# Recommended use of mpox (previously known as monkeypox) vaccine

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## Plain-language summary

Mpox (previously called monkeypox) is a disease caused by the monkeypox virus. Mpox is usually mild and people typically recover within a few weeks. It causes symptoms including a rash and skin lesions, swollen lymph nodes, fever, body aches and exhaustion. It spreads through close physical contact with an infected person.

In 2022, there were mpox outbreaks in several countries where the illness is not usually seen. This included Australia. The World Health Organization declared this a public health emergency of international concern. Mpox cases stabilised across Australia after a few months, and the [WHO declared the end of the mpox emergency](https://www.paho.org/en/news/11-5-2023-who-declares-end-mpox-emergency-calls-sustained-efforts-long-term-management-disease) on the 10th May 2023. There remains the potential for future outbreaks.

Whilst Australia did have access to the smallpox vaccine [ACAM 2000](https://www.tga.gov.au/resources/artg/153108), it did not have access to the MVA-BN vaccine, registered internationally for the prevention of smallpox and mpox before the 2022 outbreak. This meant that the Australian Technical Advisory Group on Immunisation (ATAGI) needed to make recommendations for utilising vaccines to prevent mpox. The Australian Immunisation Handbook also therefore required a new chapter on mpox.

Mpox vaccines are not part of Australia’s National Immunisation Program. But mpox vaccination is free for certain groups of people under emergency measures.

ATAGI recommends mpox vaccination for people who are at high risk of exposure to the virus. This document gives details about the recommendations in the Australian Immunisation Handbook.

## Summary of recommendations

**Vaccination before exposure to mpox: primary preventive vaccination (PPV)**

* People aged ³16 years at high risk of exposure to mpox in an outbreak setting are recommended to receive mpox vaccine
* Laboratory workers who work with smallpox or monkeypox virus are recommended to receive mpox vaccine
* Healthcare workers at higher risk of exposure to mpox may consider receiving mpox vaccine

**Vaccination after exposure to mpox: post-exposure preventive vaccination (PEPV)**

* People who are categorised by public health authorities as a high-risk mpox contact in the past 14 days are recommended to receive mpox vaccine
* People who are categorised by public health authorities as a medium-risk mpox contact in the past 14 days may consider receiving mpox vaccine

## Background and rationale

The Australian Technical Advisory Group on Immunisation (ATAGI) advises the Australian Government on clinical recommendations for vaccinations. ATAGI has developed recommendations for the use of mpox vaccine.

The recommendations reflect the current best clinical practice to prevent mpox disease. The recommendations are published online in the [Australian Immunisation Handbook](https://immunisationhandbook.health.gov.au/). Information relating to the GRADE (Grading of Recommendations, Assessment, Development and Evaluations) assessment is published on the [National Centre for Immunisation Research and Surveillance (NCIRS) website](https://ncirs.org.au/our-work/australian-immunisation-handbook).

Previously, clinical guidance on the use of mpox vaccines was published on the Australian Government Department of Health and Aged Care website. This guidance has now been incorporated into the new Handbook chapter.

### Mpox disease and the recent outbreak

Mpox is a zoonotic (transmitted between non-human animals to humans) viral illness that is endemic to rainforest areas of Central and West Africa. Human cases were first reported in 1970 in the Democratic Republic of the Congo.1,2 In recent years, cases have increased, possibly related to increasing urbanisation and decreasing population immunity since the end of widespread smallpox vaccination. Occasional human mpox cases were also reported in non-endemic countries before 2022.3-5

In 2022, a multi-country outbreak of mpox was reported in regions that are not endemic for mpox, including Australia. This is the first time ongoing human-to-human transmission has occurred in non-endemic regions.

Close contact during sexual activity has been the main driver of the global outbreak. Although anyone can contract mpox, cases in this outbreak have primarily been in the sexual networks of gay, bisexual and other men who have sex with men (GBMSM).6 People at highest risk are GBMSM who have multiple sexual partners, or attend large parties or sex-on-premises venues. However, anyone who comes in close physical contact with someone with mpox could become infected.

### Mpox vaccines

Mpox can be prevented through vaccination. Smallpox vaccines and mpox vaccines contain the vaccinia virus, which is related to both smallpox and mpox. Smallpox vaccines are also effective against mpox.

