# MP11
# COVID-19 Vaccine Handling and Management Policy

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## 1.0 Policy Statement

The COVID-19 vaccination programme is of the highest priority for the NHS. To deliver this programme safely and effectively, good practice in the handling and management of the vaccine is paramount. This policy details the overarching principles for governance of the safe and secure handling and management of COVID-19 vaccines in the end-to-end supply chain for the vaccination programme.

The objectives of this policy are as follows.

- To ensure that all staff involved in delivery of the vaccination programme are aware of, and adhere to, correct procedures for the ordering, receipt, storage and administration of the product.
- To ensure that the physical and biochemical integrity and sterility of all vaccines and related medicines is maintained.
- To ensure that all staff involved in delivery of the vaccination programme are aware of the relevant characteristics of COVID-19 vaccines and the implications this has for vaccine efficacy and patient safety.
- To provide assurance that vaccine safety, sterility, quality and efficacy are protected.
- To define key roles and responsibilities needed to deliver this assurance.
- To ensure that all staff understand their critical roles and responsibilities in delivering these objectives.

This policy is to be read alongside the Pharmacy Institutional Readiness documents (available via the Specialist Pharmacy Service website https://www.sps.nhs.uk/home/covid-19-vaccines/) and the COVID-19 Vaccine Standard Operating Procedures.

In adhering to this Policy, all applicable aspects of the Conflicts of Interest Policy must be considered and addressed. In the case of any inconsistency, the Conflicts of Interest Policy is to be considered the primary and overriding Policy.

## 2.0 Definitions

**Vaccination**
Treatment with a vaccine to produce immunity against a disease.

**COVID-19**

A disease caused by a strain of coronavirus. Formerly referred to as '2019 novel coronavirus' or '2019-nCoV'.

**COVID-19 Vaccination Programme**
Refers to the government programme to give the COVID-19 vaccination.

**Vaccination Site**
The physical location from where the vaccination programme is being delivered.

**Foundry management system**
This is the national software system used to record vaccination site readiness and assurance and manage vaccine supplies across NHSE vaccination services.

## 3.0 Accountabilities

### 3.1 Chief Executive

The Chief Executive is responsible for assigning responsibility for clinical and operational oversight of the vaccination sites. This responsibility may be delegated to an Executive Director who will be the Senior Responsible Officer (SRO) for the vaccination sites and the vaccination programme.

### 3.2 Chief Pharmacist (Clinical Director of Pharmacy)

The Chief Pharmacist is professionally accountable for the safe and secure handling and management of COVID-19 vaccine and related medicines on all vaccination sites operating within the jurisdiction of the Trust. This includes oversight of those elements of practice within mass vaccination centres and other designated vaccination sites that may impact upon product integrity, from receipt of product to vaccine administration.

The Specialist Pharmacy Services Regional Quality Assurance Specialists will work with the Chief Pharmacist to provide specialist pharmaceutical expertise in the development of systems and processes of work to ensure the safe and secure handling of the vaccine.

The Chief Pharmacist may delegate operational responsibility for oversight of ordering, receipt, storage and safe handling of vaccines and medicines to a named and suitably trained pharmacy team member at each vaccination site.

### 3.3 Clinical Lead for Vaccination Site

The Clinical Lead for the vaccination site is professionally accountable for ensuring that appropriate and formal authorisation for vaccine administration is in place such as a Patient Specific Direction, Patient Group Direction or National Protocol, and that the staff groups who are supplied with, prepare, and administer the COVID-19 vaccine are those defined as eligible to do so in accordance with the authorisation being used.
When working under the National Protocol, the Clinical Lead will ensure that a 'Shift Lead' is present for the duration of the vaccination session and this person is clearly identifiable and competent in all stages of the vaccination pathway.
The Clinical Lead is responsible for ensuring that all staff undertaking duties at the vaccination site meet the necessary training standards and competencies in line with national guidance and organisational policy.
The Clinical Lead must also ensure that staff involved in the vaccination service are able to respond to clinical incidents (including anaphylaxis) and are aware of the escalation processes for clinical incidents, including the procedure for reporting them.

### 3.4 Prescribers
When working under a Patient Specific Direction (PSD), the prescriber is legally accountable for the safe and secure handling and management of COVID-19 vaccines at the designated site under The Human Medicines Regulations (2012) Regulation 3.

### 3.5 Registered Healthcare Professionals
Healthcare professionals working under a Patient Specific Direction (PSD) or a Patient Group Direction (PGD), and anyone clinically supervising administration of the vaccines under a National Protocol also have legal accountability for ensuring the safe and secure handling requirements are met.

### 3.6 Operational Lead for Vaccination Site
The Operational Lead is responsible for the operational delivery of the vaccination programme. This includes the building, security, patient flow, administrative functions, IT, furniture, consumables and non-clinical staff.

## 4.0 Policy Detail
### 4.1 COVID-19 Vaccines
There are several COVID-19 vaccines that have received MHRA approval. Regulation 174 of the Human Regulations 2012 should now only be used if there is a new emergent pathogen. Regulation 174 enables the Medicines and Healthcare products Regulatory Agency (MHRA) to authorise use of a product on a temporary basis in response to the spread of pathogenic agents.

The characteristics of the different vaccines may vary considerably; this information is available in the Summary of Product Characteristics and Patient Information Leaflet respectively. The vaccines require specific temperature-controlled storage so cold chain management will be critical for all. Use of vaccines that have deviated from recommended storage or transportation conditions risks compromising vaccine efficacy and patient safety.

Vaccines that have not been transported or stored correctly may be ineffective or harmful; they would therefore no longer be within the terms of their product authorisation and must not be used. Means of detecting when a temperature excursion has occurred are required. The focus on avoidance of waste should also be of high priority. When the vaccine has not been transported or stored correctly, the advice issued by the Specialist Pharmacy Service (SPS) and medicine information services specific to that vaccine must be followed. The action required will vary depending on the vaccine affected.
Further information concerning COVID-19 vaccines is available here: Coronavirus » COVID-19 vaccination programme (england.nhs.uk)

### 4.2 Legal framework and practice standards
All activity is to be undertaken in accordance with the Human Medicines Regulations 2012 and Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020.

All activity is also to be aligned with relevant COVID-19 Vaccination Programme NHS policy documents marked as Classification: Official and annotated with a publication approval reference number.

In addition, adherence to national standards of good practice is required including those set by the Care Quality Commission, the National Institute for Health and Care Excellence, UK Health Security Agency, and the Royal Pharmaceutical Society of Great Britain, as detailed in Appendix 1.

### 4.3 Handling and management of vaccine and medicines in vaccination sites

All Vaccination Sites must have received Site Assurance sign off from local System and Regional Vaccine teams. This process is completed through the Foundry management system.

All activities must be carried out in accordance with:

- This policy document;
- The relevant nationally authored 'Institutional Readiness' documents and Standard Operating Procedures;
- Relevant organisational medicines policies;
- Standard good practice guidance including aseptic technique;
- Relevant Health and Safety guidance;
- National Standards including those detailed in Appendix 1.

### 4.4 Staff authorisation to be supplied with and administer COVID-19 vaccines

Appropriate and formal authorisation for vaccine administration must be in place e.g., Patient Specific Direction (prescription), Patient Group Direction or National Protocol, and all staff groups who are supplied with, prepare, and administer the COVID-19 vaccine must be defined as eligible to do so according to the formal authorisation being used.

It is the responsibility of the Clinical Lead on shift to ensure the legal framework to administer vaccine is in place during the period of activity they are overseeing.

### 4.5 Safety and security of vaccines and related medicines

The responsible Chief Pharmacist must ensure that procedures for the safe and secure handling and storage of vaccine and medicines are in place in accordance with principles and guidance encompassed in *Professional guidance on the safe and secure handling of medicines* (Royal Pharmaceutical Society of Great Britain), available on https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines.

### 4.6 Storage and transportation of vaccines

The 'cold chain' is a term used to describe the cold temperature conditions in which certain products need to be kept during storage and distribution. Maintaining the cold chain ensures that vaccines are transported and stored according to the manufacturer's recommended temperature range until the point of administration. Vaccines must be stored at the correct temperature and transported only in approved and validated packaging, and the temperature of the vaccine carrier and contents must be monitored and reviewed before use.

Storage and transportation of vaccines must be undertaken in accordance with Trust Policy MP10 – Medicines Cold Chain Policy, relevant standard operating procedures and manufacturers' information. Cold chain temperatures must be monitored correctly and any 'out of specification' recordings addressed promptly and appropriately, and a

full audit trail maintained.

### 4.7 Workforce and training

All staff undertaking duties at the vaccination site must meet the national training standards and competencies for the COVID-19 vaccination programme. A training needs assessment is required for the roles within the vaccination services, with corresponding training materials and assessment process, to enable timely and focussed workforce development.

As detailed in *Professional guidance on the safe and secure handling of medicines* (Royal Pharmaceutical Society of Great Britain) the named individual ensures that accountable individuals are competent and supported in their role as it relates to the safe and secure handling of medicines'.

The roles assigned to support the rollout of COVID-19 vaccination need to be in accordance with legislation including that detailed in the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020.

### 4.8 Clinical Incidents and Precautions

A protocol for the management of anaphylaxis and in-date anaphylaxis packs must be available at all locations undertaking vaccination. The Resuscitation Council (UK) has provided specific guidance for vaccination settings and includes the following list of drugs that should be used in the treatment of anaphylaxis:

1 Intramuscular (IM) adrenaline 1:1,000;
2 Oxygen;
3 IV 0.9% saline or Hartmann's solution 500ml or 1,000ml bags.

All vaccination sites must consider the possibility of needing to manage more than one anaphylactoid response at once or in quick succession, therefore adequate supplies must be always available to manage multiple episodes. The ability to restock items quickly is essential to reduce the risk of having to suspend vaccination.
Any needle stick injuries must be addressed in accordance with Trust Policy HS03 - Sharps Safety Policy.

Clinical incidents and enquiries are to be managed in accordance with NHS England's Standard Operating Procedure for Management of COVID-19 vaccination clinical incidents and enquiries Coronavirus » COVID-19 vaccination programme (england.nhs.uk) this involves reporting via the MHRA Yellow Card system and the process described in the SOP. All clinical incidents requiring treatment should be reported as soon as possible after the event using the fast-track incident response pathway described. The incident should also be reported via the Trusts Datix system.

### 4.9 Maintenance of records

All records must be maintained in accordance with relevant Trust policies and procedures. These include the ordering, receipt and issue of vaccines, tracking of product, plus patient-focused records including consent and administration.
Any serious adverse reactions are to be escalated for immediate senior clinical input; such situations are to be fully documented following the event and a record kept of relevant product batch numbers. A record of all serious adverse events is to be provided to the Clinical Director of Pharmacy and the Clinical Lead.

### 4.10 Data Protection

All staff have a responsibility to ensure that they do not disclose information about the service, service users, staff members and corporate documentation to unauthorised individuals.

### 4.11 Disposal of vaccines and other waste

Disposal of waste vaccines and any sharps must be undertaken in a safe and secure manner in accordance with relevant Trust policy and standard operating procedures including HS03 - Sharps Safety Policy, HS10 Waste Management Policy and any COVID-19 vaccine specific procedures.

### 4.12 Business Continuity Planning

The Chief Pharmacist will be responsible for establishing an agreed business continuity plan in relation to safe and secure handling of vaccines, and tested in line with the organisational emergency preparedness processes and NHS Core Standards for Emergency Preparedness, Resilience and Response (https://www.england.nhs.uk/ourwork/eprr/gf/). The business continuity plan should detail how the service will respond, recover and manage its services during disruption relating to people, information, security, premises including utilities, facilities (particularly refrigerator) failure, supplier, IT and data.

## 5.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this policy require any additional Capital resources | Yes |
| 2 | Does the implementation of this policy require additional revenue resources | Yes |
| 3 | Does the implementation of this policy require additional manpower | Yes |
| 4 | Does the implementation of this policy release any manpower costs through a change in practice | No |
| 5 | Are there additional staff training costs associated with implementing this policy which cannot be delivered through current training programmes or allocated training times for staff. | Yes |
| | Other comments | |

## 6.0 Equality Impact Assessment

An initial equality analysis has been carried out and it indicates that there is no likely adverse impact in relation to Personal Protected Characteristics as defined by the Equality Act 2010.

## 7.0 Maintenance

The Chief Pharmacist is responsible for ensuring that this policy is reviewed regularly in line with new national and local guidance. The COVID-19 vaccination programme is a national priority in response to the COVID-19 pandemic and as such new and updated information is being published continuously. It is the responsibility of everyone involved in the COVID-19 vaccination programme to ensure that they are aware of and acting in line with the most current national guidance and best available evidence.

The first version of this policy must be ratified by the Senior Responsible Officer, Chief Pharmacist, Chief Medical Officer and the Chairperson of the Trust Medicines Management Group. Any amendments to this policy or associated procedures must be ratified by the Trust Medicines Management Group.

## 8.0 Communication and Training

All staff involved in the COVID-19 vaccination programme must read this policy and associated procedures. For staff with responsibility for handling the vaccine, including providing supervision, this policy and associated procedures will form part of the local on-boarding process and as such each member of staff must sign to say that they have read and understand all documents.

## 9.0 Audit Process

| Criterion | Lead | Monitoring method | Frequency | Committee |
|---|---|---|---|---|
| Number and type of clinical incidents | Governance Team | Review of Datix<br><br>Review of COVID-19 Quality Dashboard | Monthly | Living Well Group Governance Committee |
| Oversight by the medicine safety group | Clinical Lead – Living Well Group | Report of audit results | Annually | Medicine Management Group |

## 10.0 References - Legal, professional or national guidelines

This procedure is based on the Model NHS COVID-19 vaccine handling and management policy 2020-21 which has been adapted for local use https://www.sps.nhs.uk/articles/model-nhs-covid-19-vaccine-handling-and-management-policy-2020-21/.

## Part A - Document Control

| | | | | |
|---|---|---|---|---|
| Policy number and Policy version:<br><br>MP11<br><br>V2.1 | Policy Title<br><br>COVID-19 Vaccine handling and management policy | Status:<br><br>Final | | Author:<br>Chief Pharmacist<br><br>Director Sponsor:<br>Chief Medical Officer |
| Version / Amendment History | Version | Date | Author | Reason |
| | 1 | December 2020 | Angela Davis | New policy |
| | 1.1 | January 2021 | Angela Davis | Policy number changed to MP11 due to this being a Medicines Policy |
| | 1.2 | February 2021 | Angela Davis | Additional information added under section 3.4 pertaining to the requirement for a 'shift lead' when working under National Protocol, and section 4.8 to reference the NHSE SOP for reporting of clinical incidents. Inclusion of Attachments 1-8. |
| | 1.3 | March 2021 | Angela Davis | Inclusion of Attachment 9. |
| | 1.4 | October 2021 | Angela Davis | Minor updates to Procedure 5, Procedure 5 Attachment 1 and Procedure 5 Attachment 2. Inclusion of Attachment 10. |
| | 1.5 | March 2022 | Angela Davis | Reviewed by Chief Medical Officer – Extended to June 2022 pending full review |
| | 1.6 | October | Angela | Extension |

| | | | | |
|---|---|---|---|---|
| | | 2022 | Davis | |
| | 2.0 | December 2022 | Nicholas Carré | Updates to all procedures in response to Autumn Booster SPS updates attachment 11, 12, 13 Update of appendix 1 to include additional resources from NHSE and UKHSA Inclusion of, |
| | 2.1 | April 2023 | Clinical Lead – Living Well Group | Update of links, addition of Clinical lead responsibility for legal framework Addition of SOP 15 & 16 Updated SOP 3, 8, 11 |

| | |
|---|---|
| Intended Recipients:<br>All staff involved in the handling and management of the COVID-19 vaccine | |
| Consultation Group / Role Titles and Date:<br>Trust Medicines Management Group December 2020<br>Trust Policy Group December 2020<br>Trust Medicines Management Group April 2023 (Virtual Approval) | |
| Name and date of Trust level group where reviewed | Trust Policy Group – December 2022<br>Trust Policy Group Virtual Approval – April 2023 – V2.1 |
| Name and date of final approval committee | Trust Management Committee – January 2023 |
| Date of Policy issue | April 2023 |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | December 2023 every year, or sooner if new information is published which impacts on this policy |
| **Training and Dissemination:** All staff involved in the COVID-19 vaccination programme must read this policy and associated procedures. For staff with responsibility for handling the vaccine, including providing supervision, this policy and associated procedures will form part of the local on-boarding process and as such each member of staff must sign to say that they have read and understand all documents. | |
| **To be read in conjunction with:** Trust Policy **MP10 Medicine Cold Chain Policy** and associated Standard Operating Procedures | |
| Initial Equality Impact Assessment (all policies): Completed Yes / No Full Equality **Impact assessment (as required):** **Completed Yes / No / NA** If you require this document in an alternative format e.g., larger print please contact Policy Administrator 8904 | |
| Monitoring arrangements and Committee | This policy will be monitored by the Trust Medicines Management Group |

| | |
|---|---|
| **Document summary/key issues covered.** This policy details the overarching principles for governance of the safe and secure handling and management of COVID-19 vaccines in the end-to-end supply chain for the vaccination programme. | |
| Key words for intranet searching purposes | Vaccine<br>Vaccination<br>COVID-19<br>Immunisation |
| High Risk Policy?<br>Definition:<br>• Contains information in the public domain that may present additional risk to the public e.g. contains detailed images of means of strangulation.<br>• References to individually identifiable cases.<br>• References to commercially sensitive or confidential systems.<br>If a policy is considered to be high risk it will be the responsibility of the author and director sponsor to ensure it is redacted to the requestee. | No |

**Part B** **Ratification Assurance Statement**

Name of document: MP 11 COVID-19 Vaccine Handling and management Policy

Name of author: Nicholas Carré
Job Title: Deputy Clinical Director of Pharmacy

I, Nicholas Carré, the above named author confirm that:

- The Policy and Procedures presented for ratification meet all legislative, best practice and other guidance issued and known to me at the time of development of the said document.

- I am not aware of any omissions to the said document, and I will bring to the attention of the Executive Director any information which may affect the validity of the document presented as soon as this becomes known.

- The document meets the requirements as outlined in the document entitled Governance of Trust- wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines(OP01).

- The document meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable.

- I have undertaken appropriate and thorough consultation on this document and I have detailed the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the document following consultation.

- I will send the document and signed ratification checklist to the Policy Administrator for publication at my earliest opportunity following ratification.

- I will keep this document under review and ensure that it is reviewed prior to the review date.

Signature of Author:

Date:

Name of Person Ratifying this document (Director or Nominee):
Job Title:
Signature:

- I, the named Director (or their nominee) am responsible for the overall good governance and management of this document including its timely review and updates and confirming a new author should the current post-holder/author change.

To the person approving this document:

Please ensure this page has been completed correctly, then print, sign and email this page only to: The Policy Administrator

## IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

| | | |
|---|---|---|
| MP11 V2 | COVID-19 Vaccine Handling and Management Policy | |
| Reviewing Group | | Date reviewed: |
| **Implementation lead:** Nicholas Carré nicholas.carre@nhs.net 07901356813 | | |

| Implementation Issue to be considered (add additional issues where necessary) | Action Summary | Action lead / s (Timescale for completion) |
|---|---|---|
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | N/A | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | N/A | |
| Development of Forms, leaflets etc; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | Consent forms in use | Already implemented |
| Strategy / Policy / Procedure communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | To all staff involved in C-19 vaccination program | Ongoing as guidance develops |
| Financial cost implementation Consider Business case development | n/a | |
| Other specific Policy issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation | | |

# COVID-19 Vaccine Procedure 1
# Standard Operating Procedure for Ordering of COVID-19 Vaccine

## 1.0 Procedure Statement

This Standard Operating procedure (SOP) describes the process for ordering COVID-19 (BNT162b2) Vaccine from Public Health England (PHE).

This procedure is based on Specialist Pharmacy Services Guidance and Future NHS COVID-19 vaccination systems training and Guidance (you will need a FutureNHS account to access this information).

## 2.0 Accountabilities

The Clinical Director of Pharmacy is professionally accountable for the supply chain and the oversight of COVID-19 vaccine stock and related medicines on all vaccination sites operating under the jurisdiction of the Trust.

Designated pharmacy staff responsible for the COVID-19 Vaccine programme are responsible for the ordering and purchasing tasks within this procedure.

## 3.0 Procedure Detail / Actions

All ordering and stock management procedures are completed within the Foundry system.

All users of Foundry must have accounts and be able to access all areas necessary for their role. For any queries relating to Foundry access users must contact: **Foundry.Support@england.nhs.uk.**

Training on Foundry can be found here (you will need a FutureNHS account to access this information).

### 3.1 Stock Holding

3.1.1 Stocktake submissions are made on the Site Stock Manager module of Foundry.

3.1.2. A weekly stocktake of vaccine must be completed for each active vaccination centre. If a stocktake has not been completed within 7 days orders will not be able to be placed.

3.1.3 Stocktake values must be entered for all vaccine types listed in Foundry. This includes zero values for vaccines not in use.

### 3.2 Allocation Requests

3.2.1 Allocation requests are made on the Supply Planner module of Foundry.

3.2.2 Each week, all active sites must submit an allocation request for vaccine supply. Requests must be made within the timescales indicated on Foundry.

3.2.3 If you miss the deadline, the allocation will not be accepted, and the vaccination site will not be able to place an order for that week.

3.2.4 Separate allocation requests must be made for each vaccine required for that week.

3.2.5 Allocation requests will be reviewed by system and region vaccine teams and either approved or adjusted based on the stock holding and vaccine bookings and administration information held within Foundry.

3.2.6 Once the allocation has been reviewed and approved the Maximum Capacity (max cap) quantity will be shown on the system. This will then be automatically transferred into the ordering module, enabling orders to be placed.

**3.3 Ordering**

3.3.1 Ordering of vaccines and consumables is completed on the ordering platform module within the Foundry system. A list of the consumables supplied with each vaccine can be found in Appendix 1.

3.3.2 On the ordering platform you will find your max cap allocation for each vaccine for the week and the deadline that orders must be placed by. The deadline is specific to the vaccination site and is dependent on your specified delivery day.

3.3.3 Select the vaccine that you wish to order and click the place order button.

3.3.4 Enter the quantity of vaccine required. This must be in multiples of the available pack size.

3.3.5 For each item ordered check the correct product and quantity before confirming.

3.3.6 Sufficient consumables will be automatically added to the order. This includes alcohol wipes, syringes and needles and patient information leaflets. Should you not require the syringe and needles or alcohol wipes, they can be adjusted after the order has been processed.

3.3.7 You can also add additional consumable such as anaphylaxis kits and needles for morbidly obese patients at this stage.

3.3.8 To adjust the consumables or quantity of vaccine required go to the “your orders” tab of the ordering platform and select edit order. You will then be able to remove and add consumables and adjust the quantity of vaccine.

3.3.9 Adjustments can only be made until the deadline stated on the system.

3.3.10 If you miss the deadline for ordering, then no vaccine can be ordered for that week.

### 3.4 Mutual Aid

3.4.1 If you have too much or not enough vaccine for any reason, a mutual aid request can be made. The Transfer Tool module in Foundry is used for this process. This allows you to offer any excess vaccine you may have to others and request a supply if you need extra. This system is reliant on vaccination sites making vaccine available and there is no guarantee of any supply being available when needed.

3.4.2 Mutual aid transfers between sites operated by RWT must be authorised by the Lead Pharmacist for COVID-19 vaccine services prior to any transfer occurring.

3.4.3 All stock transfers must be recorded on the Transfer Tool module in Foundry, and they must be a fully auditable in accordance with SOP 3: The use of cool boxes to transport COVID-19 vaccines

### 3.5 Supply of Vaccine to Hospital Vaccine Hub

3.5.1 The Pharmacy Procurement Team will manage supply of vaccine to the Hospital Vaccine Hub ensuring as far as possible the availability of sufficient in-date vaccine for all scheduled vaccinations. If any actual or potential delays in vaccine supply are identified by the Pharmacy Procurement Team, this must be escalated immediately to the Lead Pharmacist for COVID-19 Vaccine who in turn will inform the Clinical Lead for the Vaccine Hub and the Operational Lead for the Vaccine Hub.

### 3.7 Cancelling Orders

Orders can only be cancelled before the order cut off time within Foundry. To do this you would edit the order quantity to zero (see 3.3.8).

## APPENDIX 1

**Vaccine linked consumables bundle per vaccine type**

| Bundle Name | Product |
|---|---|
| Spikevax® | Combined Needle & Syringe (CNS) |
| | Steret Alcohol Wipes |
| | Patient Information Leaflet– can't be deselected |
| Spikevax® Bivalent | Combined Needle & Syringe (CNS) |
| | Steret Alcohol Wipes |
| | Patient Information Leaflet– can't be deselected |
| Comirnaty® Bivalent | Combined Needle & Syringe (CNS) |
| | Steret Alcohol Wipes |
| | Patient Information Leaflet– can't be deselected |
| Comirnaty® 30 microgram/dose | Combined Needle & Syringe (CNS) |
| | Diluent Needle & Syringe |
| | Sodium Chloride |
| | Steret Alcohol Wipes |
| | Patient Information Leaflet– can't be deselected |
| Comirnaty® 10 microgram/dose | Combined Needle & Syringe (CNS) |
| | Diluent Needle & Syringe |
| | Sodium Chloride |
| | Steret Alcohol Wipes |
| | Patient Information Leaflet– can't be deselected |

## 4.0 Equipment Required

Access to Foundry

## 5.0 Training

Designated pharmacy staff responsible for ordering vaccine must read this procedure and will already be trained in the use of Foundry.

