identified in Australia to date.

It is a very serious disease, and about 30% of people with MERS-CoV infection have died from the infection or related complications.

What are the symptoms?

- Most confirmed cases have had a rapid onset of serious respiratory illness, with fever, cough, and shortness of breath, leading to pneumonia.
- A variety of other symptoms have been reported in some cases, including muscle pain, diarrhoea, vomiting and nausea.
- An increasing number of infections are being identified in people with only mild symptoms or no symptoms (asymptomatic) who were tested because they were close contacts of seriously-ill cases.

How is it spread?

It is not yet understood exactly how people are becoming infected. In some cases there appears to have been spread from an infected person to another person in close contact. This has been seen among family members, and other patients and health care workers in hospitals caring for people with MERS-CoV infection. However, the virus does not seem to spread easily from person-to-person.

The original source of the virus is likely to be animals and MERS-CoV has been found in camels in some Middle Eastern countries where cases are occurring. Similar viruses have also been reported in bats. However, contact with camels and other animals does not appear to explain most of the human cases that are occurring. More information is needed to determine the roles that camels, bats and other animals may play in the spread of MERS-CoV.

Who is at risk?

People who are living in or travelling to affected areas of the Middle East or who have had contact with other cases may be at risk of catching the disease. People with underlying illnesses that make them more vulnerable to respiratory disease, including those with diabetes, chronic lung disease, pre-existing kidney disease, or those who have suppressed immune systems, may be at a higher risk.

How is it prevented?

There is no vaccine to prevent MERS-CoV infection. People who are travelling to affected countries should practice normal hygiene measures. Wash your hands often, and use a hand sanitiser if soap and water is not available.

It is currently recommended to minimise contact with animals in affected countries. When visiting a farm good hygiene measures should be practised, such as regular hand washing before and after touching animals, avoiding contact with sick animals, and following good food hygiene practices, including avoiding drinking raw milk, camel urine or eating food that may be contaminated with animal products unless the food is properly washed, peeled, or cooked.

People at high risk of severe disease due to MERS-CoV should consider taking additional precautions while travelling in the Middle East, such as avoiding visiting farms or market environments where camels are present.

What should I do if I become unwell after travel in the Middle East?

If you become ill or feel unwell while travelling in the Middle East, you should not wait until you arrive back in Australia to seek medical assistance. Instead you should see a doctor or go to the local emergency department.

If you have returned from travel to the Middle East within the last fourteen days and develop a fever, cough and other symptoms, you should see your doctor or go to the emergency department to work out why you are ill. It is important that you mention your symptoms and which countries you have visited in the Middle East when you first arrive at the medical practice or hospital emergency department.

You may be asked or required to wear a mask and be separated from others to prevent further spread of infection.

How is it diagnosed?

MERS-CoV is diagnosed by finding genetic material from the virus in respiratory samples such as swabs from the back of the throat and fluid from the lungs. Testing for MERS-CoV is done in public health laboratories.

How is it treated?

There is currently no specific treatment for people who are sick with MERS, but general supportive medical care can be life-saving.

What is the public health response?

The World Health Organization (WHO) is working with affected countries to minimise the risk of spread and find out more about the disease.

There have been no confirmed cases in Australia, but special procedures to prevent the spread of MERS-CoV would be put in place in the event of any suspected or confirmed cases. These would include:

- Asking the sick person to wear a surgical mask
- Health-care workers seeing patients and laboratory staff handling specimens would follow special safety guidelines, including wearing protective equipment.
- Doctors and laboratories would inform state/ territory health departments of suspected cases.
- Public Health authorities would follow up any case to identify their contacts so as to help prevent spread of the disease. Close contacts of people diagnosed or suspected of having

MERS-CoV infection would be given information about the risk of infection, and would be tested for the disease if necessary.

Public health unit staff will investigate all cases to find out how the infection occurred, identify other people at risk of infection, implement control measures and provide other advice.

Further information

- [World Health Organization \(WHO\) MERS-CoV updates](http://www.who.int/csr/disease/coronavirus_infections/en/) (www.who.int/csr/disease/coronavirus_infections/en/)
- [Australian Department of Health – MERS coronavirus website](http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-mers-cov.htm) (<http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-mers-cov.htm>)
- [Centers for Disease Control and Prevention \(USA\)](http://www.cdc.gov/coronavirus/mers/) (<http://www.cdc.gov/coronavirus/mers/>)
- Australian Department of Foreign Affairs and Trade provides information for travellers on the [Smartraveller website](http://www.smartraveller.gov.au/) (www.smartraveller.gov.au/)

This document has been released under
the Freedom Of Information Act 1982 by
the Department of Health, Disability and Ageing

Appendix 2: PHU MERS-CoV checklist

Using the MERS-CoV Investigation form, contact the patient's doctor to:

- Confirm the onset date and symptoms of the illness
- Confirm results of relevant pathology tests, or recommend that tests be done
- Find out if the case or relevant care-giver has been told what the diagnosis is before beginning the interview
- 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

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

- Complete the exposure history and other sections of the MERS-CoV Investigation Form.
- Identify close contacts according to the contact definition.

Follow-up patient's contacts to:

- Assess risk of MERS-CoV transmission and classify as close or casual contacts
- Determine current symptoms, if any, and advise on active daily monitoring of symptoms by public health unit (close contacts) or passive surveillance (casual contacts)
- Explain symptoms and need to immediately report any new symptoms
- Explain to healthcare, aged care, and childcare worker close contacts the need for work restrictions during the potential incubation period after exposure
- Explain to school student close contacts (or their carers) the need for exclusion during the potential incubation period after exposure
- Provide a MERS-CoV Disease Factsheet
- Arrange serological testing if available and appropriate.

Notify central jurisdictional communicable disease control agency

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 3: MERS-CoV Laboratory testing information

Samples suitable for testing

Respiratory samples - Upper respiratory tract

1. Nasopharyngeal swab and/or oropharyngeal swab
 - nasopharyngeal: insert a swab into each nostril parallel to the palate, leave the swab in place for a few seconds to absorb secretions
 - oropharyngeal: swab the tonsillar beds, avoiding the tongue
 - place swabs back into the accompanying transport media
2. Nasal wash/aspirates
 - collect 2-3 mL into a sterile, leak-proof, screw-top dry sterile container

Respiratory samples – Lower respiratory tract

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

There is now increasing evidence that lower respiratory tract specimens contain the highest viral loads, therefore, lower respiratory tract specimens should be collected where possible. Repeat testing (especially of lower respiratory tract specimens) in compatible cases should be performed if initial results are negative.

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 a convalescent serum collected 3 or more weeks after acute sample collection. If no acute sample was collected, a single serum sample collected 14 or more days after symptom onset may be tested.

Immunofluorescence and neutralization serology tests are used. Similar to NAT, a two stage approach using a screening followed by a confirmatory test can be employed. For screening purposes, an enzyme-immunosorbent assay (ELISA) against recombinant N protein can be used, followed by confirmatory testing using a whole virus indirect fluorescent antibody (IFA) test or microneutralization. Given that all serological tests developed so far have only been validated against a small number of convalescent sera from MERS-CoV cases, positive serological test results in the absence of nucleic acid testing (NAT) or sequencing are considered probable cases only.

Stool

2 – 5 grams of stool (formed or liquid) is collected in a sterile, leak-proof, screw-top dry sterile container.

Handling of specimens in the 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.

MERS-CoV testing

NAT using reverse-transcriptase polymerase chain reaction (RT-PCR) is the method of choice for detection of MERS-CoV. Currently, four targets are used for testing:-

- upstream region of the E protein (upE) gene
- open reading frames (ORF) 1a (ORF1a)
- ORF1b
- MERS-CoV specific nucleocapsid (N) protein gene

An algorithm using a screening assay, followed by confirmatory testing is recommended. For screening purposes, assays targeting the upE gene are appropriate. Confirmatory testing can be performed using an assay targeting the ORF1a (comparable sensitivity to upE gene), ORF1b (which is less sensitive than ORF1a or upE) or N gene. It is recommended that positive screening tests be reported to communicable diseases agencies whilst awaiting confirmatory testing.

Where available, RdRp gene (for the broad detection of β -coronavirus clade C) and/or N gene sequencing may also be considered for MERS-CoV confirmation. As the primers for the RdRp sequencing assay is highly conserved, it is not recommended that this assay be used alone for MERS-CoV confirmation, as false positive results may occur from cross-reactions with other β -coronaviruses. Further information about laboratory testing is available at:

- [Institute of Virology, Bonn](http://www.virology-bonn.de/index.php?id=40) (<http://www.virology-bonn.de/index.php?id=40>)
- [The US Food and Drug Administration](http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM355572.pdf) (<http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM355572.pdf>).

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

Viral culture is generally not performed for routine diagnosis, and should only be attempted in laboratories with appropriate experience and containment facilities. MERS-CoV replication has been previously observed on Vero and LLC-MK2 cells within 5 days of inoculation

Appendix 4: MERS-CoV Case Investigation Form

Note: This is an example form incorporating most of the fields contained in the NetEpi (database) form that has been prepared for national reporting. Central disease control agencies in individual jurisdictions should be consulted regarding their specific data collection requirements.

1	Interview	Was the person interviewed? ☐ Yes ☐ No ☐ Not applicable - If Yes, date of interview: / / (dd/mm/yyyy) - If No, specify reason not interviewed (and if someone else was interviewed):
2	Case status	☐ Confirmed ☐ Probable ☐ Suspected ☐ Excluded Notification date: / / Received date: / / Notifier:
3	Patient contact details	Family name: Given names: Residential address: Phone number (home): Phone number (work): Phone number (mobile):
4	Address type	☐ Household ☐ Aged-care facility ☐ Educational Institution ☐ Assisted ☐ Military Barracks ☐ Prison ☐ Other ☐ Unknown If Other, please specify:
5	Gender	☐ Male ☐ Female ☐ Unknown
6	Date of birth	Date of birth: / / (dd/mm/yyyy)
7	Country of birth	Country of birth: If not born in Australia, date of first arrival in Australia: / / (dd/mm/yyyy) <i>Note: if only year known, enter 01/01/[year]</i>
8	Indigenous Status	☐ Aboriginal origin ☐ Torres Strait Islander origin ☐ Both Aboriginal and Torres Strait Islander origin ☐ Not Aboriginal and Torres Strait Islander origin ☐ Not Stated / Unknown
9	Onset date of first symptoms	Did the person have symptoms? ☐ Yes ☐ No ☐ Unknown - If Yes, onset date: / / (dd/mm/yyyy)

		- Duration of symptoms:	(days)
10	Symptoms and clinical notes	Acute respiratory distress syndrome	☐ Yes ☐ No ☐ Unknown
		Arthralgia	☐ Yes ☐ No ☐ Unknown
		Conjunctivitis	☐ Yes ☐ No ☐ Unknown
		Cough	☐ Yes ☐ No ☐ Unknown
		Diarrhoea	☐ Yes ☐ No ☐ Unknown
		Fatigue	☐ Yes ☐ No ☐ Unknown
		Fever	☐ Yes ☐ No ☐ Unknown
		- Highest temperature:	(°Celsius)
		- Fever onset date:	/ / (dd/mm/yyyy)
		- Feverish by self-report?	☐ Yes ☐ No ☐ Unknown
		Chills or rigors	☐ Yes ☐ No ☐ Unknown
		Headache	☐ Yes ☐ No ☐ Unknown
		Malaise	☐ Yes ☐ No ☐ Unknown
		Myalgia	☐ Yes ☐ No ☐ Unknown
		Nausea	☐ Yes ☐ No ☐ Unknown
		Pneumonia	☐ Yes ☐ No ☐ Unknown
		Pneumonitis	☐ Yes ☐ No ☐ Unknown
		Rhinorrhoea	☐ Yes ☐ No ☐ Unknown
		Shortness of breath	☐ Yes ☐ No ☐ Unknown
		Sore throat	☐ Yes ☐ No ☐ Unknown
		Vomiting	☐ Yes ☐ No ☐ Unknown
		Other symptoms	☐ Yes ☐ No ☐ Unknown
		- If Yes, specify symptoms:	
		Clinical notes:	
11	Hospitalisation and treatment details	Was the person hospitalised?	☐ Yes ☐ No ☐ Unknown
		- Name of hospital:	
		- Hospital phone number:	
		- Date admitted:	/ / (dd/mm/yyyy)
		- Date discharged:	/ / (dd/mm/yyyy)
		Admitted to ICU/HDU?	☐ Yes ☐ No ☐ Unknown
		- Number of days in ICU/HDU:	(days)
		Oxygen therapy required?	☐ Yes ☐ No ☐ Unknown
		Intubation required?	☐ Yes ☐ No ☐ Unknown
		Mechanical ventilation required?	☐ Yes ☐ No ☐ Unknown

[illegible]

Case's medical record/chart number:										
17	Pre-existing conditions and medical history	Cardiac disease (not simple hypertension) ☐ Yes ☐ No ☐ Unknown Chronic lung disease ☐ Yes ☐ No ☐ Unknown Diabetes ☐ Yes ☐ No ☐ Unknown Haemoglobinopathy ☐ Yes ☐ No ☐ Unknown Immunosuppressive condition ☐ Yes ☐ No ☐ Unknown Liver disease ☐ Yes ☐ No ☐ Unknown Metabolic disease ☐ Yes ☐ No ☐ Unknown Neurological disorder ☐ Yes ☐ No ☐ Unknown Obesity ☐ Yes ☐ No ☐ Unknown Renal disease ☐ Yes ☐ No ☐ Unknown - If Yes, are they on dialysis? ☐ Yes ☐ No ☐ Unknown Other medical condition? ☐ Yes ☐ No ☐ Unknown - If Yes, specify: Is the person currently pregnant or was she pregnant during the illness? ☐ Yes ☐ No ☐ Unknown If Yes, number of weeks gestation at onset of symptoms: (weeks) - Pre-existing medications and conditions notes: Are they a current smoker? ☐ Yes ☐ No ☐ Unknown If Yes, number of pack years: (pack/yr.) - Do they drink alcohol? ☐ Yes ☐ No ☐ Unknown If Yes, average number of standard drinks per week: (SD/week)								
18	Travel in the Middle East and contact with other cases * Check the current case definition for a list of affected countries.	During the period of interest, did the case travel to the Middle East? * ☐ Yes ☐ No ☐ Unknown <i>Note: Transiting through an international airport (<24 hours stay, remaining within the Airport) in the Middle East is not considered to be risk factor for infection.</i> If NO → Proceed directly to Question 22: Human Exposures Did they participate in any Pilgrimages or festivals whilst in the Middle East during the 14 days prior to onset? (e.g. the Hajj or Umrah) ☐ Yes ☐ No ☐ Unknown - If Yes, give details of what, when and where:								
19	Locations visited during incubation period (during period of interest)	During the period of interest, did they visit any of the following venues or locations in the Middle East*? <table border="0"> <tr> <td>☐ Hospital</td> <td>☐ Other health facility</td> </tr> <tr> <td>☐ Farm</td> <td>☐ Swamp marsh</td> </tr> <tr> <td>☐ Zoo/petting zoo</td> <td>☐ Camping</td> </tr> <tr> <td>☐ Abattoir</td> <td>☐ Hunting</td> </tr> </table>	☐ Hospital	☐ Other health facility	☐ Farm	☐ Swamp marsh	☐ Zoo/petting zoo	☐ Camping	☐ Abattoir	☐ Hunting
☐ Hospital	☐ Other health facility									
☐ Farm	☐ Swamp marsh									
☐ Zoo/petting zoo	☐ Camping									
☐ Abattoir	☐ Hunting									

	☐ Animal market ☐ River/lake	☐ Stockyards ☐ Agricultural show
20	Animal exposures (during period of interest)	<i>Consider any contact with live or dead animals that they have had including visiting places where animals are kept, even if they didn't have direct contact with them.</i> Did they have contact with camels? ☐ Yes ☐ No ☐ Unknown - If Yes, specify:
	Did they have contact with domestic (including household pets) or wild animals? ☐ Yes ☐ No ☐ Unknown - If Yes, were any of these animals sick or dead? ☐ Yes ☐ No ☐ Unknown o If Yes, specify:	
	Were they aware of any other animal/excreta (e.g. bats, rodents, stray cats/dog, foxes, reptiles, etc.) ☐ Yes ☐ No ☐ Unknown - If Yes, specify:	
	Did they visit a market selling live animals? ☐ Yes ☐ No ☐ Unknown - If Yes, specify:	
	Did they visit any other venue at which live animals were present (e.g. farm, race course, zoo or falconry events)? ☐ Yes ☐ No ☐ Unknown - If Yes, specify:	
21	Food exposures (during period of interest)	During the period of interest, where did they normally get their food? (Specify kinds of food and locations) Did they get their food from any other locations, or did they eat any new types of food? ☐ Yes ☐ No ☐ Unknown - If Yes, describe:
	Have they eaten any foods or drunk any beverages that they think could have been unsafe or caused them to become ill? ☐ Yes ☐ No ☐ Unknown - If Yes, describe:	
	Did they eat any of the following:	
	Camel meat, camel milk or camel urine? ☐ Yes ☐ No ☐ Unknown	
	Raw fruits or vegetables? ☐ Yes ☐ No ☐ Unknown	
	Uncooked meat or eggs ☐ Yes ☐ No ☐ Unknown	
	Raw/unpasteurised milk or milk products? ☐ Yes ☐ No ☐ Unknown	
	Dried fruits or nuts ☐ Yes ☐ No ☐ Unknown	
	Did they slaughter an animal or handle raw meat (e.g. in preparation for a meal or religious offering)? ☐ Yes ☐ No ☐ Unknown - If Yes, describe:	
	Did they take any traditional medicines or use any home remedies? ☐ Yes ☐ No ☐ Unknown	

		- If Yes, give details:
22	Human exposures <i>Contact with people who were ill during the period of interest</i> Note: not restricted to Middle East contacts	During the period of interest, did they have contact with anyone who might have had a contagious illness while they were still sick? ☐ Yes ☐ No ☐ Unknown - If Yes, give details: Have they had contact with persons who are in close contact with animals because of their work? ☐ Yes ☐ No ☐ Unknown - If Yes, give details: Have they had contact with a person who had a respiratory illness/diarrhoea/vomiting? ☐ Yes ☐ No ☐ Unknown - If Yes, give details: Did they visit or care for any sick person? ☐ Yes ☐ No ☐ Unknown - If Yes, give details: - If Yes, did they have any contact with the sick person's bodily fluids, such as urine, blood, sputum or faeces? ☐ Yes ☐ No ☐ Unknown o If Yes, give details:
23	Healthcare and hospital presentation <i>These questions should be answered about healthcare and hospital presentation in the 14 days prior to onset</i> <i>Includes Australian and overseas presentations</i>	Did the case present to hospital? ☐ Yes ☐ No ☐ Unknown - If Yes, date of presentation to hospital: / / (dd/mm/yyyy) - Was the hospital presentation for MERS related symptoms? ☐ Yes ☐ No ☐ Unknown o If No, give details of what, when and where: Did the case visit any other healthcare facilities during the period of interest? ☐ Yes ☐ No ☐ Unknown - If Yes, give date of presentation: / / (dd/mm/yyyy) Was the healthcare visit for MERS-CoV symptoms? ☐ Yes ☐ No ☐ Unknown - If No, give details of what, when and where:
24	Case Found by	☐ Clinical Presentation ☐ Contact tracing/epidemiological investigation ☐ Screening ☐ Clinical and epidemiology ☐ Other: Specify:

NEW SURVEILLANCE CASE DEFINITION

The following new case definition has been developed by the Case Definitions Working Group and endorsed by the Communicable Diseases Network Australia. The implementation date is 1 July 2016.

Middle East Respiratory Syndrome Coronavirus (MERS-CoV)

Reporting

Confirmed and **probable** cases should be notified

Confirmed case

A confirmed case requires **laboratory definitive evidence**

Laboratory definitive evidence

Detection of MERS-CoV coronavirus by polymerase chain reaction (PCR) in a public health reference laboratory using the testing algorithm described in the national guideline (SoNG) and summarised below.¹

Probable case

A probable case requires **clinical evidence** AND **epidemiological evidence**

Clinical evidence

An acute respiratory infection with clinical, radiological, or histopathological evidence of pulmonary parenchymal disease (e.g. pneumonia or pneumonitis or acute respiratory distress syndrome).

