# Use of MVA-BN vaccine in response to MPOX

# Guidance for Services

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## Version Updates

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| **Date of revision** | **13/9/2022** |
| Additional information | Update: “Vaccine Preparation and Administration.” |
| | **24/6/2022** |
| Timing of vaccination calculated from **last** exposure | Update: “ Recommended Groups for Vaccination” |
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| NIAC updated recommendation | Update: Background<br>New: MVA-BN Vaccines<br>Update: “Recommended Groups for Vaccination”<br>Update: “Contraindications and precautions”<br>Update: “Post Vaccination Advice”<br>New Appendix 2 and 3 |
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| | **24/12/2024** |
| **Additional information** | Guidance document reviewed and extensively updated and revised following the declaration of a PHEIC by WHO in August 2024 and following the updated national recommendations for mpox vaccination from NIAC. Clinical and operational guidance documents combined to create an overall guidance document for the mpox response. |

# 1.0 Scope and purpose

This document has been developed by the National Immunisation Office (NIO) in collaboration with the Vaccination Subgroup of the Mpox Incident Management Team. This document is for health care workers involved in the ordering, administration and recording of mpox vaccinations in the context of the national response to the clade 1 mpox Public Health Emergency of International Concern (PHEIC) declared by the World Health Organisation (WHO) in August 2024.

# 2.0 Background

Human monkeypox was given its name in 1970 (after the virus that causes the disease was discovered in captive monkeys in 1958). On 28 November 2022, the WHO recommended using a new preferred term “mpox” as a synonym for monkeypox.

Mpox is a zoonotic disease caused by an orthopoxvirus that results in a smallpox-like disease in humans. The orthopoxvirus genus also includes variola virus (which causes smallpox), vaccinia virus and cowpox virus. The mpox virus has two different clades: Clade I (formerly the Central African or Congo Basin clade) which has two sub clades, 1a and 1b, and Clade II (formerly the West African clade) which also has two sub-clades, IIa and IIb.

Mpox infection can spread through direct contact with infected wild animals, through close contact with skin or respiratory secretions (including intimate and sexual contact) of a person with mpox, and through contact with contaminated objects or surfaces. Airborne transmission is thought to occur primarily through large respiratory droplets that generally cannot travel more than one to two metres. Close household or sexual contact poses the greatest risk of person-to-person spread, particularly direct contact with lesions. Transmission can also occur from mother to foetus. The risk of spread within community and healthcare settings is very low. The incubation period is 6-13 days (range 5-21 days).

The majority of cases experience mild to moderate symptoms lasting from two to four weeks, followed by complete recovery with supportive care.[1] Common symptoms include rash (80% (generalised 50%, genital 45%), fever ≥38.5°C (57%), headache (30%), lymphadenopathy (generalised 20%, local 20%), myalgia (25%), fatigue (20%) and sore throat (13%). The rash appears within 1 to 10 days of development of fever, usually beginning on the face and then spreading to other parts of the body. The lesions are similar to those of chickenpox. Major disease sequelae can occur and mpox can cause disfiguring scars and permanent corneal lesions.[2] The disease is more severe in young children, in pregnancy, in older people and in those with severe immunocompromise, especially if related to human immunodeficiency virus (HIV).

In July 2022, the WHO declared a multi country outbreak as a PHEIC. This outbreak was caused by the spread of clade IIb virus. The spread was mostly by sexual transmission.[3] In Ireland and internationally, infection primarily (but not exclusively) occurred in adult males who self-identified as gay, bisexual and men who have sex with men (gbMSM).[4] Mpox vaccination was used successfully as part of a multifaceted approach to contribute to the control of the 2022 mpox outbreak in Ireland, and in many other countries internationally, through targeted vaccination campaigns in at risk individuals.[4] The PHEIC was declared over in May 2023 after there had been a sustained decline in global cases due to increased immunity, behavioural change and vaccination.

On the 14th of August 2024, due to an upsurge of cases of mpox clade Ia and Ib in the Democratic Republic of Congo (DRC) and a growing number of neighbouring countries in Africa, the WHO again declared mpox a PHEIC.[3]

Information on clinical features and transmission routes in this ongoing clade I outbreak are still emerging.[5] Initial reports suggest that among cases exposed through sexual contact, some individuals only present with genital lesions rather than the more typical extensive rash.[5] Multiple modes of transmission have been reported in the ongoing clade I outbreak, including sexual and household transmission.[5] There is evidence of the transmission of clade I mpox with close household contacts, with many family clusters reported. There has also been an outbreak of clade Ib in DRC linked with extensive human to human transmission amplified by sexual contact especially through sex workers. Transmission in healthcare settings has also been reported, but it is assumed that suitable PPE was not worn. Clade I mpox is clinically more severe and has a higher case fatality rate (CFR) of 4.6-17%, compared to clade II which is reported to have a lower CFR of 0.1-3.6%.[6] There is some indication that the mortality associated with clade Ib may be lower than that of Ia, however this is based on early data (as of October 2024) and should be interpreted with caution. It has been hypothesised that the lower CFR seen with the clade Ib outbreak may be related to the lower proportion of children affected compared with clade Ia.

The European Centre for Disease Prevention and Control (ECDC) have assessed the current risk of mpox clade I infection to the general population in the European Union/European Economic Area (EU/EEA) as low.[3] The likelihood of infection for close contacts of imported cases is high, with the risk of severe disease increased in those with underlying conditions, particularly those with immunocompromise. The likelihood of infection for people with multiple sexual partners who were not previously infected or vaccinated against mpox since 2022 is deemed to be moderate. However, the risk is understandably higher in affected areas in the African continent.[3] The likelihood of mpox clade I infection for EU/EEA citizens travelling to

affected areas if they are in close contact with affected communities is high, while the likelihood of infection is low when contact with affected communities is avoided.

# 3.0 Clinical guidance

## 3.1 MVA-BN vaccine

Two mpox vaccines are distributed in the European Union (EU) both containing Smallpox Modified Vaccinia Ankara – Bavarian Nordic vector (MVA-BN). Imvanex is authorised by the European Medicines Agency (EMA),[7] and Jynneos by the Food and Drug Administration (FDA).

In September 2024, the EMA recommended extending the indication of Imvanex to adolescents from 12 to 17 years of age. This was based on interim results from a Phase 2 randomised, open label, multisite trial (DMID 22-0020) in which two doses of MVA-BN were administered to adolescents and assessed for safety and immunogenicity. The safety profile of Imvanex in adolescents was comparable to that seen in adults and no additional risk was identified.

**Therefore, the licensed indications for MVA-BN are:**

1. Imvanex: active immunisation against smallpox, mpox and disease caused by vaccinia virus in individuals aged 12 years of age and older.

2. Jynneos: prevention of smallpox and mpox disease in adults 18 years of age and older determined to be at high risk for smallpox or mpox infection.

Jynneos is considered as a suitable vaccine against mpox by the EMA Emergency Task Force together with the Committee for Medicinal Products for Human Use (CHMP) Biologics Working Party and the European Directorate for the Quality of Medicines & HealthCare.

The vaccines contain a non-replicating form of vaccinia virus that does not cause disease in humans as it cannot replicate in human cells.

### 3.1.1 Factors for consideration before vaccination

**Prior to vaccination all vaccine recipients should be given comprehensive information about the disease, the risks of contracting it, and the benefits and risks of the vaccine. They should be informed that they may develop adverse reactions similar to the prodromal symptoms of mpox infection during the first 48 hours after vaccination. An information leaflet is available at:**
**https://www.hse.ie/eng/health/immunisation/hcpinfo/mpox/**

The following should be considered for discussion prior to vaccination as part of informed consent (this list is not exhaustive):

**Rationale for vaccination**

- Vaccination is recommended is based on the individual's risk of contracting the disease.
- Vaccination is recommended as pre-exposure prophylaxis (PrEP) for those at high risk of infection, for specific healthcare workers who are at high risk of exposure and for those planning to travel to areas currently affected by clade 1 mpox outbreaks (further detail is included in the section on recommended groups for vaccination).
- Vaccination is recommended as post-exposure prophylaxis (PEP) for unvaccinated contact with a high or intermediate risk exposure. Classification of high, medium or low risk contact is as per HPSC guidance. Available at: https://www.hpsc.ie/a-z/zoonotic/monkeypox/guidance/

**Severity of illness**

- Most people who get mpox experience mild to moderate symptoms that usually last two to four weeks followed by a full recovery. However, mpox can cause serious illness particularly in pregnancy and in children and older adults and in immunocompromised individuals.
- Case fatality rates can vary depending on the mpox clade. Clade I mpox is clinically more severe and has a higher case fatality rate (CFR) of 4.6-17%, compared to clade II which is reported to have a lower CFR of 0.1-3.6%.[6] The CFR for all clades of mpox is higher in young children and in those who are immunosuppressed.