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | Yes – No |
| 2 | Does the implementation of this document require additional revenue resources | Yes – No |
| 3 | Does the implementation of this document require additional manpower | Yes – No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | Yes – No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | Yes – No |
| | Other comments | |

## Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 1 v2 | **Title of Procedure/Guidelines**<br><br>Standard Operating Procedure for Ordering COVID-19 Vaccine | **Status:**<br><br>**Final** | | **Author: Clinical Director of Pharmacy**<br><br>**Director Sponsor: Chief Medical Officer.** |
| Version / Amendment History | Version | Date | Author | Reason |
| | v1 | 29/12/2020 | Clinical Director of Pharmacy | New SOP |
| | v2 | 20/09/2022 | Deputy Clinical Director of Pharmacy | Updated process for ordering through Foundry and to include the multiple vaccine types now available. |
| **Intended Recipients:** Pharmacy Procurement staff, Designated pharmacy staff working in vaccination sites. | | | | |
| **Consultation Group / Role Titles and Date:**<br>Trust Medicines Management Group (MMG) | | | | |
| **Name and date of group where reviewed** | Medicines Management Group (MMG) 09/2022<br>Trust Policy Group – December 2022 | | | |
| **Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Medicines Management Group (MMG) 09/2022<br>Trust Management Committee – January 2023 | | | |
| **Date of Procedure/Guidelines issue** | September 2022 | | | |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | August 2023 (every 12 months) | | | |

| | |
|---|---|
| **Training and Dissemination:**<br>This procedure will form part of the COVID-19 vaccine training programme | |
| **To be read in conjunction with:**<br>COVID-19 Vaccine handling and management policy and associated procedures | |
| **Initial Equality Impact Assessment: Completed**<br>**Full Equality Impact assessment (as required): No** | |
| **Contact for Review** | Clinical Director of Pharmacy |
| **Monitoring arrangements** | Trust Medicines Management Group |
| **Document summary/key issues covered**<br>This Standard Operating procedure (SOP) describes the process for ordering COVID-19 Vaccine | |
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination |

**IMPLEMENTATION PLAN**
**To be completed when submitted to the appropriate committee for consideration/approval**

| | | |
|---|---|---|
| **Procedure/Guidelines number and version** | **Title of Procedure/Guidelines** | |
| **Reviewing Group** | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** | | |

| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
|---|---|---|
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | | |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | | |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | | |
| Financial cost implementation<br>Consider Business case development | | |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | | |

# COVID-19 Vaccine Procedure 2 Standard Operating Procedure for Receipt and Storage of COVID-19 Vaccines at 2°C – 8°C

## 1.0 Procedure Statement

This Standard Operating procedure (SOP) describes the process of receipt of refrigerated COVID-19 vaccines and recording of data attributes needed to provide data for the national vaccination programme.

If staff members are presented with frozen vaccines supplied at ultra-low temperatures this SOP must be used in conjunction with:

- COVID-19 Vaccine Procedure 2a *Receipt of frozen Comirnaty, thawing, and assigning a post-thaw expiry date* or
- COVID-19 Vaccine Procedure 2b *Receipt of frozen Spikevax, thawing, and assigning a post-thaw expiry date.*

This procedure is based on Specialist Pharmacy Services Procedure HCV 1 Receipt and storage of COVID-19 Vaccines at 2°C – 8°C.

## 2.0 Accountabilities

The Clinical Director of Pharmacy is professionally accountable for the supply chain and oversight of stock management within Pharmacy and on all vaccination sites operating within the jurisdiction of the Trust.

The COVID-19 Lead pharmacist, will ensure all staff undertaking receipt of COVID-19 vaccines are adequately trained and familiar with the contents of this SOP and SOP 2a and 2b.

Suitably trained members of staff within Pharmacy and vaccination sites are responsible for receipt of vaccines within their area, unpacking and checking them, maintaining the cold chain at all times, and storing them in the correct location immediately upon delivery. They must be familiar with this SOP before carrying out these operations.

## 3.0 Procedure Detail / Actions

Deliveries of COVID-19 Vaccines to the Trust will either be:

- at fridge temperature in a suitable fridge line container, or
- frozen in a shipping container holding dry ice.

If received frozen in dry ice, the following requirements are needed.

- Only staff suitably trained and competent in handling dry ice (carbon dioxide) may undertake the procedure to unpack the container. In addition to the personal protective equipment (PPE) provided, staff must wear clothing that covers their legs and arms, and shoes must be completely enclosed.

- Part 3.2 of this process will take place simultaneously with COVID-19 Vaccine Procedure 2a *Receipt of frozen Comirnaty, thawing, and assigning a post-thaw expiry date* **or** Procedure 2b *Receipt of frozen Spikevax, thawing, and assigning a post-thaw expiry date*. This will require two members of staff.

- One member of staff must lead on this SOP and the other member of staff must lead on following COVID-19 Vaccine Procedure 2a *Receipt of frozen Comirnaty, thawing, and assigning a post-thaw expiry date* **or** Procedure 2b *Receipt of frozen Spikevax, thawing, and assigning a post-thaw expiry date.* This will require two members of staff

- When working in pairs, it is the responsibility of both staff members to continue to observe all local COVID-19 precautions.

**COVID-19 Vaccine vials must remain upright at all times.**

### 3.1 Accepting Deliveries

3.1.1 All staff working where deliveries are made must be aware of the importance and urgency of maintaining the cold chain. All staff must read the Trust Cold Chain Policy MP10 and strictly adhere to it.

3.1.2 Before receiving a vaccine delivery ensure correct PPE is readily available:

- Fridge Line – non- latex gloves and
- Freezer line – dry-ice handling PPE (gloves/gauntlets and goggles or visor).

3.1.3 Only suitably trained members of staff can accept deliveries. Maintaining the cold chain is paramount and staff must undertake this process immediately and swiftly.

3.1.4 Retrieve the delivery note from the package and cross-check against the order information. Check:

- That the number of outer boxes matches the number listed on the delivery note, carrier's receipt or proof-of-delivery device,
- the shipment is in good condition and no damage is evident,
- the shipment is addressed correctly, and

- whether the transit time for Comirnaty 30 Concentrate, Spikevax Original or Spikevax Bivalent has exceeded 6 hours. This information will be provided by the delivery driver.

N.B there are no transit restrictions for Comirnaty 10 Concentrate.

3.1.5 If any part of the delivery is damaged, missing or otherwise not as expected, report without delay to the COVID-19 Lead pharmacist, or a member of the Senior Leadership Team.

3.1.6 If the delivery appears to be in order, accept the shipment according to the established acceptance-of-delivery process.

### 3.2 Unpacking and storing the vaccine in the refrigerator

**IMPORTANT: if the delivery is a frozen product, this part of the process will take place simultaneously with that described in COVID-19 Vaccine Procedure 2a *Receipt of frozen Comirnaty, thawing, and assigning a post-thaw expiry date* or Procedure 2b *Receipt of frozen Spikevax, thawing, and assigning a post-thaw expiry date*.**

3.2.1 Put on appropriate PPE for vaccine delivery temperature.

3.2.2 Put the delivery onto a trolley and transport it to the assigned location where it will be stored.

3.2.3 When in the assigned location remove the vaccine from the delivery package and check:

- tamper evident seal is intact,
- check for any damage and
- check the identity, batch number, expiry date and quantities against the delivery note.

3.2.4 If the transit time exceeded 6 hours (see 3.1.4), write the journey time in hours on the carton (e.g., “transported for 8 hours”). This information may be needed if the cartons are to be subsequently transported.

3.2.5 Put the vaccines in the correct vaccine refrigerator without delay with the shortest dated foremost to ensure adequate stock rotation.

3.2.6 Dispose of the delivery packaging:

- fridge line – dispose of any recyclable materials as per normal procedure, and

- frozen line – transport the container on a trolley to the secure area outside of Pharmacy Stores (refer to COVID-19 Vaccine Procedure 2a or 2b).

### 3.3 Receiving Vaccine into Stock

3.3.1 For each order, receive the goods on to the stock control system (Foundry site stock manager module).

3.3.2 If a pharmacy stock management system is in use, receipt of vaccine on to the system must capture the following product details:

- date and time received into system,
- supplier,
- Purchase order number,
- dm+d medicine name (AMP/P; this must be the 'branded' level description),
- dm+d ID code,
- pack size and number of vials received,
- batch number (this cannot be scanned and **must** be checked by a second person to ensure the correct information is recorded), and
- post thaw expiry date.

3.3.3 Endorse the delivery note with a signature and the time and date to indicate:

- the correct goods have been received,
- the quantities are correct, and
- the batch numbers and expiry dates on the delivery note are correct.

3.3.4 File the completed delivery documentation in the delivery note folder or in accordance with local delivery note procedures and retain for 2 years.

### 3.4 Dealing with Problems and Errors on Deliveries

3.4.1 In the event goods arrive:

- damaged,
- expired,
- in a quantity is different from either the order or the delivery note,
- there are any other discrepancies (e.g., unable to confirm that product has been maintained between 2°- 8°C during transit), and
- non-delivery.

Escalate to the COVID-19 Lead pharmacist or a member of the Senior Leadership Team.

3.4.2 The COVID-19 Lead pharmacist will inform the Clinical Director of Pharmacy and the System Vaccine Operational team and the supplier.

3.4.3 Quarantine the affected package in the fridge by placing it in a marked sealed

container. If a spill is evident, also refer to COVID-19 Vaccine Procedure 10. Retain any damaged goods or packaging for subsequent inspection by the supplier.

## 4.0 Equipment Required

Access to Foundry

## 5.0 Training

All staff working in Pharmacy Goods-in and Distribution must read this procedure.

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | Yes – No |
| 2 | Does the implementation of this document require additional revenue resources | Yes – No |
| 3 | Does the implementation of this document require additional manpower | Yes – No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | Yes – No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | Yes – No |
| | Other comments | |

## Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 2 v2 | **Title of Procedure/Guidelines**<br><br>Standard Operating Procedure for Receipt and Storage of COVID-19 Vaccines at 2°C – 8°C | **Status:**<br><br>**Final** | | **Author: Clinical Director of Pharmacy**<br><br>**Director Sponsor: Medical Director** |
| Version / Amendment History | Version | Date | Author | Reason |
| | v1 | 29/12/2020 | Clinical Director of Pharmacy | New SOP |
| | v2 | 20/09/2022 | Deputy Clinical Director of Pharmacy | Consolidation of SPS SOPs PVH2, AVH2 and MVH2 integrated process for all vaccine types. |
| **Intended Recipients:** Designated staff in COVID-19 vaccine services and pharmacy department | | | | |
| **Consultation Group / Role Titles and Date:**<br>Trust Medicines Management Group (MMG) | | | | |
| **Name and date of group where reviewed** | Medicines Management Group (MMG) 09/2022<br>Trust Policy Group – December 2022 | | | |
| **Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Medicines Management Group (MMG) 09/2022<br>Trust Management Committee – January 2023 | | | |
| **Date of Procedure/Guidelines issue** | September 2022 | | | |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | August 2023 every 12 months | | | |

| | |
|---|---|
| **Training and Dissemination:**<br>COVID-19 Lead Pharmacist will ensure all staff undertaking receipt of COVID-19 Vaccines are adequately trained & familiar with the contents of this SOP, SOP 2a and SOP 2b. | |
| **To be read in conjunction with:**<br>COVID-19 Vaccine handling and management policy and associated procedures | |
| **Initial Equality Impact Assessment: Completed**<br>**Full Equality Impact assessment (as required): No** | |
| **Contact for Review** | Clinical Director of Pharmacy |
| **Monitoring arrangements** | Trust Medicines Management Group |
| **Document summary/key issues covered**<br>This Standard Operating procedure (SOP) describes the process for Receipt and Storage of refrigerated COVID-19 Vaccine | |
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination |

**IMPLEMENTATION PLAN**
**To be completed when submitted to the appropriate committee for consideration/approval**

| | | |
|---|---|---|
| **Procedure/Guidelines number and version** | **Title of Procedure/Guidelines** | |
| **Reviewing Group** | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** | | |

| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
|---|---|---|
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | | |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | | |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | | |
| Financial cost implementation<br>Consider Business case development | | |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | | |

# COVID-19 Vaccine Procedure 2a Standard Operating Procedure for the Receipt of ULT Frozen Comirnaty, Thawing, and Assigning a Post-thaw Expiry Date

## 1.0 Procedure Statement

This Standard Operating Procedure (SOP) describes the process for the receipt of ULT frozen Comirnaty, thawing, and assigning a post thaw expiry date, ensuring the correct handling is observed.

This SOP is applicable to the receipt and **immediate thawing** in a refrigerator of all Comirnaty vaccines received frozen at -90°C to -60°C.

This process will take place simultaneously with that described in COVID-19 Vaccine Procedure 2 *Receipt and Immediate Storage of Thawed Pfizer-BioNTech COVID-19 Vaccine*. One person should lead on performing the tasks in this SOP and the other person on performing the tasks in SOP 2.

This procedure is based on Specialist Pharmacy Services Procedure *HCV 3 of ULT Frozen Comirnaty, thawing and assigning a post-thaw expiry date*.

## 2.0 Accountabilities

The Clinical Director of Pharmacy is professionally accountable for the supply chain and oversight of stock management within Pharmacy and on all vaccination sites operating within the jurisdiction of the Trust.

The COVID-19 Lead pharmacist will ensure all staff undertaking receipt of COVID-19 vaccines are adequately trained & familiar with the contents of this SOP and SOP 2

Suitably trained members of staff within Pharmacy and vaccination sites are responsible for receipt of vaccines within their area, unpacking and checking them, maintaining the cold chain at all times, and storing them in the correct location immediately upon delivery. They must be familiar with this SOP before carrying out these operations.

## 3.0 Procedure Detail / Actions

Only staff suitably trained and competent in handling dry ice (carbon dioxide) and the allocation of new expiry dates may perform this activity.

A second check is required at point 3.2.10. This person must also be trained and competent in handling dry ice and the allocation of new expiry dates.

This process will take place simultaneously with that described in COVID-19 Vaccine Procedure 2 *Receipt and Storage of refrigerated COVID-19 Vaccines*. Two people are required. One person should lead on performing the tasks in this SOP and the other person on performing the tasks in SOP 2.

When working in pairs, it is the responsibility of both staff members to continue to observe all local COVID-19 precautions.

### 3.1 Health and Safety rules for handling dry ice

3.1.1 Dry ice may cause cold burns, and carbon dioxide gas may cause asphyxiation if it is not allowed to escape into the atmosphere.

3.1.2 Always work in pairs when unpacking deliveries from dry ice.

3.1.3 In addition to the PPE provided (mid-length gauntlets, goggles or face shield), staff must wear clothing that covers their legs and arms, and shoes must be completely enclosed.

3.1.4 Always ensure good ventilation:

- Never move shippers containing dry ice in a lift and
- Never place shippers containing dry ice in a cold store or fridge or other unventilated areas.

3.1.5 Always leave the dry ice in the shipper.

3.1.6 First aid for dry ice burns is the same as for heat burns: treat with tepid running water and seek medical attention.

3.1.7 Only handle dry ice if you have been trained to do so.

### 3.2 Process

3.2.1 Ensure all the equipment you require for dry-ice handling is available in the preparative services room. You are required to have the following equipment available: full PPE (mid-length gauntlets and goggles or face shield), disposable gloves to wear under the gauntlets, a trolley (if necessary), a roll of Comirnaty thaw labels (see Fig.1) for expiry reduction, an ice shovel to remove the top layer of dry ice, blue sharps bin to decant dry ice into while you are unpacking the vaccine, and a pair of tweezers for removal of the labels from their backing.

3.2.2 Transport the shipping container to prep services where the vaccine is to be stored – DO NOT USE THE LIFT. On entering the preparative services room, place the shipping container on the table next to the COVID-19 vaccine fridge. Ensure all of the windows in the room are open, open the door to the pharmacy corridor, and open the windows on the pharmacy corridor to support full ventilation.

3.2.3 Ensure you work on the table next to the designated COVID-19 vaccine fridge.

3.2.4 Check the temperature display on the fridge to ensure it is between 2 and 8$^{O}$C. If it is not, do not proceed and follow the procedure for fridge temperature excursions.

3.2.5 Check that the shipping container is within its expiry date.

3.2.6 Put on the PPE, if not already done so.

3.2.7 Open the container and inner lid; use the ice shovel remove the top layer of dry ice into the blue sharps bin. Remove the carton from the shipping container and place onto the table immediately adjacent to the fridge.

3.2.8 Allow the other person to perform receipt checks according to COVID-19 Vaccine Procedure 2: *Receipt and Storage of refrigerated COVID-19 Vaccines*.

N.B. If any vials are broken, wait for them to warm above freezing temperatures and then deal with the spillage following SOP 10. No special spillage procedures are required for thawed Comirnaty COVID-19 vaccines.

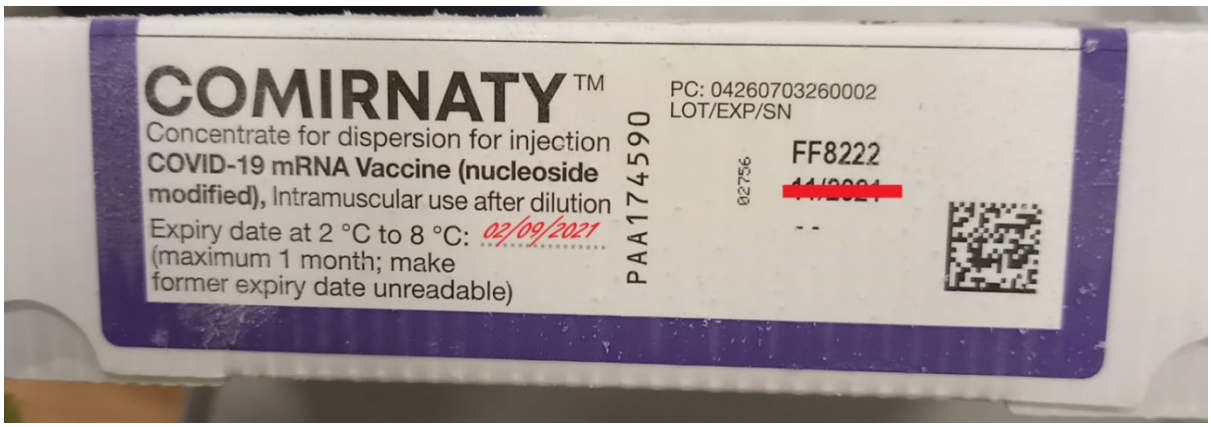
3.2.9 Return the decanted dry ice back into the shipping container and replace the inner lid to contain the dry ice.

3.2.10 Amend the expiry date:

- calculate the post-thaw expiry date (this is 31 days from removal from the shipper, provided this is not past the original expiry date0,
- write the post thaw expiry date on the carton in the space provided using a narrow-tipped permanent marker (see images below),
- cross out the original expiry date, and
- ask the other person to check that the calculated post-thaw expiry date is correct.

N.B. the expiry is calculated to the nearest day. There is no need to record expiry time. The expiry will be at midnight at the end of the calculated day of expiry.

<u>Comirnaty 30 Concentrate</u>



Comirnaty 10 Concentrate


3.2.13 Transfer the cartons into the COVID-19 vaccine fridge to thaw. This may take up to 3 hours.

3.2.14 Whilst wearing the PPE, close the shipper box and remove this to the designated area under the pharmacy canopy outside of the Pharmacy Bulk Stores doors. You should ensure the route taken avoids the use of any lifts.

3.2.15 Position the shipper container outside the door against the left-hand side wall and make sure the lid is ajar to allow gas sublimation.

3.2.16 Secure the location and leave to allow the carbon dioxide to turn to gas (sublime) for at least 24 hours.

3.2.17 Remove PPE and store in the designated clean, dry location. Each member of staff should be allocated their own visor to prevent any cross contamination.

3.2.18 Check the refrigerator is still within the range 2°C to 8°C and that no alarms are displayed. If out of range or it is showing an alarm, do not proceed; report to COVID-19 Lead Pharmacist or member of the senior leadership team.

3.2.19 Remove the apron and the disposable gloves and discard these in the appropriate waste bin. Now wash your hands.

3.2.20 Receive the COVID-19 vaccine according to COVID-19 Vaccine Procedure 2: *Receipt and Storage of refrigerated COVID-19 Vaccines*.

3.2.19 The nominated staff must return after 24hr to the shipping container to confirm if the carbon dioxide has completely sublimed. Once this is confirmed, discard the shipping container with general and cardboard waste following normal Trust procedures.

## 4.0 Equipment Required

Mid-length gauntlets

Goggles or face shield

Disposable apron and gloves

Blue sharps bin

Ice shovel

Tweezers

Thawing label

Pen

## 5.0 Training

All staff working in Pharmacy Goods-in and Distribution must read this procedure and the dry ice risk assessment.

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | Yes – No |
| 2 | Does the implementation of this document require additional revenue resources | Yes – No |
| 3 | Does the implementation of this document require additional manpower | Yes – No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | Yes – No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | Yes – No |
| | Other comments | |

## Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 2a v3 | **Title of Procedure/Guidelines**<br><br>COVID-19 Vaccine Procedure 2a Standard Operating Procedure for receipt of ULT frozen Comirnaty, thawing, and assigning of a post thaw expiry date | **Status:**<br><br>**Final** | | **Author: Clinical Director of Pharmacy**<br><br>**Director Sponsor: Chief Medical Officer** |
| Version / Amendment History | Version | Date | Author | Reason |
| | v1 | 29/12/2020 | Clinical Director of Pharmacy | New SOP |
| | V2 | 31/01/2021 | Clinical Director of Pharmacy | Extra detail added following user feedback |
| | V3 | 20/09/2022 | Deputy Clinical Director of Pharmacy | Updated and supersedes SPS VH4 |
| **Intended Recipients:** Designated staff in COVID-19 vaccine services and pharmacy department | | | | |
| **Consultation Group / Role Titles and Date:**<br>Trust Medicines Management Group (MMG) | | | | |
| **Name and date of group where reviewed** | Medicines Management Group (MMG) 09/2022<br>Trust Policy Group – December 2022 | | | |
| **Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Medicines Management Group (MMG) 09/2022<br>Trust Management Committee – January 2023 | | | |
| **Date of Procedure/Guidelines issue** | September 2022 | | | |

| | |
|---|---|
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | August 2023 every 12 months |

| | |
|---|---|
| **Training and Dissemination:**<br>Covid-19 Lead Pharmacist will ensure all staff undertaking receipt of COVID-19 Vaccines are adequately trained & familiar with the contents of this SOP, SOP 2 and SOP 2b. | |
| **To be read in conjunction with:**<br>COVID-19 Vaccine handling and management policy and associated procedures | |
| **Initial Equality Impact Assessment: Completed**<br>**Full Equality Impact assessment (as required): No** | |
| **Contact for Review** | Clinical Director of Pharmacy |
| **Monitoring arrangements** | Trust Medicines Management Group |
| **Document summary/key issues covered**<br>This Standard Operating procedure (SOP) describes the process of receipt of ULT frozen Comirnaty, thawing, and assigning a post thaw expiry date | |
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination |

**IMPLEMENTATION PLAN**
**To be completed when submitted to the appropriate committee for consideration/approval**

| | | |
|---|---|---|
| **Procedure/Guidelines number and version** | **Title of Procedure/Guidelines** | |
| **Reviewing Group** | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** | | |

| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
|---|---|---|
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | | |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | | |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | | |
| Financial cost implementation<br>Consider Business case development | | |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | | |

# COVID-19 Vaccine Procedure 2b Standard Operating Procedure for the Receipt of Frozen Spikevax, Thawing, and Assigning a Post-thaw Expiry Date

## 1.0 Procedure Statement

This Standard Operating Procedure (SOP) describes the process of the receipt of frozen Spikevax, thawing, and assigning a post thaw expiry date, ensuring the correct handling is observed.

This SOP is applicable to the receipt and **immediate thawing** in a refrigerator of all Comirnaty vaccines received frozen at -25°C to -15°C.

This process will take place simultaneously with that described in COVID-19 Vaccine Procedure 2 *Receipt and Immediate Storage of Thawed Pfizer-BioNTech COVID-19 Vaccine.* One person should lead on performing the tasks in this SOP and the other person on performing the tasks in SOP 2.

This procedure is based on Specialist Pharmacy Services Procedure *HCV 2 of ULT Frozen Comirnaty, thawing and assigning a post-thaw expiry date*

## 2.0 Accountabilities

The Clinical Director of Pharmacy is professionally accountable for the supply chain and oversight of stock management within Pharmacy and on all vaccination sites operating within the jurisdiction of the Trust.

The COVID-19 Lead pharmacist, will ensure all staff undertaking receipt of COVID-19 vaccines are adequately trained & familiar with the contents of this SOP and SOP 2

Suitably trained members of staff within Pharmacy and vaccination sites are responsible for receipt of vaccines within their area, unpacking and checking them, maintaining the cold chain at all times, and storing them in the correct location immediately upon delivery. They must be familiar with this SOP before carrying out these operations.

## 3.0 Procedure Detail / Actions

Only staff suitably trained and competent in handling dry ice (carbon dioxide) and the allocation of new expiry dates may perform this activity.

A second check is required at point 3.2.10.

This process will take place simultaneously with that described in COVID-19 Vaccine Procedure 2 *Receipt and Storage of refrigerated COVID-19 Vaccines*. Two people are required. One person should lead on performing the tasks in this SOP and the other person on performing the tasks in SOP 2.

When working in pairs, it is the responsibility of both staff members to continue to observe all local COVID-19 precautions.

### 3.1 Health and Safety rules

3.1.1 The handling of frozen vaccines does not usually require the wearing of protective gloves; however, some individual staff may not be able to tolerate cold temperatures and may need to wear lightweight gloves for comfort.

### 3.2 Process

3.2.1 Ensure all the equipment you require for frozen vaccine is available. Some staff may not be able to tolerate cold temperatures and may need to wear lightweight gloves for comfort.

