Folkhälsomyndigheten

Vaccination against mpox

– an update due to the increased spread of clade 1

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About the publication

This update of the current vaccine recommendations for protection against mpox was prompted partly because Africa CDC declared a public health emergency for the African continent on 13 August 2024 due to the increased spread of mpox in Central, East and West Africa, partly because WHO declared a global public health emergency on 14 August 2024 and finally because Sweden identified the first case of clade 1b outside the African continent on 15 August 2024.

ECDC and WHO have since upgraded the risk of the spread of clade 1, in particular clade 1b, to Europe and globally.

The Public Health Agency of Sweden will follow the clinical and epidemiological development of the outbreak caused by the three different clades of the monkeypox virus: clade 1a, clade 1b and clade 2b.

Public Health Agency of Sweden, 23 August 2024

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Summary

The increased spread of mpox within and outside of Africa has prompted an update of the Swedish recommendations for mpox vaccination. In these recommendations, recommendations have been added for travel to geographic areas with ongoing spread of infection of mpox clade 1 in the community. Vaccination is only offered the Swedish infectious disease clinics and is preceded by a medical assessment in individual cases. This is due to a global vaccine shortage. Vaccination should be seen as a complement to other infection control measures since it does not offer full protection against the disease. It is also important that unvaccinated people in previously recommended target groups are vaccinated.

Introduction

In Sweden, a national plan for vaccination against mpox has been developed on behalf of the Government Offices. The first plan was developed in 2022 after a global outbreak of mpox caused by clade 2b was found and updates have been made since then, most recently in May 2024 (1). Vaccination of recommended target groups for protection against mpox has been taking place in Sweden since August 2022 when the vaccine became available. The World Health Organization (WHO) recently published the document *Strategic Framework for Enhancing Prevention and Control of mpox 2024-2027* recommending continued vaccination, together with other infection control measures which can protect against the spread of mpox (2).

Increased spread of mpox in Africa

On 13 August 2024 the Africa Centres for Disease Control and Prevention (Africa CDC) declared a Public Health Emergency of Continental Security due to the ongoing mpox outbreak in Africa, which has resulted in mpox in 14 African countries (3). The decision was made after a significant increase in the number of mpox cases in affected countries and the spread to new countries which did not previously have outbreaks. The increase now includes all three new circulating virus types: clade 1a, clade 1b and clade 2b. At the same time, Africa CDC has expressed a need for 10 million vaccine doses for a first vaccination campaign in African countries with ongoing mpox transmission.

WHO declares global public health emergency of international concern

Due to the increased spread of mpox in Africa, on 14 August WHO declared a global public health emergency of international concern (PHEIC) (4). There are now concerns about the global spread of virus variant clade 1b in particular, which, like clade 2b, has spread relatively quickly and mainly in sexual networks where both men and women are affected. However, there is also concern that clade 1a will spread to more countries since both of these in Africa have led to a more severe clinical picture. When a global PHEICis declared, mechanisms for regulatory approval of vaccines, for example, can be set in motion and vaccines can become available in all countries which need them, even those without functioning regulatory authorities. Opportunities for financial support and the procurement of new vaccines for affected countries are also facilitated by the declaration of a global PHEIC.

Current issue from a public health perspective

Is there a need for updated vaccine recommendations in Sweden for protection against mpox, due to the increased spread of the disease in Africa and WHO’s declaration of a public health emergency of international concern?

Current epidemiology

Mpox caused by clades 1a and 1b predominates in Africa

In 2024, the Democratic Republic of the Congo (DRC) in Central Africa has reported 96% of all mpox cases in Africa and 97% of all mortality. So far, 25 of the country's 26 regions have reported approx. 19,000 cases. A smaller number of these are laboratory confirmed. Two variants of clade 1 are circulating in DRC: clade 1a is mainly circulating in the western parts of the country and clade 1b primarily in the eastern parts. Both of these virus types are causing more serious symptoms in DRC than have been reported for clade 2b in other African countries. Clade 2b has not been reported in the DRC. Women, men and children are among the reported cases. Clade 1 appears to spread more easily from close skin contact, and not mainly from sexual contact like the previous variant clade 2b. Clade 1 also causes more serious disease and a mortality of approx. 3% has been reported from DRC; this may be higher in children. We lack information about any differences in the patterns of transmission and clinical picture between clades 1a and 1b.

Epidemiological investigations in the eastern parts of DRC, where clade 1b is mainly circulating, indicate that heterosexual transmission, in particular among female sex workers, is currently driving the mpox outbreak. This pattern of transmission is different from the global outbreak in 2022 and onwards (clade 2b), which originated in Nigeria, where transmission was primarily observed in men who have sex with men. However, children and young people are also being affected to a certain extent in eastern DRC, and there are reports of vertical transmission from mother to child. There is greater uncertainty surrounding the disease and transmission of clade 1a, since children are being affected to a greater extent, as well as adults.

