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| Victorian mpox (monkeypox) vaccination program |
| Guidelines – Version 16  1 February 2024 |
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Contents

[Introduction 4](#_Toc142399358)

[Background 4](#_Toc142399359)

[Vaccine program 5](#_Toc142399360)

[Mpox vaccines approved for use in Australia 5](#_Toc142399361)

[Vaccine priority roll-out 5](#_Toc142399362)

[Mpox vaccines 6](#_Toc142399363)

[Mpox vaccines for use in Victoria 6](#_Toc142399364)

[Contraindications 7](#_Toc142399365)

[Precautions 7](#_Toc142399366)

[Route 9](#_Toc142399367)

[Schedule 9](#_Toc142399368)

[Common side effects 10](#_Toc142399369)

[Other considerations 10](#_Toc142399370)

[Previous smallpox vaccination 10](#_Toc142399371)

[Interval after infection 10](#_Toc142399372)

[Coadministration 10](#_Toc142399373)

[Completing schedules commenced overseas 11](#_Toc142399374)

[Vaccine administration errors 11](#_Toc142399375)

[Vaccine Logistics 12](#_Toc142399376)

[Presentation 12](#_Toc142399377)

[Storage 12](#_Toc142399378)

[Vaccine procurement 12](#_Toc142399379)

[Cold chain management 13](#_Toc142399380)

[Identifying a cold chain breach 13](#_Toc142399381)

[Reporting a vaccine cold chain breach 13](#_Toc142399382)

[Clinical Guidelines 14](#_Toc142399383)

[Infection prevention and control 14](#_Toc142399384)

[Hand hygiene 14](#_Toc142399385)

[Personal protective equipment (PPE) 15](#_Toc142399386)

[Cleaning and disinfection 15](#_Toc142399387)

[Waste management and disposal 15](#_Toc142399388)

[Vaccination procedures 17](#_Toc142399389)

[Preparation 17](#_Toc142399390)

[Preparation for subcutaneous administration 17](#_Toc142399391)

[Subcutaneous administration 19](#_Toc142399392)

[Considerations for multi-use vials 22](#_Toc142399393)

[Intradermal administration technique 23](#_Toc142399394)

[After vaccination 27](#_Toc142399395)

[Vaccine safety 28](#_Toc142399396)

[Storage of multiple vaccine types in a shared location 28](#_Toc142399397)

[Safety Updates 28](#_Toc142399398)

[Vaccine administration errors 28](#_Toc142399399)

[Adverse Events Following Immunisation (AEFI) – Reporting and Management 30](#_Toc142399400)

[Workforce and Regulation 32](#_Toc142399401)

[Legislative and regulatory framework 32](#_Toc142399402)

[Workforce requirements 38](#_Toc142399403)

[Emergency response 39](#_Toc142399404)

[Additional resources 40](#_Toc142399405)

[Appendix 1: Contact information 41](#_Toc142399406)

[Appendix 2: Safe vaccine storage – data loggers 42](#_Toc142399407)

[Appendix 3: Cold chain management checklists 45](#_Toc142399408)

[Appendix 4 Vaccine temperature monitoring form for outreach mobile services 47](#_Toc142399409)

[Appendix 5: Guidance – differentiating anaphylaxis from acute stress response for vaccine providers and emergency departments 48](#_Toc142399410)

[Appendix 6: Factsheet – Adverse Events Following Immunisation (AEFI) - including vaccine error 51](#_Toc142399411)

[Appendix 7: Intradermal injection – skills and competency checklist 52](#_Toc142399412)

[Appendix 8: Document history and control 54](#_Toc142399413)

| **Changes since previous version** |
| --- |
| Vaccine ordering - How to order the mpox vaccine (updated) |

# Introduction

The Victorian mpox (monkeypox) vaccination program guidelines (guidelines) provide advice and describe the minimum requirements for delivery of the mpox vaccination program as part of Victoria’s Department of Health (the department) response to the mpox outbreak.

Considerations presented in this document will continue to be updated as advised by the Australian Technical Advisory Group on Immunisation (ATAGI) and other expert opinion informed by emerging evidence.

## Background

Mpox virus is a DNA virus in the Orthopoxvirus genus, which also includes the variola virus (which causes smallpox) and vaccinia virus (which is used in smallpox vaccines). Mpox was first discovered in 1958 and there have been small outbreaks since, predominantly in Western and Central Africa. Since the eradication of smallpox in 1980, mpox has become the most important Orthopoxvirus affecting humans, however, it causes less severe disease than smallpox.

It is hypothesised that the increase in the number of cases and geographic spread of mpox in recent years is related to decreasing immunity due to cessation of smallpox vaccination, which has proven to be protective against other Orthopoxvirus, including mpox virus. This may have resulted in waning vaccine-induced population immunity and no protection for younger age groups.

Mpox virus can be transmitted from infected animals to people, or from person to person. The natural animal reservoir for mpox virus remains unknown. Mpox does not spread easily between people. Transmission between people occurs via close contact with lesions, body fluids, respiratory droplets in prolonged face-to-face contact or fomites (such as contaminated clothing or linen)[[1]](#footnote-2).

Since May 2022, there has been a global increase in mpox infections in multiple countries where the illness is not usually seen. Mpox was first reported in Australia May 2022. The World Health Organization (WHO) declared the mpox outbreak a public health emergency of international concern on 23 July 2022. On 28 July 2022, Australia’s Chief Medical Officer (CMO) declared mpox to be a Communicable Disease Incident of National Significance (CDINS). On 25 November 2022, the CMO stood down Australia's CDINS declaration for mpox due to the reduced need for a nationally coordinated response. States and territories will continue to manage the risk of mpox in line with local arrangements, and people should remain vigilant and aware of mpox symptoms. [[2]](#footnote-3).

Smallpox vaccines contain the vaccinia virus, a poxvirus related to both smallpox and mpox. Previous guidance in Australia and other countries on the use of smallpox vaccine has focused on protection against smallpox infection. ATAGI advise that vaccines using the vaccinia virus for the prevention of smallpox are likely to be effective against mpox[[3]](#footnote-4).

# Vaccine program

## Mpox vaccines approved for use in Australia

There are 2 vaccines approved for use in Australia:

1. JYNNEOS®
2. ACAM2000™

JYNNEOS® is the preferred vaccine for use in Australia based on the safety profile and ease of administration. JYNNEOS® (modified vaccinia virus Ankara – Bavarian Nordic, MVA-BN) is a vaccine used to prevent infection with smallpox and mpox viruses. It is also known as IMVAMUNE® and IMVANEX®.

The best time for a person to get the vaccine is before they are exposed to mpox. The vaccine takes approximately 14 days before it is effective. People who have been vaccinated should ensure they follow public health advice to minimise their risk of contracting mpox during this time, including by limiting sexual partners.

If a person is exposed to mpox, receiving a vaccination within 4 days after the first exposure, will provide the highest chance of avoiding disease.

Anyone at-risk who is planning to travel to a country experiencing a significant outbreak should be vaccinated 4-6 weeks before they depart to allow for maximum protection[[4]](#footnote-5).

## Vaccine priority roll-out

The mpox vaccine JYNNEOS® program is available free of charge for specific priority groups in Victoria:

### Eligibility criteria:

**Post-exposure preventive vaccination (PEPV)**  for high risk close contacts of mpox cases, preferably within 4 days, in accordance with the [Australian Technical Advisory Group on Immunisation](https://www.health.gov.au/resources/publications/atagi-clinical-guidance-on-vaccination-against-monkeypox?language=en) <https://www.health.gov.au/resources/publications/atagi-clinical-guidance-on-vaccination-against-monkeypox> clinical guidance on mpox.

**Primary preventive vaccination (PPV)** has been expanded to include:

* All sexually active gay and bisexual men (cis and trans)
* Sexual partners of those above
* Sex workers
* Immunisation providers who are administering the ACAM2000™ smallpox vaccine.
* Laboratory workers who analyse specimens from mpox cases
* Vaccination may also be considered for PPV for healthcare workers at higher risk of exposure to patients with mpox, including primary care, sexual health clinics, hospital staff and others, based on local risk assessments. The risk of transmission should be also minimised by using [infection control measures](https://www.health.gov.au/resources/publications/iceg-interim-guidance-on-monkeypox-for-health-workers) <https://www.health.gov.au/resources/publications/iceg-interim-guidance-on-monkeypox-for-health-workers>

**\***A person will start to build protection in the days after their first dose with antibodies providing protection within 2 weeks. The mpox vaccine JYNNEOS® requires two doses for maximum protection.

JYNNEOS® mpox vaccines are available through certain sexual health clinics and select health services. People eligible for mpox vaccine can contact their Local Public Health Unit (LPHU) to find their local mpox vaccination provider. Refer to [Mpox (monkeypox)](https://www.health.vic.gov.au/infectious-diseases/mpox-monkeypox) <https://www.health.vic.gov.au/infectious-diseases/mpox-monkeypox> for LPHU details.

# Mpox vaccines

## Mpox vaccines for use in Victoria

JYNNEOS® is not registered for use in Australia and has not been formally assessed by the Therapeutic Goods Administration (TGA) but has been made available via a special emergency pathway under section 18A of the Therapeutic Goods Act 1989 (Cth).

1. The **preferred** regimen for the JYNNEOS® vaccine involves a subcutaneous (SC) route of administration with an injection volume of 0.5mL.
2. JYNNEOS® vaccine may also be administered by the intradermal (ID) route with an injection volume of 0.1mL in all people.[[5]](#footnote-6).

#### ****Table. 1- JYNNEOS® vaccine product information****

|  |  |
| --- | --- |
| **Product Information** | 0.5ml vial |
| **Type of vaccine** | highly attenuated vaccine that is replication-deficient (weakened live vaccinia virus) |
| **Presentation** | Suspension |
| **Age** | ≥18 years. (≥ 16 years following risk assessment – refer to [ATAGI](https://www.health.gov.au/resources/publications/atagi-clinical-guidance-on-vaccination-against-monkeypox?language=en)) |
| **Route & dosage** | Subcutaneous (SC) – 0.5ml (1 dose per vial) |
| Intradermal (ID)– 0.1ml (up to 5 doses per vial) |
| **Primary preventive vaccination (PPV)** | Schedule - 2 doses, **at least** 28 days apart |
| [P**ost-exposure preventive vaccination (PEPV)**](#_Post_exposure_prophylaxis) | As recommended by the department  1 dose (SC) **OR** 2 doses (at least 28 days apart if no infection and continuing exposure) |

## Contraindications

A person **must not** be given the JYNNEOS® vaccine if:

* they have had a sudden life-threatening allergic reaction to a previous dose or to any ingredient of the JYNNEOS® vaccine (active substance: modified vaccinia Ankara – Bavarian Nordic live virus; other ingredients: trometamol, sodium chloride; contains small amounts of chicken host-cell DNA, chicken protein, benzonase, gentamicin, and ciprofloxacin)
* they are unwell with a high temperature (>+38.5°C). It is recommended the vaccination is postponed until the person is well[[6]](#footnote-7).
* they have active symptoms of mpox. They are advised to seek further medical advice.

## Precautions

### Vaccination against mpox for people who are immunocompromised

Precautions must be applied in vaccinating people with the following conditions leading to immunocompromise. Updated ATAGI clinical guidance recommends that JYNNEOS® vaccine may be administered **via subcutaneous OR intradermal injection AND the second dose given at 28 days** among people who fulfill the following criteria for immunocompromise.These recommendations are informed by expert opinion and are subject to updates by ATAGI.

* Primary immunodeficiency or acquired immunodeficiency: HIV/AIDS with CD4<200, or uncontrolled viraemia
* Haematologic neoplasms: leukemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders, post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months), primary immunodeficiency,
* Receipt in the last 3 months any of:
* Chemotherapy or whole-body radiotherapy
* High-dose corticosteroids (≥ 20 mg of prednisone per day, or equivalent) for at least 14 days in 1 month, or pulse corticosteroid therapy
* Biological agents and other treatments that deplete or inhibit B- or T-cell function (anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin)
* Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate (more than 0.4 mg/kg/week), leflunomide, azathioprine (at least 3 mg/kg/day), 6-mercaptopurine (at least 1.5 mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus).

There are no data yet on the immune response to the JYNNEOS® vaccine in immunosuppressed individuals. JYNNEOS® vaccine is considered safe to use in people with weakened immune systems[[7]](#footnote-8).

People who are pregnant or breastfeeding.

* JYNNEOS® vaccine has not been formally studied in people who are pregnant or lactating. ATAGI advise there are no theoretical safety concerns relating to its use in these groups. However, vaccination should only be considered when the potential benefits outweigh any potential risk to the mother and baby[[8]](#footnote-9).

### Atopic dermatitis

* People with atopic dermatitis reported a higher frequency of local and general symptoms after vaccination compared with those without this condition.
* JYNNEOS® vaccine is considered safe to use in people with atopic dermatitis (eczema)[[9]](#footnote-10).

