

Guidance Document on the Preparation and Administration of MVA-BN (Mpox) vaccines via Intradermal Injection in Community Settings

As per the NIAC guidelines, the Subcutaneous route (S/C) is preferred for Mpox vaccine administration, as the technique is familiar and adverse reactions are significantly less. However, if vaccine supplies are limited Mpox vaccine may be administered intradermally (ID), only for those aged 18 years and older.

NOTE: This guidance document has been developed for the purpose of preparing and administering two mpox vaccines, Imvanex and Jynneos both containing Smallpox Modified Vaccinia Ankara - Bavarian Nordic (MVA-BN) **only through intradermal (ID) injection** in Community Settings under individual prescription.

Document	Version 2	Document	National Immunisation Office (NIO) and
		developed by	Clinical Advisory Group (CAG)
Approval date	Nov 2022	Document	
		Approved by	
Revision date	Dec 2026	Responsibility for Implementation	Mpox Vaccinators administering Mpox 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 MVA-BN (Mpox) vaccine administration using ID injection route only. Mpox 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 Mpox 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 Mpox vaccinators) who have clinical involvement in the preparation and administration of Mpox vaccines. The scope of this document is limited to preparing and administering Mpox 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 Mpox vaccinators
- to inform Mpox vaccinators of the education and training requirements to prepare and administer a Mpox vaccine via ID route

- to ensure that all Mpox 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 Mpox vaccines.

5. Roles & Responsibilities

5.1 Responsibilities of Lead Clinician

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

5.2 Responsibilities of Mpox Vaccinators

- Complete the required education and training to prepare and administer the Mpox vaccines under ID route and complete the relevant competency assessment
- Mpox vaccines must be given under individual prescription
- Check for eligibility and obtain consent from each vaccine recipient prior to ID administration of Mpox Vaccine
- Prepare and administer Mpox vaccines via ID route
- Record/ document details of Mpox 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 Mpox 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 Mpox (JYNNEOS) vaccine intradermally" available at https://www.youtube.com/watch?v=whkGs0dug1s (Center for Disease Control and Prevention, 2022)
- Have completed the "Primary Childhood Immunisation Programme" accessible on www.hseland.ie
- Have completed the Self-Assessment of Competency Form to administer the Mpox 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 (2023) 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/mpoxvaccinationinformation/Mpox%20MVA-BN%20vaccine%20Clinical%20Guidance.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 Mpox vaccinators to attain competence in the preparation and administration of the Mpox vaccines via ID injection route

Step1: Mpox vaccinators should complete the above education and training requirements as listed in section 6

- **Step 2**: Mpox vaccinator must complete the Self-Assessment of Competency Form to administer the Mpox vaccine using the ID injection route (see Appendix 1). Mpox 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:** Mpox 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 Mpox 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 Mpox 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 Mpox 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 Mpox vaccine via ID injection route (see below)
- **Step 6:** Once the Mpox vaccinator fulfills the criteria as outlined in the Self-assessment of Competency Form the ID injection route trainer can sign the competency document. The Mpox trainee vaccinator is now eligible to administer the Mpox 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 Mpox vaccines under ID injection route varies among vaccinators to be deemed competent to administer Mpox vaccine intradermally. Vaccinators who are not familiar with the ID injection technique should observe a minimum of 3 individual vaccine recipients receiving the Mpox vaccine via the ID injection route administered by the ID injection route trainer, and also the Mpox vaccinator should administer the Mpox 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 Mpox Vaccine Administration

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

- Mpox 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 Mpox vaccines via ID route
- All practitioners are accountable for their practice including acts and omissions regardless of advice or direction received from another professional

- Follow Infection Prevention and Control standard precautions at all times i.e. personal and protective equipment.
- The Mpox 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 Mpox Vaccine

<u>NOTE:</u> 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 Mpox vaccine via the Subcutaneous (SC) route.