In the last 2-3 months, the spread of clade 1 to the DRC's neighbouring countries has been observed, such as Burundi, the Central African Republic, Kenya, the Republic of the Congo, Rwanda and Uganda. In Burundi, the Central African Republic, DRC and the Republic of the Congo, transmission of mpox clade 1 has been established in the community, while other countries are only reporting occasional imported cases.

The first cases of clade 1b identified outside of Africa

The first mpox case outside of Africa which was caused by clade 1b was reported in Sweden on 15 August 2024 (5). The second mpox case, which was reported on 22 August 2024, was in a European male who travelled to Thailand from Africa (6). Since then, according to the Thai authorities, Thailand has introduced a screening process of incoming passengers from countries with ongoing transmission of mpox. Individual additional cases have been reported in the media but have not yet been laboratory confirmed. In Sweden, geographic areas and countries with clade 1 transmission can be seen on the Public Health Agency of Sweden's Mpox page (central and southern Africa 2024–) (7).

Mpox cases of clade 2b have been reported in Sweden since 2022

Sweden has previously diagnosed 301 cases of type clade 2b, 34 of which were in 2024. From April–June 2024, 27 cases of autochthonous transmission (transmission within the same country) of type clade 2b were observed in the Stockholm area (8). Preparedness for new imported cases and smaller outbreaks is therefore necessary, especially in light of the increased spread of clades 1a and 1b in Africa.

Mpox cases reported in Europe in 2024

In 2024, almost 1,000 cases of mpox, probably of type clade 2b, have been diagnosed in Europe so far (9). However, not all of these have been sequenced and the European Centre for Disease Prevention and Control (ECDC) now recommends increased sequencing in countries with new mpox cases (10).

Goals and strategies for mpox vaccination

Mpox vaccination goals and recommendations are now being updated following the spread of clade 1 within and outside of Africa, but they also apply to the ongoing global outbreak of clade 2b.

The goals of the vaccination campaign are to prevent serious disease and death in vaccinated individuals, prevent imported cases of mpox and, in observed cases, to prevent secondary cases and the further spread of mpox in the country.

The vaccination strategies which are available for vaccination against mpox are preventive vaccination, pre-exposure prophylaxis and vaccination following exposure to a suspected or verified case of mpox, known as post-exposure prophylaxis. The vaccine can be given intradermally or subcutaneously. Intradermal administration is dose-saving, which is preferable in the event of a vaccine shortage.

On 23 August 2024, WHO published recommendations for mpox vaccination (11) and recommends pre- and post-exposure prophylaxis, if necessary, and either subcutaneous or intradermal administration and two doses, if possible. In the case of a vaccine shortage, a 1-dose intradermal strategy can be chosen.

Furthermore, ECDC recommends that national travel recommendations are issued to passengers travelling to and then returning from countries with ongoing transmission of clade 1, which is in line with the recently updated Swedish recommendations presented below (12). No EU countries have yet issued national advice on mpox vaccination prior to travel, and this will likely vary within the EU and over time.

Approved and available vaccine

In 2013, a vaccine, MVA-BN (Imvanex, Bavarian Nordic), was approved in the EU for protection against smallpox (13) in persons aged 18 years and older. In 2022, the indication was updated by the European Medicines Agency (EMA) in association with the global outbreak of mpox caused by clade 2b to also include protection against mpox. The MVA-BN vaccine contains a live, attenuated (weakened), non-replicating form of the vaccinia virus and cannot cause smallpox, mpox or any other infectious disease. Since the vaccine is non-replicating in humans, it can be handled like a killed and inactivated virus vaccine.

Following the import and transmission of mpox (clade 2b) to Sweden in May 2022, primarily but not only in the risk group men who have sex with men, Sweden, like other EU countries, received a donation of vaccine doses from the EU through the Health Emergency Preparedness and Response Authority (HERA), and a vaccine campaign began in August 2022.

The vaccine can be administered either subcutaneously (0.5 ml) or intradermally (0.1 ml). The Public Health Agency of Sweden recommends intradermal vaccination for pre-exposure prophylaxis. Two doses are recommended at an interval of at least four weeks. A second dose can be given regardless of how long time has passed since the first dose, in order to provide optimal protection for the individual.

