Vaccination against mpox using the JYNNEOS vaccine

Training for healthcare practitioners
August 2024

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Aim and Learning Outcomes for this Session

Aim:

To equip vaccinators with the knowledge they require to safely and effectively administer the JYNNEOS MVA-BN vaccine.

Learning outcomes:

By the end of this session, vaccinators should be able to:

- explain the recommendations for the use of the JYNNEOS MVA-BN vaccine and know where to access current guidance
- recognise the legal aspects of vaccine administration.
- describe the storage, handling and safe administration of the MVA-BN vaccine.

Mpox virus

- Mpox is a viral infection that causes a rash.
- It is caused by the *monkeypox virus*, a DNA virus of the orthopoxvirus genus.
- Since the global eradication of smallpox in 1980 and subsequent cessation of smallpox vaccination, mpox has emerged as the most important orthopoxvirus.
- Since May 2022, there has been a global increase in mpox Clade IIb cases reported from multiple countries where mpox is not usually seen.
- Human-to-human transmission of Clade IIb is occurring largely through sexual networks of gay, bisexual and men who have sex with men (GBMSM). It is mainly spread by skin-to-skin contact with someone who has mpox.
- Since January 2023, there has been an outbreak of a more severe strain mpox in central and eastern Africa (Clade I).

- Mpox has been notifiable in Australia since 1 June 2022.

Mpox symptoms

- Symptoms usually begin 7-14 days after exposure; this can be as short as a few days or as long as 21 days.
- Symptoms can vary but usual mpox symptoms include:
  - Rashes, pimple-like lesions or sores, particularly in areas that are hard to see such as the genitals, anus or buttocks, and on the face, arms and legs
  - Ulcers, lesions or sores in the mouth
  - Rectal pain (pain in and around the anus), which may occur without a rash
  - Fever, headache, muscle aches, backache, swollen lymph nodes, chills and/or exhaustion may occur prior to the rash or lesions developing.
- The lesions often start as a flat red rash that develops into pustules, which then form crusts or scabs and fall off.
- Presentation in vaccinated individuals can be very mild and atypical.
- Clinicians should have a very low threshold for mpox testing.

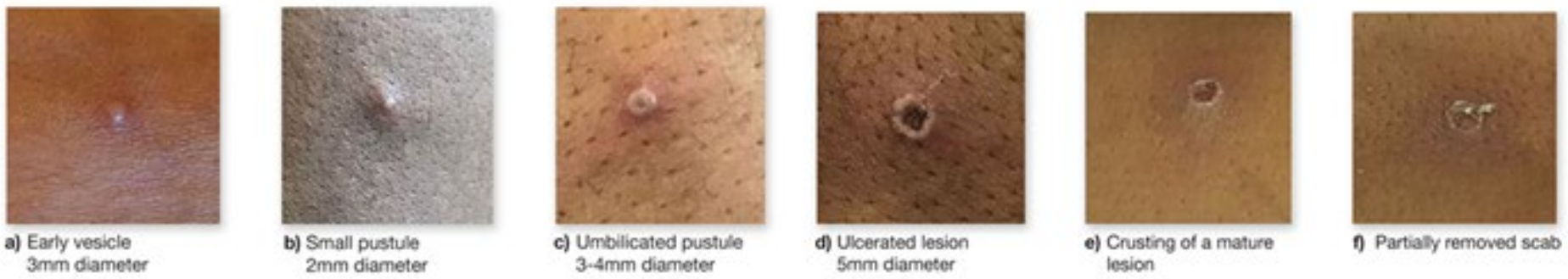

Figure: Individual mpox lesions (Image credit) United Kingdom Health Security Agency

