Recommendations for testing and isolation following COVID-19 vaccination

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OFFICIAL

Contents

Recommendations

For individuals working in environments where regular asymptomatic testing for COVID-19 is occurring, it is recommended that this continues for surveillance testing in such work environments. Any individual working in these environments who develops any COVID-19 symptoms following vaccination at their workplace should be tested with a throat-nasal swab (not saliva) test followed by immediate isolation at home.

It is also assumed that in critical operations areas, such as hotel quarantine, airport arrivals and hospitals, the rollout of the vaccine will be staggered over a number of weeks. This is to ensure that manageable numbers of people from one unit or roster will be absent should they experience adverse events following immunisation (AEFI) at the same time.

The recommendations below apply to the onset of symptoms in the 48 hours following COVID-19 vaccination. They do not apply to symptoms which predate vaccination, nor to symptoms appearing greater than 48 hours following vaccination.

For any person vaccinated in Victoria in Phase 1a of the COVID-19 vaccination program, in the 48 hours following vaccination:

- The onset of ANY **respiratory symptoms** (cough, sore throat, shortness of breath, runny nose, loss of sense of smell or taste), irrespective of the presence or otherwise of accompanying symptoms, should be assumed to be unrelated to vaccination. Isolation, assessment and testing for COVID-19 as per usual guidelines should be undertaken.

- The presence of **fever with temperature above 37.5°C** should not be assumed to be an AEFI in these high-risk populations. Isolation, assessment and testing for COVID-19 as per usual guidelines should be undertaken.
- Reporting of **fever or chills in the absence of temperature above 37.5°C** within 48 hours of vaccination may be considered a possible AEFI. This should prompt isolation and, if the symptoms persist greater than 24 hours, testing for COVID-19.
  - If an individual experiences fever or chills and is unable to take their temperature, they should present for testing for COVID-19.
  - If fever (in the absence of temperature above 37.5°C) or chills resolve completely within 24 hours of onset and no other symptoms are present, isolation may be ceased and the individual may return to normal activities.
- **Headache and/or muscle pain** within 48 hours of vaccination may be considered a possible AEFI. If mild and there are no respiratory symptoms, fever or chills, and the individual feels well enough and is willing to work, this should be discussed with their manager, especially if working in a high-risk environment such as hotel quarantine, port of entry or COVID/SCOVID unit, and decide whether to continue working or isolate at home as follows:
  - If continuing working, any development of fever, chills or respiratory symptoms should prompt immediate testing for COVID-19 (with throat-nasal swab) and isolation until results are available.
  - If continuing working, continuing asymptomatic surveillance testing (if in a context where this is recommended) with a throat-nasal swab test (not salivary test) on the first occasion of work following onset of symptoms is required, even if a throat-nasal swab had been collected in the previous week.
  - If symptoms persist for greater than 48 hours following onset, even in the absence of other symptoms of COVID-19, further assessment and consideration of isolation and testing for COVID-19 should be undertaken.

If working in a high-risk environment such as hotel quarantine, port of entry or COVID/SCOVID unit, then additional caution should be exercised in relation to any COVID-like symptoms.

If an individual who has been vaccinated has been tested for COVID-19 (other than through routine asymptomatic surveillance testing) they must continue to isolate until they receive a negative test result and their symptoms have resolved.

Discussion

There is some overlap between the expected adverse events following immunisation (AEFI) following COVID-19 vaccination and the presenting symptoms of COVID-19. This could lead to uncertainty around requirements for testing and isolation in a person with symptoms following vaccination.

Following the first dose of Pfizer COVID-19 vaccine (Comirnaty), the following AEFI have been reported among persons aged 16-55 years (with lower proportions for all these AEFI among those aged greater than 55 years (see **Appendix 1**). Those overlapping with Victorian clinical criteria for testing for COVID-19 in groups at higher risk of COVID-19 are in bold and highlighted.

AEFI reported after first dose among people aged 16-55 years of age

Symptom	Percentage
Injection site pain	83.1%
Fever	**3.7%**
Fatigue	47.4%
Headache	**41.9%**
Chills	**14.0%**
Muscle pain	**21.3%**
Joint pain	11.0%
Required paracetamol after vaccination	**27.8%**

For the Pfizer COVID-19 vaccine, the frequency of systemic side effects was higher following the second dose among persons aged 16-55 years (and was again lower among those aged greater than 55 years).