The currently available vaccine, recommended for mpox prevention, is the third-generation, replication-deficient modified vaccinia Ankara – Bavarian Nordic (MVA-BN) vaccine. The MVA-BN vaccine, known as JYNNEOS, Imvamune or Imvanex, is registered for use in the United States, United Kingdom, Canada and other countries for prevention of smallpox and mpox.

JYNNEOS is not currently registered in Australia, but it is available in Australia under emergency use provisions as part of the response to the recent mpox outbreak.

## GRADE methods

Evidence on the benefits and harms of mpox vaccine used for primary preventive vaccination (PPV; that is, vaccination before exposure to mpox) was assessed using [GRADE](https://bestpractice.bmj.com/info/toolkit/learn-ebm/what-is-grade/) (Grading of Recommendations, Assessment, Development and Evaluations) methods. The primary research question was ‘Should MVA-BN be used in healthy adults for the prevention of mpox disease?’

The benefits outcomes considered included:

percentage of participants with seroconversion (vaccinia virus neutralising antibody seroconversion rate) 28 days after vaccination

effectiveness

efficacy.

The harms outcomes considered included:

serious adverse events

local adverse events

systemic adverse events

myocarditis or pericarditis (clinically confirmed).

The certainty of the evidence for each outcome was determined by assessing the study design, risk of bias, inconsistency, indirectness and imprecision.

There was not enough evidence to allow a GRADE assessment for post-exposure preventive vaccination (PEPV; that is, vaccination after exposure to mpox).

## New recommendations

### Vaccination before exposure to mpox: primary preventive vaccination (PPV)

**People aged** ³**16 years at high risk of exposure to mpox in an outbreak setting are recommended to receive mpox vaccine**

Mpox vaccine in a 2-dose schedule is recommended for groups at high risk of exposure to mpox in an outbreak setting, as detailed below. People in these risk groups who are severely immunocompromised should be prioritised to receive the 2nd dose of mpox vaccine as close to (but not before) 28 days after the 1st dose as possible, as part of the primary preventive vaccination (PPV) schedule.

*Gay, bisexual or other men who have sex with men (GBMSM)*

PPV with mpox vaccine is recommended for GBMSM who are at increased risk of mpox disease. Proxy markers for increased risk of mpox may include:

* living with HIV
* a recent history of multiple sexual partners, participating in group sex, or attending sex-on-premises venues
* recent sexually transmitted infection or being advised to take HIV pre-exposure prophylaxis due to the number of sexual partners. While many people prescribed HIV pre-exposure prophylaxis are monogamous with an HIV-positive partner, this category can also capture those with multiple partners who are at high risk.

The number of doses and intervals between doses is outlined in [Vaccines, dosage and administration](https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/mpox#vaccines-dosage-and-administration)**.**

*Sex industry workers*

PPV with mpox vaccine is recommended for sex industry workers, particularly those whose clients belong to high-risk categories (see proxy markers for increased risk of mpox disease).

Regular sexual partners of people in the above high-risk groups may also receive mpox vaccine.

*Booster dose*

People who have previously received a smallpox vaccine (e.g. ACAM2000, Dryvax, MVA-BN etc.) are likely to have some residual protection, but may benefit from receiving a dose of mpox vaccine.

If a person who is recommended to receive PPV for mpox has had a smallpox vaccine in the past, 1 additional dose of mpox vaccine is recommended if the previous dose of a smallpox vaccine was given more than 10 years ago.

**Laboratory workers who work with smallpox or monkeypox virus are recommended to receive mpox vaccine**

Primary preventive vaccination (PPV) with mpox vaccine (for example, MVA-BN) is recommended in a 2-dose schedule for laboratory workers working with smallpox or monkeypox viruses, identified through local laboratory risk assessments (see the [PHLN Laboratory case definition](https://www.health.gov.au/resources/publications/monkeypox-laboratory-case-definition) document). People working in these environments should review their own history of smallpox vaccination, as booster doses may be appropriate for those with new or ongoing risk of exposure to mpox.7

People who are severely immunocompromised should be prioritised to receive the 2nd dose of mpox vaccine as close to 28 days after the 1st dose as possible, as part of the PPV schedule.

