AFAO BRIEFING: MONKEYPOX VACCINATION INFORMATION

5 October 2022

Executive summary

Vaccination against monkeypox is safe and an important measure to protect people, particularly gay, bisexual and men who have sex with men (GBMSM). There is a limited supply of these vaccinations, which has led to logistical and social challenges. To address these challenges, the sector has rolled out several strategies such as tailoring outreach to communities, delaying access to second doses and delivering the vaccination intradermally.

Vaccination against monkeypox is safe and is thought to be effective.

In Australia, JYNNEOS® ("JYNNEOS") is the preferred vaccine for monkeypox. Research suggests that JYNNEOS is effective against monkeypox. A recent real-world study of 1,970 subjects from Israel estimated the vaccine was 79% effective 25 days after the first dose.[1] The second dose is thought to further strengthen immunity.

JYNNEOS is a safe vaccination. Vaccine safety surveillance of 1,310 participants showed most did not experience an adverse event after their first dose of JYNNEOS. Those who did experience an adverse event reported it was mild and short-lived. Few people had to miss work, study or routine activities or attend a healthcare professional in the following days. Results were consistent across vaccinations delivered subcutaneously and intradermally. More information can be found here.

The limited supply of vaccinations has led to logistical and social challenges.

Globally, there is limited supply of JYNNEOS. This is because demand for JYNNEOS increased dramatically in a short period of time. Currently, there is only one supplier of JYNNEOS in the world.

Australia will have access to a sufficient number of doses; however, not all of them will be accessible immediately. 22,000 doses of JYNNEOS arrived in August 2022 and 78,000 doses arrived in September 2022. The remainder of the 450,000 doses that were ordered by Australia are expected to arrive in 2023.

Depending on the trajectory of the monkeypox health response, the currently limited supply could lead to challenges. These include:

- tension between states and territories to secure sufficient supply to meet demand, particularly if there is an outbreak in one or more jurisdictions; and
- ensuring individuals that are particularly at risk of monkeypox can access the vaccine, such as those who are culturally and linguistically diverse, newly arrived in Australia, living with a disability or experiencing insecure housing.

The currently limited supply also contributes to other factors that complicate the national response to monkeypox. These include:

- existing community fatigue regarding large-scale health responses after the Covid 19 pandemic response; and

- ongoing stigma against GBMSM.

There are strategies to protect the community whilst there is limited supply of vaccination.

Firstly, AFAO member organisations tailor vaccine outreach to target individuals that are most at risk. Member organisations at the state and territory levels understand the preferences of their local communities. This tailoring impacts how the vaccinations are promoted. To maximise effectiveness, member organisations require sufficient funding to develop these campaigns.

Secondly, states and territories develop their own policies to determine eligibility for first and second doses of the vaccination. Access to a second dose will be determined by vaccine supply and the proportion of eligible individuals that have had their first vaccination. As discussed above, research estimates the first dose of JYNNEOS is 79% effective against monkeypox. Hence, vaccinating a significant proportion of the eligible cohort with their first dose ensures a baseline level of protection across the community. The current guidance is the second dose of the vaccination should occur at least one month after the first dose. Experts advise the second dose will provide optimal protection against infection even if it is administered several months after the first dose.

Health experts have not confirmed the specific proportion of eligible individuals in each jurisdiction that should be vaccinated with their first dose before second doses are allowed. At present, it remains a matter for states and territories to decide, based on the Australia Technical Advisory Group on Immunisations (ATAGI) guidance on Vaccination against monkeypox. There is a risk of inequity if one state and territory starts administering second doses whilst another jurisdiction lacks the doses to provide first doses to its eligible individuals. At present, this concern is moot assuming Australia receives its promised shipment of JYNNEOS in a timely fashion.

Thirdly, the intradermal method is used to increase the number of people who can be vaccinated. Intradermal vaccination is the delivery of vaccines into the outer layers of the skin. The alternative method for delivery of vaccines is subcutaneous, which is when the vaccine is delivered under the skin. Intradermal is the preferred method for most recipients of the JYNNEOS vaccine in Australia because operators can spread one vial across five doses instead of one dose per vial with the subcutaneous method.

