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AUSTRALIAN TECHNICAL ADVISORY GROUP ON IMMUNISATION (ATAGI) CLINICAL GUIDANCE

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CLINICAL GUIDANCE ON THE USE OF VACCINES FOR PREVENTION OF MPOX IN 2024

Further details about mpox vaccination can be found in the Australian Immunisation Handbook mpox chapter.

Overview of key points

- ATAGI now recommends pre-travel vaccination for anyone (regardless of sexual orientation or gender identity) who may undertake sexual risk activities during travel to countries with transmission of clade I mpox.
- The ATAGI recommendations for mpox vaccination have been updated to remove the age restriction; people of all ages who are at risk of exposure to mpox are recommended to receive the mpox vaccination.
- ATAGI is continuing to closely monitor emerging evidence on use of mpox boosters. Currently, ATAGI does not recommend booster doses of the mpox vaccine for people who are fully vaccinated (that is, 2 doses administered at least 28 days apart), including those who are severely immunocompromised.
- ATAGI has been monitoring evolving mpox epidemiology in Central Africa and other affected regions. Currently, ATAGI does not recommend vaccination for all people travelling to areas where mpox transmission is occurring, including endemic areas in Africa with clade Ib transmission, only those people referred to above. However, all travellers to risk areas should be aware of the need for general precautions.
- Published studies suggest that the JYNNEOS mpox vaccine is moderately to highly effective in reducing the severity of symptoms associated with mpox infection in fully vaccinated individuals. Two doses of an mpox vaccine provides higher protection than a single dose. People who received the first dose >28 days ago should receive their second dose as soon as possible to maximise protection.
- Additional booster doses (i.e. in addition to the two primary doses) are not recommended by ATAGI at this time.
- Ensuring more eligible people are fully vaccinated is essential to provide protection against severe disease/clinical manifestations associated with infection. Vaccination can also reduce the risk of onwards transmission to other at-risk individuals and communities.

Background and epidemiology

- Mpox, previously known as monkeypox, is a viral disease caused by infection with the monkeypox virus (MPXV). It is part of the same family of viruses that causes smallpox.
- There are two genetically distinct MPXV clades, clade I (clade Ia and clade Ib) and clade II (clade IIa and clade IIb). In previous outbreaks in endemic African countries, clade I has caused a higher proportion of severe disease and has been more transmissible than clade II.
- The first mpox case in Australia was reported in May 2022,[1] and it was subsequently declared a Communicable Disease Incident of National Significance. Mpox cases, made up of clade II infections, peaked in August 2022 and then declined.[1]
- An mpox vaccination program was initiated in Australia in August 2022. By the end of 2022, 30,346 people received 1 dose of JYNNEOS, with another 16,954 people completing a full course (2 doses).[1]
- In 2024, there has been a resurgence of clade II cases in Australia.
- Most cases have been acquired in Australia and a small number have been in people who were fully vaccinated.

- The upsurge of mpox cases has been affecting Democratic Republic of the Congo (DRC) since 2023.[2] This includes a new strain, clade Ib, which has rapidly spread to a growing number of African countries, particularly in Central and Eastern Africa.
- On the 14 August 2024, the WHO declared the upsurge of mpox cases in the DRC and its expansion to neighbouring countries a public health emergency of international concern for the second time.[3] The WHO first declared mpox a public health emergency of international concern in July 2022 following a multi-country outbreak of mpox. The 2022 outbreak was declared over in May 2023.[3]
- There have also been several travel-associated clade I mpox cases reported in non-African countries such as Sweden, Thailand, the United Kingdom and the United States. As of 13 December 2024, there have been no reported clade I mpox cases in Australia.

Current recommendations

- Primary preventive vaccination (PPV) against mpox is now recommended for groups of all ages at risk of exposure. This includes:
    - 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 can also be considered for:
    - healthcare or humanitarian workers at risk of occupational exposure to mpox
    - sexual partners of GBMSM, sex workers and people living with HIV
- Prior to travel for any individual (regardless of sexual orientation or gender identity) who may undertake sexual risk activities in countries with transmission of clade I mpox.
- Currently, the supply of mpox vaccine is sufficient and the preferred route of administration is subcutaneous injection. Alternatively, intradermal injections have been used to maximise the use of vaccines.
- ATAGI is continuing to review evidence for use of mpox vaccines so that vaccination recommendations can be updated if necessary. More information on the current mpox vaccination advice, including recommendations for post-exposure preventive vaccination, can be found in the Australian Immunisation Handbook.

Vaccine effectiveness against mpox

- Current post-marketing observational studies suggest that JYNNEOS has moderate to high vaccine effectiveness, with 1-dose effectiveness ranging from 35.8% to 86.4% and 2-dose effectiveness ranging from 66% to 89.5%.[4-8]
- Clinical data on the vaccine effectiveness of a JYNNEOS booster (third) dose are not yet available.
- Vaccine effectiveness in fully vaccinated immunocompromised people (including people living with HIV and people who are immunodeficient due to medications or conditions) is lower than in immunocompetent people (70.2% vs. 87.8%, respectively).[9]
- Vaccine effectiveness in fully vaccinated people is similar for those who received the vaccine via the subcutaneous route (89%), intradermal route (80%) or as a mixed schedule (87%).[9]
- JYNNEOS can be given to infants, children and pregnant or breastfeeding women after a risk–benefit assessment. Although data are limited, no serious safety concerns have been observed.[10,11]

Waning immunity

- Waning of vaccine-induced immunity has been observed starting from 3–4 months post-vaccination, dropping close to baseline by 10–24 months. However, this is based on a limited number of immunogenicity studies.[12-14]
- The clinical significance of waning antibody levels is uncertain due to a lack of an established correlate of protection for mpox disease.[15]
- Breakthrough infections and re-infections can occur, but most vaccinated people experience a shorter disease course and milder symptoms than those who have not been vaccinated.[16,17] Illness onset after the second dose of JYNNEOS varies, with the median interval ranging from approximately 10 to 300 days.[17-19]

- Despite a perceived increase in mpox infections among fully vaccinated people during 2024, the rate of reported breakthrough mpox disease over a 2 year time period is estimated to be <1% in fully vaccinated people from a recent United States report.[19] However, further monitoring is required to assess longer term trends among mpox in vaccinated people.
- Immunogenicity data for a booster dose of JYNNEOS given 2 years after the primary course are very limited,[20] and clinical data on the vaccine effectiveness of an JYNNEOS booster dose are not yet available. Therefore, additional booster doses are not recommended by ATAGI at this time.

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