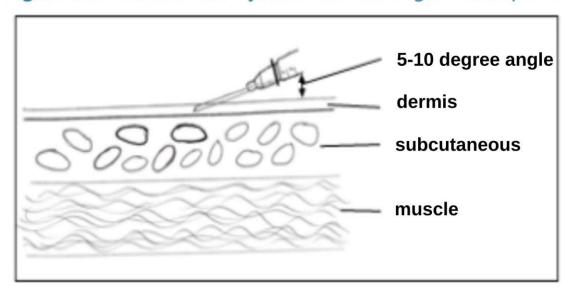
8.1 How to administer Mpox vaccine via intradermal route

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 nondominant 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 Mpox ID Injection

- Mpox 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 Mpox 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.

11. Adverse reactions

Any suspected adverse reactions (side effects) associated with vaccines from the MVA-BN (mpox) vaccine should be reported to the Health Products Regulatory Authority (HPRA). To report a suspected adverse reaction to this vaccine, please visit www.hpra.ie/report

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=whkGs0dug1s

National Clinical Guideline No. 30 (2023) Infection Prevention and Control (IPC), available at https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/

National Immunisation Advisory Committee (2023) *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/mpoxvaccinationinformation/Mpox%20MVA-BN%20vaccine%20Clinical%20Guidance.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 Mpox vaccines via Intradermal (ID) injection route

Name:				
	early in capitals			
NMBI No.	Pin/MCRN:Critical Element	Competen t Date/Initial s	Needs Practice Date/Initial S	Needs Theory Date/Initia
Part 1	 Knowledge- Self Assessment Declaration (Part 1: Applica	able for RN/R	M MPX vacc	s inator 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 Mpox vaccines under the HSE/NIAC immunisation programmes			
1.2	I understand that Mpox 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: • 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	r all Mpox vac	cinators	
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" (2023)			
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		
2.4	process in case of a procedural error, needle stick injury,		
	breach of infection control measure, etc as per the HSE		
	policy.		
	Note: 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 Mpox 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 disposes of sharps, vaccine syringes and vials and		
	other vaccine equipment safely in accordance with the		
	latest Infection prevention & control guidance.		
2.8	In the event of needle stick injury, I agree to follow guidelines		
2.0	as outlined in the 'EMI Tool Kit' available at:		
	https://www.hpsc.ie/a-z/EMIToolkit/appendices/app3.pdf		
2.0	I comply with the HSE guidance on vaccine handling,		
2.9	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 Mpox https://www.hpsc.ie/a-z/		
	zoonotic/monkeypox/mpoxvaccinationinformation/Mpox%		
	20MVA-BN%20vaccine%20Clinical%20Guidance.pdf		
	This HPSC guidance is applicable for Imvanex (MVA-BN		
	Smallpox vaccine) and Jynneos vaccines		
	3 Clinical Process and Procedure		
3.1	I can outline the inclusion/exclusion criteria for administering		
	Mpox vaccines as per NIAC Immunisation Guidelines		
	https://rcpi.access.preservica.com/uncategorized/		
	IO 4bfd5298-e826-41bb-b4f8-1ee7c8cfa38d/		
3.2	I check vaccine recipient's identity and appropriate records		
	prior to vaccination to ascertain suitability for		
L_	Mpox 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 Mpox vaccination and can address any concerns		
	vaccine recipients/carers may have		
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relevant issues such as the capacity to consent /lack of			
decision – making ability			
I ensure consent is obtained prior to vaccination and record			
this appropriately			
I demonstrate knowledge and understanding			
of contraindications and precautions to Mpox vaccines and			
can assess appropriately for these, or, if necessary, the			
need to postpone vaccination			
I check the presentation of the Mpox vaccine, the expiry			
date, how it has been stored prior to use and prepare it			
according to the vaccine manufacturer's instructions			
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			
I demonstrate good record keeping and understand the			
importance of ensuring vaccine information is recorded on			
relevant data system(s)			
I advise vaccine recipient on what to expect after vaccination			
as appropriate (e.g. local injection site reactions, fever) and			
management of these			
I provide vaccine recipient/carer with a copy of post-			
immunisation advice sheet or the product's information			
leaflet, in chosen language			
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.			
	I ensure consent is obtained prior to vaccination and record this appropriately I demonstrate knowledge and understanding of contraindications and precautions to Mpox vaccines and can assess appropriately for these, or, if necessary, the need to postpone vaccination I check the presentation of the Mpox vaccine, the expiry date, how it has been stored prior to use and prepare it according to the vaccine manufacturer's instructions 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 I demonstrate good record keeping and understand the importance of ensuring vaccine information is recorded on relevant data system(s) I advise vaccine recipient on what to expect after vaccination as appropriate (e.g. local injection site reactions, fever) and management of these I provide vaccine recipient/carer with a copy of post-immunisation advice sheet or the product's information leaflet, in chosen language 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	relevant issues such as the capacity to consent /lack of decision – making ability I ensure consent is obtained prior to vaccination and record this appropriately I demonstrate knowledge and understanding of contraindications and precautions to Mpox vaccines and can assess appropriately for these, or, if necessary, the need to postpone vaccination I check the presentation of the Mpox vaccine, the expiry date, how it has been stored prior to use and prepare it according to the vaccine manufacturer's instructions 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 I demonstrate good record keeping and understand the importance of ensuring vaccine information is recorded on relevant data system(s) I advise vaccine recipient on what to expect after vaccination as appropriate (e.g. local injection site reactions, fever) and management of these I provide vaccine recipient/carer with a copy of post-immunisation advice sheet or the product's information leaflet, in chosen language 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	relevant issues such as the capacity to consent /lack of decision – making ability I ensure consent is obtained prior to vaccination and record this appropriately I demonstrate knowledge and understanding of contraindications and precautions to Mpox vaccines and can assess appropriately for these, or, if necessary, the need to postpone vaccination I check the presentation of the Mpox vaccine, the expiry date, how it has been stored prior to use and prepare it according to the vaccine manufacturer's instructions 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 I demonstrate good record keeping and understand the importance of ensuring vaccine information is recorded on relevant data system(s) I advise vaccine recipient on what to expect after vaccination as appropriate (e.g. local injection site reactions, fever) and management of these I provide vaccine recipient/carer with a copy of post-immunisation advice sheet or the product's information leaflet, in chosen language 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

