



Guidance Document on the Preparation and Administration of Monkeypox Vaccines via Intradermal Injection in Community Settings

NOTE: This guidance document has been developed for the purpose of preparing and administering Monkeypox Vaccines (MPX) Imvanex (MVA-BN Smallpox vaccine) and Jynneos (Smallpox and monkeypox vaccine, Live, Non-replicating) only through intradermal (ID) injection in Community Settings under individual prescription.

Document	Version 1	Document developed by	National Immunisation Office (NIO) and Clinical Advisory Group (CAG)
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Revision date	Nov 2024	Responsibility for Implementation	MPX Vaccinators administering MPX vaccine through Intradermal (ID) Injection

1. Introduction

This guidance document supports the clinical practice of preparing and administering a vaccine through the intradermal (ID) route in community settings. Intradermal injection is the administration of a medicine/vaccine into the dermis layer of the inner surface of the forearm, not extending to the subcutaneous tissue. Most vaccines are administered via the intramuscular (IM) or subcutaneous (SC) route. The ID route is used for only a small number of vaccines (e.g. Imvanex, BCG). This method of vaccine administration requires healthcare professionals to be trained in the ID route of administration to ensure safe practice. This guidance document pertains to the Monkeypox (MPX) vaccine administration using ID injection route only. MPX vaccines are prescription only medicines and can only be administered under individual prescription.

2. Statement

This guidance document supports healthcare professionals in the preparation and administration of MPX vaccines to vaccine recipients under individual prescription.

3. Scope

This guidance document applies to Registered Medical Practitioners (RMPs), Registered Nurses (RNs) and Registered Midwives (RMs) working in the Health Service Executive (HSE) including agency staff working for the HSE (hereafter referred as MPX vaccinators) who have clinical involvement in the preparation and administration of MPX vaccines. The scope of this document is limited to preparing and administering MPX vaccines **only** through ID injection under individual prescription. This document does not include the administration of any other vaccines/medicines via ID injection.

4. Purpose

The purpose of this guidance document is:

- to provide clinical guidance for best practice on ID injection technique by MPX vaccinators
- to inform MPX vaccinators of the education and training requirements to prepare and administer a MPX vaccine via ID route

- to ensure that all MPX vaccines are prepared and administered safely and are consistent with high standards of care delivery
- to identify the requirements for the clinical environment for the preparation and administration of MPX vaccines.

5. Roles & Responsibilities

5.1 Responsibilities of Lead Clinician

- Supervision, management and oversight of the preparation and administration of MPX vaccines within the designated safe and clean clinical environment
- Ensure required clinical equipment is available
- Ensure MPX vaccinators are suitably trained and competent to prepare and administer MPX vaccine via ID route. Refer to the education and training requirements section of this guidance document (section 6)
- Ensure MPX vaccinators have access to relevant HSE information materials to support the safe preparation, administration and monitoring of MPX vaccines under individual prescription.

5.2 Responsibilities of MPX Vaccinators

- Complete the required education and training to prepare and administer the MPX vaccines under ID route and complete the relevant competency assessment
- MPX vaccines must be given under individual prescription via ID route
- Check for eligibility and obtain consent from each vaccine recipient prior to ID administration of MPX Vaccine
- Prepare and administer MPX vaccines via ID route
- Record/ document details of MPX vaccine administration via ID route
- Ensure vaccine recipient remains in post vaccination observation area for 15 minutes post vaccine administration to allow monitoring of any immediate reaction including anaphylactic reaction
- Report any adverse events or incidents of clinical errors to the Health Products Regulatory Authority (HPRA) and other relevant authorities and follow recommended HSE policies, procedures, protocols and guidelines (PPPGs)
- Ensure the delivery of the highest quality of care and treatment to vaccine recipients, act in their best interests, seek guidance, support and advice from lead clinician where indicated

6. Education, Training and Competence Requirements for MPX Vaccinators

- Be a Registered Nurse (RN) or Registered Midwife (RM), on the active register maintained by the NMBI
- or
- Be a Registered Medical Practitioner (RMP), on the active register maintained by the Irish Medical Council (IMC)
- Have completed an approved *Basic Life Support for Health Care Providers Course* within the last two years (i.e. Irish Heart Foundation (IHF))
- Have completed initial *National Anaphylaxis Education Programme for Health Care Professionals* accessible on www.HSELand.ie followed by a two hour classroom based skills workshop. Recertification is required every two years by completing the on-line *National Anaphylaxis Education Programme for Health Care Professionals* accessible on www.HSELand.ie
- Have completed the online ID injection route demonstration video titled “How to administer a Monkeypox (JYNNEOS) vaccine intradermally” available at <https://www.youtube.com/watch?v=TLv1mR6mECQ> (Center for Disease Control and Prevention, 2022)
- Have completed the “Immunisation Foundation Programme” accessible on www.hseland.ie
- Have completed the Self-Assessment of Competency Form to administer the Monkeypox vaccine using the ID injection route (see Appendix 1).