AEFI reported after second dose among people aged 16-55 years of age

Symptom	Percentage
Injection site pain	77.8%
Fever	**15.8%**
Fatigue	59.4%
Headache	**51.7%**
Chills	**35.1%**
Muscle pain	**37.3%**
Joint pain	21.9%
Required paracetamol after vaccination	**45.0%**

Symptoms associated with COVID-19 infection that are NOT expected AEFI include acute respiratory symptoms – cough, sore throat, shortness of breath, runny nose, loss of sense of smell or taste. The presence of any respiratory symptoms should trigger isolation and testing for COVID-19.

While far more likely to be AEFI in the 48 hours following vaccination given the very low or absent community transmission of COVID-19 in Victoria at the present time, the initial vaccination program is understandably focussed on those at greatest risk of exposure to COVID-19, and the need to ensure this workforce has high levels of testing to protect them and prevent incursions of COVID-19 into the community as far as possible.

This advice is intended to provide some guidance to balancing the need for isolation and testing for COVID-19 in high-risk populations, with the workforce and practical implications of responding to expected AEFI in these groups. It will evolve as more information becomes available regarding the pattern of AEFI in the rollout of Phase 1a vaccination in Victoria and across Australia.

The development of these recommendations has included information drawn from the following resources:

- Australian Technical Advisory Group on Immunisation (ATAGI) - Clinical guidance on use of COVID-19 vaccine in Australia in 2021. Version 1.0 5 February 2021 (see Appendix 1)
- Coronavirus (COVID-19) - Case and contact management guidelines for health services and general practitioners. 28 January 2021, v 26.1 (see Appendix 2)
- Post Vaccine Considerations for Healthcare Personnel and Residents from the US Centers for Disease Control and Prevention (see Appendix 3)

This guidance is not intended to replace clinical judgement and reasoning, including consideration of epidemiological risk factors for acquisition and transmission.

Appendices

Appendix 1

Excerpts from the Australian Technical Advisory Group on Immunisation (ATAGI) - Clinical guidance on use of COVID-19 vaccine in Australia in 2021 <https://www.health.gov.au/resources/publications/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021>

Version 1.0, 5 February 2021

Isolation or testing for COVID-19 following adverse events (p15)

Testing for SARS-CoV-2 infection or implementing (non-medically recommended) isolation of someone who develops symptoms of fever, headache, fatigue or other systemic symptoms within and lasting for <48 hours after receipt of a COVID-19 vaccine is not necessarily required. If a vaccine recipient develops the type of vaccine-related adverse events (refer to Adverse events section above) and there is complete absence of respiratory symptoms (including loss of smell), it is more likely that they have an expected vaccine response.

For Comirnaty, the median time of onset of systemic adverse events was 1–2 days after vaccine receipt, with resolution in a median of 1 day.

Local public health guidance on criteria for SARS-CoV-2 testing varies depending, in part, on local epidemiology and outbreak management, and should be followed irrespective of a history of vaccination, unless otherwise directed.

Adverse events - Comirnaty (p12-13)

In the phase II/III trial, adverse events reported within 7 days following vaccination were very common but generally mild to moderate and well tolerated.

Injection site reactions were very common, particularly pain at the injection site (refer to Table 1). Injection site pain was reported with similar frequency after dose 1 and dose 2, but occurred slightly more frequently in the younger people aged 16 to 55 years (83% post dose 1 and 78% post dose 2) than in older adults aged >55 years (71% and 66 %, respectively). Injection site redness and swelling occurred in <10% of all participants. These local reactions were generally mild to moderate, had a median time of onset on the day after vaccination and resolved within 1 to 2 days.

Systemic adverse events reported after Comirnaty vaccination were more common following the second dose (refer to Table 1). **The median onset of systemic adverse events was 1–2 days after vaccine receipt, with resolution in a median of 1 day**.25 Adverse events were generally milder and less frequent in adults aged >55 years than in those aged 16–55 years. **Most adverse events were of mild to moderate severity and did not affect daily activities.** The reported rates of diarrhoea and vomiting did not differ between vaccine and placebo recipients.

The median duration of follow-up for adverse events was 2 months after the second dose. Lymphadenopathy, though uncommon (<1%), was more common in vaccine recipients than in placebo recipients (64 cases [0.3%] versus 6 cases [<0.1%]) and is likely related to the expected immune response to the vaccine. The cases of lymphadenopathy were generally mild to moderate and resolved after a median time of 10 days. There were four cases of Bell's palsy (acute peripheral facial paralysis) in the vaccination group (with onset at 3, 9, 37 and 48 days after a dose), respectively, and no cases in the placebo group.25 However, this observed frequency was consistent with the expected background rate of Bell's palsy in the general population and thus may not have a causal relationship to vaccination.

