Seasonal Influenza Peer Vaccination Programme (SIPVP) 2020/2021

Immunisation Process
1. Introduction to Seasonal Influenza Peer Vaccination Programme (SIPVP)
2. Medicine Protocol
3. Current updates and Communications
4. Professional and Legal Aspects of Vaccinations
5. Immunisation Process
   1. Storage Handling & Transportation of vaccines
   2. Standard Infection Control and Prevention Precautions
   3. Vaccine administration/monitoring
   4. Documentation
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6. Questions & Evaluation
Learning outcomes

- Demonstrate continuing competence in accordance with the *National Immunisation Office, Seasonal Influenza Peer Vaccination Programme Guidelines for Staff* (HSE, 2019), local policies, procedures, protocols and guidelines (PPPG’s)

- Understand the management of safe and effective administration of vaccines

- Identify the principles of effective documentation and record keeping.
Storage, Handling and Transportation of Vaccines

- All medical, nursing and administrative staff involved in handling vaccines for the SIPVP should be aware of their respective responsibilities as set out in the guidelines.
- For more detailed information refer to National Immunisation Office (NIO) guidelines at [www.immunisation.ie](http://www.immunisation.ie) in the Vaccine Ordering and Storage section.
- **HSE Guidelines for maintaining the vaccine cold-chain including maintenance of vaccine fridges and management of vaccines** (Updated 15/04/2020)
- **HSE Guidelines for maintaining the vaccine cold chain in vaccine cool boxes** (Updated 15/04/2020)
Why is the cold chain important?

- Vaccines are prescription-only medicines (POMs)
The following points are conditions of the licence and if breached, contact the NIO for advice:
- To comply with regulations (PA/EU licence) vaccines must be:
  - stored within a specific temperature range of +2°C to +8°C.
  - stored in original packaging to protect from light
  - administered before expiry date.

Vaccines are sensitive biological products that may become less effective or destroyed if exposed to:
- Less than +2°C
- Above +8°C
- Direct sunlight or ultraviolet light (including fluorescent light).
Protect your Vaccines

to
Protect your Patients

Remember the 7Rs

**Read:** temperature twice daily at clinic/surgery opening and closing times.

**Record:** maximum, minimum and current temperatures.

**Reset:** after recording temperature and all 3 readings (max/min/current) should concure.

**React:** if temperature falls outside of +2°C or +8°C and document action.

**Review:** temperature records regularly (at least once a month).

**Rotate:** vaccines after each delivery with shortest date to the front.

**Remove:** expired stock from fridge immediately.

Stay between +2°C to +8°C

Strive for 5

www.immunisation.ie
Transporting Vaccines - Cool Boxes

Solid walled or vaccine specific soft walled insulated cool boxes with a probe inside of it, which is linked to the temperature display on the outside of the cool box must be used.

A data logger should be used in the cool boxes where external temperature display records only current temperature. This will provide an accurate account of temperatures reached and the duration of any temperature breach.

**Note:** Thermometer probe (or data logger) should be placed in the middle of vaccines and should not touch ice packs/gel packs. To prevent probe from moving it can be placed in an empty vaccine box, placed in the middle of the vaccines.
Each site should have SOPs on how to pack a cool box with the ice/gel packs and vaccines.

For all packing materials and equipment, ensure that the manufacturer’s recommendations are followed.

It is important to test and validate the method of packing vaccines by simulating the process and recording the cold chain for a similar period required for a typical transportation and clinic duration.

The risk of freezing of vaccines in cool boxes increases if ice/gel packs are not correctly conditioned or separated by insulating material as per SOP.

Freezing can occur in a cool box, and the risk is greatest within the first 2 hours after packing. Monitor and record the max/min and current temperature frequently for the first 2 hours.

Ice/gel packs may need to be added or removed, to maintain the temperature of the cool box between +2°C and +8°C.

**Note:** The cool box temperature monitoring device should be calibrated annually or as specified by the manufacturer. Also, with time and use, cool boxes and ice packs /gel packs may not retain their temperature and therefore the duration of their effectiveness may significantly reduce. Validation of cool-box performance is essential.
• The vaccines must be transported in their original packaging
• Only vaccines required for the estimated cohort should be brought to the clinic on any particular day
• Record the temperature in the cool box:
  - when vaccines are packed
  - upon arrival at the immunisation clinic
  - during the immunisation session
  - when returning vaccines to the fridge.
• The cool box should be placed in:
  - an appropriately ventilated room
  - away from any heat source
  - away from direct sunlight.
• The number of Ice/gel packs required can vary depending on ambient temperatures.
If the +2°C and +8°C parameters are breached, check the position of the temperature probe. It should be in an empty vaccine box positioned between the vaccines – if it is not, reset the probe and ensure it is positioned correctly away from ice packs or at the lid of cool box, then close the box firmly and recheck the temperature in 15 minutes.

