National Medicines Management Guidance for Use in Centralised HSE Vaccination Clinics.

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Version	Date Approved	List section numbers changed	Author
1	23 February 2021	Not applicable.	Centralised HSE Vaccination Clinics Medicines Management Working Group
1.1	12 March 2021	Use of the term "Large Scale Vaccination Clinics for Healthcare Workers" replaced with "Centralised HSE Vaccination Clinics". Addition of medicines management SOPs as Appendix.	Centralised HSE Vaccination Clinics Medicines Management Working Group
2.0	14 April 2021	Key changes: - *Scope and Purpose* (Page 3) – updated content on staffing in CVCs. - *Responsible Person* (Page 3/4) – requirements updated. - *Skills Required & Mandatory Training Requirements* (Page 4) – requirements updated. - References to "IT system" within the document updated to include "GS1 TrackVax system". - Appendix 3 – "COVID-19 Vaccine AstraZeneca" rebranded to "Vaxzevria® (AstraZeneca)" - New SOP CV04 *Using the TrackVax Software* added to Appendix 8. - Appendices 7, 9, 10, 11, and 12 newly added.	Centralised HSE Vaccination Clinics Medicines Management Working Group

Content

Background

As detailed in the HSE Clinical Guidance for COVID-19 Vaccination: "*The objective of the vaccination programme for SARS CoV-2 is to ensure equitable access to a safe and effective vaccine with the goals of limiting mortality and morbidity from COVID-19, protecting healthcare capacity and enabling social and economic activity*."

To achieve this overarching objective, it is essential that there are appropriate medicines management processes in place in vaccination facilities so that the quality attributes of COVID-19 vaccines are maintained and that vaccinations are administered safely, effectively and efficiently.

Scope and Purpose

The scope of the guidance document is to support healthcare professionals responsible for medicines management in the *Centralised HSE Vaccination Clinics*. The purpose of the guidance is to define the relevant medicines management processes in the COVID-19 *Centralised HSE Vaccination Clinics (CVCs)*, with a focus on the critical points of the medicines management pathways. It is recognised that the Responsible Person may have oversight of additional activities (e.g. ancillaries, logistics, stores, patient information leaflet management, vaccination cards). These are in addition to the roles and staffing requirements defined in this guidance and should be agreed locally.

While dilution of Comirnaty® will be in the pharmacy preparation area, the pharmacy staffing requirements to undertake this process are not included in the ratio detailed below.

A pharmacy team with a ratio of 1 staff member per 10 vaccination booths (see **Appendix 9**) in Centralised HSE Vaccination Clinics has been identified in order to facilitate good vaccine stewardship. This is consistent with experience from hospital clinics and large scale vaccination centres to date. The pharmacy team should ideally be led by a pharmacist who will act as the Responsible Person (see below) for the medicines management processes on each site.

The composition of the pharmacy team may include:

- Pharmacist in charge (Responsible Person)
- (Duty) Pharmacist
- Pharmaceutical technician
- Professions eligible to vaccinate (or students thereof)
- Ancillary staff

Staff skill mix may vary depending on availability of staff geographically though there will be a minimum of two pharmacists on duty. See **Appendix 9** for staffing requirements, depending on opening hours and number of vaccination booths.

Medicines Management Standard Operating Procedures (SOPs)

A suite of Standard Operating Procedures (SOPs), detailing standardised medicines management procedures for use in the *Centralised HSE Vaccination Clinics*, are included as **Appendix 8** in this document.

Responsible Person

There must be a named Responsible Person designated for each vaccination session in the vaccine clinic. The Responsible Person has overall responsibility for vaccine stewardship in the CVC as detailed in this national medicines management guidance document and the local SOPs (see **Appendix 8** for SOP templates). This will ideally be a registered Pharmacist with the relevant knowledge and skills. Other suitable professionals are a registered Nurse, or registered Doctor, again with the relevant knowledge and skills.

The Responsible Person must ensure that COVID-19 vaccines and any other medicinal products under their control at a CVC are maintained and supplied in accordance with the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2021 and the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 to 2021.

The Responsible Person must complete and sign the declaration included in **Appendix 10** of this guidance document. A copy of the signed declaration should be sent to the COVID Assistant National Direction (AND) (Email: covid.and@hse.ie) and kept on file by CVC Operations Lead to be produced if required during a subsequent inspection. It is recognised that this person may change during the lifetime of the CVC and the same steps should be followed. Updates should be communicated within one week of the new person taking over.

Skills Required & Mandatory Training Requirements

Non-vaccinator staff involved in medicines management processes in the CVCs must complete the mandatory training detailed below and sign the declaration form included in **Appendix 11** of this guidance document. This should be completed by staff members before involvement in medicines management processes.

The signed declaration should be returned to the CVC Operations Lead or the delegated Responsible Person. The signed declaration forms should be kept on file by CVC Operations Lead or delegated Responsible Person to be produced if required during a subsequent inspection.

Mandatory training:

1. Read the *Medicines Management Guidance for Use in Centralised HSE Vaccination Clinics*.
2. Read the medicines management Standard Operating Procedures in **Appendix 8** of the *Medicines Management Guidance for Use in Centralised HSE Vaccination Clinics*.
3. Successful completion of the HSELand e-learning training module *COVID-19 Vaccination Training Programme.*

Non-vaccinator staff involved in the dilution of Comirnaty® (Pfizer BioNTech) vaccine should also complete the National Antimicrobial Resistance and Infection Control (AMRIC) Team e-learning module *Aseptic Technique* available on HSELand.

HSELand training is available online from https://www.hseland.ie/ (free to access; registration required). HSELand provide certificates following successful completion of online training modules and these should be presented to the Vaccination Clinic Operations Lead or the delegated named Responsible Person as proof of completion.

Critical Processes

Receipt and Storage of Vaccines

Adapted from NIO "*HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock*"; available from: https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf .

Cold Chain Preservation & Monitoring of Fridges

See also SOP CV03 *Procedure for Fridge Monitoring in Centralised HSE Vaccination Clinics* in **Appendix 8**.

1. A pharmaceutical fridge must be used to store vaccines. When a new pharmaceutical fridge is installed or when a fridge is moved in a vaccination clinic, the manufacturer's instructions should be followed before use. It may need validation by the supplier before use. Supplier details would be available from HBS Procurement.
2. Once in situ, if a fridge is moved, then the manufacturer's instruction for use must be again followed before subsequent use.
3. The fridge should be levelled in a way that allows the door to close and seal automatically if left ajar. The door should be routinely locked.
4. The set point for the fridge temperature and alarms should take into account the need to maintain the temperature above +2°C to prevent freezing and remain less than +8°C. The temperature should be set to maintain +5°C +/- 3°C.
5. There must be a named person responsible for the monitoring of fridge temperatures during each vaccination session.
6. An automated temperature monitoring system will be used to monitor the temperature of the pharmaceutical fridges in the vaccination clinics.
7. The Responsible Person must review the data monitoring system twice each day to ensure the system is recording and to confirm that the fridge temperature remains in range. This must be completed at the start of each vaccination session before any vaccine is administered and at end of each vaccination session.
8. The Responsible Person must record the date and time the data monitoring system was reviewed as per local agreement (see **Appendix 5** for a sample template).
9. In the event of a temperature excursion outside of the recommended storage conditions, affected stock must be quarantined and the NIO contacted.
    i. Quarantined stock must be appropriately labelled and stored in a separate section of the pharmaceutical fridge.
    ii. The form in *Appendix VIII* of the NIO cold chain guidance should be completed and sent to immunisation@hse.ie .
    iii. Affected stock should not be used or disposed of but must be quarantined until advice received from the NIO.

Receipt of Vaccines

See also SOP CV02 *Receipt of Vaccine (and Diluent) Stock at Centralised HSE Vaccination Clinics* in **Appendix 8**.

1. Maintaining the cold chain is critical and staff receiving deliveries must undertake the process promptly. All staff must read the NIO Cold Chain Policy available from: https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf
2. Vaccine deliveries must be signed for and must be checked against the order for discrepancies. Any discrepancies or any damage must be reported to the NCCS immediately (Email: vaccines@udd.ie).
3. Sodium chloride 0.9% diluent used for Comirnaty® Pfizer BioNTech vaccine will be included in the same delivery as the vaccine. Sodium Chloride 0.9% is stored at room temperature in the designated storage area. No diluent is required for the COVID-19 Vaccine Moderna® or the COVID-19 Vaccine AstraZeneca®.
4. Vaccines delivered to the vaccination clinics are at a temperature of:
    a. +2°C to +8°C for Comirnaty® Pfizer BioNTech and COVID-19 Vaccine AstraZeneca
    b. -25°C to -15°C for COVID-19 Vaccine Moderna®

    Under the terms of the NCCS contract, the NCCS are responsible for maintaining and validating the temperature of the vaccines from when they accept it from the manufacturers until they deliver it to the vaccination site.

5. Upon receipt from the NCCS, vaccines must be immediately transferred from the delivery area to the designated refrigerated storage area in the vaccination clinics. Vaccines must never be stored at room temperature.
6. The QR barcodes on boxes containing the vaccines must be scanned using the electronic scanning system to upload the vaccines on the CoVax IT system and the GS1 TrackVax system for supply and administration in the

vaccination clinic. QR barcodes on boxes containing sodium chloride 0.9% supplied as diluent for the Comirnaty® Pfizer BioNTech must also be scanned for upload on the CoVax system and GS1 TrackVax system.

7. Decommissioning of COVID-19 vaccines, as required under the Falsified Medicines Directive (FMD), is completed by United Drug for vaccines supplied to vaccination clinics.
8. Vaccines must be removed from delivery boxes but not original containers and allocated to the appropriate area in pharmaceutical fridge without delay. The shortest dated vaccines should be stored in the foremost position to ensure adequate stock rotation.
9. Vaccines should always be stored in the fridge in their original packaging in an upright position.
10. If more than one brand of vaccine is being stored at a single facility, stock must be stored so that the different brands are clearly segregated either by shelf or if an additional fridge is available, in that fridge.
11. Vaccine syringes and needles are delivered in advance by the HSE in the required quantities to match the quantity of vaccine ordered/supplied.

Vaccine Labelling Workstations

1. The vaccine labelling workstation must be wipe-able with an appropriate disinfectant solution or wipe.
2. Confirm the workstation is clear and free from any other vials of vaccine. If more than one brand of vaccine is being used during the session, separate areas for the labelling of different brands should be used.
3. Before each session, disinfect the vaccine labelling area with a disinfectant wipe & discard.
4. Ensure a Sharps Bin with sufficient free capacity is available. Ensure an indelible black marker is available for defacing labels on empty vaccine vials before disposal. Other consumables required are surgical face masks and alcohol based hand rub.
   A supply of flag-labels and labels for labelling of individual vials is also required. **See Appendices 1-3 for information on the individual vaccines.**

Vaccine Labelling

- A laptop, thermal label printer, and barcode scanners are installed in the vaccine labelling area. These are ordered from covidvaccine.devices@hse.ie via the CVC Operations lead.
- The GS1 TrackVax app should be used for labelling as this enables vaccine tracking within vaccination centres, populates the vaccine tracking dashboard, and provides data for CVC KPI reports.
- Vials must be labelled individually using flag labels before use. The flag label should not obscure the original vial label.
- Two staff labels must be scanned to generate a label; the two staff members will undertake the first and second check of the label.
- The time interval from the removal of vials from the fridge to use by the vaccinator should be kept to a minimum.