People who have previously received a smallpox vaccination only need one dose of MVA-BN since immunological memory lasts for up to 50 years (14). In Sweden, the smallpox vaccine was included in the paediatric vaccination programme usually at around two months of age (Barnmiljöutredningen [Commission on the environment of children] (SOU 1975:30). Stockholm: The Ministry of Health and Social Affairs) and vaccination ceased in 1976. Vaccination was discontinued due to the eradication of smallpox and was welcomed since the vaccine was reactogenic and caused some unwanted side effects. In other countries such as DRC, vaccination ceased for the first time in the 1980s, although smallpox was already eradicated as early as 1971 (15). People with immunodeficiency (for example, people with immunodeficiency caused by disease or medication, including chemotherapy and radiation) and who have previously been vaccinated against smallpox, are recommended to have two booster doses, i.e.; a total of three doses. For smallpox-vaccinated individuals with a well-controlled HIV-infection also one dose is recommended.

For post-exposure prophylaxis, the vaccine should be given subcutaneously (0.5 ml). People who are given one dose for post-exposure prophylaxis are recommended to have a second dose if they have not contracted mpox.

Subcutaneous administration (0.5 ml) is also recommended for the following groups for both pre- and post-exposure prophylaxis:

- people aged 17 years or younger
- people with atopic dermatitis
- people with a known tendency to develop keloids
- people with immunodeficiency (except well-controlled HIV).

Vaccination clinics

The vaccine is only available for recommended target groups at the greatest risk of mpox and is therefore administered at the country's infectious disease clinics. A medical needs assessment by a physician is needed prior to vaccination. This is due to the global vaccine shortage.

Vaccine effectiveness

The vaccine effectiveness against mpox caused by clade 2b has been studied in 12 observational studies, and a meta-analysis of these shows that one dose given subcutaneously provides 76% protection (95% CI 64–88%) and two doses given subcutaneously provide 82% protection (95% CI 72–92%) (16). Intradermal vaccination provides an equivalent vaccine effectiveness after vaccination (17, 18). In contrast to this good vaccine effectiveness data, the vaccine effectiveness after post-exposure measured in a meta-analysis of data in seven studies was observed to be only 20% (95% CI 24–65%) (16), which suggests that we should strive for pre-exposure prophylaxis where possible.

Although the vaccine effectiveness has been shown to be good, some breakthrough infections occur after vaccination (19), since no vaccine provides complete protection and protection is dependent on, for example, the infectious dose that an individual has been exposed to. In case of symptom development which could be indicative of mpox, vaccinated people are also encouraged to contact their healthcare provider for diagnostics and other infection control measures. These infections are often less serious than in the unvaccinated. Waning immunity is thought to be a possible cause of breakthrough infections.

Vaccine effectiveness has not been published for clade 1, but immunogenicity has been studies in healthcare staff who took part in a clinical trial in DRC (20). Approx. 95% of vaccinated people developed a good immune response, measured in the form of binding antibodies.

Vaccine safety

No serious side effects have been reported in the major global vaccination campaign from 2022–2024, which mostly comprised adults aged 18 years and older. Redness, tenderness, swelling and itching are reported at the site of injection. Temporary tiredness, headache and muscle pain can occur.

Contraindications are

- an allergic reaction to a previous dose of MVA-BN or an allergic reaction to ingredients in the vaccine, such as gentamicin, ciprofloxacin or egg protein
- severe immunodeficiency
- pregnancy or breast-feeding.

The Public Health Agency of Sweden recommends that children are vaccinated against mpox after exposure to a suspected or confirmed mpox case. Over 2,000 children have been vaccinated without the occurrence of any side effects.

Co-vaccination

MVA-BN can be given at the same time as other inactivated vaccines, for example the influenza vaccine. However, co-vaccination with COVID-19 vaccines is not recommended since older generation smallpox vaccines and certain COVID-19 vaccines have led to myocarditis or pericarditis in rare cases. Co-vaccination with other live vaccines is not recommended, except in exceptional circumstances prior to a trip abroad and after medical assessment of benefit and risk, until more experience has been gained.

Development of new mpox vaccines and increased capacity

The rapid development of mRNA-based vaccines is expected. Two vaccine companies, BioNTech/Pfizer (NCT05988203) and Moderna (NCT05995275), started their development as early as 2022 and have completed phase 1 and phase 2 trials. The vaccine producer Bavarian Nordic is also expanding its vaccine production capacity.

Recommendations

Extended vaccine recommendations are required since there has been an increase in mpox, particularly in Africa. However, vaccination against mpox should be seen as a complement to other infection control measures since it does not offer full protection against the disease. In order to prevent severe illness and death in individuals, reduce the risk of imported cases of mpox and prevent secondary cases and transmission in the Swedish society, the existing vaccine recommendations for mpox have now been extended to include people at an increased risk of mpox due to travel to geographic areas where there is ongoing transmission of mpox caused by clade 1 in the community. In geographic areas with ongoing transmission of mpox in the community, sexual transmission or close physical contact for a longer period in a household are the most common routes of transmission, but transmission in the healthcare system also occurs. These areas will continue to be monitored by the Public Health Agency of Sweden, and the webpage Mpox (central and southern Africa 2024–) will be updated regularly.