3.2.2 Check:

- the number of shippers matches the number listed on the delivery note, carrier's receipt or proof-of-delivery device,
- all shippers are in good condition and no damage is evident,
- all shippers are addressed correctly, and
- the shippers have not expired.

3.2.3 Transport the shipping container to the location where the vaccine is to be stored.

3.2.4 Check the temperature display on the fridge to ensure it is between 2 and 8$^{O}$C. If it is not, do not proceed and follow procedure for fridge temperature excursions.

3.2.5 Put on the PPE, if not already done so.

3.2.6 Open the container and remove the carton from the shipping container and place onto the table immediately adjacent to the fridge.

3.2.7 Allow the other person to perform receipt checks according to COVID-19 Vaccine Procedure 2: *Receipt and Storage of refrigerated COVID-19 Vaccines*.

N.B. If any vials are broken, wait for them to warm above freezing temperatures and then deal with the spillage following SOP 10. No special spillage procedures are required for thawed Comirnaty COVID-19 vaccines.

3.2.9 Complete one thaw label (see Appendix 1) for each carton detailing:

- time and date removed from the shipper,
- time and date of expiry (i.e. 30 days from removal from the shipper), and

- batch number.

N.B. the expiry is calculated to the nearest day. There is no need to record expiry time. The expiry will be at midnight at the end of the calculated day of expiry.

3.2.10 Obtain a check from another suitably trained and competent person:

- check the thawed expiry date and time calculation,
- check the batch number,
- check that there are exactly the same number of completed thaw labels as there are cartons, and
- sign the labels to confirm the check is complete.

3.2.11 Cross through the original expiry on the carton.

3.2.12 Attach one thaw label to each of the cartons, ensuring that the original batch number is not covered.

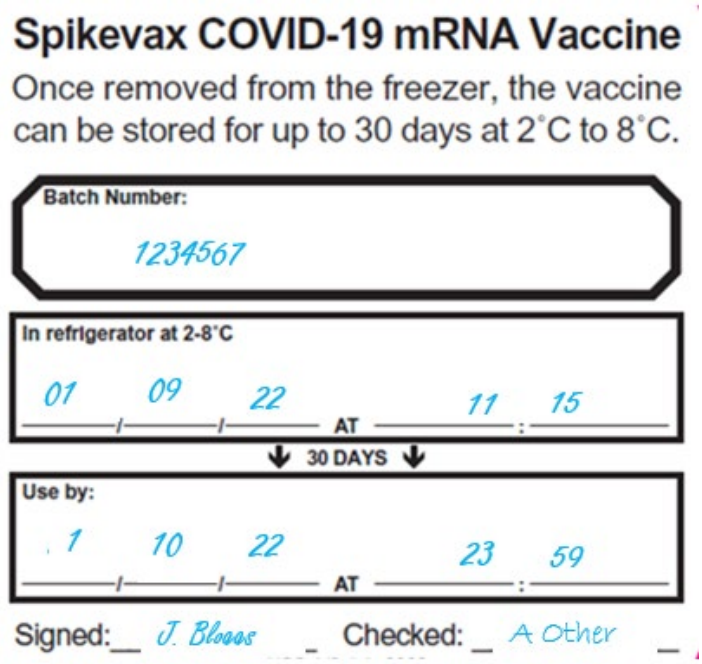
3.2.13 Transfer the cartons into the COVID-19 vaccine fridge to thaw. This may take up to 24 hours.

3.2.14 Check the refrigerator is still within the range 2°C to 8°C and that no alarms are displayed. If out of range or is showing an alarm, do not proceed and report to COVID-19 Lead Pharmacist or member of the senior leadership team.

3.2.15 Receive the COVID-19 vaccine according to COVID-19 Vaccine Procedure 2: Receipt and Storage of refrigerated COVID-19 Vaccines.

**Appendix 1**

Example of a completed thaw label. If blank thaw labels are not available, the template below may be used as an example for locally printed labels.



## 4.0 Equipment Required

Lightweight gloves

Thawing label

Pen

## 5.0 Training

All staff working in Pharmacy Goods-in and Distribution must read this procedure and the dry ice risk assessment.

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | Yes – No |
| 2 | Does the implementation of this document require additional revenue resources | Yes – No |
| 3 | Does the implementation of this document require additional manpower | Yes – No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | Yes – No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | Yes – No |
| | Other comments | |

## Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 2b v1 | **Title of Procedure/Guidelines**<br><br>COVID-19 Vaccine Procedure 2a Standard Operating Procedure for receipt of frozen Spikevax, thawing, and assigning of a post thaw expiry date | **Status:**<br><br>**Final** | | **Author: Clinical Director of Pharmacy**<br><br>**Director Sponsor: Medical Director** |
| Version / Amendment History | Version | Date | Author | Reason |
| | v1 | 20/09/2022 | Deputy Clinical Director of Pharmacy | New SOP |

| | |
|---|---|
| **Intended Recipients:** Designated staff in COVID-19 vaccine services and pharmacy department | |
| **Consultation Group / Role Titles and Date:**<br>Trust Medicines Management Group (MMG) | |
| **Name and date of group where reviewed** | Medicines Management Group (MMG) 09/2022<br>Trust Policy Group – December 2022 |
| **Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Medicines Management Group (MMG) 09/2022<br>Trust Management Committee – January 2023 |
| **Date of Procedure/Guidelines issue** | September 2022 |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | August 2023 every 12 months |

| | |
|---|---|
| **Training and Dissemination:**<br>COVID-19 Lead Pharmacist will ensure all staff undertaking receipt of COVID-19 Vaccines are adequately trained & familiar with the contents of this SOP, SOP 2 and SOP 2b. | |
| **To be read in conjunction with:**<br>COVID-19 Vaccine handling and management policy and associated procedures | |
| **Initial Equality Impact Assessment: Completed**<br>**Full Equality Impact assessment (as required): No** | |
| **Contact for Review** | Clinical Director of Pharmacy |
| **Monitoring arrangements** | Trust Medicines Management Group |
| **Document summary/key issues covered**<br>This Standard Operating procedure (SOP) describes the process of receipt of frozen Spikevax, thawing, and assigning a post thaw expiry date | |
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination |

**IMPLEMENTATION PLAN**
**To be completed when submitted to the appropriate committee for consideration/approval**

| | | |
|---|---|---|
| **Procedure/Guidelines number and version** | **Title of Procedure/Guidelines** | |
| **Reviewing Group** | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** | | |

| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
|---|---|---|
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | | |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | | |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | | |
| Financial cost implementation<br>Consider Business case development | | |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | | |

# COVID-19 Vaccine Procedure 3 Standard Operating Procedure for the use of Cool-boxes to Transport COVID-19 Vaccines to End User Locations and for Mutual Aid

## 1.0 Procedure Statement

This SOP describes the processes for:

- removing vaccine vials from the refrigerator and preparing them for transport,
- transcribing the post-thaw expiry dates onto vial transport container,
- preparing a cool box for use,
- transporting the cool box to end user locations, and
- receipt of vaccines at end-user locations.

The term user location refers to Trust vaccination sites, Pop-up sites as well as care homes or patients' homes. Vaccine should be ordered and delivered wherever possible to the location where it is to be used.

This procedure is based on Specialist Pharmacy Services Procedure *HCV 6 use of cool boxes to transport COVID-19 vaccines.*

This procedure MUST be read in conjunction with Trust Policy MP10 Medicine Cold Chain Policy.

The following are excluded from the scope.

- Returning un-used sealed vials to original dispatching site. This may be necessary in exceptional circumstances only. Refer to NHSE Standard Operating Procedure: roving and mobile models: *Coronavirus » Standard operating procedure: Roving and mobile models (england.nhs.uk)*.
- Movement of punctured vials. NHSE has published a position statement which provides further information on the microbial contamination risks associated with moving punctured vials and identifies potential risk reduction measures. *Coronavirus » Position statement for reducing microbial risk when transporting COVID-19 vaccines in pop up, roving, and mobile models (england.nhs.uk)*

If any of the three scenarios above are approved, the transport principles described in this SOP will remain generally applicable.

## 2.0 Accountabilities

The Clinical Director of Pharmacy is professionally accountable for the safe and secure transportation of vaccines ensuring maintenance of the cold chain at all times and a documented audit trail.

Suitably trained members of staff within Pharmacy or the COVID-19 vaccine service are responsible for transporting the vaccine safely and securely from its storage location to the end user location, maintaining the cold chain at all times, and storing the vaccines in the correct location immediately upon delivery.

All steps undertaken in section 3.2 are classed as assembly of medicines and must be undertaken by or under the supervision of a doctor, registered nurse, or pharmacist under Regulation 3A of Human Medicines (Coronavirus) (Further Amendments) Regulations 2020. These listed healthcare professionals can work under this regulation to label coronavirus vaccine as long as they are acting in the course of their professional duties for the purpose of the supply of the vaccine.

## 3.0 Procedure Detail / Actions

### 3.1 Preparing the cool box

3.1.1 Validated medical grade cool boxes must be used to provide ongoing assurance that the vaccines will be maintained within the cold chain temperature range during transport to the vaccine hub.

3.1.2 Cool boxes must be suitable for the duration of use. Calibration certificates and cold chain validation documents must be stored in the pharmacy procurement office for reference.

3.1.3 Cool packs must be prepared according to the manufacturer's instructions.

3.1.4 The required number of cool packs must be placed in the cool box according to the manufacturer's instructions.

3.1.5 Using a thermometer wait until the cool box temperature has dropped to between $2^{O}C$ and $8^{O}C$.

3.1.6 Place the cool box next to the COVID-19 vaccine fridge.

### 3.2 Selecting, labelling and packing the vaccine

3.2.1 Care must be taken to minimise exposure of the vaccine to room temperature. The process should be undertaken swiftly, and fridge door openings must be kept to a minimum.

3.2.2 Carefully remove the original pack from the fridge ensuring the vials are kept upright at all times. Check the label on the box to ensure that the vaccine has not expired and confirm that if it was a frozen pack of vaccine that it has been allowed to thaw for a minimum of 3 or 24 hours dependent on the vaccine type.

3.2.3 If a full carton is selected, label it with the remaining journey time only (see table 1).

3.2.4 If individual vials are selected:

- place them in a suitable container; if a rigid box is used, use packing materials to prevent excessive movement of the vials within the box.
- label the container with:
    - name of vaccine,
    - number of vials,
    - post-thaw expiry date (from outer carton from which the vials have been removed),
    - For VidPrevtyn Beta only, the outer carton (co-pack) batch number
    - Journey time remaining (see table), if applicable.

**Table 1**

| **Vaccine** | **Total time permitted for transport at 2°C and 8°C** | **Assumed journey time already elapsed during journey from SPLs** | **Assumed remaining journey time available** |
|---|---|---|---|
| Comirnaty 30 Concentrate | 48 hours | 6 hours | 42 hours |
| Comirnaty 10 Concentrate | 10 weeks | Not applicable | Not applicable |
| Comirnaty Bivalent Original / Omicron BA.1 | 10 weeks | Not applicable | Not applicable |
| Comirnaty Bivalent Original / Omicron BA.4-5 | 10 weeks | Not applicable | Not applicable |
| Spikevax Original | 12 hours | 6 hours | 6 hours |
| Spikevax Bivalent | 12 hours | 6 hours | 6 hours |
| VidPrevtyn Beta **AFTER MIXING** | 6 hours | 0 hours | 6 hours |

3.2.5 Pack the original pack into the cool box in such a way that it remains upright and minimises the movement of the vials. Take care to ensure that any frozen ice packs do not come into direct contact with the product.

### 3.3. Transport of vaccine to the end user location

3.3.1 Agitation of the vials should be minimised during the transportation, so care should be taken to transport the cool box in such a way so that it remains upright and stable throughout the journey.

3.3.2 Travel to the end user location.

3.3.3 On arrival check that:

- the journey time was less than the remaining journey time written on the vaccine container (if applicable),
- the journey time was less than the time for which the cool box is validated (if applicable),

the temperature inside box is between 2 and 8$^{O}$C (if thermometer in use); if not, the vaccine should be quarantined in the refrigerator and advice sought from the Clinical Lead on shift,

- download the data logger information and review to confirm the temperature was maintained between 2$^{O}$C and 8$^{O}$C during the vaccine transfer (store this electronic record for 2 years), and
- update the remaining journey time left after transport on the carton or container (if applicable).

3.3.4 If the vaccine is transferred to another vaccination site or pop-up with a refrigerator, with the Clinical Lead, put the vaccines in the designated vaccine refrigerator without delay with the shortest dated foremost to ensure adequate stock rotation.

3.3.5 If the vaccine is transferred to a care home, patient home or other location without refrigeration available, keep it within the cool box and use the vaccine immediately on arrival, using one of the following:

SOP 5 Preparation of Comirnaty 30 Concentrate,
SOP 6 Preparation of Comirnaty 10 Concentrate,
SOP 7 Preparation of Spikevax Original Vaccine,
SOP 8 Preparation of Comirnaty Bivalent Original / Omicron BA.1 Vaccine,
SOP 9 Preparation of Spikevax Bivalent Vaccine.
SOP 14 Preparation of Nuvaxovid Vaccine
SOP15 Preparation of Vidprevtyn Beta Vaccine
SOP16 Preparation of Comirnaty Bivalent Original / Omicron BA.4-5 Vaccine

3.3.4 The delivery person and Clinical Lead should sign for delivery and confirmation of cold chain integrity.

3.3.5 Return cool box and cool packs to their original location, ensure these are cleaned and stored correctly for further use following the department procedure.

**3.4 Mutual Aid Transfer**

3.4.1 It is the responsibility of the person receiving the mutual aid supply to transport and monitor the temperature of the vaccine.

3.4.1 Mutual aid transfers can only happen with permission from the system and region in accordance with mutual aid ordering. Coronavirus » Transfer of COVID-19 vaccines between NHS vaccination sites (england.nhs.uk)

3.4.2 Mutual aid paperwork (see appendix 1) must be in place and temperature records must be kept for 2 years.

## 4.0 Equipment Required

- Medical grade cool box that has been validated for the required time from packing to receipt at the end user location.
- Thermometer (if required and not integral to cool box).
- Temperature data logger.
- Cool packs, chilled or frozen according to the manufacturer's instructions.
- Information about loading the cool box (e.g., cool box manufacturer's instructions for packing).
- Packaging materials e.g., bubble wrap, foam and cardboard supports.
- Container for small number of vaccines e.g., box or self-sealing bag
- Blank label & indelible pen.
- Mutual aid paperwork.

## 5.0 Training

All staff working in COVID-19 vaccine sites and Pharmacy Distribution and Pharmacy Delivery Services must read this procedure.

**ATTACHMENT 1 – SOP3 Appendix 1 – Mutual Aid Transfer Record Form**

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | Yes – No |
| 2 | Does the implementation of this document require additional revenue resources | Yes – No |
| 3 | Does the implementation of this document require additional manpower | Yes – No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | Yes – No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | Yes – No |
| | Other comments | |

## Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 3 v4 | **Title of Procedure/Guidelines**<br><br>Standard Operating Procedure for for the use of cool boxes to transport COVID-19 Vaccines to end user locations and for Mutual Aid | **Status:**<br><br>**Final** | | **Author: Clinical Director of Pharmacy**<br><br>**Director Sponsor: Medical Director** |
| Version / Amendment History | Version | Date | Author | Reason |
| | v1 | 29/12/2020 | Clinical Director of Pharmacy | New SOP |
| | V2 | 31/01/2021 | Clinical Director of Pharmacy | Additional information added to clarify procedure following user feedback |
| | V3 | 20/09/2022 | Deputy Clinical Director of Pharmacy | Update to SPS SOPS Includes travel times for vaccines. |
| | V4 | 30/03/2023 | Clinical Lead – Living Well Group | Update to SPS SOP to include Spring 2023 Booster vaccines and digitization of MA requests. Web links updated |
| **Intended Recipients:** All Pharmacy Staff participating in the COVID-19 Vaccine delivery programme, Pharmacy Distribution and Delivery staff, all staff involved in the provision of Covid-19 Vaccine services | | | | |
| **Consultation Group / Role Titles and Date:**<br>Trust Medicines Management Group (MMG) | | | | |
| **Name and date of group where reviewed** | Medicines Management Group (MMG) 09/2022<br>Trust Policy Group – December 2022 | | | |

| | |
|---|---|
| **Name and date of final approval committee (if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Medicines Management Group (MMG) 04/2023<br>Trust Policy Group – Virtual Approval – April 2023 |
| **Date of Procedure/Guidelines issue** | April 2023 |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | April 2026 |

**Training and Dissemination:**
All Pharmacy Staff participating in the COVID-19 vaccine delivery programme and Pharmacy Distribution and Delivery Staff are required to read this procedure.

**To be read in conjunction with:**
COVID-19 Vaccine handling and management policy and associated procedures
Trust Policy MP10 Cold Chain Policy

**Initial Equality Impact Assessment: Completed**
**Full Equality Impact assessment (as required): No**

| | |
|---|---|
| **Contact for Review** | Clinical Lead – Living Well Group |
| **Monitoring arrangements** | Trust Medicines Management Group |

**Document summary/key issues covered**
This Standard Operating procedure (SOP) describes the process for the use of cool boxes to transport COVID-19 vaccines to end user locations

| | |
|---|---|
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination<br>Transporting<br>Mutual Aid |

**IMPLEMENTATION PLAN**
**To be completed when submitted to the appropriate committee for consideration/approval**

| **Procedure/Guidelines number and version** | **Title of Procedure/Guidelines** | |
|---|---|---|
| **Reviewing Group** | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** | | |

| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
|---|---|---|
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | | |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | | |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | | |
| Financial cost implementation<br>Consider Business case development | | |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | | |

**MP11 SOP 3 Appendix 1:**

# Mutual Aid Vaccine Transfer Record Form

| | | | | | |
|---|---|---|---|---|---|
| Date of Transfer | | Time of transfer at Donor site | | Time of **arrival** at recipient site | |
| Vaccine Donor Site Name | | | | | |
| Donor Site Type | **PCN** | **Community Pharmacy** | **Mass Vaccination centre** | **HH/HH+** | |
| Donor Site Clinical Lead: | Name | | Designation | | |
| Mutual Aid Agreed by BCWB SRO and SVOC? | **Yes** | **No** | Mutual Aid Agreed by Place CCG Lead Primary Care Pharmacist | **Yes** | **No** |
| Donor site fridge temperature | | Prior to transfer. Check the Fridge log at donor site to ensure temperature has been in range. | | | |
| Confirm stock check at donor site - Stock intact and undamaged/ Stock quantity is correct: | **Yes** | **No** | Assurance from Donor of cold chain maintenance prior to transfer (Donor to sign and print) | | |
| Vaccine name being transferred (circle) | **Pfizer** | **AstraZeneca** | **Other please list** | | |
| Quantity (Number of vials) being transfer (as per Mutual aid agreement) | | | | | |
| Vaccine Batch Number (if Pfizer please include V number) | | | | | |
| Vaccine expiry date | | | | | |
| Vaccine expiry time (if Pfizer) | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| Vaccine Recipient Site Name | | | | | |
| Recipient Site Type | **PCN** | **Community Pharmacy** | **Vaccination centre** | **Hospital Hub** | |
| Recipient Site Clinical Lead: | Name | | Designation | | |

**Please note** – it is essential to maintain the cold chain during transfer. Temperature **must** remain between 2-8$^{o}$C at all times.
The vials must **not** be shaken, so care should be taken to place the cool box in the vehicle in such a way so that it remains stable throughout the journey. Ideally temperature must be monitored throughout the journey, if safe to do so.

| | | | | | |
|---|---|---|---|---|---|
| Recipient has a validated cool box (as per the SOP) | **Yes** | **No** | **If No please discuss with donor site if a cool box is available for loan.** | | |
| Cool box temperature at donor site | | Prior to transfer. Check the Fridge log at donor site to ensure temperature has been in range. | | | |
| Cool box temperature in range at point of packing? | **Yes** | **No** | **Observed by both donor and recipient. Please sign** | | |
| Recipient verified the quantity of vaccine and batch numbers are correct? | **Yes** | **No** | **Recipient, please sign** | | |
| Record temperature of cool box on **arrival** at recipient site: | | Confirm temperature during transfer has been maintained between 2 and 8$^{o}$C? Confirmation required via Data logger :Follow cold chain SOP | | **Yes** | **No** |
| Confirm Stock check at recipient site - Stock intact and undamaged: | **Yes** | **No** | **If No, please quarantine damaged stock and report on Foundry and Datix.** | | |
| Record Temperature of fridge at recipient site: | | Confirm stock transfer to fridge and running balance updated: | | **Yes** | **No** |
| Name and Signature of Person transferring vaccine to fridge (if different from recipient transferring vaccine): | | | | | |

# COVID-19 Vaccine Procedure 4
# Standard Operating Procedure for Stocktaking and Reconciliation of COVID-19 Vaccine

## 1.0 Procedure Statement

This Standard Operating procedure (SOP) describes the requirements for stocktaking and reconciliation of COVID-19 vaccine.

## 2.0 Accountabilities

The Clinical Director of Pharmacy is professionally accountable for the safe and secure handling of the vaccine.

The COVID-19 Lead Pharmacist has operational responsibility for ensuring a documented stock balance is maintained at all vaccination sites, reconciliation of the stock balance with vials issued and doses administered, investigation of any anomalies, and reporting of any concerns to the Clinical Director of Pharmacy and Clinical Lead. The COVID-19 Lead Pharmacist may delegate all or parts of this task to another registered healthcare professional e.g. pharmacy technician or registered nurse.

## 3.0 Procedure Detail / Actions

3.1 A separate register for each vaccine will be used to record the number of vials of vaccine received, the number of vials of vaccines issued, the number of vials of vaccine wasted (e.g., due to expiry), and a running stock balance.

3.2 Stock counts must be conducted for each vaccine at the beginning and end of the day by a suitably trained member of staff. The clinical lead must be notified of any discrepancies immediately

3.3 The person performing the stock count must work efficiently to minimise the time the door of the fridge is left open (an approved app such as count things or a photograph of the vials may be taken to aid counting the vials). The Trust Cold Chain Policy MP10 must be followed.

### 3.4 Stock Count

- Physical count of each vaccine vial.
- Check of expiry dates
- Appropriate stock rotation (shortest dated stock is foremost)
- Documentation of balance in register.

### 3.5 Stock Reconciliation

Stock reconciliation will be completed at least weekly by the COVID-19 Lead Pharmacist or delegated registered healthcare professional and includes the following verification of the physical stock count of each vaccine with:

- total stock balance from last reconciliation,
- stock used since last reconciliation (reconcile number of vials issued from stock register, number of doses administered from workstation logs, and number of patients from record form),
- stock received since last reconciliation,
- damaged, unused or expired stock since last reconciliation (see table below for codes), and
- confirm that all wastage, mutual aid transfers and lost vials/doses are recorded on Foundry.

| ID | Name | Description | Vaccine/ Medical | Consumables | PPE |
|---|---|---|---|---|---|
| 1 | Contamination | The item (e.g. vaccine, diluent) has been contaminated | x | | X |
| 2 | Site Fridge/Freezer Malfunction | The item was stored in a temperature controlled environment that failed | X | | |
| 3 | Transport Breakdown | The item was in transit between locations when the vehicle it was in broke down, resulting in a temperature excursion | X | | |
| 4 | Excess Stock | Where a vaccination team reach the end of an allotted shift or job, and have surplus vaccines that cannot be returned to stock | X | | |
| 5 | Expired shelf-life | Where the expiry date for the product in its current state has been exceeded | X | | X |
| 6 | Waste at Point of Care | Where the prepped dose was refused by the patient | X | | |
| 7 | Improper Storage | The item had not been stored in accordance with instructions (e.g. left out of fridge) | X | X | X |
| 8 | Damaged/Dropped | The item is broken (e.g. vial dropped onto concrete floor) | X | X | X |
| 9 | Lost/ Stolen | The item has gone missing and is assumed lost or stolen | X | X | X |
| 10 | Refused at Delivery | The item has been delivered in a form that is unusable (e.g. temperature excursion or damaged item) | X | X | X |
| 11 | Reconstitution/ dilution /prep error | A mistake was made when drawing up the vaccine, making the dose unusable | X | | |

### 3.5 Resolution of any discrepancies

Discrepancies must be investigated and escalated immediately to the Clinical Director of Pharmacy and Clinical Lead.

## 4.0 Equipment Required

Stock register

## 5.0 Training

All staff involved in the handling of COVID-19 vaccine are required to read this procedure.