**Vaccine effectiveness**

- It takes two weeks after the vaccination course is completed to be fully immunised.
- The MVA-BN vaccine has been shown to be a safe vaccine and is effective against mpox clade II infection and severe disease.[3]
    - The vaccine effectiveness of two pre-exposure vaccine (PPV) doses is estimated as 82% (95% CI: 72-92), while even one PPV dose provides effectiveness of 76% (95% CI: 64-88).[8]
    - For post-exposure vaccination (PEPV) the vaccine effectiveness was estimated at 20% (95%CI: - 24-65).[8]
    - In individuals who experienced infection after being vaccinated, the disease was less severe compared to unvaccinated individuals.[9]

- The MVA-BN vaccine is expected to have similar vaccine effectiveness against mpox clade I. However, there is limited evidence specifically relating to the effectiveness offered by MVA-BA against mpox clade I.[10,11]
- The MVA-BN vaccine has been shown to offer protection specifically against mpox clade I in a small number of preclinical studies.
- Additional information on vaccine efficacy and effectiveness is included in the NIAC Chapter 13a Mpox available at: https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

**Duration of protection and need for booster vaccination**

- The duration of MVA-BN protection against mpox is uncertain but may range from 2 to 10 years based on the duration of protection of first generation smallpox vaccines.
- Longer term MVA-BN mpox vaccine effectiveness studies are needed to determine the duration of protection provided by vaccination.
- There are, as yet, no vaccine effectiveness studies specifically focused on the use of MVA-BN vaccine as a booster following receipt of either a one or two dose primary series.
- Additional information on duration of protection and booster vaccination is included in the NIAC Chapter 13a Mpox available at: https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

**Importance of the timing of vaccination administration after exposure**

- For **post-exposure prophylaxis (PEP),** if a vaccine is given within 4 days of exposure the vaccine may prevent disease but if given between day 5-14 after date of exposure vaccination may reduce symptoms but may not prevent disease.
- There is no evidence that vaccination beyond 14 days from exposure confers any benefit, however, vaccination beyond 14 days can be considered in those who are severely immunocompromised in consultation with their treating specialist.

**Vaccine safety**

- Evidence on the safety of MVA-BN (Imvanex) primary series from clinical trials and post marketing surveillance continues to indicate that the vaccine demonstrates an acceptable safety profile.
- The most common adverse events reported are injection site pain, redness, swelling and systemic reactions such as fatigue, headache, and myalgia. No cases of severe neurological disease or myocarditis were reported in clinical trials or post marketing surveillance.

- Generally, the second dose is better tolerated than the first.

## 3.2 Vaccine dose and route of administration

### 3.2.1 Dose

**Each dose of MVA-BN vaccine is 0.5ml given subcutaneously (SC) in the deltoid area. The course is two doses no less than four weeks apart.** It takes two weeks after the vaccination course is completed to be fully immunised.

### 3.2.2 Route of administration

**The SC route is preferred as the technique is familiar and adverse reactions are significantly less.**

However, if vaccine supplies are limited, MVA-BN mpox vaccine may be administered **intradermally (ID)** in the volar (palmar) side of the forearm **for those aged 18 years and older**. If the volar (palmar) side of the forearm is not an option (e.g., scarring or patient preference), the vaccine may be administered ID into the deltoid area. Two 0.1ml doses no less than four weeks apart are required.

Available data regarding ID administration are based on two doses of vaccine no less than four weeks apart so it is important that the vaccine course is completed.

ID administration should be performed by health professionals appropriately trained in the correct administration of ID vaccines. Additional guidance on the preparation and administration of mpox vaccines via intradermal injection in community settings is available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/mpox/

A person who has received their first vaccine dose SC may receive the second dose ID. Those whose 18th birthday occurs between their first and second dose may complete the series with the alternative ID dosing. Those who received their first vaccine dose ID may receive the second dose SC.

### 3.2.3 Considerations in those with previous smallpox vaccination

For those who have had previous smallpox vaccination, the vaccination course is one 0.5ml dose SC in the deltoid area or 0.1ml ID in the volar (palmar) side of the forearm or in the deltoid area. However, for a primary vaccination course, those who are immunocompromised require two doses no less than four weeks apart **regardless of whether they have had previous smallpox vaccination.** For a primary vaccination course, a person is fully immunised two weeks after the completion of a course.

## 3.3 Recommended groups for vaccination

The National Immunisation Advisory Committee (NIAC) updated their recommendations for mpox vaccination with MVA-BN vaccine for pre-exposure prophylaxis (PrEP) and post exposure prophylaxis (PEP) in September 2024. The updated NIAC chapter is Chapter 13a and this guidance should be used in conjunction with this document and is available at:

https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

### 3.3.1 Pre-exposure prophylaxis vaccination (PrEP)

1. Vaccination should be offered as soon as practicable to **those at high risk of infection** who are unvaccinated or partially vaccinated, e.g., gay, bisexual and men who have sex with men (gbMSM), sex workers and others at high risk of mpox exposure. Further information on identification of those in recommended groups for vaccination is contained in Section 3.4 of this document.

2. Vaccination should be considered for designated **healthcare and laboratory staff** (including domestic staff etc.) who will be involved in the management of mpox cases or their samples based on a health and safety risk assessment. While the priority is to ensure appropriate infection prevention and control (IPC) measures are followed, the MVA-BN mpox vaccine may provide additional protection depending on the nature and timing of exposure risk. When wearing suitable PPE and applying correct precautions, the risk of acquiring clade IIb (B.1 lineage) infection is low. There is less certainty about the transmissibility of clade I. Transmission of clade I infection in healthcare settings has been reported but in settings where it is assumed that suitable PPE has not been worn. In the current mpox vaccination programme, the healthcare staff who are being prioritised for mpox vaccination are outlined in the operational section of this document; in the vaccination process section. Mpox IPC guidance is available at: https://www.hpsc.ie/a-z/zoonotic/monkeypox/guidance/

3. Vaccination is recommended for persons who are planning to **travel to areas currently affected by clade I mpox outbreaks**, following discussion with a healthcare provider, if the likelihood of close contact with affected local communities within these areas is high (e.g. aid workers, and those living or working with affected communities). Where feasible, this discussion should occur 4-6 weeks prior to travel to allow time to complete the two-dose schedule. The decision to offer the vaccine prior to travel should also consider an individual's risk of severe disease. There is an increased risk for complications and/or death from mpox in children, in pregnancy, and in those who are immunocompromised. In

the current mpox vaccination programme, vaccination will be offered to humanitarian aid workers who are planning to travel to areas currently affected by clade I mpox outbreaks. The recommendation to provide vaccination to other people travelling to affected areas is not currently operationalised.

Mpox vaccine should be made available to all who are at risk of infection as outlined above (1-3) as soon as it is practicable.

All those at risk of infection as outlined above (1-3) who are **incompletely vaccinated** with only one dose should receive a second vaccine dose as soon as practicable.

Those who are **incompletely vaccinated** are:

- Any person who is not immunocompromised and with no history of smallpox vaccination who has had only one dose of mpox vaccine.
- Any person who is immunocompromised who has had only one dose of mpox vaccine, regardless of previous smallpox vaccination status.

Booster mpox vaccination for PrEP in those who have completed the two-dose primary course is not currently recommended.

### 3.3.2 Post exposure prophylaxis vaccination (PEP)

1. Persons with a **high/intermediate exposure** to mpox who are unvaccinated should be offered one dose of the vaccine within four days of exposure. If there is likelihood of ongoing exposure, those who have not had smallpox vaccination require a second dose given four weeks after the first.
2. In persons with a **high/intermediate exposure** to mpox who were vaccinated against mpox more than two years prior to the exposure, a booster dose should be considered within four days of exposure as post exposure prophylaxis.

The vaccine may prevent the onset of symptoms if given within four days of last exposure. If given within 5 to 14 days after the date of last exposure, it may reduce the symptoms but may not prevent the disease. There is no evidence that vaccination beyond 14 days from exposure confers any benefit however vaccination beyond 14 days could be considered in those who are severely immunocompromised in consultation with their treating specialist.

### 3.3.3 Children and pregnancy

As of September 2024, the licence for Imvanex was extended by the EMA to include use in adolescents aged 12-17 years.[7] This was based on interim results from a Phase 2 randomised, open label, multisite trial (DMID 22-0020) in which two doses of MVA-BN were administered

to adolescents and assessed for safety and immunogenicity. The safety profile of Imvanex in adolescents was comparable to that seen in adults and no additional risk was identified.

Currently available MVA-BN mpox vaccines are not licensed in children less than 12 years old or in pregnancy but they may be considered as pre or post exposure prophylaxis following an individual benefit-risk assessment. Additional information on vaccination in specific risk cohorts including children and in pregnancy is included in the Specific Risk Cohorts section of this document.

The vaccination course required for individuals for whom vaccination is recommended by NIAC is summarised in Table 1.

**Table 1: NIAC recommendations for vaccination course for pre and post exposure prophylaxis with MVA-BN vaccine in response to mpox**

| Group | No previous smallpox vaccination | Previous smallpox vaccination |
|---|---|---|
| **PrEP**<br>1: Those at high risk of infection who are unvaccinated or partially vaccinated<br>2: Designated healthcare and laboratory staff**<br>3.Those planning to travel to areas currently affected by clade 1 mpox outbreaks*** | Two doses four weeks apart | One dose * |
| **PEP**<br>1: High/intermediate risk contacts who are unvaccinated | One dose within 4 days of exposure. If there is a likelihood of on-going exposure give a second dose four weeks after the first dose.**** | One dose within 4 days of exposure * |
| 2: High/intermediate risk exposure who were vaccinated more than two years prior to exposure | Consider giving one dose within 4 days of exposure as PEP.**** | Consider giving one dose within 4 days of exposure as PEP.**** |

** Immunocompromised individuals who have previously received smallpox vaccination will require two doses.*

*** Based on a health and safety risk assessment. Eligible groups for the current mpox vaccination programme are outlined in the operational section of this document; in the vaccination process section*

**** Following discussion with a healthcare provider. In the current mpox vaccination programme, vaccination will be offered to humanitarian aid workers who are planning to travel to areas currently affected by clade I mpox outbreaks. The recommendation to provide vaccination to other people travelling to affected areas is not currently operationalised*

***** If given within 5 to 14 days after the date of last exposure, it may reduce the symptoms but may not prevent the disease. There is no evidence that vaccination beyond 14 days from exposure confers any benefit however vaccination beyond 14 days could be considered in those who are severely immunocompromised in consultation with their treating specialist*.