  See Appendices 1-3 for sample labels and information on the labelling of the individual vaccines.

Allocation & End of Session Process

See also SOP CV07 *End of Day Medicines Management Process in* **Appendix 8.**

1. To ensure judicious use of vaccine, only vaccine that will be used during the vaccination session should be removed from the fridge. Planning should be based on initial numbers of people scheduled for the first few hours of the vaccination session (and accounting for persons who “did not attend”).
2. A monitoring process should be in place thorough out the vaccination session to assess vaccinations planned versus vaccines allocated and administered
3. To avoid wastage of any doses, before the end of the session liaise with the site lead to coordinate the removal of vials from the fridge to align with the number of remaining confirmed appointments for the session but with specific focus on the number of persons who are registered and present on site.

4. After the session clear and clean the work station. Disinfect the vaccine preparation bench/table with a disinfectant wipe & discard.
5. Wipe any reusable vaccine transport trays with an alcohol impregnated wipe.
6. Perform a stock check and liaise with site lead to ensure adequate stock level in place for the next vaccination session.
7. Update the "asset batch list" on the ICT system for the site to reduce the quantity by the number of vials used during the session.
8. At the end of each day, use the automated temperature monitoring system to check the fridge is working within range (2°-8°C) and that the temperature has not gone out of this range.

Secure Storage and Disposal of Vaccines

See also SOP CV05 *Procedure for Discarding of COVID-19 Vaccine Vials in Centralised HSE Vaccination Clinics* in **Appendix 8**.

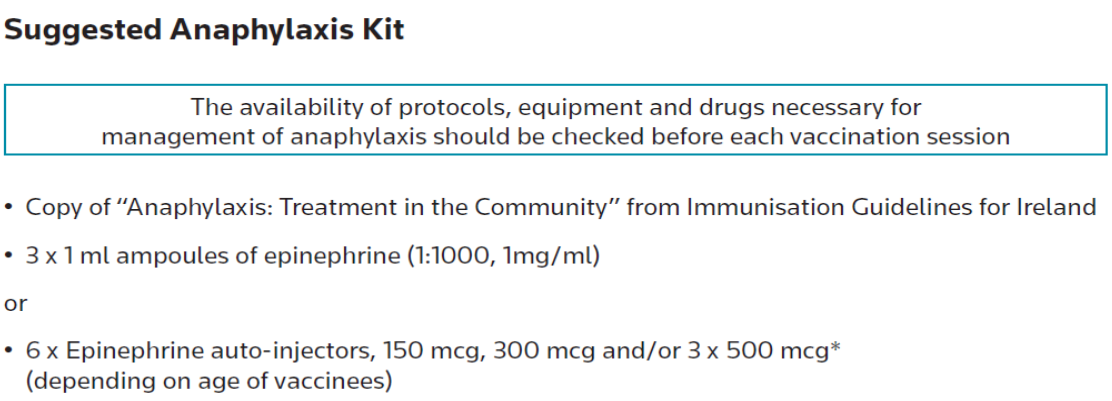
1. Vaccines must be stored securely at all points of use between receipt and use/disposal.
2. Waste must be handled in such a way as to prevent theft and/or misuse.
3. Once all doses from the vial have been used, a new vial is supplied and the waste/empty vials should be returned from vaccination booths to the pharmacy area. Using the GS1 TrackVax barcoded label, scan the vial in as returned.
4. Flag labels and original vial labels should be removed or defaced using an indelible black marker.
5. Waste vaccines and empty vials must be disposed of into sharps bins.
6. The date and time the vial has been discarded will be recorded from the return barcode scan and will be reported from GS1 TrackVax.
7. Vials that have not been returned should be notified to the CVC Operations Lead.
8. Sharps bins containing returned vaccine vials should not be left unattended during vaccination session and should be locked at the end of each working day.
9. The sharps bins should be labelled as per the requirements of local waste management arrangements.
10. Original cartons must have their labels defaced using permanent black marker pens, and placed into appropriate waste sack for disposal, as soon as possible after they become empty.
11. The NIO may periodically request end of session reports. See Appendix 1 of *Clinical Guidance for COVID-19 Vaccination* for session report forms. The reporting function in GS1 TrackVax will support these requests.

Anaphylaxis Kits

See also SOP CV06 *Procedure for Managing Stock of Epinephrine (Adrenaline) in Centralised HSE Vaccination Clinics* in **Appendix 8.**

1. HSE Procurement supply Resuscitation Bags for the purpose of managing anaphylactic reactions in the centralised vaccination clinics.
2. The Resuscitation Bags are supplied **without** epinephrine (adrenaline). Epinephrine must be ordered separately from the nominated Pharmacy for delivery to the CVCs. Three vials of epinephrine 1ml 1:1000 1mg/ml is required per kit.
3. The epinephrine must be added to the Resuscitation Bags to complete the anaphylaxis kit.
4. Further supply of epinephrine must be ordered as needed to replace used or expired product.

Figure 1 Excerpt from "Anaphylaxis: Treatment in the Community" from Immunisation Guidelines for Ireland.



Suggested Anaphylaxis Kit

The availability of protocols, equipment and drugs necessary for management of anaphylaxis should be checked before each vaccination session

- Copy of "Anaphylaxis: Treatment in the Community" from Immunisation Guidelines for Ireland
- 3 x 1 ml ampoules of epinephrine (1:1000, 1mg/ml)

or

- 6 x Epinephrine auto-injectors, 150 mcg, 300 mcg and/or 3 x 500 mcg* (depending on age of vaccinees)

Vaccine Specific Medicines Information Enquiries

- Vaccine specific Medicines Information (MI) enquiries should be submitted by other healthcare professionals working in the centralised vaccination clinics. Vaccinators should submit enquiries on behalf of vaccine recipients.
- A laptop is installed in the vaccine labelling area. The laptop should have internet access available to facilitate the processing of vaccine specific MI enquiries.
- The key information sources for processing MI enquiries, including a list of *Frequently Asked Questions*, are listed on the NIO website and are detailed in **Appendix 4** of this guidance document.

Appendix 1 Comirnaty® (Pfizer/BioNTech) Vaccine Specific Advice

Please refer to the Summary of Product Characteristics and the following resources Comirnaty® (Pfizer BioNTech) COVID-19 mRNA Vaccine available from the NIO website:

- Comirnaty® (PfizerBioNTech) Summary Sheet
- SOP - Management of Comirnaty® COVID-19 Vaccine guidance at local hubs Version 6.0
- Preparing Comirnaty® (PfizerBioNTech) COVID-19 mRNA Vaccine Version 3.0

Overview of Handling Recommendations for the Comirnaty® (Pfizer/BioNTech) Vaccine			
Receiving vaccine from National Cold Chain Service (NCCS)	Diluting and labelling vaccine in pharmacy preparation area	Drawing vaccine into syringes	Administering vaccine and completing record
Step 1: Receive vaccine from NCCS	**Step 2: Dilute and label vaccine**	**Step 3: Draw vaccine from diluted vial into syringes**	**Step 4: Vaccinate and complete record**
Transfer vaccine from delivery area to refrigerated area *– maintain cold chain conditions* Scan QR barcodes on vaccine outer containers and sodium chloride 0.9% diluent outer containers using electronic scanner for upload of stock to CoVax system and GS1 TrackVax system Place in temperature-monitored pharmaceutical fridge in vaccination area	Confirm pre-dilution "use by" date and time of vial not expired Dilute vaccine vial with 1.8ml of Sodium Chloride (0.9%) *- gently invert 10 times before and after dilution* Confirm liquid is white to off-white *- no discolouration / non-standard particulate matter* Post dilution, vaccine vial is stable for **six hours** *- at room temperature* Print pharmacy label and add to diluted vaccine vial - *two staff labels must be scanned using the GS1 TrackVax system to generate a label; the two staff members will undertake the first and second check of the label*	Confirm post-dilution date and "discard time" has not expired *- dilution was within last 6 hours* Use a new sterile syringe for each drawing of the vaccine *- before each drawing clean top of vial with single use 70% alcohol swab (allow to air dry)* Draw exactly 0.3ml of vaccine into the syringe *- as many complete 0.3ml doses as possible should be drawn up from each vial*	Confirm post-dilution date and "discard time" has not expired *- dilution was within last 6 hours* Verify volume is 0.3ml Administer vaccine *- dispose of used needle and syringe in sharps bin* Complete vaccination record in the CoVax system When all doses administered, return empty vial to pharmacy for reconciliation and safe disposal At end of session, complete the NIO vaccine reconciliation form
Vaccines should be stored in the fridge in original packaging in an upright position *- until they are required for step 2* **If transferring vials onsite** *- maintain cold chain conditions* *- vials must be upright* *- vials must not be touching*	**Pre-dilution, vaccine vials are only stable at room temperature for two hours** *- post-dilution stable for six hours*	**Doses drawn up in syringes should be used as soon as possible** *- must be used within 6 hours of dilution of the vial.*	**If pharmacy not available for disposal, the waste/empty vials should be managed as agreed locally** *- deface flag labels and original vial labels using permanent marker to ensure that they cannot be misused* *- discard empty vial in sharps bin and record date and time of discard*
For all steps, keep vials in upright position, avoid any shaking / knocking of vials and ensure temperature is controlled			

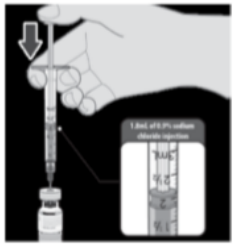
Figure 2 Preparation of Comirnaty® Pfizer/BioNTech Vaccine

(see Preparing Comirnaty® (PfizerBioNTech) COVID-19 mRNA Vaccine Version 3.0 for full information)

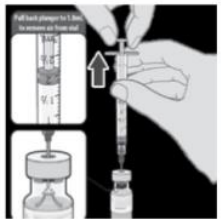
STEP 1 PREPARING FOR DILUTION

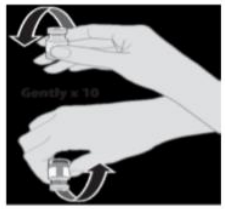
- Check the "***use before***" date and time on the box containing the vials with a colleague
- Remove the vial from the box in the fridge/ cool box
- Gently invert vial 10 times prior to dilution. **Do not shake**
- Inspect the liquid in the vial prior to dilution
  Should be an off-white solution. It may contain white to off-white amorphous particles.
- Remove cap
- Clean with 70% alcohol swab and allow it to air dry fully

STEP 2. DILUTION



- Twist to separate one ampoule of sodium chloride from other ampoules if attached
- Check product and expiry date with colleague
- Open the ampoule by twisting the cap using standard aseptic technique
- Connect syringe tightly to sodium chloride ampoule (no needle is required)
- Withdraw 1.8ml of Sodium Chloride 0.9% Solution for Injection
- Cross check correct amount withdrawn with colleague





- Discard the ampoule and any remaining diluent in it into waste bin
- Attach 21 gauge green needle to the syringe
- Insert diluent slowly into the vaccine vial. You may feel some pressure in the vial as you add the diluent.
- Do not remove the needle from the vial. Keeping the needle above the level of the liquid, slowly withdraw 1.8 ml of air into the empty diluent syringe to equalise the pressure.
- Remove needle and syringe from vial.
- Dispose of the needle and syringe in a sharps bin.
- Gently invert the diluted solution 10 times. **Do not shake.**
  Diluted vaccine should be an off-white solution with no visible particles. Discard if particles present.
- Discard the diluted vaccine if particulates or discolouration are present
- Dispose green needle and syringe into yellow sharps bin

STEP 3. LABELING THE VIAL

- Label the diluted vial with the date and ***"discard time"*** (6 hours after time of dilution) using a 24 hour format.
  Do not use the diluted vaccine after this date and time.

  e.g. vial diluted at 10.00 01/01/2021. Discard time is 16.00 01/01/2021
- After dilution, the vial contains up to 7 doses* of 0.3 ml
- Diluted vaccines can be stored between 2°Cand 30°C but must be used within 6 hours following dilution.
- Bring the vial to your vaccination table/site for vaccine preparation and administration

For the dilution of one Comirnaty® Pfizer BioNTech vial the following are required:

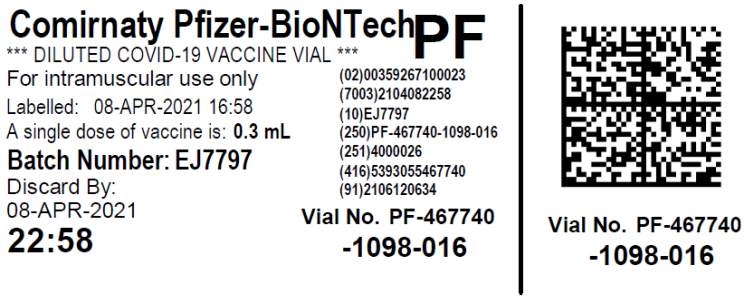
Dilution should be completed using Aseptic Non-Touch Technique (ANTT).