### Confirmed anaphylaxis to egg

* JYNNEOS® vaccine may contain trace residues of chicken egg protein and for individuals with confirmed anaphylaxis to egg; there is a theoretical risk of allergic reaction.

### History of keloid scarring

* Individuals with a history of keloid scarring are not recommended to receive JYNNEOS® via the intradermal route. The subcutaneous route is preferred.

### Aged under 18 years

* JYNNEOS® has not been approved for use in people under 18 years of age in regions/countries where it is registered. There are limited safety data for this age group. However, paediatric studies of other vaccines using modified vaccinia virus as a vector have not demonstrated significant safety concerns. In the current outbreak, people in high-risk GBMSM groups ≥16 years of age are recommended to receive vaccination as potential benefits outweigh potential risks[[10]](#footnote-11).

## Route

Subcutaneous

The **preferred regimen** for the JYNNEOS® vaccine involves a subcutaneous (SC) route of administration with an injection volume of 0.5mL.

ATAGI recommend the first dose of [**post-exposure preventive vaccination (PEPV)**](#_Post_exposure_prophylaxis) should be administered by the subcutaneous route.

ATAGI recommends that all individuals with a **history of keloid scarring**, receive the JYNNEOS® vaccine via subcutaneous route

Intradermal

JYNNEOS® vaccine may also be administered by the intradermal (ID) route with an injection volume of 0.1mL in all people.[[11]](#footnote-12)[[12]](#footnote-13) [[13]](#footnote-14). This technique must only be used by trained and competent immunisers to minimise inadvertent underdosing, leakage or subcutaneous injection

Refer to the [schedule](#_Schedule) and the [subcutaneous administration](#_Subcutaneous_administration) sections of the guidelines for further information.

## Schedule

#### Primary preventive vaccination (PPV)

Emergency approval for 2 doses, at least 28 days apart\*.

* Administered via subcutaneous **(preferred)** or intradermal route.
* Administered via subcutaneous route **to people with a history of keloid scarring**.
* Dose 2 should be administered **as close to 28 days after the first dose** as possible to people with certain conditions or on therapies leading to [immunocompromise](#_People_who_are)\*

#### Post-exposure preventive vaccination (PEPV)

Emergency approval following assessment and contact management by the Department of Health/Local public health units.

* Vaccination within 4 days of first exposure to an infectious case (vaccination between 4 to 14 days is anticipated to attenuate disease).
* Administer **1st dose via** [**subcutaneous route**](#_Subcutaneous_administration) to all individuals.
* Schedule is:
  + 1 dose – **OR**
  + 2 doses (if mpox infection has not occurred and there is ongoing exposure risk), at least 28 days apart\*. 2nd PEPV dose may be administered by the subcutaneous or intradermal route.

\***The second dose does not need to be repeated if given later than 28 days after the first dose**[[14]](#footnote-15)

## Common side effects

Common local side effects reported in clinical studies after receiving the JYNNEOS® vaccine include injection site pain, redness, swelling, induration(hardening) or itch.

Common systemic side effects include muscle aches, headache, fatigue, nausea, chills, fever.

People with atopic dermatitis (eczema) may be more likely to have side localised effects after vaccination compared to those without this condition

A clinical study comparing the safety of the intradermal route of administration to subcutaneous administration of this vaccine showed slightly increased rates of injection site redness and hardening in those who received an intradermal injection.[[15]](#footnote-16).

# Other considerations

## Previous smallpox vaccination

People assessed at high risk of mpox virus infection who have received a smallpox vaccine dose more than ten years ago are recommended to receive a single dose of the JYNNEOS® vaccine administered via the subcutaneous or intradermal route.

## Interval after infection

People who have had mpox virus infection during this outbreak are not recommended to be vaccinated at this time as they are likely to have immune protection from their infection.

## Coadministration

JYNNEOS® is a live attenuated **non-replicating vaccine** that vaccine may be given at the same time as other vaccines, preferably at different anatomical sites.

The live attenuated JYNNEOS® **vaccine** does not replicate and for the purposes of timing and spacing recommendations behaves like a non-live vaccine[[16]](#footnote-17). The standard principle of a 28 day interval between live vaccines[[17]](#footnote-18) (e.g. Yellow Fever vaccine) and JYNNEOS® vaccine does not apply.

It is not known if JYNNEOS® is associated with a risk of myocarditis. In cases of specific clinical concern, spacing JYNNEOS® and a COVID-19 vaccine apart by two weeks may be considered. People should consult their GP for an assessment to determine any increased risk for myocarditis and/or pericarditis and recommendation to delay administration of JYNNEOS® or COVID-19 vaccines.

Any decision to delay administration should be balanced against the need for earlier protection and the potential to miss an opportunity to vaccinate[[18]](#footnote-19).

## Completing schedules commenced overseas

People who have received one dose of JYNNEOS® (or equivalent vaccine) overseas should wait at least 28 days before they get a second dose of JYNNEOS®.

Vaccine administration errors

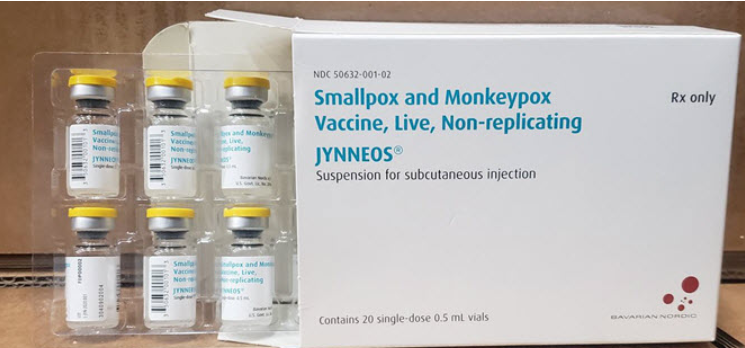
Interim recommendations for JYNNEOS® vaccine administration errors and deviations, reporting and management are available in the [vaccine errors](#_Adverse_Events_Following) section of these guidelines.

Vaccine Logistics

This section provides information specific to the presentation and storage for the JYNNEOS® (Bavarian Nordic) mpox vaccine.

## Presentation

**Figure 1 – JYNNEOS® vaccine presentation**



JYNNEOS® vaccine vial contains a suspension for injection.

Each vial comprises 0.5 mL suspension.

There are **20 vials per pack**. The pack dimensions are L: 9.8 x W: 12.90 x H: 4.7 cm.

When thawed, JYNNEOS ® vaccine is a milky, light yellow to pale white coloured suspension.

## Storage

JYNNEOS® mpox vaccine is **light sensitive**. Store the vaccine in the original packaging to protect the contents from light.

The vaccine has a storage temperature of -50°C. It will be delivered thawed and should be stored in a purpose-built vaccine refrigerator at temperature range (+2°C to +8°C) and not re-frozen. Once thawed, the vaccine must be kept at +2°C to +8°C and has a shelf life of 24 weeks.

On removal from storage temperature of -50°C a **revised expiry date label** will be applied to the box. Ensure vials are stored in the original box. Refer to the revised label to prevent vaccine administration error.

## Vaccine procurement

JYNNEOS® mpox vaccine is available to order through [Onelink online](https://www.onelinkonline.net/). <https://www.onelinkonline.net/>

Please note the following information before ordering the vaccine:

* The minimum amount that can be ordered is one box, containing 20 vials.
* Providers should commence with an order for one box and increase stock only as demand  indicates.

# Cold chain management

Vaccine cold chain management guidelines are contained within Department of Health [*National Vaccine Storage Guidelines ‘Strive for 5’* (2019) 3rd Ed.](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5) <https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5>.

These guidelines include recommendations to maintain cold chain at +2 to +8°C, for transport, storage and duration of any mobile or outreach clinics. Specific recommendations for mobile clinics may be found in sections 7, 9 and Appendix 7 of the [Strive for 5 guidelines](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5), and [Appendices 3 and 4](#_Appendix_3:_Cold) of these guidelines.

## Identifying a cold chain breach

A cold chain breach may occur when vaccine is stored outside the recommended temperature range of +2 to +8°C.

Any service storing vaccines must have a strategy for dealing with cold chain breaches. In case of a power failure or fridge breakdown, a backup plan should be practiced by all key personnel. Alternate purpose-built vaccine fridges/coolers should be able to contain the full vaccine stock supply.

The time and temperature must be recorded as soon as practicable after the breach commences.

## Reporting a vaccine cold chain breach

The following actions must be implemented:

* Isolate affected vaccines in the recommended temperature range.
* Label ‘**Do not use’**.
* Report **all** cold chain breaches **directly to** [immunisation@health.vic.gov.au](mailto:immunisation@health.vic.gov.au)

If advised to discard the vaccine, also complete the [vaccine and wastage report](https://forms.office.com/pages/responsepage.aspx?id=H2DgwKwPnESciKEExOufKCSmZxDa3xhBuPAJN3fVuqtUNjk1T0YwTFBNUlE4WUtUQlRMNjRJRUszTiQlQCN0PWcu&web=1&wdLOR=c65936C97-057B-4635-B1F7-5085EDD821EF).

**Patients who are inadvertently administered a cold chain breached vaccine:**

A cold chain breached vaccine that has been administered inadvertently is consider a [vaccine administration error](#_Adverse_Events_Following) and must be reported to SAEFVIC.

SAEFVIC operating hours are 9.00am to 4.30pm, Monday to Friday (except public holidays). The online system is always available.

* call SAEFVIC Immunisation Hotline (1300 882 924 option 1) and
* complete [SAEFVIC online report form](https://dhhsvicgovau.sharepoint.com/sites/RHPEMImmunisationUnit-DHHS-GRP/Shared%20Documents/General/Mpox/Clinical/Victorian%20Mpox%20vaccination%20guidelines/SAEFVIC%20online%20report%20form) <<https://www.safevac.org.au/Home/Info/VIC>>

# Clinical Guidelines

## Infection prevention and control

Standard precautions are work practices that achieve a basic level of infection prevention and control (IPC). IPC precautions and work practices are to be maintained by all staff, in all settings, at all times. Standard precautions include (but is not limited to):

* hand hygiene
* use of personal protective equipment (PPE)
* safe use and disposal of sharps
* waste management
* aseptic technique
* routine environmental cleaning.

Further IPC advice can be found in the NHMRC (2019) [Australian Guidelines for the Prevention and Control of Infection in Healthcare](https://www.nhmrc.gov.au/about-us/publications/australian-guidelines-prevention-and-control-infection-healthcare-2019) <https://www.nhmrc.gov.au/about-us/publications/australian-guidelines-prevention-and-control-infection-healthcare-2019> .

## Hand hygiene

Image of 5 moments of hand hygiene. 
Before touching patient
Before a procedure
After a procedure
After touching patient
After touching patient surroundingsStaff should perform **hand hygiene** before and after every encounter in accordance with the 5 Moments for Hand Hygiene. Glove use is not recommended when vaccinating. Glove use is not a substitute for hand hygiene and if used, hand hygiene must be performed before and after application of gloves and must be changed after each encounter.

Further information about the 5 Moments for Hand Hygiene and resources such as hand hygiene posters can be found at [Australian Commission on Safety and Quality in Health Care](https://www.safetyandquality.gov.au/our-work/infection-prevention-and-control/national-hand-hygiene-initiative/materials-support-improved-hand-hygiene-australia) website

**Figure 2 – Five moments of hand hygiene**

<https://www.safetyandquality.gov.au/our-work/infection-prevention-and-control/national-hand-hygiene-initiative/materials-support-improved-hand-hygiene-australia>

## Personal protective equipment (PPE)

Vaccination providers must keep up to date with the latest recommendations regarding use of PPE for the Victorian health sector during the mpox outbreak response and coronavirus pandemic response.

This is detailed on the department’s [Personal protective equipment (PPE)](https://www.health.vic.gov.au/covid-19-infection-prevention-control-guidelines/personal-protective-equipment-ppe) web page. <https://www.health.vic.gov.au/guide-conventional-use-ppe-covid-19-doc>

This web page includes guidance on risk ratings and associated changes to PPE requirements, advice regarding use of PPE such as extended use, and information on caring for skin and preventing facial injuring during extended use of respirators.

Assess risk levels associated with client health when attending post exposure preventative vaccination (PEPV). Recommended minimum level of required PPE includes fluid repellent surgical mask, eye protection such as face shield/goggles, water repellent gown and gloves. Further guidance is provided in the following resource, which is updated regularly [Infection Prevention and Control Expert Group Interim Guidance on Monkeypox for Health Workers](https://www.health.gov.au/resources/publications/iceg-interim-guidance-on-monkeypox-for-health-workers) . <https://www.health.gov.au/resources/publications/iceg-interim-guidance-on-monkeypox-for-health-workers>

## Cleaning and disinfection

* All providers should have an environmental cleaning and disinfection schedule. The schedule should list which surfaces are to be cleaned, how frequently, what cleaning and disinfectant product(s) to use and by whom.
* All surfaces should be free of clutter to enable cleaning to occur.
* All shared equipment is to be cleaned and disinfected between each use as per healthcare service protocols and manufacturers’ instructions.