## 3.4 Identification of those in recommended groups for vaccination

### 3.4.1 PrEP

#### *Those at high risk of infection who are unvaccinated or partially vaccinated*

In April 2023, the Health Service Executive (HSE) mpox Clinical Advisory Group (CAG) updated its recommendation on the eligible populations considered to be at high risk of infection who are advised to consider mpox **PrEP** vaccination (**Box 1**). These groups remain appropriate and relevant in the context of the 2024 PHEIC.

**Box 1: MPOX Primary Prevention Vaccination CAG Recommendations April 2023**

These recommendations relate to individuals who have not completed full mpox vaccination course, or had mpox infection, within the last two years and who fall into the below risk group for infection and should be considered for PrEP:

Men who have sex with men or transgender women who have sex with men who are: sexually active with likelihood of remaining sexually active in the next 3 months

AND one of the following:

reported condomless anal sex with at least two partners over the last 6 months

likely to engage in condomless anal sex in the next 3 months

episode of documented or reported acute STI over the last 12 months

documented or reported use of HIV post-exposure prophylaxis following sexual exposure (PEPSE) over the last 12 months

reported engagement in chemsex over the last 6 months.

In addition, the **updated NIAC recommendations in September 2024** also include **sex workers** in the groups who are at high risk of mpox infection.

#### *Healthcare and laboratory staff*

NIAC have also recommended **PrEP** vaccination for health workers such as designated **healthcare and laboratory staff** (including domestic staff etc.) involved in the management of mpox cases. In the current mpox vaccination programme, the **healthcare and laboratory staff who are being prioritised for mpox vaccination are outlined in the operational section** of this document; in the vaccination process section.

***Those planning to travel to area currently affected by the clade 1 mpox outbreak***

**PrEP** vaccination is recommended for those planning to travel to the area currently affected by clade 1 outbreak following a discussion with a healthcare provider, if the likelihood of close contact with affected local communities within these areas is high (e.g. aid workers, and those living or working with affected communities). The decision to offer the vaccine prior to travel should also consider an individual's risk of severe disease. In the current mpox programme vaccination **will be offered to humanitarian aid workers** who are **travelling to areas currently affected by clade 1 mpox outbreak**. The recommendation to provide vaccination to other people travelling to affected areas is not currently operationalised.

### 3.4.2 PEP

Prior to vaccination in the context of **PEP**, please review the latest HPSC guidance on management of contacts available at:

https://www.hpsc.ie/a-z/zoonotic/monkeypox/guidance/

The management of contacts is based on the individual's risk of contracting the disease – this is classified as high, intermediate or low risk contact depending on nature, proximity of contact and if they are a healthcare worker. Contact management (including recommendation for vaccination) varies on this risk categorisation.

## 3.5 Advice on booster vaccination

There are, as yet, no effectiveness studies specifically focused on the use of MVA-BN vaccine as a booster following receipt of either a one or two dose primary series. Most countries do not currently recommend booster vaccination as pre-exposure prophylaxis following MVA-BN primary series.

NIAC does not currently recommend booster mpox vaccination for pre-exposure prophylaxis in those who have completed the two-dose primary course.

NIAC will continue to monitor both mpox epidemiology in Ireland and emerging data on duration of protection and update recommendations as needed. Given there is still some uncertainty about duration of protection, in persons with a high/intermediate exposure to mpox who were vaccinated against mpox more than two years prior to the exposure, NIAC recommend that a booster dose should be considered within 4 days of exposure as post exposure prophylaxis.

## 3.6 Specific risk cohorts

In certain risk cohorts there are limited data available and additional information should be considered prior to vaccination as summarised in Table 2. It should be noted that mpox may

cause severe illness in pregnancy, children, older adults and immunocompromised individuals. Morbidity and mortality associated with infection from all clades of mpox virus is higher in children and those with immunocompromising conditions.[12-14] In 2023, the CDC reported that 94% of those who died from mpox in the recent clade II outbreak were immunocompromised by HIV infection.[15] Global studies also demonstrate that advanced, uncontrolled HIV and other causes of immunosuppression such as solid organ transplant, increase the risk of hospitalisation and adverse outcomes from mpox.[13,16]

Further information on vaccination for those in specific risk cohorts is contained in Chapter 13a of the NIAC guidelines available at:
https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

**Table 2: Additional information about vaccination in specific at risk population groups**

| Population Group | Available information | NIAC recommendation |
|---|---|---|
| Immunocompromised | The immune response may be lower than in those who are immunocompetent. | The vaccine can be administered SC or ID in those with immunocompromise aged 18 years and older, although the immune response may be lower than in those who are immunocompetent. |
| Pregnancy | Data on the use of MVA-BN in pregnancy are limited with fewer than 300 reported pregnancy outcomes. Animal studies have not shown direct or indirect harmful effects with respect to reproductive toxicity.[7] As it is a non-replicating vaccine, there is no theoretical reason for concerns in pregnancy, and the expected adverse events profile should be similar to that observed in non-pregnant individuals.[17]<br>Pregnancy is a concern for severity of illness and this should be considered in any benefit-risk assessment and discussion. | Consideration may be given to using the vaccine in pregnancy for those at increased risk following individual benefit risk assessment. |
| Breastfeeding | Use of vaccine in breastfeeding is not contraindicated. | Consideration may be given to using the vaccine for those at increased risk who are breastfeeding, following individual benefit risk assessment |

*Contd.*

**Table 2: Additional information about vaccination in specific at risk population groups (continued)**

| Population Group | Available information | NIAC recommendation |
|---|---|---|
| Children and adolescents aged 12-17 years | A similar immune response in adolescents and adults infers that the vaccine will provide similar protection in adolescents to that expected in adults.[7] The safety profile of Imvanex in adolescents is comparable to that seen in adults and no additional risk has been identified.[7] | The licenced indication for Imvanex is active immunisation against smallpox, mpox and disease caused by vaccinia virus in individuals 12 years of age and older. Imvanex can be administered to adolescents (SC) following informed consent. |
| Children aged less than 12 years | While the MVA-BN vaccine is not currently licensed in children under 12 years of age, several paediatric studies of other vaccines using MVA as a vector - often at a considerably higher dose than used in MVA-BN- have shown a reassuring side effect profile. The adverse event profile of MVA-BN is expected to be similar to that of the TB and malaria candidate vaccines which use MVA, providing some reassurance of its use in children. | Currently available MVA-BN mpox vaccines are not licensed in children less than 12 years of age but they may be considered as pre or post exposure prophylaxis following an individual benefit-risk assessment. |

*Please refer to the NIAC chapter 13a for additional information, available at: https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland*

## 3.7 Contraindications and precautions

The contraindications to MVA-BN vaccination are:

- Anaphylaxis to any of the vaccine constituents (these include benzonase, chicken protein (including egg), gentamicin, ciprofloxacin and trometamol).
- Intradermal administration is not recommended for those with a history of keloid scar formation. They should receive subcutaneous (SC) vaccination.

Precautions:

- If the patient has an acute febrile illness defer vaccination until recovery **unless the risks of deferral outweigh the low risks of vaccination.**
- There should be an interval of four weeks between the vaccine and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis.
- No interval is required between a COVID-19 vaccine or influenza vaccine and an MVA-BN mpox vaccine. The vaccines should be given in different arms.
- MVA-BN other live vaccines such as MMR, varicella or yellow fever should be administered on the same day or else four weeks apart.

## 3.8 Vaccine constituents

- Modified Vaccinia Ankara – Bavarian Nordic Live virus
- Trometamol
- Sodium chloride
- Water for injections
- This vaccine contains trace residues of chicken protein, benzonase, gentamicin and ciprofloxacin

## 3.9 Vaccine storage

The vaccine is delivered from the manufacturer to the National Cold Chain Service (NCCS) frozen and is stored in a frozen state in NCCS. The expiry of the vaccine is dependent on temperature at which it is maintained. The expiry date is only applicable to the vials if they remain frozen at -80$^{o}$C.

The vaccine is delivered in its thawed state at temperatures between +2$^{o}$C and +8$^{o}$C.

The USE BEFORE date will be printed on the label that has been affixed to the box by the NCCS. The USE BEFORE date reflects an 8 week shelf-life after thaw (i.e. removal from the freezer in NCCS) when vaccine is stored at +2$^{o}$C and +8$^{o}$C in the dark.

Vaccine should not be administered after the USE BEFORE date, irrespective of the expiry date.

The vaccine comes in glass vials that contains 0.5 ml. The vaccine is delivered in the original boxes of 20 vials. The vaccine should be stored in the original package to maintain the vial in the dark.

If the vial is punctured and all the contents are not used, the vial should be stored at +2°C to +8°C and used within eight hours of the first puncture.

## 3.10 Vaccine preparation and administration via the subcutaneous (SC) route

Prior to administration the patient should be provided with the manufacturers Patient Information Leaflet and the HSE information leaflet. After counselling for the risk, benefits and potential side effects of receiving the vaccine, a consent form should be signed by the patient and a prescription written by a doctor for the supply and administration of the vaccine. Leaflets and consent forms can be found at: https://www.hse.ie/eng/health/immunisation/hcpinfo/mpox/

All vaccinators must be appropriately trained to administer vaccines via the SC route and should be up to date with basic life support and anaphylaxis training, with an anaphylaxis kit available in the event of anaphylaxis.

Step 1: The vaccine should be allowed to reach room temperature (15°C - 25°C) before use.

Step 2: Hold the vaccine vial upright and swirl gently for at least 30 seconds before each use.