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | Yes – No |
| 2 | Does the implementation of this document require additional revenue resources | Yes – No |
| 3 | Does the implementation of this document require additional manpower | Yes – No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | Yes – No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | Yes – No |
| | Other comments | |

## Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 4 v2 | **Title of Procedure/Guidelines**<br><br>Standard Operating Procedure for Stocktaking and Reconciliation of Pfizer-BioNTech COVID-19 Vaccine at the Hospital Vaccination Hub | **Status:**<br><br>**Final** | | **Author: Clinical Director of Pharmacy**<br><br>**Director Sponsor: Chief Medical Officer** |
| Version / Amendment History | Version | Date | Author | Reason |
| | v1 | 29/12/2020 | Clinical Director of Pharmacy | New SOP |
| | v2 | 20/09/2022 | Deputy Clinical Director of pharmacy | Inclusion of Foundry recording and reconciliation frequency changes. Removal of SPS reference as no longer available |
| **Intended Recipients:** All Vaccinators and Pharmacy Staff participating in the COVID-19 Vaccine delivery programme | | | | |
| **Consultation Group / Role Titles and Date:**<br>Trust Medicines Management Group (MMG) | | | | |
| **Name and date of group where reviewed** | Medicines Management Group (MMG) 10/2022<br>Trust Policy Group – December 2022 | | | |
| **Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Trust Medicines Management Group (MMG) 10/2022<br>Trust Management Committee – January 2023 | | | |
| **Date of Procedure/Guidelines issue** | September 2022 | | | |

| | |
|---|---|
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | August 2023 every 12 months |
| **Training and Dissemination:**<br>All Vaccinators and Pharmacy Staff participating in the COVID-19 vaccine delivery programme are required to read this procedure. | |
| **To be read in conjunction with:**<br>COVID-19 Vaccine handling and management policy and associated procedures<br>Trust Policy MP10 Cold Chain Policy | |
| **Initial Equality Impact Assessment: Completed**<br>**Full Equality Impact assessment (as required): No** | |
| **Contact for Review** | Clinical Director of Pharmacy |
| **Monitoring arrangements** | Trust Medicines Management Group |
| **Document summary/key issues covered**<br>This Standard Operating procedure (SOP) describes the process for Stocktaking and Reconciliation of COVID-19 Vaccine | |
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination |

**IMPLEMENTATION PLAN**
**To be completed when submitted to the appropriate committee for consideration/approval**

| | | |
|---|---|---|
| **Procedure/Guidelines number and version** | **Title of Procedure/Guidelines** | |
| **Reviewing Group** | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** | | |

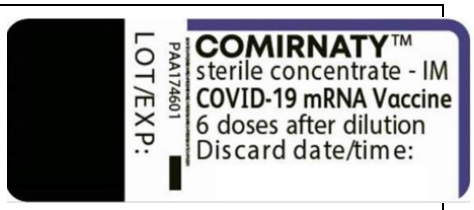
| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
|---|---|---|
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | | |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | | |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | | |
| Financial cost implementation<br>Consider Business case development | | |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | | |

# COVID-19 Vaccine Procedure 5 Standard Operating Procedure for Preparation of 0.3mL Syringes Using Comirnaty 30 Concentrate for Adults and Adolescents

## 1.0 Procedure Statement

This SOP describes the process for preparation of ready to administer **0.3mL** syringes using **Comirnaty COVID-19 mRNA Vaccine 30micrograms/0.3ml dose concentrate for dispersion for injection multidose vials (Comirnaty 30 Concentrate).**

Different strengths and formulations of Comirnaty vaccine are available. Ensure the correct procedure is selected for the strength and formulation required. This SOP is for use with **(Comirnaty 30 Concentrate)** with the label format:




This procedure covers the process from the removal of vials of thawed vaccine from the outer carton in the refrigerator, or removal of individual vials from a cool box, up until the point of administration. This includes assigning a room temperature expiry, the dilution of the concentrate vial, and the preparation of syringes for administration.

This procedure may be adapted to suit either of the following models.

- One person performing dilution and drawing up of syringes to administer by themselves.
- One person performing dilution and who passes the diluted vial to a vaccinator to draw up individual doses into syringes.
- One person both diluting the vial and drawing up individual doses into syringes and passing the syringe to the vaccinator. This model requires additional local risk assessment, and the introduction of local controls to reduce the risk of needle stick injuries on transfer between individuals.

This procedure is based on Specialist Pharmacy Services Procedure *PCV 1 – Preparation of 0.3mL syringes using Comirnaty 30 Concentrate for adults and adolescents.*

## 2.0 Accountabilities

The Clinical Director of Pharmacy is professionally accountable for the safe and secure handling and management of COVID-19 vaccine and related medicines on all vaccination sites operating within the jurisdiction of the Trust.

The Clinical Lead for the vaccination site is professionally accountable for ensuring that appropriate and formal authorisation for vaccine administration is in place (PSD, PGD or National Protocol), and that the staff groups who are supplied with, prepare, and administer the COVID-19 vaccine are those defined as eligible to do so in accordance with the authorisation being used. When working under the National Protocol the Clinical Lead will ensure that a 'Clinical Supervisor' is present for the duration of the vaccination session and this person is clearly identifiable and competent in all stages of the vaccination pathway. The Clinical Lead is also responsible for ensuring that all staff undertaking duties at the vaccination site meet the training standards and competencies for the vaccination programme.

When working under a PSD, the prescriber is legally accountable for the safe and secure handling and management of the COVID-19 vaccine under The Human Medicines Regulations (2012) Regulation 3.

Registered healthcare professionals working under a PSD, PGD or the National Protocol and non-registered staff working under the National Protocol are responsible for ensuring the safe and secure handling requirements are met and must follow this procedure.

## 3.0 Procedure Detail / Actions

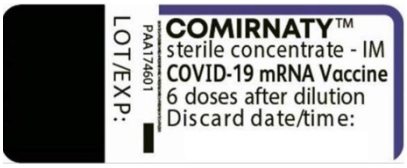
### 3.1 Removal of vaccines from original carton

**If removing a single vial from a cool box proceed directly to step 3.2**

3.1.1 Remove the required number of thawed concentrated vaccine vials from the original carton in the refrigerator. If there is more than one carton, use the one with the shortest post-thaw expiry date and time. One vial contains sufficient vaccine for 6 doses when diluted.

3.1.2 To reduce waste, the number of vials removed should be enough to cover no more than approximately 1 hour of anticipated usage.

3.1.3 Check you have selected the correct presentation of the Comirnaty vaccine. This procedure is intended for use with the Comirnaty **30 Concentrate** presentation. Check label format on the vial selected matches the picture below:




NB: The Comirnaty **30 Concentrate** presentation does not state the dose on the label, however, it does uniquely state **'6 doses after dilution'.**

3.1.4 Check the vial is within the post-thaw expiry date written on the carton.

3.1.5 Transfer the concentrated vaccine vials removed from the fridge into a plastic opaque box labelled 'CONCENTRATED VACCINE VIALS'. Confirm this box is empty before adding the new vial. Close the lid on the box.

3.1.6 Complete a '*Concentrate Room Temperature Expiry Label*' (see below for example) with:

- time and date removed from the refrigerator (use 24-hour clock format),
- time and date of expiry: the expiry is 2 hours from the point the concentrated vaccine vials are removed from the fridge,
- The batch number of the concentrated vaccine vials, and
- The signature of person completing the label.

Stick the completed label on the box lid.

Concentrate Room Temperature Expiry Label

**Comirnaty 30 Concentrate**

Concentrate Room Temperature Bag Expiry Label

**Removed from refrigerator**:
DD/MM/YY at HH:MM

Batch No:

**Discard after:**
DD/MM/YY at HH:MM

Signed:

Checked:

3.1.7 A second person must check that all the details on the label are correct and the correct vaccine has been selected by confirming the product name on the vial. The second person must document this check by signing the label.

3.1.8 Document vaccine removal from the fridge in the stock register as per COVID-19 Vaccine Procedure 4 - *Stocktaking and Reconciliation of COVID-19 Vaccine*.

3.1.9 Once removed from the fridge and stored at room temperature, the vials must be:

- diluted within 2 hours and
- then used within 6 hours once diluted.

3.1.8 Take the box to the vaccine preparation station.

**3.2 Workstation preparation**

3.2.1 Confirm the preparation workstation is clear and free from any other vials of vaccine.

3.2.2 Ensure a yellow lidded sharps bin with sufficient free capacity is available.

3.2.3 Ensure an indelible pen is available and a workstation log with information completed for start of session.

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3.2.4 Put on apron.

3.2.5 Clean workstation with disinfectant wipes and discard into a clinical waste bin.

3.2.6 Following the RWT Infection Prevention Policy, wash hands thoroughly. Put on disposable gloves and an apron (if not already wearing one) and ensure a face mask is worn.

### 3.3 Dilution

**This process will take place at a separate workstation to administration of the vaccine. When working under the National Protocol it is a condition of the protocol that the dilution process be supervised by a pharmacist, nurse or doctor. To meet this supervisory requirement the vaccination session clinical lead (senior nurse) must be physically present on the vaccination hub to refer to if required.**

3.3.1 Assemble the following materials required to perform dilution:

- sodium chloride 0.9% ampoule 5mL (preservative free) X 1,
- 2mL or 3mL syringe X 1,
- 21g or finer needle X 1,
- sterile single use 70% alcohol swab x2, and
- Comirnaty 30 Concentrate Workstation log.

3.3.2 When ready to begin the dilution process, bring a single vial of concentrate Comirnaty **30 concentrate** vaccine into the centre of the workstation.

**N.B. Only one vaccine vial may be in use in the preparation workstation at any one time.**

When removing the concentrated vaccine vial, check the assigned room temperature expiry on the box of concentrated vaccine vials has not been exceeded. Remove a single vial and close the lid of the vial box.

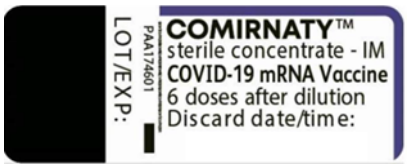
3.3.3 If working with vials from a cool box at 2-8$^{O}$C:

- check the vial is within the post-thaw expiry date by checking the label on the vial transport container (refer to SOP 3: *Use of cool boxes to transport COVID-19 vaccines to end user locations), and*
- Remove a single vial and close the lid of the cool box.

3.3.4 Check the identity of the vial. This procedure is intended for use with Comirnaty **30 Concentrate** presentation.

- Check the vial has a purple cap.

- Check label format on the vial selected matches the picture below:




NB: The Comirnaty **30 concentrate** presentation does not state the dose on the label, however, it does uniquely state **'6 doses after dilution'.**

3.3.5 Allow the vaccine vial to come to room temperature if it is still cold from being in the fridge or cool box.

### 3.4 Dilute the Vial

3.4.1 Slowly invert the vial 10 times to mix contents thoroughly, DO NOT shake it. One inversion requires the vial to be fully rotated back to an upright position. Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.

3.4.2 Remove the purple vial dust cover and cleanse the vaccine vial stopper with a single use 70% alcohol swab and discard the swab into a clinical waste bin. Set the concentrated vaccine vial to one side.

3.4.3 Cleanse the top and shoulders of 5mL ampoule of preservative free sodium chloride 0.9% with a single use 70% alcohol swab and discard the swab into a clinical waste bin.

3.4.4 Attach a 21g or finer needle to a 2mL or 3mL syringe.

3.4.5 Using aseptic technique, snap the top off a 5mL of preservative free sodium chloride 0.9% ampoule and use the 2mL or 3mL syringe and 21g or finer needle to draw up **1.8 mL** of preservative free sodium chloride 0.9%.

3.4.6 Self-check the volume of sodium chloride 0.9% drawn up is **1.8 mL.** Request a second independent check of the volume drawn up. The person performing the dilution and the person undertaking the second check must sign the workstation log.

3.4.7 Dispose of the remainder of the 5mL preservative free sodium chloride 0.9% ampoule into a yellow lidded sharps bin.

3.4.8 Dilute the concentrate vaccine vial by adding 1.8 mL of preservative free sodium chloride 0.9% to the vial.

- To minimise the risk of stopper coring and particles entering the vial:
  - insert the needle vertically through the centre ring of the vial stopper and
  - Do not twist or rotate the needle once inserted.

- During the addition, keep the needle tip in the air space of the vial at all times. Equalise the pressure by adding the sodium chloride 0.9% solution for injection in gradual steps and allowing air to vent back into the syringe repeatedly until all of the sodium chloride 0.9% solution for injection has been added and there is 1.8mL air in the syringe.

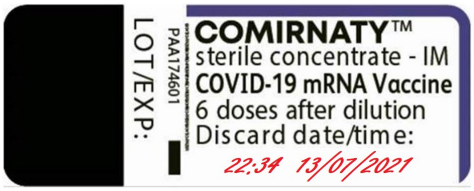
N.B. If using a syringe with an auto retracting needle, depressing the plunger fully will cause the needle to retract prematurely. If the above technique is not used the full 1.8mL may therefore not be added to the vial.

3.4.9 Dispose of the syringe and needle into a yellow lidded sharps bin.

3.4.10 Slowly invert the vial 10 times to mix contents thoroughly, DO NOT shake it. One inversion requires the vial to be fully rotated back to an upright position.

3.4.11 The diluted vaccine should present as an off-white solution with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present.

3.4.12 Calculate and write the time / date of post-dilution **expiry** on the vial label as shown below in red below. Use 24-hour clock format.




N.B. The expiry is 6 hours from the point of dilution, but the vial should still be used as soon as practically possible.

3.4.13 Do not remove another vial of concentrated vaccine from the lidded box until the vial of diluted vaccine has left the preparation workspace or has been discarded.

**3.5 Withdrawal into syringes**

3.5.1 Assemble the following materials into a plastic tray:

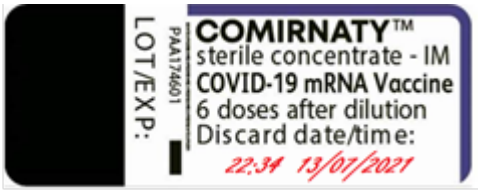
- diluted Comirnaty 30 Concentrate vial X 1,
- 1mL syringe with integrated 23g (or finer) x 25mm needle X 6, and
- single use 70% alcohol swab x 6

3.5.2 Carefully transfer the tray to the administration area. Movement of the vaccine should be limited due to the fragility of the vaccine.

3.5.3. Check the vial is within the hand-written post-dilution expiry time on the label.

3.5.4 Check the identity of the vial. This procedure is intended for use with the Comirnaty **30 concentrate** presentation.

- Check label format on the vial selected matches the picture below:




NB: The Comirnaty **30 concentrate** presentation does not state the dose on the label, however, it does uniquely state '6 doses after dilution'.

3.5.5 Cleanse the vial stopper with a single use 70% alcohol swab, and discard swab in a clinical waste bin.

3.5.6 Using aseptic technique, draw up **0.3mL** of the diluted vaccine using a new 1mL syringe with integrated 23g (or finer) x 25mm needle.
N.B.

- A 21g or finer x 38mm needle and 1mL syringe should be used for administering the vaccine to morbidly obese patients.
- If using a syringe with an auto retracting needle depressing the plunger will cause the needle to retract prematurely.

3.5.7 Adjust to remove air bubbles with the needle still in the vial to avoid loss of diluted vaccine.

3.5.8 Self-check that the volume withdrawn is **0.3mL.** Request a second check of volume. The vaccinator and person carrying out the second check must sign the workstation log.

3.5.9 Visually inspect the syringes for particles and leaks. Discard if they are observed.

3.5.10 The newly filled syringe must be used for immediate administration.

3.5.11 Steps 3.5.3 to 3.5.10 may be repeated a further five times to produce a total of six syringes from each diluted vaccine vial. Each time the vial bung is punctured, this should be in a different location to previous points of puncture on the bung.

3.5.12 If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

3.5.13 After the sixth dose has been taken from the vial or if expiry has been exceeded, remove the label from the vial and attach to the workstation log. Discard the used diluted vaccine vial into a yellow lidded sharps bin.

3.5.14 At the end of the session, remove all unused vials from the lidded box 'CONCENTRATED VACCINE VIALS' and discard into a yellow lidded sharps bin. Vials must not be stored between sessions or returned to the refrigerator. At this stage remove the label - '*Concentrate room temperature expiry label*' from the box and clean it in readiness for the next batch. Document any unused vials on the audit paperwork**. Note that every reasonable effort must be made to safely use all available vaccine and therefore not waste doses; before discarding unused vials or doses permission must be sought from the Clinical Lead (senior nurse).**

3.5.15 Empty outer cartons must be disposed of in a secure manner which prevents theft. Score through label text with a permanent marker and cut the box up into pieces before disposal in confidential waste.

### 3.6 Dealing with deviations from this procedure

3.6.1 Any deviations from this procedure must immediately be reported to the supervising pharmacist or clinical supervisor (senior nurse).

3.6.2 An audit worksheet (the workstation log) must be completed for each vial at each stage throughout the process by the vaccinators and the team overseeing stock control. Where vaccine is discarded, this must be recorded on the work station log and one of the following codes documented:

| ID | Name | Description | Vaccine/ Medical | Consumables | PPE |
|---|---|---|---|---|---|
| 1 | Contamination | The item (e.g. vaccine, diluent) has been contaminated | x | | X |
| 2 | Site Fridge/Freezer Malfunction | The item was stored in a temperature controlled environment that failed | X | | |
| 3 | Transport Breakdown | The item was in transit between locations when the vehicle it was in broke down, resulting in a temperature excursion | X | | |
| 4 | Excess Stock | Where a vaccination team reach the end of an allotted shift or job, and have surplus vaccines that cannot be returned to stock | X | | |
| 5 | Expired shelf-life | Where the expiry date for the product in its current state has been exceeded | X | | X |
| 6 | Waste at Point of Care | Where the prepped dose was refused by the patient | X | | |
| 7 | Improper Storage | The item had not been stored in accordance with instructions (e.g. left out of fridge) | X | X | X |
| 8 | Damaged/Dropped | The item is broken (e.g. vial dropped onto concrete floor) | X | X | X |
| 9 | Lost/ Stolen | The item has gone missing and is assumed lost or stolen | X | X | X |
| 10 | Refused at Delivery | The item has been delivered in a form that is unusable (e.g. temperature excursion or damaged item) | X | X | X |
| 11 | Reconstitution/ dilution /prep error | A mistake was made when drawing up the vaccine, making the dose unusable | X | | |

## 4.0 Equipment Required

Comirnaty 30 Concentrate Vaccine

Plastic opaque box labelled 'CONCENTRATED VACCINE VIALS'.

Printed labels: 'Concentrate Room Temperature Expiry Label'

Yellow lidded sharps bins

Indelible pen

Workstation logs

Appropriate personal protective equipment including apron and face mask

Disposable gloves

Disinfectant wipes

Clinical waste bins

Sodium chloride 0.9% ampoules 5mL (preservative free)

2mL or 3mL Syringes

21g (or finer) needles

Plastic trays

1ml syringes with integrated 23g (or finer) x 25mm needle (supplied with vaccine)

Single use 70% alcohol swabs

## 5.0 Training

All staff operating under this procedure must meet the training standards and competencies for the COVID-19 vaccination programme.

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | Yes – No |
| 2 | Does the implementation of this document require additional revenue resources | Yes – No |
| 3 | Does the implementation of this document require additional manpower | Yes – No |

| | | |
|---|---|---|
| 4 | Does the implementation of this document release any manpower costs through a change in practice | Yes – No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | Yes – No |
| | Other comments | |

**Attachment 1 Comirnaty 30 Workstation Log**

## Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 5 v4 | **Title of Procedure/Guidelines**<br><br>Standard Operating Procedure for Preparation of Comirnaty 30 Concentrate | **Status:**<br><br>**FINAL** | | **Author: Clinical Director of Pharmacy**<br><br>**Director Sponsor: Chief Medical Officer** |
| Version / Amendment History | Version | Date | Author | Reason |
| | 1 | 29/12/2020 | Clinical Director of Pharmacy | New SOP |
| | 2 | 21/01/2021 | Clinical Director of Pharmacy | Updated to include:<br>• Changes to national SOP<br>• Allowance for 6th dose<br>• Reference to the National Protocol |
| | 3 | 30/09/2021 | Clinical Director of Pharmacy | Updated to include:<br>• Changes to national SOP<br>• Information pertaining to Comirnity brand of Pfizer vaccine<br>• Provision for unregistered staff in line with National Protocol |
| | 4 | 20/09/2022 | Deputy Clinical Director of Pharmacy | Update to reflect use of Comirnaty 30 concentrate and align to latest SPS SOP |
| **Intended Recipients:** All staff delivering the COVID-19 vaccination programme | | | | |
| **Consultation Group / Role Titles and Date:**<br>Trust Medicines Management Group (MMG) | | | | |
| **Name and date of group where reviewed** | Medicines Management Group (MMG) 09/2022 | | | |

| | |
|---|---|
| | Trust Policy Group – December 2022 |
| **Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Trust Management Committee – January 2023 |
| **Date of Procedure/Guidelines issue** | September 2022 |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | August 2023 12 monthly |

**Training and Dissemination:**
This procedure will form part of the COVID-19 vaccine training programme which all new vaccinators are required to complete

**To be read in conjunction with:**
COVID-19 Vaccine handling and management policy and associated procedures

**Initial Equality Impact Assessment: Completed**
**Full Equality Impact assessment (as required): No**

| | |
|---|---|
| **Contact for Review** | Clinical Director of Pharmacy |
| **Monitoring arrangements** | Trust Medicines Management Group |

**Document summary/key issues covered**
This Standard Operating procedure (SOP) describes the process for preparation of Comirnaty 30 Concentrate Vaccine

| | |
|---|---|
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination<br>Comirnaty 30 Concentrate |

**IMPLEMENTATION PLAN**
**To be completed when submitted to the appropriate committee for consideration/approval**

| | | |
|---|---|---|
| **Procedure/Guidelines number and version** | **Title of Procedure/Guidelines** | |
| **Reviewing Group** | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** | | |

| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
|---|---|---|
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | | |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | | |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | | |
| Financial cost implementation<br>Consider Business case development | | |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | | |

# COVID-19 Vaccine Procedure 6 Standard Operating Procedure for Preparation of 0.2mL Syringes Using Comirnaty 10 Concentrate for Children 5-11 Years

## 1.0 Procedure Statement

This SOP describes the process for preparation of ready to administer **0.2mL** syringes of **Comirnaty Children 5-11 years COVID-19 mRNA Vaccine 10micrograms/0.2ml dose concentrate for dispersion for injection (Comirnaty 10 concentrate).**

Different strengths and formulations of Comirnaty vaccine are available. Ensure the correct procedure is selected for the strength and formulation required. This SOP is for use with (Comirnaty **10 Concentrate**) with the label format:


This procedure covers the process from the removal of vials of thawed vaccine from the outer carton in the refrigerator, or removal of individual vials from a cool box, up until the point of administration. This includes assigning a room temperature expiry, the dilution of the concentrate vial, and the preparation of syringes for administration.

This procedure may be adapted to suit one of the following models.

- One person performing dilution and drawing up of syringes to administer by themselves.
- One person performing dilution and passing the diluted vial to a vaccinator to draw up individual doses into syringes.
- One person both diluting the vial and drawing up individual doses into syringes and passing the syringe to the vaccinator. This model requires additional local risk assessment and the introduction of local controls to reduce the risk of needle stick injuries on transfer between individuals.

This procedure is based on Specialist Pharmacy Services Procedure *PCV 2 – Preparation of 0.2mL syringes using Comirnaty 10 Concentrate for children 5-11 years.*

## 2.0 Accountabilities

The Clinical Director of Pharmacy is professionally accountable for the safe and secure handling and management of COVID-19 vaccine and related medicines on all

vaccination sites operating within the jurisdiction of the Trust.

The Clinical Lead for the vaccination site is professionally accountable for ensuring that appropriate and formal authorisation for vaccine administration is in place (PSD, PGD or National Protocol), and that the staff groups who are supplied with, prepare, and administer the COVID-19 vaccine are those defined as eligible to do so in accordance with the authorisation being used. When working under the National Protocol the Clinical Lead will ensure that a 'Clinical Supervisor' is present for the duration of the vaccination session and this person is clearly identifiable and competent in all stages of the vaccination pathway. The Clinical Lead is also responsible for ensuring that all staff undertaking duties at the vaccination site meet the training standards and competencies for the vaccination programme.

When working under a PSD, the prescriber is legally accountable for the safe and secure handling and management of the COVID-19 vaccine under The Human Medicines Regulations (2012) Regulation 3.

Registered healthcare professionals working under a PSD, PGD or the National Protocol and non-registered staff working under the National Protocol are responsible for ensuring the safe and secure handling requirements are met and must follow this procedure.

## 3.0 Procedure Detail / Actions

### 3.1 Removal of vaccines from original carton

**If removing a single vial from a cool box proceed directly to step 3.2**

3.1.1 Remove the required number of thawed concentrated vaccine vials, from the original carton in the refrigerator. If there is more than one carton, use the one with the shortest post-thaw expiry. One vial contains sufficient vaccine for 10 doses when diluted.

3.1.2 To reduce waste, the number of vials removed should be enough to cover no more than approximately 1 hour of anticipated usage.

3.1.3 Check you have selected the correct presentation of the Comirnaty vaccine. This procedure is intended for use with the Comirnaty **10 concentrate** presentation. Check label format on the vial selected matches the picture below:


NB: The Comirnaty **30 concentrate** presentation does not state the dose on the label, however, it does uniquely state **'10 doses after dilution'**

3.1.4 Check the vial is within the post-thaw expiry date written on the carton thaw label.

3.1.5 Transfer the concentrated vaccine vials removed from the fridge into a plastic opaque box labelled 'CONCENTRATED VACCINE VIALS'. Confirm this box is empty before adding the new vial. Close the lid on the box.

3.1.6 Complete a '*Concentrate Room Temperature Expiry Label*' (see below for example) with:

- time and date removed from the refrigerator using tha 24-hour clock format,
- time and date of expiry (the expiry is 12 hours from the point the concentrated vaccine vials are removed from the fridge),
- the batch number of the concentrated vaccine vials, and
- the signature of person completing the label.

NB. Once removed from a refrigerator and prior to dilution the vials may be stored up to 12 hours at up to 30°C.

Stick the completed label on the box lid.

Concentrate Room Temperature Expiry Label

**Comirnaty 10 Concentrate**

Concentrate Room Temperature Bag Expiry Label

**Removed from refrigerator**:
DD/MM/YY at HH:MM

Batch No:

**Discard after:**
DD/MM/YY at HH:MM

Signed:

Checked:

3.1.7 A second person must check that the all the details on the label are correct and that the correct vaccine has been selected by confirming the product name on the vial. The second person must document this check by signing the label.

3.1.8 Document vaccine removal from the fridge in the stock register as per COVID-19 Vaccine Procedure 4 - *Stocktaking and Reconciliation of COVID-19 Vaccine*.

3.1.9 Once removed from the fridge and stored at room temperature, the vials must be:

- diluted within 12 hours and

- then used within 12 hours once diluted.