- One **undiluted** vaccine vial (*do not remove from the fridge until needed*)
- Sodium chloride 0.9% (preservative free) solution for injection 10mL ampoule x 1
- A 2.5ml, 3ml or 5ml Syringe x 1
- 21 gauge green needle x 1
- Sterile single use 70% alcohol antiseptic swabs x 2
- Yellow Sharps Bin

Comirnaty® Pfizer BioNTech label fields

1. Only apply a label to **DILUTED** vials. Undiluted vials must not be labelled.
2. Flag-labels should be used to label vials; the flag label should not obscure the original vial label.
3. Label fields:
    a. The "batch number" is the batch number on the product box.
    b. The date and time diluted is the time of label generation. No more than two hours at room temperature should elapse between removal from fridge and dilution.
    c. Labels must include the date and "discard time" using a 24 hour format. The discard time and date is 6 hours from the time of labelling.

Sample label for Comirnaty® (Pfizer BioNTech) Covid-19 Vaccine:



Contents of Tray to Vaccinator

For every vial the following should be supplied in a clean reusable tray:

- Labelled vial of **diluted** Comirnaty® Pfizer BioNTech vaccine* x1 (*do not remove from the fridge until needed*)
- 70% alcohol swabs x 7
- 1mL syringe x 7
- 23 gauge blue needles x 7

Appendix 2 COVID-19 Vaccine Moderna® Specific Advice

Please refer to the Summary of Product Characteristics and the following resources for the COVID-19 Vaccine Moderna® available from the NIO website for full information:

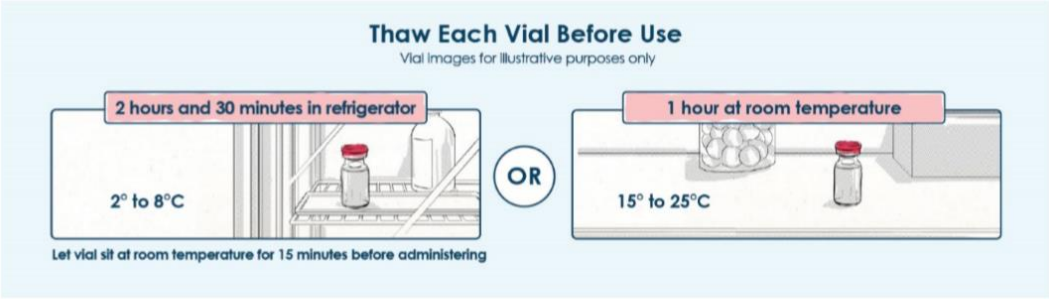
- COVID-19 Vaccine Moderna® Summary Sheet
- SOP - Management of COVID-19 Vaccine Moderna® Guidance at Vaccination Clinics

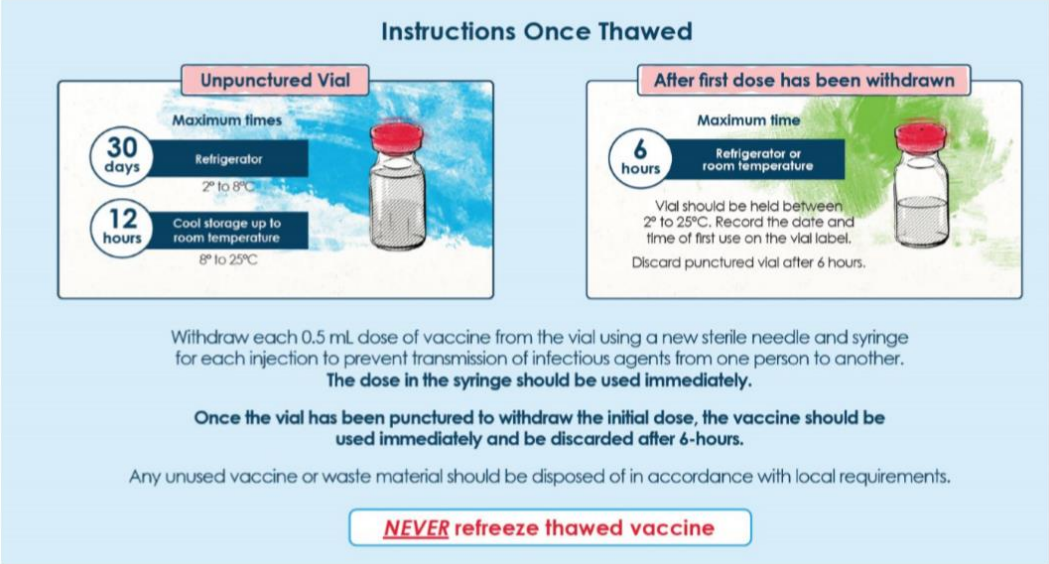
Simple Overview of the Handling Recommendations for the COVID-19 Vaccine Moderna®			
Receiving vaccine from National Cold Chain Service (NCCS)	Thawing and labelling of vaccine in pharmacy preparation area	Drawing vaccine into syringes	Administering vaccine and completing record
Step 1: Receipt vaccine from NCCS	**Step 2: Thaw and label vaccine vials before drawing into syringes**	**Step 3: Draw vaccine from vial into syringes**	**Step 4: Vaccinate and complete record**
Vaccine is delivered at -25°C to -15°C from NCCS Transfer vaccine from delivery area to refrigerated area *- maintain cold chain conditions* Scan QR barcodes on vaccine outer containers using electronic scanner for upload of stock to CoVax system and GS1 TrackVax system Place in temperature-monitored pharmaceutical fridge in vaccination area Document new "use by" date on vaccine box *- in fridge: use within 30 days* *- usage times based on start of thawing*	Confirm "use by" date has not expired Vaccine must be given sufficient time to thaw following delivery from NCCS before use To thaw vaccine before use *- thaw for 2.5 hours in fridge* *- or thaw for one hour at room temperature* Holding vial upright, swirl vial gently after thawing *- do **not** shake the vial* Confirm liquid is white to off-white *- no discolouration / non-standard particulate matter* Print pharmacy label and add to vaccine vial *- two staff labels must be scanned using the GS1 TrackVax system to generate a label; the two staff members will undertake the first and second check of the label*	Use thawed vaccine vial *- if from fridge must first stand at room temperature for 15 min* Confirm date and "discard time" has not expired Swirl vial gently after thawing and after each withdrawal- *keep vial upright* *- COVID-19 Vaccine Moderna® is a ready to use vaccine.* Use a new sterile syringe for each drawing of the vaccine *- before each drawing clean top of vial with single use 70% alcohol swab (allow to air dry)* Draw exactly 0.5ml of vaccine into the syringe *- as many complete 0.5mL doses as possible should be drawn up from each vial*	Confirm date and "discard time" has not expired Verify volume is 0.5ml Administer vaccine *- dispose of used needle and syringe in sharps bin* Complete vaccination record in the CoVax system When all doses administered, return empty vial to pharmacy for reconciliation and safe disposal At end of session, complete the NIO vaccine reconciliation form
Vaccines should be stored in the fridge in their original packaging in an upright position *- until they are required for step 2* **If transferring vials onsite** *- maintain cold chain conditions* *- vials must be upright* *- vials must not be touching*		**Doses drawn up in syringes should be used as soon as possible** *- must be used within the 6 hour discard time.*	**If pharmacy not available for disposal, the waste/empty vials should be managed as agreed locally** *- deface flag labels and original vial labels using permanent marker to ensure that they cannot be misused* *- discard empty vial in sharps bin and record date and time of discard*
For all steps, keep vials in upright position, avoid any shaking / knocking of vials and ensure temperature is controlled.			

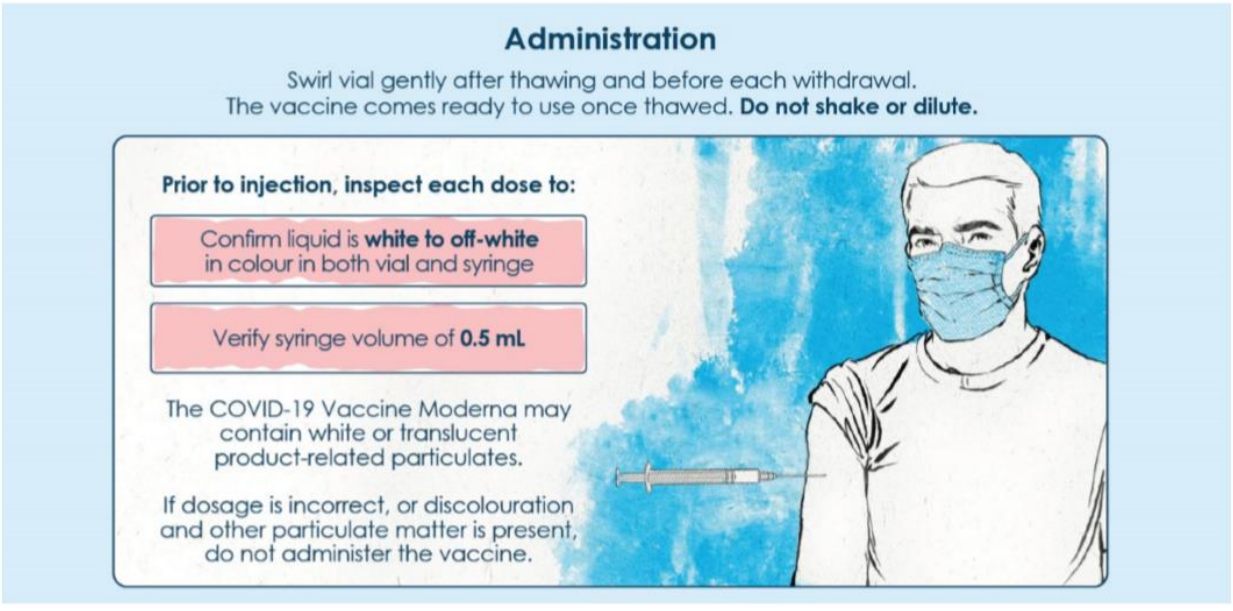
Figure 3 Instructions for COVID-19 Vaccine Moderna®

(see SOP - Management of COVID-19 Vaccine Moderna® Guidance at Vaccination Clinics for full information).