Further information regarding environmental cleaning in the context of the COVID-19 pandemic can be found under the cleaning section of the department’s [Standard and transmission-based precautions](https://www.health.vic.gov.au/covid-19-infection-prevention-control-guidelines/standard-and-transmission-based-precautions)  <<https://www.health.vic.gov.au/covid-19-infection-prevention-control-guidelines/standard-and-transmission-based-precautions>>

Further information regarding environmental cleaning for mpox can be found [Infection Prevention and Control Expert Group Interim Guidance on Monkeypox for Health Workers](https://www.health.gov.au/resources/publications/iceg-interim-guidance-on-monkeypox-for-health-workers)

. <https://www.health.gov.au/resources/publications/iceg-interim-guidance-on-monkeypox-for-health-workers>

## Waste management and disposal

At minimum, standard precautions apply, and waste should be disposed of in line with state legislation regarding clinical and related waste. All waste should be segregated into appropriate waste streams, for example general waste and clinic waste, including sharps. Vaccination providers must follow their normal waste management processes for the disposal of vaccine vials. Further information regarding the management of clinical and related waste can be found at:

[Clinical and Related Waste Guidance – Supplement for Healthcare Staff](https://www.health.vic.gov.au/publications/clinical-and-related-waste-guidance-supplement-for-healthcare-staff) <https://www.health.vic.gov.au/publications/clinical-and-related-waste-guidance-supplement-for-healthcare-staff>

Environment Protection Authority (EPA) Victoria: [Clinical and related waste: Operational guidance](https://www.epa.vic.gov.au/about-epa/publications/iwrg612-1) <https://www.epa.vic.gov.au/about-epa/publications/iwrg612-1>

# Vaccination procedures

Providers must administer the JYNNEOS® vaccine in line with [ATAGI clinical guidance on vaccination against mpox](https://www.health.gov.au/resources/publications/atagi-clinical-guidance-on-vaccination-against-monkeypox?language=en).<https://www.health.gov.au/resources/publications/atagi-clinical-guidance-on-vaccination-against-monkeypox > and these guidelines.

For general information regarding vaccination procedures refer to the [Australian Immunisation Handbook,](https://immunisationhandbook.health.gov.au/contents/vaccination-procedures/administration-of-vaccines) <https://immunisationhandbook.health.gov.au/contents/vaccination-procedures/administration-of-vaccines>

* following the steps for pre-vaccination screening
* completing [JYNNEOS® vaccine consent](https://www.health.gov.au/resources/publications/monkeypox-mpx-consent-form-for-jynneosr-vaccination)  <https://www.health.gov.au/resources/publications/mpox-monkeypox-consent-form-for-jynneosr-vaccination>
* preparing for vaccination (equipment)
* administering vaccines
* steps after vaccination including r[eporting an adverse event following vaccination](#_Adverse_Events_Following_2) (AEFI)

## Preparation

Ensure that:

* vaccine refrigerator displays minimum/maximum temperatures within +2°C to +8°C range before removing the vaccine. Refer to [‘Strive for 5’ guidelines](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5)<https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5>.
* you take the correct vaccine from the refrigerator
* the vaccine is within the expiry date
* check interval between doses
* complete pre vaccination screening
* complete [JYNNEOS® vaccine consent](https://www.health.gov.au/resources/publications/mpox-monkeypox-consent-form-for-jynneosr-vaccination)
* wash your hands with soap and water or use an alcohol-based hand rub.

## Preparation for subcutaneous administration

Prepare the appropriate injection equipment for subcutaneous administration as per Immunisation handbook.

If more than one person is being vaccinated at the same visit, prepare vaccines for one person at a time to avoid potential error.

* JYNNEOS® vials should be kept refrigerated until use.
* Whenthawed, JYNNEOS® is a milky, light yellow to pale white coloured suspension.
* Swirl the vial gently before use for at least 30 seconds.

Remove the cap carefully to maintain sterility of the rubber bung. There is generally no need to wipe the rubber bung of single-dose vials with an alcohol swab if it is visibly clean. If there is visible contamination or the rubber bung is inadvertently touched, clean the bung with a single-use swab. Allow time for the bung to dry before drawing up the contents. For further guidance, please refer to state/territory or hospital infection prevention and control guidelines.

* use a new, sterile, disposable 19- or 21-gauge needle and a sterile syringe
* enter the vial through the centre of the bung and withdraw **a dose of 0.5 mL**
* Change the needle to a **25-27mm gauge, 16mm length needle,** before giving the injection. If using a safety needle system, draw up the vaccine, then draw back on the syringe to remove as much vaccine as possible from the tip of the needle. Then remove any air to the tip of the syringe without re-priming the needle.

**Figure 3 – process for checking and drawing up for subcutaneous injection**

|  |  |
| --- | --- |
| Check product informationCheck product information | Prepare equipment, dish, syringe, 19Gdrawing up needle & 25-27G needle for administration  Prepare equipment |
| Check vaccine vial expiryCheck vaccine label and expiry | Image JYNNEOS vial JYNNEOS® Vial |
| Insert 19G needle into the rubber bung & withdraw 0.5mls  Insert **19G needle** into the rubber bung & withdraw 0.5mls. | Change to 25-27mm gauge, 16mm length needleChange to **25-27mm gauge, 16mm length needle** |

## Subcutaneous administration

### Skin cleaning

If the skin is visibly clean, there is no need to wipe it with an antiseptic (such as an alcohol wipe). If you use alcohol or other disinfecting agents to clean skin that is visibly dirty, the skin mustbe allowed to dry before injecting the vaccine. This prevents inactivation of live vaccines and reduces the likelihood of irritation at the injection site.

### Subcutaneous injection technique

JYNNEOS® vaccine is administered by subcutaneous [injection](https://immunisationhandbook.health.gov.au/technical-terms#subcutaneous-injection) at a 45° angle to the skin into fatty tissue.

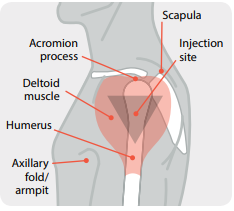
The standard needle for administering vaccines subcutaneously is a 25–27-gauge needle, 16 mm long, in all people.

If a vaccine that is registered for subcutaneous administration is inadvertently given intramuscularly, it is usually not necessary to repeat the dose. The immune response is unlikely to be affected[[19]](#footnote-20).

### Injection sites – adolescents and adults

The subcutaneous tissue over the deltoid muscle is the recommended site for vaccination in adolescents and adults. There is no difference in efficacy between a subcutaneous injection and a **deep** subcutaneous injection[[20]](#footnote-21).

**Identifying the injection site** – Deltoid ([Image CDC](https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-Injection-adult.pdf#:~:text=%C2%83%20Recommended%20site%3A%20Deltoid%20muscle%20in%20the%20upper,below%20the%20bone%20and%20above%20the%20axillary%20fold%2Farmpit.))

* expose the person’s arm completely from top of the shoulder to the elbow
* roll up the persons’ sleeve or remove their shirt if needed
* locate the shoulder tip (acromion) and the muscle insertion at the middle of the humerus (deltoid tuberosity)
* draw an imaginary inverted triangle below the shoulder tip using the anatomical markers
* the deltoid injection site is halfway between the acromion and deltoid Refer to the following images.

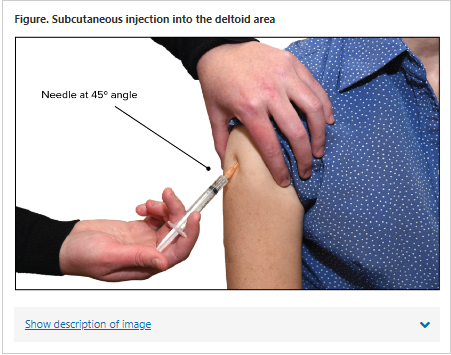
**[Figure 2. Subcutaneous injection into the deltoid area](https://immunisationhandbook.health.gov.au/node/505) - angle of insertion

Image [Australian Immunisation Handbook](https://immunisationhandbook.health.gov.au/contents/vaccination-procedures/administration-of-vaccines)    
Preparation for intradermal administration

JYNNEOS® vaccine may be administered via the intradermal route to people without a history of keloid scaring.

* A single dose 0.5 ml JYNNEOS® vial may be used as a JYNNEOS® multidose vial delivering up to five doses of 0.1 ml per injection for intradermal administration.

#### Prepare equipment

Prepare the appropriate injection equipment for the vaccine being given

* 1 ml low dead space syringe. Low dead space syringes minimise vaccine waste. 1ml syringe aids visibility of dose and stability for administration.
* JYNNEOS® vaccine vial
* **25 – 27 gauge needle to draw up** the recommended 0.1 ml dose. Larger gauge needles may be used, however smaller gauge needles may minimise vaccine wastage.
* **26 – 27-gauge 10 mm needle with short bevel** for administration
* Cotton ball (optional)
* Alcohol swabs

In group sessions, and where possible, prepare vaccines for one person at a time to maintain cold chain and avoid potential error.

* JYNNEOS® vials should be kept refrigerated until use.
* When thawed, JYNNEOS® vaccine is a milky, light yellow to pale white coloured suspension.
* Swirl the vial gently before use for at least 30 seconds.
* Remove the cap carefully to maintain sterility of the rubber bung.
* For subsequent access, clean the rubber bung with an alcohol swab and allow to dry every time the vial is accessed.

#### **Table 3 Procedures for drawing up multiple ID doses from a standard** JYNNEOS® **vial**[[21]](#footnote-22)

|  |  |  |  |
| --- | --- | --- | --- |
| **Step** | **Method for extraction of a single dose of JYNNEOS**® **vaccine at a time** | **Method for extraction of multiple doses of JYNNEOS**® **vaccine using different needles for drawing up and administration** | **Method for extraction of multiple doses of JYNNEOS**® **vaccine using the same needle for drawing and administration** |
|  | This method is recommended whenever one or more doses will be extracted from a vial and the remaining contents of the vial will be stored.  Use an aseptic technique throughout this procedure | This method is only appropriate where multiple doses from a vial are to be drawn up in immediate succession for administration within a single vaccination session.  Use an aseptic technique throughout this procedure.  Vials should never be stored with a drawing up needle attached. | This method uses the same needle to draw up and administer a vaccine dose.  Use an aseptic technique throughout this procedure.  This method of extraction may reduce risk of vaccine wastage |
| A | Attach a sterile drawing up needle to a sterile syringe and insert the needle through the bung into the vial. | Attach a sterile drawing up needle to a sterile syringe and insert the needle through the bung into the vial. | Attach a sterile **26-27 gauge** 10mm long injection needle to a sterile syringe and insert the needle through the bung into the vial |
| B | Draw up 0.1mL for a single dose. Do not touch the shaft of the needle and avoid moving the needle in and out of the vial. | Draw up 0.1mL for a single dose. Do not touch the shaft of the needle and avoid moving the needle in and out of the vial. | Draw up 0.1mL for a single dose. Do not touch the shaft of the needle and avoid moving the needle in and out of |
| C | Remove the filled syringe with the drawing up needle attached.  Do not leave the drawing up needle in the vial.  Avoid touching the top of the vial. | Remove the filled syringe from the drawing up needle, leaving the drawing up needle in the bung. | Remove the filled syringe with the needle attached. Avoid touching the top of the vial. |
| D | Detach the filled syringe from the drawing up needle and attach a new sterile injection needle (26-27-gauge, 10 mm long)  Mark the vial with time of first puncture.  Return the vial to +2 to +8°C storage  For subsequent access, clean the rubber bung with an alcohol swab and allow to dry every time the vial is accessed. | Attach a new sterile injection needle (26-27-gauge, 10 mm long) to the filled syringe, ready for administration to the patient.  Without delay or distraction, attach a new sterile syringe to the drawing up needle to draw up each 0.1mL dose.  Attach a new sterile injection needle (26-27-gauge, 10 mm long) to each filled syringe.  Up to 5 doses may be extracted if low dead space syringes are used.  Do not pool excess vaccine from multiple vials. | If doses are not going to be administered immediately, the needle must be sheathed (using safe aseptic technique).  Repeat the procedure for all required doses. |
| E | Administer the dose as soon as possible after drawing up.  Any unused doses from a punctured vial must be discarded after 8 hours, even if stored at +2 to +8°C. | The prepared dose can be administered immediately or must be used as soon as practical for the next recipient.  Until ready to be administered, store any prepared syringes in a suitably sized, clean container. Syringes must be protected from light, labelled with the drawing up time, expiry time and stored at +2 to +8°C.  Vaccines must be used within **1 hour if kept at room temperature or 8 hrs of first puncture of the vial.**  Discard any filled syringe where there is suspicion that contamination or a sterility breach has occurred.  Any unused doses that have been withdrawn into a syringe must be discarded after 8 hours, even if stored at +2 to +8°C. | The prepared dose can be administered immediately or must be used as soon as practical for the next recipient.  Until ready to be administered, store any prepared syringes in a suitably sized, clean container. Syringes must be protected from light, labelled with the drawing up time, expiry time and stored at +2 to +8°C.  Vaccines must be used **within 1 hour if kept at room temperature, or 8 hrs of first puncture of the vial.**  Discard any filled syringe where there is suspicion that contamination or a sterility breach has occurred.  Any unused doses that have been withdrawn into a syringe must be discarded after 8 hours, even if stored at +2 to +8°C |

## Considerations for multi-use vials

### Infection control

There is an increased risk of blood-borne viruses or bacterial contamination with the use of multi-dose vials due to an increased risk of cross contamination. These risks can be mitigated by:

* maintaining standard principles of infection control and strict aseptic technique when accessing multi-dose vials
* preparing doses of vaccines from multi-dose vials in a clean, designated medication preparation area
* following [Clinical Guidelines](#_Clinical_Guidelines) and [preparation of vaccine](#_Preparation_for_intradermal) process outlined above
* discarding a multi-dose vial if the vaccine’s integrity or sterility is compromised
* referring to the provider’s facility Infection Prevention and Control Guidelines.