Recommended:

- Complete the HSeLand e-learning module “Storing and Managing Vaccines” available at www.hseland.ie

Required Reading

- Immunisation Guidelines for Ireland
<https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/>
- National Immunisation Advisory Committee (2022) *Anaphylaxis: Immediate Management in the Community* available at:
<https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf>

- Health Protection Surveillance Centre (HPSC) Supporting Information for Healthcare Workers: Use of MVA-BN vaccine in response to monkeypox
<https://www.hpsc.ie/a-z/zoonotic/monkeypox/vaccination/V3%20monkeypox%20clinical%20guidance%2026082022.pdf>
- Summary of Product Characteristics (SmPC) of the MPX vaccines, available at www.hpra.ie
- Health Service Executive Policy on the Management of Sharps and Prevention of Sharp Injuries (HSE 2022)

6.1 Recommended process pathway for MPX vaccinators to attain competence in the preparation and administration of the MPX vaccines via ID injection route

- *Step 1:* MPX vaccinators should complete the above education and training requirements as listed in section 6
- *Step 2:* MPX vaccinator must complete the Self-Assessment of Competency Form to administer the MPX vaccine using the ID injection route (see Appendix 1). MPX vaccinator should discuss with the clinical lead/ ID injection route trainer if there is any deficit in competence and agree how this will be addressed
- *Step 3:* MPX vaccinator should liaise with the clinical lead/ ID injection route trainer to undertake a minimum of 3 observations of ID injection route i.e. “3 individual vaccine recipients receiving the MPX vaccine via the ID injection route administered by the ID injection route trainer” to progress in attaining self-competency on ID injection route. The ID injection route trainer should obtain informed consent from the vaccine recipient before proceeding with administration of MPX vaccine via ID injection route under individual prescription
- *Step 4:* The date and time of the observations should be recorded in the Self-assessment of Competency Form (Appendix 1)(see below)
- *Step 5:* When the MPX vaccinator feels competent in the ID injection route, she /he should organise with the clinical lead /ID injection route trainer to be supervised in the preparation and administration of the Monkeypox vaccine via ID injection route (see below)
- *Step 6:* Once the MPX vaccinator fulfills the criteria as outlined in the Self-assessment of Competency Form the ID injection route trainer can sign the competency document. The MPX trainee vaccinator is now eligible to administer the MPX vaccines via ID injection route independently. A copy of the completed and signed-off Self-assessment of Competency Form must be provided to the clinical lead.

Note: The number of observations and supervised administration of MPX vaccines under ID injection route varies.

The MPX vaccinator should observe a minimum of 3 individual vaccine recipients receiving the MPX vaccine via the ID injection route administered by the ID injection route trainer, and also the MPX vaccinator should administer the MPX vaccine using the ID injection route to 3 individual vaccine recipients under the direct supervision of the ID injection route trainer. The inclusion of local training practice utilising training aids may be considered if necessary but it is not mandatory.

7. Preparation for MPX Vaccine Administration

Prior to administration of the vaccine the MPX vaccinator must adhere to the following:

- MPX vaccines should be prepared and administered only by vaccinators trained in safe procedures, aware of the risks involved and who have demonstrated their competence in administration of MPX vaccines via ID route
- All practitioners are accountable for their practice including acts and omissions regardless of advice or direction received from another professional
- The MPX vaccinator should administer the MPX vaccine into a recommended site only. NIAC recommends MPX 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. This information is available at <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/ch13a.pdf>
- Follow Infection Prevention and Control standard precautions at all times i.e. personal and protective equipment.
- The MPX vaccinator must perform hand hygiene as per “WHO 5 moments of hand hygiene” before and after each vaccine administration.
- The skin does not require cleansing before the vaccine is administered unless visibly dirty. In this instance the skin can be cleaned with soap and water. If an alcohol wipe is used the skin should be allowed to dry before the vaccine is administered

8. Administration of MPX Vaccine

NOTE: As per the NIAC guidelines, ID administration is **NOT** recommended for those with a history of keloid scar formation and for those aged less than 18 years. These cohorts should receive the MPX vaccine via the Subcutaneous (SC) route.