*Booster doses*

People who have previously received a smallpox vaccine (e.g. ACAM2000, Dryvax, MVA-BN etc.) are likely to have some residual protection, but may benefit from receiving a dose of mpox vaccine.

Previously vaccinated laboratory workers with ongoing risk of occupational exposure may be considered for a booster. Boosters should be given at 10-yearly intervals.

**Healthcare workers at higher risk of exposure to mpox may consider receiving mpox vaccine**

Primary preventive vaccination (PPV) with mpox vaccine may be considered for healthcare workers at higher risk of exposure to patients with mpox, based on local risk assessments. This may include workers in primary care, sexual health clinics, hospital staff and others. 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).

Prioritisation for PPV should consider supply. If supply is constrained, at-risk population groups should be prioritised over other groups such as healthcare workers. This approach presumes that adequately trained personnel are available to administer the vaccine.

People who are severely immunocompromised should be prioritised to receive the 2nd dose of mpox vaccine as close to 28 days after the 1st dose as possible, as part of the PPV schedule.

*Booster doses*

People who have previously received a smallpox vaccine (e.g. ACAM 2000, Dryvax, MVA-BN) are likely to have some residual protection, but may benefit from receiving a dose of mpox vaccine.

Previously vaccinated healthcare workers with ongoing risk of occupational exposure may be considered for a booster. Boosters should be given at 10-yearly intervals.

#### Evidence for the recommendations

##### Immunogenicity and effectiveness

There are no direct data from clinical trials on the effectiveness of MVA-BN against smallpox or mpox, and only emerging post-licensure data on effectiveness against mpox in the current outbreak. Vaccine effectiveness estimates from observational studies ranged from 36% to 86% for a single dose of MVA-BN,8-11 and 66%12 to 86%9 for a complete 2-dose course in people considered at high risk of mpox.

Indirect evidence for vaccine effectiveness of MVA-BN includes immunogenicity data from previous clinical trials. In these studies, seroconversion rates after receiving MVA-BN ranged from 71.2% to 100% at 2 weeks after 2 subcutaneous doses.11-20

##### Effectiveness after intradermal vaccination

Vaccine effectiveness for intradermal administration appears to be comparable to subcutaneous administration, based on indirect immunogenicity data and observational studies.

In a phase II trial, 524 participants were randomised to receive a standard (0.5 mL) dose of MVA-BN vaccine subcutaneously or a fractional dose (0.1 mL) intradermally.13 Peak neutralising antibody titres against the vaccinia virus after 2 doses of intradermal MVA-BN were shown to be non-inferior to titres after 2 doses of subcutaneous MVA-BN. According to a United States jurisdictional case–control study, adjusted vaccine effectiveness for a complete 2-dose course was 80.3% for intradermal administration and 88.9% for subcutaneous administration.9

##### Vaccine safety

In randomised clinical trials, 74.6% to 98.1% of participants experienced any local adverse event after receiving MVA-BN via the subcutaneous route, and 35.9% to 80.5% experienced any systemic adverse event.13-22 Post-licensure surveillance safety data from Australia and the United States showed a self-reported adverse event rate of 25% to 47%.23,24 The most commonly reported local adverse events were injection site pain, redness, swelling and induration. The most commonly reported systemic adverse events were muscle pain, headache, fatigue, nausea and chills. The rate of reported serious vaccine-related adverse events is very low in data from clinical trials and use in the 2022 outbreak.

Data from a clinical trial showed no significant differences in the frequency of systemic adverse events in healthy adults who received MVA-BN intradermally or subcutaneously.13 However, local reactogenicity (erythema and induration) was higher in the intradermal group (100%) than in the subcutaneous group (84.4%). A higher rate of moderate or severe local reactions was reported in the intradermal group (94.8%) than in the subcutaneous group (58.1%), and the reactions lasted longer in the intradermal group.

Vaccine safety surveillance data from Australia and the United States reported a slightly higher rate of adverse events in people receiving MVA-BN via the intradermal route (dose 1: 53%; dose 2: 35%) compared to the subcutaneous route (dose 1: 47%; dose 2: 31%), but all the events were mild and local to the injection site.24,25

##### Duration of immunity

Clinical studies have shown evidence of protection against the vaccinia virus 2 years after a primary course of the MVA-BN vaccine.26 In people who had received a primary course of MVA-BN 2 years previously, a booster dose of MVA-BN led to a rapid increase in neutralising antibody titres, which remained elevated at 6 months.27

The duration of protection against monkeypox virus infection after 1 primary dose of MVA-BN is currently unknown beyond 4 weeks.