### Pre-preparing syringes

Pre-preparing syringes with vaccines is not recommended due to:

* uncertainty of vaccine stability
* risk of contamination
* increased risk of potential errors in administration
* potential for vaccine wastage.

If you are in a setting where pre-preparing multiple doses is required, draw up the minimum number of doses necessary to keep the immunisation session running efficiently. These doses must be labelled with the date and time the vial was accessed, protected from light and used as soon as possible. Ensure [cold chain range +2 to +8C](#_Cold_chain_management) is maintained.

For outreach/mobile immunisation sessions: you should transport the vial and draw up the dose at the site of administration.

### Storage and usage

* Maintain cold chain storage of +2 to +8°C, protect from sunlight and freezing where required.
* Store vial in original box, with revised expiry date (time from removal from –50°C).
* Always label a multi-dose vial with the date and time of first access.
* For new vials: note the date and time the vial was first punctured. Once the vial is punctured, **you must discard it after 8 hours**[[22]](#footnote-23). Place vial back in fridge between every dose. Do not keep vial outside at room temperatures.
* Check vaccines for signs of deterioration, such as a change in colour or clarity. If there are signs of deterioration, refer to the vaccine product information. Do not use the vaccine.

## Intradermal administration technique

### Training

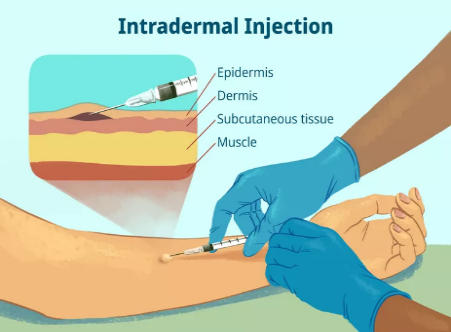
The intradermal injection technique requires additional training. Refer to the [Workforce and Regulation](#_Workforce_requirements_2) section of these guidelines. Only trained vaccination providers can use this technique.

### Skin cleaning

If the skin is visibly clean, there is no need to wipe it with an antiseptic (such as an alcohol wipe). If you use alcohol or other disinfecting agents to clean skin that is visibly dirty, the skin **must** be allowed to dry before injecting the vaccine. This prevents inactivation of live vaccines and reduces the likelihood of irritation at the injection site.

### Identifying injection sites – Intradermal

Intradermal administration involves injecting the vaccine superficially between the epidermis and the hypodermis layers of the skin. Evidence informing the intradermal use recommendation was based on vaccine administration at the inner aspect of the forearm however, other administration sites, such as the deltoid or the upper back below the scapula, are also acceptable[[23]](#footnote-24)

The chosen site should be free from lesions, rashes, moles and heavy dark tattoos. Injection should produce a noticeable pale elevation of the skin (bleb) [[24]](#footnote-25)  
Image – [Intradermal injection](https://www.verywellhealth.com/monkeypox-intradermal-jynneos-vaccine-6455582)

### Image of deltoid for visual identification of area for Intradermal injection and angle of insertion into skin layers.Alternative site for Intradermal injection

Identify the region where the deltoid muscle inserts into the humerus.

This is just above the midpoint of the upper arm[[25]](#footnote-26)

Consider appropriate patient position for access by the vaccinator to provide stability and ease of injection (lying or sitting).

Image - [Intradermal administration at the deltoid](https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html)

### Intradermal injection technique overview

* Use a **short (10 mm) 26–27 gauge needle with a short bevel** in all people.
* Inject vaccine into the inner (volar) surface of the forearm or over the deltoid.
* Stretch the skin between a finger and thumb. Insert the bevel to a distance approximately 2 mm into the dermis, with the bevel facing upwards. The bevel should be visible through the transparent epidermis.
* You should feel considerable resistance as you give the injection. If there is no resistance, the needle may be in the subcutaneous tissues. A correct [intradermal injection](https://immunisationhandbook.health.gov.au/technical-terms#intradermal-injection) should raise a blanched bleb of about 7 mm diameter that looks like orange peel.
* If the injection is not intradermal, withdraw the needle and repeat at a new site.
* No more than one additional ID injection should be attempted, by a vaccinator who is confident in the technique. Alternatively give 0.5mL dose subcutaneously (withdrawn from a new vial).

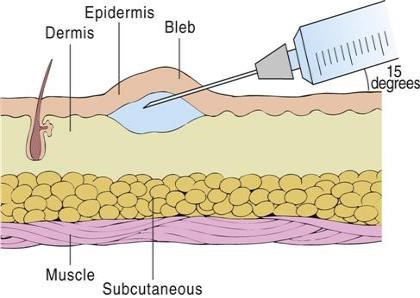
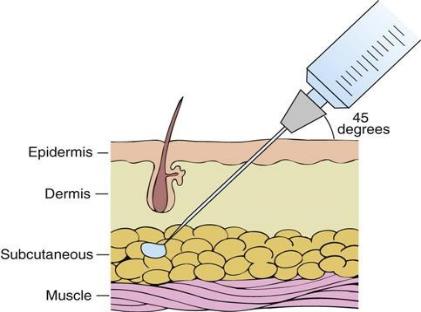
A person who presents for their second JYNNEOS® vaccine dose who is still experiencing erythema or induration at the site of intradermal administration of the first vaccine dose (e.g., the forearm) may have the second dose administered via the subcutaneous route or intradermally in the contralateral forearm.

Refer [to Centres for Disease Prevention and Control (CDC)](https://www.youtube.com/watch?v=TLv1mR6mECQ) for a video of the intradermal technique. <<https://www.youtube.com/watch?v=TLv1mR6mECQ>>

### Angle of insertion – Intradermal

While pulling the skin taut, position the needle with the bevel facing up and insert the needle at a 5-to-15-degree angle into the dermis.

**Image -Correct** angle of insertion **Image** – **Incorrect** angle of insertion for ID

Images – [Nurse Key Parenteral-administration-intradermal-subcutaneous-and-intramuscular-routes/](https://nursekey.com/11-parenteral-administration-intradermal-subcutaneous-and-intramuscular-routes/)

#### Table 4 Method of intradermal injection

|  |  |
| --- | --- |
| Ensure adequate lighting in vaccination area and that patient has a comfortable area to rest forearm for the intradermal vaccination procedure.  Stretch the skin between a finger and thumb on the forearm. | Steps in Intradermal injection Stretch the skin |
| Insert the bevel into the dermis, bevel uppermost, to a distance of about 2 mm. The bevel should be visible through the transparent epidermis. The angle of the needle insertion should be 5-15° to skin plane | Steps in Intradermal injection Insert the bevel into the dermis, bevel uppermost, to a distance of about 2 mm. Angle of the needle insertion should be 5-15° to skin plane |
| You should feel considerable resistance as you give the injection. If there is no resistance, the needle may be in the subcutaneous tissues. A correct [intradermal injection](https://immunisationhandbook.health.gov.au/technical-terms#intradermal-injection) should raise a blanched bleb of about 7 mm diameter that looks like orange peel. | Steps in Intradermal injection A correct intradermal injection should raise a blanched bleb of about 7 mm diameter that looks like orange peel |
| If the injection is not intradermal, withdraw and replace the needle, and repeat at a new site.  No more than one additional ID injection should be attempted, by a vaccinator who is confident in the technique. | Steps in Intradermal injection If the injection is not intradermal, withdraw and replace the needle, and repeat at a new site |

Images – [CDC How to administer JYNNEOS vaccine intradermally](https://www.bing.com/videos/search?q=monkeypox+cdc+intradermal+vaccination+youtube&&view=detail&mid=EEB3C443954A620900B3EEB3C443954A620900B3&&FORM=VRDGAR&ru=%2Fvideos%2Fsearch%3Fq%3Dmonkeypox%2Bcdc%2Bintradermal%2Bvaccination%2Byoutube%26FORM%3DHDRSC4)

## After vaccination

Observe patient for 15 minutes after vaccination or 30 minutes if they have a history of anaphylaxis to gentamycin, ciprofloxacin, chicken or egg protein[[26]](#footnote-27).

Following vaccination, the patient should be given written [Information about the JYNNEOS® vaccine](https://www.health.gov.au/resources/publications/mpox-monkeypox-information-on-jynneosr-vaccine) and mpox. <https://www.health.gov.au/resources/publications/mpox-monkeypox-information-on-jynneosr-vaccine>

This should include possible reactions to the vaccine, how to manage side effects, and when and where to seek further advice if required. The patient should be advised to monitor for fever and, if individuals are concerned about their health at any time, they should seek advice from their immunisation provider, GP or Emergency department.

# Vaccine safety

## Storage of multiple vaccine types in a shared location

Recommendations to reduce the risk of administration errors and vaccine wastage when sites are managing different vaccines:

* Dedicate sessions for the mpox JYNNEOS® vaccine
* Assign dedicated staff members at the vaccination site, to administer only one type of the vaccine
* Ensure clear labelling of the shelf/location where each type of vaccine vials is located, to reduce the risk of selection error

## Safety Updates

SAEFVIC (Surveillance of Adverse Events Following Vaccination in the Community) provide vaccine safety surveillance service in Victoria, for reporting any significant adverse events following immunisation (AEFI) and vaccine administration error. SAEFVIC confidentially collects, analyses, provides clinical advice, and reports data about significant AEFI and vaccine administration errors as part of monitoring vaccine safety in Victoria. SAEFVIC will closely monitor vaccine safety surveillance of the mpox vaccination program.

Further information and the SAEFVIC and the reporting portal may be found at [SAEFVIC](https://www.mcri.edu.au/research/research-areas/infection-and-immunity/saefvic) <https://www.safevac.org.au/Home/Info/VIC>.

## Vaccine administration errors

Immunisation errors can include errors in vaccine storage, handling, preparation, or administration. Vaccination administration errors should be reported to SAEFVIC for vaccine safety surveillance review. For more information on submitting a SAEFVIC report refer to:

* [SAFEVAC Reporting](https://www.safevac.org.au/Home/Info/VIC) <https://www.safevac.org.au/Home/Info/VIC>
* Email: [enquiries@saefvic.org.au](mailto:enquiries@saefvic.org.au)
* Ph: 1300 882 924 (option 1)

Cold chain breaches (CCB) are reportable to the Department of Health. Report **all** cold chain breaches **directly** to [immunisation@health.vic.gov.au](mailto:immunisation@health.vic.gov.au)

Interim recommendations for JYNNEOS® vaccine administration errors and deviations are available in table below. Further advice from ATAGI is expected to follow.

Table 5. Interim recommendations for JYNNEOS® vaccine administration errors and deviations. Source[: Centres for Disease Control and Prevention](https://www.cdc.gov/poxvirus/mpox/interim-considerations/errors-deviations.html) <<https://www.cdc.gov/poxvirus/mpox/interim-considerations/errors-deviations.html>>

|  |  |  |
| --- | --- | --- |
| **Error Type** | **Administration error/deviation** | **Interim Recommendation** |
| **Site** | Incorrect site | Do not repeat dose. Inform the recipient of the potential for local and systemic adverse events. |
| **Route** | Incorrect route resulting in lower-than-authorised dose administered (e.g., inadvertent subcutaneous administration of 0.1 mL when intradermal route was intended, i.e., no visible “wheal” was formed). | Repeat dose immediately via intended route (no minimum interval). No more than one additional ID injection should be attempted, by a vaccinator who is confident in the technique.  Alternatively give 0.5mL dose subcutaneously (withdrawn from a new vial).  Repeated dose should be placed at least 2.5cm away from the inadvertent site. |
| **Route** | Other incorrect route (e.g., inadvertent intramuscular administration, when subcutaneous route was intended). | Do not repeat dose. Inform the recipient of the potential for local and systemic adverse events. |
| **Dosage** | If the incorrect dosage is administered, resulting in a lower-than-authorized dose (e.g., recipient pulled away, leaked out of a syringe), | If the process of administering a vaccine is interrupted (such as by syringe–needle disconnection) and **most** of the dose has not been given, repeat the whole dose as soon as practicable[[27]](#footnote-28).  Repeated dose should be placed at least 2.5cm away from the inadvertent site placement |
| **Dosage** | If the incorrect dosage is administered, resulting in a higher-than-authorized dose (e.g., >0.1 mL administered ID). | Do not repeat dose. Inform the recipient of the potential for local and systemic adverse events. |
| **Intervals** | Interval between first and second dose less than the recommended minimum interval. | Repeat dose after the dose given in error by at least the recommended interval of 28 days **if** the person is  [immunocompromised](#_Vaccination_against_mpox). Otherwise, do not repeat dose. |
| **Intervals** | Interval between first and second dose greater than the recommended interval. | Do not restart the series. Administer the second dose as soon as possible. |
| **Storage and handling** | Dose administered after improper storage and handling (i.e., temperature excursion) | Contact the Immunisation Unit via email – [immunisation@health.vic.gov.au](mailto:immunisation@health.vic.gov.au) |
| **Storage and handling** | Dose administered past the expiration/beyond-use date | Contact the Immunisation Unit via email – [immunisation@health.vic.gov.au](mailto:immunisation@health.vic.gov.au) |

## Adverse Events Following Immunisation (AEFI) – Reporting and Management

Vaccination providers should reasonably anticipate three medical emergencies associated with vaccination: fainting, hyperventilation, and anaphylaxis. All clinical staff should have up to date CPR training and immuniser training in managing anaphylaxis response.