3.1.8 Take the box to the vaccine preparation station.

**3.2 Workstation preparation**

3.2.1 Confirm the preparation workstation is clear and free from any other vials of vaccine.

3.2.2 Ensure a yellow lidded sharps bin with sufficient free capacity is available.

3.2.3 Ensure an indelible pen is available and a workstation log with information completed for start of session.

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3.2.4 Put on apron.

3.2.5 Clean workstation with disinfectant wipes and discard into a clinical waste bin.

3.2.6 Following the RWT Infection Prevention Policy, wash hands thoroughly. Put on disposable gloves and an apron (if not already wearing one) and ensure a face mask is worn.

**3.3 Dilution**

**This process will take place at a separate workstation to administration of the vaccine. When working under the National Protocol it is a condition of the protocol that the dilution process be supervised by a pharmacist, nurse or doctor. To meet this supervisory requirement the vaccination session Clinical Lead (senior nurse) must be physically present on the vaccination hub to refer to if required.**

3.3.1 Assemble the following materials required to perform dilution:

- sodium chloride 0.9% ampoule 5mL (preservative free) X 1,
- 2mL or 3mL Syringe X 1,
- 21g or finer needle X 1,
- sterile single use 70% alcohol swab x2, and
- Comirnaty 10 concentrate workstation log

3.3.2 When ready to begin the dilution process, bring a single vial of Comirnaty **10 concentrate** vaccine into the centre of the workstation.

**N.B. Only one vaccine vial may be in use in the preparation workstation at any one time.**

When removing the concentrated vaccine vial, check that the assigned room temperature expiry on the box of concentrated vaccine vials has not been exceeded. Remove a single vial and close the lid of the vial box.

3.3.3 If working with vials from a cool box at 2-8$^{O}$C:

- check the vial is within the post-thaw expiry date by checking the label on the vial transport container (refer to SOP 3: *Use of cool boxes to transport COVID-19 vaccines to end user locations), and*
- remove a single vial and close the lid of the cool box.

3.3.4 Check the identity of the vial. This procedure is intended for use with Comirnaty **10 concentrate** presentation.

- Check the vial has an orange cap.
- Check label format on the vial selected matches the picture below:


NB: The Comirnaty **10 concentrate** presentation does not state the dose on the label, however, it does uniquely state **'10 doses after dilution'.**

3.3.5 Allow the vaccine vial to come to room temperature if it is still cold from being in the fridge or cool box.

### 3.4 Dilute the Vial

3.4.1 Slowly invert the vial 10 times to mix contents thoroughly, DO NOT shake it. One inversion requires the vial to be fully rotated back to an upright position. Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.

3.4.2 Remove the orange vial dust cover and cleanse the vaccine vial stopper with a single use 70% alcohol swab and discard the swab into a clinical waste bin. Set the concentrated vaccine vial to one side.

3.4.3 Cleanse the top and shoulders of the 5mL ampoule of preservative free sodium chloride 0.9% with a single use 70% alcohol swab and discard the swab into a clinical waste bin.

3.4.4 Attach a 21g or finer needle to a 2mL or 3mL syringe.

3.4.5 Using aseptic technique, snap the top off a 5mL of preservative free sodium chloride 0.9% ampoule and use the 2mL or 3mL syringe and a 21g or finer needle to draw up **1.3 mL** of preservative free sodium chloride 0.9%.

3.4.6 Self-check the volume of sodium chloride 0.9% drawn up is **1.3 mL.** Request a second independent check of the volume drawn up. The person performing the dilution and the person undertaking the second check must sign the workstation log.

3.4.7 Dispose of the remainder of the 5mL preservative free sodium chloride 0.9% ampoule into a yellow lidded sharps bin.

3.4.8 Dilute the concentrate vaccine vial by adding **1.3mL** of preservative free sodium chloride 0.9% to the vial.

- To minimise the risk of stopper coring and particles entering the vial:
  - insert the needle vertically through the centre ring of the vial stopper, and
  - do not twist or rotate the needle once inserted.

- During the addition, keep the needle tip in the air space of the vial at all times. Equalise the pressure by adding the sodium chloride 0.9% solution for injection in gradual steps and allowing air to vent back into the syringe repeatedly until all of the sodium chloride 0.9% solution for injection has been added and there is 1.3mL air in the syringe.

N.B. If using a syringe with an auto retracting needle, depressing the plunger fully will cause the needle to retract prematurely. If the above technique is not used the full 1.3mL may therefore not be added to the vial.

3.4.9 Dispose of syringe and needle into a yellow lidded sharps bin.

3.4.10 Slowly invert the vial 10 times to mix contents thoroughly, DO NOT shake. One inversion requires the vial to be fully rotated back to an upright position.

3.4.11 The diluted vaccine should present as an off-white solution with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present.

3.4.12 Calculate and write the time / date of post-dilution **expiry** on the vial label as shown below in red below. Use 24-hour clock format.


N.B. The expiry is 12 hours from the point of dilution, but the vial should still be used as soon as practically possible.

3.4.13 Do not remove another vial of concentrated vaccine from the lidded box until the vial of diluted vaccine has left the preparation workspace / been discarded.

### 3.5 Withdrawal into syringes

3.5.1 Assemble the following materials into a plastic tray:

- diluted Comirnaty **10 Concentrate** vial X 1,
- 1mL syringe with integrated 23g (or finer) x 25mm needle X 10, and
- a single use 70% alcohol swab x 10.

3.5.2 Carefully transfer the tray to the administration area. Movement of the vaccine should be limited due to the fragility of the vaccine.

3.5.3. Check the vial is within the hand-written post-dilution expiry time on the label.

3.5.4 Check the identity of the vial. This procedure is intended for use with the Comirnaty **10 concentrate** presentation.

- Check label format on the vial selected matches the picture below:


NB: The Comirnaty **10 concentrate** presentation does not state the dose on the label, however, it does uniquely state '10 doses after dilution'.

3.5.5 Cleanse the vial stopper with a single use 70% alcohol swab, and discard swab in a clinical waste bin.

3.5.6 Using aseptic technique, draw up **0.2mL** of the diluted vaccine using a new 1mL syringe with integrated 23g (or finer) x 25mm needle.

N.B. If using a syringe with an auto retracting needle, depressing the plunger will cause the needle to retract prematurely.

3.5.7 Adjust to remove air bubbles with the needle still in the vial to avoid loss of diluted vaccine.

3.5.8 Self-check the volume withdrawn is **0.2mL.** Request a second check of volume. The vaccinator and person carrying out the second check must sign the workstation log.

3.5.9 Visually inspect the syringes for particles and leaks. Discard if these are observed.

3.5.10 The newly filled syringe must be used for immediate administration.

3.5.11 Steps 3.5.3 to 3.5.10 may be repeated a further five times to produce a total of six syringes from each diluted vaccine vial. Each time the vial bung is punctured, this should be in a different location to previous points of puncture on the bung.

3.5.12 If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

3.5.13 After the tenth dose has been taken from the vial, or if expiry has been exceeded, remove the label from the vial and attach to the workstation log. Discard the used diluted vaccine vial into a yellow lidded sharps bin.

3.5.14 At the end of the session, remove all unused vials from the lidded box 'CONCENTRATED VACCINE VIALS' and discard them into a yellow lidded sharps bin. Vials must not be stored between sessions or returned to the refrigerator. At this stage remove the label - '*Concentrate room temperature expiry label*' from the box and clean it in readiness for the next batch. Document any unused vials on the audit paperwork**. Note that every reasonable effort must be made to safely use all available vaccine and therefore not waste doses; before discarding unused vials or doses permission must be sought from the Clinical Lead (senior nurse).**

3.5.15 Empty outer cartons must be disposed of in a secure manner which prevents theft. Score through label text with a permanent marker and cut the box up into pieces before disposal in confidential waste.

**3.6 Dealing with deviations from this procedure**

3.6.1 Any deviations from this procedure must immediately be reported to the supervising pharmacist or clinical supervisor (senior nurse).

3.6.2 An audit worksheet (the workstation log) must be completed for each vial at each stage throughout the process by the vaccinators and the team overseeing stock control. Where vaccine is discarded, this must be recorded on the work station log and one of the following codes documented:

| ID | Name | Description | Vaccine/ Medical | Consumables | PPE |
|---|---|---|---|---|---|
| 1 | Contamination | The item (e.g. vaccine, diluent) has been contaminated | x | | X |
| 2 | Site Fridge/Freezer Malfunction | The item was stored in a temperature controlled environment that failed | X | | |
| 3 | Transport Breakdown | The item was in transit between locations when the vehicle it was in broke down, resulting in a temperature excursion | X | | |
| 4 | Excess Stock | Where a vaccination team reach the end of an allotted shift or job, and have surplus vaccines that cannot be returned to stock | X | | |
| 5 | Expired shelf-life | Where the expiry date for the product in its current state has been exceeded | X | | X |
| 6 | Waste at Point of Care | Where the prepped dose was refused by the patient | X | | |
| 7 | Improper Storage | The item had not been stored in accordance with instructions (e.g. left out of fridge) | X | X | X |
| 8 | Damaged/Dropped | The item is broken (e.g. vial dropped onto concrete floor) | X | X | X |
| 9 | Lost/ Stolen | The item has gone missing and is assumed lost or stolen | X | X | X |
| 10 | Refused at Delivery | The item has been delivered in a form that is unusable (e.g. temperature excursion or damaged item) | X | X | X |
| 11 | Reconstitution/ dilution /prep error | A mistake was made when drawing up the vaccine, making the dose unusable | X | | |

## 4.0 Equipment Required

Comirnaty 30 Concentrate Vaccine

Plastic opaque box labelled ‘CONCENTRATED VACCINE VIALS’.

Printed labels: ‘Concentrate Room Temperature Expiry Label’

Yellow lidded sharps bins

Indelible pen

Workstation logs

Appropriate personal protective equipment including apron and face mask

Disposable gloves

Disinfectant wipes

Clinical waste bins

Sodium chloride 0.9% ampoules 5mL (preservative free)

2mL or 3mL Syringes

21g (or finer) needles

Plastic trays

1ml syringes with integrated 23g (or finer) x 25mm needle (supplied with vaccine)

Single use 70% alcohol swabs

## 5.0 Training

All staff operating under this procedure must meet the training standards and competencies for the COVID-19 vaccination programme.

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | Yes – No |
| 2 | Does the implementation of this document require additional revenue resources | Yes – No |
| 3 | Does the implementation of this document require additional manpower | Yes – No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | Yes – No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | Yes – No |
| | Other comments | |

**Attachment 1 Comirnaty 10 Workstation Log**

## Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 6 v1 | **Title of Procedure/Guidelines**<br><br>Standard Operating Procedure for Preparation of Comirnaty 10 Concentrate | **Status:**<br><br>**FINAL** | | **Author: Clinical Director of Pharmacy**<br><br>**Director Sponsor: Chief Medical Officer** |
| Version / Amendment History | Version | Date | Author | Reason |
| | 1 | 20/09/2022 | Deputy Clinical Director of Pharmacy | New SOP |
| **Intended Recipients:** All staff delivering the COVID-19 vaccination programme | | | | |
| **Consultation Group / Role Titles and Date:**<br>Trust Medicines Management Group (MMG) | | | | |
| **Name and date of group where reviewed** | Medicines Management Group (MMG) 09/2022<br>Trust Policy Group – December 2022 | | | |
| **Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Trust Management Committee – January 2023 | | | |
| **Date of Procedure/Guidelines issue** | September 2022 | | | |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | August 2023 12 monthly | | | |

| | |
|---|---|
| **Training and Dissemination:**<br>This procedure will form part of the COVID-19 vaccine training programme which all new vaccinators are required to complete | |
| **To be read in conjunction with:**<br>COVID-19 Vaccine handling and management policy and associated procedures | |
| **Initial Equality Impact Assessment: Completed**<br>**Full Equality Impact assessment (as required): No** | |
| **Contact for Review** | Clinical Director of Pharmacy |
| **Monitoring arrangements** | Trust Medicines Management Group |
| **Document summary/key issues covered**<br>This Standard Operating procedure (SOP) describes the process for preparation of Comirnaty 10 Concentrate Vaccine. | |
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination<br>Comirnaty 10 Concentrate |

**IMPLEMENTATION PLAN**
**To be completed when submitted to the appropriate committee for consideration/approval**

| | | |
|---|---|---|
| **Procedure/Guidelines number and version** | **Title of Procedure/Guidelines** | |
| **Reviewing Group** | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** | | |

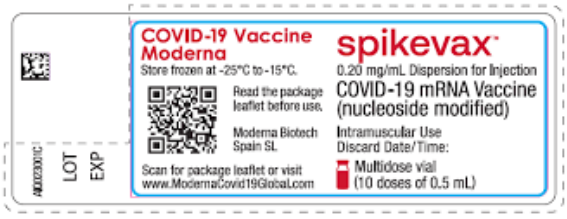
| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
|---|---|---|
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | | |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | | |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | | |
| Financial cost implementation<br>Consider Business case development | | |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | | |

# COVID-19 Vaccine Procedure 7 Standard Operating Procedure for Preparation of Spikevax Original 0.5mL (Primary Course Dose) and 0.25mL (Booster Dose) Syringes for Administration

## 1.0 Procedure Statement

This SOP describes the process for preparation of ready-to-administer 0.5mL (primary course dose) and 0.25mL (booster dose) syringes of Spikevax COVID-19 mRNA (nucleoside modified vaccine 0.1mg/0.5mL dose dispersion for injection (Spikevax **Original**) prior to immediate administration.

Different strengths and formulations of Spikevax vaccine are available. Ensure the correct procedure is selected for the strength or formulation required. This SOP is for use with Spikevax **Original** with the label format:




This procedure covers the process from the removal of vials of thawed vaccine from the outer carton in the refrigerator, or removal of individual vials from a cool box, up until the point of administration. This includes assigning an expiry date and time after the first dose withdrawal and the preparation of syringes for administration.

This procedure may be adapted to suit either of the following models:

- one person to both draw up individual doses into syringes and administer the vaccine or
- One person to draw up individual doses into syringes and pass the syringe to a vaccinator. This model requires additional local risk assessment and the introduction of local controls to reduce the risk of needle stick injuries on transfer between individuals.

This procedure is based on Specialist Pharmacy Services Procedure *PCV 4 – Preparation of Spikevax original booster and primary course*

## 2.0 Accountabilities

The Clinical Director of Pharmacy is professionally accountable for the safe and secure handling and management of COVID-19 vaccine and related medicines on all vaccination sites operating within the jurisdiction of the Trust.

The Clinical Lead for the vaccination site is professionally accountable for ensuring that appropriate and formal authorisation for vaccine administration is in place (PSD,

PGD or National Protocol), and that the staff groups who are supplied with, prepare, and administer the COVID-19 vaccine are those defined as eligible to do so in accordance with the authorisation being used. When working under the National Protocol, the Clinical Lead will ensure that a clinical supervisor is present for the duration of the vaccination session and this person is clearly identifiable and competent in all stages of the vaccination pathway. The Clinical Lead is also responsible for ensuring that all staff undertaking duties at the vaccination site meet the training standards and competencies for the vaccination programme.

When working under a PSD, the prescriber is legally accountable for the safe and secure handling and management of the COVID-19 vaccine under The Human Medicines Regulations (2012) Regulation 3.

Registered healthcare professionals working under a PSD, PGD or the National Protocol and non-registered staff working under the National Protocol are responsible for ensuring the safe and secure handling requirements are met and must follow this procedure.

## 3.0 Procedure Detail / Actions

### 3.1 Workstation preparation

3.1.1 Confirm the preparation workstation is clear and free from any other vials of vaccine.

3.2.2 Ensure a yellow lidded sharps bin with sufficient free capacity is available.

3.2.3 Ensure an indelible pen is available and a workstation log with information completed for start of session.

.

3.2.4 Put on apron.

3.2.5 Clean workstation with disinfectant wipes and discard into a clinical waste bin.

3.2.6 Following RWT Infection Prevention Policy, wash hands thoroughly. Put on disposable gloves and apron (if not already wearing one) and ensure a face mask is worn.

3.3 When ready to begin preparation select one vial of Spikevax **Original** vaccine.

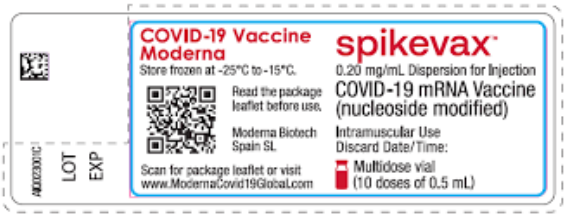
3.3.1 If working with vials stored in a refrigerator:

- if there is more than one batch of vaccine vials, use the one with the shortest expiry,
- check the post thaw expiry on the carton has not been exceeded, and
- remove a single vial and close the carton.

3.3.2 If working with vials from a cool box at 2-8$^{O}$C:

- check the vial is within the post-thaw expiry date by checking the label on the vial transport container (refer to SOP 3: *Use of cool boxes to transport COVID-19 vaccines to end user locations) and*
- remove a single vial and close the lid of the cool box.

3.3.3 Check the identity of the vial. This procedure is intended for use with the Spikevax **Original** vaccine. Check that the label format on the vial selected matches the image below:




3.3.4 Assemble the following materials required to prepare syringes:

- Spikevax **Original** vial X 1,
- 1mL syringe with integrated 23g (or finer) x 25mm needle x 1 per dose and
- sterile single use 70% alcohol swab x 1 per dose.

3.3.5 Swirl the vial by gently rotating in a circular motion several times. Do not shake it.

3.3.6 Inspect the vial visually for foreign particulate matter and, or discoloration prior to administration. If foreign particulate matter or discolouration is present, the vaccine should not be administered.

N.B. Spikevax **Original** is a white to off-white dispersion. It may contain white or translucent product-related particulates.

3.3.7 Confirm if the **0.5mL** primary course dose or the **0.25mL** booster dose is required by the patient.

3.3.8 Cleanse the vial stopper with a single use 70% alcohol swab, and discard swab in a clinical waste bin.

3.3.9 Using aseptic technique, draw up **0.5mL** primary course dose or the **0.25mL** booster dose of the vaccine using a new 1mL syringe with integrated 23g or finer x 25mm needle.

N.B.

- a 21g or finer x 38mm needle and 1mL syringe should be used for administering the vaccine to morbidly obese patients, and
- if using a syringe with an auto retracting needle, depressing the plunger will cause the needle to retract prematurely.

3.3.10 Adjust to remove air bubbles with the needle still in the vial to avoid loss of vaccine.

3.3.11 Check volume withdrawn is **0.5mL** for a primary course dose or **0.25mL** for a booster dose**.** Request a second check of volume. The vaccinator and person carrying out the second check must sign the workstation log.

3.3.12 Visually inspect the syringes for foreign particulate matter and leaks. Discard if they are observed.

3.3.13 The newly filled syringe must be used for immediate administration.

After first dose withdrawal, use the vial as soon as practically possible and within 6 hours (stored at $2^0$C to $25^0$C). Document the expiry date and time (24-hour format, e.g., 14:00) on the vial after first use.

3.3.14 Steps 3.3.3 to 3.3.13 may be repeated to produce further doses. The vial may only be punctured a maximum of 20 times. It is normal for liquid to remain in the vial after withdrawing the final dose.

N.B. to minimise the risk of stopper coring and particles entering the vial:

- insert the needle through a fresh point in the inner ring of the vial stopper each time,
- each time the vial bung is punctured, do so in a different location to previous points of puncture on the bung working methodically around the inner ring of the vial stopper tracking previous puncture points, and
- do not puncture the stopper outside of the inner ring as this may increase the risk of coring.

3.3.15 If the amount of vaccine remaining in the vial cannot provide a full dose, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

3.5.13 After the final dose has been taken from the vial or if expiry has been exceeded, remove the label from the vial and attach to the workstation log. Discard the used diluted vaccine vial into a yellow lidded sharps bin.

3.5.14 At the end of the session, remove all unused vials from the workstation and discard into a yellow lidded sharps bin. Vials must not be stored between sessions or returned to the refrigerator. **Note that every reasonable effort must be made to safely use all available vaccine and therefore not waste doses; before discarding unused vials or doses permission must be sought from the Clinical Lead (senior nurse).**

3.5.15 Empty outer cartons must be disposed of in a secure manner which prevents theft. Score through label text with a permanent marker and cut the box up into pieces before disposal in confidential waste.

### 3.6 Dealing with deviations from this procedure

3.6.1 Any deviations from this procedure must immediately be reported to the clinical supervisor (senior nurse).

3.6.2 An audit worksheet (the workstation log) must be completed for each vial at each stage throughout the process by the vaccinators and the team overseeing stock control. Where vaccine is discarded, this must be recorded on the workstation log and one of the following codes documented:

| ID | Name | Description | Vaccine/ Medical | Consumables | PPE |
|---|---|---|---|---|---|
| 1 | Contamination | The item (e.g. vaccine, diluent) has been contaminated | x | | X |
| 2 | Site Fridge/Freezer Malfunction | The item was stored in a temperature controlled environment that failed | X | | |
| 3 | Transport Breakdown | The item was in transit between locations when the vehicle it was in broke down, resulting in a temperature excursion | X | | |
| 4 | Excess Stock | Where a vaccination team reach the end of an allotted shift or job, and have surplus vaccines that cannot be returned to stock | X | | |
| 5 | Expired shelf-life | Where the expiry date for the product in its current state has been exceeded | X | | X |
| 6 | Waste at Point of Care | Where the prepped dose was refused by the patient | X | | |
| 7 | Improper Storage | The item had not been stored in accordance with instructions (e.g. left out of fridge) | X | X | X |
| 8 | Damaged/Dropped | The item is broken (e.g. vial dropped onto concrete floor) | X | X | X |
| 9 | Lost/ Stolen | The item has gone missing and is assumed lost or stolen | X | X | X |
| 10 | Refused at Delivery | The item has been delivered in a form that is unusable (e.g. temperature excursion or damaged item) | X | X | X |
| 11 | Reconstitution/ dilution /prep error | A mistake was made when drawing up the vaccine, making the dose unusable | X | | |

### 4.0 Equipment Required

Spikevax original Vaccine

Yellow lidded sharps bins

Indelible pen

Workstation logs

Appropriate personal protective equipment including apron and face mask

Disposable gloves

Disinfectant wipes

Clinical waste bins

Plastic trays

1ml syringes with integrated 23g (or finer) x 25mm needle (supplied with vaccine)

Single use 70% alcohol swabs

## 5.0 Training

All staff operating under this procedure must meet the training standards and competencies for the COVID-19 vaccination programme.

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | Yes – No |
| 2 | Does the implementation of this document require additional revenue resources | Yes – No |
| 3 | Does the implementation of this document require additional manpower | Yes – No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | Yes – No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | Yes – No |
| | Other comments | |

## Attachment 1 Spikevax Original Workstation Log

## Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 7 v1 | **Title of Procedure/Guidelines**<br><br>Standard Operating Procedure for Preparation of Spikevax original vaccine booster and primary course | **Status:**<br><br>**FINAL** | | **Author: Clinical Director of Pharmacy**<br><br>**Director Sponsor: Chief Medical Officer** |
| Version / Amendment History | Version | Date | Author | Reason |
| | 1 | 20/09/2022 | Deputy Clinical Director of Pharmacy | New SOP |
| **Intended Recipients:** All staff delivering the COVID-19 vaccination programme | | | | |
| **Consultation Group / Role Titles and Date:**<br>Trust Medicines Management Group (MMG) | | | | |
| **Name and date of group where reviewed** | Medicines Management Group (MMG) 09/2022<br>Trust Policy Group – December 2022 | | | |
| **Name and date of final approval committee (if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Trust Management Committee – January 2023 | | | |
| **Date of Procedure/Guidelines issue** | September 2022 | | | |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | August 2023 12 monthly | | | |

| | |
|---|---|
| **Training and Dissemination:**<br>This procedure will form part of the COVID-19 vaccine training programme which all new vaccinators are required to complete | |
| **To be read in conjunction with:**<br>COVID-19 Vaccine handling and management policy and associated procedures | |
| **Initial Equality Impact Assessment: Completed**<br>**Full Equality Impact assessment (as required): No** | |
| **Contact for Review** | Clinical Director of Pharmacy |
| **Monitoring arrangements** | Trust Medicines Management Group |
| **Document summary/key issues covered**<br>This Standard Operating procedure (SOP) describes the process for preparation of Spikevax original vaccine booster and primary course. | |
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination<br>Spikevax original |

**IMPLEMENTATION PLAN**
**To be completed when submitted to the appropriate committee for consideration/approval**

| **Procedure/Guidelines number and version** | **Title of Procedure/Guidelines** | |
|---|---|---|
| **Reviewing Group** | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** | | |

| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
|---|---|---|
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | | |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | | |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | | |
| Financial cost implementation<br>Consider Business case development | | |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | | |

# COVID-19 Vaccine Procedure 8 Standard Operating Procedure for Preparation of Comirnaty Bivalent Original/Omicron BA.1 0.3mL Syringes for Administration

## 1.0 Procedure Statement

This SOP describes the process for preparation of ready-to-administer 0.3mL syringes of Comirnaty Original/Omicron BA.1 COVID-19 mRNA Vaccine 15micrograms/15micrograms/0.3mLdose dispersion for injection (**Comirnaty Bivalent Original / Omicron BA.1)** prior to immediate administration.

Different strengths and formulations of Comirnaty vaccine are available. Ensure the correct procedure is selected for the strength or formulation required. This SOP is for use with **Comirnaty Bivalent Original / Omicron BA.1)** with the following label format:


This procedure covers the process from the removal of vials of thawed vaccine from the outer carton in the refrigerator, or removal of individual vials from a cool box, up until the point of administration. This includes assigning an expiry date and time after the first dose withdrawal and the preparation of syringes for administration.