Step 3: Inspect the vial. The SmPC states: “The suspension should be visually inspected for particulate matter and discoloration before use. In the event of any damage to the vial, foreign particulate matter and/or variation of physical aspect being observed, discard the vaccine“.[7] If this situation arises please see Appendix 1 for actions

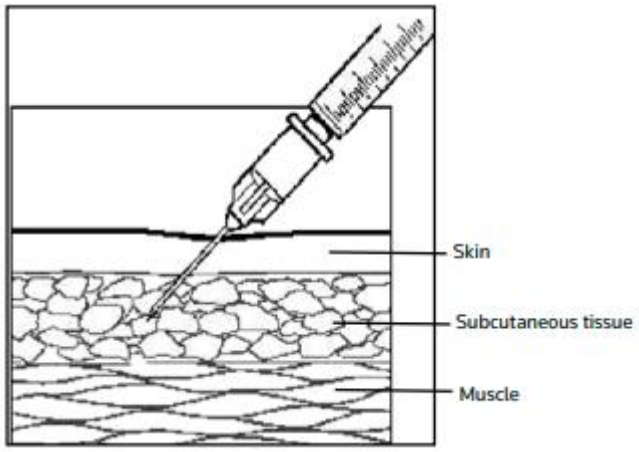
Step 4: Withdraw 0.5ml (one dose) from the vial (using a 1ml graduated syringe and 38mm long, 21 gauge needle).

Step 5. Replace the needle on the syringe with one suitable for subcutaneous administration (16mm long, 23- to 25-gauge needle). The vaccine should be administered subcutaneously into the deltoid region (as below)

Step 6: Insert needle at 45$^{o}$ angle to the skin (figure 1). Gently pinch up subcutaneous tissue to prevent injecting into muscle. Aspiration prior to injection is not required.

Technique:[18]

Figure 1: Subcutaneous injection-correct angle and depth of insertion




**Note: Any leftover vaccine in the vial and clinical waste should be discarded appropriately. The vaccine is not to be co-administered or mixed with other vaccines.**

## 3.11 Vaccine preparation and administration via the intradermal (ID) route

Prior to administration the patient should be provided with the manufacturers Patient Information Leaflet and the HSE information leaflet. After counselling for the risk, benefits and potential side effects of receiving the vaccine, a consent form should be signed by the patient and a prescription written by a doctor for the supply and administration of the vaccine. Leaflets and consent forms can be found at: https://www.hse.ie/eng/health/immunisation/hcpinfo/mpox/

Additional guidance on the preparation and administration of mpox vaccines via intradermal injection in community settings is available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/mpox/

All vaccinators must be appropriately trained to administer vaccines via the intradermal route and should be up to date with basic life support and anaphylaxis training, with an anaphylaxis kit available in the event of anaphylaxis.

When possible, low dead volume syringes and/or needles should be used to extract up to five doses (0.1ml each) from a single vial. If standard syringes and needles are used, there may not be sufficient volume to obtain five doses from a single vial.

Step 1: The vaccine should be allowed to reach room temperature before use.

Step 2: Hold the vaccine vial upright and swirl gently for at least 30 seconds before each use.

Step 3: Inspect the vial. The suspension should be visually inspected for particulate matter and discoloration before use. In the event of any damage to the vial, foreign particulate matter and/or variation of physical aspect being observed, discard the vaccine. If this situation arises please see Appendix 1 for actions.

Step 4: Clean the vaccine vial stopper with a single-use antiseptic swab before each use.

Step 5: Using a 1ml syringe and a 25-27G, 10-16mm needle carefully withdraw 0.1 ml of vaccine.

Do **NOT** combine residual vaccine from multiple vials.

**Extreme care must be taken during repeated puncture of the bung to withdraw doses as the stability of the bung is unknown. If the bung becomes damaged, discard the vial.**

Step 6: Administer the vaccine by ID injection into the volar aspect (palmar side) of the forearm or in the deltoid area.

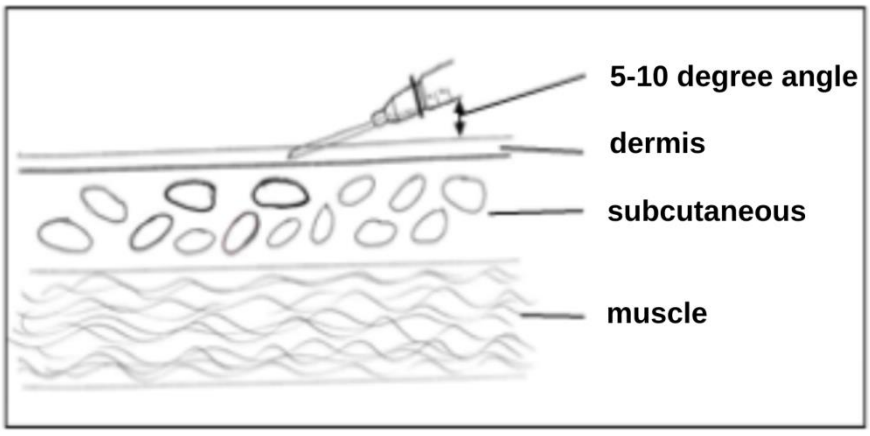
Step 7: Using the finger and thumb of the non-dominant hand, stretch the skin at the mid-point of the volar (palmar) side of the forearm or in the deltoid area.

Step 8: Insert the needle into the dermis with the bevel facing upwards, at an angle of 5-10 degrees, to a distance of 2-3 mm. The bevel should be covered by skin and visible through the epidermis.

Step 9: Slowly inject 0.1ml. When given correctly, an ID injection should raise a blanched bleb or wheal.

Technique:[18]

Figure 2: Intradermal injection-correct angle and depth of insertion



**If no resistance is felt when the needle is inserted, the needle may be in SC tissue.**

**In this case, withdraw the needle and repeat the injection at a new site.**

Once the vial is punctured and all the contents are not used, the vial should be stored at +2°C to +8°C and used as soon as possible and within eight hours of the first puncture.

A person who presents for their second ID vaccine dose who is still experiencing erythema or induration at the site of first dose intradermal vaccine administration may have the second dose administered intradermally in the contralateral forearm or in the deltoid area.

It may be helpful to view the CDC video 'How to administer a JYNNEOS vaccine intradermally'. https://www.cdc.gov/poxvirus/mpox/video/administer-jynneos-vaccine-intradermally/intradermal-JYNNEOS.html

## 3.12 Infection prevention and control for the administration of the MVA-BN vaccine

Prior to preparation and administration of MVA-BN mpox vaccines, hand hygiene should be performed as per the "WHO five moments of hand hygiene" with emphasis on:

- Before vaccine preparation
- Before drawing up and administering the vaccine
- Before and after each recipient contact

PPE should be worn as per HPSC guidance for healthcare staff doing any care for potential contacts, this will require a risk assessment for PPE and precautions. A risk assessment is required to identify cleaning and decontamination of surfaces and environment following vaccination (if the vaccine is given outside the home). The latest IPC guidance is available at: Guidance - Health Protection Surveillance Centre

## 3.13 Adverse events

The patient should be informed of the possible side effects prior to vaccination. The most common adverse reactions observed in clinical trials were injection site reactions and common systemic reactions typical for vaccines which were mild to moderate in intensity and resolved without intervention within seven days following vaccination. Adverse reaction rates reported after either vaccination dose were similar.

### 3.13.1 Subcutaneous (SC) administration

**Local**

Very common: injection site erythema, induration, pain, pruritus and swelling.

Common: injection site discolouration, haematoma, nodule, warmth.

**General**

Very common: fatigue, headache, myalgia and nausea.

Common: appetite disorder, arthralgia, fever, pain in extremity, pyrexia, rigors/chills.

**Note: Those with atopic dermatitis may have higher rates of local and general adverse reactions following vaccination. In clinical trials of those with atopic dermatitis, 7% experienced exacerbation of their condition after vaccination.**

### 3.13.2 Intradermal (ID) administration

A 2015 clinical study of Jynneos evaluated the safety of a two-dose series of 0.1ml given ID compared to 0.5ml given SC. The proportion of those with erythema, induration or itching was significantly higher after ID vaccination compared to SC and the reactions lasted longer in the ID group. Over a third had mild injection site skin discoloration lasting six or more months. Pain at the injection site was less commonly reported and systemic reactions were similar to those after SC administration.[19]

## 3.14 Post vaccination advice and reporting adverse events

NIAC advises that "Vaccine providers should consider observing patients (seated or supine) for 15 minutes following administration of any vaccine to decrease the risk for injury should syncope occur."[18]

Vaccine recipients should be informed that they may experience prodromal symptoms of mpox infection in the two days (48hours) after vaccination.

The administration of the vaccine including patient details, batch number and use before date and route of administration should be recorded.

Any paper consent forms should be kept locally in line with policies on storage of immunisation records.

Any immediate adverse events should be recorded on the patient immunisation records.

The post vaccination leaflet should be completed and given to the patient.

Vaccine recipients should be informed it is recommended by NIAC there should be an interval of four weeks between the MVA-BN vaccines and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis.

Consent forms for adults and children, the information leaflet and the post vaccination advice are available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/mpox/

The Health Products Regulatory Authority (HPRA) is responsible for managing the national pharmacovigilance system. The HPRA reports nationally occurring adverse reactions to the EMA. Healthcare professionals and members of the public are encouraged to report any suspected adverse reactions (including known side effects) to the HPRA following the instructions available on the HPRA website www.hpra.ie. As much information as is known should be provided, and where possible, the vaccine batch number should be included.