### Steps for managing an adverse event following immunisation

An adverse event following immunisation (AEFI) is an unwanted or unexpected event following the administration of a vaccine(s). AEFIs may be caused by a vaccine(s) or may occur by coincidence (that is, the event would have occurred regardless of vaccination). AEFIs also include conditions that may occur following the incorrect handling or administration of a vaccine.

The following documents contain official general advice on managing medical emergencies associated with vaccination:

* [Recognising and treating anaphylaxis[[28]](#footnote-29)](https://immunisationhandbook.health.gov.au/resources/handbook-tables/table-recognition-and-treatment-of-anaphylaxis)
* [ATAGI (2022) Managing anaphylaxis[[29]](#footnote-30)](https://immunisationhandbook.health.gov.au/resources/tables/table-recognition-and-treatment-of-anaphylaxis)
* [Preparing an anaphylaxis response kit[[30]](#footnote-31) | The Australian Immunisation Handbook (health.gov.au)](https://immunisationhandbook.health.gov.au/resources/publications/preparing-an-anaphylaxis-response-kit)
* [Anaphylaxis Clinical Care Standard](https://www.bettersafercare.vic.gov.au/clinical-guidance/emergency/anaphylaxis-adults) developed by Safer Care Victoria[[31]](#footnote-32)
* [Appendix 6 – Guidance for differentiating anaphylaxis from acute stress response for vaccine providers and emergency departments](#_Appendix_11:_Factsheet)
* [MVEC resources and video on Allergy and COVID-19 vaccines](https://mvec.mcri.edu.au/references/covid-19-vaccines-and-allergy/)[[32]](#footnote-33)

### Fainting and syncopal seizures

There may be variations in the frequency and type of adverse events following immunisation, with anxiety/pain related reactions to any vaccine is likely to be higher for adolescents than adults. An Australian study[[33]](#footnote-34) showed the occurrence of syncope and seizures following vaccination administrating is higher in children and adolescents compared to adults.

While most cases of fainting and syncopal seizures are not serious, some people may sustain injury from high impact falls, so it is important to have a safe vaccinating environment and an awareness of the clinical signs of a faint/syncope.

### Serious or unexpected AEFI

Serious or unexpected AEFI require urgent direct notification:

* via the online <https://www.safevac.org.au/Home/Info/VIC> <https://www.safevac.org.au/Home/Info/VIC>
* .Ph: 1300 882 924 (option 1)

### Reporting an immediate AEFI (at place of vaccination)

All medically attended AEFI must be reported to SAEFVIC immediately after the event. Medically attended events are defined as medical assistance from the onsite clinician, paramedic attendance or transfer to an emergency department or hospital admission.

Please refer to [Appendix 6 Adverse events following immunisation (AEFI)](#_Appendix_11:_Factsheet) for a factsheet that can be printed out and displayed for vaccination site staff to easily locate contact information.

### Reporting a delayed AEFI (outside place of vaccination)

Vaccinees are advised to seek medical attention from their local general practitioner or emergency department should a delayed AEFI occur. Following medical attention, clinicians should report an AEFI to SAEFVIC via usual practices either online [www.saefvic.org.au](http://www.saefvic.org.au) or by phone call (as above). Vaccinees can find more information online at [https://saefvic.online/report](https://urldefense.proofpoint.com/v2/url?u=https-3A__saefvic.online_report&d=DwMFaQ&c=JnBkUqWXzx2bz-3a05d47Q&r=Prstbg9FDDpDwrfiVC5_3hkxcuzTzLWe8RCWlj3iF4M&m=oNYP1VPAYmyOgkSydAaKPAAWu3xAeONRn3GAhmmzzCk&s=ba84EnFRi1WH_Ayf00F5LLHEVBOr5KlQEn3JPbqY_Tk&e=).

### Managing anaphylaxis and other serious AEFI

Serious AEFI such as anaphylaxis is a rare adverse event that can occur after administration of a vaccine.

It is recommended all vaccination providers is the ability to monitor, manage and report AEFIs and to have incident management measures in place (and documented), ensuring staff are fully informed of any relevant procedures and able to report any clinical incident. Vaccination sites also have a duty of care to respond to other medical emergencies that may occur on site.

Refer to guidance contained in [Appendix 5: Guidance – differentiating anaphylaxis from acute stress response for vaccine providers and emergency departments](#_Appendix_5:_Guidance).

Vaccination providers should consider the following below for each vaccination site:

* All staff working at the vaccination site should be trained on anaphylaxis management, including their points of escalation in the case of a medical emergency.
* Vaccination sites (including all mobile clinics) that refer to a standard emergency response procedure should clearly document how their emergency response applies at their vaccination site
* Anaphylaxis kits must be available onsite where the vaccination program is occurring.
* An experienced clinician, who is trained and authorised to possess and administer adrenaline, must be available on site and able to respond in the case of anaphylaxis following vaccine administration.
* Anaphylaxis training is recommended for all staff administering the vaccinates. The recommended training is the Australian Society of Clinical Immunology and Allergy (ASCIA) [Anaphylaxis e-Learning for Health Professionals.](http://etraininghp.ascia.org.au/anaphylaxis)
* AEFI involving adrenaline administration, defibrillator use, transfer to hospital care, life-threatening AEFI, or death, require IMMEDIATE notification to [SAEFVIC](https://www.safevac.org.au/Home/Info/VIC) <www.saefvic.org.au>.

# Workforce and Regulation

## Legislative and regulatory framework

Vaccination providers should be familiar with the legal and legislative framework in which they operate. The information provided in this section is not intended to serve as legal advice. Vaccination providers are advised to seek independent advice from legal professionals.

### Obtaining consent for vaccination

There is a legal obligation to obtain valid consent prior to a medical procedure, including administering a vaccine. Verbal or implied consent is acceptable and written consent is not required (although it may be obtained in some settings as per local practices). Refer to the Commonwealth Consent form for JYNNEOS® vaccination[[34]](#footnote-35)

For consent to be considered legally valid, the Australian Immunisation Handbook[[35]](#footnote-36) describes the following elements as necessary:

* It must be given by a person with legal capacity, and of sufficient intellectual capacity to understand the implications of receiving a vaccine.
* It must be given voluntarily in the absence of undue pressure, coercion, or manipulation.
* It must cover the specific procedure that is to be performed.
* It can only be given after the potential risks and benefits of the relevant vaccine, the risks of not having it, and any alternative options have been explained to the person.
* The person must have the opportunity to seek more details or explanations about the vaccine or its administration.
* The information must be provided in a language or by other means that the person can understand. Where appropriate, involve an interpreter or cultural support person.
* Consent must be obtained before vaccination, after establishing that there are no medical condition(s) that contraindicate vaccination.

Discussions, statements, and decisions about treatment can be recorded in the person’s health care record, including but not limited to the outcomes of any assessment of the decision-making capacity of the person.

### Consent for persons aged under 18 years

For certain procedures, including vaccination, an adolescent may be determined to be mature enough to understand the risks and benefits, and thereby provide informed consent. This principle applies to people under the age of 18 years requesting mpox vaccination. In accordance with the [*Medical Treatment Planning and Decisions Act 2016 (Vic)*](https://www.legislation.vic.gov.au/in-force/acts/medical-treatment-planning-and-decisions-act-2016/009) (MTPD Act) <<https://www.legislation.vic.gov.au/in-force/acts/medical-treatment-planning-and-decisions-act-2016/009>>, a medical treatment decision maker for an adolescent (‘child’ is the term used within the MTPD Act) will be the adolescent’s parent or guardian or other person with parental responsibility for the adolescent who is reasonably available and willing and able to make the medical treatment decision. For the purposes of the MTPD Act, an adolescent (or child) means any person under the age of 18 years.

For adolescents under the age of 18 years, who are presenting for mpox vaccination without a parent, guardian or other medical treatment decision maker, capacity to consent will be assessed based on the principles outlined in *Gillick v West Norfolk and Wisbech Area Health Authority*. Adolescents assessed as being ‘*Gillick competent*’ can consent to the mpox vaccination[[36]](#footnote-37). These principles are enshrined in section 4 of the MTPD Act.

Where possible, mpox vaccination providers will use experienced immunisers to provide information about the mpox vaccine and obtain consent for the vaccination of adolescents against mpox.

Before administering the mpox vaccination to a person under the age of 18 years, the immuniser must assess whether:

1. the adolescent understands the information relevant to the decision to be vaccinated and the effect of that decision (that is, they understand an explanation of the information given by the immuniser in a way that is appropriate to the adolescent’s circumstances, whether by using modified language, visual aids or any other means);

2. the adolescent can retain that information to the extent necessary to make the decision;

3. the adolescent uses or weighs that information as part of their decision-making process; and

4. the adolescent communicates the decision, and their views and needs as to the decision in some way, including by speech, gestures or other means.

There is no presumption that an adolescent has capacity; therefore, it is important to consider all of the above factors in relation to the adolescent’s individual circumstances.

An adolescent should be provided with practicable and appropriate support in making and communicating any decision as to vaccination. This includes:

* using information or formats tailored to the particular needs of the person;
* communicating or assisting a person to communicate the person’s decision;
* giving a person additional time and discussing the matter with the person; and
* using technology that alleviates the effects of a person’s disability.

Immunisers who are assessing whether an adolescent has decision making capacity should take reasonable steps to conduct the assessment at a time and in an environment in which the adolescent’s decision-making capacity can be most accurately assessed.

Immunisers who decide not to administer the mpox vaccine based on their assessment of the individual’s capacity to provide informed consent in line with the principles above, should refer the individual back to their medical practitioner.

If the adolescent refuses a mpox vaccination that a parent and/or guardian has given consent for, respect the adolescent’s wishes.

As detailed above, discussions, statements and decisions about treatment can be recorded in the person’s health care record, including but not limited to the outcomes of any assessment of the decision-making capacity of the person.

### Keeping and accessing records related to vaccination

It is the responsibility of the vaccination service provider to ensure that the administration of all vaccination records complies with relevant legislation.

### Privacy

Each vaccination provider should have its own privacy policy. Copies should be readily available to the public upon request, including at immunisation sessions.

Providers should be mindful of client privacy when conducting administrative procedures, collecting personal information and administering vaccines.

In addition to the above legislation, the use and management of vaccination records are also governed by the following:

* [*Public Records Act 1973*](https://www.legislation.vic.gov.au/in-force/acts/public-records-act-1973/041)<<https://www.legislation.vic.gov.au/in-force/acts/public-records-act-1973/041>
* [*Health Insurance Commission Act 1973*](https://urldefense.proofpoint.com/v2/url?u=https-3A__www.legislation.gov.au_Details_C2004A00100&d=DwMGaQ&c=JnBkUqWXzx2bz-3a05d47Q&r=zQI8nIUxsvUTvUnJCXgiVSy5OkIlD-RWtx5voOru6N0&m=jJt8K5iQQeOnfA8OZU2YDCRaP83ffR3oiQMvqceCQck&s=rz_kdWrVrFKBWQ5Vxrx-5b7SM4we53F4LKM7PsYPsuE&e=)<<https://www.legislation.gov.au/Details/C2004A00100>>
* [Australian Standards for Record Management](https://urldefense.proofpoint.com/v2/url?u=https-3A__www.efilecabinet.com_as-2Diso-2D15489-2Daustralian-2Drecords-2Dmanagement-2Dstandard&d=DwMGaQ&c=JnBkUqWXzx2bz-3a05d47Q&r=zQI8nIUxsvUTvUnJCXgiVSy5OkIlD-RWtx5voOru6N0&m=jJt8K5iQQeOnfA8OZU2YDCRaP83ffR3oiQMvqceCQck&s=x2dGkWhO7WopLXwV7f_EJIHWngN6w2P_1kzoPfiuNas&e=) – AS ISO 15489 <[AS ISO 15489 Australian Records Management Standard (efilecabinet.com)](https://www.efilecabinet.com/as-iso-15489-australian-records-management-standard/)>

Health services are also subject to confidentiality obligations pursuant to the *[Health Service Act 1988](https://www.legislation.vic.gov.au/in-force/acts/health-services-act-1988/180)* <https://www.legislation.vic.gov.au/in-force/acts/health-services-act-1988/180>. A health service must not disclose any information acquired except to carry out functions, exercise powers or disclose information authorised to be disclosed under *the Health Services Act 1988*, or another Act. The disclosure of information by a health service is permitted in circumstances where the person to whom the information relates has given their prior consent to the disclosure.