AND

No possibility of laboratory confirmation for MERS-CoV because the patient or samples are not available for testing.

Epidemiological evidence

Close contact with a laboratory-confirmed case

1. To consider a case as laboratory-confirmed, one of the following conditions must be met:
 - A positive PCR result for at least two different specific targets on the MERS-CoV genome.
 - One positive PCR result for a specific target on the MERS-CoV genome and an additional different PCR product sequenced, confirming identity to known sequences of MERS-CoV.

Health has a new website. [Visit our new website](#)

([https://www.health.gov.au/?](https://www.health.gov.au/?utm_source=health.gov.au&utm_medium=callout&utm_content=header&utm_campaign=digital_transformation)

[utm_source=health.gov.au&utm_medium=callout&utm_content=header&utm_campaign=digital transformation](https://www.health.gov.au/?utm_source=health.gov.au&utm_medium=callout&utm_content=header&utm_campaign=digital_transformation))



The
Department
of Health

Middle East Respiratory Syndrome coronavirus (MERS-CoV) Laboratory Case Definition (LCD)

The Public Health Laboratory Network have developed a standard case definition for the diagnosis of diseases which are notifiable in Australia. This page contains the laboratory case definition for MERS-CoV.

Page last updated: 28 November 2014

Version:

Authorisation: PHLN

Consensus Date:

1 PHLN Summary Laboratory Definition

1.1 Condition:

Middle East Respiratory Syndrome coronavirus (MERS-CoV)

1.1.1 WHO laboratory-confirmed criteria

A positive PCR result for at least two different specific targets on the MERS-CoV genome
OR

One positive PCR result for a specific target on the MERS-CoV genome and an additional different PCR product sequenced, confirming relatedness to known sequences of MERS-CoV.

A case with a positive PCR result for a single specific target without further testing, but with a history of potential exposure and consistent clinical signs, is considered a probable case.

At present, positive serology (MERS-CoV-specific antibodies) results in the absence of PCR testing or sequencing are considered probable cases of MERS-CoV infection if they meet the clinical case definition.



2 The disease

2.1 Infectious agent

Coronaviruses are a large and diverse family of viruses that include viruses that are known to cause illness in humans and animals. Four human coronaviruses (hCoV) are known causes of respiratory infections of mild to moderate severity. These include the betacoronaviruses hCoV-OC43 and hCoV-HKU1, and the alphacoronaviruses hCoV-229E and hCoV-NL63. Severe acute respiratory syndrome coronavirus (SARS-CoV) and MERS-CoV are betacoronaviruses that can cause severe respiratory infection. MERS-CoV is genetically distinct from SARS-CoV.

2.2 Reservoir

It is likely that the MERS-CoV has come from an animal source. MERS-CoV has been found in camels in Qatar and a bat in Saudi Arabia. Sera from camels in a few other countries (but not Australia) have also tested positive for antibodies to MERS-CoV, indicating they were previously infected with MERS-CoV or a closely related virus. However, it is not known if camels are the source of the virus for human infections. More information is needed to identify the possible role that camels, bats, and other animals may play in MERS-CoV transmission.

2.3 Mode of transmission

The mode or modes of transmission of MERS-CoV are not fully known.

There have been some cases with a strong history of exposure to camels, including at least one cluster where the camels also tested seropositive, but there have been many sporadic cases with no history of prior exposure to camels or other animals. Analysis of genetic sequence data suggests multiple independent introductions into human populations, rather than from a single zoonotic event.

Although there have been multiple clusters of cases in which human-to-human transmission has occurred, sustained human-to-human transmission has not been observed. Clusters of human-to-human transmission have been observed in healthcare facilities, among family members and between co-workers. However, the mechanism by which transmission occurred in all of these cases, whether respiratory (e.g. coughing, sneezing) or direct physical contact with the patient or contamination of the environment by the patient, is unknown.

Infection control recommendations for managing suspect, probable and confirmed cases are consistent with those recommended for SARS-CoV. As information becomes available, these recommendations will be re-evaluated and updated as needed.

2.4 Incubation period

[↑ top of page](#)

From 2 to 14 days, with a median of ~5 days.

2.5 Infectious period

The duration of infectivity following MERS-CoV infection is unknown. Standard precautions should always be applied; additional isolation precautions should be used during the duration of symptomatic illness and continued for at least 24 hours after the resolution of symptoms.



Given that little information is currently available on viral shedding and the potential for transmission of MERS-CoV, testing for viral shedding should assist the decision making when readily available. Individual patient factors (e.g. age, immune status, other co-morbidities) should also be considered in situations where there is concern that a patient may be shedding the virus for prolonged periods.

2.6 Clinical presentation and outcome

Clinical presentation ranges from asymptomatic to severe pneumonia with acute respiratory distress syndrome and multi-organ failure. Nearly all symptomatic patients have presented with respiratory symptoms and one third of patients have had gastrointestinal symptoms.

Typically, the disease starts with fever and cough, chills, sore throat, myalgia and arthralgia, followed by dyspnoea, and rapidly progresses to pneumonia, often requiring mechanical ventilation and other organ support.

The case fatality rate for confirmed cases is ~30% but this may decrease as mild or asymptomatic cases are identified during contact tracing of known cases.

2.7 Persons at increased risk of disease

Cases who are elderly, immunocompromised or with co-morbidities have an increased mortality rate.

2.8 Disease occurrence and public health significance

There have been no confirmed MERS-CoV cases reported in Australia to date. MERS-CoV is also not a national notifiable disease at present, but is notifiable in some States such as Western Australia.

As of 17th July 2014, 834 laboratory-confirmed cases of human infection with MERS-CoV have been reported to WHO, including at least 288 related deaths. MERS-CoV updates can be found at the [WHO website](http://www.who.int/csr/disease/coronavirus_infections/en/)(http://www.who.int/csr/disease/coronavirus_infections/en/).

At the time of writing, the affected countries in the Middle East include Iran, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia (KSA), United Arab Emirates (UAE) and Yemen; in Africa: Algeria, Egypt and Tunisia; in Europe: France, Germany, Greece, Italy, the Netherlands and the United Kingdom; in Asia: Malaysia and Philippines; and in North America: the United States of America (USA).

WHO expects that additional cases of MERS-CoV infection will be reported from the Middle East, and that it is likely that cases will continue to be exported to other countries by tourists, travellers, guest workers or pilgrims who might acquire infection following exposure to an animal (for example, while visiting farms or markets) or human source (possibly in a health care setting). Until more is understood about mode of transmission and risk factors for infection, cases resulting from zoonotic transmission are likely to continue to occur, and may seed limited community transmission within household and possibly significant hospital-associated outbreaks.

3 Clinical case definitions

3.1 Confirmed case

- A confirmed case requires laboratory definitive evidence of infection with MERS-CoV

3.2 Probable case

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- A person with an acute respiratory infection with clinical, radiological, or histopathological evidence of pulmonary parenchymal disease (e.g. pneumonia or Acute Respiratory Distress Syndrome (ARDS)); AND
- Either no possibility of laboratory confirmation for MERS-CoV because the patient or samples are not available for testing; or results of laboratory testing awaited AND
- Close contact with a laboratory-confirmed case (see the Contact Management section below for guidance on identifying close contacts).

Notes:

- Transiting through an international airport (<24 hours stay, remaining within the airport) in the Middle East is not considered to be risk factor for infection.
- Countries in the Middle East and immediate surrounding areas may be defined as:
- Bahrain, Iraq, Iran, Israel, Jordan, Kuwait, Lebanon, Oman, Palestinian territories, Qatar, Saudi Arabia, Syria, the United Arab Emirates (UAE), and Yemen.
- Laboratory definitive evidence: to consider a case as laboratory-confirmed, one of the following conditions must be met: (WHO MERS-CoV testing algorithm)
- A positive MERS-CoV PCR result (note that WHO currently recommend PCR for at least two different specific targets on the MERS-CoV genome, or alternatively one positive PCR result for a specific target on the MERS-CoV genome and an additional different PCR product sequenced, confirming relatedness to known sequences of MERS-CoV. While this is endorsed as good practice for Australia to provide confirmation of initial cases it is not considered practical as an ongoing routine diagnostic approach.

3.3 Suspect case/Patient under investigation

MERS-CoV testing should be considered for:

- Individuals with pneumonia or pneumonitis and history of travel to, or residence in, the Middle East, in the 14 days before illness onset; OR
- Individuals with pneumonia or pneumonitis and history of contact with those mentioned above in the 14 days before illness onset.
- Healthcare workers with pneumonia or pneumonitis, who have been caring for patients with severe acute respiratory infections, particularly patients requiring intensive care, without regard to place of residence or history of travel, where another cause has not been confirmed.

Note: Also consider in laboratory workers who have handled clinical specimens from confirmed MERS-CoV cases without adequate infection control precautions.

Refer to the CDNA surveillance case definitions website(<http://www.health.gov.au/casedefinitions>) for updated case definitions.

4 Laboratory testing

4.1 Testing guidelines

Patients to be considered for MERS-CoV testing are described under the Suspect case/Patient under investigation case definition (above).



Transmission-based contact and airborne precautions must be used when collecting respiratory specimens. These are described in NHMRC: Australian Guidelines for the Prevention and Control of Infection in Healthcare – 2010 (particularly section B2.4), and include:

- Contact precautions, including close attention to hand hygiene
- Airborne transmission precautions, including routine use of a P2 respirator, disposable gown, gloves, and eye protection when entering a patient care area
- A requirement for negative pressure air-handling
- Place clearly labeled specimens for transport in a biohazard specimen bag (leak-proof specimen bags that have a separate sealable pocket for the specimen) with a clearly written request form
- Deliver all specimens by hand, do not use pneumatic-tube specimen transport systems
- Notify the receiving laboratory as soon as possible that a specimen is being transported.

See Appendix 1 for requirements for specimen handling and transport to the laboratory.

4.2 Samples suitable for testing

↑ top of page

4.2.1 Respiratory samples

Upper respiratory tract samples

Nasopharyngeal swab and/or oropharyngeal swab

- nasopharyngeal: insert a swab into each nostril parallel to the palate, leave the swab in place for a few seconds to absorb secretions
- oropharyngeal: swab the tonsillar beds, avoiding the tongue
- place swabs back into the accompanying transport media

Nasal wash/aspirates

- collect 2-3 mL into a sterile, leak-proof, screw-top dry sterile container

Lower respiratory tract samples

Bronchoalveolar lavage, tracheal aspirate, pleural fluid

- collect 2-3 mL into a sterile, leak-proof, screw-top sputum collection cup or dry sterile container

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

There is now increasing evidence that lower respiratory tract specimens such as contain the highest viral loads, therefore, lower respiratory tract specimens should be collected where possible. Repeat testing (especially of lower respiratory tract specimens) in compatible cases should be performed if initial results are negative.

4.2.2 Serology



Serum should be collected during the acute phase of the illness (preferably within the first 7 of symptom onset), stored, and tested in parallel with a convalescent serum collected 3 or more weeks after acute sample collection.

If no acute sample was collected, a single serum sample collected 14 or more days after symptom onset may be tested.

At the time of writing, limited indirect fluorescent antibody (IFA) serology is available but only specificity can be established without access to significant numbers of positive sera. Only a single MERS-CoV positive sample has been available for validation purposes thus far. Hence serology should be used sparingly as an adjunct to detection of virus in acute cases. Serology may be useful in cases where MERS-CoV is strongly suspected but non-confirmed with nucleic acid testing (NAT). Collection of paired acute and convalescent sera is recommended. Positive serological test results in the absence of NAT or sequencing are considered probable cases only.

In some other countries neutralization serology tests are used for confirmation purposes. Similar to NAT, a two stage approach using a screening followed by a confirmatory test can be employed. In the absence of positive sera with which to establish, calibrate and control such an assay this approach is not possible in Australia. For screening purposes, an enzyme-immunosorbent assay (ELISA) against recombinant N protein can be used.

4.2.3 Stool

2 – 5 grams of stool (formed or liquid) is collected in a sterile, leak-proof, screw-top dry sterile container.

4.3 Testing of other pathogens

Routine tests for acute pneumonia/pneumonitis should be performed where indicated, including bacterial cultures, acute and convalescent serology, urinary antigen testing and tests for influenza and other respiratory viruses.

4.4 Handling of specimens in the laboratory

Laboratory staff should handle specimens under PC2 and PC3 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 (see Appendix 1 and 2).

4.5 MERS-CoV testing

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NAT using reverse-transcriptase polymerase chain reaction (RT-PCR) is the method of choice for detection of MERS-CoV. Currently, four targets may be used for testing:-

- upstream region of the E protein (upE) gene
- open reading frame (ORF) 1a (ORF1a)
- ORF1b
- MERS-CoV specific nucleocapsid (N) protein gene



An algorithm using a screening assay, followed by confirmatory testing is recommended for certainty of diagnosis of the initial cases. For screening purposes, assays targeting the upE gene are appropriate. Confirmatory testing can be performed using an assay targeting the ORF1a (comparable sensitivity to upE gene), ORF1b (which is less sensitive than ORF1a or upE) or N gene. It is recommended that positive screening tests be reported to communicable diseases agencies whilst awaiting confirmatory testing.

Where available, RdRp gene (for the broad detection of b-coronavirus clade C) and/or N gene sequencing may also be considered for MERS-CoV confirmation. As the primers for the RdRp sequencing assay are highly conserved, it is not recommended that this assay be used alone for MERS-CoV confirmation, as false positive results may occur from cross-reactions with other b-coronaviruses. Further information about laboratory testing is available at (<http://www.virology-bonn.de/index.php?id=40>) and (<http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM355572.pdf>). Testing algorithms may also need to be revised pending further information about the virus, and the number of specimens received in the laboratory for testing.

Viral culture is generally not performed for routine diagnosis, and should only be attempted in laboratories with appropriate experience and containment facilities. MERS-CoV replication has been previously observed on Vero and LLC-MK2 cells within 5 days of inoculation.

4.6 Quality assurance

In 2013, the RCPA Quality Assurance Programs conducted two novel coronavirus (MERS-CoV) surveys under the RCPAQAP Biosecurity module. As clinical samples, live or inactivated virus, were not available for testing, each survey contained three simulated specimens generated using recombinant plasmids.

The first survey contained varying concentrations of MERS-CoV E, RdRp, N, ORF1a and ORF1b RNA transcripts, whilst the second survey included MERS-CoV and hCoV-NL63 RNA transcripts. Seven laboratories participated in the survey, using in-house developed NAT and commercial assays. In survey 1, 6 of 7 laboratories were able to detect MERS-CoV. In survey 2, 6 of 7 laboratories were able to detect MERS-CoV, but 4 of 6 laboratories (one laboratory using a commercial assay was not able to detect MERS-CoV or hCoV-NL63) falsely detected MERS-CoV in samples containing hCoV-NL63 transcripts.

Although both surveys were conducted using RNA transcripts generated using recombinant plasmids, they highlighted that cross-reactivity and/or cross-contamination during NAT may be an issue for laboratories testing MERS-CoV.

Appendix 1. Suitable specimens and transport requirements (modified from WHO Laboratory testing for Middle East Respiratory Syndrome Coronavirus [available at:

(http://who.int/csr/disease/coronavirus_infections/MERS_Lab_recos_16_Sept_2013.pdf?ua=1))

Specimen type	Transport medium	Transport to laboratory	Dangerous goods shipping category
Sputum	No	4°C (if a delay in testing of > 48 hours, consider freezing and shipping with dry ice)	Biological substance, Category B



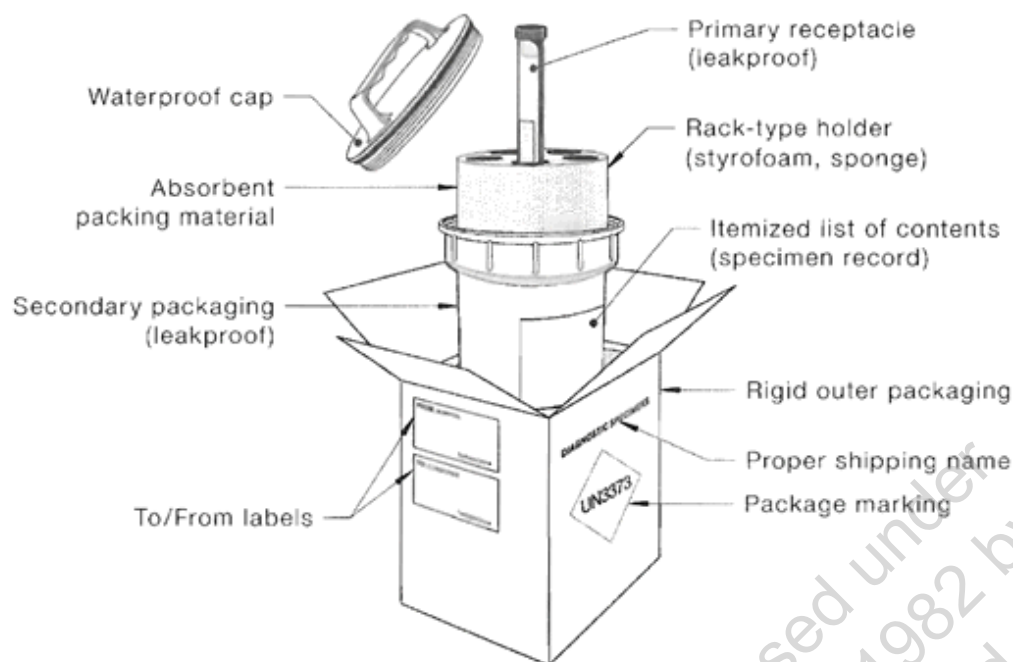
Bronchoalveolar lavage	No	4°C (if a delay in testing of > 48 hours, consider freezing and shipping with dry ice)	Biological substance, Category B
Tracheal aspirate	No	4°C (if a delay in testing of > 48 hours, consider freezing and shipping with dry ice)	Biological substance, Category B
Nasopharyngeal aspirate	No	4°C (if a delay in testing of > 48 hours, consider freezing and shipping with dry ice)	Biological substance, Category B
Combined nasopharyngeal/oropharyngeal swabs	Viral transport media	4°C (if a delay in testing of > 48 hours, consider freezing and shipping with dry ice)	Biological substance, Category B
Tissue from biopsy or autopsy including lung	Viral transport media	4°C (if a delay in testing of > 48 hours, consider freezing and shipping with dry ice)	Biological substance, Category B
Serum for serological testing	No	4°C or frozen and shipped on dry ice	Biological substance, Category B

Category B packaging preparation includes: manufacturer's instructions followed, good quality packaging, primary receptacles sealed and leakproof, primary receptacle closures secured with secondary means (optional), multiple fragile primaries wrapped individually, sufficient absorbent inside each secondary, secondary packaging properly sealed and leakproof, primary or secondary receptacle 95 kPa pressure compliant, itemized list of contents between secondary and outer packaging, rigid outer packaging, at least one surface of outer packaging is 100 mm x 100 mm

Figure 1. Packing and labelling of Category B infectious substance

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Appendix 2. Guidelines for laboratory staff working with MERS-CoV (modified from CDC Interim laboratory biosafety guidelines for handling and processing specimens associated with Middle East Respiratory Syndrome Coronavirus – version 2

(<http://www.cdc.gov/coronavirus/mers/guidelines-lab-biosafety.html>)

Activities involving manipulation of potentially infected specimens should be performed in a PC2 facility in a Class 2 biosafety cabinet using PC2 work practice:

- aliquoting and/or diluting specimens
- performing diagnostic tests that do not involve propagation of viral agents in vitro or in vivo
- nucleic acid extraction procedures involving potentially infected specimens

Activities that must be performed in a PC3 facility using PC3 work practices:

- MERS-CoV propagation in cell culture
- initial characterization of viral agents recovered in cultures of MERS-CoV specimens

5 References

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Surveillance case definitions for human infection with novel coronavirus (nCoV)

Interim guidance v2

15 January 2020

WHO/2019-nCoV/Surveillance/v2020.2



This document summarizes WHO recommendations for surveillance of the novel coronavirus (nCoV) recently identified in Wuhan, China (2019-nCoV). WHO will update these recommendations as new information becomes available on the situation.