# 4.0 Operational guidance

## 4.1 Vaccine ordering

### 4.1.1 Vaccine ordering for sexual health clinics

- For vaccine ordering or delivery enquiries please email vaccines@udd.ie – ordering is not available online.
- The vaccines will have a maximum 'use before' date of 8 weeks from the date of delivery. Please only order sufficient vaccines for those that will likely attend a clinic in less than 8 weeks from the time of receiving the order.
- When emailing the order, please do so in line with your NCCS delivery calendar, i.e. before 3pm on your order cut-off date. Provide your pharmacy NCCS account number and the details of the cohort to be vaccinated, e.g. sexual health clinic attendees, healthcare workers
- Once you have placed your order and have confirmation of delivery, please arrange the clinic times.
- Vaccines come in boxes of 20 vials (with an 8-week USE BEFORE date).
- Note each vial contains 0.5ml which is one dose SC or up to 5 doses if given ID (0.1ml per dose).

### 4.1.2 Vaccine ordering for close contacts in the community

For vaccine access/ordering for mpox PEP:

- In the first instance HSE Vaccination Operational Base will contact their local sexual health clinic to obtain vaccines from their stock
- If no stock available in the sexual health clinic, the Operational Base will order vaccines from the NCCS.
- For vaccine ordering or delivery enquiries from the NCCS please email vaccines@udd.ie
- If vaccine is required on the same day or out of hours this will be facilitated where necessary.
- If an mpox vaccine is needed out of hours or on a Bank Holiday then the HSE Vaccination Operational Base should provide all details of their cold chain account, address and the out of hours contact person's name and phone number to the local Regional CPHM on call who is leading on the mpox response. This person will contact the National Health Protection CPHM on call who will order the vaccine from NCCS.
- The vaccines will be supplied in boxes of 20 vials (with an 8-week USE BEFORE date).

- Any balance remaining after vaccination of close contacts is to be transferred to the closest sexual health clinic participating in PrEP, to ensure the vaccine is administered before the use by date.

## 4.2 Vaccine Equipment

### 4.2.1 Subcutaneous administration

Needles:

- For drawing up the vaccine – 38mm long, 21 gauge needle
- For administrating the vaccine – 16mm long, 23-25 gauge needle

Syringes:

- 1ml graduated syringe

### 4.2.2 Intradermal administration

When possible, low dead volume syringes and/or needles should be used.

Needle for drawing up and administering (you don't need to change needles):

- 25-27 gauge, 10-16mm long needle

Syringe:

- 1ml low dead volume syringes

Orders should be placed by emailing your request and delivery address to vaccine.support@jmc.ie, emails should specify the above materials for MPX administration. They will be delivered the next day to the service.

## 4.3 Pre exposure vaccination

### 4.3.1 HCW peer led vaccination

- Phased approach with vaccination of the NIU, STI/ID/PrEP/HIV clinic workforce and laboratory staff in phase 1
- Later phases will include ED and other HCW
- The phased approach will be kept under review and adapted as needed in response to the evolving situation

### 4.3.2 Participating sexual health clinics

Participating sexual Health Clinics will offer a three phase vaccination opportunity:

1. Opportunistic vaccination offer to individuals attending clinic on the days HSE vaccinators are on site.

2. Semi-opportunistic vaccination offer to individuals who are part of your clinic. Clinics should work to identify individuals and give them the opportunity to be vaccinated on a day when the HSE vaccinators are in place.

3. A Public facing opportunity to avail of vaccination – the scale of this will dependant on 1 and 2 above.

Two HSE Vaccinators will be available to Sexual Health Clinics on pre agreed days. The vaccinator will:

- Complete the medical eligibility and consent prior to administering the vaccine.
- Report on the number of Dose 1 and Dose 2 vaccinations administered in each clinic
- Manage the vaccine during the clinic session, recording on the Session Report Form
- Provide the recipient with post vaccination advice
- Vaccinators will be either a registered Nurse or Midwife, will have undergone all the relevant training and work within their own protocols.

The Sexual Health Clinic will:

- Provide a space for the HSE vaccinators to work
- Provide Consent forms, patient information leaflets and vaccination cards to the vaccinators on the day of each clinic, available at https://www.hse.ie/eng/health/immunisation/hcpinfo/mpox/
- Order and store the vaccines based on locally agreed requirements
- Prescribe the vaccines (the vaccine must be prescribed by a Doctor)
- Provide Medical cover (including anaphylaxis response) and governance for the clinic
- Safely store and retain the consent forms and any other data obtained during the clinic.

The arrangements between each Sexual Health Clinic and the HSE vaccinators should be managed via a named person within the Sexual Health Clinic and the vaccinator clinical lead relevant to your location.

### 4.3.3 Community vaccination

Future phase to include Community Vaccination will be determined by the Vaccination Subgroup.

## 4.4 Post exposure vaccination

### 4.4.1 Sexual contacts of mpox cases

Sexual contacts of mpox cases will be provided the opportunity for post exposure vaccination for close contacts. This pathway will be primarily managed through Sexual Health Clinics at which the index case was diagnosed. In the event that it is not possible to provide post exposure vaccination to sexual contacts at the Sexual Health Clinic within the post exposure window, sexual health clinics should make contact with their nearest Mpox Vaccination team using the agreed referral form, to arrange for vaccination in the community, see 4.2.2, which

includes provision of an electronic prescription from the Sexual Health clinic to allow for vaccine administration.

Of note, NIAC recommends that where there is an ongoing risk of exposure to contacts that they should be offered a second dose.

### 4.4.2 Non sexual contacts

High and intermediate risk contacts are identified by Public Health. Those who are unvaccinated should be offered the vaccine within four days of exposure. Vaccination can be given within 5 to 14 days after the date of last exposure.

### 4.4.3 Non sexual contacts pathway

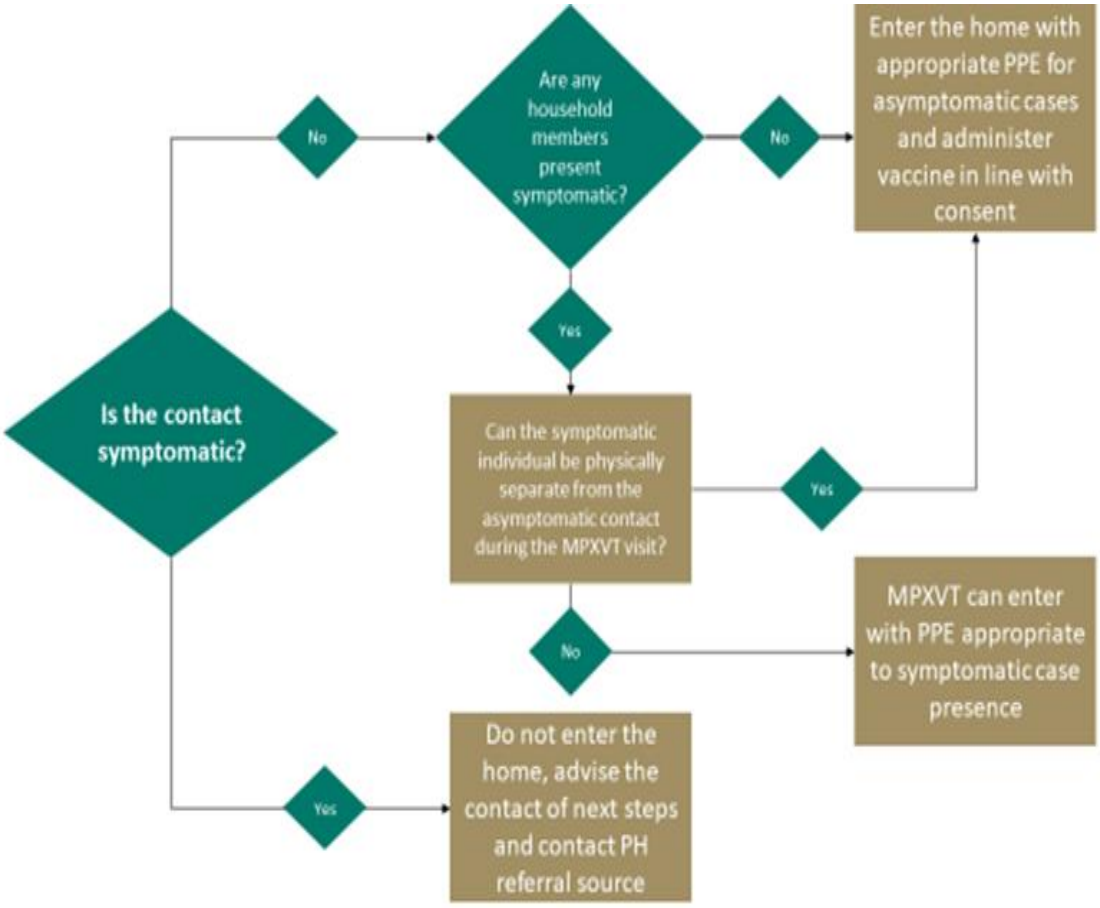
- Regional Departments of Public Health (hereafter "referral agent") will send a referral form (see Appendix 4 for Referral Form) and prescription for the close contact to their nearest Mpox Vaccination Team (MPXVT). Dedicated healthmail address in each Health Region, see Appendix 3 – Contact Details for referrals.
- The MPXVT will agree with the contact(s) a suitable date and time for administration of MVA-BN vaccine, prioritising as indicated on referral form. The MPXVT will ensure the close contact(s) received the patient information leaflet from the referral agent, and provide the close contact(s) with a vaccination information (Information leaflet) after vaccination, or before if not already received. The vaccination may take place at the person's residence or at a vaccination clinic, whichever is available to the MPXVT.
- The MPXVT, upon receipt of referral, will conduct a wellness check and confirm symptomatic status and determine the presence of any symptomatic household members via telephone in advance of the appointment and confirm date and time of proposed vaccination.
- The MPXVT will inform the referral agent of the agreed date and time of vaccination.
- The MPXVT will conduct another wellness check and confirm symptomatic status at the earliest opportunity on the scheduled vaccination day and determine the presence of any symptomatic household members.
- The Mpox close contact will attend a vaccination clinic at the appointment time, or if receiving vaccination in their home the MPXVT will arrive at the agreed time.
- The MPXVT will complete the consent and eligibility questionnaire, available at https://www.hse.ie/eng/health/immunisation/hcpinfo/mpox/
- The Vaccinator will complete the vaccination and provide the close contact(s) with a post vaccination advice leaflet, which is the record of vaccination and includes the vaccine name, batch number and the date of vaccination, available at https://www.hse.ie/eng/health/immunisation/hcpinfo/mpox/.