All health services should ensure they are aware of their obligation under the *Health Services Act 1988* and takes steps, including but not limited to ensuring the notification requirement below are complied with, to ensure that the health service remain compliant with its confidentiality obligations.

### Privacy notification

As routine practice, vaccinees or their guardians should be informed that immunisation information will be passed to Australian Immunisation Register and under what circumstances this information is released.

In accordance with the *Health Records Act 2001* guardians and adult vaccinees should be given appropriate notice regarding the use of health information collected as part of the immunisation service[[37]](#footnote-38).

Health privacy principle (HPP) 1.4 extracted from the *Health Records Act 2001* is reprinted below and outlines the information that should be notified to individuals in relation to their health information.

*At or before the time (or, if that is not practicable, as soon as practicable thereafter) an organisation collects health information about an individual from the individual, the organisation must take steps that are reasonable in the circumstances to ensure that the individual is generally aware of:*

*(a)    the identity of the organisation and how to contact it; and*

*(b)    the fact that he or she is able to gain access to the information; and*

*I    the purposes for which the information is collected; and*

*(d)    to whom (or the types of individuals or organisations to which) the organisation usually discloses information of that kind; and*

*I    any law that requires the particular information to be collected; and*

*(f)        the main consequences (if any) for the individual if all or part of the information is not provided.*

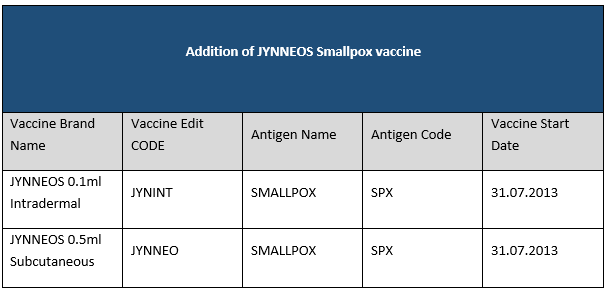
### Reporting data to the Australian Immunisation Register (AIR)

It is strongly recommended vaccination service providers report all monkeypox vaccinations to the AIR. Due to the modes of transmission of mpox, it is recognised that some people may not wish for their record of vaccination for mpox be uploaded to AIR. In such cases, respect the wishes of the patient and do not upload their AIR record. A record in the patient’s clinical record must still occur.

The following manner and period of reporting will apply:

* Manner of reporting: electronic or if this is not reasonably practical then in written form
* Reporting period: within 24 hours, and no more than 10 working days after the vaccination
* Personal information: Medicare number (if applicable), name, date of birth, gender
* Vaccine information: brand name, dose number and batch number, date of administration
* Provider information: provider number, name and contact details.

**Table 5 – JYNNEOS® vaccine codes for reporting doses to AIR**



Practice management software is required to send data about vaccines to the AIR. If a service provider does not have practice management software or they need to view an individual’s immunisation record held on the AIR, they can access the AIR using [Health Professional Online Services (HPOS)](https://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos) <<https://www.servicesaustralia.gov.au/hpos>>. Further information about how to register and access the AIR is available from Services Australia refer to [PRODA (Provider digital access)](https://www.servicesaustralia.gov.au/organisations/business/services/proda-provider-digital-access) <https://www.servicesaustralia.gov.au/organisations/business/services/proda-provider-digital-access>

### Feedback and complaints

Consumer feedback is a valuable resource and should be encouraged in all aspects of the program. Complaints should be responded to in consultation with the consumer to reach suitable resolution, outcomes should then be used to drive quality improvement.

Systems should be in place to ensure:

* consumers and their needs are key organisational priorities
* consumers are provided with the relevant knowledge to participate fully in their care to extent they wish
* clear, open and respectful communication exists between consumers and staff at all levels of the health system
* services respond to the diverse needs of consumers and the community
* the rights and responsibilities of consumers are respected and promoted to the community, consumers, carers, clinicians and other health service staff, as required by the Australian Commission on Safety and Quality in Health Care [Australian Charter of Healthcare Rights](https://www.safetyandquality.gov.au/consumers/working-your-healthcare-provider/australian-charter-healthcare-rights) <https://www.safetyandquality.gov.au/our-work/partnering-consumers/australian-charter-healthcare-rights>
* consumers are actively invited to provide feedback on their experiences of care
* services learn from and act on the feedback on clinical care and service delivery as provided by consumers in order to make improvements
* consumers are provided with the opportunity and information to fully participate in organisational processes for planning, monitoring and improving services
* consumer participation processes are monitored for their effectiveness in empowering consumers to fully partner in their care
* complaints are responded to compassionately, completely and in a timely fashion, with feedback provided to all parties about the action resulting from their input
* issues arising from complaints are analysed, reported and used to improve care and services.

For an overview of all contact pathways please refer to [Appendix 1 – Conta](#_Appendix_1:_Contact_1)ct Information.

### Occupational health and safety

[*The Occupational Health and Safety Act 2004*](https://www.worksafe.vic.gov.au/occupational-health-and-safety-act-and-regulations)*[[38]](#footnote-39)* and related regulations aim to keep Victorian workplaces safe. The Act, in conjunction with the [Australian Guidelines for the Prevention and Control of infection in Healthcare 2019](https://www.nhmrc.gov.au/about-us/publications/australian-guidelines-prevention-and-control-infection-healthcare-2019)[[39]](#footnote-40) should guide the development of occupational health and safety protocols of the services. Vaccination providers should maintain up to date, easily retrievable protocols relevant to their scope of practice in immunisation concerning all relevant aspects of occupational health and safety including, but not limited to:

* blood spills
* disposal of infectious waste
* needle stick injuries
* medication errors
* equipment used
* using multidose vials
* repetitive strain injury
* prevention of transmission of infectious diseases in the health care setting
* safety of interior and exterior of venues where immunisation sessions are held

All staff should be familiar with the content of the protocols and how to follow them.

### Professional indemnity insurance

Service providers are required to hold appropriate insurance for the administration of vaccines and provision of a vaccination service. Health professionals should consult with their insurance provider regarding insurance appropriate to their circumstances, including the provision of care outside of employer premises or clinical placement providers’ premises, as relevant to the insured party/ies.

## Workforce requirements

**Medical practitioners and nurse practitioners**

Vaccination providers are responsible for deploying a skilled workforce in sufficient numbers to meet the obligations of provision of mpox vaccines. Medical practitioners and nurse practitioners (within their scope of practice) can authorise administration by an instruction or independently administer the mpox vaccine.

A nurse practitioner is authorised to obtain, possess, use, supply or prescribe substances in Schedules 2, 3, 4 or 8 that are approved by the Minister for Health, in the lawful practice of their profession as a nurse practitioner (section 13 of the *Drugs, Poisons and Controlled Substances Act 1981*). The scope of practice of individual nurse practitioners is supported by their employer’s clinical governance framework[[40]](#footnote-41).

Medical practitioners are authorised to obtain, possess, use, supply or prescribe most medicines and poisons for the lawful practice of their profession (section 13 of the *Drugs, Poisons and Controlled Substances Act 1981*), i.e. for the medical treatment of patients under their care[[41]](#footnote-42).

**Nurse immunisers and pharmacist immunisers**

Nurse immunisers and pharmacist immunisers, who are already authorised under the *Drugs, Poisons and Controlled Substances Regulations 2017* (Vic) to administer Schedule 4 poisons, now have provisions for administering the mpox vaccine without an instruction from an authorised prescriber, enabled through updates to the Secretary Approval: Nurse Immunisers[[42]](#footnote-43) and Secretary Approval: Pharmacist Immuniser[[43]](#footnote-44), respectively. Mandatory training and limitations apply. Nurse immunisers and pharmacist immunisers undertaking intradermal mpox vaccine administration must undertake additional training detailed in the ‘Training requirements’ section below. Further details about nurse immunisers and pharmacist immunisers are available from the department’s [Immunisers in Victoria](https://www.health.vic.gov.au/immunisation/immunisers-in-victoria) webpage at: <https://www.health.vic.gov.au/immunisation/immunisers-in-victoria>.

**Registered nurses**

Registered nurses assessed as competent and performing duties within their individual scope of practice may administer JYNNEOS® vaccine upon instruction from a medical or nurse practitioner.

### Training requirements

The department has provided guidance on the pre-requisite training modules, and skills and competencies to deliver the JYNNEOS® vaccine via prescribed routes.

It is the responsibility of each mpox vaccination provider to:

* identify members of the workforce who need to complete pre-requisite training modules
* access or structure a training plan accordingly
* confirm and document that training has been completed
* ensure staff have the appropriate experience or have demonstrated the skills and competencies to fulfill their role safely within their individual scope of practice.

### Training activities

The department’s mpox vaccination eLearning module is now available through the [Victorian Immunisation Learning Hub](https://vic-immunisation-learning.com/). <https://vic-immunisation-learning.com/>

The proposed training will not equip nurse immunisers or pharmacist immunisers to provide all the necessary care in the instances of **post-exposure preventive vaccination (PEPV)**  **for high-risk close contacts** of mpox cases. This process requires specialist counselling and comprehensive public health measures to be considered – including contact tracing. This process should be undertaken by appropriately trained specialist sexual health/public health/infectious disease clinicians. Authorised immunisers who are working within a clinical model and team that supports this specialist care, can perform the mpox vaccinations where the specialist care activities can be performed by an appropriately trained specialist clinician (i.e. a medical practitioner or nurse practitioner or infectious disease/sexual health expert, not the immuniser).

### Victorian Mpox Intradermal technique competency checklist

An intradermal injection skills and competencies checklist has been developed as a guide for local public health units and health services to verify that vaccinators are deemed clinically skilled and competent in the technique of intradermal injection. [Refer to Appendix 7](#_Appendix_7:_Intradermal)

Please contact [immunisation@health.vic.gov.au](mailto:immunisation@health.vic.gov.au) for further information about intradermal injection technique training opportunities.

## Emergency response

Mpox vaccination providers are to ensure that they have suitably qualified and experienced workforce available to respond to any adverse event following immunisation (AEFI).

Providers must ensure an appropriate clinical response in the case of an emergency, and must make certain that:

* an experienced clinician, who is trained and authorised to possess and administer adrenaline, is available on site and able to respond in the case of anaphylaxis following vaccine administration
* vaccinations can continue regardless of an AEFI
* sufficient workforce is available to deliver vaccination, supervise vaccination and respond to the AEFI concurrently
* the emergency response is in addition to vaccination supervision requirements.

Refer to further guidance refer to:

[Appendix 5- Guidance – differentiating anaphylaxis from acute stress response for vaccine providers and emergency departments](#_Appendix_5:_Guidance)

[Appendix 6 Factsheet – Adverse events following immunisation (AEFI)](#_Appendix_6:_Factsheet)

# Additional resources

The Commonwealth Government and ATAGI have developed a collection of resources containing advice and guidance for providers:

* ATAGI Updated clinical guidance on vaccination against monkeypox (mpox) Version 4.0, 12 December 2022 <<https://www.health.gov.au/resources/publications/atagi-clinical-guidance-on-vaccination-against-monkeypox?language=en>
* Mpox (monkeypox) – Consent form for JYNNEOS® vaccine 26 August 2022 <<https://www.health.gov.au/resources/publications/mpox-monkeypox-consent-form-for-jynneosr-vaccination>>
* Infection Prevention and Control Expert Group Interim Guidance on Monkeypox for Health Workers 24 June 2022

<<https://www.health.gov.au/resources/publications/iceg-interim-guidance-on-monkeypox-for-health-workers>>

* Information on JYNNEOS® (modified vaccinia Ankara – Bavarian Nordic, MVABN) vaccine. Updated 26 August 2022

<<https://www.health.gov.au/resources/publications/mpox-monkeypox-information-on-jynneosr-vaccine?language=en>>

* Interim guidance provided by the Infection Prevention and Control Expert Group (ICEG) on Monkeypox (MPX) for healthcare workers | Australian Government <<https://www.health.gov.au/resources/publications/iceg-interim-guidance-on-monkeypox-for-health-workers>>
* Victorian Government; Disease Information and advice – Mpox (monkeypox) <<https://www.health.vic.gov.au/infectious-diseases/mpox-monkeypox>>
* Victorian Government – Clinical and related waste guidance- Supplement for healthcare staff

< <https://www.health.vic.gov.au/publications/clinical-and-related-waste-guidance-supplement-for-healthcare-staff>>