This interim guidance was adapted from WHO's guidance materials published for Middle East Respiratory coronavirus (MERS-CoV) and will be updated regularly.

Surveillance

Objectives of surveillance

The primary objectives of surveillance are to:

1. Detect cases/clusters of nCoV infection and any evidence of amplified or sustained human-to-human transmission;
2. Determine risk factors and the geographic risk area for infection with the virus.

Additional clinical and epidemiological investigations are needed to:

1. Determine key clinical characteristics of the illness, such as incubation period, spectrum of disease, and the clinical course of the disease.
2. Determine key epidemiological characteristics of nCoV infection, such as exposures that result in infection, risk factors, secondary attack rates, and modes of transmission.

The following people should be investigated and tested for nCoV infection

Case definitions for surveillance

3. Severe acute respiratory infection (SARI) in a person, with history of fever and cough requiring admission to hospital, with no other etiology that fully explains the clinical presentation¹ (clinicians should also be alert to the possibility of atypical presentations in patients who are immunocompromised);

AND any of the following:

- a. a history of travel to or a person who lived in Wuhan, Hubei Province China in the 14 days prior to symptom onset; or
 - b. the disease occurs in a health care worker who has been working in an environment where patients with severe acute respiratory infections are being cared for, without regard to place of residence or history of travel.
2. The person develops an unusual or unexpected clinical course, especially sudden deterioration despite appropriate treatment, without regard to place of residence or history of travel, even if another etiology has been identified that fully explains the clinical presentation.
 3. A person with acute respiratory illness of any degree of severity who, within 14 days before onset of illness, had any of the following exposures:
 - a. close physical contact² with a confirmed case of nCoV infection; or
 - b. a healthcare facility in a country where hospital-associated nCoV infections have been reported; or
 - c. visiting or working in a live animal market in Wuhan, China
 - d. [direct contact with animals (if animal source is identified) in countries where the nCoV is known to be circulating in animal populations or where human infections have occurred as a result of presumed zoonotic transmission.]³

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¹ Testing should be according to local guidance for management of community-acquired pneumonia. Examples of other etiologies include *Streptococcus pneumoniae*, *Haemophilus influenzae* type B, *Legionella pneumophila*, other recognized primary bacterial pneumonias, influenza viruses, and respiratory syncytial virus.

²Close contact³ is defined as:

- Health care associated exposure, including providing direct care for nCoV patients, working with health care workers infected with nCoV,

visiting patients or staying in the same close environment of a nCoV patient.

- Working together in close proximity or sharing the same classroom environment with a nCoV patient
- Traveling together with nCoV patient in any kind of conveyance
- Living in the same household as a nCoV patient

The epidemiological link may have occurred within a 14-day period before or after the onset of illness in the case under consideration.

³ To be added once/if animal source is identified as a source of infection

Clinical management of severe acute respiratory infection when novel coronavirus (nCoV) infection is suspected

Interim guidance

12 January 2020

WHO/nCoV/Clinical/2020.1



Introduction

This is the first edition of this document for novel coronavirus, an adaption of WHO Clinical management of severe acute respiratory infection when MERS-CoV infection is suspected publication (2019).

This document is intended for clinicians taking care of hospitalised adult and paediatric patients with severe acute respiratory infection (SARI) when a nCoV infection is suspected. It is not meant to replace clinical judgment or specialist consultation but rather to strengthen clinical management of these patients and provide to up-to-date guidance. Best practices for SARI including IPC and optimized supportive care for severely ill patients are essential.

This document is organized into the following sections:

1. Triage: recognize and sort patients with SARI
2. Immediate implementation of appropriate infection prevention and control (IPC) measures
3. Early supportive therapy and monitoring
4. Collection of specimens for laboratory diagnosis
5. Management of hypoxemic respiratory failure and acute respiratory distress syndrome (ARDS)
6. Management of septic shock
7. Prevention of complications
8. Specific anti-nCoV treatments
9. Special considerations for pregnant patients

These symbols are used to flag interventions:

- Do:** the intervention is beneficial (strong recommendation) **OR** the intervention is a best practice statement
- Don't:** the intervention is known to be harmful.
- Consider:** the intervention may be beneficial in selected patients (conditional recommendation) **OR** be careful when considering this intervention.

This document aims to provide clinicians with updated interim guidance on timely, effective, and safe supportive management of patients with nCoV and SARI, particularly those with critical illness.

The recommendations in this document are derived from WHO publications.¹⁻⁴ Where WHO guidance is not available, we refer to evidence-based guidelines. Members of a WHO global network of clinicians, and clinicians who have treated SARS, MERS or severe influenza patients have reviewed the recommendations (see Acknowledgements). For queries, please email outbreak@who.int with 'nCoV clinical question' in the subject line.

1. Triage: early recognition of patients with SARI associated with nCoV infection

✓ **Triage:** recognize and sort all patients with SARI at first point of contact with health care system (such as the emergency department). Consider nCoV as a possible etiology of SARI under certain conditions (see Table 1). Triage patients and start emergency treatments based on disease severity.

Remarks: nCoV may present with mild, moderate, or severe illness; the latter includes severe pneumonia, ARDS, sepsis and septic shock. Early recognition of suspected patients allows for timely initiation of IPC (see Table 2). Early identification of those with severe manifestations (see Table 2) allows for immediate optimized supportive care treatments and safe, rapid admission (or referral) to intensive care unit according to institutional or national protocols. For those with mild illness, hospitalization may not be required unless there is concern for rapid deterioration. All patients discharged home should be instructed to return to hospital if they develop any worsening of illness.

Table 1. Definitions of patients with SARI, suspected of nCoV*

SARI	An ARI with history of fever or measured temperature $\geq 38^{\circ}\text{C}$ and cough; onset within the last ~10 days; and requiring hospitalization. ⁵ However, the absence of fever does NOT exclude viral infection. ⁶
Surveillance case definitions for nCoV*	- Severe acute respiratory infection (SARI) in a person, with history of fever and cough requiring admission to hospital, with no other etiology that fully explains the clinical presentation¹ (clinicians should also be alert to the possibility of atypical presentations in patients who are immunocompromised); AND any of the following: - A history of travel to Wuhan, Hubei Province China in the 14 days prior to symptom onset; or - the disease occurs in a health care worker who has been working in an environment where patients with severe acute respiratory infections are being cared for, without regard to place of residence or history of travel; or - the person develops an unusual or unexpected clinical course, especially sudden deterioration despite appropriate treatment, without regard to place of residence or history of travel, even if another etiology has been identified that fully explains the clinical presentation. - A person with acute respiratory illness of any degree of severity who, within 14 days before onset of illness, had any of the following exposures: - close physical contact² with a confirmed case of nCoV infection, while that patient was symptomatic; or - a healthcare facility in a country where hospital-associated nCoV infections have been reported;

*see <https://www.who.int/health-topics/coronavirus> for latest case definitions

¹ Testing should be according to local guidance for management of community-acquired pneumonia. Examples of other etiologies include *Streptococcus pneumoniae*, *Haemophilus influenzae* type B, *Legionella pneumophila*, other recognized primary bacterial pneumonias, influenza viruses, and respiratory syncytial virus.

²Close contact² is defined as:

- Health care associated exposure, including providing direct care for nCoV patients, working with health care workers infected with nCoV, visiting patients or staying in the same close environment of a nCoV patient.
- Working together in close proximity or sharing the same classroom environment with a nCoV patient
- Traveling together with nCoV patient in any kind of conveyance
- Living in the same household as a nCoV patient

The epidemiological link may have occurred within a 14-day period before or after the onset of illness in the case under consideration.

Table 2. Clinical syndromes associated with nCoV infection

Uncomplicated illness	Patients with uncomplicated upper respiratory tract viral infection, may have non-specific symptoms such as fever, cough, sore throat, nasal congestion, malaise, headache, muscle pain or malaise. The elderly and immunosuppressed may present with atypical symptoms. These patients do not have any signs of dehydration, sepsis or shortness of breath.
Mild pneumonia	Patient with pneumonia and no signs of severe pneumonia. Child with non-severe pneumonia has cough or difficulty breathing + fast breathing: fast breathing (in breaths/min): <2 months, ≥60; 2–11 months, ≥50; 1–5 years, ≥40 and no signs of severe pneumonia.
Severe pneumonia	Adolescent or adult: fever or suspected respiratory infection, plus one of respiratory rate >30 breaths/min, severe respiratory distress, or SpO ₂ <90% on room air (adapted from [1]). Child with cough or difficulty in breathing, plus at least one of the following: central cyanosis or SpO ₂ <90%; severe respiratory distress (e.g. grunting, very severe chest indrawing); signs of pneumonia with a general danger sign: inability to breastfeed or drink, lethargy or unconsciousness, or convulsions. Other signs of pneumonia may be present: chest indrawing, fast breathing (in breaths/min): <2 months, ≥60; 2–11 months, ≥50; 1–5 years, ≥40. ² The diagnosis is clinical; chest imaging can exclude complications.
Acute Respiratory Distress Syndrome⁷⁻⁹	Onset: new or worsening respiratory symptoms within one week of known clinical insult. Chest imaging (radiograph, CT scan, or lung ultrasound): bilateral opacities, not fully explained by effusions, lobar or lung collapse, or nodules. Origin of oedema: respiratory failure not fully explained by cardiac failure or fluid overload. Need objective assessment (e.g. echocardiography) to exclude hydrostatic cause of oedema if no risk factor present. Oxygenation (adults): - Mild ARDS: 200 mmHg < PaO₂/FiO₂ ≤ 300 mmHg (with PEEP or CPAP ≥5 cmH₂O,⁷ or non-ventilated⁸) - Moderate ARDS: 100 mmHg < PaO₂/FiO₂ ≤ 200 mmHg with PEEP ≥5 cmH₂O,⁷ or non-ventilated⁸) - Severe ARDS: PaO₂/FiO₂ ≤ 100 mmHg with PEEP ≥5 cmH₂O,⁷ or non-ventilated⁸) - When PaO₂ is not available, SpO₂/FiO₂ ≤ 315 suggests ARDS (including in non-ventilated patients) Oxygenation (children; note OI = Oxygenation Index and OSI = Oxygenation Index using SpO₂): - Bilevel NIV or CPAP ≥5 cmH₂O via full face mask: PaO₂/FiO₂ ≤ 300 mmHg or SpO₂/FiO₂ ≤ 264 - Mild ARDS (invasively ventilated): 4 ≤ OI < 8 or 5 ≤ OSI < 7.5 - Moderate ARDS (invasively ventilated): 8 ≤ OI < 16 or 7.5 ≤ OSI < 12.3 - Severe ARDS (invasively ventilated): OI ≥ 16 or OSI ≥ 12.3
Sepsis^{10,11}	Adults: life-threatening organ dysfunction caused by a dysregulated host response to suspected or proven infection, with organ dysfunction*. Signs of organ dysfunction include: altered mental status, difficult or fast breathing, low oxygen saturation, reduced urine output, fast heart rate, weak pulse, cold extremities or low blood pressure, skin mottling, or laboratory evidence of coagulopathy, thrombocytopenia, acidosis, high lactate or hyperbilirubinemia. Children: suspected or proven infection and ≥2 SIRS criteria, of which one must be abnormal temperature or white blood cell count.
Septic shock^{10,12}	Adults: persisting hypotension despite volume resuscitation, requiring vasopressors to maintain MAP ≥65 mmHg and serum lactate level >2 mmol/L. Children (based on [12]): any hypotension (SBP <5 th centile or >2 SD below normal for age) or 2-3 of the following: altered mental state; tachycardia or bradycardia (HR <90 bpm or >160 bpm in infants and HR <70 bpm or >150 bpm in children); prolonged capillary refill (>2 sec) or warm vasodilation with bounding pulses; tachypnea; mottled skin or petechial or purpuric rash; increased lactate; oliguria; hyperthermia or hypothermia.

Abbreviations: ARI, acute respiratory infection; BP, blood pressure; bpm, beats/minute; CPAP, continuous positive airway pressure; FiO₂, fraction of inspired oxygen; MAP, mean arterial pressure; NIV, noninvasive ventilation; OI, Oxygenation Index; OSI, Oxygenation Index using SpO₂; PaO₂, partial pressure of oxygen; PEEP, positive end-expiratory pressure; SBP, systolic blood pressure; SD, standard deviation; SIRS, systemic inflammatory response syndrome; SpO₂, oxygen saturation. *If altitude is higher than 1000m, then correction factor should be calculated as follows: PaO₂/FiO₂ x Barometric pressure/760.

* The SOFA score ranges from 0 to 24 and includes points related to 6 organ systems: respiratory (hypoxemia defined by low PaO₂/FiO₂), coagulation (low platelets), liver (high bilirubin), cardiovascular (hypotension), central nervous system (low level of consciousness defined by Glasgow Coma Scale), and renal (low urine output or high creatinine). Sepsis is defined by an increase in the Sequential [Sepsis-related] Organ Failure Assessment (SOFA) score¹³ of ≥2 points. Assume the baseline score is zero if data are not available

2. Immediate implementation of appropriate IPC measures

IPC is a critical and integral part of clinical management of patients and should be initiated at the point of entry of the patient to hospital (typically the Emergency Department). Standard precautions should always be routinely applied in all areas of health care facilities. Standard precautions include hand hygiene; use of PPE to avoid direct contact with patients' blood, body fluids, secretions (including respiratory secretions) and non-intact skin. Standard precautions also include prevention of needle-stick or sharps injury; safe waste management; cleaning and disinfection of equipment; and cleaning of the environment.

Table 2. How to implement infection prevention and control measures for patients with suspected or confirmed nCoV infection ^{14,15}

At triage	Give suspect patient a medical mask and direct patient to separate area, an isolation room if available. Keep at least 1 meter distance between suspected patients and other patients. Instruct all patients to cover nose and mouth during coughing or sneezing with tissue or flexed elbow for others. Perform hand hygiene after contact with respiratory secretions
Apply droplet precautions	Droplet precautions prevent large droplet transmission of respiratory viruses. Use a medical mask if working within 1-2 metre s of the patient. Place patients in single rooms, or group together those with the same etiological diagnosis. If an etiological diagnosis is not possible, group patients with similar clinical diagnosis and based on epidemiological risk factors, with a spatial separation. When providing care in close contact with a patient with respiratory symptoms (e.g. coughing or sneezing), use eye protection (face-mask or goggles), because sprays of secretions may occur. Limit patient movement within the institution and ensure that patients wear medical masks when outside their rooms.
Apply contact precautions	Droplet and contact precautions prevent direct or indirect transmission from contact with contaminated surfaces or equipment (i.e. contact with contaminated oxygen tubing/interfaces). Use PPE (medical mask, eye protection, gloves and gown) when entering room and remove PPE when leaving. If possible, use either disposable or dedicated equipment (e.g. stethoscopes, blood pressure cuffs and thermometers). If equipment needs to be shared among patients, clean and disinfect between each patient use. Ensure that health care workers refrain from touching their eyes, nose, and mouth with potentially contaminated gloved or ungloved hands. Avoid contaminating environmental surfaces that are not directly related to patient care (e.g. door handles and light switches). Ensure adequate room ventilation. Avoid movement of patients or transport. Perform hand hygiene.
Apply airborne precautions when performing an aerosol generating procedure	Ensure that healthcare workers performing aerosol-generating procedures (i.e. open suctioning of respiratory tract, intubation, bronchoscopy, cardiopulmonary resuscitation) use PPE, including gloves, long-sleeved gowns, eye protection, and fit-tested particulate respirators (N95 or equivalent, or higher level of protection). (The scheduled fit test should not be confused with user seal check before each use.) Whenever possible, use adequately ventilated single rooms when performing aerosol-generating procedures, meaning negative pressure rooms with minimum of 12 air changes per hour or at least 160 litres/second/patient in facilities with natural ventilation. Avoid the presence of unnecessary individuals in the room. Care for the patient in the same type of room after mechanical ventilation commences.

Abbreviations: ARI, acute respiratory infection; PPE, personal protective equipment

3. Early supportive therapy and monitoring

✓ Give supplemental oxygen therapy immediately to patients with SARI and respiratory distress, hypoxaemia, or shock.

Remarks: Initiate oxygen therapy at 5 L/min and titrate flow rates to reach target SpO₂ ≥90% in non-pregnant adults and SpO₂ ≥92-95 % in pregnant patients.¹² Children with emergency signs (obstructed or absent breathing, severe respiratory distress, central cyanosis, shock, coma or convulsions) should receive oxygen therapy during resuscitation to target SpO₂ ≥94%; otherwise, the target SpO₂ is ≥90%.⁴ All areas where patients with SARI are cared for should be equipped with pulse oximeters, functioning oxygen systems and disposable, single-use, oxygen-delivering interfaces (nasal cannula, simple face mask, and mask with reservoir bag). Use contact precautions when handling contaminated oxygen interfaces of patients with nCoV infection.

✓ Use conservative fluid management in patients with SARI when there is no evidence of shock.

Remarks: Patients with SARI should be treated cautiously with intravenous fluids, because aggressive fluid resuscitation may worsen oxygenation, especially in settings where there is limited availability of mechanical ventilation.¹⁶

✓ Give empiric antimicrobials to treat all likely pathogens causing SARI. Give antimicrobials within one hour of initial patient assessment for patients with sepsis.

Remarks: Although the patient may be suspected to have nCoV, administer appropriate empiric antimicrobials within **ONE hour** of identification of sepsis.¹⁷ Empiric antibiotic treatment should be based on the clinical diagnosis (community-acquired pneumonia, health care-associated pneumonia [if infection was acquired in healthcare setting], or sepsis), local epidemiology and susceptibility data, and treatment guidelines. Empiric therapy includes a neuraminidase inhibitor for treatment of influenza when there is local circulation or other risk factors, including travel history or exposure to animal influenza viruses.¹⁸ Empiric therapy should be de-escalated on the basis of microbiology results and clinical judgment.

✗ Do not routinely give systemic corticosteroids for treatment of viral pneumonia or ARDS outside of clinical trials unless they are indicated for another reason.

Remarks: A systematic review of observational studies of corticosteroids administered to patients with SARS reported no survival benefit and possible harms (avascular necrosis, psychosis, diabetes, and delayed viral clearance).¹⁹ A systematic review of observational studies in influenza found a higher risk of mortality and secondary infections with corticosteroids; the evidence was judged as very low to low quality due to confounding by indication.²⁰ A subsequent study that addressed this limitation by adjusting for time-varying confounders found no effect on mortality.²¹ Finally, a recent study of patients receiving corticosteroids for MERS used a similar statistical approach and found no effect of corticosteroids on mortality but delayed lower respiratory

tract (LRT) clearance of MERS-CoV.²² Given lack of effectiveness and possible harm, routine corticosteroids should be avoided unless they are indicated for another reason. See section 6 for the use of corticosteroids in sepsis.

- ✔ **Closely monitor patients with SARI for signs of clinical deterioration, such as rapidly progressive respiratory failure and sepsis, and apply supportive care interventions immediately.**

Remarks: Application of timely, effective, and safe supportive therapies is the cornerstone of therapy for patients that develop severe manifestations of nCoV.

- ✔ **Understand the patient's co-morbid condition(s) to tailor the management of critical illness and appreciate the prognosis. Communicate early with patient and family.**

Remarks: During intensive care management of SARI, determine which chronic therapies should be continued and which therapies should be stopped temporarily. Communicate proactively with patients and families and provide support and prognostic information. Understand the patient's values and preferences regarding life-sustaining interventions.