Mpox transmission

- Mpox mainly spreads from one person to another by direct skin-to-skin contact, semen and other bodily fluids, contaminated objects such as bedding or clothes, and breathing in droplets breathed out by someone who has mpox (but this is rare).
- People with mpox may be infectious up to 4 days prior to the onset of symptoms until all the lesions have crusted, the scabs have fallen off and a fresh layer of skin has formed underneath, and any rectal pain has completely resolved. To reduce the risk of transmission to others, people with mpox should follow the NSW Health recommendations for cases.
- It is not known how long *mpox virus* remains present in semen and other genital excretions. People who have mpox should abstain from sex for the duration of their infection and should use condoms when engaging in sexual activity for 12 weeks after recovery. They should also not donate any human tissue, including blood, cells, tissue, breast milk, semen, or organs (while unwell and for 12 weeks following clearance).

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Vaccination to prevent mpox

- Smallpox vaccines can provide protection against mpox because the two viruses are closely related.
- NSW Health provides a vaccine against smallpox called JYNNEOS, which is the USA brand.
- JYNNEOS can be safely used by all groups of people, including those who are immunocompromised. It is a replication-deficient vaccine containing live attenuated Modified Vaccinia Ankara (MVA) virus.
- JYNNEOS is produced by Bavarian Nordic (BN) and is often called MVA-BN. Its brand names in Canada (Imvamune) and Europe/UK (Imvanex).
- In human and animal studies, JYNNEOS demonstrates very limited replication capability and low neuropathogenicity, while retaining immunogenic properties, including protective immune responses against a variety of orthopox viruses.
- As JYNNEOS cannot replicate in mammalian cells, it does not produce a lesion at the site of vaccination, unlike previous smallpox vaccines. The vaccine **does not** contain smallpox virus (Variola virus) and **cannot** cause or spread smallpox.
- This learning module will discuss vaccination using the JYNNEOS vaccine.

Vaccine recommendations for JYNNEOS vaccine

In NSW, JYNNEOS vaccine is recommended as a primary preventative vaccination (PPV) for the following groups:

- All sexually active gay, bisexual or other men who have sex with men (GBMSM)
- Sex workers, particularly those whose clients are at risk of mpox exposure
- People living with HIV, if at risk of mpox exposure
- Laboratory personnel working with orthopoxviruses

PPV may also be considered for:

- Healthcare workers at risk of exposure to patients with mpox
- Sexual partners of GBMSM, sex workers and people living with HIV
- Anyone at greater risk of a poor clinical outcome from mpox infection, such as individuals who are immunocompromised

- Post-exposure preventative vaccination (PEPV) is recommended for contacts of mpox cases who have not previously received two doses of JYNNEOS vaccine. Ideally, contacts should receive PEPV within 4 days of last exposure of last exposure to a case but can receive it up to 14 days since last exposure.

- Two doses of the vaccine are required for maximum protection, given at least 28 days apart.

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Efficacy of the JYNNEOS vaccine

- JYNNEOS efficacy studies looked at protective efficacy against smallpox, however, licensing studies have been conducted using challenge with *monkeypox virus*.
- Animal studies using JYNNEOS vaccine have shown high efficacy against mpox, from 6 days after a single dose of vaccine.
- Human trials of JYNNEOS suggested 2 doses of vaccine are immunogenic, generating antibody levels considered protective against smallpox, and by extrapolation, mpox as well.
- There is limited evidence on whether the vaccine can prevent or modify disease when given post-exposure.
- Although the full course comprises 2 doses, some immunological response to the first dose can be detected within the first 2 weeks.
- Rapid vaccination may therefore prevent infection and/or modify disease severity for cases with longer incubation periods.
- It is likely that 2 doses provide up to 85% protection against mpox and 1 dose up to 65%.
- The second dose can be given several months after the first dose and still generate maximal immunity.