There were no substantive differences in the frequency of adverse events overall observed in the clinical trial by age, sex, race, ethnicity or baseline SARS-CoV-2 status subgroups. There was no evidence of

enhanced COVID-19 disease in vaccinated individuals who developed SARS-CoV-2 infection after completing vaccination, with only one severe case in the eight vaccine failures.31

Table 1: Frequency of select common adverse events reported within 7 days following each dose of Comirnaty (30µg per dose) in phase II/III trial (the US Food and Drug Administration, 2020)

Table col head	16-55 years of age		Over 55 years of age	
	Dose 1	Dose 2	Dose 1	Dose 2
Injection site pain	83.1%	77.8%	71.1%	66.1%
Fever	3.7%	15.8%	1.4%	10.9%
Fatigue	47.4%	59.4%	22.6%	50.5%
Headache	41.9%	51.7%	25.2%	39%
Chills	14.0%	35.1%	6.3%	22.7%
Muscle pain	21.3%	37.3%	13.9%	28.7%
Joint pain	11.0%	21.9%	8.6%	18.9%
Required paracetamol	27.8%	45%	19.9%	37.7%

Appendix 2

Excerpts from Coronavirus (COVID-19) - Case and contact management guidelines for health services and general practitioners. 28 January 2021, v 26.1

Who should be tested for COVID-19?

Asymptomatic testing

People without symptoms should **not** be tested except in special circumstances as directed by the department, such as:

- as part of an outbreak investigation/response (active case finding)
- all primary close contacts and returned international travelers at the start and the end of quarantine as directed by the department.
- prior to surgery as directed by the department
- as part of department-led enhanced surveillance to:
  - investigate how widespread COVID-19 is in the community, or
  - detect and reduce transmission, particularly in Higher prevalence groups and settings and Settings with high-risk of transmission.

Suspected case

Patients who meet the following clinical criteria should be tested:

Fever OR chills in the absence of an alternative diagnosis that explains the clinical presentation*

OR

Acute respiratory infection (e.g. cough, sore throat, shortness of breath, runny nose, loss of smell or loss of taste)**

*Clinical discretion applies; consider potential for co-infection (e.g. SARS-CoV-2 and influenza).

**Older people may present with other atypical symptoms including functional decline, delirium, exacerbation of underlying chronic condition, falls, loss of appetite, malaise, nausea, diarrhoea and myalgia.

Other clinical symptoms

People in the following groups should be tested if they have new onset of other clinical symptoms associated with COVID-19 (such as headache, myalgia, stuffy nose, nausea, vomiting, diarrhoea):

- People at high-risk of severe disease
- Higher prevalence groups and settings
- Settings with high-risk of transmission.

Clinical judgement and reasoning should be used, including consideration of epidemiological risk factors for acquisition and transmission.

Priority groups and settings

Priority settings and groups are those that are disproportionately affected by adverse health outcomes. Outbreaks in other groups have a disproportionate effect on the community, including provision of essential services and are therefore prioritised for public health management.

Higher prevalence groups and settings

A patient is considered higher risk for COVID-19 if:

- presenting with acute respiratory tract infection
- presenting with fever without another immediately apparent cause (for example, urinary tract infection or cellulitis)
- they are in Quarantine for any reason, including:
  - they have travelled overseas and have onset of symptoms within 14 days of return
  - they are a Primary close contact or Secondary close contact of a Confirmed Case of COVID-19
- they are a resident in an aged care facility where there is an outbreak
- they have lived in or visited a geographically localised area at high-risk of exposure – see Exposure sites

Settings with high-risk of transmission

Once a confirmed case of COVID occurs in these settings, the risk of rapid transmission is high.

Places where people **reside in groups**, for example:

- aged care facilities
- military residential settings
- boarding schools
- boarding houses
- homeless shelters
- correctional facilities
- remote industrial sites with accommodation
- Aboriginal rural and remote communities
- high density residential buildings.

Workplace settings where previous outbreaks have shown large scale amplification, for example:

- schools
- abattoirs
- other low temperature food processing, storage and supply chain facilities
- hotel quarantine
- freight drivers who travel interstate and are required to get tested through the National Freight Movement Protocol
- healthcare services
- aged care facilities
- nightclubs and bars
- workplaces with highly casualised or mobile workforces.

Appendix 3

US Centers for Disease Control and Prevention resources

- Post Vaccine Considerations for Healthcare Personnel <https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html>
- Post Vaccine Considerations for Residents <https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-residents.html>.

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