4. Collection of specimens for laboratory diagnosis

WHO guidance on specimen collection, processing, and laboratory testing, including related biosafety procedures, is available.²³

- ✔ **Collect blood cultures for bacteria that cause pneumonia and sepsis, ideally before antimicrobial therapy. DO NOT delay antimicrobial therapy to collect blood cultures.**
- ✔ **Collect specimens from BOTH the upper respiratory tract (URT; nasopharyngeal and oropharyngeal) AND lower respiratory tract (LRT; expectorated sputum, endotracheal aspirate, or bronchoalveolar lavage) for nCoV testing by RT-PCR. Clinicians may elect to collect only LRT samples when these are readily available (for example, in mechanically ventilated patients).**
- ✔ **Serology for diagnostic purposes is recommended only when RT-PCR is not available.²³**

Remarks: Use appropriate PPE for specimen collection (droplet and contact precautions for URT specimens; airborne precautions for LRT specimens). When collecting URT samples, use viral swabs (sterile Dacron or rayon, not cotton) and viral transport media. Do not sample the nostrils or tonsils. In a patient with suspected novel coronavirus, especially with pneumonia or severe illness, a single URT sample does not exclude the diagnosis, and additional URT and LRT samples are recommended.²³ LRT (vs. URT) samples are more likely to be positive and for a longer period.²³ Clinicians may elect to collect only LRT samples when these are readily available (for example, in mechanically ventilated patients). Sputum induction should be avoided due to increased risk of increasing aerosol transmission.

Remarks: Dual infections with other respiratory viral infections have been found in SARS and MERS cases. At this stage we need detailed microbiologic studies in all suspected cases. Both URT and LRT specimens can be tested for other respiratory viruses, such as influenza A and B (including zoonotic influenza A), respiratory syncytial virus, parainfluenza viruses, rhinoviruses, adenoviruses, enteroviruses (e.g. EVD68), human metapneumovirus, and endemic human coronaviruses (i.e. HKU1, OC43, NL63, and 229E). LRT specimens can also be tested for bacterial pathogens, including *Legionella pneumophila*.

- ✔ **In hospitalized patients with confirmed nCoV infection, repeat URT and LRT samples should be collected to demonstrate viral clearance. The frequency of specimen collection will depend on local circumstances but should be at least every 2 to 4 days until there are two consecutive negative results (both URT and LRT samples if both are collected) in a clinically recovered patient at least 24 hours apart. If local infection control practice requires two negative results before removal of droplet precautions, specimens may be collected as often as daily.**

5. Management of hypoxemic respiratory failure and ARDS

- ✔ **Recognize severe hypoxemic respiratory failure when a patient with respiratory distress is failing standard oxygen therapy.**

Remarks: Patients may continue to have increased work of breathing or hypoxemia even when oxygen is delivered via a face mask with reservoir bag (flow rates of 10-15 L/min, which is typically the minimum flow required to maintain bag inflation; FiO₂ 0.60-0.95). Hypoxemic respiratory failure in ARDS commonly results from intrapulmonary ventilation-perfusion mismatch or shunt and usually requires mechanical ventilation.

- 1 **High-flow nasal oxygen (HFNO) or non-invasive ventilation (NIV) should only be used in selected patients with hypoxemic respiratory failure. The risk of treatment failure is high in patients with MERS treated with NIV, and patients treated with either HFNO or NIV should be closely monitored for clinical deterioration.**

Remark 1: HFNO systems can deliver 60 L/min of gas flow and FiO₂ up to 1.0; paediatric circuits generally only handle up to 15 L/min, and many children will require an adult circuit to deliver adequate flow. Compared to standard oxygen therapy, HFNO reduces the need for intubation.²⁴ Patients with hypercapnia (exacerbation of obstructive lung disease, cardiogenic pulmonary oedema), hemodynamic instability, multi-organ failure, or abnormal mental status should generally not receive HFNO, although emerging data suggest that HFNO may be safe in patients with mild-moderate and non-worsening hypercapnia.²⁵ Patients receiving HFNO should be in a monitored setting and cared for by experienced personnel capable of endotracheal intubation in case the patient acutely deteriorates or does not improve after a short trial (about 1 hr). Evidence-based guidelines on HFNO do not exist, and reports on HFNO in MERS patients are limited.²⁶

Remark 2: NIV guidelines make no recommendation on use in hypoxemic respiratory failure (apart from cardiogenic pulmonary oedema and post-operative respiratory failure) or pandemic viral illness (referring to studies of SARS and pandemic influenza).²⁷ Risks include delayed intubation, large tidal volumes, and injurious transpulmonary pressures. Limited data suggest a high failure rate when MERS patients receive NIV.²⁸ Patients receiving a trial of NIV should be in a monitored setting and cared for by experienced personnel capable of endotracheal intubation in case the patient acutely deteriorates or does not improve after a short trial (about 1 hr). Patients with hemodynamic instability, multiorgan failure, or abnormal mental status should not receive NIV.

Remark 3: Recent publications suggest that newer HFNO and NIV systems with good interface fitting do not create widespread dispersion of exhaled air and therefore should be associated with low risk of airborne transmission.²⁹⁻³¹

✔ Endotracheal intubation should be performed by a trained and experienced provider using airborne precautions.

Remarks: Patients with ARDS, especially young children or those who are obese or pregnant, may desaturate quickly during intubation. Pre-oxygenate with 100% FiO₂ for 5 minutes, via a face mask with reservoir bag, bag-valve mask, HFNO, or NIV. Rapid sequence intubation is appropriate after an airway assessment that identifies no signs of difficult intubation³².

The following recommendations in this section pertain to mechanically ventilated patients with ARDS.^{17,33} These focus on adults; consensus-based recommendations for children are available.³⁴

✔ Implement mechanical ventilation using lower tidal volumes (4–8 ml/kg predicted body weight, PBW) and lower inspiratory pressures (plateau pressure <30 cmH₂O).

Remarks: This is a strong recommendation from a clinical guideline for patients with ARDS,³³ and is suggested for patients with sepsis-induced respiratory failure who do not meet ARDS criteria.¹⁷ The initial tidal volume is 6 ml/kg PBW; tidal volume up to 8 ml/kg PBW is allowed if undesirable side effects occur (e.g. dyssynchrony, pH <7.15). Hypercapnia is permitted if meeting the pH goal of 7.30–7.45. Ventilator protocols are available.³⁵ The use of deep sedation may be required to control respiratory drive and achieve tidal volume targets. Although high driving pressure (plateau pressure–PEEP) may more accurately predict increased mortality in ARDS compared to high tidal volume or plateau pressure,³⁶ RCTs of ventilation strategies that target driving pressure are not currently available.

✔ In patients with severe ARDS, prone ventilation for >12 hours per day is recommended.

Remarks: Application of prone ventilation is strongly recommended for adult and paediatric patients with severe ARDS³³ but requires sufficient human resources and expertise to be performed safely.^{37,38}

✔ Use a conservative fluid management strategy for ARDS patients without tissue hypoperfusion.

Remarks: This is a strong guideline recommendation;¹⁷ the main effect is to shorten the duration of ventilation. See reference [39] for details of a sample protocol.

① In patients with moderate or severe ARDS, higher PEEP instead of lower PEEP is suggested.

Remarks: PEEP titration requires consideration of benefits (reducing atelectrauma and improving alveolar recruitment) vs. risks (end-inspiratory overdistension leading to lung injury and higher pulmonary vascular resistance). Tables are available to guide PEEP titration based on the FiO₂ required to maintain SpO₂.³⁵ A related intervention of recruitment manoeuvres (RMs) is delivered as episodic periods of high continuous positive airway pressure [30–40 cm H₂O], progressive incremental increases in PEEP with constant driving pressure, or high driving pressure; considerations of benefits vs. risks are similar. Higher PEEP and RMs were both conditionally recommended in a clinical practice guideline.³³ For PEEP, the guideline considered an individual patient data meta-analysis⁴⁰ of 3 RCTs. However, a subsequent RCT of high PEEP and prolonged high-pressure RMs showed harm, suggesting that the protocol in this RCT should be avoided.⁴¹ Monitoring of patients to identify those who respond to the initial application of higher PEEP or a different RM protocol, and stopping these interventions in non-responders, is suggested.⁴²

① In patients with moderate-severe ARDS (PaO₂/FiO₂ <150), neuromuscular blockade by continuous infusion should not be routinely used.

Remarks: One trial found that this strategy improved survival in patients with severe ARDS (PaO₂/FiO₂ <150) without causing significant weakness,⁴³ but results of a recent larger trial found that use of neuromuscular blockade with high PEEP strategy was not associated with survival when compared to a light sedation strategy without neuromuscular blockade⁴⁴. Continuous neuromuscular blockade may still be considered in patients with ARDS in certain situations: ventilator dyssynchrony despite sedation, such that tidal volume limitation cannot be reliably achieved; or refractory hypoxemia or hypercapnia.

① In settings with access to expertise in extracorporeal life support (ECLS), consider referral of patients with refractory hypoxemia despite lung protective ventilation.

Remarks: A recent guideline made no recommendation about ECLS in patients with ARDS.³³ Since then, an RCT of ECLS for patients with ARDS was stopped early and found no statistically significant difference in the primary outcome of 60-day mortality between ECLS and standard medical management (including prone positioning and neuromuscular blockade).⁴⁵ However, ECLS was associated with a reduced risk of the composite outcome of mortality and crossover to ECLS,⁴⁵ and a *post hoc* Bayesian analysis of this RCT showed that ECLS is very likely to reduce mortality across a range of prior assumptions.⁴⁶ In patients with MERS-CoV infection, ECLS vs. conventional treatment was associated with reduced mortality in a cohort study.⁴⁷ ECLS should

only be offered in expert centres with a sufficient case volume to maintain expertise and that can apply the IPC measures required for nCoV patients.⁴⁸

- ✗ Avoid disconnecting the patient from the ventilator, which results in loss of PEEP and atelectasis. Use in-line catheters for airway suctioning and clamp endotracheal tube when disconnection is required (for example, transfer to a transport ventilator).

6. Management of septic shock

- ✓ Recognize septic shock in adults when infection is suspected or confirmed AND vasopressors are needed to maintain mean arterial pressure (MAP) ≥ 65 mmHg AND lactate is ≥ 2 mmol/L, in absence of hypovolemia. Recognize septic shock in children with any hypotension (systolic blood pressure [SBP] $< 5^{\text{th}}$ centile or > 2 SD below normal for age) or 2-3 of the following: altered mental state; tachycardia or bradycardia (HR < 90 bpm or > 160 bpm in infants and HR < 70 bpm or > 150 bpm in children); prolonged capillary refill (> 2 sec) or warm vasodilation with bounding pulses; tachypnea; mottled skin or petechial or purpuric rash; increased lactate; oliguria; hyperthermia or hypothermia.

Remarks: In the absence of a lactate measurement, use MAP and clinical signs of perfusion to define shock. Standard care includes early recognition and the following treatments within 1 hour of recognition: antimicrobial therapy and fluid loading and vasopressors for hypotension.⁴⁹ The use of central venous and arterial catheters should be based on resource availability and individual patient needs. Detailed guidelines are available for the management of septic shock in adults¹⁷ and children.^{2,3,12}

- ✓ In resuscitation from septic shock in adults, give at least 30 ml/kg of isotonic crystalloid in adults in the first 3 hours. In resuscitation from septic shock in children in well-resourced settings, give 20 ml/kg as a rapid bolus and up to 40-60 ml/kg in the first 1 hr.

- ✗ Do not use hypotonic crystalloids, starches, or gelatins for resuscitation.

- ① Fluid resuscitation may lead to volume overload, including respiratory failure. If there is no response to fluid loading and signs of volume overload appear (for example, jugular venous distension, crackles on lung auscultation, pulmonary oedema on imaging, or hepatomegaly in children), then reduce or discontinue fluid administration. This step is particularly important where mechanical ventilation is not available. Alternate fluid regimens are suggested when caring for children in resource-limited settings⁵⁰

Remarks: Crystalloids include normal saline and Ringer's lactate. Determine need for additional fluid boluses (250-1000 ml in adults or 10-20 ml/kg in children) based on clinical response and improvement of perfusion targets. Perfusion targets include MAP (> 65 mmHg or age-appropriate targets in children), urine output (> 0.5 ml/kg/hr in adults, 1 ml/kg/hr in children), and improvement of skin mottling, capillary refill, level of consciousness, and lactate. Consider dynamic indices of volume responsiveness to guide volume administration beyond initial resuscitation based on local resources and experience.¹⁷ These indices include passive leg raises, fluid challenges with serial stroke volume measurements, or variations in systolic pressure, pulse pressure, inferior vena cava size, or stroke volume in response to changes in intrathoracic pressure during mechanical ventilation.

Starches are associated with an increased risk of death and acute kidney injury vs. crystalloids. The effects of gelatins are less clear, but they are more expensive than crystalloids.^{51,52} Hypotonic (vs. isotonic) solutions are less effective at increasing intravascular volume. Surviving Sepsis also suggests albumin for resuscitation when patients require substantial amounts of crystalloids, but this conditional recommendation is based on low-quality evidence.¹⁷

- ✓ Administer vasopressors when shock persists during or after fluid resuscitation. The initial blood pressure target is MAP ≥ 65 mmHg in adults and age-appropriate targets in children.
- ① If central venous catheters are not available, vasopressors can be given through a peripheral IV, but use a large vein and closely monitor for signs of extravasation and local tissue necrosis. If extravasation occurs, stop infusion. Vasopressors can also be administered through intraosseous needles.
- ① If signs of poor perfusion and cardiac dysfunction persist despite achieving MAP target with fluids and vasopressors, consider an inotrope such as dobutamine.

Remarks: Vasopressors (i.e. norepinephrine, epinephrine, vasopressin, and dopamine) are most safely given through a central venous catheter at a strictly controlled rate, but it is also possible to safely administer them via peripheral vein⁵³ and intraosseous needle. Monitor blood pressure frequently and titrate the vasopressor to the minimum dose necessary to maintain perfusion and prevent side effects. Norepinephrine is considered first-line in adult patients; epinephrine or vasopressin can be added to achieve the MAP target. Because of the risk of tachyarrhythmia, reserve dopamine for selected patients with low risk of tachyarrhythmia or those with bradycardia. In children with cold shock (more common), epinephrine is considered first-line, while norepinephrine is used in patients with warm shock (less common).

No RCTs have compared dobutamine to placebo for clinical outcomes.¹⁷

7. Prevention of complications

Implement the following interventions (Table 3) to prevent complications associated with critical illness. These interventions are based on Surviving Sepsis¹⁷ or other guidelines,⁵⁴⁻⁵⁷ and are generally limited to feasible recommendations based on high quality evidence.

Table 3. Prevention of complications

Anticipated Outcome	Interventions
Reduce days of invasive mechanical ventilation	- Use weaning protocols that include daily assessment for readiness to breathe spontaneously - Minimize continuous or intermittent sedation, targeting specific titration endpoints (light sedation unless contraindicated) or with daily interruption of continuous sedative infusions
Reduce incidence of ventilator-associated pneumonia	- Oral intubation is preferable to nasal intubation in adolescents and adults - Keep patient in semi-recumbent position (head of bed elevation 30-45°) - Use a closed suctioning system; periodically drain and discard condensate in tubing - Use a new ventilator circuit for each patient; once patient is ventilated, change circuit if it is soiled or damaged but not routinely - Change heat moisture exchanger when it malfunctions, when soiled, or every 5-7 days
Reduce incidence of venous thromboembolism	Use pharmacological prophylaxis (low molecular-weight heparin [preferred if available] or heparin 5000 units subcutaneously twice daily) in adolescents and adults without contraindications. For those with contraindications, use mechanical prophylaxis (intermittent pneumatic compression devices).
Reduce incidence of catheter-related bloodstream infection	Use a checklist with completion verified by a real-time observer as reminder of each step needed for sterile insertion and as a daily reminder to remove catheter if no longer needed
Reduce incidence of pressure ulcers	Turn patient every two hours
Reduce incidence of stress ulcers and gastrointestinal bleeding	- Give early enteral nutrition (within 24-48 hours of admission) - Administer histamine-2 receptor blockers or proton-pump inhibitors in patients with risk factors for GI bleeding. Risk factors for gastrointestinal bleeding include mechanical ventilation for ≥48 hours, coagulopathy, renal replacement therapy, liver disease, multiple comorbidities, and higher organ failure score
Reduce incidence of ICU-related weakness	Actively mobilize the patient early in the course of illness when safe to do so

8. Specific anti-Novel-CoV treatments and clinical research

❗ There is no current evidence from RCTs to recommend any specific anti-nCoV treatment for patients with suspected or confirmed nCoV.

✅ Unlicensed treatments should be administered only in the context of ethically-approved clinical trials or the Monitored Emergency Use of Unregistered Interventions Framework (MEURI), with strict monitoring.

<https://www.who.int/ethics/publications/infectious-disease-outbreaks/en/>

✅ Clinical characterization protocols are available, including the SPRINT-SARI <https://isaric.tghn.org/sprint-sari/> and WHO-ISARIC forms available at <https://isaric.tghn.org/protocols/severe-acute-respiratory-infection-data-tools/>. Contact outbreak@who.int for additional questions.

9. Special considerations for pregnant patients

✅ Pregnant women with suspected or confirmed nCoV should be treated with supportive therapies as described above, taking into account the physiologic adaptations of pregnancy.

✅ The use of investigational therapeutic agents outside of a research study should be guided by individual risk-benefit analysis based on potential benefit for mother and safety to fetus, with consultation from an obstetric specialist and ethics committee.

✅ Emergency delivery and pregnancy termination decisions are challenging and based on many factors: gestational age, maternal condition, and fetal stability. Consultations with obstetric, neonatal, and intensive care specialists (depending on the condition of the mother) are essential.

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Novel Coronavirus (nCoV) v1

Operational Support & Logistics
Disease Commodity Packages

Agent's Biosafety Level: (to be confirmed): BSL2, Virus culture BSL3

Related links: MERS-CoV [\[LINK\]](#)

Epidemic Potential: Under investigation

Last Update: 11 Jan 2020

Managing Epidemics Handbook (MERS) [\[LINK\]](#)

SURVEILLANCE		Diagnosis		
		Sample Collection		
Laboratory confirmation of a nCoV case will trigger an thorough investigation. Because there currently is not a PCR test available testing may take several days or longer, WHO's recommended strategy is to begin an investigation immediately, thus requiring immediate operational support and supplies.	Upper and lower respiratory samples (nasopharyngeal and sputum samples); lower respiratory specimens preferred	Polymerase Chain Reaction (PCR)	Immunoassay	Culture
		no commercial rRT-PCR kits yet available; see interim nCoV laboratory guidance	Not yet available	Viral transport medium

Note: Many diagnostic supplies are also used for Case Management purposes, but have been included only in Surveillance.

Laboratory Testing for a novel Coronavirus is in development

PREVENTION & CONTROL	Travel & Trade	Vaccine	Infection Protection & Control (IPC)
The mode(s) of transmission of the nCoV are currently unknown. Available information suggests that the nCoV is zoonotic and causes infections in humans through contact with infected animals (to be confirmed). Current data suggests that there is no or limited human-to-human transmission. For other coronaviruses such as MERS-CoV and SARS-CoV, human-to-human transmission occurred due to breaches in IPC practices. Thus, the central focus of any prevention/control strategy is protecting healthcare workers with appropriate IPC supplies and ensuring basic health logistics at responding facilities.	Animal source has not yet been identified	Several vaccine candidates for MERS-CoV are in development.	Respiratory (standard, droplet IPC); Airborne precautions for aerosolized generating procedures, Personal Protective Equipment (PPE) for screening Use of PPE for at-risk health facilities

Please see WHO MERS guidance [\[LINK\]](#)

R&D Blueprint [\[LINK\]](#)

CASE MANAGEMENT	Treatment			Personal Protective Equipment (PPE)
There is no specific treatment or vaccines for the nCoV, however there are ongoing R&D efforts for MERS-CoV. See WHO current guidance on case management for MERS. Guidance on case management for the nCoV from Wuhan is in development.	Aetiological	Supportive		PPE for at-risk health facilities Respiratory (standard, droplet IPC); Airborn precautions for aerosolized generating procedures, Possibly Home Care Kits for home isolation of asymptomatic cases or mildly symptomatic (in the case of a large outbreak)
	Several candidates under consideration for evaluation. On outbreak-specific basis, the Monitored Emergency Use of Unregistered Interventions (MEURI) may be considered. Please refer to most recent WHO guidance.	Oxygen Therapy Mechanical Ventilation of severe cases (40%) Use of Oximeter highly recommended Intubation, ICU, ECMO required for severe patients	Antibiotics, Pain/Fever	

Key outbreak control activities considered for material supply

- **Supportive treatment** (oxygen, antibiotics, hydration & fever/pain relief) to reduce mortality
- **Personal Protective Equipment** and material for the establishment of IPC measures at health care level to reduce transmission

Note: Products for Surveillance, Prevention & Control, and Case Management are undergoing rapid and continuous development and refinement. For greater clarity, please refer to most recent applicable WHO technical guidance.