Safety of the JYNNEOS vaccine

- Data from multiple clinical trials shows that JYNNEOS vaccine causes fewer adverse events than previous smallpox vaccines.
- Although local injection site reactions and influenza-like illness symptoms are common, serious adverse events are rare.
- The most common side effects seen following JYNNEOS vaccination in clinical trials were:
  - headache,
  - nausea,
  - myalgia (muscle pain),
  - tiredness,
  - injection site reactions (pain, redness, swelling, hardening and itching).
- Reactions were mild to moderate in intensity and resolved without intervention within 7 days following vaccination.
- Rates of adverse events reported after first dose, second dose or booster dose were similar, but anecdotally the frequency of adverse events, particularly local site reactions, appears to be higher in those who have received previous live smallpox vaccine.

Reported reactions to JYNNEOS

Very common (may affect >1 in 10 people)	Common (may affect up to 1 in 10 people)	Uncommon (may affect up to 1 in 100 people)	Very uncommon (may affect up to 1 in 1000 people)
headache	chills	nose and throat infection, upper respiratory tract infection	sinus infection
aching muscles	fever	swollen lymph nodes underarm swelling, pain in the armpit	influenza-like illness
feeling sick	joint pain	abnormal sleep	hives
tiredness	pain in extremities	dizziness, abnormal skin sensations	skin discolouration, bruising, lump
pain, redness, swelling, hardness or itching at the injection site	loss of appetite	muscle stiffness	sweating/night sweats
	discolouration, bruising or warmth at the injection site	sore throat, runny nose, cough	muscle cramps, pain, weakness
		diarrhoea, vomiting, abdominal pain, dry mouth	swelling of ankles, feet, fingers, face, mouth, throat
		rash, itch, skin inflammation, skin discolouration, bruising flushing, feeling unwell chest pain	faster heart beat; back, neck, abdominal pain ear and throat ache; dry mouth; spinning sensation (vertigo); migraine; nerve disorder causing weakness, tingling or numbness, drowsiness blisters at injection site; weakness, feeling unwell; pink eye

Contraindications and precautions

- JYNNEOS is contraindicated in those who have had a sudden life-threatening allergic reaction to a previous dose of, or to any components of the JYNNEOS vaccine.
- The vaccine contains trometamol, sodium chloride and water for injections.
- It may also contain trace amounts of chicken protein, benzonase, gentamicin and ciprofloxacin from the manufacturing process.
- Immunocompromised people, including those receiving immunosuppressive therapy, may have a diminished immune response to JYNNEOS.
- Vaccination with JYNNEOS may not protect all recipients.
- Minor illnesses without fever or systemic symptoms are not valid reasons to postpone immunisation.
- If an individual is acutely unwell, immunisation may be postponed until they have fully recovered to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine.
- Vaccination given after the onset of signs or symptoms of mpox, after a diagnosis of mpox, or after recovery from mpox is not expected to provide benefit.

Precautions

Children

- JYNNEOS has not been formally studied in children aged under 18 years.
- The Australian Technical Advisory Group on Immunisation (ATAGI) advises that vaccination with JYNNEOS in children can be considered, especially for individuals in high-risk groups aged 16 years and older, after discussing the risks and benefits of vaccination with their immunisation provider.

Pregnancy / breastfeeding

- JYNNEOS is not contraindicated for people who are pregnant or breastfeeding, however, these people should discuss the benefits and risks with a doctor prior to vaccination.

Atopic dermatitis

- People with atopic dermatitis are known to have developed more site-associated reactions and generalised symptoms following JYNNEOS vaccination.
- People with atopic dermatitis need to have an individual risk assessment before being offered vaccination to assess the risk from exposure, the risk of side effects from vaccination and the potential use of alternative preventive interventions.

Immunosuppression

- JYNNEOS is not contraindicated for people who are immunosuppressed.
- JYNNEOS has been demonstrated to be safe in people with HIV infection.