The vaccine comes ready for use once it is thawed. Do not shake or dilute the vaccine.



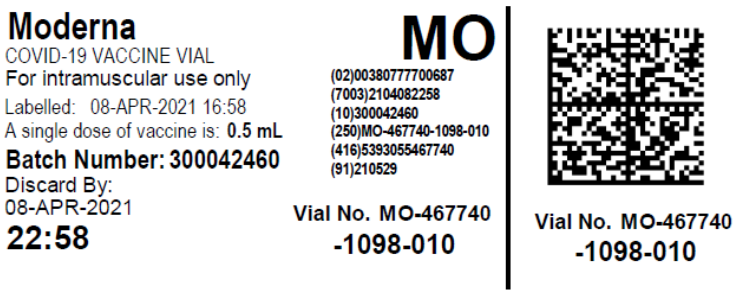




COVID-19 Vaccine Moderna® label fields

1. Flag-labels should be used to label vials. The flag label should not obscure the original vial label.
2. Label fields:
    a. The “batch number” is the batch number on the product box.
    b. The date and time is the time of label generation.
    c. Labels must include the date and “discard time” using a 24 hour format. The discard time and date is 6 hours from the time of label generation using a 24 hour format.

Sample label for COVID-19 Vaccine Moderna®:



Contents of Tray to Vaccinator

For every vial the following should be supplied in a clean reusable tray:

- Labelled COVID-19 Vaccine Moderna® vial* x1 (*do not remove from the fridge until needed*)
- 70% alcohol swabs x 12
- 1mL syringe x 12
- 23 gauge blue needle x 12

Appendix 3 Vaxzevria® (AstraZeneca) Specific Advice

Please refer to the Summary of Product Characteristics and the following resources for Vaxzevria® (AstraZeneca) available from the NIO website for full information:

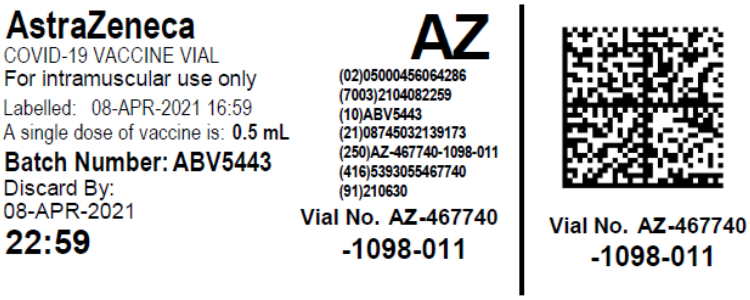
SOP - Management of COVID-19 Vaccine AstraZeneca® Guidance at Vaccination Clinics Version 2.0

Simple Overview of the Handling Recommendations for Vaxzevria® (AstraZeneca)			
Receiving vaccine from National Cold Chain Service (NCCS)	Labelling of vaccine in pharmacy preparation area	Drawing vaccine into syringes	Administering vaccine and completing record
Step 1: Receipt vaccine from NCCS	**Step 2: Label vaccine vials before drawing into syringes**	**Step 3: Draw from vial into syringes**	**Step 4: Vaccinate and complete record**
Transfer vaccine from delivery area to refrigerated area - *maintain cold chain conditions* Scan QR barcodes on vaccine outer containers using electronic scanner for upload of stock to CoVax system and GS1 TrackVax system Place in temperature-monitored pharmaceutical fridge in vaccination area	Confirm "use by" date has not expired Confirm liquid is colourless to slightly brown, clear to slightly opaque solution with no particulates visible. - *Discard the vaccine if particulates or differences in described appearance, are present* Print pharmacy label and add to vaccine vial - *two staff labels must be scanned using the GS1 TrackVax system to generate a label; the two staff members will undertake the first and second check of the label*	Confirm date and "discard time" has not expired Do **not** shake the vial - Vaxzevria (AstraZeneca) *is a ready to use vaccine* Use a new sterile syringe for each drawing of the vaccine - *before each drawing clean top of vial with single use 70% alcohol swab (allow to air dry)* Draw exactly 0.5ml of vaccine into the syringe - *as many complete 0.5mL doses as possible should be drawn up from each vial* Vaxzevria® (AstraZeneca) vaccine contains genetically modified organisms (GMOs) - *no special handling requirements for routine handling* - *spillages should be disinfected with an appropriate antiviral disinfectant (e.g. 70% alcohol)*	Confirm date and "discard time" has not expired Verify volume is 0.5ml Administer vaccine - *dispose of used needle and syringe in sharps bin* Complete vaccination record in the CoVax system When all doses administered, return empty vial to pharmacy for reconciliation and safe disposal At end of session, complete the NIO vaccine reconciliation form
Vaccines should be stored in the fridge in their original packaging in an upright position - *until they are required for step 2* **If transferring vials onsite** - *maintain cold chain conditions*		**Doses drawn up in syringes should be used as soon as possible** - *must be used within the 6 hour discard time.*	**If pharmacy not available for disposal, the waste/empty vials should be managed as agreed locally** - *deface flag labels and original vial labels using permanent marker to ensure that they cannot be misused* - *discard empty vial in sharps bin and record date and time of discard*
For all steps, avoid any shaking / knocking of vials and ensure temperature is controlled.			

Vaxzevria® (AstraZeneca) label fields

1. Flag-labels should be used to label vials. The flag label should not obscure the original vial label.
2. Label fields:
    a. The “batch number” is the batch number on the product box.
    b. The date and time is the time of label generation.
    c. Labels must include the date and “discard time” using a 24 hour format. The discard time and date is 6 hours from the time of label generation using a 24 hour format.

Sample label for Vaxzevria® (AstraZeneca):



Contents of Tray to Vaccinator

For every vial the following should be supplied in a clean reusable tray:

- Labelled Vaxzevria® (AstraZeneca) vial* x1 (*do not remove from the fridge until needed*)
- 70% alcohol swabs x 12
- 1mL syringe x 12
- 23 gauge blue needle **OR** 25 gauge orange needle x 12

Appendix 4 Key COVID-19 Vaccine Information Resources for Health Professionals

Information resources will be reviewed in response to new information for COVID-19 vaccines, please check online for the most recent version of the information sources listed.

Vaccine specific Medicines Information Queries	
Key Information Resources	
General	
FAQs for Healthcare Professionals:	https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/faqscovidvacc/covid19faqhcps.html
Clinical Guidance for COVID-19 Vaccination	https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf
Vaccine studies	https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/covidstudies/covid19studies.html
Immunisation Guidelines	https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/immunisationguidelines.html
Statement on Fever-NIAC	https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/postcovidfever1220.pdf
Allergies	
FAQs about Covid-19 vaccines for people with pre-existing allergic conditions- NIAC & IAAI	https://www.rcpi.ie/news/releases/frequently-asked-questions-about-covid-19-vaccines-for-people-with-pre-existing-allergic-conditions/
Pregnancy and Breastfeeding	
Pregnancy and Breastfeeding- Comirnaty- RCPI ObsGyn, RCPI & NIAC	https://rcpi-live-cdn.s3.amazonaws.com/wp-content/uploads/2021/02/QA-for-pregnant-or-breastfeeding-women-and-their-doctors-about-COVID-19-vaccination_Update.pdf
Decision aid for pregnant women- RCPI ObsGyn & IMPS	https://www.rcpi.ie/news/releases/covid-19-vaccine-decision-aid-for-pregnant-women/
Bleeding disorders	
Advice on administration of the COVID-19 vaccine by intra-muscular injection for people with bleeding disorders- NCC	https://haemophilia.ie/wp-content/uploads/2021/01/Administration-of-the-IM-COVID-19-vaccine-to-people-with-bleeding-disorders-080121.pdf
Rheumatology	
Specific Guidance for SARS-CoV-2 vaccination in Rheumatology patients- NCP Rheum	https://hse.drsteevenslibrary.ie/c.php?g=679077&p=4922165
Cold Chain	
HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock- NIO	https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf
HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes- NIO	https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio02.pdf
Specific Vaccines:	
Comirnaty®	

SmPC	https://www.medicines.ie/medicines/comirnaty-concentrate-for-dispersion-for-injection-35059/spc
EMA- EPAR*	https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty
Supporting documents- NIO	https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/comirnaty/cvinfo.html
Covid-19 Vaccine AstraZeneca®	
SmPC	https://www.medicines.ie/medicines/covid-19-vaccine-astrazeneca-35051/spc
Recommendations for the use of COVID-19 vaccine AstraZeneca® in Ireland- NIAC	https://www.rcpi.ie/news/releases/recommendations-for-the-use-of-covid-19-vaccine-astrazeneca-in-ireland-niac/
EMA-EPAR	https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-astrazeneca
Supporting documents- NIO	https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/astrazeneca/azvinfo.html
Covid-19 Vaccine Moderna®	
EMA-EPAR	https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-moderna
Supporting documents- NIO	https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/moderna/mvinfo.html
Covid-19 Vaccine Janssen®	
EMA-EPAR	https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-janssen

*This includes SmPC and PIL among other documents.

Glossary	
EMA	European Medicines Agency
EPAR	European public assessment report
IAAI	Irish Association of Allergy and Immunology
IMPS	Irish Medicines in Pregnancy Service
NCC	National Coagulation Centre
NCP Rheum	National Clinical Programme for Rheumatology
NIAC	National Immunisation Advisory Committee
NIO	National Immunisation Office
RCPI	Royal College of Physicians of Ireland
RCPI ObsGyn	Institute of Obstetricians and Gynaecologists
SmPC	Summary of product characteristics

Appendix 5 Sample Temperature Monitoring Record Form

Vaccination Clinic	Confirmed automated temperature monitoring system reviewed and fridge temperature in range (+2°C to +8°C) (Y/N)	Date	Time (24hour)	Name

Appendix 6 Guideline Development Group

Member detail	Role	Organisation
Fionnuala King	Working Group Chair & Member of LSVC Sub-Group.	Acute Operations
Joan Peppard	Member of the LSVC Sub-Group & Chief Pharmacist with Experience of Hospital Vaccination Clinic.	Midlands Regional Hospital, Tullamore
Muriel Pate	Medication Safety Specialist Pharmacist.	National Quality Improvement Programme
Marie Philbin	Vaccination Clinic Experience.	Antimicrobial Resistance and Infection Control (AMRIC)
Mariangela Toma	Pharmacist in National Immunisation Office (NIO).	National Immunisation Office
Brian Cleary	Experience of hospital vaccination clinic.	Rotunda Hospital
Paul Gilvarry	Experience in national guideline development.	Acute Hospitals Drug Management Programme

Appendix 7 – Communication from the Pharmaceutical Society of Ireland on the Role of Registered Pharmacists in Centralised HSE Vaccination Clinics.

Clarification Note

The PSI has received a number of queries seeking information on the role of registered pharmacists in Mass Vaccination Centres (MVC).