INTERVENTION	COMMODITY	TECHNICAL DESCRIPTION	
SURVEILLANCE	Sample Collection	Triple packaging boxes	Triple packaging boxes for transport. [LINK]
		Viral Transport Medium	Medium for specimen to transport to laboratory
		Sharps container boxes	Puncture resistant container for collection and disposing of used, disposable and auto-disable syringes, needles, 5 L capacity accommodating approximately 100 syringes. Boxes prominently marked.
		Viral Transport Medium	Viral Transport Medium with Swab, Medium 3 ml
	Diagnostics	Criteria for selection of specific diagnostic tests may include historical efficacy, adherence to any existing Target Product Profiles, ease of use, necessary throughput, distribution and logistics requirements, and manufacturer production capacity. For some pathogens, consideration may need to be given to the presence of mutations in targeted gene sequences or proteins. WHO can advise on the selection of tests on a case by case basis as determined by a specific event.	
Prevention & Control	PPE - Standard	Gloves, examination	Gloves, examination, nitrile, powder-free, non-sterile. Cuff length preferably reach mid-forearm (eg. minimum 280mm total length. Sizes, S, M, L Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm.
		Mask, surgical	Medical/surgical mask, high fluid resistance, good breathability, internal and external faces should be clearly identified, structured design that does not collapse against the mouth (e.g. duckbill, cup-shaped)
		Gown	Single use, fluid resistant, disposable, length mid-calf to cover the top of the boots, light colours preferable to better detect possible contamination, thumb/finger loops or elastic cuff to anchor sleeves in place.

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Oxygen concentrators	Device concentrates oxygen from ambient air. On 4 antistatic swivel castors, 2 with brakes. Integrated handle allows for easy moving and positioning. Oxygen sensing device is integrated and measures concentration at flow meter entrance. Four-step filtering of air-intake, including bacterial filter. All filters replaceable, coarse filter washable/reusable. Continuous monitoring with visual and audible alerts, on low/high output pressure, low oxygen concentration, power failure and battery test. Operating conditions: Temperature between 5 to 45 degrees Celsius, Relative humidity max. 90% without condensation. Spare parts should be required for operating at least one year.	WHO Core: Concentrator, Oxygen [LINK] Oxygen Concentrator Technical Guidelines [LINK]	
(Oxygen concentrator) Flow splitter	Splitter of oxygen flow provided by an oxygen concentrator. Each flow can be adjusted individually via its flow meter, range: 0.125 to 2LPM (Liter Per Minute). The output nozzle can either be fit with tubing or left blank. Input pressure: 50 to 350kPa.		
Oxygen prongs, nasal, non-sterile, single use	Nasal prongs (nasal cannula) is a device designed for easy administration of oxygen and comfort of patient. The device consists of a plastic tube which fits behind the ears, and a set of two prongs which are placed in the nostrils. Soft twin prongs nasal tips to ensure equal oxygen flow to both. Star lumen main tube to avoid accidental blockage. Adjustable, smoothly finished, nasal tips for maximum patient comfort. Soft funnel shaped connector to facilitate easy connection to oxygen source. Oxygen tube length: approximately 2m.		
Oxygen tube, extension	Tube used to deliver oxygen through the nose. Material: PVC. Automatic, open distal (patient) end, with 6 to 12 lateral eyes. Proximal end with connector enabling the tube to be connected to an oxygen supply tube of any diameter (e.g. serrated male conical lip). Sterile, for single patient use. Diameter: CH 10. Length: 40cm		
Portable ventilator	a) Tidal volume up to 1,000 mL b) Pressure (Inspiratory) up to 80 cm H2O c) Volume (Inspiratory) up to 120 L/min d) Respiratory rate: up to 60 breaths per minute. e) SIMV Respiratory Rate: up to 40 breaths per minute. f) CPAP/PEEP up to 20 cm H2O. g) Pressure support up to 45 cm H2O. h) FIO2 between 21 to 100 % i) Inspiratory and expiratory times up to at least 2 sec and 8 sec respectively j) I:E Ratio at least from 1:1 to 1:3. 2 Modes of ventilation: a) Volume controlled. b) Pressure controlled. c) Pressure support. d) Synchronized intermittent mandatory ventilation (SIMV) with pressure support. e) Assist / control mode f) CPAP/PEEP Alarms required: FIO2, minute volume, pressure, PEEP, apnoea, occlusion, high respiration rate, disconnection System alarms required: power failure, gas disconnection, low battery, vent inoperative, self diagnostics If alarm silencing feature is incorporated, it must be temporary and clearly displayed when activated Air and externally supplied oxygen mixture ratios fully controllable Inlet gas supply (O2) pressure range at least 35 to 65 psi Medical air compressor, integral to unit, with inlet filter.	• ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes (Australia, Canada and EU) • ISO 14971:2007 Medical devices -- Application of risk management to medical devices IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance • IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems • IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests • ISO 80601-2-12:2011 Medical electrical equipment -- Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators	
Pulse Oximeter	Compact portable device measures arterial blood oxygen saturation (SpO2), heart rate and signal strength. Measuring range: SpO2 30 to 100% (minimum graduation 1%), Heart rate 20 to 250 bpm (minimum graduation 1bpm). Line-powered, or Extra-batteries/rechargeable batteries are required at least one year.	ISO 80601-2-61:2011 or equivalent	
Laryngoscope	A hand-held device (i.e., non-endoscopic rigid type) intended to be used by anaesthesia/emergency service personnel to manipulate the tongue, preventing it from obstructing the oropharynx and enabling a clear view of the trachea for the insertion of an endotracheal (ET) tube prior to the delivery of inhalation anaesthesia and/or ventilation. It has a handle containing batteries to power its light (a small built-in light bulb or fibre-optic light) for airway illumination, and a curved or straight blade of various designs and lengths that can be hinged/interchanged or integral. Some types can be magnetic resonance imaging (MRI) compatible. This is a reusable device to improve respiratory status of a patient, and to help in the treatment evaluation of patients suffering from chronic respiratory disorders (e.g., asthma, emphysema). • Large hollow, cylindrical, slightly ribbed handle • Handle made of either chromium-plated or stainless steel • Can be opened to insert two batteries (type LR14, size C, 1.5 V) • Stud contact, fitting various sizes and types of depressors	ISO 7376:2009 Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation	WHO [LINK]
Set of stainless steel depressors	Miller type: • Straight Nr 1, length approx. 100 mm MacIntosh type: • Curved Nr 2, length approx. 110 mm • Curved Nr 3, length approx. 135 mm • Curved Nr 4, length approx. 155 mm		
Endotracheal tube, without cuff	• Open distal end and Magill-type point with oral angle of 37.5°. • Standard connector (ext. Ø 15mm) at the proximal end enabling the tube to be connected to the ventilation system. • Radio opaque mark. • With Murphy's eye. • Graduations. • Endotracheal tube without cuff. • Size: Ø internal 3mm or 3.5mm • Material: Polyvinyl chloride (PVC). • Disposable. • Sterile. • Initial sterilisation method: Ethylene oxide gas or Gamma radiation.		

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CASE MANAGEMENT

Endotracheal tube, with cuff	• Open distal end and Magill-type point with oral angle of 37.5°. • Standard connector (ext. Ø 15mm) at the proximal end enabling the tube to be connected to the ventilation system. • Radio opaque mark. • With Murphy's eye. • Graduations. • Endotracheal tube without cuff. • Size: Ø internal 6.5mm, 7mm, 7.5mm or 8mm • Material: Polyvinyl chloride (PVC). • Disposable. • Sterile. • Initial sterilisation method: Ethylene oxide gas or Gamma radiation.	
Carbon dioxide detector	• Disposable • Colorimetric • Sizes compatible with child and adult endotracheal tube	
Portable ultrasound scanner	High performance ultrasound scanner	
Portable ultrasound probes, included with scanner	Convex abdominal probe, frequency range: 2.5 / 3.5 / 5.0 MHz	
Resuscitator, adult	Resuscitator to ventilate adult (body weight over 30kg), with compressible self-refilling ventilation bag, capacity: 1475-2000ml Resuscitator operated by hand, Ventilation with ambient air, Resuscitator shall be easy, to disassemble and reassemble, to clean and disinfect, and be autoclavable. All parts must be manufactured from high-strength, long-life materials and require no special maintenance or storage conditions.	ISO10651-4: Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators;
Resuscitator, child	Resuscitator to ventilate child (body weight 7-30kg), With compressible self-refilling ventilation bag, child, capacity: 500-700ml and non-rebreathing valve with pressure limiting valve, patient connector Resuscitator operated by hand, Ventilation with ambient air, Resuscitator shall be easy, to disassemble and reassemble, to clean and disinfect, and be autoclavable. All parts must be manufactured from high-strength, long-life materials and require no special maintenance or storage conditions.	ISO10651-4: Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators;
Airway, Guedel, sterile, single use (range of sizes)	Child sizes: 00, 0, 1; Adult sizes: 2, 3, 4 • Oro-pharyngeal airway, Guedel type. • Semi-rigid, transparent. • Proximal (or buccal) end straight and reinforced. • Flange colour coded and/or marked with corresponding size number. • Size: Airway Guedel, size 00, approximately 40mm; size 0, approx. 50mm; size 1, approx. 60 mm; size 2, approx. 70mm; size 3 approx. 80 mm; size 4 approx. 90mm • Material: Polyethylene/vinyl acetate (EVA) - Polyvinyl chloride (PVC). • Sterile, single patient use. • Initial sterilisation method: • Ethylene oxide gas or gamma radiation.	
Compound Sodium Lactate Solution	Compound solution of sodium lactate (Ringer's lactate), injection solution, w/o IV set and needle, 1000ml	
Infusion giving set	Infusion giving set, with inlet and needle, sterile, single-use	
Paracetamol	Paracetamol, 500mg, tablets	
Gloves, examination	Gloves, examination, nitrile, powder-free, non-sterile. Cuff length preferably reach mid-forearm (eg. minimum 280mm total length. Sizes, S, M, L Outer glove should have long cuffs, reaching well above the wrist, ideally to mid-forearm.	• EU standard directive 93/42/EEC Class I, EN 455, • EU standard directive 89/686/EEC Category III, EN 374, • ANSI/ISEA 105-2011, • ASTM D6319-10 • or equivalent
Gloves, surgical, length to forearm large (longer than examination gloves)	Gloves, surgical, nitrile, powder-free, single use. Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm.	• EU standard directive 93/42/EEC Class I, EN 455, • ANSI/ISEA 105-2011, • ASTM 6319-10 • or equivalent
Face shield	Made of clear plastic and provides good visibility to both the wearer and the patient. Adjustable band to attach firmly around the head and fit snugly against the forehead. Fog resistant (preferable). Completely cover the sides and length of the face. May be re-usable (made of robust material which can be cleaned and disinfected) or disposable.	• EU standard directive 86/686/EEC, EN 166/2002, • ANSI/ISEA Z87.1-2010, • or equivalent
Fit Test Kit	To evaluate effectiveness of seal for tight fitting respiratory protection devices	OSHA 29 CFR 1910.134 Appendix A
Particulate respirator, grade N95 or higher	N95 or FFP2 respirator, or higher Good breathability with design that does not collapse against the mouth (e.g. duckbill, cup-shaped)	"N95" respirator according to US NIOSH, or "FFP2" according to EN 149

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PPE Health Care Facilities

Mask, surgical	Medical/surgical mask, high fluid resistance, good breathability, internal and external faces should be clearly identified, structured design that does not collapse against the mouth (e.g. duckbill, cup-shaped)	EN 14683 Type IIR performance ASTM F2100 level 2 or level 3 or equivalent; • Fluid resistance at minimum 120 mmHg pressure based on ASTM F1862-07, ISO 22609, or equivalent • Breathability: MIL-M-36945C, EN 14683 annex C, or equivalent • Filtration efficiency: ASTM F2101, EN14683 annex B, or equivalent
Scrubs, tops	Tunic/tops, woven, scrubs, reusable or single use, short sleeved (tunic/tops), worn underneath the coveralls or gown.	
Scrubs, pants	Trouser/pants, woven, scrubs, reusable or single use, short sleeved (tunic/tops), worn underneath the coveralls or gown	
Gown	Single use, fluid resistant, disposable, length mid-calf to cover the top of the boots, light colours preferable to better detect possible contamination, thumb/finger loops or elastic cuff to anchor sleeves in place.	• Option 1: fluid penetration resistant: EN 13795 high performance, or AAMI PB70 level 3 performance or above, or equivalent • Option 2: blood borne pathogens penetration resistant: AAMI PB70 level 4 performance, or (EN 14126-B) and partial body protection (EN 13034 or EN 14605), or equivalent
Goggles, protective	Good seal with the skin of the face, Flexible PVC frame to easily fit with all face contours with even pressure, Enclose eyes and the surrounding areas, Accomodate wearers with prescription glasses, Clear plastic lens with fog and scratch resistant treatments, Adjustable band to secure firmly so as not to become loose during clinical activity, Indirect venting to avoid fogging, May be re-usable (provided appropriate arrangements for decontamination are in place) or disposable.	• EU standard directive 86/686/EEC, EN 166/2002, • ANSI/ISEA Z87.1-2010, or equivalent
Alcohol-based hand rub	Bottle of 100ml	
Bio-hazardous bag	Disposal bag for bio-hazardous waste, 30x50cm, with "Bio Hazard" print, autoclavable polypropylene. 50 or 70 micron thickness	
Body bag	Made of linear enforced, U-shape zipper and 2 zipper pulls with tie ribs. adult size 250x120cm Protector Body Bag specifications: • 6 handles • Impermeable, linear reinforced LLDPE, LDPE, EVA, PEVA, (avoid PVC), minimum thickness 400 microns; • Should be able to hold 100-125 kilos (200-250 lbs). • Should contain no chlorides: burning of chlorides pollute the environment and can cause damage to retort chambers. Body bags should be non carcinogenic to health of funeral workers when used for cremations. • At least 6 handles included in the body bag to allow burial team to hand carry it safely • Heat-sealed: insure superior strength and safety. • Provide full containment of blood borne pathogens • Cracking point of 25 - 32 degrees below zero • Shelf life: minimum 10 years • Bag and hands should be white color	
Chlorine	NaDCC, granules, 1kg, 65 to 70% + dosage spoon	

Infection prevention and control during health care when novel coronavirus (nCoV) infection is suspected

Interim guidance

January 2020



WHO/2019-nCoV/IPC/v2020.1

Introduction

This is the first edition of infection prevention and control (IPC) guidance when a novel coronavirus (nCoV) is suspected. It has been adapted from WHO's IPC recommendations for MERS-CoV (Infection prevention and control during health care for probable or confirmed cases of Middle East respiratory syndrome coronavirus [MERS-CoV] infection, interim guidance October 2019, WHO/MERS/IPC/15.1 Rev 1¹), based on our current knowledge of the situation in Wuhan, China and experiences with SARS-CoV and MERS-CoV².

WHO will update these recommendations as new information becomes available on the situation in Wuhan, China.

This guidance is intended for health-care workers (HCWs), health-care managers, and IPC teams. Full guidelines are available at *Infection prevention and control of epidemic- and pandemic-prone acute respiratory infections in health care*².

Principles of infection prevention and control strategies associated with health care with suspected nCoV

IPC strategies to prevent or limit infection transmission in health-care settings include the following:

1. Early recognition and source control
2. Application of Standard Precautions for all patients
3. Implementation of empiric additional precautions (droplet and contact and whenever applicable airborne precautions) for suspected cases
4. Administrative controls
5. Environmental and engineering controls

1. Early recognition and source control

Clinical triage including early recognition and immediate placement of patients in separate area from other patients (source control) is an essential measure for rapid identification and appropriate isolation and care of patients with suspected nCoV infection. To facilitate early identification of suspect cases, healthcare facilities should:

- Encourage HCWs to have a high level of clinical suspicion
- Institute screening questionnaire and
- Post signage in public areas reminding symptomatic patients to alert HCWs.

Promotion of respiratory hygiene is an important preventative measure.

Suspected nCoV patients should be placed in an area separate from other patients, and additional IPC (droplet and contact) precautions promptly implemented.

2. Application of Standard Precautions for all patients

Standard Precautions include hand and respiratory hygiene; use of Personal protective equipment (PPE) depending on risk; prevention of needle-stick or sharps injury; safe waste management; environmental cleaning and sterilization of patient-care equipment and linen.

Ensure the following respiratory hygiene measures:

- Offer a medical mask for suspected nCoV infection for those who can tolerate it
- Cover nose and mouth during coughing or sneezing with tissue or flexed elbow for others
- Perform hand hygiene after contact with respiratory secretions.

Personal protective equipment (PPE). Rational, correct³, and consistent use of available PPE and appropriate hand hygiene⁴ also helps to reduce the spread of the pathogens. PPE effectiveness depends on adequate and regular supplies, adequate staff training, proper hand hygiene and specifically appropriate human behaviour².

Ensure that environmental cleaning and disinfection procedures are followed consistently and correctly. Thorough cleaning of environmental surfaces with water and detergent and applying commonly used hospital level disinfectants (such as sodium hypochlorite) is an effective and sufficient procedure. Manage laundry, food service utensils and medical waste in accordance with safe routine procedures².

3. Implementation of empiric additional precautions for suspected nCoV infections

3.1 Contact and Droplet precautions for suspected nCoV infection:

- In addition to Standard Precautions, all individuals, including family members, visitors and HCWs should apply Contact and Droplet precautions
- Place patients in adequately ventilated single rooms. For naturally ventilated general ward rooms this is considered to be 160 L/second/patient⁵;
- When single rooms are not available, cohort patients suspected of nCoV infection together;

- Place patient beds at least 1m apart;
- Where possible, cohort HCWs to exclusively care for cases to reduce the risk of spreading transmission due to inadvertent infection control breaches;
- Use a medical mask (for specifications please see ^{2,6});
- Use eye/facial protection (i.e. goggles or a face shield);
- Use a clean, non-sterile, long-sleeved fluid resistant gown;
- Use gloves;
- Use either single use disposable equipment or dedicated equipment (e.g. stethoscopes, blood pressure cuffs and thermometers). If equipment needs to be shared among patients, clean and disinfect between each patient use (e.g. ethyl alcohol 70%);
- Refrain from touching eyes, nose or mouth with potentially contaminated hands;
- Avoid the movement and transport of patients out of the room or area unless medically necessary. Use designated portable X-ray equipment and/or other important diagnostic equipment. If transport is required, use pre-determined transport routes to minimize exposures to staff, other patients and visitors and apply medical mask to patient;
- Ensure that HCWs who are transporting patients wear appropriate PPE as described in this section and perform hand hygiene;
- Notify the receiving area of necessary precautions as soon as possible before the patient's arrival;
- Routinely clean and disinfect patient-contact surfaces;
- Limit the number of HCWs, family members and visitors in contact with a patient with suspected nCoV infection;
- Maintain a record of all persons entering the patient's room including all staff and visitors.

3.2 Airborne precautions for aerosol-generating procedures for suspected nCoV infection:

Some aerosol generating procedures have been associated with increased risk of transmission of coronaviruses (SARS-CoV and MERS-CoV) such as tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, manual ventilation before intubation and bronchoscopy^{7,8}.

Ensure that HCWs performing aerosol-generating procedures:

- Use a particulate respirator at least as protective as a NIOSH-certified N95, EU FFP2 or equivalent ^{2,6}; when putting on a disposable particulate respirator, always perform the seal-check⁶. Note that if the wearer has facial hair (beard) this can prevent a proper respirator fit⁶.
- Eye protection (i.e. goggles or a face shield);
- Clean, non-sterile, long-sleeved gown and gloves;
- If gowns are not fluid resistant, use a waterproof apron for procedures with expected high fluid volumes that might penetrate the gown²;

- Perform procedures in an adequately ventilated room; i.e. at least natural ventilation with at least 160 l/s/patient air flow or negative pressure rooms with at least 12 air changes per hour (ACH) and controlled direction of air flow when using mechanical ventilation
- Limit the number of persons present in the room to the absolute minimum required for the patient's care and support.