* Victorian Government Mpox (monkeypox) – Better Health Channel

< <https://www.betterhealth.vic.gov.au/mpox-monkeypox>>

Contact information

For monkeypox vaccine specific queries please contact the Immunisation Unit via email <immunisation@health.vic.gov.au>

# Appendix 1: Contact information

|  |  |  |
| --- | --- | --- |
| Who to contact | When to contact | How to contact? |
| SAEFVIC | **Moderate/ unexpected and serious AEFI; vaccine administration errors**   * For AEFI involving adrenaline administration, defibrillator use, transfer to hospital care, life-threatening AEFI, or death, call SAEFVIC Immunisation Hotline, and complete SAEFVIC online report form. * For all other AEFI and vaccine errors, complete SAEFVIC online report form | **Phone:** 1300 882 924 (option 1) (Mon – Fri 9am – 4.30pm)  **Online Form:**  [www.saefvic.org.au](http://www.saefvic.org.au) |
| Victorian Department of Health | * Vaccine reporting → Complete weekly report and wastage report * Clinical advice * Reporting vaccine errors | **LPHU, Health Services and Sexual health clinics reporting:** [Mpox Vaccine Usage and Wastage Report](https://forms.office.com/pages/responsepage.aspx?id=H2DgwKwPnESciKEExOufKCSmZxDa3xhBuPAJN3fVuqtUNjk1T0YwTFBNUlE4WUtUQlRMNjRJRUszTiQlQCN0PWcu&web=1&wdLOR=c65936C97-057B-4635-B1F7-5085EDD821EF)  **Clinical advice:** [immunisation@health.vic.gov.au](mailto:immunisation@health.vic.gov.au) |
| Victorian Department of Health | * All cold chain breaches should be escalated to the Department of Health | **Email:** [immunisation@health.vic.gov.au](mailto:immunisation@health.vic.gov.au) |
| Australian Immunisation Register (AIR) | * Access the AIR through HPOS using a [PRODA](https://www.servicesaustralia.gov.au/how-to-set-up-your-access-to-air?context=23401) account – [Health Professional Online Services](https://www.servicesaustralia.gov.au/australian-immunisation-register-for-health-professionals) (HPOS) * Documenting vaccine encounters to AIR | **Phone:** 1800 653 809 |

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# Appendix 2: Safe vaccine storage – data loggers

#### Purpose-built vaccine refrigerators

Purpose-built vaccine refrigerators are the **only suitable option** for vaccine storage.

Purpose-built vaccine refrigerators are specifically designed to store vaccines and should be used for all vaccine storage. Purpose-built vaccine refrigerators have the following advantages:

* a stable, uniform and controlled cabinet temperature between +2°C and +8°C
* standard alarm and safety features that alert to and/or prevent irregular temperature fluctuations in the cabinet
* inbuilt digital temperature monitoring (inbuilt data logger) and/or digital temperature indicators (minimum and maximum temperature displays)
* effective temperature recovery after the refrigerator door has been opened
* potential for most of the internal space to be used for vaccine storage; ask the manufacturer how to pack the refrigerator to accommodate the maximum quantity of vaccine.

**Domestic refrigerators (including bar fridges) are not built or designed to store vaccines and must not be used** **for vaccine storage**.

Blood refrigerators are specifically designed to store blood products at a controlled temperature between +2°C and +6°C. This means that, if necessary, it is acceptable to store vaccines and blood products in the same refrigerator. Temperature monitoring will still be required[[44]](#footnote-45).

#### What is a data logger?

Temperature data loggers are small electronic devices that measure temperatures at pre-set time intervals and record the results over a period of time. Data loggers should be set to record temperatures at 5-minute intervals.

Some purpose-built vaccine refrigerators have an inbuilt data logger. Information from the data logger should be downloaded at least weekly (or more frequently if recommended by the manufacturer), reviewed and digitally stored.

#### What information do data loggers provide?

Data loggers provide an accurate indication of vaccine refrigerator temperatures and can be used to map ‘cold spots’ or investigate problems. Loggers use a similar measuring principle to chart recorders; however, they record the data electronically. The data can be stored by the monitoring system and can also be downloaded to a computer.

**Twice-daily minimum and maximum temperatures must still be manually recorded as a timely alert to any breach in the cold chain.** If a data logger is used for routine temperature monitoring (instead of a minimum/maximum thermometer), it must have a visual display of minimum/maximum temperatures to allow twice-daily real-time readings to be viewed and manually recorded.

Many data loggers can be programmed to alarm when a temperature outside the +2°C to +8°C range is recorded.

#### Using a data logger

The data logger and the minimum/maximum thermometer should be co-located in the refrigerator; otherwise, different recordings can occur. If the data logger and probe have a fixed position in the refrigerator and cannot be moved, the vaccines should be stored as close as practicable to the probe.

The results from the data logger can be printed in graph and numerical formats, including times that the temperature was recorded outside the +2°C to +8°C range, and the minimum and maximum temperatures.

All staff should be trained in how to operate and manage the data logger and interpret its readings. Data logging will help immunisation service providers to get to know their refrigerator.

#### Continuous logging

All vaccine refrigerators should have a permanent data logger in place to continuously measure the refrigerator temperature at pre-set 5-minute intervals. The data should be downloaded at least weekly, in addition to twice-daily minimum/maximum recordings. The data logger can be a portable digital data logger or may be built into the refrigerator.

#### Benefits of continuous temperature monitoring

Continuous temperature monitoring:

* provides information on the duration of a cold chain breach and supplements a cold chain audit
* confirms that the cold chain has been maintained and provides accurate knowledge of the vaccine refrigerator temperature
* identifies times when there is a risk of vaccines freezing (0°C or below) — for example, overnight, long weekends and when the refrigerator is not in use
* assists staff to understand the functioning of the refrigerator
* identifies temperature fluctuations between the refrigerator shelves and the location of any cold spots on each shelf
* supports accreditation documentation and audits
* helps to assess the refrigerator thermometer’s accuracy.

#### Cold Chain resources

[National vaccine storage guidelines – Strive for 5](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5)

[Victorian Department of Health – Cold Chain Management](https://www.health.vic.gov.au/immunisation/cold-chain-management) (note different reporting requirements for JYNNEOS vaccine

Cold chain reporting – [immunisation@health.vic.gov.au](mailto:immunisation@health.vic.gov.au)

[TagAlert® - validation of cold chain management for the delivery of vaccines](https://www.health.vic.gov.au/immunisation/cold-chain-monitoring-during-vaccine-transport)

Checklist for data loggers

1. Place the data logger where it is easily seen and in the middle of the vaccines.
2. Measure the current, minimum and maximum temperatures twice daily, and record them.
3. Set the alarm system to alarm outside the +2°C to +8°C range. Check that the alarm is working.
4. Train all staff to recognise the alarm and download information from the data logger.
5. Download and record information as soon as possible after an alarm is activated.
6. If recordings are outside the +2°C to +8°C range, follow the cold chain breach protocol (see the [National Vaccine Storage Guidelines – Strive for 5](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5), [Appendix 3](mailto:Appendix%203)) and notify the Immunisation Unit directly via [immunisation@health.vic.gov.au](mailto:immunisation@health.vic.gov.au)
7. Regularly check and record the accuracy of the data logger. Record the date the accuracy check is done. To check the accuracy, place a second data logger in the refrigerator next to the existing data logger to obtain comparison temperature readings. Inbuilt data loggers should be checked for accuracy according to the manufacturer’s recommendation.
8. Change the battery according to the manufacturer’s recommendation, or when the battery life displayed on either the data logger or computer set-up screen is low. Record the date the battery is changed. Life of the replaceable battery may be dependent on usage (e.g., how frequently the temperature is recorded, and data are downloaded).

# Appendix 3: Cold chain management checklists

#### Receipt of vaccines on delivery

|  |  |  |
| --- | --- | --- |
| **Step** | **What to do** | **Complete** |
| 1 | Vaccines must be received by immunisation staff who are educated in cold chain management. |  |
| 2 | Sign the delivery docket and return it to the courier. |  |
| 3 | Check the temperature monitoring device. |  |
| 4 | Check that the vaccine consignment matches the delivery invoice. |  |
| 5 | Place the vaccines in a purpose-built vaccine fridge with a data logger and minimise the time that the vaccine fridge door is open. |  |
| 6 | Rotate vaccines so that the stock with the earliest indication for use is used first. |  |
| 7 | Do not remove vaccines from their packets – this protects them from light and temperature fluctuation. |  |
| 8 | Document vaccine delivery and record and reset fridge temperatures. |  |

#### Mobile / outreach immunisation clinics, or emergency storage of vaccines

|  |  |  |
| --- | --- | --- |
| Step | What to do | Complete |
| 1 | Remove ice packs/gel packs from the freezer:   * Place the number of packs you require for your cooler on the bench to ‘sweat’ (see *Strive for 5* Section 9.2 for information about conditioning ice packs/gel packs). [<https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5>](https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5) * Place the ice packs/gel packs in your cooler to chill the inside of the cooler. |  |
| 2 | Remove the ice packs/gel packs from the cooler and place insulating material (bubble-wrap or polystyrene chips) in the bottom of the cooler. |  |
| 3 | Reset the minimum/maximum thermometer and insert the thermometer probe inside an empty vaccine box with the product information intact. |  |
| 4 | Make sure the minimum/maximum temperature is between 2C and 8C at the time the vaccines are placed in the cooler. |  |
| 5 | Place the data logger next to the thermometer probe. |  |
| 6 | YOU ARE NOW READY TO MOVE YOUR VACCINES INTO THE COOLER.  Place the vaccine stock in the cooler with the box containing the thermometer probe and the data logger in the center.  **Note:** All vaccines should remain in their original packaging until they are administered or returned to a purpose-built vaccine refrigerator — this prevents damage from exposure to light and ambient temperature.  Surround the vaccines with packing material and place conditioned ice packs/gel packs on the top before closing the cooler. Ensure that vaccine stock is not in direct contact with the ice packs/gel packs, to minimize risk of freezing. Close the cooler lid and fix the digital thermometer display to the outside of the cooler. Keep the cooler out of direct sunlight. |  |
| 7 | Record the date, time, and minimum and maximum temperatures on the temperature chart. Then record temperatures at the following times:   * every 15 minutes for the first hour * hourly thereafter, provided the temperatures are stable. * Reset the min/max temperature after every reading   **Note:** See [Appendix 4 – Vaccine temperature monitoring form](#_Appendix_4_Vaccine). Freezing vaccines occurs most commonly in the first 2 hours of storage in a cooler. |  |
| 8 | Ensure that ice packs/gel packs do not become displaced and have direct contact with vaccines — this may freeze the vaccines and render them unviable. Remove vaccines from the cooler only as they are required. |  |
| 9 | Download the data logger on return to base. Any cold chain breach outside the range of +2°C to +8°C for longer than 15 minutes must be reported to the Department. |  |
| 10 | Only move vaccines back to a purpose-built vaccine refrigerator in which the temperature is between +2°C and +8°C. |  |
| 11 | Protect vaccines from light exposure by keeping them in their vaccine packaging. Store open vial and prepared vaccines in opaque containers. |  |

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# Appendix 4 Vaccine temperature monitoring form for outreach mobile services

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Date and Time** | **Activity** | **Temp between +2°C to +8°C Yes/No** | **Min** | **Max** | **Current** | **Signature and comments** |
|  | Receipt of vaccines, confirm cold chain maintained in transit |  |  |  |  | No. of vials: |
|  | Transfer to cooler |  |  |  |  |  |
|  | 15 min check |  |  |  |  |  |
|  | 15 min check |  |  |  |  |  |
|  | 15 min check |  |  |  |  |  |
|  | 15 min check |  |  |  |  |  |
|  | Hourly check |  |  |  |  |  |
|  | Hourly check |  |  |  |  |  |
|  | Hourly check |  |  |  |  |  |
|  | Hourly check |  |  |  |  |  |
|  | Hourly check |  |  |  |  |  |
|  | Hourly check |  |  |  |  |  |
|  | Hourly check |  |  |  |  |  |
|  | Hourly check |  |  |  |  |  |
|  | Hourly check |  |  |  |  |  |
|  | Hourly check |  |  |  |  |  |
|  | Hourly check |  |  |  |  |  |
|  | Hourly check |  |  |  |  |  |
|  | Return to purpose-built vaccine fridge or facility |  |  |  |  | Remaining vials |

# 

# Appendix 5: Guidance – differentiating anaphylaxis from acute stress response for vaccine providers and emergency departments

Anaphylaxis can be a life-threatening condition. The mainstay of management is adrenaline. There are no contraindications for the use of intramuscular adrenaline in the setting of anaphylaxis.

There are however a number of conditions that can mimic anaphylaxis, such as vagal reactions, anxiety and vocal cord dysfunction. While it can be difficult to distinguish at times between these three conditions, if you suspect anaphylaxis, follow appropriate guidelines from your workplace and transfer to hospital. If there is uncertainty around diagnosis, treatment of anaphylaxis should not be withheld.