### Vaccination after exposure to mpox: post-exposure preventive vaccination (PEPV)

**People who are categorised by public health authorities as a high-risk mpox contact in the past 14 days are recommended to receive mpox vaccine**

High-risk contacts may include sexual contacts, household contacts or healthcare workers. For detailed guidance on risk categorisation for contacts, seek the advice of the local public health unit and see the [Communicable Diseases Network of Australia (CDNA) Series of National Guidelines](https://www.health.gov.au/resources/collections/cdna-series-of-national-guidelines-songs?utm_source=health.gov.au&utm_medium=callout-auto-custom&utm_campaign=digital_transformation) on mpox.

If indicated, post-exposure preventive vaccination (PEPV) with mpox vaccine should be given as soon as possible after the first exposure to a confirmed mpox case. Vaccination within 4 days of first exposure to an infectious case will provide the highest likelihood of preventing disease. Vaccination between 4 and 14 days after exposure is likely to attenuate disease.

People who have previously received a smallpox vaccine (before the 2022 mpox outbreak), and who are eligible for PEPV, should receive PEPV as soon as possible, regardless of the timing of the previous smallpox vaccine dose.

Where a decision is made to provide PEPV, a single dose of MVA-BN mpox vaccine should be given via the subcutaneous route. If mpox disease has not occurred and there is an ongoing exposure risk, the 2nd dose of mpox vaccine should be given at least 28 days after the 1st dose, to complete a primary course for long-term protection. The 2nd dose may be given as either 0.5 mL via the subcutaneous route or 0.1 mL via the intradermal route.

*Women who are pregnant or breastfeeding*

PEPV during pregnancy may be considered after a risk–benefit assessment.

Safety data for the use of MVA-BN in pregnancy are limited, but no concerns have been identified to date.28 Any decision on the use of the vaccine should take into account the likelihood of mpox disease in pregnancy, and the risks to both the mother and foetus.

*Infants and children*

Where PEPV is indicated for a child, off-label use of MVA-BN mpox vaccine is possible.

MVA-BN has not been specifically studied in a clinical trial in children, but no serious safety concerns have been observed in children using MVA-BN for PEPV.29

MVA-BN mpox vaccine can be used in children when the benefits of vaccination outweigh the potential risks. To help parents make this assessment, they should be provided with information about the risks of mpox disease in children, the potential benefits of vaccination in the local epidemiological context and the current limitations of safety data in children.

**People who are categorised by public health authorities as a medium-risk mpox contact in the past 14 days may consider receiving mpox vaccine**

For detailed guidance on risk categorisation for contacts, seek the advice of the local public health unit and see the [Communicable Diseases Network of Australia (CDNA) Series of National Guidelines](https://www.health.gov.au/resources/collections/cdna-series-of-national-guidelines-songs?utm_source=health.gov.au&utm_medium=callout-auto-custom&utm_campaign=digital_transformation) on mpox.

If indicated, post-exposure preventive vaccination (PEPV) with mpox vaccine should be given as soon as possible after the first exposure to a confirmed mpox case. Vaccination within 4 days of first exposure to an infectious case will provide the highest likelihood of preventing disease. Vaccination between 4 and 14 days after exposure is likely to attenuate disease.

People who have previously received a smallpox vaccine previously (before the 2022 mpox outbreak), and who are eligible for PEPV, should receive PEPV as soon as possible, regardless of the timing of the previous smallpox vaccine dose.

Where a decision is made to provide PEPV, a single dose of MVA-BN mpox vaccine should be given via the subcutaneous route. If mpox disease has not occurred and there is an ongoing exposure risk, the 2nd dose of mpox vaccine should be given at least 28 days after the 1st dose, to complete a primary course for long-term protection. The 2nd dose may be given as either 0.5 mL via the subcutaneous route or 0.1 mL via the intradermal route.

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PEPV during pregnancy may be considered after a risk–benefit assessment.