JYNNEOS: delayed vaccination and administration with, before or after other vaccines

- If the JYNNEOS course is interrupted or delayed, it should be resumed using JYNNEOS vaccine but the first dose does not need to be repeated.
- JYNNEOS may be given concomitantly with other vaccines noting a theoretical risk of an attenuated immune response if administered close to live vaccines
- There is no evidence of any safety concerns from giving other vaccines at the same time as the JYNNEOS vaccine, **although it may make the attribution of any adverse events more difficult.**
- Whether JYNNEOS is associated with a risk of myocarditis is uncertain. For primary preventative vaccination purposes only, spacing JYNNEOS and an mRNA COVID-19 vaccine apart by several weeks may be considered for people with increased risk of myocarditis and/or pericarditis following an mRNA COVID-19 vaccine, (e.g. young adult males).
- Where individuals in an eligible cohort present having recently received one or more inactivated or another live vaccine, JYNNEOS vaccination should still be given.
- It is generally better for vaccination to proceed to avoid any further delay in protection and to avoid the risk of the individual not returning for a later appointment.

Training requirements for vaccinators

As per NSW Health: Mpox statewide protocol for the supply and administration of JYNNEOS vaccine:

- Vaccine to be administered by authorised health practitioners.
- Registered nurses and medical practitioners must:
  - have read and understood this module
  - have current cardio-pulmonary resuscitation (Basic Life Support) competency
  - have received prior training to recognise and manage anaphylaxis including the use of adrenaline (epinephrine)
  - remain up to date on any new advice from the Australian Technical Advisory Group on Immunisation (ATAGI) or Therapeutic Goods Administration (TGA) regarding additional precautions or consent requirements
  - practice in accordance with any local conditions
  - ensure appropriate records are retained.

Registered Nurse Administration

- An authorised nurse/midwife immuniser may supply and administer JYNNEOS vaccine under the NSW AUTHORISED REGISTERED NURSES AND MIDWIVES VACCINATION STANDARDS

- Registered nurses, who are not authorised nurse/midwife immunisers, can administer JYNNEOS:
  - at the direction and under the authority of a medical practitioner, or
  - under a medication standing order allowing the administration of the vaccine.

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Section 18A exemption

JYNNEOS vaccine is not TGA approved.

- **Section 18A** Therapeutic Goods Act 1989
  - Therapeutic Goods (Medicines-MVA-BN) (Emergency) **Exemption** (no. 2) 2022 (until 2030)
  - Specific to: MVA-BN a modified vaccinia Ankara virus, also known as Imvanex, Imvamune and JYNNEOS
  - Applicable to the National Stockpile (NMS goods), and for CHOs (CHO goods).
- Further information can be found in the Australian Immunisation Handbook.
- In NSW, vaccination can only proceed according NSW Health: Mpox statewide protocol for the supply and administration of JYNNEOS vaccine.

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Vaccine recommendations: Primary preventative vaccination (PPV)

- The complete primary preventative vaccine course with JYNNEOS in immunocompetent individuals is 2 doses given at least 4 weeks apart.
- For individuals with a history of receiving a single dose of a live smallpox vaccine, a single dose of JYNNEOS is recommended if it has been more than 10 years since their smallpox vaccine.
- Live vaccine was only used up to the 1970s, so vaccinated individuals will at least 45 years or older, and should have a distinctive scar (which normally looks like a circular dent in the left upper arm). Australian estimates: those born prior to 1980- approx. 30% (mostly immigrants) have been vaccinated against smallpox.

Vaccine recommendations: Post-exposure preventative vaccination (PEPV)

- Vaccination with JYNNEOS for post-exposure preventative vaccination should be offered to people who:
  - have not received two doses of JYNNEOS vaccine or it is more than 10 years since smallpox vaccine, and
  - have known or presumed exposure to a person with mpox , and / or
  - have certain risk factors and recent experiences that might make them more likely to have been exposed to mpox.
- If indicated, contacts should be administered PEPV as soon as possible, ideally within 4 days of last exposure to prevent disease.
- Administration of PEPV can be considered up to 14 days as it may attenuate disease severity.
- If exposure has been intermittent or continuous, post-exposure vaccination should be ideally given within 4 days of the last exposure.
- Contacts presenting for PEPV who have received a single dose of JYNNEOS vaccine should be offered a second dose if at least 28 days has passed since their first dose.
- As the vaccine may only attenuate rather than prevent disease in some cases, contacts who have received post-exposure vaccination require equivalent follow up to those contacts who are unvaccinated.
- Refer to the Post-exposure preventative vaccination (PEPV) for mpox on the NSW Health website for more information