8.1 How to administer MPX vaccine via intradermal route

The following information is obtained from the Immunisation Guidelines of Ireland (NIAC).

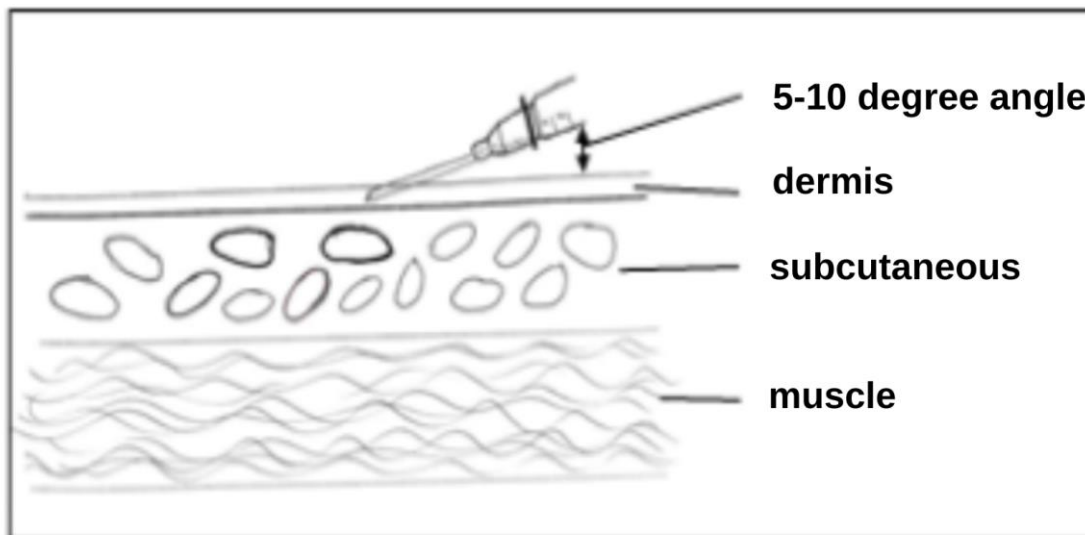
Intradermal Injection Technique

- Use a 1ml syringe with a 10-16 mm, 25-26G short-bevelled needle
- Expel all air bubbles
- Slightly stretch the skin over the injection site with thumb and index finger of

the non-dominant hand

- Insert the needle almost parallel (5-10 degrees) to the surface, bevel upwards, to a distance of 2-3 mm. The bevel should be covered by skin and visible through the epidermis
- Slowly inject the dose. When given correctly, an ID injection should raise a blanched bleb or wheal. 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

Figure 2.7. Intradermal injection-correct angle and depth of insertion



- Release the stretched skin and hold the syringe in place with thumb and forefinger of your non-dominant hand. Maintain stability of limb and needle at all times
- Grip the body of the syringe between the first and middle fingers of your dominant hand. Do not aspirate. Slowly depress the plunger with your thumb. You should feel fairly firm resistance during depression
- Remove the needle. Use a cotton ball to lightly blot any blood. Do not press down or massage the area. Bandages should not be used.

9. Post Administration of MPX ID Injection

- MPX Vaccinators dispose of sharps immediately, without recapping the needle, into the sharps container, which must be available at the point of care.
- Perform hand hygiene (use alcohol hand gel/ soap and water)

10. Observation Post MPX Vaccine Administration

The vaccine recipient must be advised to remain seated in the post vaccination observation area for 15 minutes to allow monitoring of any immediate reaction including possible anaphylactic reaction and must be advised to report any side effects to the RMP/RN/RM.

References

An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord Altranais

Immunisation Guidelines for Ireland. National Immunisation Advisory Committee Available at: <http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/>

Centers for Disease Control and Prevention (2022). How to administer a JYNNEOS vaccine intradermally. <https://www.youtube.com/watch?v=TLv1mR6mECQ>

Melbourne Vaccination Education Centre (2022). Intradermal vaccination. <https://mvec.mcri.edu.au/references/intradermal-vaccination/>.