However, if adrenaline is administered, it is important to reassure the person receiving the adrenaline of the possibility of an alternate diagnosis, but that the adrenaline is being given as it is safe to do so. The possible diagnosis of anaphylaxis can be reassessed at later stage.

An adrenaline autoinjector (EpiPen) prescription is not required post discharge following a queried vaccine adverse reaction.

To help confirm the possibility of anaphylaxis, a serum tryptase should be taken within 30 minutes to 2 hours after the onset of symptoms and 24 hours after symptoms have resolved. A serum tryptase assists in a retrospective review of the case, guides diagnosis and assists in reassuring the person regarding future vaccinations.

**Reporting adverse events following immunisation**

|  |
| --- |
| All unexpected or medically attended AEFI to be reported to SAEFVIC via online reporting at <<https://www.safevac.org.au/Home/Info/VIC>>  Medically attended events are defined as a visit to general practitioner, emergency department, or hospital admission  **Serious adverse events following immunisation require urgent reporting**  **AEFI that result in**   * Transfer to hospital care * CPR * Defibrillator use * Life threatening incidents * Death   **Action required**   * Manage the AEFI by usual clinical pathways * Immediately notify SAEFVIC via phone 1300 882 924 (Option 1) Mon-Fri 9am to 4.30pm) * Submit an AEFI report online to <<https://www.safevac.org.au/Home/Info/VIC>> |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Acute stress response | | | aNAPHYLAXIS |
| Sign and Symptom | **Vasovagal reaction** | **Generalised** | **Vocal cord dysfunction (VCD)** |  |
| Onset (after injection) | Before, few seconds to minutes after injection. May present after 5 mins if the individual stands suddenly | Before, few seconds to minutes after injection | A few seconds to minutes after injection and up to 2 hours post administration. | Within 30 mins after injection most start within 15 mins. In rare cases in can be within 60 mins |
| Clustering\* | Can occur | Can Occur | Can Occur | Uncommon |
| Serum Tryptase | Not elevated | Not elevated | Not elevated | Elevated |
| system |  |  |  |  |
| Neurological and other symptoms | Fainting sensation, dizziness, loss of consciousness in some cases or head spinning.  Transient loss consciousness with good response to lying flat, with or without Tonic-Clonic seizure | Fearfulness, sensation of dizziness, light headedness. Tingling around the lips, spasms in the hands, feet | Fearfulness, sensation of dizziness, light headedness. Tingling around the lips, spasms in the hands, feet | Uneasiness, restlessness, agitation, loss of consciousness, little response when supine or lying flat |
| Respiratory | Normal to deep breaths, can be slow with a few seconds of apnoea in some cases. | Fast and shallow, difficulty getting air in,  Stridor and cough.  Throat symptoms without objective signs of angioedema can predominate (sensation of lump in throat)  Hypoxia does not occur | Difficulty getting air in,  Stridor and cough.  Throat symptoms without objective signs of angioedema can predominate (sensation of lump in throat)  Hypoxia does not usually occur  Audible wheeze without auscultation.  Symptoms out of proportion to objective measures.  Voice often quiet | Respiratory difficulties, coughing, sneezing, wheezing, stridor.  In severe cases respiratory arrest.  Hypoxia can occur. |
| Cardiovascular | ↓ heart rate with or without *transient* ↓in blood pressure  Preserved carotid pulse  Transient hypotension can occur | ↑heart rate, normal or ↑systolic blood pressure  Palpitations; Chest pain | ↑heart rate, normal or ↑systolic blood pressure  Palpitations | ↑ heart rate, ↓ blood pressure, circulatory arrest |
| Skin | Diaphoresis, clammy skin, pallor,  sense of warmness over skin. | Tingling around mouth and hands  Flushing over chest and face | Tingling around mouth and hands  Flushing over chest and face | Warm skin progressing to clammy and pallor,  pruritus and urticaria,  swelling of the face and tongue |
| Gastrointestinal | Nausea, vomiting, abdominal cramps | Nausea | Rarely | Nausea, vomiting, abdominal pain, diarrhoea (this can be pronounced with incontinence) |
| Treatment | Place client in a recumbent position and elevate legs above head  Ventilate the room well  Place cold, damp cloth on face  Give reassurance | Place cold damp cloth on face  Give reassurance  Offer drink of water | Give Reassurance.  Offer drink of water or a warm drink | As per anaphylaxis guidelines |
| Prevention | Do not vaccinate a standing person  Before vaccinating ask if the person tends to faint, if so, ask patient to lie down. | Ask person if they are prone to anxiety/stress episodes. If so, ask for measures which assist person  Do not vaccinate standing up | Ask if person has a past history of VCD. If so, ask which measures assist in managing condition. | Ask if the person has had anaphylaxis to any vaccine components |

NB: At times only one symptom may be present for each of the conditions. i.e. Anaphylaxis may have only hypotension without cutaneous or respiratory symptoms or a vasovagal may just present with loss of consciousness

[Information for COVID-19 vaccine providers | Coronavirus Victoria](https://www.coronavirus.vic.gov.au/information-COVID-19-vaccine-providers), Appendix 6: *Guidance – differentiating anaphylaxis from acute stress response for vaccine providers and emergency departments*

# Appendix 6: Factsheet – Adverse Events Following Immunisation (AEFI) - including vaccine error

An Adverse Event Following Immunisation (AEFI) is any untoward medical occurrence that happens following administration of a vaccine. An AEFI can be coincidentally associated with the timing of immunisation without necessarily being caused by the vaccine or immunisation process.

**Reporting adverse events following immunisation**

|  |
| --- |
| All unexpected or medically attended AEFI are to be reported to SAEFVIC via online reporting at <<https://www.safevac.org.au/Home/Info/VIC>>  Medically attended events are defined as a visit to general practitioner, emergency department, or hospital admission  **Serious adverse events following immunisation require urgent reporting**  **AEFI that result in**   * Transfer to hospital care * CPR * Defibrillator use * Life threatening incidents * Death   **Action required**   * Manage the AEFI by usual clinical pathways * Immediately notify SAEFVIC via phone 1300 882 924 (Option 1) Mon-Fri 9am to 4.30pm) * Submit an AEFI report online to <<https://www.safevac.org.au/Home/Info/VIC>> |

**For clinical assessment and advice following vaccine error**

A vaccine administration error is any preventable event that may cause or lead to inappropriate vaccine use or patient harm. Where [guidance](#_Vaccine_safety) is not provided in this document, contact SAEFVIC for clinical assessment and advice.

**For more information on submitting a SAEFVIC report refer to**:

* [SAFEVAC Reporting](https://www.safevac.org.au/Home/Info/VIC)  <https://www.safevac.org.au/Home/Info/VIC>
* Email: [enquiries@saefvic.org.au](mailto:enquiries@saefvic.org.au)
* Ph: 1300 882 924 (option 1)

# Appendix 7: Intradermal injection – skills and competency checklist

Intradermal Injection technique

September 2022

Purpose

The clinical skills and competencies checklist is to verify that vaccinators are deemed clinically skilled and competent in the technique of intradermal injection. This checklist is intended as a guide to support providers in the assessment of competency in this technique.

This checklist must be completed and issued by an appropriately experienced clinician (for example, a medical practitioner, nurse practitioner or other specialist clinician) proficient in the injection technique via the intradermal route and can oversee the clinical skills and competencies of a vaccinator.

This checklist should be made available as evidence of their competency in this technique and will augment further training in the administration of JYNNEOS® vaccine across all sexual health centres, health services and Local Public Health Units in Victoria.

Further information regarding mpox and the *Victorian mpox vaccination program guidelines* refer to the Department of Health Mpox web page[Monkeypox | health.vic.gov.au](https://www.health.vic.gov.au/infectious-diseases/monkeypox) <<https://health.vic.gov.au/infectious-diseases/monkeypox>>.

|  |  |  |
| --- | --- | --- |
| **Vaccination Service Provider**  Organisation where appropriately skilled clinician proficient in the administration of intradermal vaccination (person completing this form) is assessing as clinically competent | | Click or tap here to enter text. |
| **Health professional Name**  Name of person / worker requiring assessment. | | Click or tap here to enter text. |
| **Profession** | Registered Nurse / Midwife  Nurse immuniser  Pharmacist immuniser  Other (approved clinician) |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Competencies displayed by the worker in the technique of intradermal injection** | | | | *Tick to confirm* |
| Can demonstrate collection of required equipment.  Equipment may include:   * medical waste (sharps) container * 1ml syringe * appropriate drawing-up needle — preferably 25-27 gauge * 26 -27-gauge 10mm long needle for administration * clean cottonwool | | | |  |
| Can demonstrate correct preparation of the consumer   * Comfortable area to rest arm, ideally opposite the clinician * Safely rotate forearm to visualise volar aspect * Ensure adequate lighting | | | |  |
| Can demonstrate stretching of skin between finger and thumb over the volar aspect of the forearm   * Chooses site approximately 10cm below antecubital area | | | |  |
| Can demonstrate correct insertion of bevel into the dermis   * Bevel uppermost * Distance of @2mm * Bevel visible through transparent epidermis * Angle of insertion is 5-15 degrees into skin plane * Senses resistance when injecting | | | |  |
| Can demonstrate production of a raised bleb of @7mm diameter, that looks like orange peel | | | |  |
| Can demonstrate correct disposal of sharps and any clinical waste | | | |  |
| Demonstrates an understanding of escalation points in instances of:   * Unsuccessful intradermal injection technique | | | |  |
| Has successfully completed a minimum of three to five supervised vaccinations using the intradermal injection administration technique | | | |  |
| **Details of person completing this form** | | | | |
| **Name** | Click or tap here to enter text. | **Signature** |  | |
| **Position** | Click or tap here to enter text. | **Date** | Click or tap to enter a date. | |

# Appendix 8: Document history and control

|  |  |  |
| --- | --- | --- |
| **Version** | **Publishing date** | **New updates** |
| 4 | 09/09/2022 | **Schedule –** added ATAGI guidance  Advice if dose 2 given after 28 days  **Addition of table**  Table 4 – Codes for adding JYNNEOS® vaccine doses to AIR  **SAEFVIC contact details** updated  **Addition of Appendix 7**  Intradermal injection – skills and competency checklist |
| 4.1 | 12/09/2022 | **Cold chain reporting**  Revised contact details for reporting all cold chain breaches |
| 4.2 | 16/09/2022 | **Preparation of equipment**  Use of a 25-27 gauge needle to extract vaccine may minimise vaccine wastage  **Table 3 Methods of dose extraction for multidose vials**  Drawing up and administering with the same 25-27 gauge needle |
| 4.3 | 19/09/2022 | **Eligibility for pre-exposure vaccination**  Criteria clarified |
| 5 | 4/10/2022 | Nurse immunisers and pharmacist immunisers – Secretary Approvals amended to enable monkeypox vaccine administration 03/10/2022 |
| 5 | 4/10/2022 | Minor updates to ‘Training activities’ section |
| 6 | 11/10/2022 | **Eligibility for vaccination –** as per vaccine supply |
| 6 | 11/10/2022 | **Identifying sites for Intradermal injection** – description of landmarks over the deltoid as an alternative site for intradermal injection. |
| 7 | 21/10/2022 | **Coadministration**  Clarification of considerations for interval between vaccines |
| 8 | 03/11//2022 | Eligibility for MPX vaccine updated |
| 8 | 03/11//2022 | Clarification Interval between JYNNEOS**®** vaccine and other live vaccines not required. |
| 9 | 09/12/2022 | Update – Monkeypox to mpox as per WHO recommendations  Appendix 1 – Updated contact information |
| 10 | 16/12/2022 | Updated terminology on mpox vaccines for pre-exposure and post-exposure prophylaxis (PPV, PEPV)  Updated eligibility to receive vaccine  Updated recommendations for people with severe immunocompromise – can receive ID JYNNEOS® vaccine  Updated co-administration guidance for COVID-19 vaccines  Updated table 3 - Minor updates handling procedures for use of multidose vials (section E)  Updated table 5 – Vaccine errors and deviations – Clarity regarding recommendations after incorrect route ID administration  Updated Appendix 6 – Updated - report vaccine error to SAEFVIC |
| 11 | 16/01/2023 | Updated background, Updated web links |
| 12 | 01/02/2023 | JYNNEOS® vaccine may be given via subcutaneous route for PPV & PEPV to all people |
| 13 | 27/02/2023 | Expanded eligibility for Primary preventative vaccination |
| 14 | 08/08/2023 | Clarification regarding PEPV dose timing after exposure – link to ATAGI guidance |
| 15 | 22/08/2023 | Vaccine program - How to access the mpox vaccine (updated) |
| 16 | 01/02/2024 | Vaccine ordering - How to order the mpox vaccine (updated) |
| To receive this publication in an accessible format [email Immunisation unit](mailto:immunisation@health.vic.gov.au) <immunisation@health.vic.gov.au>.  Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.  © State of Victoria, Australia, Department of Health September 2022.  Available at [Monkeypox](https://www.health.vic.gov.au/infectious-diseases/monkeypox) < https://www.health.vic.gov.au/infectious-diseases/monkeypox > | | |

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