- The MPXVT will inform the referral agent of the completed vaccination, or provide an update if the vaccination did not proceed.
- The MPXVT will agree with the referral agent how and to where the consent form is to be returned to public health.
- Public health to retain consent forms in line with their retention policy.

4.4.3.1 Contacts vaccination pathway incorporates the following elements:

- Identification of high and intermediate risk contacts eligible for vaccination (Responsibility of Public Health)
- Referral pathway: this includes the roles and responsibilities of nominated referral agents (Public Health), the referral process, including minimum data requirements, and consent for referral and eligibility considerations.
- Mpox Vaccination Team: the roles and responsibilities of the MPXVT include both co-ordination and administration functions within their area in processing referrals for home vaccination, organising the home vaccination as contacts are identified, ordering and managing vaccine supplies and other associated consumables, and activity reporting to the referring public health department and the National Vaccination Programmes Office.

### 4.4.4 Vaccination decision process



### 4.4.5 Responsibility of referring agent

It is the responsibility of Public Health to inform the MPXVT of the individual who requires vaccination. The referral must include (please refer to Appendix 4 for Referral Form & minimum dataset):

- First Name
- Surname
- Gender M/F
- DOB
- PPSN (the *vaccine can be given if PPSN is not provided).*
- Contact Phone Number (mobile)
- Next of Kin
- Next of Kin Contact Number (mobile)
- Home Address incl. Eircode
- Date of last exposure (Day 0)
- Identify if High Risk or Intermediate Risk
- Referrer Name
- Referrer Contact Number
- GP Practice Name

One post-exposure prophylaxis vaccine will be offered to contacts, for the purposes of controlling an outbreak.

A new referral will be made to the MPXVT for those who are recommended a second vaccination based on continuing exposure.

Referrals will not be accepted from any other referral source. Referrals will only be accepted once this criterion is met and verified by referring clinicians/service. Vaccinations will not proceed for individuals inappropriately referred under this programme.

The pathway will open to referrals on 27th December 2024. See Appendix 3 for contact details.

**Referral agents should:**

- Identify individuals that meet the criteria of a high and intermediate risk contact of Mpox
- Prior to making a referral, the referral agent should consult with the contact or their family or legal guardian (when they are consenting on behalf of a minor under the age of 16) to ensure they wish to proceed with vaccination and consent to the referral being

made. The referral agent should undertake a risk/benefit discussion with the contact and signpost/provide them with links to the information leaflet on the HSE website.

- Prescribe the vaccine for the close contacts. The vaccine must be prescribed by a Doctor.
- Email the prescription to the MPXVT along with the referral form. (See Appendix 5 for e-prescription).
- The vaccine recipient should be informed about the "off-label" use of the vaccine in response to Mpox.
- Inform these individuals that their details have been submitted and they will be contacted by the Mpox vaccination team regarding their appointment. Address any concerns that the individual may have about the vaccine and the consent process. Ensure individuals are contactable and correct contact details are provided.
- Complete and return the referral form to their local MPXVT as outlined in Appendix 4. It is the responsibility of the referral agent to complete the referral form in full and obtain all data required to make a complete referral (see Appendix 4 for minimum data set).
- Referral agents should maintain a record of referrals made for home vaccination, including the dates referrals were made.

### 4.4.6 Responsibilities of mpox vaccination team (MPXVT)

- Review list of those to be vaccinated and determine schedule
- Contact individuals to confirm, reconfirm medical eligibility and establish current symptomatic status, determine the presence of any symptomatic household members, confirm appointment times as close as possible to date and time of vaccination and signpost/provide them with links to the information leaflet on the HPSC website. (clinical MPXVT member)
- Collect vaccine and consumables to include anaphylaxis kit (member of MPXVT)
- Transport vaccines in temperature controlled cool boxes. (member of MPXVT)
- Orders vaccines via National Cold Chain Service will be placed by the relevant MPXVT via National Cold Chain email vaccines@udd.ie, please refer to section 4.1.2 (clinical MPXVT member)

### 4.4.7 Referrals

**Referral Channel:** The MPXVT will establish a dedicated secure email (Appendix 3) for the receipt of referrals for vaccination of contact(s).

**Query Channel:**

- MPXVT can contact immunisation@hse.ie regarding clinical vaccination queries. This service is available 9am – 5pm Monday to Friday and only answers enquires from healthcare professionals.
- Complex medical issues will require clinical assessment by treating physician.
- Concerns about eligibility for vaccination should be referred to the referral agent.
- Individuals administered with the vaccine can refer to the aftercare leaflet.

**Referral Management**: The MPXVT will implement a standardised process to:

- Receive referrals including acknowledgement of receipt of referral (see Appendix 3)
- Validation of referral: data quality check, establish symptomatic status, determine the presence of any symptomatic household members, confirm individual is medically fit to receive the vaccine and has no contraindications
- Acceptance of referral including acknowledgement to referral agent and individual that referral for vaccination has been accepted including the date and time of appointment. If not accepted the referral agent should be advised of the reasons and the MPXVT should work with the referral agent to resolve as quickly as possible.
- Contact the individual to advise them of vaccine information available on HSE website in advance of the formal consent procedure on the day of vaccination.
- Prepare documentation for day of vaccination:
    - HSE Age Appropriate Consent Form
    - HSE Patient Leaflet Information and Manufacturer's Patient Information Leaflet
    - HSE Aftercare Leaflet

### 4.4.8 Preparation for home vaccination visit

**Before arriving at the home**

- The individual scheduled for vaccination should be contacted at the earliest opportunity on the scheduled day in order to reconfirm symptomatic status, presence of any symptomatic household members, contraindications and consent.
- Prepare all documents required for the journey (planned route, individuals details)
- Collect vaccine, consumables and leaflets from a base location; CVC
- Contact the individual(s) to carry out consent, symptomatic status check and eligibility questions at least 30 minutes before arrival

**On arrival at the home**

- Confirm any symptomatic household members are physically distant from the contact and MPXVT for the duration of the vaccination visit
- Identify the team and individual and make introductions
- Perform a Point of Care Risk Assessment for every contact with every patient, including asymptomatic close contacts who require vaccination. A PCRA will guide the appropriate choice and use of Personal Protective Equipment (PPE).
- Provide individual with copies of the HSE patient leaflet and vaccine manufacturer's Patient Information Leaflet and answer any questions regarding vaccination. Prepare vaccination workspace /waste disposal and management of sharps
- Comply with the HPSC guidance in relation to PPE; surgical mask and gloves. The waste will be managed as clinical waste. https://www.hpsc.ie/a-z/zoonotic/monkeypox/guidance/IPC%20for%20HCW%20for%20Possible%20or%20Confirmed%20Monkeypox%20Infection.pdf
- Further guidance on PPE, donning (putting on) and doffing (taking off) procedures can be found in the National Clinical Excellence Committee (NCEC) National Clinical Guideline No. 30 Infection Prevention and Control Volume 1 page 103. The sequence for putting on and removing PPE is illustrated in posters and videos on the HSPC website.
- Education modules on putting on and taking off PPE safely are also available on HSeLanD.
- Comply with the HPSC guidance in relation to Standard Precautions to be used with all patients at all times:
    - Hand Hygiene
    - Alcohol-based hand rub
    - Respiratory hygiene and cough etiquette
    - Management of blood and body fluid spills
    - Management of waste
- Pre vaccination preparation
- Individual confirms understanding of risks/ and benefits of vaccination, reconfirms medical eligibility, symptomatic status and signs consent form.
- Vaccinate individual
- Provide the individual with post vaccine advice sheet which includes the vaccine record for the individual
- Stay with individual for 15 minutes or longer, as appropriate, for post vaccination observation

- Treat and record any immediate adverse reactions
- Vaccinators should ensure that the individual in the home setting is provided with evidence of vaccination and aftercare information.
- Vaccinators must carry all necessary equipment including anaphylaxis kit and be trained in management of anaphylaxis and BLS.
- A risk assessment by the MPXVT may identify the need for a responsible adult to remain with the individual following vaccination.
- Advice to be given by vaccinator at time of vaccination to recipient of vaccine; if you are unwell post vaccination, please look at your information and aftercare leaflet for the common side-effects which will settle of their own accord over 24 to 48 hours. If you have temperature or soreness in your arm, you can take paracetamol or ibuprofen (whatever you normally take) to relieve these symptoms.
- For out of hours' care, please contact your GP by phone in the first instance, advising them you are a contact of Mpox. If you are unwell enough to need to attend hospital, please phone them and tell them you are a contact of an mpox case before attending in person.
- Ensure safe storage of open sharps boxes, see Appendix 7
- Take off PPE following appropriate HPSC guidance and store in clinical waste bag to transport back to base for disposal.
- Contact the administration member of the team to let them know that the individual has been vaccinated / in order to confirm via secure email to the referrer.
- Return Consent Form to team administrator.