4. Administrative controls²

Administrative controls and policies that apply to prevention and control of transmission of nCoV infections include establishment of sustainable IPC infrastructures and activities; HCWs training; patients' care givers education; policies on early recognition of acute respiratory infection potentially due to nCoV, access to prompt laboratory testing for identification of the etiologic agent; prevention of overcrowding especially in the Emergency department; provision of dedicated waiting areas for symptomatic patients and appropriate placement of hospitalized patients promoting an adequate patient-to-staff ratio; provision and use of regular supplies; IPC policies and procedures for all facets of healthcare provisions - with emphasis on surveillance of acute respiratory infection potentially due to nCoV among HCWs and the importance of seeking medical care; and monitoring of HCW compliance, along with mechanisms for improvement as needed.

5. Environmental and engineering controls

These include basic health-care facility infrastructures⁹. These controls address ensuring adequate environmental ventilation⁵ in all areas within a health-care facility, as well as adequate environmental cleaning. Spatial separation of at least 1-meter distance should be maintained between each suspect patient and others. Both controls can help reduce the spread of many pathogens during health care¹⁰.

Duration of contact and droplet precautions for nCoV infection

Standard precautions should always be applied at all times. Additional contact and droplet precautions should continue until the patient is asymptomatic. More comprehensive information on the nCoV infection mode of transmission is required to define duration of additional precautions.

Collection and handling of laboratory specimens from patients with suspected nCoV

All specimens collected for laboratory investigations should be regarded as potentially infectious, and HCWs who collect, or transport clinical specimens should adhere rigorously to Standard Precautions to minimize the possibility of exposure to pathogens^{11,12}.

- Ensure that HCWs who collect specimens use appropriate PPE (eye protection, medical mask,

long-sleeved gown, gloves). If the specimen is collected under aerosol generating procedure, personnel should wear a particulate respirator at least as protective as a NIOSH-certified N95, EU FFP2 or equivalent

- Ensure that all personnel who transport specimens are trained in safe handling practices and spill decontamination procedures.
- Place specimens for transport in leak-proof specimen bags (secondary container) that have a separate sealable pocket for the specimen (i.e. a plastic biohazard specimen bag), with the patient's label on the specimen container (primary container), and a clearly written laboratory request form.
- Ensure that health-care facility laboratories adhere to appropriate biosafety practices and transport requirements according to the type of organism being handled.
- Deliver all specimens by hand whenever possible. DO NOT use pneumatic-tube systems to transport specimens.
- Document patients full name, date of birth of suspected nCoV of potential concern clearly on the accompanying laboratory request form. Notify the laboratory as soon as possible that the specimen is being transported.

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Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases

Interim guidance

17 January 2020

WHO/2019-nCoV/laboratory/2020.3



1. Introduction

The purpose of this document is to provide interim guidance to laboratories and stakeholders involved in laboratory testing of patients who meet the definition of suspected case of pneumonia associated with a novel coronavirus identified in Wuhan, China (See: [Surveillance case definitions for human infection with novel coronavirus, Interim guidance](#)).

Various existing WHO documents have been adapted for use in the drafting of this document, including WHO laboratory guidance for MERS-CoV (1-11). As information about the etiology, clinical manifestations and transmission of disease in the cluster of respiratory disease patients identified in Wuhan is evolving, WHO continues to monitor developments and will revise these recommendations as necessary.

The etiologic agent responsible for the cluster of pneumonia cases in Wuhan has been identified as a novel betacoronavirus, (in the same family as SARS-CoV and MERS-CoV) via next generation sequencing (NGS) from cultured virus or directly from samples received from several pneumonia patients. Electron microscopy revealed a virus with a characteristic crown morphology: a coronavirus. Working directly from sequence information, the team developed a series of genetic amplification (PCR) assays used by laboratories associated with the China CDC to detect several dozen cases as of today.

Full genome sequence data from the viruses have been shared officially with WHO and on the GISAID platform (<https://www.gisaid.org/>) and can inform the development of specific diagnostic tests for this emergent coronavirus. It is expected that validated PCR tests will become available soon. Until that time, the goals of diagnostic testing are to detect conventional causes of pneumonia early, to support disease control activities, and to work with reference laboratories that can perform pan coronavirus detection and directed sequencing.

2. Suspected case definition

For case definition see: [WHO Surveillance case definitions for human infection with novel coronavirus](#).

3. Specimen collection and shipment

Rapid collection and testing of appropriate specimens from suspected cases is a priority and should be guided by a laboratory expert. As extensive testing is still needed to confirm the 2019-nCoV and the role of mixed infection has not been verified, multiple tests may need to be performed and sampling sufficient clinical material is recommended. Local guidelines should be followed regarding patient or guardian's informed consent for specimen collection, testing and potentially future research.

Assure SOPs are available, and the appropriate staff is trained and available for appropriate collection, specimen storage, packaging and transport. There is still limited information on the risk posed by the reported coronavirus found in Wuhan, but it would appear samples prepared for molecular testing could be handled as would samples of suspected human influenza (2, 7-9). Attempts to culture the virus may require heightened biosafety control measures.

Samples to be collected (see Table 1 for details on sample collection and storage):

1. Respiratory material* (nasopharyngeal and oropharyngeal swab in ambulatory patients and sputum (if produced) and/or endotracheal aspirate or bronchoalveolar lavage in patients with more severe respiratory disease)
2. Serum for serological testing, acute sample and convalescent sample (this is additional to respiratory materials and can support the identification of the true agent, once serologic assay is available)

*Modifiable with information on whether upper or lower respiratory material is better for coronavirus detection.

A single negative test result, particularly if this is from an upper respiratory tract specimen, does not exclude infection. Repeat sampling and testing, lower respiratory specimen is strongly recommended in severe or progressive disease. A positive alternate pathogen does not necessarily rule out either, as little is yet known about the role of coinfections.

Reference 2, 3, 7

Table 1. Specimens to be collected from symptomatic patients

Guidance on specimen collection (adapted from reference 5)

Specimen type	Collection materials	Transport to laboratory	Storage till testing	Comment
Nasopharyngeal and oropharyngeal swab	Dacron or polyester flocked swabs*	4 °C	≤5 days: 4 °C >5 days: -70 °C	The nasopharyngeal and oropharyngeal swabs should be placed in the same tube to increase the viral load.
Bronchoalveolar lavage	sterile container *	4 °C	≤48 hours: 4 °C >48 hours: -70 °C	There may be some dilution of pathogen, but still a worthwhile specimen
(Endo)tracheal aspirate, nasopharyngeal aspirate or nasal wash	sterile container *	4 °C	≤48 hours: 4 °C >48 hours: -70 °C	
Sputum	sterile container	4 °C	≤48 hours: 4 °C >48 hours: -70 °C	Ensure the material is from the lower respiratory tract
Tissue from biopsy or autopsy including from lung	sterile container with saline	4 °C	≤24 hours: 4 °C >24 hours: -70 °C	
Serum (2 samples acute and convalescent possibly 2-4 weeks after acute phase)	Serum separator tubes (adults: collect 3-5 ml whole blood)	4 °C	≤5 days: 4 °C >5 days: -70 °C	Collect paired samples: • acute – first week of illness • convalescent – 2 to 3 weeks later
Whole blood	collection tube	4 °C	≤5 days: 4 °C >5 days: -70 °C	For antigen detection particularly in the first week of illness
Urine	urine collection container	4 °C	≤5 days: 4 °C >5 days: -70 °C	

*For transport of samples for viral detection, use VTM (viral transport medium) containing antifungal and antibiotic supplements. For bacterial or fungal culture, transport dry or in a very small amount of sterile water. Avoid repeated freezing and thawing of specimens.

Aside from specific collection materials indicated in the table also assure other materials and equipment are available: e.g. transport containers and specimen collection bags and packaging, coolers and cold packs or dry ice, sterile blood-drawing equipment (e.g. needles, syringes and tubes), labels and permanent markers, PPE, materials for decontamination of surfaces.

Safety procedures during sample collection and transport

All specimens collected for laboratory investigations should be regarded as potentially infectious, and HCWs who collect, or transport clinical specimens should adhere rigorously to infection prevention and control guidelines and national or international regulations for the transport of dangerous goods (infectious substances) to minimize the possibility of exposure to pathogens (14). Implement the appropriate infection prevention and control precautions, guidance on IPC for the 2019-nCoV has been drafted (11).

Assure good communication with the laboratory and provide needed information

To assure proper and fast processing of samples and to assure adequate biosafety measures in the laboratory, communication and information sharing is essential. Be sure you have alerted the laboratory of the urgency and situation before sending the sample. Also assure that specimens are

correctly labelled, and diagnostic request forms are filled out properly and clinical information is provided (see box: information to be recorded).

Information to be recorded:

- Patient information – name, date of birth, sex and residential address, unique identification number, other useful information (e.g. patient hospital number, surveillance identification number, name of hospital, hospital address, room number, physicians' name and contact information, name and address for report recipient),
- Date and time of sample collection,
- Anatomical site and location of specimen collection,
- Tests requested,
- Clinical symptoms and relevant patient history (including vaccination and antimicrobial therapies received, epidemiological information, risk factors).

Infection prevention measurements during sample collection for a novel coronavirus (route of transmission unknown but suspected to be respiratory)

Ensure that Health Care workers (HCWs) who collect specimens follow the following guideline and use the adequate PPE: Infection prevention and control during health care when novel coronavirus (nCoV) infection is suspected, interim guidance, January 2020 (11) and other IPC guidance (10, 15-17).

Ensure that HCWs performing **aerosol-generating procedures** (i.e. aspiration or open suctioning of respiratory tract specimens, intubation, cardiopulmonary resuscitation, bronchoscopy) use additional precautions (for details see detailed guidelines mentioned above):

- Respirators (NIOSH-certified N95, EU FFP2 or equivalent, or higher level of protection). When putting on a disposable particulate respirator, always check the seal/fitness. Be aware that the presence of facial hair (e.g. beard) may prevent a proper respirator fit for the wearer. In some countries, a powered air-purifying respirator (PAPR) is utilized instead of a respirator.
- Eye protection (i.e. goggles or a face shield).
- Clean, long-sleeved gown and gloves. If gowns are not fluid resistant, a waterproof apron should be used for procedures where it is expected that fluid might penetrate the gown
- Perform procedures in an adequately ventilated room: at a minimum natural ventilation with at least 160l/s/patient air flow, or negative pressure rooms with at least 12 air changes per hour and controlled direction of air flow when using mechanical ventilation
- Limit the number of persons present in the room to the minimum required for the patient's care and support; and
- Follow WHO guidance for steps of donning and doffing PPE. Perform hand hygiene before and after contact with the patient and his or her surroundings and after PPE removal.
- Waste management and decontamination procedures: Ensure that all materials used is disposed appropriately. Disinfection of work areas and decontamination of possible spills of blood or infectious body fluids should follow validated procedures, usually with chlorine-based solutions.

Specifics for transport of samples to laboratory:

- Ensure that personnel who transport specimens are trained in safe handling practices and spill decontamination procedures.
- Follow the requirements in the national or international regulations for the transport of dangerous goods (infectious substances) as applicable (14).
- Deliver all specimens by hand whenever possible. Do not use pneumatic-tube systems to transport specimens.
- State the full name, date of birth of the suspected case clearly on the accompanying request form. Notify the laboratory as soon as possible that the specimen is being transported.

Packaging and shipment to another laboratory

Transport of specimens within national borders should comply with applicable national regulations. International Transport Regulations. Novel coronavirus specimens should follow the UN Model Regulations, and any other applicable regulations depending on the mode of transport being used. More information may be found in the WHO Guidance on regulations for the Transport of Infectious Substances 2019-2020 (Applicable as from 1 January 2019) (14). A summary on transport of infectious substances can also be found in Toolbox 4 of the Managing epidemics handbook (1).

4. Effective usage of Global Laboratory Networking

Timely and accurate laboratory testing of specimens from cases under investigation is an essential part of the management of emerging infections. All countries should have access to reliable testing, either nationally or internationally, in laboratories willing to perform primary detection or confirmatory testing, and novel pathogen detection. WHO is currently working closely with collaborating centres and experts to assure diagnostics will be developed and validated promptly. WHO can assist Member States to access testing internationally should the need arise.

5. Testing of 2019-nCoV in reference laboratories

2019-nCoV testing for patients that meet the suspected case definition

Patients that meet the case definition for suspected 2019-nCoV should be screened for the virus with PCR (details below). If case management requires, screen also for other common causes of respiratory illness according to local guidelines (1,5,7). As coinfections can occur, all patients that meet the case definition should be tested for 2019-nCoV regardless of whether a conventional respiratory pathogen is found. If testing does not occur in an expert/reference laboratory it is encouraged to send the sample for confirmation to a regional, national or international reference laboratory with pan-coronavirus or specific 2019-nCoV detection capacity. WHO can assist Member States to identify laboratories able to provide this support.

Nucleic acid amplification tests for 2019-nCoV

As sequence information from the 2019-nCoV has recently been made available, PCR assays can be designed to detect these sequences. PCR assay design optimization can be a complicated process, and a useful option is to contact the experienced laboratories publicizing their assays and request access to their assay chemistries.

Laboratories may desire to use a pan-coronavirus assay for amplification followed by sequencing of amplicons from non-conserved regions for characterization and confirmation. The importance of the need for confirmation of results of testing with pan-coronavirus primers is underscored by the fact that four human coronaviruses (HCoV) are endemic globally: HCoV-229E, HCoV-NL63, HCoV-HKU1 as well as HCoV-OC43. The latter two are betacoronaviruses. Two other betacoronaviruses that cause zoonotic infection in humans are MERS-CoV, acquired by contact with dromedary camels and SARS arising from civets and cave-dwelling horseshoe bats.

Alternatively, amplification and detection of 2019-nCoV specific sequences can be diagnostic without the necessity for further sequencing. In the case of surprising findings or for less-experienced laboratories, external assistance should

be sought from a reference laboratory that can deploy additional or confirmatory assays.

Once specific NAAT assays are developed and validated, confirmation of cases of the novel virus infection will be based on specific detection of unique sequences of viral nucleic acid by reverse-transcriptase polymerase chain reaction (RT-PCR). Alternative NAAT techniques with advantages of greater speed or simplicity of use may also become available.

Serological testing

Serological testing may be useful to confirm immunologic response to a pathogen from a specific viral group, e.g. coronavirus. Best results from serologic testing requires the collection of paired serum samples (in the acute and convalescent phase) from cases under investigation.

Sequencing in outbreaks

Sequence data can provide valuable information for understanding the origin of a virus and how it is spreading. WHO has published a Draft code of conduct for the handling of Genetic Sequence Data related to outbreaks (see https://www.who.int/blueprint/what/norms-standards/GSDDraftCodeConduct_forpublicconsultation-v1.pdf?ua=1). For situations where data providers seek retention of ownership of their data, models with data access agreements (such as GISAIID) have been used to facilitate rapid sharing of genetic sequence data. Laboratories are encouraged to share sequence data with WHO and the scientific community to assist in the rapid development and distribution of diagnostic assays in at risk countries. The uploading and public access to sequence data should occur prior to journal publication. Medical journals should ensure

that their policies actively support pre-publication sharing of pathogen genetic sequence data together with appropriate acknowledgement. WHO can assist Member States to identify laboratories able to provide support and advise them on the management of sequence data related to an outbreak.

Specifics for biosafety practices in the laboratory

Ensure that health laboratories adhere to appropriate biosafety practices. Any testing on clinical specimens from patient meeting the case definition should be performed in appropriately equipped laboratories by staff trained in the relevant technical and safety procedures. National guidelines on the laboratory biosafety should be followed in all circumstances. General information on laboratory biosafety guidelines, see the WHO Laboratory Biosafety Manual, 3rd edition (8). There is still limited information on the risk posed by the reported coronavirus found in Wuhan, but it would appear samples prepared for molecular testing could be handled as would samples of suspected human influenza (2, 7-9).

It is recommended that all manipulations in laboratory settings of samples originating from suspected or confirmed cases of novel coronaviruses can be conducted according to WHO recommendations available at: https://www.who.int/csr/disease/coronavirus_infections/BiosafetyInterimRecommendationsNovelCoronavirus2012_31Oct12.pdf?ua=1 Information on biosafety for SARS, a Betacoronavirus that can cause severe respiratory disease can be consulted at [https://www.who.int/csr/sars/biosafety2003_04_25/en/and other guidance](https://www.who.int/csr/sars/biosafety2003_04_25/en/and_other_guidance).

Table 2. Tests to be performed in expert laboratories for patients meeting the case definition

Test	Type of sample	Comments
In laboratories that have validated broad coronavirus RT-PCR assays it is advised to check the primers against the published 2019-nCoV sequence and check if primers are overlapping and have the capacity to detect the 2019-nCoV. On a positive results sequencing should be performed to determine the precise virus detected (e.g. on an amplicon of a non-conserved region).	Respiratory sample	Collect on presentation. Done by an expert laboratory.
NAAT for 2019n-CoV when it becomes available (assays currently under validation)	Respiratory sample	Collect on presentation. Done by an expert laboratory until validation has been finalized.
Whole genome sequencing	Respiratory sample	Collect on presentation. Done by an expert laboratory.
Serology, broad corona virus serology on paired samples if available.	Serum	Paired samples necessary for confirmation, the first sample collected in week 1 of illness and the second collected 3-4 weeks later. If a single serum sample can be collected, collect at least 3 weeks after onset of symptoms. Done by expert laboratory until more information on performance of available assays.

6. Reporting of cases and test results

Laboratories should follow national reporting requirements, but in general, suspected cases should be reported to relevant public health authorities as soon as the laboratory receives a specimen, even before any testing is performed. All test results, whether positive or negative, should likewise be immediately reported to national authorities. If the infection becomes widespread, laboratories should notify public health authorities immediately of each new confirmed case or positive screening test if there will be a delay in confirmatory testing. Laboratories should also periodically report the number of negative test results to public health.

States Parties to the IHR are reminded of their obligations to share with WHO relevant public health information for events for which they notified WHO, using the decision instrument in Annex 1 of the IHR (2005) (18).

Detection of a possible human case of emerging pathogen causing severe acute respiratory disease should immediately be notified to local, subnational and national public health authorities. This will allow these authorities to make immediate decisions about launching the investigation and the extent of response measures. Detection of such a case should be used to trigger notification of traditional and non-traditional health providers, hospitals and outpatient. Facilities, and community leaders in the area where the case patients lived or travelled, as part of active case-finding efforts. In line with the International Health Regulations (IHR) (2005), the national health authority must notify WHO within 24 hours of all events that may constitute a public health emergency of international concern according to defined criteria. The IHR decision instrument should be used to determine whether an event is to be notified to WHO. Further guidance on the use of the IHR decision instrument, including examples of its application, is available. The national animal health authority must notify OIE of certain animal diseases detected on its territory. OIE focal points should be contacted for further details.

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National capacities review tool for a novel coronavirus (nCoV)

10 Jan 2020

WHO/2019-nCoV/Readiness/v2020.1



**World Health
Organization**

The main aim of the national capacities review tool is to better understand existing capacities in the area of detection and response to a novel coronavirus (nCoV) that is zoonotic and causes respiratory disease. The tool was developed with other coronaviruses, such as SARS-CoV and MERS-CoV, in mind and in consultation with member states. This information will help national authorities to i) identify main gaps ii) perform risk assessments and iii) plan for additional investigations, response and control actions.