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Consent

- Before giving any vaccine, vaccinators must ensure that they have obtained informed consent from the vaccinee.
- In order to be able to consent to vaccination, the vaccinee should receive an explanation of the treatment and its benefits and risks, either verbally from a clinician, or in the form of a leaflet or letter.
- The requirement for completing a written consent form was recently removed from the protocol. Either a verbal consent or use of the national standardised consent form is acceptable.
- Online consent is also obtained by clients using the vaccination administration management (VAM) platform or another electronic record system.

Storage and handling of JYNNEOS vaccine

- For distribution, the vaccine will be transported at +2°C to +8°C to designated vaccination providers.
- Once received, the Vaccine must be stored at +2°C to +8°C and must not be re-frozen.
- The vaccine is stabilised at -50°C and brought directly to +2°C to +8°C it is stable at +2°C to +8°C for 24 weeks.
- When stored at +2°C to +8°C it must remain in this temperature until immediately before administration.
- The vaccine must not be used after the expiration date shown on the vial label.
- The vaccine is provided as a suspension for injection in single dose vials (0.5 ml). It is available in packs containing 20 single dose vials.
- If there is a cold chain breach, contact the Public Health Unit (PHU) on 1300 066 055.
- Store in original package in order to protect from light.

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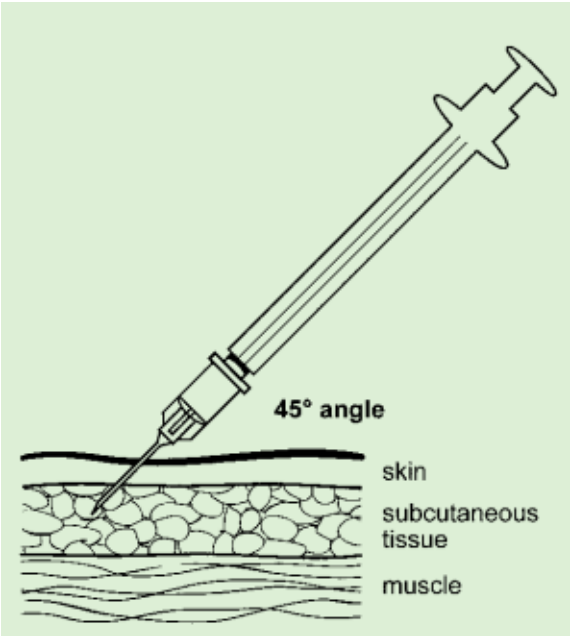
Administration of JYNNEOS

- The vaccine should be allowed to reach room temperature before use.
- Once the frozen vaccine has been thawed, JYNNEOS is a light yellow to pale white milky suspension for injection.
- Swirl vial gently before use for at least 30 seconds.
- Visually inspect the suspension prior to administration.
- If particles and/or discolouration or abnormal appearance are seen, the vaccine should be quarantined and appropriate advice sought.
- A single dose is 0.5 ml which should be given by deep subcutaneous (SC) injection, preferably into the deltoid region of the upper arm in adults (thigh in children < 1 year).
- SC injections should be given with the needle at a 45º angle to the skin and skin should be bunched, not stretched.