**Post-Vaccination – Administration Member**

- Ensure vaccinator confirms vaccine administration complete.
- Confirm with referral source, via secure email, that vaccination has been completed.
- Copy the consent form and send the original by registered post to the referral agent to agreed address. Once the referral agent confirms in writing (email) receipt of the original, then the copy can be destroyed in line with data management requirements by MPXVT.

**Individual unwell on day of planned vaccination**

In the event that an individual is unwell and is unable to receive a vaccination, the MPXVT will not vaccinate and will contact the referral agent and advise them of the individual's condition.

The MPXVT should aim to reschedule the individual for the vaccine at a later date when clinically appropriate, depending on referral agents' advice and individual's condition.

### 4.4.9 Reporting

The MPXVT will agree with the referral agent the appropriate address to be utilised in order that consent forms are returned to the appropriate public health team. The MPXVT will report to the National Vaccination Programmes office using the template included in their Master Reporting Template.

**Data retention requirements**: The MPXVT and the vaccination leads have responsibility for data gathering and forwarding completed consent form and other relevant data to the referring public health department. The MPXVT will agree with the referral agent the appropriate address to be utilised in order that age appropriate consent forms are returned appropriately via registered post.

Vaccine consent forms should be collated by the Mpox vaccination teams, a copy should be held by the MPXVT and the original sent by registered post to the referral agent. Once the original copy is received by the referral agent the copy can be confidentially shredded.

There is no ICT System to record and manage data relating to Mpox vaccination. Vaccination consent will be required to be captured on the day on a pre-printed form. The MPXVT administration team will print the consent form, patient information and aftercare leaflet. These are available via the following link: https://www.hse.ie/eng/health/immunisation/hcpinfo/mpox/

### 4.4.10 Clinical governance

The MPXVT will operate within their existing clinical governance arrangements as outlined in *Clinical Governance of COVID-19 Vaccines from Operational Bases V1.0, available on sharefile https://healthirl.sharefile.eu/home/shared/fo0e94a2-4c18-4f90-ab82-43cae539ac48*

## 4.5 Consent

### 4.5.1 Consent for referral

The referral source must outline the vaccination model and confirm that the contact wishes to proceed with the vaccination or that the vaccination is in accordance with the individual's will and preference. In the case of children under the age of 16 consent is to be obtained from their parent or legal guardian.

### 4.5.2 Consent for vaccination

Eligibility and consent will be undertaken by the MPXVT in the home/clinic in advance of the vaccination for PEP. Eligibility and consent will be undertaken by the vaccinator in the STI services.

The individual's medical eligibility must be assessed before consent. Bearing in mind that all individuals are presumed to have capacity to give consent, an assessment of capacity should **only** take place when there are concerns about an individual's capacity.

## 4.6 Incident reporting

The Health Products Regulatory Authority (HPRA) must be informed using the Adverse Reaction Report (Yellow) Card System available at: www.hpra.ie

In the event of an incident occurring during a vaccination session, an incident report form must be completed by the professional primarily involved in the incident and forwarded to the relevant manager for review and sign off. Managers must ensure the following:

- All immediate safety issues are dealt with to mitigate risk of recurrence
- Service user and staff care, and support is in place, as necessary
- Open disclosure takes place
- The incident is inputted and recorded on the National Incident Management System (NIMs)
- Review incident in accordance with the HSE Incident Management Framework
- Learning is implemented and shared, as appropriate

If there is a vaccine administration error, e.g. an incorrect vaccine is administered to one or more individuals, the National Immunisation Office (NIO) must also be informed. Such an error must be reported to the relevant line manager.

The incident and all actions taken must be recorded and the relevant National Incident Report Form completed (National Incident Report Form - NIRF-- 01-V 11 March 2020) and administrative support is in place to input all incidents on the NIMs.
https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf

## 4.7 Programme reporting

There is currently no electronic immunisation information system to record Mpox vaccinations.

All activity in Sexual Health Clinics will be recorded and reported using Template 1, Appendix 8. Where the STI service is supported by HSE vaccinators, the HSE vaccinators will complete this template and return as part of the weekly Master Reporting. Where the STI service is delivering the programme within its own resources, where possible, it will complete Template 1 and return to Covid.and@hse.ie each Tuesday by noon detailing the activity for the previous week.

The MPXVT will report to the National Vaccination Programmes office weekly as part of their weekly Master Reporting. (Appendix 8, Template 2).

The National Vaccination Programmes office will provide a weekly update to the Chair of Mpox NIMT and the Chair of the Vaccination subgroup.

Further options are being explored to report data based on the information recorded in the mpox consent forms. This guidance will be updated once available once further information is available.

# Appendix 1 – Steps to be undertaken when a vaccinator is concerned regarding quality defects or particulates in a vial

When a vaccinator is concerned regarding quality defects or particulates in a vial the following steps should be followed:

- The vaccinator should contact another healthcare professional (HCP) and ask for a second opinion
- The affected vial should be returned to the fridge and kept there in Quarantine (between +2˚C and +8˚C)
- The vial in quarantine should be placed in a clearly marked area in the fridge "Quarantine - do not use"
- The vaccinator and senior experienced HCP should check the other vials in this batch in their fridge by removing one vial at a time and ensuring that the duration out of the fridge is kept to a minimum (less than 2 minutes) and the vial is kept in the dark except when being inspected.
- If more vials are considered defective, they should calculate the impact of placing vials into quarantine and arrange for additional deliveries if required.
- The HPRA, and National Immunisation Office (NIO) should be emailed with details of the issue and with a photograph of vial identifying the defect (if possible).
- The NIO will follow up and contact other locations where this batch has been delivered if necessary.

Please ensure vaccines are stored between +2$^{o}$C and +8$^{o}$C and in the dark.

Should vaccines be exposed to temperatures outside of these parameters please contact the NIO immediately.

Contacts for National Immunisation Office Pharmacists: pharmacynio@hse.ie

# Appendix 2 – Resources to support vaccination

The NIO has produced the following documents (approved by the mpox IMT) to support vaccinators.

- HSE Patient information leaflet
- Consent forms (children and adults)
- Post Vaccination leaflet (which includes a vaccination record card)
- Guidance on the preparation and administration of mpox vaccines via intradermal injection in community settings
- The link to the SmPC on EMA website is available at: https://www.ema.europa.eu/en/medicines/human/EPAR/imvanex

The NIAC immunisation guidelines on mpox (Chapter 13a) are available at: https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

# Appendix 3 – Contact details for referrals.

**The referral agent must submit a fully completed referral form and prescription to their closest location from the list below:**

| Public Health Area | Email addresses for referrals |
|---|---|
| A | mpxreferral.dublinnorth@healthmail.ie |
| B | MPXreferral.east@healthmail.ie |
| C | MPXreferral.south@healthmail.ie |
| D | mpxreferral.cork@healthmail.ie |
| E | MPXreferral.west@healthmail.ie |
| F | mpxreferral.galway@healthmail.ie |

# Appendix 4 – Referral form including minimum dataset

| Cover Page Monkeypox Close Contact Referral Form | |
|---|---|
| **Instructions:** | |
| 1. Fill in your Details in the space allocated below on this Page. | |
| 2. Please read the Data Dictionary on next tab to understand the fields that need to be completed. | |
| 3. Complete all identified fields on the template with your patient data. | |
| **Referrer Details** | |
| Full Name | |
| Address | |
| Contact No. | |
| | Note: Number format - 353 XX XXXXXXX |
| Email Address | |

**Minimum Data Set**

| Field Name | Mandatory/Optional |
|---|---|
| Forename | M |
| Surname | M |
| Gender | M |
| Date of Birth | M |
| PPSN | M |
| Contact Number (Mobile) | M |
| Next of Kin Name | M |
| Next of Kin Contact Number (Mobile) | M |
| Home Address Line 1 (Full Street Address) | M |
| Home Address Line 2 (City) | M |
| County | M |
| Eircode | O |
| Date of last exporsure | M |
| identify if High Risk or Intermediate Risk | M |
| Indicate if 2nd dose is required | M |
| Referrer name | M |
| Referrer Contact Number | M |
| GP Practice Name | M |

*Please note if the person does not have a PPSN vaccination can proceed without, but it is preferred when available.*

## Appendix 5 – E prescription

### Public Health PRESCRIPTION, Mpox Close Contact Vaccination

**Note:* ***This is a prescription. The duration refers to the duration of the prescription. Information regarding the ongoing treatment plan for a medicine can be obtained separately, if necessary, from the responsible physician.***

| | | | |
|---|---|---|---|
| **Patient Name:** | | **Gender:** | |
| **Date of Birth:** | | **Age:** | |
| **Address:** | | | |
| **Patient's Contact Phone Number:** | | | |
| **Public Health Department:** | | | |
| **Primary Consultant:** | | | |
| **Known Allergies:** | | | |

| **Drug** | **Dose** | **Route** | **Frequency** | **Duration/ Quantity** | **Repeat by (If applicable)** |
|---|---|---|---|---|---|
| Jynneos | 0.5ml | SC | Stat | X1 | |

**Comments (e.g. changes to medicines/discontinued medicines)**

| | | | |
|---|---|---|---|
| **Date of issue:** | | | |
| **Doctor Name:** | | **Contact Number:** | |
| **MCRN:** | | | |

# Appendix 6 – Session report form

Also available online on sharefile: https://healthirl.sharefile.eu/home/shared/fob9844d-514a-4be4-9d01-0d9048e6a90f