If the temperature is still outside the permitted range, place the vaccine under quarantine in the cool box/fridge, and contact the NIO. The NIO will carry out a risk assessment and will advise on a case by case basis whether it is appropriate to use the vaccines or whether they should be discarded.

Vaccines exposed to either UV or fluorescent light can lose potency. Any vaccine that has been removed from its packaging should be used within the time specified in PIL/SmPC. If it is not used within this timeframe then it should be discarded safely into a sharps bin.

Reconstituted vaccines lose potency even when stored between +2°C and +8°C. The potency loss depends on the vaccine and duration since reconstitution cf. PIL/SmPC.
• Standard Precautions-IPC are evidence based clinical work practices and measures to minimise, prevent and control the transmission of infectious agents in healthcare settings

• Please refer to local and national HPSC guidelines on infection control.
Additional IPC measures due to COVID-19

- Physical distancing measures & signage
- PPE requirement: safe use of face masks
- Respiratory hygiene
- Cleaning pre and post vaccine session
- Please refer to HPSC guidelines for up to date information on infection prevention and control:
  - [https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/guidanceforhealthcareworkers/](https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/guidanceforhealthcareworkers/)
Standard Precautions (IPC) for Immunisation

- Hand hygiene
- Safe injection practices
- Safe management of sharps/waste
- Management of needle stick injuries.
Hand Hygiene

How to Handrub?

1. Before touching the patient
2. Before clean/aseptic procedure
3. After body fluid exposure risk
4. After touching the patient
5. After touching patient surroundings.
Immunisation Process

• Proper vaccine administration is integral to ensuring the optimal safety and effectiveness of vaccine

• Vaccinators should be competent in vaccine administration

• Programmes are available through some CNMEs/CNEs to facilitate education and training in injection technique if required.
There are many components to the Immunisation process

- **Before Vaccination**
  - Communication – current updates and valid consent
  - Assessment (eligibility under Medicine Protocol)
  - Administer and record vaccine

- **After Vaccination**
  - An information card, stating date & time of vaccination must be given to all healthcare recipients
  - Post vaccination monitoring (15 minutes)
  - Reporting adverse events, errors and near misses
  - Recognition and management of anaphylaxis or suspected anaphylaxis
  - Immunisation documentation.

Refer to supporting national/local policies in immunisations.
Resources and Equipment

- Appropriate validated/medically approved Cool Box with max/min thermometer display
- Sufficient Cool Packs to regulate temperature
- Vaccines
- Emergency bag with resuscitation equipment, medicines
- Mobile phone access
- Sharps bins, bags for disposal of hazardous waste healthcare risk waste
- Bags for recycling
- Alcohol hand gel/hand washing facilities
- Documentation.
Vaccine Administration

- Preparation
- Injection site
- Injection technique

These are all important factors as each factor can affect both the **immunogenicity** and the **risk of local reactions** at the injection site.
Preparation of HCW

- Correct identity
- Check valid consent has been obtained
- Check vaccine expiry date
- Explanation of procedure
- Maintain privacy & dignity
- Assess for any contraindications to administering the vaccine
- Refer to supporting NIO SIPVP Guidelines for staff (2019)

- [www.immunisations.ie](http://www.immunisations.ie)
Preparation and Administration of all vaccines in accordance with manufacturers guidelines (SmPC) Medicine Protocols, and NMBI medicines guidelines

- Use pre-packed vaccines. Vaccine comes in pre-filled syringe
- Check expiry date.
Injection site

- Vaccine to be given Intramuscularly into the deltoid muscle
- Assess injection site by observation and palpitation. If any evidence of trauma or damage, do not use
- Identify and landmark injection site.

Stop and practice finding correct site
• Ensure the healthcare recipient is in relaxed position to allow the muscle to relax – i.e. flex arm across chest

• Swift needle entry (insertion at 90° angle and do not aspirate, slow injection, swift needle withdrawal equates to less pain

  (NIAC, 2020)
Skin Preparation

• Not required if clean skin
• Visibly dirty skin: wash with soap & water
• Avoid alcohol swabs

• Post Administration
  – Use gauze swabs if required
  – Application of a plaster is not routinely recommended (plaster reactions can be confused with vaccine reactions) (NIO, 2020)
Administration of Vaccine

• Aseptic Non-Touch Technique (ANTT) throughout the procedure – check local policies and guidelines

• Best practice: pre-filled syringes

• Medicine management 5 rights (NMBI, 2007)

• Vaccines should be discarded upon expiration or any time there are concerns regarding the sterility of the vaccine
Intramuscular Injection Technique

• Use a designated sterile needle
• The needle should be inserted at a 90 degree angle to the skin
• The skin should be stretched flat
• Aspiration is not necessary
• Swift needle entry, slow injection and swift needle withdrawal equates to less pain
• Apply light pressure for several seconds with gauze
• Needle needs to be long enough to ensure vaccine is injected into muscle
• Do not massage the area after injection
• There is little difference in local adverse reactions or immune responses between needles of the same length but different gauges.