I. DETECTION

National Laboratory System

1. Which coronaviruses (CoV) diagnostic tests is the country capable of conducting?
 - a. List the laboratories testing for CoV from human and animal health sectors along with the tests performed (PCR -CoV specific or panCoV-, sequencing, culture, serology, others)?
 - b. How many samples can each of these lab(s) process every day?
 - c. Does the country have a quality assurance program to ensure the quality of testing for CoVs by these laboratories (e.g. accreditation schemes, EQA program (proficiency-testing or rechecking), access to positive quality control materials)? Please list what is in place and the current gaps.
 - d. Are there national guidelines for clinicians on laboratory testing for SARI or CoV (including the specimens to be collected and tests to be requested)?
2. Currently, which CoV diagnostic tests are conducted in the country?
3. How are laboratory data shared between human and animal health laboratories and with surveillance system(s)?
4. Please describe the structure of the laboratory system, including number of public health and animal labs, at local, intermediate levels/district, and national levels.
 - a. Does the country have a national reference laboratories for CoV?
 - b. Are there hospital laboratories testing for CoV? If so, which hospitals?
 - c. Do local clinicians have the custom of using the laboratory system? Are there national guidelines for clinicians on which specimens should be collected for SARI/nCoV?
 - d. What systems exist for returning laboratory results back to practitioners? How long does this take?
 - e. How many samples can each of the lab(s) process for molecular testing (RT-PCR)?
5. Have national laboratories been accredited for CoV?
 - a. If yes, to what standard?

- b. Are guidelines and protocols for quality management system enforced and in use by public and animal health laboratories?
 - c. Is there a national body that oversees Internal Quality Controls and External Quality Assessment schemes for public health laboratories at national, regional and local levels?
6. How is laboratory data on zoonotic diseases shared between human and animal health laboratories?
7. Is Personal Protective Equipment available and used by laboratory staff?
8. Is the specimen referral network documented for nCoV?
 - a. Is there an arrangement with an overseas laboratory for testing when novel respiratory pathogen is suspected?
 - b. Are there infectious substance certified shippers at key laboratories which may ship the specimens abroad?
 - c. Are funds available to ship specimens?
 - d. Are triple packages available to ship specimens?
 - e. Are MTAs in place with overseas laboratories?
 - f. Are laboratories able to receive specimens from abroad for testing for CoVs/nCov (e.g. import permits)? If yes, are they willing to test at no charge for WHO or other Member States and/or assist with shipping costs?
9. Are standardized SOPs in place for specimen collection, packaging, and transport for emerging pathogens?
10. Does the country have a national EQA program (proficiency-testing or rechecking) for CoVs?

Surveillance and Risk Assessment

1. Is there an event-based surveillance system in place?
2. Does the country have the ability to quickly enhance current surveillance?
 - a. Can triggers/criteria/case definitions for investigation be quickly added to the system?
 - b. Does the country have a system to inform HCW and labs of the criteria to test and signal and who to report to, including the private sector?
3. Is there a functioning respiratory disease surveillance system in place, such as ILI, SARI, ARI or pneumonia surveillance systems?
4. Is a nCoV infection a national notifiable disease?
 - a. Have health authorities conducted specific training/s on the use of case definitions, how to identify suspected cases on a clinical basis as well as initiate early case management and contact tracing?
5. Is the private sector included in the respiratory surveillance system?
6. Do the public health staff at local/regional and/or national levels have the skills to analyze the surveillance data to detect SARI/pneumonia outbreaks/clusters?
7. For zoonotic pathogens, is data shared between human and animal health sectors? If so, how?
8. Does capacity exist to conduct risk assessment using available multiple sources of information?
9. Does the country have tools to collect, report, analyze case-based information?

Rapid Response Team (RRT)

1. Are there Public Health RRTs available in the country?
2. How are RRTs identified and assigned when alerts are identified?
 - a. If yes, are the RRTs available at both national and subnational level?
 - b. What disciplines are included in the RRTs? Do the RRTs also include representatives from the animal sector?
 - c. Are the RRTs trained for respiratory disease outbreaks, including emerging diseases/pneumonia/SARI outbreak/cluster investigation?
 - d. Are the needed resources (logistics and financial) secured to ensure the timely response?
3. Are there guidelines, SOPs and contact tracing and follow up forms available with the teams?
4. Is Personal Protective Equipment available for RRTs? Are they trained to use PPE properly/how is PPE use evaluated?
5. Are RRT trained specifically in contact tracing?
6. Are RRT trained in biological sample collection for respiratory pathogens?
7. Does the country have surge capacity for contact tracing?
8. Does the country have tools to follow up cases and contacts?

II. RESPONSE

Command and Coordination

1. Does the country have a national public health emergency preparedness and response plan that can address respiratory diseases including novel coronaviruses?
2. Does an Emergency operation Center (EOC)/Incident Management Structure (IMS) exist in the country?
3. Is there a multisectoral commission or a multidisciplinary emergency response committee?
 - a. How are other Ministries involved in emerging diseases preparedness and response?
4. Are there other partners willing to be involved in the emergency response?
5. Is there political engagement should there be an event?
6. Is there dedicated financial support for emerging disease surveillance, preparedness and response in the country?
7. Are there dedicated public health laws related to infectious diseases (e.g., quarantine, restriction of movement)?

Risk Communication

1. Is there a team of risk communication, communications or health promotion professionals at the national and subnational levels who are trained in risk communication and can be called upon to design and implement risk communication strategies during crises? Is there surge support available within the government, in partner agencies or elsewhere to cover increased communication needs during a public health crisis?

2. Are risk communication personnel invited to participate as equal partners in risk assessment, in rapid response teams and at response coordination meetings (e.g. at the public health emergency operations center)?
3. Are there mechanisms in place for the rapid clearance of timely and transparent communication messaging and materials in such crisis situations? Do those in senior government leadership – including those outside of the Ministry of Health or equivalent – understand the importance of releasing timely and transparent information to protect the public's health even when there is uncertainty (e.g. the cause, effective treatment, severity of pathogen) or when there may be political sensitivities.
4. Is it clear which government agency is leading on risk communication for an event of this nature and how communication will be coordinated across ministries and partners, and across different levels of government (e.g. which agency speaks first on which issue, what specific topics and audiences will be best addressed through which agency/partner, how will messaging be aligned)?
5. Is there capacity to develop and implement strategies to engage with at-risk or affected communities, including through their influencers (e.g., community leaders, religious leaders, health workers, traditional healers, etc.) and existing networks (e.g. women's groups, community health volunteers, unions, social mobilizers for polio, malaria, HIV)?
6. Are there systems in place to detect and quickly respond to misunderstandings, misinformation, rumors and frequently asked questions detected through the monitoring of media coverage, social media and hotlines or through healthcare worker and/or community networks? Is there a mechanism in place to utilize this information for revising risk communication strategy?

Point of Entry

1. Is there a public health emergency contingency plan, that can be used for potential nCoV events, is in place at each designated PoE?
 - a. Are staff working at PoE aware of the appropriate action to manage ill passenger(s) detected before boarding, on board conveyances (such as planes and ships) and on arrival at PoE?
 - b. Is a stockpile of PPE in place at PoE for assessing ill travelers?
 - c. Is there an appropriate place for rapid health assessment and isolation, in the event of detecting a potential nCoV case at PoE?
 - d. Is there a mechanism for safely transporting ill travelers to designated hospitals, including the identification of adequate ambulance services?
 - e. Are procedures and means in place for communicating information on ill travelers between conveyances and PoE, as well as between PoE and national health authorities?
 - f. Have ground services for environmental cleaning and disinfection at PoE been identified? If so, has the cleaning and disinfection protocol for potential nCoV events been put in place?
2. Are there means to provide incoming and outgoing travelers from/to affected countries, as well as travel, transport and tourism sectors with relevant information about the disease?

Case Management

1. Are there medical teams trained on SARI case management?
2. Are there ambulance teams trained to transport SARI patients?
3. Are there specific health facilities assigned to provide care to a patient/s with SARI?
 - a. Are any health facilities designated to manage patients with CoV infection?
4. Do the health care facilities have the appropriate knowledge, training and sensitivities to carry out safe and respectful burials?

5. What is the ICU capacity in country?
6. What provisions for mechanical ventilation, N95 masks, surgical masks, gloves, coveralls, etc.?

Infection Prevention and Control

1. Is there a functioning IPC program in each hospital/health care facility in the area where cases are suspected/identified/transferred?
2. Is there a national IPC authority that has developed IPC guidance and/or monitor IPC at the hospital level? Does the national IPC authority gather, analyze, document, and report data on health care-associated infections HAI at the country level?
3. Is the triaging system for patients with Acute Respiratory Illness (ARI) applied in the health facilities? If so, is the triage system adequate?
4. Are standard and/or droplet precautions are applied for all patients with suspected, or a confirmed high threat pathogen?
5. Are airborne precautions applied for all patients who require aerosol-generating procedures?
6. Is there a need/plan for patient placement and transportation based on the clinical status of nCoV patient?
7. What isolation facilities are available for nCoV patients?
8. What controls are/would be in place to limit visitors of patients and require PPE for visitors of nCoV patients?
9. Is Personal Protective Equipment available for medical staff? If so, what PPE is available, how is it used/use assessed?
10. Does a protocol/strategy for environmental cleaning and disinfection exist? If so, is it adequate?
11. Does a system for the proper collection and disposal of nCoV contaminated medical waste exist?
12. Is there an infection control team responsible to follow up exposed HCWs and decide to permit a healthcare worker to resume his/her work? What policies are in place to test and isolate (if positive) HCWs in contact with patients?
13. Is there a strategy to deal with patient/s exposed to a confirmed nCoV patient available?

Logistics, Procurement and Supply Management

1. Is there a Logistics & Supply focal point in the country assigned to the response and is able to link with all pillars for supply forecasting?
2. Is there a procurement mechanism in place in the country?
3. Is there a sufficient storage capacity in the country?
4. Is there a stock management system available in the country?
5. Is there a transport & distribution system available in the country?

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WHO recommendations to reduce risk of transmission of emerging pathogens from animals to humans in live animal markets

On 31 December 2019, WHO was informed of cases of pneumonia of unknown etiology (unknown cause) detected in Wuhan City, Hubei Province of China. A novel coronavirus (2019-nCoV) was identified as the causative virus by Chinese authorities on 7 January.

Investigations are ongoing to evaluate the source of the outbreak, mode(s) of transmission and the extent of infection. Available evidence on the 2019-nCoV virus and previous experience with other coronavirus (MERS-CoV and SARS-CoV) and other respiratory viruses (e.g., avian influenza) suggest that there may be zoonotic transmission associated with the 2019-nCoV.

In light of available evidence and past experience, WHO makes the following general recommendations:

- As a general precaution, anyone visiting live animal markets, wet markets or animal product markets, should practice general hygiene measures, including regular hand washing with soap and potable water after touching animals and animal products, avoiding touching eyes, nose or mouth with hands, and avoiding contact with sick animals or spoiled animal products. Any contact with other animals possibly living in the market (e.g., stray cats and dogs, rodents, birds, bats) should be strictly avoided. Attention should also be taken to avoid contact with potentially contaminated animal waste or fluids on the soil or structures of shops and market facilities
- The consumption of raw or undercooked animal products should be avoided. Raw meat, milk or animal organs should be handled with care, to avoid cross-contamination with uncooked foods, as per good food safety practices.

Recommendations for at-risk groups

- Until more is understood about the 2019-nCoV, people with underlying medical conditions are considered at higher risk of severe disease. Therefore, individuals with these underlying medical conditions should avoid contact with live animal markets, stray animals and wild animals, should not eat animal raw meat. Such recommendations should also be disseminated to travellers and tourists with underlying medical conditions.

- Slaughterhouse workers, veterinarians in charge of animal and food inspection in markets, market workers, and those handling live animals and animal products should practice good personal hygiene, including frequent hand washing after touching animals and animal products. They should consider wearing protective gowns, gloves, masks while professionally handling animals and fresh animal products. Equipment and working stations should be disinfected frequently, at least once a day. Protective clothing should be removed after work and washed daily. Workers should avoid exposing family members to soiled work clothing, shoes, or other items that may have come into contact with potentially contaminated material. It is therefore recommended that protective clothes and items remain at the workplace for daily washing.
- Based on available information, it is not known if the 2019-nCoV has any impact on the health of animals and no particular event has been reported in any species. As a general recommendation, sick animals should never be slaughtered for consumption; dead animals should be safely buried or destroyed and contact with their body fluids should be avoided without protective clothes. Veterinarians should maintain a high level of vigilance and report any unusual event detected in any animal species present in the markets to veterinary authorities.

Related Link

[coronavirus topic page](#)

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Risk communication and community engagement readiness and initial response for novel coronaviruses (nCoV)

Interim guidance v1

January 2020

WHO/2019-nCoV/RCCE/v2020.1



This document provides WHO checklists for risk communication and community engagement (RCCE) readiness and initial response for novel coronaviruses (nCoV) recently identified in Wuhan, China (2019-nCoV). The objective of this document is to provide actionable guidance for countries to implement effective RCCE strategies which will help protect the public's health in the early response to nCoV. This document includes recommended RCCE goals and actions for countries preparing for nCoV cases and for countries that have confirmed nCoV cases.

WHO will update these recommendations as new information becomes available on the situation in Wuhan, China. This interim guidance was adapted from WHO's RCCE guidance and training materials.

Why is it important to include RCCE as part of a national public health emergency response?

Every public health emergency faces new communication challenges and lessons learned. These challenges can lead to a range of outcomes including loss of trust, reputation, economy and at worst case – lives. While there are always new lessons to be learned, there are actions we know will work. This is a call to leaders to ensure RCCE is an essential role in your health emergency preparedness and response for the following reasons.

One of the most important and effective interventions in public health response to any event is to proactively communicate what is known, what is unknown and what is being done to get more information with the objective of saving lives and minimizing adverse consequences.

RCCE helps prevent infodemics (the spread of misinformation), builds trust in the response and increases the probability that health advice is followed. It minimizes and manages false rumours and misunderstanding that undermine response and may lead to further disease spread.

Proactive communication and engagement with the public and at risk populations on a consistent basis can help alleviate confusion and misunderstanding.

People have the right to be informed and understand the health risks they face, in addition to that of their loved ones.

The perception of risk among affected populations often differs from that of experts and authorities. Effective RCCE can help bridge that gap by determining what people know, feel and do related to disease outbreaks, as well as what they ought to know and do to bring the outbreak under control. Effective RCCE helps transform and deliver complex scientific knowledge which is understood by, accessible to, and trusted by populations and communities.

Effective RCCE uses community engagement strategies to involve communities in the response and develops acceptable yet effective interventions to stop further amplification of the outbreak and for individual and group protective measures.

RCCE is essential for surveillance, case reporting, contact tracing, caring for the sick and clinical care, gathering local support for any logistic and operational needs of the response.

RCCE readiness checklist for countries preparing for a possible outbreak

Goals

- ☐ Prepare to communicate with unknown information and uncertainty
- ☐ Assess national and subnational communication capacity (persons and resources)
- ☐ Identify the main actors, and form partnerships
- ☐ Plan for activation and implementation of RCCE plan
- ☐ Train emergency RCCE staff and potential surge staff on plans and procedures

Action steps

Risk Communication Systems

- ☐ Ensure that highest levels of government agree to include RCCE in preparedness and response activities and is ready to release information to protect the public's health rapidly, transparently and accessibly
- ☐ Review existing RCCE plan and consider adjustments for a respiratory outbreak
- ☐ Agree on procedures for timely release of information such as clearance procedures for messages and information products – keep clearance chains short
- ☐ Prepare a budget for communication (including scale-up)
- ☐ Set up a RCCE team and define roles and responsibilities

Internal and partner coordination

- ☐ Identify partners to include other agencies, organizations, community planners, health care workers, etc., with their contact information (in the case of this outbreak consider Ministry of Agriculture, Travel and Tourism, hospital systems, etc.) – should an outbreak occur, these partners should be activated into a multi-sectoral RCCE response team
- ☐ Assess the communication capacity of all relevant partners – identify typical target audiences and channels of communication used by partners
- ☐ Plan and agree on communication roles and responsibilities through standard operating procedures (SOPs) (e.g. which agency speaks first on which issue, what specific topics and audiences will be best addressed through which agency/partner, how will messaging be aligned)

Public communication

- ☐ Review the roster of spokespeople at all levels, listing their expertise in anticipated public health threats, and, if necessary, train them
- ☐ Produce and pre-test message templates
- ☐ Identify key media; create and update a list of journalists, and foster media relations
- ☐ Identify media and other communication channels and influencers and assess their potential reach for potential target audiences – use channels and influencers trusted, preferred and regularly used by target audiences

Communication engagement with affected communities

- ☐ Establish methods for understanding the concerns, attitudes and beliefs of key audiences
- ☐ Identify target audiences, and gather information on their knowledge and behaviours (e.g. who they trust, how they are likely to receive information, their daily habits, their concerns, etc.)
- ☐ Identify existing community influencers (e.g. community leaders, religious leaders, health workers, traditional healers, etc.) and networks (e.g. women's groups, community health volunteers, unions, social mobilizers for polio, malaria, HIV) that can be repurposed for community engagement

Addressing uncertainty, perceptions and misinformation management

- ☐ Prepare to begin communicating before the full picture is known by ensuring leaders agree to communicate with
- ☐ Establish a system for monitoring and, if necessary, responding to rumours, misinformation and frequently asked questions

Capacity building

- ☐ Consider training needed for RCCE responders on what is known and unknown about novel coronavirus, current plans and procedures as well as sub-national preparation for RCCE response

RCCE initial response checklist for countries where one or more cases have been identified

Goals

- ☐ Adapt and apply action steps from readiness checklist above if not already completed
- ☐ Establish, build and/or maintain trust with population through regular two way communication and engagement that regularly addresses misunderstanding, misinformation, rumours and frequently asked questions
- ☐ Encourage people to adopt protective behaviours
- ☐ Manage expectations and communicate uncertainties
- ☐ Coordinate and encourage collaboration among response partners
- ☐ Assess initial risk perception of affected and at risk populations
- ☐ Provide information and guidance

Action steps

Risk Communication Systems

- ☐ Adapt existing RCCE plan to the response, and activate the RCCE response team and plan
- ☐ Identify and activate spokespersons for the emergency
- ☐ Draw up timelines for communication activities and products
- ☐ Monitor RCCE response by identifying processes that delay information release and create confusion among affected populations

Internal and partner coordination

- ☐ Activate SOPs for RCCE coordination with other response agencies and partners
- ☐ Link national, regional and local RCCE operations
- ☐ Assign responsibilities for internal (to each response agency) and external (to the public) communication
- ☐ Coordinate message preparation, consistency and dissemination

Public communication

- ☐ Announce the health threat early and often and update after a risk assessment and an analysis of risk perception
- ☐ Provide information as soon as it is received, even if it is not complete and openly explain the degree to which information is uncertain (manage uncertainty), provide the public regular channels to get updated information (e.g. hotlines, website, etc.)
- ☐ Use trusted and effective communication channels that target audiences regularly use
- ☐ Identify and activate trusted influencers for the audiences

Communication engagement with affected communities

- ☐ Conduct a rapid risk perception analysis based on existing formal and informal information
- ☐ Segment the audiences for the communication response (e.g. affected people, health care workers, political leaders, donors, etc.)
- ☐ Translate materials into relevant languages and adapt to literacy levels

Addressing uncertainty, perceptions and misinformation management

- ☐ Communicate what is known and what is not known - explain degree to which uncertainty still exists
- ☐ Activate rumour monitoring, verification and response mechanisms
- ☐ Monitor mass and social media, hotlines, health care worker feedback from patients and community concerns and continually apply feedback into adapted RCCE strategy

Capacity building

- ☐ Plan regular updated guidance to all RCCE responders
- ☐ Train surge staff
- ☐ Consider training leaders, responders and spokespersons on RCCE guidance as needed

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CDNA Extra Ordinary Teleconference Summary Notes

20 January 2020

2. Strategic Discussion

The discussion opened with members being advised that the Centers for Disease Control and Prevention (CDC) had issued an update stating that the United States had implemented border control measures in response to the novel coronavirus outbreak in Wuhan, China.

Members noted that there have been three cases of novel coronavirus diagnosed outside of Wuhan, with no epidemiological links to the seafood market from which it originated.

Dr Bennett asked what the Commonwealth has done in response to the outbreak. Ms Owens advised members that an Incident Management Team has been stood up in the Office of Health Protection.