Healthcare risk waste management segregation packaging and storage guidelines for healthcare risk waste 4th edition November 2010, available at http://www.lenus.ie/hse/bitstream/10147/120929/1/healthcare_waste_packaging2010.pdf

National Immunisation Advisory Committee (2022) Anaphylaxis: Immediate Management in the Community. Available at <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf>

Health Protection Surveillance Centre Supporting Information for healthcare workers: Use of MVA-BN vaccine in response to monkeypox <https://www.hpsc.ie/a-z/zoonotic/monkeypox/vaccination/V3%20monkeypox%20clinical%20guidance%2026082022.pdf>

Nursing and Midwifery Board of Ireland (2021) *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives*. Dublin: Nursing and Midwifery Board of Ireland available at: <http://www.nmbi.ie/Standards-Guidance/Code>

Nursing and Midwifery Board of Ireland (2020) *Guidance for Registered Nurses and Midwives on Medication Administration*. Dublin: Nursing and Midwifery Board of Ireland

Nursing and Midwifery Board of Ireland (2022) *Practice Standards for Midwives*. Dublin: Nursing and Midwifery Board of Ireland available at: <http://www.nmbi.ie/Standards-Guidance/Midwives-Standards>

Nursing and Midwifery Board of Ireland (2015) *Recording Clinical Practice. Guidance to Nurses and Midwives*. Dublin: Nursing and Midwifery Board of Ireland available at: <http://www.nmbi.ie/Standards-Guidance/More-Standards-Guidance/Recording-Clinical-Practice>

Nursing and Midwifery Board of Ireland (2015) *Scope of Nursing and Midwifery Practice Framework*. Dublin: Nursing and Midwifery Board of Ireland available at: <http://www.nmbi.ie/Standards-Guidance/Scope-of-Practice/Nursing-Practise-Scope-Definition>.



Self-Assessment of Competency to administer Monkeypox vaccines via Intradermal (ID) injection route

Name: _____

Print clearly in capitals

NMBI Pin/MCRN: _____

No.	Critical Element	Competent Date/Initials	Needs Practice Date/Initials	Needs Theory Date/Initials
Part 1 Knowledge- Self Assessment Declaration (Part 1: Applicable for RN/RM MPX vaccinator only)				
1.1	I practice within my scope of practice (Scope of Nursing and Midwifery Practice Framework, Nursing and Midwifery Board of Ireland (NMBI, 2015) to undertake administration of Monkeypox (MPX) vaccines under the HSE/NIAC immunisation programmes			
1.2	I understand that MPX vaccines are prescription only medicines (POM) and prior to administration require a valid prescription for Imvanex (MVA-BN Smallpox vaccine) /Jynneos vaccines			
1.3	I understand the role and function of medicine protocols in the context of NMBI and NIAC guidelines in relation to: <ul style="list-style-type: none"> · The Code of Professional and Ethical Conduct for Registered Nurses and Registered Midwives (NMBI, 2021) · Scope of Nursing and Midwifery Practice Framework (NMBI, 2015) · Guidance for Registered Nurses and Midwives on Medication Administration (NMBI, 2020) · Guidance to Nurses and Midwives on Medication Management (An Bord Altranais, 2007) · NIAC Immunisation Guidelines for Ireland available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/ 			
Part 2 Core Skills- Self Assessment Declaration and competency for all MPX vaccinators				
2.1	I have attended an approved Basic Life Support for Health Care Providers Course within the last two years (i.e. Irish Heart Foundation (IHF))			
2.2	I have successfully completed the HSE National Anaphylaxis Programme and am familiar with NIAC protocol titled "Anaphylaxis: Immediate Management in the Community" (2022)			
2.3	I demonstrate knowledge on how to respond to an immediate serious adverse event following vaccination and know the location of anaphylaxis and emergency care equipment and how and when to use it			