In response, we wish to clarify the following:

1. MVCs are intended by Government to play a key role in the national vaccination programme.
2. MVCs operate under the governance of the HSE. The specific details regarding the operation of such centres, and the particular roles required of pharmacists, can only be provided by the HSE.
3. It is the PSI's view that MVCs do not fall within the definition of a 'retail pharmacy business' (RPB) as defined in the Pharmacy Act 2007 and, therefore, the operation and governance of the MVCs does not fall within the remit of the Pharmacy Act or of the regulatory roles established under the Act (i.e., superintendent and supervising pharmacist).
4. A registered pharmacist undertaking any role within an MVC does so under the general governance and oversight of the HSE (or the Hospital Group concerned) and the specific management structure within the particular MVC.
5. All pharmacists working within an MVC are also subject to the PSI Code of Conduct for Pharmacists.
6. Every pharmacist has professional responsibilities under the Code of Conduct and is expected to use their professional judgement and clinical expertise in responding to patient needs and in ensuring patient safety.
7. For clarity, all non-pharmacist staff (who might normally work in a hospital pharmacy) and who are assigned to an MVC, do so under the governance and oversight of the HSE (or the Hospital Group concerned) and the specific management structure within the particular MVC.

For information on the role of Pharmacists as **vaccinators** in MVCs and required training, please see: HERE

PSI – The Pharmacy Regulator
19 March 2021

SOP Number: CV01

Title: Start of Day Medicines Management Process

Version: 1

Author: Centralised HSE Vaccination Clinics Medicines Management Working Group.

SOP History

Approved by:	Centralised HSE Vaccination Clinics Subgroup
Version Number:	1
Approval Date:	12/03/2021
Date for revision:	August 2021

Version	Date Approved	List section numbers changed	Author
1	12/03/2021	Not applicable.	Centralised HSE Vaccination Clinics Medicines Management Working Group

1.0 Purpose

To define the start of day medicines management processes that must be completed in the Centralised HSE Vaccination Clinics.

2.0 Scope

This SOP is for use in Centralised HSE Vaccination Clinics. These processes should be completed before the first vaccine of the vaccination session is administered.

3.0 Definitions

Term	Definition
Responsible Person	The Responsible Person has overall responsibility for the medicines management processes during the vaccination session. This may be a registered Pharmacist with the relevant knowledge and skills.

4.0 Equipment
Nil.

5.0 Responsibilities
It is the responsibility of the Responsible Person to ensure that this SOP is followed.

6.0 Procedure

a. Check the automated temperature monitoring system used to monitor the temperature of the pharmaceutical fridge(s) in the vaccination clinic. Ensure the system is recording and confirm that the fridge temperature is in range (+2°C to +8°C) and has not gone out of this range. See SOP03 Fridge Monitoring.

b. Perform a physical stock count of COVID-19 vaccine vials. Confirm the physical stock count for each brand of COVID-19 vaccine matches the stock count recorded on the GS1 TrackVax system.

c. Confirm the target dose number for the vaccination session with the vaccination clinic Operations Lead. If more than one brand of COVID-19 vaccine is being used during the vaccination session, confirm the target dose number for each brand and the vaccinator booths being supplied with each vaccine brand.

d. Based on the target dose number, calculate the total number of vials of COVID-19 vaccine required for the vaccination session. If more than one brand of COVID-19 vaccine is required for the vaccination session, calculate the total number of vials required for each brand. Confirm sufficient vials in stock for the administration of the target dose number. If there is insufficient stock of vaccine, notify the Operations Lead immediately.

e. Confirm there is a sufficient quantity of the following available for administration of the target number of doses for the session:
    i. Sharps Bin(s) with sufficient free capacity.
    ii. Sterile 23 gauge needles.
    iii. Sterile 1mL syringes.
    iv. For Comirnaty® only: sodium chloride 0.9% (preservative-free), 21 gauge needles, and 2.5ml, 3ml or 5ml syringes for dilution of Comirnaty®.
    v. 70% single-use alcohol swabs.
    vi. Flag-labels and labels for labelling.
    vii. Indelible black marker for defacing labels on empty vaccine vials and defacing the outer containers before disposal.
    viii. Surgical face masks and alcohol based hand rub.

    If there is insufficient stock, notify the Operations Lead. Stock should be managed allowing for logistics and scheduling as agreed locally.

f. The staff badges must be activated on GS1 TrackVax daily in order to work. An administrator level password is required for this task.

g. Clean the vaccine labelling area with a disinfectant wipe & discard.

h. Clean reusable vaccine transport trays with alcohol impregnated wipes.

i. Attend local operations or governance meetings scheduled by the Operations Lead.

7.0 Related Documents and References

N/A

8.0 Appendices

N/A

SOP Number:CV02

Title: Receipt of Vaccine (and Diluent) Stock at Centralised HSE Vaccination Clinics

Version: 1

Author: Centralised HSE Vaccination Clinics Medicines Management Working Group.

SOP History

Approved by:	Centralised HSE Vaccination Clinics Subgroup
Version Number:	1
Approval Date:	12/03/2021
Date for revision:	August 2021

Version	Date Approved	List section numbers changed	Author
1	12/03/2021	Not applicable.	Centralised HSE Vaccination Clinics Medicines Management Working Group

1.0 Purpose

To set a standardised protocol of procedures for receipt and checking of COVID-19 vaccine (and diluent for Corminaty®) stock, and entering the stock onto the IT system.

2.0 Scope

This SOP is for use in Centralised HSE Vaccination Clinics. Maintaining the cold chain is critical and staff receiving deliveries must undertake the process promptly. All staff must read the NIO Cold Chain Policy available from: https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf

This SOP includes:
•Receipt and examination of vaccines (and diluent for Corminaty®).
•Uploading stock on IT system.

3.0 Definitions

Term	Definition
Responsible Person	The Responsible Person has overall responsibility for the medicines management processes during the vaccination session. This may be a registered Pharmacist with the relevant knowledge and skills.

4.0 Equipment

Pharmaceutical grade fridge(s)
Scanner
Computer

5.0 Responsibilities

It is the responsibility of the Responsible Person to ensure that this SOP is followed.

6.0 Procedure

Maintaining the cold chain is critical and staff receiving deliveries must undertake the process promptly. The time vaccine is handled outside of the recommended storage temperature must be kept to a minimum during the processes detailed below for receiving and checking stock. If there is any delay in completing these processes, stock must be placed in a pharmaceutical fridge and labelled appropriately to indicate that the receipt/checking of the stock is pending.

- Ensure all boxes or totes are placed in the designated area on receipt.
- Check all labels and invoices to ensure stock has been sent to correct vaccination centre.
- Check boxes or totes are not damaged and that security seals or tape are not broken.
- Count the number of boxes and check this matches the delivery docket, where received.
- Sign a delivery docket if required and if the docket's details are correct.
- Where a discrepancy arises, amend the documentation before signing.
- Any discrepancies or any damage must be reported to the NCCS immediately (Email: vaccines@udd.ie)
- Sodium chloride 0.9% diluent used for Comirnaty® Pfizer BioNTech vaccine will be included in the same delivery as the vaccine. Sodium chloride 0.9% is stored at room temperature in the designated storage area. No diluent is required for the COVID-19 Vaccine Moderna® or the COVID-19 Vaccine AstraZeneca®.
- Vaccines delivered to the vaccination centres are at the temperature of:
    - $+2^0$C to $+8^0$C for Comirnaty® Pfizer BioNTech and COVID-19 Vaccine AstraZeneca
    - -25^0C to -15^0C for COVID-19 Vaccine Moderna®
- Under the terms of the NCCS contract, the NCCS are responsible for maintaining and validating the temperature of the vaccines from when they accept it from the manufacturers until they deliver it to the vaccination site.
- Upon receipt from the NCCS, vaccines must be immediately transferred from the delivery area to the designated refrigerated storage area in the vaccination centre. Vaccines must never be stored at room temperature.

- The QR barcodes on boxes containing vaccines must be scanned using the electronic scanning system to upload the vaccines on the IT system to be available for use by vaccinators. QR barcodes on boxes containing sodium chloride 0.9% supplied as diluent for the Comirnaty® Pfizer BioNTech must also be scanned for upload on the system. See separate SOP04: Using Vaccine Scanning App.
- Note: Decommissioning of COVID-19 vaccines, as required under the Falsified Medicines Directive (FMD), is completed by United Drug for vaccines supplied to vaccination centres.
- Remove vaccines from delivery boxes but not original containers and allocate to the appropriate area in the pharmaceutical fridge without delay. The shortest dated vaccines should be in the foremost position to ensure adequate stock rotation.
- Store vaccines in the fridge in their original packaging and in an upright position.
- If more than one brand of vaccine is being stored at a single facility, stock must be stored so that the different brands are clearly segregated by shelf or if an additional fridge is available, in that fridge.

7.0 Related Documents and References

N/A

8.0 Appendices

N/A

SOP Number: CV03

Title: Procedure for Fridge Monitoring in Centralised HSE Vaccination Clinics

Version: 1

Author: Centralised HSE Vaccination Clinics Medicines Management Working Group.

SOP History

Approved by:	Centralised HSE Vaccination Clinics Subgroup
Version Number:	1
Approval Date:	12/03/2021
Date for revision:	August 2021

Version	Date Approved	List section numbers changed	Author
1	12/03/2021	Not applicable.	Centralised HSE Vaccination Clinics Medicines Management Working Group

1.0 Purpose

To set a standardised protocol of procedures to be followed when recording temperatures of pharmaceutical fridges used to store COVID-19 vaccines in Centralised HSE Vaccination Clinics, including the management of temperature excursions.

2.0 Scope

This SOP is for use in Centralised HSE Vaccination Clinics.

3.0 Definitions

Term	Definition
Responsible Person	The Responsible Person has overall responsibility for the medicines management processes during the vaccination session. This may be a registered Pharmacist with the relevant knowledge and skills.

Term	Definition

4.0 Equipment
Pharmaceutical fridge.
Automated fridge temperature monitoring system.

5.0 Responsibilities
It is the responsibility of the Responsible Person to ensure that this SOP is followed.

6.0 Procedure

a. Ensure the pharmaceutical fridge used to store COVID-19 vaccinations in the vaccination clinic is levelled in a way that allows the door to close and seal automatically if left ajar. The door should be routinely locked.

b. The set point for the fridge temperature and alarms should take into account the need to maintain the temperature above +2°C to prevent freezing and remain less than +8°C. The temperature should be set to maintain +5°C +/- 3°C.

c. An automated temperature monitoring system is used to monitor the temperature of the pharmaceutical fridges in the vaccination clinic. Review the automated data monitoring system twice each day to ensure the system is recording and to confirm that the fridge temperature remains in range. This must be completed at the start of each vaccination session before any vaccine is administered and at end of each vaccination session.

d. Record the date and time the data monitoring system was reviewed as per local agreement (see **Appendix 8.1** for a sample template). Records of completed Temperature Monitoring Record Forms must be maintained as agreed locally.

e. In the event of a temperature excursion outside of the recommended storage conditions, affected stock must be quarantined and the NIO contacted.
   i. Quarantined stock must be appropriately labelled and stored in a separate section of the pharmaceutical fridge.
   ii. The form in *Appendix VIII* of the NIO cold chain guidance should be completed and sent to immunisation@hse.ie.
   Alternatively, an email detailing the temperature excursion can be sent to immunisation@hse.ie . The email should include the following information:
   - The brand of vaccine(s) affected
   - The duration of the temperature excursion
   - The maximum temperature the vaccines were exposed to
   - The role of the person reporting the temperature excursion
   - Details of the organisation, including the name of the vaccination clinic.
   iii. Affected stock should not be used or disposed of but must be quarantined until advice received from the NIO.

f. In the event of a fridge failure, transfer stock to an alternative working pharmaceutical fridge in the vaccination clinic, if available. In the event that there is a fridge failure and there is no alternative pharmaceutical fridge available, or in the event of a power outage, organise a transfer of stock to an alternative location with a working pharmaceutical fridge with available space.

g. The Operations Lead has overall responsibility for operations on the site, including monitoring the automated fridge monitoring system. The Operations Lead may request to delegate responsibility to the Responsible Person. Locally agreed escalation processes should be followed in the event of an out-of-hours fridge alarm, temperature excursion, or fridge failure.

h. When a new pharmaceutical fridge is installed or when a fridge is moved in a vaccination clinic, the manufacturer's instructions should be followed before use. It may need validation by the supplier before use. Supplier details would be available from HBS Procurement.

i. Once in situ, if a fridge is moved, then the manufacturer's instruction for use must be again followed before subsequent use.