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MVA-BN mpox vaccine can be used in children when the benefits of vaccination outweigh the potential risks. To help parents make this assessment, they should be provided with information about the risks of mpox disease in children, the potential benefits of vaccination in the local epidemiological context and the current limitations of safety data in children.

#### Evidence for the recommendations

There was not enough evidence to allow a GRADE assessment for PEPV (that is, vaccination after exposure to mpox). Evidence of PEPV for mpox was based on extrapolation from low-quality historical data of protection against smallpox, and more recent use in isolated outbreaks of mpox in non-endemic countries.

A 2019 review of human smallpox outbreak data from 1882 to 1973 calculated an overall effectiveness of PEPV against smallpox with any smallpox vaccine of 45% (interquartile range: 25.5% to 64.5%). There was wide variation in the timing of vaccination after exposure.30 A study obtaining consensus opinions from experts using the Delphi technique estimated the effectiveness of post-exposure smallpox vaccination in preventing disease at 1–3 days after exposure to be 80%.31

There are insufficient data to estimate effectiveness against mpox in the most recent outbreak. MVA-BN has only been used for PEPV in a limited number of high-risk contacts. In 2 French studies of MVA-BN used for PEPV, 1 study reported a breakthrough infection rate of 4% (12/276 participants), including 10 cases within 5 days of vaccination.32 The other reported a rate of 10% (11/108 participants), with a median time between vaccination and symptom onset of 5 days.33 The clinical course in breakthrough cases was mild, and no patients required hospitalisation. The average incubation time of the monkeypox virus was shown to be 7–9 days.34 Breakthrough cases presenting within 5–7 days after vaccination would not be considered fully immunised.

## Benefits

Key benefits of these recommendations include the following:

People who are most at risk of mpox infection can receive a safe and effective vaccine. This helps to prevent infection in people at high risk of exposure, and also makes it less likely that infection will be passed on to other people, especially those who have a higher risk of severe disease (such as children and pregnant women).

People who have already been exposed to mpox can receive a safe and effective vaccine that likely reduces the chance of mpox occurring and the severity of the disease if it does occur.

A new chapter for mpox in the Australian Immunisation Handbook means that mpox information is incorporated into a single website along with recommendations about other vaccines in Australia. Immunisation providers will have all the information they need from a single source.

## Potential risks

The potential risks that may arise from the recommendations include the following:

MVA-BN vaccine can be administered either subcutaneously or intradermally. Fractional intradermal dosing may be used as a dose-sparing strategy when there are supply constraints and for PPV only. Immunisation providers need specific training in the intradermal administration technique. There is a higher potential for adverse events and administration errors using the intradermal route. Incorrect administration may mean the person receiving the vaccine is not adequately protected against mpox.

Data on vaccine safety in pregnant women, infants and children aged <16 years are limited, although no safety concerns are expected or have been identified to date. PEPV for these groups should only be done after assessing the risks and benefits.

MVA-BN vaccine is not licensed for use in children. This means that PEPV in infants and children constitutes off-label use of MVA-BN vaccine. PEPV for children should only occur after assessing the risks and benefits.

## Preference and values

The recommendations for the use of mpox vaccines are in line with best clinical advice. It is expected that these recommendations will result in additional protection for people who are most at risk of mpox infection. This is consistent with societal expectations of the best use of vaccines in Australia.

There is no published Australian research investigating the preferences and values of people who received mpox vaccine during the 2022 outbreak. The willingness of people to be vaccinated was dynamic throughout the outbreak and depended on the perceived risk posed by the disease. Clinical experts have observed important variability in values and engagement with vaccination programs between high-risk groups and the general public. Demographics affected by any future outbreaks are unclear. This means it is not known whether the values expressed by populations most affected by the 2022 mpox outbreak can be extrapolated to other populations.

These recommendations are not funded under the National Immunisation Program. Immunisation providers should check the current funding status in their state or territory for each individual’s situation.

## Additional information in the Australian Immunisation Handbook

The Handbook chapter on mpox has the same structure as other Handbook chapters. This includes information on:

vaccines, dosage and administration

contraindications and precautions

adverse events

nature of the disease

clinical features

epidemiology

vaccine information

transporting, storing and handling vaccines

public health management

variations from product information.

## Glossary

A [glossary of technical terms](https://immunisationhandbook.health.gov.au/technical-terms) is available on the Australian Immunisation Handbook website.

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