Jurisdictional Update

Jurisdiction	Update
NSW	Dr Selvey advised members of the following: • Sydney has three direct flights to Wuhan. • Two suspected cases reported, both cleared of novel coronavirus. • Initial advice was provided to GPs and clinics, to aid in diagnosis. • Looking closely at the Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS) Series of National Guidelines (SoNGs) for guidance.
VIC	Dr Van Diemen advised members of the following: • Chief Health Officer (CHO) alert was issued last week. • No suspected cases reported as yet.
SA	Dr Flood advised members of the following: • Public health alert has been issued. • One potential case that turned out to be influenza.
TAS	s47F advised members of the following: • Tasmania has contacted clinicians and laboratories with information following the prior extra ordinary meeting. • Some community concern, but not much response this week.
WA	Dr Huppatz advised members of the following: • WA issued an alert two weeks ago. • Currently having discussions with labs about testing. • No suspected cases.
NT	Dr Krause advised members of the following: • NT have issued an alert after the last extra ordinary meeting. • Shared knowledge from the Commonwealth situation reports, particularly with laboratories and infection control people in hospitals. • No suspected cases.
QLD	Dr Bennett advised members of the following: • Issued alert last week.

	- Received notification of two suspected cases on 10 January 2020. Both cases had been to Wuhan, though one case had had no contact with the seafood market. Both presented with flu-like illness. - One case was detected coming through Singapore with a fever, but nothing more was done except for advising the case to seek medical attention if they got worse. Samples went to the Victorian Infectious Disease Reference Laboratory (VIDRL), but came back negative. All further samples came back negative, including for more common viruses. - Second case tested positive for influenza.
VIDRL / PHLN	Dr Catton advised members of the following: - NSW, VIC and QLD have testing capacity for coronavirus. - Every second night a teleconference is convened by the World Health Organization (WHO) to share information regarding laboratory aspects. Nothing has come out of these meetings that is not on ProMED. These teleconferences are scheduled to continue. - China released the virus sequence last week, which has enabled the team to map cases against that sequence. A broad coronavirus assay will pick up the Wuhan virus. - Currently using SARS as a provisional positive control. - Primers have been made available on the WHO website, which should pick up anything. - Dr Catton has worked on a draft laboratory guideline, outlining what samples should be taken and what procedures should be conducted in the labs. The Public Health Laboratory Network (PHLN) have reviewed, and the advice seems consistent with CDC advice. Dr Catton agreed to circulate draft laboratory guidelines to all CDNA JEG members, noting that this is not an official PHLN document. - SA enquired whether Dr Catton's document is consistent with WHO. Dr Catton advised that he hasn't seen the WHO guidelines, but he is happy to take this on notice and check.
Commonwealth	Ms Owens advised members of the following: - An Incident Management Team has been stood up, and the National Incident Room will be activated shortly. - The lack of information from WHO has been noted; most of what is being reported in the media hasn't been confirmed by WHO. - Risk assessment has commenced, and will be finished soon. - The Commonwealth is working with VIDRL and have confirmed that we can test for the Wuhan virus in Australia. - Increased media over the weekend and today (20 January 2020), which was likely triggered by the CDC announcement that they will do screening at three main airports. The Commonwealth has answered this media, and the Chief Medical Officer (CMO) put out a statement on 19 January 2020 addressing this. - Currently looking at potential border measures. Have spoken to the Department of Agriculture about what's feasible. - Currently looking at collecting more information about flights coming into Australia that have originated in Wuhan. - The Australian Health Protection Principal Committee (AHPPC) are holding a meeting this afternoon (20 January 2020).

	Dr Newton advised members of the following: As at 19 January 2020, media are reporting: • 198 cases of novel coronavirus and three deaths. • Since 17 January 2020, approximately 136 new cases have been identified in patients with previously unexplained pneumonia. • Of these new cases, all are adults aged 25-89 years. Approximately 50% are male (78) and 25% female. • Of the 198 confirmed cases, 28 have recovered or been discharged, 126 have mild illness, 35 are listed as severe and nine are in critical condition. • There are 817 close contacts being monitored. • Four cases have been reported outside of Wuhan, China. Two in Thailand, one in Japan and one in Shenzhen, China. All cases reported travelled to Wuhan, China. Clinical presentation/symptoms • Symptoms reported include: fever, difficulty breathing, non-specific upper respiratory tract infection symptoms such as cough and sore throat and chest radiographs showing bilateral pneumonic infiltrations. Transmission • WHO is reporting evidence of limited human-to-human transmission, given some cases have reported no exposure to the Huanan seafood wholesale market. • There is no clear evidence of sustained transmission and there is not enough information to fully assess the extent of transmission.
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Case Definition and SoNG

Members agreed to formalise a case definition and SoNG, similar to MERS, and to form a working group to progress this work as quickly as possible. Dr Tobin advised that NSW have commenced work on modifying the MERS SoNG for the novel coronavirus, noting that key points to discuss are timing, inclusion of fever, testing for other respiratory viruses and the management of patients. Dr Tobin advised that he was happy to share this work with CDNA JEG members. Drs Tobin, Van Diemen, Bennett and Catton advised that they would be happy to take part in this working group, with s47E(c), s47F, the Commonwealth Technical Writer for SoNGs, to take the lead.

Listed Human Disease (LHD)

Members discussed the need to make the novel coronavirus a Listed Human Disease (LHD). Ms Owens advised that the Commonwealth currently rely on the travelling with illness checklist, but this would only be effective if the novel coronavirus was made an LHD.

s47E(c), s47F advised members that the current checklist is geared towards MERS and avian flu, as the questions are surrounding contact with camels, birds and poultry. The only way the checklist can be updated to include more relevant questions to the novel coronavirus, is if it was made an LHD. Dr Flood asked if it was easy to un-list a disease. s47E(c), s47F advised that while this has not been done before, in theory, it should be quite simple. Dr Bennett noted that novel influenza viruses of

pandemic potential are listed as an LHD; it would be good to have the same for novel coronaviruses.

s47E(c), s47F commented that this could be possible, but legal advice would have to be sought.

Members agreed to recommend the novel coronavirus be listed as an LHD, and noted that the next step would be to consult with the CHO's at the upcoming AHPPC meeting on 20 January 2020.

Communicable Disease Incident of National Significance (CDINS)

Members discussed the need to go through the process of declaring the novel coronavirus a CDINS.

s47F took members through the triggers for a CDINS. All members agreed to recommend to the CMO that the novel coronavirus be made a CDINS.

Border Measures

Members discussed border measures that are currently in place. Ms Owens advised members that the U.S. are currently taking the temperatures of every person returning from Wuhan on a direct flight.

The Commonwealth has spoken to the Department of Agriculture about issuing a handout to all passengers on direct flights from Wuhan to Sydney, noting that this would have to be provided in a variety of languages. To reach those passengers on connecting flights, digital banners will be put in place, advising that if patients get sick they should consult their GP and inform them of all travel history. CDNA JEG members were supportive of the current border measures in place, and agreed that this approach should be provided to AHPPC this afternoon (20 January 2020). It was recommended that more information should be gathered surrounding the effectiveness of screening for fever in other countries versus the pick-up rates.

CDNA JEG will consider other border control measures as more information about the current outbreak becomes available.

Members agreed that another extra ordinary teleconference would likely need to be held again shortly, to discuss the latest developments of the novel coronavirus outbreak in Wuhan.

Actions

- Dr Catton to circulate draft laboratory guidelines to all CDNA JEG members, once endorsed by PHLN.
- Dr Tobin to share his work on modifying the MERS SoNG for the novel coronavirus.
- Drs Tobin, Van Diemen, Bennett, s47F Flood and Catton to nominate members to take part in the novel coronavirus working group, with s47E(c), s47F to take the lead.
- Discussions around adding the novel coronavirus as an LHD to be had at AHPPC on 20 January 2020.
- CDNA JEG to recommend making the novel coronavirus a CDINS to the CMO.
- AHPPC to be advised of the current border control approach in Australia.
- CDNA Secretariat to organise a follow up meeting pending discussion with the Chair.



Biosecurity (Listed Human Diseases) Amendment Determination 2020

I, Professor Brendan Murphy, Director of Human Biosecurity, make the following legislative instrument.

Dated *21st January 2020*

Professor Brendan Murphy
Director of Human Biosecurity

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the Department of Health, Disability and Ageing

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This document has been released under
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the Department of Health, Disability and Ageing

1 Name

This instrument is the *Biosecurity (Listed Human Diseases) Amendment Determination 2020*.

2 Commencement

This instrument commences on the day it is registered.

3 Authority

This instrument is made under subsection 42(1) of the *Biosecurity Act 2015*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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Schedule 1—Amendments

Biosecurity (Listed Human Diseases) Determination 2016

1 Section 4

After “(g) yellow fever”, add
“; (h) human coronavirus with pandemic potential”.

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EXPLANATORY STATEMENT

Biosecurity Act 2015

Biosecurity (Listed Human Diseases) Amendment Determination 2020

Authority

The *Biosecurity Act 2015* (the Act) provides the primary legislative means and a regulatory framework for the Australian Government to manage the risk of pests and diseases from entering Australian territory and causing harm to animal, plant and human health, the environment and the economy. The Act manages biosecurity risks – including the risk of listed human diseases – entering Australian territory, or emerging, establishing or spreading in Australian territory.

Subsection 42(1) of the Act provides that the Director of Human Biosecurity may determine, in writing, a human disease to be a listed human disease if the disease may be communicable and may cause significant harm to human health.

Purpose

The purpose of *Biosecurity (Listed Human Diseases) Amendment Determination 2020* (the instrument) is to add human coronavirus with pandemic potential to the list of human diseases in this instrument. The disease is required to be listed in the instrument to allow human biosecurity measures under Chapter 2 of the Act to be imposed, thereby allowing Australia to manage and respond to biosecurity risks to human health caused by that virus.

Background

On 5 January 2020, the World Health Organization (WHO) notified Member States under the *International Health Regulations (2005)* (IHR) of an outbreak of pneumonia of unknown cause in Wuhan city, China. The cause of the outbreak has since been determined as a novel coronavirus.

Under the IHR, the WHO has recommended that health authorities work with travel, transport and tourism sectors to provide travellers with information to reduce the general risk of acute respiratory infections, including at points of entry and through conveyance operators.

All powers under Chapter Two of the Act require that the disease be a listed human disease for the power to apply. These powers include the ability to screen incoming passengers for signs and symptoms of a listed human disease, the ability to impose Human Biosecurity Control Orders on those who are suspected or confirmed as having a listed human disease and implementing further risk mitigation measures.

To enable compliance with the WHO's recommendations, and to implement additional border measures under the Act, it is necessary for human coronavirus with pandemic potential to be determined as a listed human disease. The inclusion of human coronavirus with pandemic potential enables application of border measures under the Act in order to manage this or other emerging coronaviruses and their potential for human to human transmission.

Consultation

Subsection 42(2) of the Act requires that before making a determination under section 42, the Director of Human Biosecurity must consult with the chief health officer (however described) for each State and Territory and the Director of Biosecurity.

The Director of Human Biosecurity consulted the States and Territories and the Director of Biosecurity. The Australian Health Protection Principal Committee and the Communicable Diseases Network Australia, comprising Chief Health Officers and communicable disease experts across state and territory governments, met via teleconference on 20 January 2020, and endorsed the addition of

human coronavirus with pandemic potential as a listed human disease.

The Director of Biosecurity, Mr Daryl Quinlivan, was also consulted in regards to the determination and on 21 January 2020 confirmed his support of the amendment.

The instrument commences on the day it is registered.

The instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

A provision by provision description of the instrument is contained in Attachment 1.

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ATTACHMENT 1**Provision by provision description of the *Biosecurity (Listed Human Diseases) Amendment Determination 2020*****1. Name**

Section 1 provides that the name of the instrument is *Biosecurity (Listed Human Diseases) Amendment Determination 2020*.

2. Commencement

Section 2 provides that this legislative instrument commences on the day it is registered.

3. Authority

Section 3 specifies that this instrument is made under subsection 42(1) of the *Biosecurity Act 2015*.

4. Schedules

Section 4 provides that instruments included in the schedule to this instrument are amended or repealed as set out in the applicable items in the schedule.

Schedule 1 – Amendments

Item 1 of Schedule 1 provides that section 4 of the *Biosecurity (Listed Human Diseases) Determination 2016*, which is the list of Listed Human Diseases, is amended to include 'human coronavirus with pandemic potential' in that list.

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Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Biosecurity (Listed Human Diseases) Amendment Determination 2020

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The *Biosecurity (Listed Human Diseases) Amendment Determination 2020* adds ‘human coronavirus with pandemic potential’ as a listed human disease, and therefore enables the application of a range of measures under the *Biosecurity Act 2015*.

Human rights implications

This legislative instrument engages and is consistent with Article 12(1) of the International Covenant on Economic, Social and Cultural Rights by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

This instrument provides the means of protecting public health in Australia through enabling the application of human biosecurity measures to manage the risk of human coronavirus with pandemic potential entering Australian territory, or emerging, establishing, or spreading in Australian territory or a part of Australian territory.

Conclusion

This legislative instrument is compatible with human rights because it promotes the human right to an adequate standard of living and the highest attainable standard of physical and mental health.

Professor Brendan Murphy
Director of Human Biosecurity
Chief Medical Officer
Department of Health

s47E(c), s47F

From: Humanbiosecurity
Sent: Tuesday, 21 January 2020 10:18 AM
To: Legislative Instruments; Humanbiosecurity
Cc: s47E(c), s47F
Subject: Biosecurity (Listed Human Diseases) Amendment Determination 2020 for Registration [SEC=OFFICIAL]
Attachments: Biosecurity (Listed Human Diseases) Amendment Determination 2020 - signed.pdf

Good morning

Please find the **attached** *Biosecurity (Listed Human Diseases) Amendment Determination 2020* executed by the Director of Human Biosecurity, Professor Brendan Murphy, for registration.

Please contact s47E(c), s47F at s47E(c), s47F [@health.gov.au](mailto:s47E(c), s47F@health.gov.au) with any questions.

Kind regards

s47E(c), s47F

Departmental Officer – Border Health Section
Health Emergency Management

Office of Health Protection | Chief Medical Officer Group

Australian Government Department of Health

T: 02 6289 s47E(c), s47F [@health.gov.au](mailto:s47E(c), s47F@health.gov.au)

Location: Scarborough House 3.230

PO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present

s47E(c), s47F

From: Humanbiosecurity
Sent: Tuesday, 21 January 2020 1:09 PM
To: Legislative Instruments; Humanbiosecurity
Cc: s47E(c), s47F
Subject: RE: Biosecurity (Listed Human Diseases) Amendment Determination 2020 for Registration [SEC=OFFICIAL]
Attachments: Registration Request Spreadsheet 2020 - Border Input.XLSX; FINAL Biosecurity (Listed Human Diseases) Amendment Determination 2020.DOCX; FINAL ES - human coronavirus with pandemic potential january 2020.docx; CMO CLEARED: Explanatory Statement - Listed Human Disease - Human coronavirus w pandemic potential [SEC=OFFICIAL]

Hi s47E(c), s47F

Please find the requested documents attached;

Completed Registration Request Spreadsheet

1. WORD version of the signed instrument
2. Scanned (PDF) version of explanatory statement approved by Professor Brendan Murphy (word version attached to email verifying CMO cleared)
3. WORD version of explanatory statement approved by Professor Brendan Murphy

Please let me know if you have any questions.

Kind regards

s47E(c), s47F

**Departmental Officer – Border Health Section
 Health Emergency Management**

Office of Health Protection | Chief Medical Officer Group
 Australian Government Department of Health
 T: 02 6289 s47E(c), s47F [@health.gov.au](mailto:s47E(c), s47F@health.gov.au)
 Location: Scarborough House 3.230
 PO Box 9848, Canberra ACT 2601, Australia

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From: Legislative Instruments
Sent: Tuesday, 21 January 2020 10:53 AM
To: Humanbiosecurity ; Legislative Instruments
Cc: s47E(c), s47F
Subject: RE: Biosecurity (Listed Human Diseases) Amendment Determination 2020 for Registration [SEC=OFFICIAL]

Thanks s47E(c), s47F

Can you please complete the attached registration spreadsheet and return it along the following documents:

1. WORD version of the signed instrument
2. Scanned (PDF) version of explanatory statement approved by Professor Brendan Murphy
3. WORD version of explanatory statement approved by Professor Brendan Murphy

Kind regards

s47E(c),
s47F

Legislative Instruments and Executive Council Liaison Officer
FOI and Legislation Support Section

Legal Advice & Legislation Branch
Legal & Assurance Division
Australian Government Department of Health
T: (02) 6289 s47E(c),
s47F

From: Humanbiosecurity <Humanbiosecurity@health.gov.au>

Sent: Tuesday, 21 January 2020 10:18 AM

To: Legislative Instruments <Legislative.Instruments@health.gov.au>; Humanbiosecurity
<Humanbiosecurity@health.gov.au>

Cc: s47E(c), s47F <[s47E\(c\), s47F@health.gov.au](mailto:s47E(c), s47F@health.gov.au)>; s47E(c), s47F <[s47E\(c\), s47F@health.gov.au](mailto:s47E(c), s47F@health.gov.au)>

Subject: Biosecurity (Listed Human Diseases) Amendment Determination 2020 for Registration [SEC=OFFICIAL]

Good morning

Please find the **attached** *Biosecurity (Listed Human Diseases) Amendment Determination 2020* executed by the Director of Human Biosecurity, Professor Brendan Murphy, for registration.

Please contact s47E(c), s47F at s47E(c), s47F <[s47E\(c\), s47F@health.gov.au](mailto:s47E(c), s47F@health.gov.au)> with any questions.

Kind regards

s47E(c), s47F

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Location: Scarborough House 3.230
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Date made	Name of instrument	Series/identifer number (OPTIONAL)
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The date signed
or made by the
rule maker.
Use format:
xx/xx/xxxx

e.g. *National Health (Concession or
entitlement card fee) Determination 2010*

Insert identifier or series number, if used.
E.g. PB28 of 2012.

Biosecurity (Listed Human Diseases)
21/01/2020 Amendment Determination 2020

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Commencement	Urgent registration?	Brief description of instrument
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When does the instrument commence.
Use format: xx/xx/xxxx

If is registration is urgently required please provide required date.

Please note OPC requires the Department to give sufficient notice for registration after 4PM and a service fee is navable.

Describe briefly what the instrument actually does. This information is required for registration and appears on the Federal Register of Legislation. Please use proper punctuation.
(Please keep length 1 to 2 Sentences)

Date of registration
21/01/2020

Identifies Listed Human Diseases under the
21/01/2020 Biosecurity Act 2015

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Enabling legislation	Enabling provision	Name of instrument(s) that are affected by this instrument
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Please list other instruments that will be affected by this instrument.

Name of the Act which gives the power for the instrument to be made.

The section of the Act under which the instrument has been made.

Alternatively, provide the registration numbers (e.g. F2017C00100 for National Health (Eligible midwives) Determination 2010)

Biosecurity Act 2015

Section 42(1)

NIL

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Documents incorporated by reference?	Contact/ Invoicing officer	Phone No	Division
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Is the content of any external documents referred to in the instrument. E.g. the Hospital Casemix Protocol (HCP), ISO 9001

Contact officer for invoicing purposes.

Phone number of contact officer.

Division of contact officer.

NIL

s47E(c), s47F

02 6289

s47E(c), s47F

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Branch	Section
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Branch of contact
officer.

Section of
contact
officer.

Health
Emergency
Management

Border
Health

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Biosecurity (Listed Human Diseases) Amendment Determination 2020

I, Professor Brendan Murphy, Director of Human Biosecurity, make the following legislative instrument.

Dated

Professor Brendan Murphy
Director of Human Biosecurity

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1 Name

This instrument is the *Biosecurity (Listed Human Diseases) Amendment Determination 2020*.

2 Commencement

This instrument commences on the day it is registered.

3 Authority

This instrument is made under subsection 42(1) of the *Biosecurity Act 2015*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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Schedule 1—Amendments

Biosecurity (Listed Human Diseases) Determination 2016

1 Section 4

After “(g) yellow fever”, add
“; (h) human coronavirus with pandemic potential”.

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