The intradermal method is thought to be effective. A 2015 study states intradermal administration of the monkeypox vaccine elicited a similar antibody response compared to the subcutaneous injections. Intradermal vaccination against monkeypox is used in several other jurisdictions including the United States.[2]

Intradermal vaccination will not be appropriate for all groups. These groups include those who are severely immunocompromised, have certain skin condition and those using the vaccination as post-exposure prophylaxis (PEP). Most people using the vaccination as a pre-exposure prophylactic can receive the vaccination intradermally.

There are some barriers against the use of intradermal vaccination in the community. These barriers are that:

- the workforce lacks capability. As intradermal vaccination is a less commonly used technique, some medical practitioners lack knowledge and training to deliver vaccines intra-dermally. Some jurisdictions require their workforce to review relevant information for intradermal administration prior to administering the vaccination and require clinics to ensure any staff administering vaccine are competent in intradermal administration technique and staff are competent in drawing up from a multi-dose vial.[3]
- there is confusion around messaging. Media have been calling intradermal vaccination a "new" vaccination method.[4] The technique itself is not new. Intradermal vaccination has been used to stretch out a short supply of shots in other instances, including for polio.[5] There is concern that community members may presume subcutaneous vaccination is more effective than intradermal. As discussed above, intradermal vaccination has been shown to deliver a similar antibody response compared to subcutaneous injections. We advise stakeholders to be careful in how they share information on the vaccination delivery, in particular the positioning of subcutaneous versus intradermal.
- intradermal vaccination can leave a temporary mark. A 2015 study found 36% of trial participants who received intradermal vaccine had mild injection site inflammation, redness, or discoloration lasting at least six

months.[6] Marks can lead to stigmatisation. The fear of having a mark that is visible to others could reduce uptake of the vaccination. To abate concerns around stigma, medical practitioners who are administering the vaccination can offer to do the injection into another site like the deltoid instead of the forearm, which may be easier to cover with clothing.

- there is insufficient uptake of the vaccination. Jurisdictions administering the vaccines in settings with low numbers of eligible individuals may opt to vaccinate via the subcutaneous method because once the vial is opened, it might expire before there is time to vaccinate multiple people intradermally.

We encourage you to share these FAQs regarding intradermal vaccination with your communities.

We have included a sample of questions and answers that community organisations can publicise widely.

- What are intradermal vaccinations? Intradermal vaccination is a form of vaccine delivery that injects the vaccine into the outer layers of the skin as opposed to the subcutaneous method which delivers vaccine under the skin.
- Why are intradermal vaccinations being used to protect against monkeypox? A smaller dose of vaccine is required for intradermal vaccinations compared to subcutaneous vaccination. This means Australia can vaccinate more people with our limited amount of vaccine.
- Is intradermal vaccination as effective as the standard approach to vaccination? Evidence suggests so. A 2015 study states that intradermal administration of the monkeypox vaccine elicited a similar antibody response compared to subcutaneous injections. Intradermal vaccination against monkeypox is used in several other jurisdictions including the United States.[7] Intradermal vaccination has also been used for other vaccines such as the polio vaccine.
- Is there any special guidance after I get an intradermal vaccination? You should avoid touching or covering the vaccination site with anything (band aid, clothing etc.). The site of the vaccination may be sore for a couple days.
- Is it possible to administer the intradermal injection in a location that is not the forearm? The intradermal vaccination can theoretically occur anywhere on the body, but the forearm is the default site because it is typically a flat surface with less hair than other parts of the body. In some states and territories, healthcare workers can provide the vaccination into the deltoid (upper arm). Using the deltoid may increase the likelihood of failure, which means the person administering would need to try again. We recommend speaking with the healthcare worker administering the vaccine to find the best option for you.

---

[1] Ronen Arbel, "Effectiveness of a single-dose Modified Vaccinia Ankara in Human Monkeypox: an observational study," September 2022.
[2] https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html.
[3] https://www.health.nsw.gov.au/Infectious/Documents/mpxv-protocol.pdf.
[4] https://www.forbes.com/sites/madelinehalpert/2022/08/22/nih-will-study-new-dose-sparing-monkeypox-vaccination-method/?sh=15bad0b41924.
[5] https://www.forbes.com/sites/madelinehalpert/2022/08/22/nih-will-study-new-dose-sparing-monkeypox-vaccination-method/?sh=15bad0b41924.
[6] https://www.sciencedirect.com/science/article/pii/S0264410X15008762.
[7] https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html.