7.0 Related Documents and References

N/A

8.0 Appendices

Appendix 8.1 Sample Temperature Monitoring Record Form

Vaccination Clinic	Confirmed automated temperature monitoring system reviewed and fridge temperature in range (+2°C to +8°C) (Y/N)	Date	Time (24hour)	Name

SOP Number: CV04

Title: Using the TrackVax Software

Version: 1

Author: Centralised HSE Vaccination Clinics Medicines Management Working Group.

SOP History

Version	Date	Reason for Change
1	09/04/2021	N/A
2		

1.0 Purpose

To outline the key functions of the TrackVax Software (provided by GS1 Ireland) when used to support the vaccine stewardship practices on site as detailed in the Centralised HSE Vaccination Clinic Operating Model. This SOP should be read in alongside the **TrackVax for Central Vaccination Clinics SOP**.

2.0 Scope

This SOP is for use in Centralised HSE Vaccination Clinics.This SOP is intended to outline when the TrackVax Software should be used. It also gives short step by step guide to the use of the TrackVax. For a greater level of detail please consult the **TrackVax for Central Vaccination Clinics SOP**.
The following actions will be described:

1. Printing and activation of staff badge labels
2. Uploading stock onto TrackVax
3. Printing of labels for the supply of vaccines (vial mode)
4. Allocation of vaccines to vaccination booths (optional)
5. Returning Empty Vials, Recording Dose Yield and Discards (vial mode)
6. Verification process for vaccine doses allocated versus given and recorded on Covax
7. Dashboard (local and national) and Reporting

3.0 Definitions

Term	Definition
Responsible Person	The Responsible Person has overall responsibility for the medicines management processes during the vaccination session. This may be a registered Pharmacist with the relevant knowledge and skills.
TrackVax for Vaccination Clinics	TrackVax is a standards based software to electronically track vaccines through the vaccine lifecycle – vaccine receipt, vial or syringe labelling, tracking, vaccine vial disposal in order to report vaccine distribution and reconcile it with vaccine administration at centralised vaccination clinics. Hereafter it shall be referred to as TrackVax

Term	Definition

4.0 Equipment

4.1 Hardware:

- Laptop connected to internet
- Scanner
- Label Printer (pref. 300dpi*)

4.2 Consumables:

- White Labels (102mm x36 mm)
- Vial Flag Label (38mmx174mm)

4.3 Software:

- TrackVax (provided by GS1 Ireland)
- Label printer is set as default printer
- Teamviewer (free version) for remote install and support

5.0 Responsibilities

It is the responsibility of the Responsible Person to ensure that this SOP is followed.

6.0 Procedure

6.1 **Action**	**Printing off staff badge labels**
Level of access required	**Responsible Person or delegate**

Figure 1. Staff icon

6.1.1 **Process:**

- Select “Staff” from Main menu (see Figure 1.)
- Search & Highlight staff members you wish to print badges for on the list
- Select “Staff Badge” button to print
- If “Staff” not visible then select “Add Locally” from menu to select or Add staff to central list and then Select ‘Add Locally’ to add staff to local staff list

6.1.2 **Notes:**

Staff barcodes are required to use TrackVax to:

- Print labels or verify the printing process
- Additional functions: ‘Reprint Vial Label’, ‘Cancel Vial Label’, ‘Amend Vial Doses’ or ‘Additional Syringe’

This should be done as part of the Start of Day Process as described in SOP01. Staff barcodes for those who will be required to undertake the tasks outlined above should be printed/activated at this point.

Staff barcodes are for a set location and period of time (e.g. 8am-8pm).

When assigning a ‘PIN Number’ pharmacists should use their PSI registration number.

See Figure 2.

Figure 2 Sample Staff Badge

6.2 **Action:**	**Uploading stock onto the App**
Level of access required:	**Standard User**

Figure 2 Receive vaccines icon

6.2.1 **Process:**

- Scan vaccine boxes (for some vaccines you may be asked to Enter Quantity of Vials per box)
- Click “Save” for each box, when all boxes scanned click “Load Boxes” and click “Back” to return to main menu

6.2.2 **Notes:**

As per SOP02 all deliveries of vaccines need to be scanned onto to TrackVax.
This step is required to record the boxes and quantity of vials contained upon receipt to the centre. This updates the “In Stock” section of the dashboard, per corresponding vaccine.

There is a double scan of stock currently as the 'test system' is not uploading data to Covax.ie: The stock still needs to be scanned into the GS1 App for upload to Covax. In the future this may be integrated in the live system.

6.3 **Action:**	**Printing and activating of labels for the supply of vaccines- Vial mode**
Level of access required:	**User barcodes x 2**

Figure 3 Supply labels icon

6.3.1 **Process (i):**

- Scan vaccine box- not the vial.
- Enter Qty of Vials you are labelling
- Scan staff badge of "Labelled by" and "Checked By" and Select "Print X Vial Label(s)".
- Apply Flag and label to vial(s)

6.3.2 **Notes:**

When supplying a vaccine vial to vaccinators a vial label is to be affixed to the vial.

The dashboard will be updated for "Supplied" and "In Use".

See figure 4a

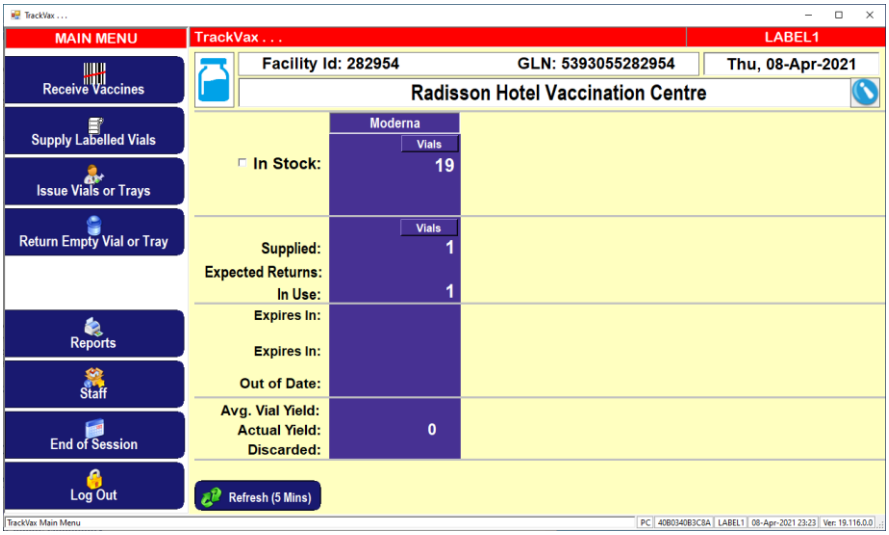


Figure 4a Sample Dashboard

There is an optional feature to allocate a vaccine vial to a specific vaccination booth when issuing the vials. This can be done in the 'supply labelled vials' screen if only one vial label is being printed OR in the 'Issue Vials or Trays' screen if more than one vial label is being printed (eg: at the start of the day)

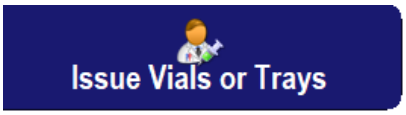


Figure 5 Issue Vials or Trays

7.3.3 **Process (i)**: -Allocating vaccine vials to vaccination booths

- Scan vial label or 'double click' on vial in list on screen
- Enter vaccination bay number into 'Issue to Bay' field
- Click on 'Issue Vial'

Two Users with valid User Barcodes are required for this step:
i. Two staff labels must be scanned using TrackVax to generate a label; the two staff members will undertake the first and second check of the label

Ensure Vial Mode is selected. There is also a functionality to label trays and syringes which is not described in this version of the SOP but maybe in future versions.

6.4 **Action:**	**Returning Empty Vials, Recording Dose Yield and Discards (vial mode)**
Level of access required:	**Standard User**

Figure 6. Return Empty Vial or Tray icon

6.4.1 **Process:**

- Scan Vial Label
- Enter Dose Yield
- If you are discarding doses you need to record a reason from the selection
- If Vial label not available ('reprint vial label' function in 'issue vial labels' screen can be used which requires two person check/scan)

6.4.2 **Notes:**

As per SOP05 returned vials are to be recorded on TrackVax. The user will return or discard vials (or verify the return or discard of vials) and record (or verify) vial yield (Vaccinators will be asked to record manually on the label the number of doses administered for each vial. See Figure 7). The dashboard will be updated accordingly.

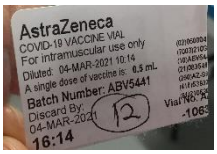


Figure 7 Sample vial label

7.0 Related Documents and References

SOP01
SOP02
SOP05

8.0 Appendices

N/A

SOP Number: CV05

Title: Procedure for Discarding of COVID-19 Vaccine Vials in Centralised HSE Vaccination Clinics.

Version: 1

Author: Centralised HSE Vaccination Clinics Medicines Management Working Group.

SOP History

Approved by:	Centralised HSE Vaccination Clinics Subgroup
Version Number:	1
Approval Date:	12/03/2021
Date for revision:	August 2021

Version	Date Approved	List section numbers changed	Author
1	12/03/2021	Not applicable.	Centralised HSE Vaccination Clinics Medicines Management Working Group

1.0 Purpose

To set a standardised protocol of procedures for discarding COVID-19 vaccine vials in the Centralised HSE Vaccination Clinics.

2.0 Scope

This SOP is for use in Centralised HSE Vaccination Clinics. Vaccines must be stored securely at all points of use between receipt and disposal. Waste must be handled in such a way as to prevent theft and/or misuse.

- Using the TrackVax barcoded label, scan the vial in as returned.

3.0 Definitions

Term	Definition
Responsible Person	The Responsible Person has overall responsibility for the medicines management processes during the vaccination session. This may be a registered Pharmacist with the relevant knowledge and skills.

Term	Definition

4.0 Equipment
Indelible black marker

5.0 Responsibilities
It is the responsibility of the Responsible Person to ensure that this SOP is followed.

6.0 Procedure

a. Flag labels and original vial labels should be removed or defaced using an indelible black marker.

b. Discard empty vials and waste vaccines into sharps bins.

c. The date and time the vial has been discarded will be recorded from the return barcode scan and will be reported from GS1 TrackVax. If required, vaccine reconciliation forms are available from the National Immunisation Office website (Available from: https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/)

- Comirnaty® -Vaccine Reconciliation Form for clinic settings Version 1.0 4 March 2021 **Please note this is an editable PDF**

- Moderna® -Vaccine Reconciliation Form for clinic settings Version 1.0 4 March 2021 **Please note this is an editable PDF**

- AstraZeneca® - Vaccine Reconciliation Form for clinic settings Version 1.0 4 March 2021 **Please note this is an editable PDF**

d. Sharps bins containing returned vaccine vials must be stored in a supervised area and not left unattended during the vaccination session. These sharps bins should be locked at the end of each working day.

e. Label the sharps bins as per the requirements of local waste management arrangements. Details are available from the Operations Lead.

f. Labels on the original cartons should be defaced using indelible black marker. Place into appropriate waste sack for disposal, as soon as possible after they become empty.

g. Details of vaccine dose reconciliation are automatically recorded on the GS1 TrackVax system. If the GS1 TrackVax system is unavailable, confirm that manual records are being maintained locally

in the centralised vaccination clinic using the vaccine reconciliation forms (as detailed in point “c” above). Completed vaccine reconciliation forms should be emailed to immunisation@hse.ie .