This procedure may be adapted to suit either of the following models:

- one person to both draw up individual doses into syringes and administer the vaccine or
- One person to draw up individual doses into syringes and pass the syringe to a vaccinator. This model requires additional local risk assessment, and the introduction of local controls to reduce the risk of needle stick injuries on transfer between individuals.

This procedure is based on Specialist Pharmacy Services Procedure *PCV 3 – Preparation of Comirnaty Bivalent Original / Omicron BA.1 Vaccine.*

## 2.0 Accountabilities

The Clinical Director of Pharmacy is professionally accountable for the safe and secure handling and management of COVID-19 vaccine and related medicines on all vaccination sites operating within the jurisdiction of the Trust.

The Clinical Lead for the vaccination site is professionally accountable for ensuring that appropriate and formal authorisation for vaccine administration is in place (PSD, PGD or National Protocol), and that the staff groups who are supplied with, prepare, and administer the COVID-19 vaccine are those defined as eligible to do so in accordance with the authorisation being used. When working under the National Protocol, the Clinical Lead will ensure that a clinical supervisor is present for the duration of the vaccination session and this person is clearly identifiable and competent in all stages of the vaccination pathway. The Clinical Lead is also responsible for ensuring that all staff undertaking duties at the vaccination site meet the training standards and competencies for the vaccination programme.

When working under a PSD, the prescriber is legally accountable for the safe and secure handling and management of the COVID-19 vaccine under The Human Medicines Regulations (2012) Regulation 3.

Registered healthcare professionals working under a PSD, PGD or the National Protocol and non-registered staff working under the National Protocol are responsible for ensuring the safe and secure handling requirements are met and must follow this procedure.

## 3.0 Procedure Detail / Actions

### 3.1 Workstation preparation

3.1.1 Confirm the preparation workstation is clear and free from any other vials of vaccine.

3.2.2 Ensure a yellow lidded sharps bin with sufficient free capacity is available.

3.2.3 Ensure an indelible pen is available and a workstation log with information completed for start of session.

.

3.2.4 Put on apron.

3.2.5 Clean workstation with disinfectant wipes and discard into a clinical waste bin.

3.2.6 Following RWT Infection Prevention Policy, wash hands thoroughly. Put on disposable gloves and apron (if not already wearing one) and ensure a face mask is worn.

3.3 When ready to begin preparation select one vial of **Comirnaty Bivalent Original / Omicron BA.1)** vaccine.

3.3.1 If working with vials stored in a refrigerator:

- if there is more than one batch of vaccine vials, use the one with the shortest expiry,
- check the post thaw expiry on the carton has not been exceeded, and
- Remove a single vial and close the carton.

3.3.2 If working with vials from a cool box at 2-8$^{O}$C:

- check the vial is within the post-thaw expiry date by checking the label on the vial transport container (refer to SOP 3: *Use of cool boxes to transport COVID-19 vaccines to end user locations), and*
- remove a single vial and close the lid of the cool box.

3.3.3 Check the identity of the vial. This procedure is intended for use with the **Comirnaty Bivalent Original / Omicron BA.1)** vaccine.

- Check the vial has a grey cap.
- Check label format on the vial selected matches the image below:


3.3.4 Assemble the following materials required to prepare syringes:

- **Comirnaty Bivalent Original / Omicron BA.1)** vial X 1,
- 1mL syringe with integrated 23g (or finer) x 25mm needle x 6, and
- sterile single use 70% alcohol swab x 6.

3.3.5 Gently mix by inverting the vial 10 times, DO NOT shake it. One inversion requires the vial to be fully rotated back to an upright position. Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.

3.3.6 Inspect the vial visually for foreign particulate matter and, or discoloration prior to administration. If particulate matter or discolouration is present, the vaccine should not be administered.

N.B. After mixing the vaccine should present as a white to off-white dispersion with no particulates visible.

3.3.7 Confirm the **0.3mL** booster course dose of **Comirnaty Bivalent Original / Omicron BA.1)** is required by the patient

3.3.8 Remove the grey vial dust cover and cleanse the vial stopper with a single use 70% alcohol swab, and discard swab in a clinical waste bin.

3.3.9 Using aseptic technique, draw up **0.3mL** of the vaccine using a new 1mL syringe with integrated 23g or finer x 25mm needle.

N.B.

- a 21g or finer x 38mm needle and 1mL syringe should be used for administering the vaccine to morbidly obese patients, and

- if using a syringe with an auto retracting needle, depressing the plunger will cause the needle to retract prematurely.

3.3.10 Adjust to remove air bubbles with the needle still in the vial to avoid loss of vaccine.

3.3.11 Check volume withdrawn is **0.3mL**. Request a second check of volume. The vaccinator and person carrying out the second check must sign the workstation log.

3.3.12 Visually inspect the syringes for foreign particulate matter and leaks. Discard if these are observed.

3.3.13 The newly filled syringe must be used for immediate administration.

After first dose withdrawal, use the vial as soon as practically possible and within 12 hours (stored at $2^0$C to $30^0$C). Document the expiry date and time (24-hour format, e.g. 14:00) on the vial after first use.

3.3.14 Steps 3.3.3 to 3.3.13 may be repeated a further five times to produce a total of six syringes from each vial. Each time the vial bung is punctured, this should be in a different location to previous points of puncture on the bung.

N.B. to minimise the risk of stopper coring and particles entering the vial:

- Insert the needle through a fresh point in the inner ring of the vial stopper each time,
- each time the vial bung is punctured, it should be in a different location to previous points of puncture working methodically around the inner ring of the vial stopper tracking previous puncture points, and
- do not puncture the stopper outside of the inner ring as this may increase the risk of coring.

3.3.15 If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

3.5.13 After the final dose has been taken from the vial or if expiry has been exceeded, remove the label from the vial and attach to the workstation log. Discard the used diluted vaccine vial into a yellow lidded sharps bin.

3.5.14 At the end of the session, discard any remaining part vials. Vials must not be stored between sessions or returned to the refrigerator. **Note that every reasonable effort must be made to safely use all available vaccine and therefore not waste doses; before discarding unused vials or doses permission must be sought from the Clinical Lead (senior nurse).**

3.5.15 Empty outer cartons must be disposed of in a secure manner which prevents theft. Score through the label text with a permanent marker and cut the box up into pieces before disposal in confidential waste.

### 3.6 Dealing with deviations from this procedure

3.6.1 Any deviations from this procedure must immediately be reported to the clinical supervisor (senior nurse).

3.6.2 An audit worksheet (the workstation log) must be completed for each vial at each stage throughout the process by the vaccinators and the team overseeing stock control. Where vaccine is discarded, this must be recorded on the workstation log and one of the following codes documented:

| ID | Name | Description | Vaccine/ Medical | Consumables | PPE |
|---|---|---|---|---|---|
| 1 | Contamination | The item (e.g. vaccine, diluent) has been contaminated | x | | X |
| 2 | Site Fridge/Freezer Malfunction | The item was stored in a temperature controlled environment that failed | X | | |
| 3 | Transport Breakdown | The item was in transit between locations when the vehicle it was in broke down, resulting in a temperature excursion | X | | |
| 4 | Excess Stock | Where a vaccination team reach the end of an allotted shift or job, and have surplus vaccines that cannot be returned to stock | X | | |
| 5 | Expired shelf-life | Where the expiry date for the product in its current state has been exceeded | X | | X |
| 6 | Waste at Point of Care | Where the prepped dose was refused by the patient | X | | |
| 7 | Improper Storage | The item had not been stored in accordance with instructions (e.g. left out of fridge) | X | X | X |
| 8 | Damaged/Dropped | The item is broken (e.g. vial dropped onto concrete floor) | X | X | X |
| 9 | Lost/ Stolen | The item has gone missing and is assumed lost or stolen | X | X | X |
| 10 | Refused at Delivery | The item has been delivered in a form that is unusable (e.g. temperature excursion or damaged item) | X | X | X |
| 11 | Reconstitution/ dilution /prep error | A mistake was made when drawing up the vaccine, making the dose unusable | X | | |

## 4.0 Equipment Required

Comirnaty Bivalent Original / Omicron BA.1

Yellow lidded sharps bins

Indelible pen

Workstation logs

Appropriate personal protective equipment including apron and face mask

Disposable gloves

Disinfectant wipes

Clinical waste bins

Plastic trays

1ml syringes with integrated 23g (or finer) x 25mm needle (supplied with vaccine)

Single use 70% alcohol swabs

## 5.0 Training

All staff operating under this procedure must meet the training standards and competencies for the COVID-19 vaccination programme.

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | Yes – No |
| 2 | Does the implementation of this document require additional revenue resources | Yes – No |
| 3 | Does the implementation of this document require additional manpower | Yes – No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | Yes – No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | Yes – No |
| | Other comments | |

**Attachment 1** **Comirnaty Bivalent Original / Omicron BA.1 Workstation Log**

## Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 8 v2 | **Title of Procedure/Guidelines**<br><br>Standard Operating Procedure for Preparation of Comirnaty Bivalent Vaccine | **Status:**<br><br>**FINAL** | | **Author: Clinical Director of Pharmacy**<br><br>**Director Sponsor: Chief Medical Officer** |
| Version / Amendment History | Version | Date | Author | Reason |
| | 1 | 20/09/2022 | Deputy Clinical Director of Pharmacy | New SOP |
| | 2 | 30/03/2022 | Clinical Lead – Living Well Group | Updated title and vaccine description to differentiate between different bivalent vaccines in use updated attachment 1 |
| **Intended Recipients:** All staff delivering the COVID-19 vaccination programme | | | | |
| **Consultation Group / Role Titles and Date:**<br>Trust Medicines Management Group (MMG) | | | | |
| **Name and date of group where reviewed** | Medicines Management Group (MMG) 04/2023 | | | |
| **Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Trust MMG 04/2023 | | | |
| **Date of Procedure/Guidelines issue** | April 2023 | | | |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | April 2026 | | | |
| **Training and Dissemination:**<br>This procedure will form part of the COVID-19 vaccine training programme which all new vaccinators are required to complete | | | | |
| **To be read in conjunction with:**<br>COVID-19 Vaccine handling and management policy and associated procedures | | | | |

| | |
|---|---|
| **Initial Equality Impact Assessment: Completed**<br>**Full Equality Impact assessment (as required): No** | |
| **Contact for Review** | Clinical Director of Pharmacy |
| **Monitoring arrangements** | Trust Medicines Management Group |
| **Document summary/key issues covered**<br>This Standard Operating procedure (SOP) describes the process for preparation Comirnaty Bivalent Vaccine | |
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination<br>Comirnaty Bivalent<br>Original / Omicron BA.1 |

**IMPLEMENTATION PLAN**
**To be completed when submitted to the appropriate committee for consideration/approval**

| | | |
|---|---|---|
| **Procedure/Guidelines number and version** | **Title of Procedure/Guidelines** | |
| **Reviewing Group** | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** | | |

| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
|---|---|---|
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | | |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | | |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | | |
| Financial cost implementation<br>Consider Business case development | | |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | | |

# Pfizer BIVALENT Comirnaty® Original/Omicron BA.1 COVID-19 Vaccine

| Date | | Workstation identifier | |
|---|---|---|---|

| | |
|---|---|
| Workstation cleaned and set up for session | |
| All unused vials removed from storage box and discarded | |
| Workstation cleared and cleaned | |

| Issues identified codes | |
|---|---|
| A | Vial Dropped - do not use |
| B | Syringe dropped - do not use |
| C | Vial discoloured or contained particles |
| D | Syringe contained particles |
| E | Other (give detail) |

**Vials received at workstation**

| Product | Batch number | Expiry date | Date | Time | Confirm fridge temp | Vial check | Completed by | Checked by |
|---|---|---|---|---|---|---|---|---|
| Comirnaty® Bivalent Original / Omicron BA.1 COVID-19 Vaccine 0.3mL dose | | | | | | | | |

| Name of vaccinator : | | Name of second checker: | |
|---|---|---|---|
| Vaccination room temp: | | Vial Expiry Date/Time (12 Hours after the first puncture): | |

| | 0.3mL Doses drawn up & checked (first check by person drawing up and second check signed by person overseeing - if applicable) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Dose | 1 | 2 | 3 | 4 | 5 | 6 | Issues identified (enter appropriate letter above) | Comments |
| Time: | | | | | | | | |
| Patient's name: | | | | | | | | |
| Signature of vaccinator: | | | | | | | | |
| Signature of second checker: | | | | | | | | |

*Written by: SPS/Nicholas Carre*

*Approved by: Trust MMG*

*Authorised by: Directorate Governance*

Version:2.0
Issue date: 30/03/2023
Review date 30/03/2026
All forms to be stored on site

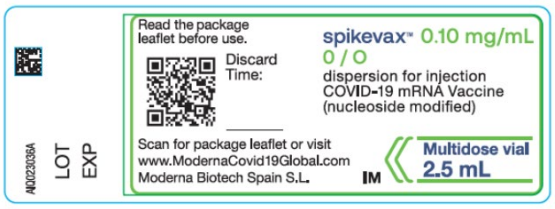
# COVID-19 Vaccine Procedure 9 Standard Operating Procedure for Preparation of Spikevax Bivalent 0.5mL (Booster Dose) Syringes for Administration

## 1.0 Procedure Statement

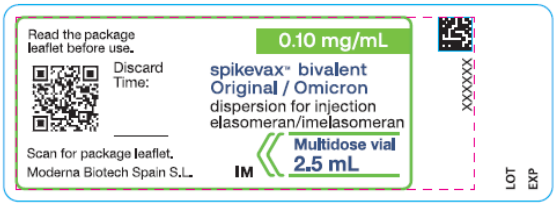
This SOP describes the process for preparation of **ready-to-administer** 0.5mL (booster dose) syringes of Spikevax Original/Omicron 0.10 mg/mL dispersion for injection (Spikevax **Bivalent**) prior to immediate administration.

Different strengths and formulations of Spikevax vaccine are available. Ensure the correct procedure is selected for the strength and formulation required. This SOP is for use with Spikevax **Bivalent** with the label formats:

Vial label – initial supply 2.5mL (5 doses)




Vial label –subsequent supply 2.5mL (5 doses)




Vial label – initial supply 5mL (10 doses)


This procedure covers the process for the removal of vials of thawed vaccine from the outer carton in the refrigerator, or removal of individual vials from a cool box, up until the point of administration. This includes assigning an expiry date and time after the first dose withdrawal and the preparation of syringes for administration.

This procedure may be adapted to suit either of the following models:

- one person to both draw up individual doses into syringes and administer the vaccine, or.
- one person to draw up individual doses into syringes and pass the syringe to a vaccinator. This model requires additional local risk assessment, and the introduction of local controls to reduce the risk of needle stick injuries on transfer between individuals.

This procedure is based on Specialist Pharmacy Services Procedure *PCV 5 – Preparation of Spikevax Bivalent Vaccine.*

## 2.0 Accountabilities

The Clinical Director of Pharmacy is professionally accountable for the safe and secure handling and management of COVID-19 vaccine and related medicines on all vaccination sites operating within the jurisdiction of the Trust.

The Clinical Lead for the vaccination site is professionally accountable for ensuring that appropriate and formal authorisation for vaccine administration is in place (PSD, PGD or National Protocol), and that the staff groups who are supplied with, prepare, and administer the COVID-19 vaccine are those defined as eligible to do so in accordance with the authorisation being used. When working under the National Protocol the Clinical Lead will ensure that a clinical supervisor is present for the duration of the vaccination session and this person is clearly identifiable and competent in all stages of the vaccination pathway. The Clinical Lead is also responsible for ensuring that all staff undertaking duties at the vaccination site meet the training standards and competencies for the vaccination programme.

When working under a PSD, the prescriber is legally accountable for the safe and secure handling and management of the COVID-19 vaccine under The Human Medicines Regulations (2012) Regulation 3.

Registered healthcare professionals working under a PSD, PGD or the National Protocol and non-registered staff working under the National Protocol are responsible for ensuring the safe and secure handling requirements are met and must follow this procedure.

## 3.0 Procedure Detail / Actions

### 3.1 Workstation preparation

3.1.1 Confirm the preparation workstation is clear and free from any other vials of vaccine.

3.2.2 Ensure a yellow lidded sharps bin with sufficient free capacity is available.

3.2.3 Ensure an indelible pen is available and a workstation log with information completed for start of session.

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3.2.4 Put on apron.

3.2.5 Clean the workstation with disinfectant wipes and discard into a clinical waste bin.

3.2.6 Following RWT Infection Prevention Policy, wash hands thoroughly. Put on disposable gloves and apron (if not already wearing one) and ensure a face mask is worn.

3.3 When ready to begin preparation select one vial of Spikevax **Bivalent** vaccine.

3.3.1 If working with vials stored in a refrigerator:

- if there is more than one batch of vaccine vials, use the one with the shortest expiry,
- check the post thaw expiry on the carton has not been exceeded, and
- remove a single vial and close the carton.

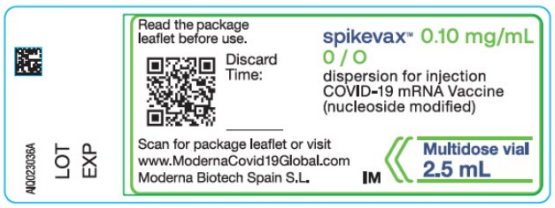
3.3.2 If working with vials from a cool box at 2-8$^{O}$C:

- check the vial is within the post-thaw expiry date by checking the label on the vial transport container ( refer to SOP 3: *Use of cool boxes to transport COVID-19 vaccines to end user locations)* and
- remove a single vial and close the lid of the cool box.

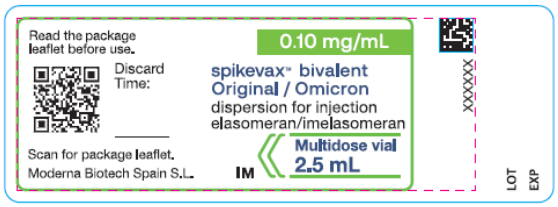
3.3.3 Check the identity of the vial. This procedure is intended for use with the Spikevax **Bivalent** vaccine.

- Check label format on the vial selected matches one of the images below:

Vial label – initial supply 2.5mL (5 doses)




Vial label –subsequent supply 2.5mL (5 doses)




Vial label – initial supply 5mL (10 doses)


NB: Initial Spikevax **bivalent** supply will state '0/O' on the label and subsequent supply will state 'bivalent Original/Omicron'.

3.3.4 Assemble the following materials required to prepare syringes:

- Spikevax **Bivalent** vial X 1,
- 1mL syringe with integrated 23g (or finer) x 25mm needle x 5 (or 10), and
- sterile single use 70% alcohol swab x 5 (or 10).

3.3.5 Swirl the vial by gently rotating in a circular motion several times. Do not shake.

3.3.6 Inspect the vial visually for foreign particulate matter and, or discoloration prior to administration. If foreign particulate matter or discolouration is present, the vaccine should not be administered.

N.B. Spikevax **Bivalent** is a white to off-white dispersion. It may contain white or translucent product-related particulates.

3.3.7 Confirm the **0.5mL** booster course dose is required by the patient.

3.3.8 Cleanse the vial stopper with a single use 70% alcohol swab, and discard swab in a clinical waste bin.

3.3.9 Using aseptic technique, draw up **0.5mL** of the vaccine using a new 1mL syringe with integrated 23g or finer x 25mm needle.

N.B.

- a 21g or finer x 38mm needle and 1mL syringe should be used for administering the vaccine to morbidly obese patients, and
- if using a syringe with an auto retracting needle, depressing the plunger will cause the needle to retract prematurely.

3.3.10 Adjust to remove air bubbles with the needle still in the vial to avoid loss of vaccine.

3.3.11 Check volume withdrawn is **0.5mL**. Request a second check of volume. The vaccinator and person carrying out the second check must sign the workstation log.

3.3.12 Visually inspect the syringes for foreign particulate matter and leaks. Discard if these are observed.

3.3.13 The newly filled syringe must be used for immediate administration.

After first dose withdrawal, use the vial as soon as practically possible and within 6 hours (stored at $2^0$C to $25^0$C). Document the expiry date and time (24-hour format, e.g. 14:00) on the vial after first use.

3.3.14 Steps 3.3.3 to 3.3.13 may be repeated a further four (or nine) times to produce a total of five (or ten) syringes from each vial. Each time the vial bung is punctured, this should be in a different location to previous points of puncture on the bung.

N.B. To minimise the risk of stopper coring and particles entering the vial:

- insert the needle through a fresh point in the inner ring of the vial stopper each time,

- each time the vial bung is punctured this should be in a different location to previous points of puncture working methodically around the inner ring of the vial stopper tracking previous puncture points, and.
- do not puncture the stopper outside of the inner ring as this may increase the risk of coring.

3.3.15 If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

3.5.13 After the final dose has been taken from the vial or if expiry has been exceeded, remove the label from the vial and attach to the workstation log. Discard the used diluted vaccine vial into a yellow lidded sharps bin.

3.5.14 At the end of the session, discard any remaining part vials. Vials must not be stored between sessions or returned to the refrigerator. **Note that every reasonable effort must be made to safely use all available vaccine and therefore not waste doses; before discarding unused vials or doses permission must be sought from the Clinical Lead (senior nurse).**

3.5.15 Empty outer cartons must be disposed of in a secure manner which prevents theft. Score through label text with a permanent marker and cut the box up into pieces before disposal in confidential waste.

**3.6 Dealing with deviations from this procedure**

3.6.1 Any deviations from this procedure must immediately be reported to the clinical supervisor (senior nurse).

3.6.2 An audit worksheet (the workstation log) must be completed for each vial at each stage throughout the process by the vaccinators and the team overseeing stock control. Where vaccine is discarded, this must be recorded on the work station log and one of the following codes documented:

| ID | Name | Description | Vaccine/ Medical | Consumables | PPE |
|---|---|---|---|---|---|
| 1 | Contamination | The item (e.g. vaccine, diluent) has been contaminated | x | | X |
| 2 | Site Fridge/Freezer Malfunction | The item was stored in a temperature controlled environment that failed | X | | |
| 3 | Transport Breakdown | The item was in transit between locations when the vehicle it was in broke down, resulting in a temperature excursion | X | | |
| 4 | Excess Stock | Where a vaccination team reach the end of an allotted shift or job, and have surplus vaccines that cannot be returned to stock | X | | |
| 5 | Expired shelf-life | Where the expiry date for the product in its current state has been exceeded | X | | X |
| 6 | Waste at Point of Care | Where the prepped dose was refused by the patient | X | | |
| 7 | Improper Storage | The item had not been stored in accordance with instructions (e.g. left out of fridge) | X | X | X |
| 8 | Damaged/Dropped | The item is broken (e.g. vial dropped onto concrete floor) | X | X | X |
| 9 | Lost/ Stolen | The item has gone missing and is assumed lost or stolen | X | X | X |
| 10 | Refused at Delivery | The item has been delivered in a form that is unusable (e.g. temperature excursion or damaged item) | X | X | X |
| 11 | Reconstitution/ dilution /prep error | A mistake was made when drawing up the vaccine, making the dose unusable | X | | |

## 4.0 Equipment Required

Spikevax Bivalent Vaccine

Yellow lidded sharps bins

Indelible pen

Workstation logs

Appropriate personal protective equipment including apron and face mask

Disposable gloves

Disinfectant wipes

Clinical waste bins

Plastic trays

1ml syringes with integrated 23g (or finer) x 25mm needle (supplied with vaccine)

Single use 70% alcohol swabs

## 5.0 Training

All staff operating under this procedure must meet the training standards and competencies for the COVID-19 vaccination programme.

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | Yes – No |

| | | |
|---|---|---|
| 2 | Does the implementation of this document require additional revenue resources | Yes – No |
| 3 | Does the implementation of this document require additional manpower | Yes – No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | Yes – No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | Yes – No |
| | Other comments | |

**Attachment 1 Spikevax Bivalent Workstation Log**

## Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 9 v1 | **Title of Procedure/Guidelines**<br><br>Standard Operating Procedure for Preparation of Spikevax Bivalent Vaccine | **Status:**<br><br>**FINAL** | | **Author: Deputy Clinical Director of Pharmacy**<br><br>**Director Sponsor: Chief Medical office** |
| Version / Amendment History | Version | Date | Author | Reason |
| | 1 | 20/09/2022 | Deputy Clinical Director of Pharmacy | New SOP |
| **Intended Recipients:** All staff delivering the COVID-19 vaccination programme | | | | |
| **Consultation Group / Role Titles and Date:**<br>Trust Medicines Management Group (MMG) | | | | |
| **Name and date of group where reviewed** | Medicines Management Group (MMG) 09/2022<br>Trust Policy Group – December 2022 | | | |
| **Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Trust MMG<br>09/2022<br>Trust Management Committee – January 2023 | | | |
| **Date of Procedure/Guidelines issue** | September 2022 | | | |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | August 2023 12 monthly | | | |

| | |
|---|---|
| **Training and Dissemination:**<br>This procedure will form part of the COVID-19 vaccine training programme which all new vaccinators are required to complete | |
| **To be read in conjunction with:**<br>COVID-19 Vaccine handling and management policy and associated procedures | |
| **Initial Equality Impact Assessment: Completed**<br>**Full Equality Impact assessment (as required): No** | |
| **Contact for Review** | Clinical Director of Pharmacy |
| **Monitoring arrangements** | Trust Medicines Management Group |
| **Document summary/key issues covered**<br>This Standard Operating procedure (SOP) describes the process for preparation Spikevax Bivalent Vaccine | |
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination<br>Spikevax Bivalent |

**IMPLEMENTATION PLAN**
**To be completed when submitted to the appropriate committee for consideration/approval**

| **Procedure/Guidelines number and version** | **Title of Procedure/Guidelines** | |
|---|---|---|
| **Reviewing Group** | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** | | |
| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | | |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | | |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | | |
| Financial cost implementation<br>Consider Business case development | | |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | | |

# COVID-19 Vaccine Procedure 10 Standard Operating Procedure for Handling of Spillages and Breakages of COVID-19 Vaccines

## 1.0 Procedure Statement

This Standard Operating Procedure (SOP) describes the method to be used to safely deal with a spillage and breakage of all COVID-19 vaccine.