(NIAC, 2020)
Warnings and Precautions for Use:

• The intradermal or intravenous routes must not be used

• As with all injectable vaccines, medical resources and Epinephrine (Adrenaline) must be readily available in case of a rare anaphylactic event.

• Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis incorporating Medication Protocol for the Administration of Epinephrine (Adrenaline) Injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis (HSE 2019), available at http://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrrenalineprotocol.pdf
Safe Management of Sharps/Waste

• Please follow HPSC Standard Precautions:

• [https://www.hpsc.ie/a-z/microbiologyantimicrobialresistance/infectioncontrolandhaid/standardprecautions/File,3600,en.pdf](https://www.hpsc.ie/a-z/microbiologyantimicrobialresistance/infectioncontrolandhaid/standardprecautions/File,3600,en.pdf)

• Sharps bins should be replaced once two thirds full

• Dispose of sharps immediately without recapping the needle into the sharps container.
## Documentation

- Vaccine consent forms
- Vaccine Information Leaflets
- Vaccine Administration Card
- Health Products Regulatory Authority Adverse Reaction Reporting forms
- Medicine protocol
- National Incident Management System Form NIRF-01-v11

## Recording

- Record
  - vaccine name
  - stick the vaccine label which has the batch number & expiry date details
  - dosage
  - injection site
  - date and time of administration of vaccine
  - name, signature and PIN of vaccinator
  - adverse events
All staff should be familiar with the following documents:


**Including the following:**

- *Seasonal Influenza Peer Vaccination Programme 2020: Guidelines for Staff* (HSE, 2020)
- Medicine Protocol for the Administration of Quadrivalent Influenza Vaccine (split virion, inactivated), [marketed as *Quadrivalent Influenza Vaccine (split virion, inactivated)* and as *Vaxigrip Tetra*] to nurses, midwives, healthcare workers, agency staff, contract workers and volunteers by registered nurses and registered midwives

- Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) for each vaccine at [www.hpra.ie](http://www.hpra.ie)
Data Management

• Consent forms sent to Occupational Health Service for recording, statistical analysis and storage

• No local copies to be kept

• Send with ‘Clinic Summary Document’ and keep copy of this document for local records – See National Immunisation Office Seasonal Influenza Peer Vaccination Programme 2019: Guidelines for Staff HSE, Appendix IV
Errors and Near Misses

• In the case of medication errors that directly involve the recipient HCW, i.e. wrong medication/dose/route being administered or another medication error, the registered nurse or midwife must remain with the person and closely monitor them for any adverse reactions.

• Vital signs should be recorded and the recipient HCW should be reviewed by the Occupational Health Physician or other appropriate physician.

• The incident must be reported to the relevant line manager as soon as possible.
Errors and Near Misses Cont’d

• The incident and all actions taken must be recorded and the relevant National Incident Management Report Form (NIRF) completed as soon as is practicable after the event occurs and within one working day (National Incident Report Form (NIRF 01 – V11)) (2020) available at: https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf

• The recipient HCW and/or significant others should be informed of the incident

• An incident report form must be completed by the nurse or midwife and forwarded to local or regional Risk Manager as per local policy

• Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined below.
Adverse or Suspected Reactions

• The relevant nursing or midwifery staff should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out online at [http://www.hpra.ie](http://www.hpra.ie) or through use of the yellow card system which is available in a downloadable format from the HPRA website, or on request from the HPRA.

• The recipient HCW’s General Practitioner should be informed of any reported adverse reaction.

• The incident and all actions taken must be promptly recorded in accordance with the *Management of a Patient with Anaphylaxis: Treatment in the Community* (National Immunisation Advisory Committee 2019), available online at [https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf).
Needle Stick Injury

• BLEED
• WASH
• COVER
• REPORT

• Refer ‘EMI Tool Kit’
  (https://www.hpsc.ie/a-z/EMIToolkit/)
  and to Local policies
References

• An Bord Altranais (2007) Guidance to Nurses and Midwives on Medication Management Dublin: An Bord Altranais
• Canadian Agency for Drugs and Technologies in Health 2014 Aspirating versus not aspiration prior to injection medication. Comparative Clinical Evidence Guidelines.
• Health Service Executive (2019) Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or Suspected Anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection BP 1:1,000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis. Dublin: Health Service Executive
• SARI. Infection prevention and control for Primary care in Ireland – A guideline for General Practice (2013)