**Mobile Vaccination Team Vaccination session report form**

**Operational Base Name:**_____

| | |
|---|---|
| **Clinic Type:** | **Date:** / / |
| **Site name:** | |
| **Site address:** | |
| | |
| **Facility ID:** | |
| **Site contact person:** | **Tel:** |

Emergency drugs and equipment checked_____

**Signature:**_____ **Signature:** _____

| **Vaccine (Brand name)** | **Batch Number 1** | **Expiry date/ use before date** | **Batch number 2** | **Expiry date/ use before date** |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

***Add temperature and initials in space provided***

| **Temperature & time** | **Before leaving Operational Base;** | | **Start of session;** | | **End of session;** | | **On return to Op Base fridge;** | |
|---|---|---|---|---|---|---|---|---|
| Box 1 | Temp | | Temp | | Temp | | Temp | |
| Box 2 | Temp | | Temp | | Temp | | Temp | |
| Box 3 | Temp | | Temp | | Temp | | Temp | |
| Box 4 | Temp | | Temp | | Temp | | Temp | |

| | | | | |
|---|---|---|---|---|
| **Vaccine names** | | | | |
| **Target population- if known** | | | | |
| **Number vaccinated** | | | | |
| **No consent** | | | | |

| | | | | |
|---|---|---|---|---|
| *Consent refused* | | | | |
| *DNA or Absent* | | | | |

**Number of Vaccination Team Members at Session:**

**Vaccinators:**

**Administrators:**

**Name of designated vaccinator:**

**PIN of designated vaccinator:**

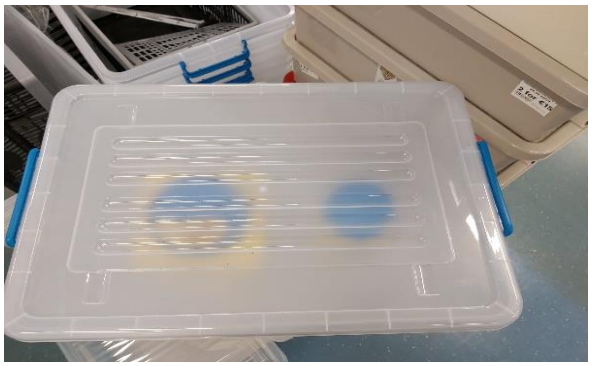
**Signature of person filling in form:_____ Date:**

**Print name in block capitals:**

MVT Session Report Form – September 2023

# Appendix 7 – Points for improving safety when transporting a sharps box in your car:

1. Complete a risk assessment for the transportation of sharps boxes and implement the control measures
2. Ensure appropriate PPE and training is provided to persons who handle sharps
3. Use the appropriate sharps box. Bring a new sharps box for the visit and close the box when treatment is complete.
4. Close the sharps box before transport and complete the closure details on the label.
5. Store the sharps box upright in a secure manner.
6. Secure it within the car boot.
7. Possibly look to place the sharps bin in a secondary plastic container/box (see examples below).
8. Try to schedule the journey so that you are driving straight to the location where the closed sharps bin will be disposed/ stored at i.e. that you are not driving around with the sharps box in the car for longer than necessary.
9. Ensure appropriate PPE is used when handling and transporting sharps.
10. If in the event of a road traffic accident, inform the emergency services as soon as possible that healthcare risk waste sharps are being transported in the boot.



*June 2020: Guidance as provided by the Healthcare Risk Waste Sub -Group following consultation with DGSA Advisor EcoOnline*

# Appendix 8 – Reporting templates

**Template 1 – STI Services**

| MPOX Clinic Return | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **CHO** | **Week Commencing** | **Operational Base Responsible** | **Clinic Date** | **Clinic Location** | **Dose 1 Vaccines administered** | **Dose 2 Vaccines administered** | **PEP booster vaccination administered*** | **Number of doses administered for Pre Exposure** | **Number of doses administered for Post Exposure** |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |

**A PEP booster vaccination is for people who completed an mpox primary vaccination course more than two years ago and have been recommended to receive another mpox vaccine as a booster.*

**Template 2 – Close Contacts**

| **Date** | **Location** | **Number of Referrals Received for Dose One** | **Number of referrals Received for Dose Two** | **Number of Referrals Accepted by MPX Team** | **Number of referrals not accepted by MPX Team** | **Number of referrals DNA/CNA/Declined etc** | **Number of Vaccinations administered 0-4 days since last exposure** | **Number of vaccinations administered 5-14 days since last exposure** | **Number of Vaccinations Administered Dose 1** | **Number of Vaccinations Administered Dose 2** | **Total Vaccinations Administered P/W** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | |

# References


1. World Health Organization. Monkeypox Geneva. WHO; [Available from: https://www.ecdc.europa.eu/en/all-topics-z/monkeypox/factsheet-health-professionals].
2. Damon IK. Status of human monkeypox: clinical disease, epidemiology and research. Vaccine. 2011;29 Suppl 4:D54-9. 10.1016/j.vaccine.2011.04.014
3. European Centre for Disease Prevention and Control. Risk assessment for the EU/EEA of the mpox epidemic caused by monkeypox virus clade I in affected African countries – 16 August 2024. Stockholm: ECDC; 2024.
4. Dillon C, O'Donnell K, McKeown P, Lyons F, Browne C, Fallon U, et al. Mpox outbreak - Response and epidemiology of confirmed cases in Ireland from May 2022 to May 2023. Ir Med J. 2024;117(6):975.
5. World Health Organization. Multi-country outbreak of mpox, External situation report #35- 12 August 2024. Geneva: WHO; 2024.
6. Bunge EM, Hoet B, Chen L, Lienert F, Weidenthaler H, Baer LR, et al. The changing epidemiology of human monkeypox-A potential threat? A systematic review. PLoS neglected tropical diseases. 2022;16(2):e0010141. 10.1371/journal.pntd.0010141
7. European Medicines Agency. EMA Imvanex. EMA; 2024.
8. Pischel L, Martini BA, Yu N, Cacesse D, Tracy M, Kharbanda K, et al. Vaccine effectiveness of 3rd generation mpox vaccines against mpox and disease severity: A systematic review and meta-analysis. Vaccine. 2024;42(25):126053. https://doi.org/10.1016/j.vaccine.2024.06.021
9. Guagliardo SAJ, Kracalik I, Carter RJ, Braden C, Free R, Hamal M, et al. Monkeypox Virus Infections After 2 Preexposure Doses of JYNNEOS Vaccine - United States, May 2022-May 2024. MMWR Morb Mortal Wkly Rep. 2024;73(20):460-6. 10.15585/mmwr.mm7320a3
10. Palich R, Jedrzejewski T, Schneider L, Qatib N, Orriere T, Gosset D, et al. High uptake of vaccination against mpox in men who have sex with men (MSM) on HIV pre-exposure prophylaxis (PrEP) in Paris, France. Sexually Transmitted Infections. 2023;99(8):552-3. 10.1136/sextrans-2023-055885
11. Svartstein A-SW, Knudsen AD, Heidari S-L, Heftdal LD, Gelpi M, Benfield T, et al. Mpox Incidence and Vaccine Uptake in Men Who Have Sex with Men and Are Living with HIV in Denmark. Vaccines (Basel). 2023;11(7):1167.
12. Huhn GD, Bauer AM, Yorita K, Graham MB, Sejvar J, Likos A, et al. Clinical Characteristics of Human Monkeypox, and Risk Factors for Severe Disease. Clinical Infectious Diseases. 2005;41(12):1742-51. 10.1086/498115
13. Garneau WM, Jones JL, Dashler GM, Mostafa HH, Judson SD, Kwon N, et al. Risk Factors for Hospitalization and Effect of Immunosuppression on Clinical Outcomes Among an Urban Cohort of Patients With Mpox. Open forum infectious diseases. 2023;10(12):ofad533. 10.1093/ofid/ofad533
14. Miller MJ, Cash-Goldwasser S, Marx GE, Schrodt CA, Kimball A, Padgett K, et al. Severe Monkeypox in Hospitalized Patients - United States, August 10-October 10, 2022. MMWR Morb Mortal Wkly Rep. 2022;71(44):1412-7. 10.15585/mmwr.mm7144e1
15. McQuiston JH, Braden CR, Bowen MD, McCollum AM, McDonald R, Carnes N, et al. The CDC Domestic Mpox Response - United States, 2022-2023. MMWR Morb Mortal Wkly Rep. 2023;72(20):547-52. 10.15585/mmwr.mm7220a2
16. Mitjà O, Alemany A, Marks M, Lezama Mora JI, Rodríguez-Aldama JC, Torres Silva MS, et al. Mpox in people with advanced HIV infection: a global case series. The Lancet. 2023;401(10380):939-49. 10.1016/S0140-6736(23)00273-8
17. Khalil A, Samara A, O'Brien P, Morris E, Draycott T, Lees C, et al. Monkeypox vaccines in pregnancy: lessons must be learned from COVID-19. The Lancet Global Health. 2022;10(9):e1230-e1. 10.1016/S2214-109X(22)00284-4
18. National Immunisation Advisory Committee. General immunisation procedures. Ireland: RCPI; 2022.

19. Frey SE, Wald A, Edupuganti S, Jackson LA, Stapleton JT, El Sahly H, et al. Comparison of lyophilized versus liquid modified vaccinia Ankara (MVA) formulations and subcutaneous versus intradermal routes of administration in healthy vaccinia-naïve subjects. Vaccine. 2015;33(39):5225-34. 10.1016/j.vaccine.2015.06.075
20. Deng L, Lopez LK, Glover C, Cashman P, Reynolds R, Macartney K, et al. Short-term Adverse Events Following Immunization With Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN) Vaccine for Mpox. JAMA. 2023;329(23):2091-4. 10.1001/jama.2023.7683