This procedure is based on Specialist Pharmacy Services Procedure *HCV 7 Dealing with spillages of COVID-19 vaccines*.

## 2.0 Accountabilities

The shift Clinical Lead is accountable for ensuring spillages of COVID-19 vaccine are managed safely and in line with this SOP.

All staff handling the COVID-19 vaccine are responsible for managing spillages of COVID-19 vaccine according to this SOP.

## 3.0 Procedure Detail / Actions

Warn others that there has been a spill.
Assess the spillage: if this procedure cannot be followed or there are any other concerns about safety, escalate to the shift Clinical Lead.

### 3.1 Spillages on skin/eyes

3.1.1 Staff must be aware of location of handwashing facilities and eyewash kits.

3.1.2 Spillages on skin should be washed with soap and water.

3.1.3 If a vaccine is splashed in the eyes, rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Medical advice should be sought.

### 3.2 Spillages on surfaces

3.2.1 Spillages must be cleared up quickly wearing gloves.

3.2.2 The spillage should be soaked up with paper towels, taking care to avoid skin puncture from glass or needles.

3.2.3 Gloves, towels, etc. should be disposed of in accordance with Trust Policy.

3.2.4 The area should be cleaned and disinfected.

### 3.3 Reporting

3.3.1 Report the spill to the Clinical Lead.

3.3.2 Where the spill is to skin or eyes, a Datix must be completed and the individual must be monitored and any adverse effects reported.

3.3.3 Record the number of broken or contaminated vials on the supervision log

## 4.0 Equipment Required

Surgical gloves

Paper towels

Yellow lidded sharps bins

## 5.0 Training

Staff participating in the delivery of the COVID-19 Vaccination Programme are required to read this procedure.

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | Yes – No |
| 2 | Does the implementation of this document require additional revenue resources | Yes – No |
| 3 | Does the implementation of this document require additional manpower | Yes – No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | Yes – No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | Yes – No |
| | Other comments | |

## Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 10 v2 | **Title of Procedure/Guidelines**<br><br>Standard Operating Procedure for Handling of Spillages and Breakages of COVID-19 Vaccine | **Status:**<br><br>**FINAL** | | **Author: Clinical Director of Pharmacy**<br><br>**Director Sponsor: Chief Medical Officer** |
| Version / Amendment History | Version | Date | Author | Reason |
| | v1 | 29/12/2020 | Clinical Director of Pharmacy | New SOP |
| | v2 | 222/09/2022 | Deputy Clinical Director of Pharmacy | Updated to include reference to all COVID-19 vaccines |
| **Intended Recipients:** All staff delivering the COVID-19 vaccination programme | | | | |
| **Consultation Group / Role Titles and Date:**<br>Trust Medicines Management Group (MMG) | | | | |
| **Name and date of group where reviewed** | Medicines Management Group (MMG) 09/2022<br>Trust Policy Group – December 2022 | | | |
| **Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Medicines Management Group (MMG) 09/2022<br>Trust Management Committee – January 2023 | | | |
| **Date of Procedure/Guidelines issue** | September 2022 | | | |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | August 2023 12 months | | | |

| | |
|---|---|
| **Training and Dissemination:**<br>This procedure will form part of the COVID-19 vaccine training programme which all new vaccinators are required to complete | |
| **To be read in conjunction with:**<br>COVID-19 Vaccine handling and management policy and associated procedures | |
| **Initial Equality Impact Assessment: Completed**<br>**Full Equality Impact assessment (as required): No** | |
| **Contact for Review** | Clinical Director of Pharmacy |
| **Monitoring arrangements** | Trust Medicines Management Group |
| **Document summary/key issues covered**<br>This Standard Operating procedure (SOP) describes the method to be used to safely deal with a spillage of COVID-19 vaccine. | |
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination |

**IMPLEMENTATION PLAN**
**To be completed when submitted to the appropriate committee for consideration/approval**

| | | |
|---|---|---|
| **Procedure/Guidelines number and version** | **Title of Procedure/Guidelines** | |
| **Reviewing Group** | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** | | |

| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
|---|---|---|
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | | |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | | |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | | |
| Financial cost implementation<br>Consider Business case development | | |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | | |

# COVID-19 Vaccine Procedure 11
# The Management and Administration of Multiple Vaccines in a Single Vaccination Clinic Setting

## 1.0 Procedure Statement

This Standard Operating Procedure (SOP) describes the process for the administration of multiple COVID-19 vaccines in a single vaccination clinic setting.

The aim of the SOP is to ensure the safe handling of different vaccines within the same physical location and to avoid medication administration error.

This procedure was developed using the SPS *guidance for sites when handling multiple vaccines.*

## 2.0 Accountabilities

The Clinical Director of Pharmacy is professionally accountable for the safe and secure handling and management of all vaccines across all vaccination sites operating within the jurisdiction of the Trust.

The Clinical Lead for the vaccination site is professionally accountable for ensuring that appropriate and formal authorisation for vaccine administration is in place, for example National Protocol, PSD or PGD, and the staff groups who are working are those defined as eligible to do so in accordance with the authorisation being used. The Clinical Lead is also responsible for ensuring that all staff undertaking duties at the vaccination site meet the training standards and competencies for the vaccination programme.

A Clinical Lead must be physically present at all times and is responsible for provision of vaccination under the protocol at all times and must be identifiable to service users. The Clinical Lead is responsible for provision of safe care during the vaccination session.

The Operational Lead for the vaccination site is accountable for all administration processes required to support vaccination. A designated Business Manager may be identified by the Operational Lead to deputise at the vaccination site, this includes appointment management that allows for flexibility to meet the needs of the staff where possible.

The COVID-19 Lead Pharmacist is accountable to the day-to-day management of all vaccines and must be contactable at all times that vaccination sites are operational. They must complete a weekly assurance visit to each active vaccination site.

## 3.0 Procedure Detail / Actions

### VACCINE ASSURANCE VISITS

3.1 The COVID-19 Lead pharmacist must complete weekly assurance visits to each site and complete the pharmacy supervision of COVID-19 Vaccine Checklist (attachment 2)

### VACCINATION SESSION SET UP AND CLOSE DOWN

3.2 Before the start of every vaccination clinic, the COVID-19 Vaccination session record (Attachment 1) must be completed by the Clinical Lead.

3.3 The document must remain live throughout the session and all sections must be fully completed.

3.4 The close-down process must be completed before the clinic and the vaccination team leave each night.

3.5 The supervision log must be kept with the vaccination worksheets completed on the same day.

3.6 These will be reviewed as part of the COVID-19 lead pharmacist stock reconciliation checks. (see COVID-19 Procedure 4 – Stocktaking and reconciliation of COVID-19 vaccine)

### SAFETY BRIEF

3.7 The Clinical Lead will conduct a ‘Safety Brief’ at the start of each vaccination session. All staff must attend the Safety Brief. If a member of staff starts part way through a vaccination session they must report to the Clinical Lead for a Safety Brief. A copy will be retained.

3.8 The Safety Brief will include, but is not limited to, the following.

- Introduction of the Team (supervisor, vaccinators, pharmacy, admin, security).
- Identification of Clinical Lead, registered staff members and unregistered vaccinators.
- Confirmation that all staff have completed training, have been signed off against the national protocol(s) and have been approved to vaccinate.
- Confirmation that any information displayed is accurate and current.
- The vaccines to be used.
- Which legal mechanism is being used e.g., written instruction, national protocol etc.
- Reiteration of doses.
- Any changes to processes .
- Any clinical updates.

- Lessons learned from clinical incidents.

**NATIONAL PROTOCOLS / PGD / PSD / Written Instructions**

3.3 National Protocols, PGDs, PSDs or Written instructions must be followed in accordance with the legislative requirements.

3.4 Only registered vaccinators are authorised to complete the initial clinical assessment, provide information and advice, and consent the person to be vaccinated.

3.5 Only registered vaccinators are authorised to administer vaccines against a written instruction.

3.6 Registered and unregistered vaccinators are permitted to prepare and administer vaccines against a National Protocol. Unregistered vaccinators must be supervised by a registered member of staff.

3.7 In the event that a vaccine is to be administered against a patient specific direction or patient group direction, a registered vaccinator must administer the vaccine.

**Vaccine Storage and Preparation**

3.8 Each different type of vaccine must kept in a separate, clearly marked area of the fridge or a different fridge should be used to separate the different vaccines.

3.9 The door to the room where vaccines are stored must be kept shut at all times when not in use and the fridge and room door locked when the room is left unattended.

3.10 When COVID vaccines require dilution, there must be a separate preparation area for each different vaccine. If there is insufficient space to achieve, this only one vaccine can be prepared at a time and the checklist for clear-down of the current vaccine dilution area (Appendix 1) must be used to close the preparation area down before commencing the preparation of a different vaccine.

3.11 Where there is space for multiple preparation areas, the vaccines must be kept physically separate this will be achieved by using separate workstations in the vaccine preparation room identified. For dilution and administration, different coloured trays will be used.

3.12 Each different vaccine will have a differently coloured tray that they are placed in once they have been prepared for use. The colours may vary at different vaccination sites.

3.13 Using the poster in Appendix 2, the vaccination site must display a record of the colours to be used for each vaccine in all vaccination preparation and vaccine administration areas.

3.14 There must be a maximum of one vial of diluted COVID vaccine on the vaccine preparation area at any time.

**Vaccine workstation management**

3.15 Wherever possible, vaccinators and vaccination workstations must be assigned to a specific vaccine.

3.16 Where this is not possible and a different vaccine is required, the current vaccine must be returned to the vaccine preparation room and the alternative vaccine taken to the vaccination workstation

3.17 Wherever possible, vaccinators and vaccination workstations must be assigned to a specific vaccine.

3.18 Lidded trays containing diluted vaccine and syringes must be collected from the vaccine preparation room and taken immediately to the vaccine workstation.

3.19 Only **one** type of COVID vaccine can be in the vaccination workstation at any time.

3.20 If the COVID-19 vaccine and another clinically appropriate vaccine are being used in a single workstation, a maximum of 5 pre-filled vaccine syringes can be in the same workstation as one COVID vaccine.

3.21 Where COVID-19 and influenza vaccines are used at the same workstation, the COVID vaccine must be kept on the top of the vaccine workstation and the other vaccine must be on the bottom of the vaccine workstation.

3.22 Where this is not possible and a different vaccine is required, the current vaccine must be returned to the vaccine preparation room and the alternative vaccine taken to the vaccination workstation

3.23 At the end of each vaccination session, every effort will be made to use all available unexpired doses. After this, any remaining vaccine will be disposed of and must not be returned to the fridge and the wastage recorded.

**Clinical assessment and administration**

3.24 All vaccination sites must have an operation flow document that is displayed in a staff area at all times.

3.25 The patients' demographics will be requested. These will be cross checked using a Vaccination Software (e.g. NIVS/NIMS/Pinnacle/EVA).

3.26 Once the vaccination record has been clarified, a registered vaccinator will complete the initial clinical assessment, provision of information and advice, and obtain informed consent for ALL service users for EACH vaccine being offered.

3.27 Where appropriate, service users to be vaccinated will be offered up to two vaccines at the same time. The clinical assessor undertaking the clinical assessment will gain informed consent and will determine which vaccine(s) are to be given.

3.28 Separate consent forms will be used for each vaccine. Where a vaccine is NOT appropriate for administration, the registered vaccinator will annotate the consent form accordingly.

3.29 Consent will be documented on the relevant consent forms available on the computerised system for all vaccines. A written parental consent form will also be used for children aged 5 – 15 years of age.
Where a vaccine is NOT appropriate for administration, the clinical assessor will annotate the consent form accordingly.

3.30 All vaccinators (registered or unregistered) must operate within the legal framework under which they are administering the vaccine (e.g., National Protocol or PGD) and must follow the appropriate SOP for COVID-19 vaccines.

3.31 Where the registered vaccinator is working alone, they will administer the vaccine that is in the pre-filled syringe first and then the COVID-19 vaccine. The vaccines should be administered in different arms.

3.32 Where the registered vaccinator is working with another vaccinator (registered or unregistered), the first registered vaccinator will administer the vaccine in the prefilled syringe. The second registered vaccinator or unregistered vaccinator will prepare and then administer the COVID-19 vaccine.

3.33 The vaccinator (registered or non-registered) will request second check to confirm COVID-19 Vaccine and dosage before administering.

3.34 Vaccinators should verbally confirm the vaccine to be given with the service user before administering the vaccine.

3.35 Vaccinators must ensure that the person to be vaccinated is ready e.g., sleeves appropriately rolled up, door closed, if necessary, before removing the vaccine from the vaccine workstation.

3.36 Vaccinators must work from one vaccine workstation and must not walk about with vaccines.

3.37 Vaccinators are responsible for all vaccines on their workstation and must not leave them unattended.

3.38 All reasonable efforts must be taken to ensure that vaccinators are not interrupted or distracted whilst they are vaccinating.

3.39 In the event that an incident occurs or a vaccinator deviates from this procedure, the Clinical Lead must be informed immediately. The incident must be logged on the Datix system and the vaccinator may be required to undergo further training and competency assessment. All incidents must be discussed at Safety Briefings to ensure learning and improve patient safety.

## 4.0 Equipment Required

The appropriate vaccine(s) for the scheduled vaccination clinic

PPE

Alcohol gel

Sharps Bin

Coloured trays

Alcohol wipes

Safe sharp needle and syringes

Computer software

Consent forms

Patient Information

## 5.0 Training

All staff operating under this procedure must meet the training standards and competencies for the COVID-19 vaccination.

Attachment 1 – COVID-19 Vaccination Session Record
Attachment 2 – Pharmacy Supervision Assurance Checklist of COVID-19 Vaccines

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | No |
| 2 | Does the implementation of this document require additional revenue resources | No |
| 3 | Does the implementation of this document require additional manpower | No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | No |
| | Other comments | |

## 7.0 Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 11 V3 | **Title of Procedure/Guidelines**<br>Standard Operating Procedure for the administration of multiple vaccines in a single vaccination clinic setting | **Status:**<br>Final | | **Author: Nicholas Carré**<br>For local procedures and guidelines Lead Sponsor:<br>Clinical Director of Pharmacy |
| Version / Amendment History | Version | Date | Author | Reason |
| | v1 | 23/3/22 | Deputy Clinical Director of Pharmacy | New SOP |
| | V2 | 20/09/2022 | Deputy Clinical Director of Pharmacy | Updated to allow use of additional vaccines outside influenza and COVID-19 |
| | V3 | 30/03/2023 | Clinical Lead – Living Well Group | Updated appendix 2 to reflect current COVID-19 vaccines for Spring Booster 2023 |
| **Intended Recipients:** All staff working in RWT COVID-19 Vaccination sites | | | | |
| **Consultation Group / Role Titles and Date: One Wolverhampton Living Well Group Manager, Clinical Director of Pharmacy, Clinical Lead, Alfred Squire Vaccination Hub** | | | | |
| **Name and date of group where reviewed** | Trust Medicine Management Group (MMG) 04/2023 | | | |
| **Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Trust MMG 04/2023 | | | |

| | |
|---|---|
| **Date of Procedure/Guidelines issue** | April 2023 |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | April 2026 |

**Training and Dissemination:**
This procedure will form part of the COVID-19 vaccine training programme which all new vaccinators are required to complete. All staff working on the vaccination hub will be required to read this procedure this includes vaccinators, pharmacy and admin staff.

**To be read in conjunction with**
MP 11 COVID-19 vaccines

**Initial Equality Impact Assessment: Completed**
**Full Equality Impact assessment (as required): No**

| | |
|---|---|
| **Contact for Review** | Clinical Director of Pharmacy |
| **Monitoring arrangements** | Trust Medicines Management Group |

**Document summary/key issues covered**
This Standard Operating Procedure (SOP) describes the process for the management of multiple vaccination types (e.g. COVID-19 /Flu) whilst vaccinating in a single vaccination clinic setting.

| | |
|---|---|
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination |

## APPENDIX 1 - Checklist for clear-down of current vaccine dilution area

| | |
|---|---|
| Name of Person completing checklist | |
| Date & Time of changeover | |
| | |
| **Clear down of "Current" vaccine** | |
| Current Vaccine in use **Clearly print** | |

| Action | Initials or N/A |
|---|---|
| Confirm all current vaccine removed from preparation areas | |
| Confirm all diluent for current vaccine removed from preparation areas (mark N/A for ready to use vaccines) | |
| Confirm all vaccine-specific disposables (dilution syringes, administration syringe & needle packs etc.) are removed from all preparation areas | |
| Confirm all current dosing or preparation posters have been removed from the area | |
| Confirm all current vaccine preparation instructions and flowcharts for current vaccine removed from the area | |
| Update the COVID vaccination session records to document the time when the change in the vaccine type being prepared happened | |

**APPENDIX 2 - Vaccine Colour identifier**

| Vaccine | Tray Colour |
|---|---|
| **VidPrevtyn Beta**<br>**For 65 years and Over** | |
| **Comirnaty 10**<br>**for Children 5-11 years** | |
| **Comirnaty Bivalent Original / Omicron BA.4-5**<br>**For 12 years and over** | |
| **Vaccine name:** | |
| **Vaccine name:** | |

| Vaccine | Tray Colour |
|---|---|
| **Vaccine name:** | |
| **Vaccine name:** | |
| **Vaccine name:** | |
| **Vaccine name:** | |

| Date | / / |
|---|---|

| Vaccination Site | |
|---|---|

| Start of Session Approval | |
|---|---|
| Fridge temperatures checked, in range and reset | |
| Work stations clear | |
| Stock check completed | |
| Anaphylaxis kits given out to each room | |
| Vaccine(s) in use this session | |

**Issues identified during session (reported to PCN Clincial Lead)**

| |
|---|
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| |
| |
| |
| |
| |

| Clinical Lead | | | |
|---|---|---|---|
| Name | | | |
| registration No | | | |
| Start time | | finish time | |
| Name | | | |
| registration No | | | |
| Start time | | finish time | |
| Name | | | |
| registration No | | | |
| Start time | | finish time | |
| Name | | | |
| registration No | | | |
| Start time | | finish time | |

| End of session close down | |
|---|---|
| Workstation logs returned and completed and counted | |
| All unused vials removed and discarded | |
| Workstations cleared and disinfected | |
| Stock check complete | |
| Fridge temperatures checked, in range and reset | |
| lock fridge and secure key | |
| ensure cardboard put out of door for cleaners and full sharps bins put for disposal | |
| Anaphylaxis kits returned to pharmacy room | |
| Vaccination session closed - ensure pharmacy door locked as you leave | |

The Royal Wolverhampton NHS Trust

# COVID-19 Vaccine Procedure 11
# Pharmacy Supervision of COVID-19 Vaccines Checklist

**Vaccination Site name:** _____ **Date:** _____

| **1. Workforce** | **Signature** |
|---|---|
| Identify the Clinical Lead and introduce yourself. Ensure the name of the Clinical Lead is displayed in a public area. | |
| Identify any new vaccinators and gain assurance from the Clinical Lead that they have completed the necessary training and are signed-off as competent, or if not signed-off as competent they will be under-going supervised practice. Ensure the vaccinators at the site are signed off against the most current version of the COVID-19 vaccine PGD and protocols. | |
| Identify who is managing the vaccine supply for that day. | |
| **2. Information** | |
| Identify when the pre-session safety huddle is to commence and ensure that any new information about the vaccine and / or the vaccination service is communicated<br>Huddle time:<br>Notes of any items discussed at the huddle: | |
| Update the information board in the staff room with any new information about the vaccine that staff providing the service need to be aware of | |
| **3. Equipment & Facilities** | |
| Check the fridges are working within range (2-8°C) and there have been no excursions.<br><br>Confirm that fridge temperatures are being recorded and the thermometer has been reset<br><br>Confirm that data loggers are in place and operational.<br><br>Download the latest data and check temperature stability. Attach a copy to this record.<br><br>Confirm any temperature excursions have been appropriately managed (If applicable).<br><br>Confirm the record sheet and instructions on how to reset the maximum and minimum fridge temps are located with the fridge. | |
| Check the ambient temperature of the vaccine preparation room.<br><br>Confirm that ambient temperatures are being recorded and the thermometer has been reset.<br><br>Confirm that ambient temperatures are within the required range.<br><br>Confirm any temperature excursions have been appropriately managed (If applicable). | |
| Ensure the vaccine preparation station is clear and cleaned ready for the session.<br><br>**Cleaned by :** **Time:** | |
| Ensure there are 2 sealed anaphylaxis packs available in each vaccine bay. There should be a laminated copy of the anaphylaxis protocol with each anaphylaxis pack. | |

| | |
|---|---|
| Check the drug cupboards in the clinical room and check that there is sufficient stock of fluids and second –line anaphylaxis medicines (if applicable). | |
| Confirm with the Clinical Lead that the resus trollies have been checked. | |
| Check all medicines are in date and have not expired. | |
| Order any additional medicines required from Pharmacy by ringing pharmacy procurement on ext 81711. | |
| **4. Vaccine and Consumables** | |
| Ensure that the vaccine vials are in date.<br><br>Ensure vaccine vials currently in use by vaccinators have not expired.<br><br>Confirm the vaccinators have the latest worksheets and are completing them correctly (check 10 sheets).<br><br>Count the vaccine vials (see SOP 4, a photograph of the vials may be taken to aid counting without removing the vaccine from the fridge) and reconcile the physical count against the number of vaccine vials recorded in the controlled drugs register. Sign the stock register to confirm the stock count.<br><br>Observe vaccinators process for preparing the vaccine for use. Confirm they are operating in accordance with MP11 procedures. | |
| Confirm that the vaccination tray colours are displayed in all areas as required by the MP11 procedure. | |
| Confirm the correct coloured trays hold the correct vaccine. | |
| Confirm that vaccine is being managed in accordance with MP11 procedure 11. | |
| Confirm there is no vaccine that will go out of date before use. Implement Mutual Aid to avoid the loss of vaccine due to expiry. | |
| When not in use:<br>• confirm that the fridge door is firmly closed and locked and the temperature is within range (2-8°C),<br>• confirm that drug cupboards are locked, and<br>• confirm that keys to the fridge and drugs cupboard are held by the clinical lead or delegated registered practitioner or securely stored in the key cabinet. | |
| Ensure all in-use sharps bins are locked away. | |
| Ensure any empty vaccine boxes are defaced and disposed of as confidential waste. | |
| Confirm there is a COVID-19 Vaccination session record completed for every day the site was operational. | |

**Date:** **Time:** **Signed:**

**Print Name:**

# COVID-19 Vaccine Procedure 12 Managing Temperature Excursions of COVID-19 Vaccines

## 1.0 Procedure Statement

This Standard Operating Procedure describes the process for managing a cold chain incident.

This procedure is based on Specialist Pharmacy Services Guidance and *MP10 Medicine Cold Chain Policy*.

## 2.0 Accountabilities

The Clinical Director of Pharmacy is professionally accountable for the integrity of COVID-19 vaccine on all vaccination sites operating under the jurisdiction of the Trust.

Suitably trained staff are responsible for the management of a cold chain incident

## 3.0 Procedure Detail / Actions

*3.1* Should there be a cold chain incident follow RWT Trust procedure *MP10 Medicine Cold Chain Policy.*

3.2 In addition, the COVID-19 Cold Chain Incident checklist (appendix 1) must be completed.

3.3 Once internal investigations are completed the decision to report the excursion must be taken following Appendix 2

## APPENDIX 1

### COVID-19 Cold Chain Incident Checklist – for temperature excursions outside all cold-chain systems (refrigerators, cool boxes etc.)