- *Intradermal administration of the JYNNEOS vaccine was undertaken when vaccine supplies were constrained. From January 2023, the vaccine should be administered subcutaneously only.*
- *As per the ATAGI, the subcutaneous and intradermal routes of administration for JYNNEOS are interchangeable. If the first dose of JYNNEOS was administered via the intradermal route, the second dose can be administered subcutaneously.*

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Disposal

- Equipment used for vaccination, including used vials, ampoules or syringes, should be disposed of by placing them in a proper, puncture-resistant ‘sharps box’ according to local protocols and in accordance with NSW *Public Health Regulations 2012* and NSW *Blood and Body Substances Occupational Exposure Prevention guideline* (GL2024_002).
- Sharps waste and empty vials should be placed into yellow lidded waste bins and sent for incineration; there is no need for specific designation as GMO waste (as considered non-viable).
- An appropriate virucidal disinfectant should be available for managing spills in all settings where vaccination is administered.
- Any potentially contaminated gloves and aprons used can be disposed of in appropriately colour-coded and labelled bags for offensive waste.
- See: NSW *Clinical and Related Waste Management for Health Services* (PD2020_049).

Recording

- JYNNEOS vaccination is to be recorded in the Australian Immunisation Register (AIR) unless client requests to opt out.
- The following information should be recorded for each person:
  - Name
  - Address
  - Date of birth
  - Medicare number (if available) including position on card
  - Sex
  - Phone number
  - Whether the person has any relevant conditions, including precautions or contraindications, established above
  - That they have received the relevant information sheet and appropriate post-immunisation advice
  - Vaccine name, the date and time the vaccine was administered, batch number, site of vaccine injection and name of vaccination service provider and medical practitioner (if provider is a RN).
- Following vaccination, observe the patient for 15 minutes, and check the patient has no signs or symptoms requiring clinical review prior to discharge.
- Record the administration of each vaccine.

Post vaccination information

- Any fever following vaccination should be monitored and if individuals are concerned about their health at any time, they should seek advice from their immunisation provider, GP or emergency department.
- Following vaccination, vaccine recipients should be given written information about possible reactions to the vaccine, how to treat these, and when and from whom to seek further advice if required.
- A JYNNEOS fact sheet, the NSW Health mpox fact sheet and What to do after you get your mpox vaccine should be given to vaccinees.

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Reporting adverse events after immunisation (AEFIs) in NSW

- Adverse event after immunisation are reportable events under the Public Health Act.
- Contact the Public Health Unit (PHU) on 1300 066 055 or complete the TGA national AEFI reporting form www.tga.gov.au/form/national-adverse-events-following-immunisation-aefi-reporting-form#aefi-form.
- Provide any relevant medical reports and investigations for serious AEFI.
- Contact PHU if you are unsure whether a clinical event is an AEFI.
- Clinicians can contact the Immunisation Advice Line for specialist immunisation advice during business hours on 1800 679 477 or schn-nswiss@health.nsw.gov.au.

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Resources

- NSW Health mpox hub https://www.health.nsw.gov.au/mpox
- Australian Immunisation Handbook: Mpox https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/mpox-previously-known-as-monkeypox
- NSW Health: Mpox State-wide Protocol for the Supply and Administration of JYNNEOS Vaccine www.health.nsw.gov.au/Infectious/factsheets/Pages/mpxv-protocol.aspx
- ATAGI interim statement on the use of vaccines for prevention of mpox in 2024 https://www.health.gov.au/resources/publications/atagi-interim-statement-on-the-use-of-vaccines-for-prevention-of-mpox-in-2024?language=en
- Australian Government monkeypox (mpox) resources https://www.health.gov.au/resources/collections/monkeypox-mpox-resources
- NSW Health mpox fact sheet https://www.health.nsw.gov.au/Infectious/factsheets/Pages/mpox.aspx
- Clinical Excellence Commission Mpox (Monkeypox) Infection Prevention and Control Information for clinicians https://www.cec.health.nsw.gov.au/__data/assets/pdf_file/0003/728148/infection-prevention-and-control-information-for-clinicians-mpox.pdf

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