7.0 Related Documents and References

N/A

8.0 Appendices

N/A

SOP Number: CV06

Title: Procedure for Managing Stock of Epinephrine (Adrenaline) in Centralised HSE Vaccination Clinics.

Version: 1

Author: Centralised HSE Vaccination Clinics Medicines Management Working Group.

SOP History

Approved by:	Centralised HSE Vaccination Clinics Subgroup
Version Number:	1
Approval Date:	12/03/2021
Date for revision:	August 2021

Version	Date Approved	List section numbers changed	Author
1	12/03/2021	Not applicable.	Centralised HSE Vaccination Clinics Medicines Management Working Group

1.0 Purpose

To set a standardised protocol of procedures to manage stock of epinephrine (adrenaline) used for the management of anaphylactic reactions in Centralised HSE Vaccination Clinics.

2.0 Scope

This SOP is for use in Centralised HSE Vaccination Clinics.

3.0 Definitions

Term	Definition
Responsible Person	The Responsible Person has overall responsibility for the medicines management processes during the vaccination session. This may be a registered Pharmacist with the relevant knowledge and skills.

Term	Definition

4.0 Equipment
Nil.

5.0 Responsibilities
It is the responsibility of the Responsible Person to ensure that this SOP is followed.

6.0 Procedure

a. HSE Procurement supply Resuscitation Bags for the purpose of managing anaphylactic reactions in the Centralised HSE Vaccination Clinics. The Resuscitation Bags are supplied **without** epinephrine (adrenaline). The epinephrine must be added to the Resuscitation Bags in the vaccination clinic to complete the anaphylaxis kit. Three vials of epinephrine 1ml 1:1000 1mg/ml is required per anaphylaxis kit.

b. For the treatment of anaphylaxis epinephrine is the agreed medication to be available in all vaccination clinics and its use within a vaccination clinic is covered by S.I. 698 of 2020. Availability of any additional medicines must be agreed locally.

c. Epinephrine must be ordered separately by a pharmacist or the Responsible Person for delivery to the Centralised HSE Vaccination Clinics. Epinephrine should be ordered from a designated pharmacy agreed locally by the governing Community Healthcare Organisation (CHO) / Hospital Group (HG).

d. Staff allocated to the pharmacy area are responsible for ensuring the epinephrine is distributed to the resuscitation bags. Epinephrine is a prescription only medicine and stock should be placed in secure storage outside of vaccination clinic operating hours.

e. Further supply of epinephrine should be ordered from a designated pharmacy, agreed locally by the governing CHO / HG, as needed to replace used or expired product.

Figure 1 Excerpt from “Anaphylaxis: Treatment in the Community” from Immunisation Guidelines for Ireland.

Suggested Anaphylaxis Kit

The availability of protocols, equipment and drugs necessary for management of anaphylaxis should be checked before each vaccination session

- Copy of "Anaphylaxis: Treatment in the Community" from Immunisation Guidelines for Ireland
- 3 x 1 ml ampoules of epinephrine (1:1000, 1mg/ml)

or

- 6 x Epinephrine auto-injectors, 150 mcg, 300 mcg and/or 3 x 500 mcg* (depending on age of vaccinees)

7.0 Related Documents and References

HSE Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis,
available from:
https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/protocols/anaphylaxis2016.pdf .

Anaphylaxis: Treatment in the Community from Immunisation Guidelines for Ireland, available from:
https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf

8.0 Appendices

N/A

SOP Number: CV07

Title: End of Day Medicines Management Process

Version: 1

Author: Centralised HSE Vaccination Clinics Medicines Management Working Group.

SOP History

Approved by:	Centralised HSE Vaccination Clinics Subgroup
Version Number:	1
Approval Date:	12/03/2021
Date for revision:	August 2021

Version	Date Approved	List section numbers changed	Author
1	12/03/2021	Not applicable.	Centralised HSE Vaccination Clinics Medicines Management Working Group

1.0 Purpose

To define the end of day medicines management processes that should be completed in the Centralised HSE Vaccination Clinics. The overarching aim of these processes is to support a zero wasted-vaccine approach and to minimise the need for the use of "standby lists" to use excess out-of-the-fridge vaccine doses that are not required for the session's scheduled appointments.

2.0 Scope

This SOP is for use in Centralised HSE Vaccination Clinics.

3.0 Definitions

Term	Definition
Responsible Person	The Responsible Person has overall responsibility for the medicines management processes during the vaccination session. This may be a registered Pharmacist with the relevant knowledge and skills.

Term	Definition

4.0 Equipment
Nil.

5.0 Responsibilities
It is the responsibility of the Responsible Person to ensure that this SOP is followed.

6.0 Procedure

a. To avoid wastage of any doses before the end of the session liaise with the vaccination clinic Operations Lead to confirm the number of remaining confirmed appointments for the session and the planned number of vaccinators for the remaining time. Vaccine preparation should be adjusted to meet the expected demand and accounting for DNA's late in the evening.

b. Based on the number of confirmed appointments remaining for the session and actual people who have registered, calculate the total number of vials of COVID-19 vaccine required for remainder of the vaccination session. Coordinate the removal of vials from the fridge to align with the remaining appointments and specifically in the last few hours of the clinic, align vaccine requirements with the number of people who are registered and in the queue. .

c. After all doses for the session have been administered, perform a physical stock count of COVID-19 vaccine vials. Confirm the physical stock count for each brand of COVID-19 vaccine matches the stock count recorded on the IT system.

d. After the session clear and clean the vaccine preparation and labelling work station. Clean the vaccine preparation and labelling bench/table with a disinfectant wipe & discard.

e. Confirm that the reusable vaccine transport trays are cleaned and disinfected using alcohol impregnated wipes.

f. Confirm there is a sufficient quantity of the following available for the next session:
   i. Sharps Bin with sufficient free capacity
   ii. Indelible black marker for defacing labels on empty vaccine vials before disposal
   iii. Surgical face masks and alcohol based hand rub
   iv. Sterile 23 gauge needles
   v. Sterile 1mL syringes
   vi. 70% single-use alcohol swabs.
   vii. For Comirnaty® only: sodium chloride 0.9% (preservative-free), 21 gauge needles, and 2.5ml, 3ml or 5ml syringes for dilution of Comirnaty®.
   viii. Sufficient quantity of flag-labels and labels for labelling.

   If insufficient quantities are in stock, advise the Operations Lead.

g. Check the automated temperature monitoring system used to monitor the temperature of the pharmaceutical fridge(s) in the vaccination clinic. Ensure the system is recording and confirm that the fridge temperature is in range (+2°C to +8°C) and has not gone out of this range. Ensure pharmaceutical fridge(s) are locked at the end of the day. See SOP No. 03 Fridge Monitoring.

7.0 Related Documents and References

SOP No.03 Fridge Monitoring

8.0 Appendices

N/A

Recruitment of Medicines Management staff for Centralised HSE Vaccination Clinics

Title of Guidance Development Group:		Workforce Model Subgroup of the Centralised HSE Vaccination Clinics Medicines Management Working Group.	
Approved by:		Centralised HSE Vaccination Clinics Subgroup.	
Version Number:		1	
Approval Date:		24 March 2021	
Date for revision:		August 2021	
Version	**Date Approved**	**List section numbers changed**	**Author**
1	24 March 2021	Not applicable.	Workforce Model Subgroup of the Centralised HSE Vaccination Clinics Medicines Management Working Group.

Recruitment of Medicines Management staff for Centralised HSE Vaccination Clinics.

The importance of vaccine stewardship is a key component in planning for the opening of the Centralised HE Vaccination Clinics which require a safe, effective and efficient medicines management process. Availability of vaccine supplies is currently the rate limiting factor in the roll out of the national programme therefore it is essential to have robust processes in place for vaccine stewardship.

A pharmacy team with a ratio of 1 staff member: per 10 vaccination booths in Centralised HE Vaccination Clinics has been identified in order to facilitate good vaccine stewardship. This is consistent with experience from hospital clinics and large scale vaccination centres to date. The pharmacy team should be led by a pharmacist with overall responsibility for the medicines management processes on each site. The composition of the pharmacy team may include:

- Pharmacist in charge (Responsible person as per the Medicines Management for Centralised HSE Vaccination Clinics guidance)
- (Duty) Pharmacist.
- Pharmaceutical technician/ other registered professional
- Ancillary staff

Staff skill mix may vary depending on availability of staff geographically though there will be a minimum of 2 pharmacists on duty. See table 1 for staffing requirements, depending on opening hours and number of vaccination booths.

General Description

A detailed description of the Medicines Management processes to support vaccine stewardship is documented in "Medicine Management Guidance for use in Centralised HSE Vaccination Clinics v01."

Briefly it consists of a number of steps

- Receipt and secure storage of vaccine
- Distribution, workflow management and dose reconciliation
- Responding to Medicines Information queries from vaccinators and clients
- Validation and management of the cold chain

Other responsibilities related to the pharmacy area include although not limited to;

- Participation in site specific operational and clinical meetings
- Liaison with logistics re the supply of consumables such as needles, syringes etc.
- Supply of vaccine pre-printed information to clients
- Management of a pharmacy roster

Workflow

The staffing workforce required is within the parameters of the Centralised HSE Vaccination Clinics workforce model. The work flow it supports is as described in "Medicine Management Guidance for use in Centralised HSE Vaccination Clinics v01" only.

Roles

All roles in Centralised HE Vaccination Clinics should be recruited locally either directly or via agency or by redeployment. The only role being recruited through the national recruitment campaign is that of vaccinator.

Pharmacist in charge (Responsible person as per the guidance). This pharmacist will be operationally responsible for Medicines Management (vaccine stewardship) on the site, reporting to site Operations Lead with professional support from the relevant Integration Governance Steering Group Pharmacy Lead. This pharmacist will be responsible for activities as outlined above. The pharmacist in charge shall be remunerated at a salary equivalent to a Chief II Pharmacist (HSE grade code 3271).

Pharmacist. There will be a minimum of two pharmacists on duty per shift, one of whom may be the Pharmacist-in charge. The duty pharmacists will be paid at a rate equivalent to a Senior Pharmacist (HSE grade code 3239).

Remuneration for pharmacists already employed in the public health sector, who work, in excess of the full time weekly hours for their grade are covered by the Remuneration arrangements for Pharmacists working on Covid 19 vaccination roll-out memo (Ref: CERS 03/2021- REISSUE.)

Remuneration for contracted hours worked by pharmacists not already employed in the public health sector should be paid an hourly rate, pro-rata to the first point of the relevant HSE salary scale above.

A pharmacist contracted by HSE is covered under SI 698 of 2020 to act as a vaccinator with the relevant discipline specific training approved by the regulator. The SI does not refer to pharmacists covering the medicines management (vaccine stewardship) role in a Centralised HE Vaccination Clinics. Pharmacists in the medicines management (vaccine stewardship) role should be ***employed*** as pharmacists and paid as outlined above.