Below you can find the vaccine recommendations presented in their entirety, including the expanded but limited travel recommendations which have been developed for increased protection against mpox, since clade 1 is now spreading in Africa with the risk of global transmission.

The following target groups are recommended for *pre-exposure prophylaxis*:

- men and transgender people who have sex with men and who have an increased risk of mpox (for example, have multiple or new sexual contacts, have recently had a sexually transmitted infection or are receiving pre-exposure prophylaxis against HIV)
- sex worker community who provides sexual services
- people who have an increased risk of exposure to mpox and who are considered by their employer to be in need of vaccination, for example laboratory staff who work with the propagation of, or concentrated amounts of infectious monkeypox virus
- people who are travelling to a geographic area with ongoing transmission of mpox in the community and who may be at *particular risk* of exposure. For example, this may be relevant to healthcare staff, workers and volunteers in refugee camps, aid and frontline workers or others who intend to
    - stay in geographic areas with ongoing transmission of mpox in the community, *and*
    - have close physical contact with people in the local community, *and*
    - the recommended infection control measures in the general travel recommendations are not considered to be sufficient.

Vaccination must always be preceded by an individual needs assessment by a medical doctor at an infectious disease or sexual health clinic.

For information on which geographic areas that have ongoing transmission of mpox clade 1 in the community, please see the Public Health Agency of Sweden's website.

The following target groups are recommended for *post-exposure prophylaxis:*

- people who have had sexual or other close contact, such as a household contact including children, with a person who has a suspected or laboratory-confirmed mpox infection.

As a result of the new expanded vaccination recommendations, an increased need to vaccinate children and young people up to the age of 18 will likely occur. In agreement with the EMA, the vaccine producer has begun clinical trials, which they undertook to do on approval of the vaccine product for protection against mpox. The first clinical trial in which children aged 12–17 years received two full doses of MVA-BN (Jynneos) has been completed and the vaccine producer has submitted an application to the European Medicines Agency to obtain EU approval for these target groups, expected shortly. In 2024, additional clinical trials are planned in collaboration between the vaccine producer and the Coalition for Epidemic Preparedness Innovations (CEPI), in which children aged 2–11 years will be included (21, 22). Further, trials in even younger children and maternal vaccination are currently being planned.

The Public Health Agency of Sweden has previously recommended pre- and post-exposure prophylaxis for children, regardless of their age, after an individual medical assessment. Children are recommended to have two doses of MVA-BN (0.5 ml) subcutaneously. The vaccine recommendations are based on the experience gained from the first-generation smallpox vaccines, which, until 1976, were given to infants at the age of two months as part of the Swedish paediatric vaccination programme (SOU 1975:30). Experience has also been gained from previous clinical trials where MVA-BN was used as a vector in candidate vaccines for tuberculosis, malaria and HIV, and where children from five months of age were included (23).

Countries such as the UK and USA also recommend pre- and post-exposure prophylaxis for children and young people under 18 years if necessary (24, 25). MVA-BN has been shown to be safe in all the above-mentioned clinical trials and in routine practice during the last two years in Europe and North America.

Planned follow-up and identified knowledge gaps

Vaccine coverage

Mpox vaccination is documented at each infectious disease clinic or clinic for sexually transmitted infections where vaccination takes place, but there is no documentation in the national immunisation registry. This is because mpox vaccination is not covered by a national vaccination programme. The possibility of expanding the documentation of mpox vaccination will be reviewed. In the past, aggregated and anonymised data has been collected at national level to roughly follow vaccine coverage in recommended target groups. A need for increased vaccine coverage in recommended target groups has been identified.

It has been noted that most of the cases reported to SmiNet in 2024 were in unvaccinated people. This means that increased vaccine coverage is desirable in all recommended target groups, particularly prior to trips abroad.

Breakthrough infections after vaccination must be investigated with laboratory confirmation and providing the usual infection control measures as well as reported to SmiNet.

Sequencing of diagnosed cases of mpox

All PCR-positive samples (polymerase chain reaction method, PCR) for mpox should be sent to the Public Health Agency of Sweden for sequencing until further notice. Sequencing is used for clade typing and is currently free of charge.

How long does the mpox vaccine provide protection?

The MVA-BN has been used for protection against mpox since August 2022. All the above-mentioned vaccine effectiveness studies report short-term vaccine effectiveness. None of the studies have studied long-term vaccine effectiveness. There is currently a great need for such data as several research groups, including a Swedish group, have reported waning humoral immunity (26). It may be necessary to recommend a third dose, but scientific studies are needed for the introduction of such a strategy at population level, as this would mean an increased need for vaccine doses amidst the current shortage.

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