minimum of	x vaccinators are required to observe and of a intradermal injections under direct supered competent to administer Intradermal Mp	rvision	of an I			
	adermal Injection Technique Observed	Ox vac	cine.			
	,	Date	Date	Date		
	Signature:					
		Supervise d Assessme		Competence Demonstrate d Y/N	Signature	
		nts				
	Skill Required	Date	Date	Date		
Competency	Positions vaccine recipient appropriately and chooses appropriate vaccination site					
4.1	i.e. use of forearm as outlined in Section 7 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 competer	ence:	
	·····	
Date to be achieved:		
Supporting evidence of measures take	en to achieve competence:	
I have been deemed competent to prepare to administer Mpox vaccine.	pare and administer the Mpox Vaccines. I have been deemed as using the intradermal route.	
competent to administer Mpox vaccine I (RN/ RM) acknowledge my responsib	•	
competent to administer Mpox vaccine I (RN/ RM) acknowledge my responsib Midwifery Board of Ireland (2015) Scop	es using the intradermal route. bility to maintain my own competence in line with the Nursing are of Nursing and Midwifery Practice Framework and current be	
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competent to administer Mpox vaccine. I (RN/ RM) acknowledge my responsib Midwifery Board of Ireland (2015) Scop evidence. Name & Signature of the Vaccinator NI Date: Name & Signature of the ID injection	es using the intradermal route. Solity to maintain my own competence in line with the Nursing are of Nursing and Midwifery Practice Framework and current be MBI PIN/MCRN:	est
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