Pharmaceutical technician. The pharmaceutical technician will provide support for the medicine management services provided with application of an appropriate skill mix. The pharmaceutical technician will be paid at a rate equivalent to a pharmaceutical technician (HSE grade codes 3212 or 3021 depending on their experience). Registered professionals may also support medicines management services provided with an application of an appropriate skill mix. Other graduates with relevant skills may also be employed in this role. This recruitment should be in consultation with the Pharmacist in charge who will have best sight of the skill mix needed

Ancillary staff. If adequate numbers of pharmaceutical technicians cannot be recruited then consideration can be given to recruiting ancillary staff to provide support for the medicine management services. This recruitment should be in consultation with the Pharmacist in charge who will have best sight of the skill mix needed. Possible HSE Grade codes include 362X and 3013.

If a pharmaceutical technician employed in the public health sector works overtime in a Centralised HSE Vaccination Clinic, it is proposed that remuneration described in the "Remuneration arrangements for Pharmaceutical Technicians working on Covid 19 vaccination roll-out" (Ref: CERS 04/2021) CERS memo for pharmaceutical technician overtime arrangements.

Remuneration for contracted hours worked for include pharmaceutical technicians not already employed in the public health sector should be paid an appropriate hourly rate, pro-rata to the first point of the relevant HSE salary scale above.

Runners/Logistic support

This role is currently supported by the Defence Forces in a number of Centralised HSE Vaccination Clinics. In the absence of the Defence Forces this role will be undertaken by Multi-task attendants and will be remunerated as Multi-Task attendant, HSE grade code 6015. This role will be task orientated and include;

a) Preparation vaccine trays with consumables.
b) Preparation of vaccine card with date and batch number
c) Delivery vaccine to the vaccinators
d) Return of used vials to the pharmacy area
e) Cleaning of vaccination trays for reuse
f) Replenishment of vaccination booths with required consumables
g) Return of full sharps bins to waste management area and replenish same in booths
h) Receipt and stock management of consumables in pharmacy and consumables store

The table below provides more details on staffing levels for medicines management and pharmacy support staffing in Centralised HSE Vaccination Clinics. This will need to be checked to ensure compliance with standard employment terms and conditions.

The following assumptions have been made in developing the staff requirements;

- The work flow it supports is as described in "Medicine Management Guidance for use in Centralised HSE Vaccination Clinics v01" only.
- While not desirable from a Medication Safety perspective, more than one vaccine may be administered during a single session of a Centralised HSE Vaccination Clinic.
- The clinic-lead Centralised HSE Vaccination Clinic model will continue with medicine management support from pharmacy staff
- The roles as outlined remain within the medication management remit.
- Automation of the labelling and vial tracking through use of appropriate software will be available. Requirement to track vaccine through the clinic via paper will revert the workforce model to the original ratio of 1 staff member: 10 vaccination booths.
- The workforce model will be reassessed if the workflow changes to vaccine dose delivery by pre-filled syringe.
- The runner role will be filled from the Healthcare assistant (1:10 vaccination booths) staffing as per the DOH Workforce model.
- The number of WTE required per clinic will be pro rata to the opening hours of the clinic.

The following has been drawn from experience to date in Aviva and Citywest:

- pharmacy operations need to start at least 30 minutes before the vaccinators
- pharmacy operations may not close until all vials have been returned and reconciliations completed
- there is an on-going requirement for Medicines Information queries support during clinic hours
- Close liaison with both operational and clinical vaccination leads is required achieve a zero wasted-vaccine approach and to minimise the need for the use of "standby lists". These may be needed to use excess out-of-the-fridge vaccine doses that are not required for the session's scheduled appointments but should be minimised through judicious vaccine management.
- Clear reporting and governance lines are defined.

Table 1: Staffing requirements based on Clinic Opening Hours and No. of Vaccination Booths in operation

No of booths	Days per week	Staff level on duty	P'cist IN	P'cist out	No of hours PW	Pharmacy team hours PW	Contract hours	No of WTEs required	No of pharmacists WTE	No of technicians WTE
up to 11	5	2	07:30:00	18:30:00	55	110	37.5	3.0	2	1
up to 11	5	2	07:30:00	21:30:00	70	140	37.5	3.7	2	2
up to 11	7	2	07:30:00	18:30:00	77	154	37.5	4.1	3	1
up to 11	7	2	07:30:00	21:30:00	98	196	37.5	5.2	3	2
up to 21	5	3	07:30:00	18:30:00	55	165	37.5	4.4	2	2
up to 21	5	3	07:30:00	21:30:00	70	210	37.5	5.6	2	4
up to 21	7	3	07:30:00	18:30:00	77	231	37.5	6.2	3	3
up to 21	7	3	07:30:00	21:30:00	98	294	37.5	7.8	3	5
up to 31	5	4	07:30:00	18:30:00	55	220	37.5	5.9	2	4
up to 31	5	4	07:30:00	21:30:00	70	280	37.5	7.5	3	5
up to 31	7	4	07:30:00	18:30:00	77	308	37.5	8.2	3	5
up to 31	7	4	07:30:00	21:30:00	98	392	37.5	10.5	4	7
up to 41	5	5	07:30:00	18:30:00	55	275	37.5	7.3	2 or 3	3 or 4
up to 41	5	5	07:30:00	21:30:00	70	350	37.5	9.3	3 or 4	5 or 6
up to 41	7	5	07:30:00	18:30:00	77	385	37.5	10.3	4	6
up to 41	7	5	07:30:00	21:30:00	98	490	37.5	13.1	4	9
up to 51	5	6	07:30:00	18:30:00	55	330	37.5	8.8	3 or 4	5 or 6
up to 51	5	6	07:30:00	21:30:00	70	420	37.5	11.2	3 or 4	7 or 8
up to 51	7	6	07:30:00	18:30:00	77	462	37.5	12.3	4	8
up to 51	7	6	07:30:00	21:30:00	98	588	37.5	15.7	5	11

Appendix 10 – Declaration Form for Named Responsible Person

I _____ (Print Name in Full) confirm that:

- I am responsible for ensuring that the staff involved in medicines management processes in _____(name of the CVC) Centralised Vaccination Clinic have completed the appropriate training (all staff must complete the declaration form in **Appendix 11**):

  Yes □ No □

- I am responsible for ensuring the supply of COVID-19 vaccines, and any other medicine(s), in the CVC are maintained and supplied in accordance with the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2021 and the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 to 2021:

  Yes □ No □

Name: _____ Professional Registration Number (PSI/MCRN/ /NMBI): _____

Signed: _____ Dated: _____

Signed declaration forms should be sent to the COVID Assistant National Direction (AND) (Email: covid.and@hse.ie) and kept on file by CVC Operations Lead to be produced if required during subsequent inspection.

Appendix 11 – Declaration Form for Medicines Management Staff

I _____ (Print Name in Full) confirm that:

- I have read and understood the *Medicines Management Guidance for Use in Centralised HSE Vaccination Clinics*:

  Yes □ No □

- I have read and understood the medicines management Standard Operating Procedures in **Appendix 8** of the *Medicines Management Guidance for Use in Centralised HSE Vaccination Clinics*:

  Yes □ No □

- I have completed the HSE Land e-learning training module *COVID-19 Vaccination Training Programme*

  Yes □ No □

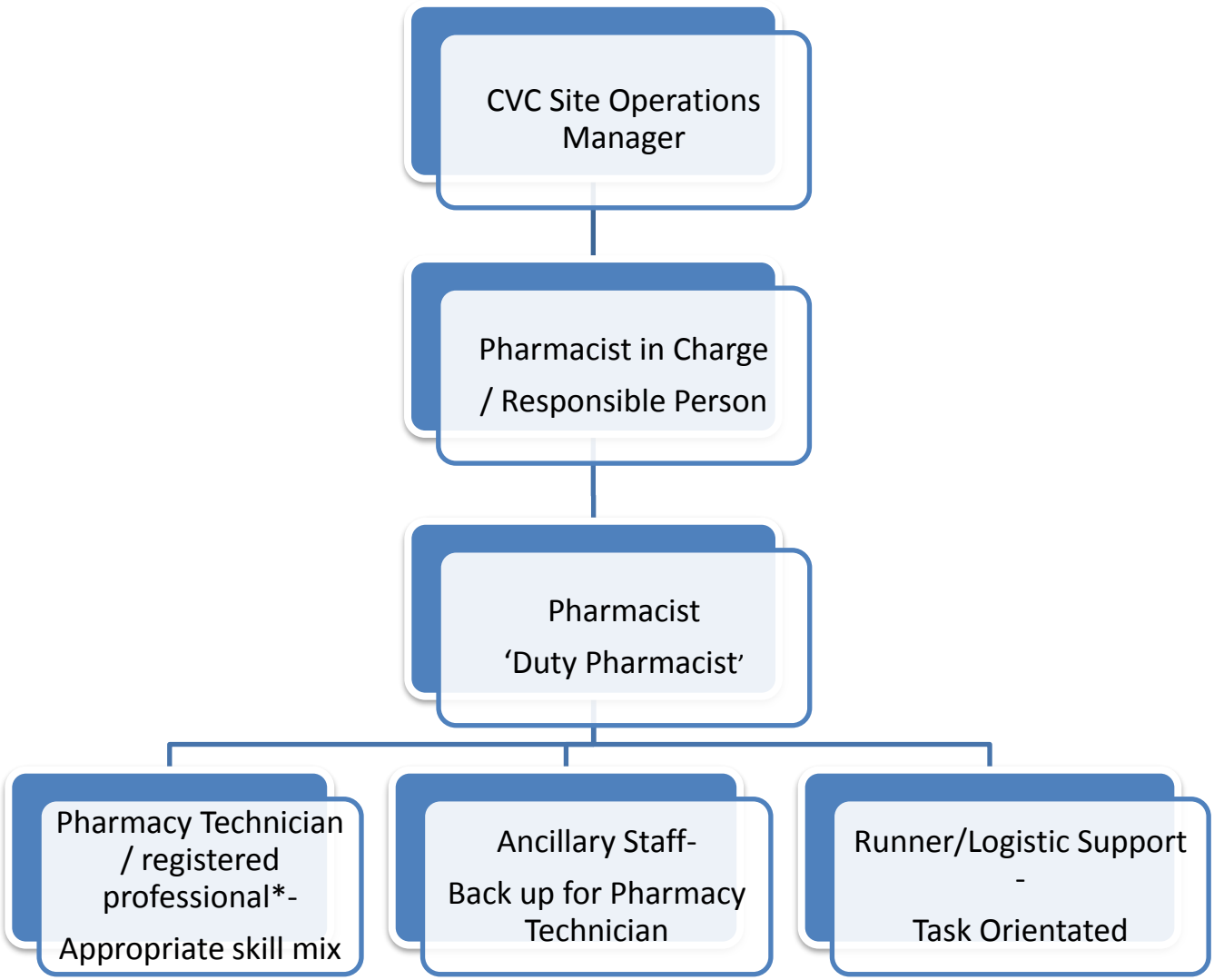
  (HSE Land certificate of completion should also be presented to the Vaccination Clinic Operations Lead or the delegated named Responsible Person).

Name: _____ Professional Registration Number (if applicable): _____

Signed: _____ Dated: _____

Signed declaration forms should be presented to the Vaccination Clinic Operations Lead or the delegated named Responsible Person for the Vaccination Clinic.

Appendix 12 - Organisational Structure for Medicines Management Teams in Centralised HSE Vaccination Clinics



*Graduates with relevant skills may also undertake this role