2.4	I demonstrate knowledge of incident response and reporting process in case of a procedural error, needle stick injury, breach of infection control measure, etc as per the HSE policy. <u>Note:</u> The incident and all actions taken must be promptly recorded and the relevant National Incident Management Report Form completed: https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf			
2.5	I understand the following in relation to the recording of the preparation and administration of MPX vaccine: · Documentation of the details of the vaccine to include the vaccine label which has the batch number and expiry date details · Date and time and site of administration of vaccine · Vaccinator ID (name, signature and NMBI PIN/MRCN)			
2.6	I have knowledge of the donning and doffing of personal protective equipment (PPE) as required and demonstrate good practice in infection prevention and control. I use aseptic technique when preparing vaccines and handling injection equipment (e.g. syringes, needles) to prevent contamination and infection.			
2.7	I dispose of sharps, vaccine syringes and vials and other vaccine equipment safely in accordance with guidance for Healthcare Risk Waste HSE (2010).			
2.8	In the event of needle stick injury, I agree to follow guidelines as outlined in the 'EMI Tool Kit' available at: https://www.hpsc.ie/a-z/EMIToolkit/appendices/app3.pdf			
2.9	I comply with the HSE guidance on vaccine handling, delivery and storage including the maintenance of the cold chain in accordance with the HPSC Supporting Information for healthcare workers: Use of MVA-BN vaccine in response to monkeypox https://www.hpsc.ie/a-z/zoonotic/monkeypox/vaccination/V3%20monkeypox%20clinical%20guidance%2026082022.pdf This HPSC guidance is applicable for Imvanex (MVA-BN Smallpox vaccine) and Jynneos vaccines			
Part 3 Clinical Process and Procedure				
3.1	I can outline the inclusion/exclusion criteria for administering MPX vaccines as per NIAC Immunisation Guidelines https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/ch13a.pdf			
3.2	I check vaccine recipient's identity and appropriate records prior to vaccination to ascertain suitability for MPX vaccination			
3.3	I demonstrate ability to answer vaccine recipients/carer questions, referring to leaflets to aid explanations/discussion as appropriate and using interpreter if necessary to ensure patient/carer/staff informed. I know who to refer to or who to contact if further detail or advice is required			
3.4	I can clearly and confidently discuss the benefits and risks of MPX vaccination and can address any concerns vaccine recipients/carers may have			

3.5	I demonstrate knowledge of consent requirements and any relevant issues such as the capacity to consent /lack of decision – making ability			
3.6	I ensure consent is obtained prior to vaccination and record this appropriately			
3.7	I demonstrate knowledge and understanding of contraindications and precautions to MPX vaccines and can assess appropriately for these, or, if necessary, the need to postpone vaccination			
3.8	I check the presentation of the MPX vaccine, the expiry date, how it has been stored prior to use and prepare it according to the vaccine manufacturer's instructions			
3.9	I complete all necessary documentation, recording type and product name of vaccine, batch number, expiry date, dose administered, site used, date given and name and signature			
3.10	I demonstrate good record keeping and understand the importance of ensuring vaccine information is recorded on relevant data system(s)			
3.11	I advise vaccine recipient on what to expect after vaccination as appropriate (e.g. local injection site reactions, fever) and management of these			
3.12	I provide vaccine recipient/carer with a copy of post-immunisation advice sheet or the product's information leaflet, in chosen language			
3.13	I recognise my individual limitations and know where to refer individuals where there may be more complex requirements or a more experienced vaccinator is required i.e. Discuss with the clinical lead/ID injection technique trainer.			

Part 4: MPX vaccinators are required to observe and demonstrate the administration of a minimum of 3 intradermal injections under direct supervision of an ID injection route trainer to be deemed competent to administer Intradermal Monkeypox Vaccine.

Intradermal Injection Technique Observed						
		Date	Date	Date		
	Signature:					
		Supervised Assessments			Competence Demonstrated Y/N	Signature
	Skill Required	Date	Date	Date		
Competency 4.1	Positions vaccine recipient appropriately and chooses appropriate vaccination site i.e. use of forearm as outlined in Section 7					
4.2	Demonstrates correct Intradermal injection technique					

Plan of action for further improvement as agreed with the ID injection route trainer and actions necessary to achieve competence:

Action necessary to achieve competence:

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Date to be achieved:.....

Supporting evidence of measures taken to achieve competence:

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*I have been deemed competent to prepare and administer the Monkeypox Vaccines. I have been deemed competent to administer Monkeypox vaccines using the intradermal route.
I (RN/ RM) acknowledge my responsibility to maintain my own competence in line with the Nursing and Midwifery Board of Ireland (2015) Scope of Nursing and Midwifery Practice Framework and current best evidence.*

Name & Signature of the Vaccinator NMBI PIN/MCRN: _____

Date: _____

Name & Signature of the ID injection route trainer MCRN/NMBI pin: _____

Date: _____