**Please give as much detail as possible when completing this form to enable a more timely response.**

Additional information that can support you completing this form can be found here: https://www.sps.nhs.uk/articles/managing-temperature-excursions-for-covid-19-vaccines/

| **Enquirer and background information** | | | |
|---|---|---|---|
| **Name and job role** | | | |
| **Organisation** | | | |
| **Email address** | | | |
| **Telephone number** | | | |
| **Vaccination site name and address** | | | |
| **RVOC/CARS reference number** | | | |
| **Date and time of incident** | | | |
| **Date and time incident form completed** | | | |
| **Vaccine information – Include manufacturer, brand name and strength and form of vaccine** | | | |
| **Manufacturer, brand name, strength and presentation (e.g. concentrate vial, pre-filled syringe)** | **Batch Number** | **Expiry date and time** | **Post thaw use by date/time** |
| ***e.g. Comirnaty 30microgram/dose concentrate vial*** | ***01234*** | ***4.15pm 28/4/22*** | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| *Please append additional pages or lines to this table if there are more affected vaccines.* | | | |
| **If the vaccine is a concentrate, has it been diluted or is it a ready-diluted preparation?** | | | |

| | |
|---|---|
| **Date(s) vaccine(s) defrosted** | |
| **Number of vials affected** | |
| **Number of doses affected** | |
| **Were any patients administered affected vaccine? If yes, how many?** | |
| **Confirmation that the vaccine is currently under correct storage conditions and quarantined.** | |
| **Temperature excursion information** | |
| **Where did the excursion occur –** in transit between sites, in a fridge/cool box or left out of temperature-controlled storage? Give details of the incident. | |
| **Temperature excursion START time** – what was the date and time of last recorded storage within the designated temperature range? | |
| **Temperature excursion END time -** when did vaccines return to correct storage temperature conditions? | |
| **TOTAL DURATION of temperature excursion (include hours/minutes) [If multiple excursions include details of duration for each one]** | |
| **What were the minimum and maximum temperatures during this excursion?** | |
| **Date and time temperature excursion was discovered by staff.** | |
| **You must provide copies of the temperature monitoring records for this excursion:**<br>**1. a photograph or scan of the max/min and current temperature log; and**<br>**2. a trace/graph of the recording from the data-logger and/or data-logger raw data in spreadsheet form**<br>**Ensure all monitoring forms submitted are legible and fully completed with site info etc.** | |
| **Has the temperature of the refrigerator/validated cool box or storage system returned to within 2-8 deg C? What is the current temperature?** | |

| | |
|---|---|
| **Has the cause of the temperature excursion been rectified? What was it?** (e.g. restocking the refrigerator, incorrectly packed cool box, busy clinic, power failure) | |
| **When was the min/max thermometer last reset?** | |
| **Have any of the vaccines involved in this incident previously been exposed to temperatures outside their designated temperature?** | |
| **Has there been any other incident that might impact on the stability of the vaccine?** For example – have the vaccine vials been dropped, were the vaccine vials not upright when delivered, were the vaccine vials agitated whilst being transported? Give | |
| **Additional questions if the incident involves refrigerator or validated cool box storage** | |
| **Type of refrigerator or cool box** Medicine/pharmacy or domestic. Include make/model details if available. | |
| **Was the medical grade, validated refrigerator/cool box purchased/supplied specifically for temperature-controlled storage of medicines?** | |
| **How old is the refrigerator or cool box?** | |
| **What alerted you to the temperature excursion/storage event?** Thermometer out of range; Load probe out of range; alarming; data logger; other | |
| **Is the refrigerator /cool box overloaded and is there sufficient space for air to circulate?** Provide picture of loading if uncertain. | |
| **Is there an alarm fitted on the refrigerator / cool box and if so:** Confirm the high and low temperature alarm set points? After how long outside of the designated temperature range does the alarm sound? Is it attached to the refrigerator / cool box or a logging system? | |

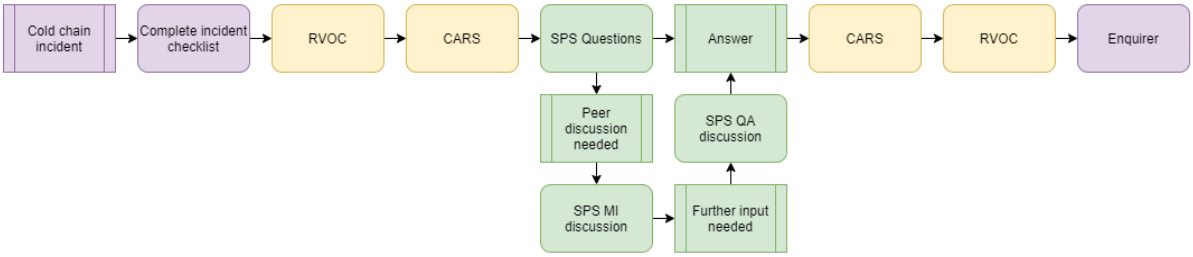
| | |
|---|---|
| **If the alarm had gone off, what controls are in place to ensure a response? Would anyone have heard it?** (E.g. at night.) | |
| **What is your preparation process for cool packs** – do you chill or freeze the cool packs prior to use? Do you have an SOP/process to manage this aspect of cool box use? | |
| **Temperature monitoring system information** | |
| **What type of thermometer(s) used?** Integral to refrigerator or cool box, Battery operated independent thermometer, Data logger, Load probe. | |
| **How often are refrigerator/cool box temperatures recorded? (e.g. daily, twice daily, each time its opened, continuous).** Provide information for each of the thermometers in use. | |
| **Which thermometer recorded the temperature excursion?** | |
| **Where is temperature probe positioned in the refrigerator / cool box? E.g. top, middle, bottom of refrigerator; touching the side of the refrigerator; touching an icepack.** | |
| **Does temperature excursion relate to load probe (probe placed in mock product) or an air probe?** | |
| **Refrigerator servicing information (if there has been a refrigerator malfunction)** | |
| **When was the refrigerator last serviced?** | |
| **When was the integral thermometer last calibrated?** | |
| **Has the refrigerator been temperature mapped?** | |
| **Has an engineer checked the refrigerator since the incident? What did their report say?** | |
| **Rectifying steps taken** | |
| **Have steps been taken to prevent the problem recurring?** | |
| **Have you quarantined the vaccines?** | |

| | |
|---|---|
| **What future actions are planned? When will they be implemented? CARS/NHSE Region will be in contact to discuss further if necessary** | |

**Save this document as a word file, not a PDF file**

## APPENDIX 2

### Process for reporting temperature excursion incidents




## 4.0 Equipment Required

None

## 5.0 Training

Designated pharmacy staff responsible for ordering vaccine must read this procedure and will already be trained in the use of Foundry

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | Yes – No |
| 2 | Does the implementation of this document require additional revenue resources | Yes – No |
| 3 | Does the implementation of this document require additional manpower | Yes – No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | Yes – No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | Yes – No |
| | Other comments | |

## Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 12 v1 | **Title of Procedure/Guidelines**<br><br>Standard Operating Procedure for managing Temperature Excursions of COVID-19 Vaccine | **Status:**<br><br>**Final** | | **Author: Clinical Director of Pharmacy**<br><br>**Director Sponsor: Chief Medical Officer** |
| Version / Amendment History | Version | Date | Author | Reason |
| | v1 | 29/12/2020 | Deputy Clinical Director of Pharmacy | New SOP |
| **Intended Recipients:** Pharmacy Procurement staff, Designated pharmacy staff working in vaccination sites. | | | | |
| **Consultation Group / Role Titles and Date:**<br>Trust Medicines Management Group (MMG) | | | | |
| **Name and date of group where reviewed** | Medicines Management Group (MMG) 09/2022<br>Trust Policy Group – December 2022 | | | |
| **Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Medicines Management Group (MMG) 09/2022<br>Trust Management Committee – January 2023 | | | |
| **Date of Procedure/Guidelines issue** | September 2022 | | | |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | August 2023 (every 12 months) | | | |
| **Training and Dissemination:**<br>This procedure will form part of the COVID-19 vaccine training programme | | | | |
| **To be read in conjunction with:**<br>COVID-19 Vaccine handling and management policy and associated procedures | | | | |

| | |
|---|---|
| **Initial Equality Impact Assessment: Completed**<br>**Full Equality Impact assessment (as required): No** | |
| **Contact for Review** | Clinical Director of Pharmacy |
| **Monitoring arrangements** | Trust Medicines Management Group |
| **Document summary/key issues covered**<br>This Standard Operating procedure (SOP) describes the process for managing temperature excursions of COVID-19 Vaccine | |
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination |

**IMPLEMENTATION PLAN**
**To be completed when submitted to the appropriate committee for consideration/approval**

| | | |
|---|---|---|
| **Procedure/Guidelines number and version** | **Title of Procedure/Guidelines** | |
| **Reviewing Group** | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** | | |

| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
|---|---|---|
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | | |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | | |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | | |
| Financial cost implementation<br>Consider Business case development | | |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | | |

## ATTACHMENT 12 APPENDIX 1

### COVID-19 Cold Chain Incident Checklist – for temperature excursions outside all cold-chain systems (refrigerators, cool boxes etc.)

**Please give as much detail as possible when completing this form to enable a more timely response.**

Additional information that can support you completing this form can be found here: https://www.sps.nhs.uk/articles/managing-temperature-excursions-for-covid-19-vaccines/

| **Enquirer and background information** | | | |
|---|---|---|---|
| **Name and job role** | | | |
| **Organisation** | | | |
| **Email address** | | | |
| **Telephone number** | | | |
| **Vaccination site name and address** | | | |
| **RVOC/CARS reference number** | | | |
| **Date and time of incident** | | | |
| **Date and time incident form completed** | | | |
| **Vaccine information – Include manufacturer, brand name and strength and form of vaccine** | | | |
| **Manufacturer, brand name, strength and presentation (e.g. concentrate vial, pre-filled syringe)** | **Batch Number** | **Expiry date and time** | **Post thaw use by date/time** |
| ***e.g. Comirnaty 30microgram/dose concentrate vial*** | ***01234*** | ***4.15pm 28/4/22*** | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| *Please append additional pages or lines to this table if there are more affected vaccines.* | | | |
| **If the vaccine is a concentrate, has it been diluted or is it a ready-diluted preparation?** | | | |
| **Date(s) vaccine(s) defrosted** | | | |

| | |
|---|---|
| **Number of vials affected** | |
| **Number of doses affected** | |
| **Were any patients administered affected vaccine? If yes, how many?** | |
| **Confirmation that the vaccine is currently under correct storage conditions and quarantined.** | |
| **Temperature excursion information** | |
| **Where did the excursion occur –** in transit between sites, in a fridge/cool box or left out of temperature-controlled storage? Give details of the incident. | |
| **Temperature excursion START time** – what was the date and time of last recorded storage within the designated temperature range? | |
| **Temperature excursion END time -** when did vaccines return to correct storage temperature conditions? | |
| **TOTAL DURATION of temperature excursion (include hours/minutes) [If multiple excursions include details of duration for each one]** | |
| **What were the minimum and maximum temperatures during this excursion?** | |
| **Date and time temperature excursion was discovered by staff.** | |
| **You must provide copies of the temperature monitoring records for this excursion:**<br>**1. a photograph or scan of the max/min and current temperature log; and**<br>**2. a trace/graph of the recording from the data-logger and/or data-logger raw data in spreadsheet form**<br>**Ensure all monitoring forms submitted are legible and fully completed with site info etc.** | |
| **Has the temperature of the refrigerator/validated cool box or storage system returned to within 2-8 deg C? What is the current temperature?** | |

| | |
|---|---|
| **Has the cause of the temperature excursion been rectified? What was it?** (e.g. restocking the refrigerator, incorrectly packed cool box, busy clinic, power failure) | |
| **When was the min/max thermometer last reset?** | |
| **Have any of the vaccines involved in this incident previously been exposed to temperatures outside their designated temperature?** | |
| **Has there been any other incident that might impact on the stability of the vaccine?** For example – have the vaccine vials been dropped, were the vaccine vials not upright when delivered, were the vaccine vials agitated whilst being transported? Give | |
| **Additional questions if the incident involves refrigerator or validated cool box storage** | |
| **Type of refrigerator or cool box**<br>Medicine/pharmacy or domestic.<br>Include make/model details if available. | |
| **Was the medical grade, validated refrigerator/cool box purchased/supplied specifically for temperature-controlled storage of medicines?** | |
| **How old is the refrigerator or cool box?** | |
| **What alerted you to the temperature excursion/storage event?**<br>Thermometer out of range; Load probe out of range; alarming; data logger; other | |
| **Is the refrigerator /cool box overloaded and is there sufficient space for air to circulate?**<br>Provide picture of loading if uncertain. | |
| **Is there an alarm fitted on the refrigerator / cool box and if so:**<br>Confirm the high and low temperature alarm set points? After how long outside of the designated temperature range does the alarm sound? Is it attached to the refrigerator / cool box or a logging system? | |
| **If the alarm had gone off, what controls are in place to ensure a response? Would anyone have heard it?** (E.g. at night.) | |

| | |
|---|---|
| **What is your preparation process for cool packs** – do you chill or freeze the cool packs prior to use? Do you have an SOP/process to manage this aspect of cool box use? | |
| **Temperature monitoring system information** | |
| **What type of thermometer(s) used?** Integral to refrigerator or cool box, Battery operated independent thermometer, Data logger, Load probe. | |
| **How often are refrigerator/cool box temperatures recorded? (e.g. daily, twice daily, each time its opened, continuous).** Provide information for each of the thermometers in use. | |
| **Which thermometer recorded the temperature excursion?** | |
| **Where is temperature probe positioned in the refrigerator / cool box? E.g. top, middle, bottom of refrigerator; touching the side of the refrigerator; touching an icepack.** | |
| **Does temperature excursion relate to load probe (probe placed in mock product) or an air probe?** | |
| **Refrigerator servicing information (if there has been a refrigerator malfunction)** | |
| **When was the refrigerator last serviced?** | |
| **When was the integral thermometer last calibrated?** | |
| **Has the refrigerator been temperature mapped?** | |
| **Has an engineer checked the refrigerator since the incident? What did their report say?** | |
| **Rectifying steps taken** | |
| **Have steps been taken to prevent the problem recurring?** | |
| **Have you quarantined the vaccines?** | |
| **What future actions are planned? When will they be implemented? CARS/NHSE Region will be in contact to discuss further if necessary** | |

# COVID-19 Vaccine Procedure 13 Using the COVID-19 Vaccinator Competency Assessment Tool

## 1.0 Procedure Statement

This Standard Operating Procedure provides the UK Health Security Agency competency assessment tool for COVID-19 vaccinators.

## 2.0 Accountabilities

The Clinical Director of Pharmacy is professionally accountable for the integrity of COVID-19 vaccine on all vaccination sites operating under the jurisdiction of the Trust.

All members of staff who are clinical supervisors, clinical assessors or vaccinators are accountable for completing all necessary training and competency assessments.

## 3.0 Procedure Detail / Actions

3.1 All clinicians, vaccinators and clinical supervisors of vaccinators must have completed a UKHSA Vaccinator competency assessment which can be found here:

UKHSA COVID-19 Vaccinator Assessment Tool.

3.2 The document can be completed as a self-assessment but must be reviewed by the COVID-19 Vaccination Clinical Lead, Lead Pharmacist or Shift Clinical Lead prior to commencing work at a vaccination clinic.

3.3 Any statements made in the document must be confirmed with evidence e.g. training certificates.

3.4 Once satisfied the assessor must confirm and document for which vaccines that competence has been signed off.

3.5 If applicable, any exclusions or restrictions in practice must be recorded and an action plan put in place.

3.6 When any actions have been completed to remove any exclusions or restrictions the assessment form must be updated, reviewed and signed..

3.7 A copy of the completed assessment tool must be stored in the member of staff's training file.

3.8 The assessment tool document must be updated to include any new vaccines that are released and used in the vaccination clinics.

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | Yes – No |
| 2 | Does the implementation of this document require additional revenue resources | Yes – No |
| 3 | Does the implementation of this document require additional manpower | Yes – No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | Yes – No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | Yes – No |
| | Other comments | |

## Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 13 v1 | **Title of Procedure/Guidelines**<br><br>Using the COVID-19 Vaccinator Competency Assessment Tool | **Status:**<br><br>**Final** | | **Author: Deputy Clinical Director of Pharmacy**<br><br>**Director Sponsor: Chief Medical Officer** |
| Version / Amendment History | Version | Date | Author | Reason |
| | v1 | 30/09/2022 | Deputy Clinical Director of Pharmacy | New SOP |
| **Intended Recipients:** Pharmacy Procurement staff, Designated staff working in vaccination sites. | | | | |
| **Consultation Group / Role Titles and Date:**<br>Trust Medicines Management Group (MMG) | | | | |
| **Name and date of group where reviewed** | Medicines Management Group (MMG) 10/2022<br>Trust Policy Group – December 2022 | | | |
| **Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Medicines Management Group (MMG) 10/2022<br>Trust Management Committee – January 2023 | | | |
| **Date of Procedure/Guidelines issue** | September 2022 | | | |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | August 2023 (every 12 months) | | | |
| **Training and Dissemination:**<br>This procedure will form part of the COVID-19 vaccine training programme | | | | |
| **To be read in conjunction with:**<br>COVID-19 Vaccine handling and management policy and associated procedures | | | | |

| | |
|---|---|
| **Initial Equality Impact Assessment: Completed**<br>**Full Equality Impact assessment (as required): No** | |
| **Contact for Review** | Clinical Director of Pharmacy |
| **Monitoring arrangements** | Trust Medicines Management Group |
| **Document summary/key issues covered**<br>This Standard Operating procedure (SOP) describes the process for the assessment of vaccinators | |
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination<br>Competency Assessment |

**IMPLEMENTATION PLAN**
**To be completed when submitted to the appropriate committee for consideration/approval**

| | | |
|---|---|---|
| **Procedure/Guidelines number and version** | **Title of Procedure/Guidelines** | |
| **Reviewing Group** | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** | | |

| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
|---|---|---|
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | | |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | | |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | | |
| Financial cost implementation<br>Consider Business case development | | |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | | |

# COVID-19 Vaccine Procedure 14 Standard Operating Procedure for Preparation of Nuvaxovid Syringes for Administration

## 1.0 Procedure Statement

This SOP describes the process for preparation of **ready-to-administer** 0.5mL dose syringes of Nuvaxovid COVID-19 vaccine prior to immediate administration.

This procedure covers the process for the removal of vials of vaccine from the outer carton in the refrigerator, or removal of individual vials from a cool box, up until the point of administration. This includes assigning an expiry date and time after the first dose withdrawal and the preparation of syringes for administration.

This procedure may be adapted to suit either of the following models:

- one person to both draw up individual doses into syringes and administer the vaccine, or.
- one person to draw up individual doses into syringes and pass the syringe to a vaccinator. This model requires additional local risk assessment, and the introduction of local controls to reduce the risk of needle stick injuries on transfer between individuals.

This procedure is based on Specialist Pharmacy Services vaccine procedures

## 2.0 Accountabilities

The Clinical Director of Pharmacy is professionally accountable for the safe and secure handling and management of COVID-19 vaccine and related medicines on all vaccination sites operating within the jurisdiction of the Trust.

The Clinical Lead for the vaccination site is professionally accountable for ensuring that appropriate and formal authorisation for vaccine administration is in place (PSD) and that the staff groups who are supplied with, prepare, and administer the COVID-19 vaccine are those defined as eligible to do so in accordance with the authorisation being used. The Clinical Lead is also responsible for ensuring that all staff undertaking duties at the vaccination site meet the training standards and competencies for the vaccination programme.

When working under a PSD, the prescriber is legally accountable for the safe and secure handling and management of the COVID-19 vaccine under The Human Medicines Regulations (2012) Regulation 3.

Registered healthcare professionals working under a PSD are responsible for ensuring the safe and secure handling requirements are met and must follow this procedure.

## 3.0 Procedure Detail / Actions

### 3.1 Workstation preparation

3.1.1 Confirm the preparation workstation is clear and free from any other vials of vaccine.

3.2.2 Ensure a yellow lidded sharps bin with sufficient free capacity is available.

3.2.3 Ensure an indelible pen is available and a workstation log with information completed for start of session.

.

3.2.4 Put on apron.

3.2.5 Clean the workstation with disinfectant wipes and discard into a clinical waste bin.

3.2.6 Following RWT Infection Prevention Policy, wash hands thoroughly. Put on disposable gloves and apron (if not already wearing one) and ensure a face mask is worn.

3.3 When ready to begin preparation select one vial of Nuvaxovid vaccine.

3.3.1 If working with vials stored in a refrigerator:

- if there is more than one batch of vaccine vials, use the one with the shortest expiry,
- check the expiry on the carton has not been exceeded, and
- remove a single vial and close the carton.

3.3.2 If working with vials from a cool box at 2-8$^{O}$C:

- check the vial is within the expiry date by checking the label on the vial transport container ( refer to SOP 3: *Use of cool boxes to transport COVID-19 vaccines to end user locations)* and
- remove a single vial and close the lid of the cool box.

N.B. Unopened Nuvaxovid vaccine can be stored between 2-25 $^{O}$C for up to 12 hours. Storage at 25°C is not the recommended storage or shipping condition but may guide decisions for use in case of temporary temperature excursions.

3.3.3 Check the identity of the vial. This procedure is intended for use with the Nuvaxovid vaccine.

3.3.4 Assemble the following materials required to prepare syringes:

- Nuvaxovid vaccine vial X 1,
- 1mL syringe with integrated 23g (or finer) x 25mm needle x 10 and
- sterile single use 70% alcohol swab x 10.

3.3.5 Swirl the vial by gently rotating in a circular motion several times. Do not shake.

3.3.6 Inspect the vial visually for foreign particulate matter and, or discoloration prior to administration. If foreign particulate matter or discolouration is present, the vaccine should not be administered.

N.B. Nuvaxovid is a colourless to slightly yellow, clear to mildly opalescent dispersion free from visible particles

3.3.7 Confirm the **0.5mL** dose is required by the patient.

3.3.8 Cleanse the vial stopper with a single use 70% alcohol swab, and discard swab in a clinical waste bin.

3.3.9 Using aseptic technique, draw up **0.5mL** of the vaccine using a new 1mL syringe with integrated 23g or finer x 25mm needle.

N.B.

- a 21g or finer x 38mm needle and 1mL syringe should be used for administering the vaccine to morbidly obese patients, and
- if using a syringe with an auto retracting needle, depressing the plunger will cause the needle to retract prematurely.

3.3.10 Adjust to remove air bubbles with the needle still in the vial to avoid loss of vaccine.

3.3.11 Check volume withdrawn is **0.5mL**. Request a second check of volume. The vaccinator and person carrying out the second check must sign the workstation log.

3.3.12 Visually inspect the syringes for foreign particulate matter and leaks. Discard if these are observed.

3.3.13 The newly filled syringe must be used for immediate administration.

After first dose withdrawal, use the vial as soon as practically possible and within 6 hours (stored at $2^0$C to $25^0$C). Document the expiry date and time (24-hour format, e.g. 14:00) on the vial after first use.

3.3.14 Steps 3.3.3 to 3.3.13 may be repeated a further nine times to produce a total of ten syringes from each vial. Each time the vial bung is punctured, this should be in a different location to previous points of puncture on the bung.

N.B. To minimise the risk of stopper coring and particles entering the vial:

- insert the needle through a fresh point in the inner ring of the vial stopper each time,
- each time the vial bung is punctured this should be in a different location to previous points of puncture working methodically around the inner ring of the vial stopper tracking previous puncture points, and.

- do not puncture the stopper outside of the inner ring as this may increase the risk of coring.

3.3.15 If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

3.5.13 After the final dose has been taken from the vial or if expiry has been exceeded, remove the label from the vial and attach to the workstation log. Discard the used diluted vaccine vial into a yellow lidded sharps bin.

3.5.14 At the end of the session, discard any remaining part vials. Vials must not be stored between sessions or returned to the refrigerator. **Note that every reasonable effort must be made to safely use all available vaccine and therefore not waste doses; before discarding unused vials or doses permission must be sought from the Clinical Lead (senior nurse).**

3.5.15 Empty outer cartons must be disposed of in a secure manner which prevents theft. Score through label text with a permanent marker and cut the box up into pieces before disposal in confidential waste.

### 3.6 Dealing with deviations from this procedure

3.6.1 Any deviations from this procedure must immediately be reported to the clinical supervisor (senior nurse).

3.6.2 An audit worksheet (the workstation log) must be completed for each vial at each stage throughout the process by the vaccinators and the team overseeing stock control. Where vaccine is discarded, this must be recorded on the work station log and one of the following codes documented:

| ID | Name | Description | Vaccine/ Medical | Consumables | PPE |
|---|---|---|---|---|---|
| 1 | Contamination | The item (e.g. vaccine, diluent) has been contaminated | x | | X |
| 2 | Site Fridge/Freezer Malfunction | The item was stored in a temperature controlled environment that failed | X | | |
| 3 | Transport Breakdown | The item was in transit between locations when the vehicle it was in broke down, resulting in a temperature excursion | X | | |
| 4 | Excess Stock | Where a vaccination team reach the end of an allotted shift or job, and have surplus vaccines that cannot be returned to stock | X | | |
| 5 | Expired shelf-life | Where the expiry date for the product in its current state has been exceeded | X | | X |
| 6 | Waste at Point of Care | Where the prepped dose was refused by the patient | X | | |
| 7 | Improper Storage | The item had not been stored in accordance with instructions (e.g. left out of fridge) | X | X | X |
| 8 | Damaged/Dropped | The item is broken (e.g. vial dropped onto concrete floor) | X | X | X |
| 9 | Lost/ Stolen | The item has gone missing and is assumed lost or stolen | X | X | X |
| 10 | Refused at Delivery | The item has been delivered in a form that is unusable (e.g. temperature excursion or damaged item) | X | X | X |
| 11 | Reconstitution/ dilution /prep error | A mistake was made when drawing up the vaccine, making the dose unusable | X | | |

## 4.0 Equipment Required

| | |
|---|---|
| Nuvaxovid Vaccine | Disposable gloves |
| Yellow lidded sharps bins | Disinfectant wipes |
| Indelible pen | Clinical waste bins |
| Workstation logs | Plastic trays |

1ml syringes with integrated 23g (or finer) x 25mm needle (supplied with vaccine)

Single use 70% alcohol swabs

Appropriate personal protective equipment including apron and face mask

## 5.0 Training

All staff operating under this procedure must meet the training standards and competencies for the COVID-19 vaccination programme.

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | Yes – No |
| 2 | Does the implementation of this document require additional revenue resources | Yes – No |
| 3 | Does the implementation of this document require additional manpower | Yes – No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | Yes – No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | Yes – No |
| | Other comments | |

## Attachment 1 Nuvaxovid Workstation Log

## Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 14 v1 | **Title of Procedure/Guidelines**<br><br>Standard Operating Procedure for Preparation of Nuvaxovid Vaccine | **Status:**<br><br>**FINAL** | | **Author: Deputy Clinical Director of Pharmacy**<br><br>**Director Sponsor: Chief Medical office** |
| Version / Amendment History | Version | Date | Author | Reason |
| | 1 | 20/09/2022 | Deputy Clinical Director of Pharmacy | New SOP |
| **Intended Recipients:** All staff delivering the COVID-19 vaccination programme | | | | |
| **Consultation Group / Role Titles and Date:**<br>Trust Medicines Management Group (MMG) | | | | |
| **Name and date of group where reviewed** | Medicines Management Group (MMG) 09/2022<br>Trust Policy Group – December 2022 | | | |
| **Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Trust MMG<br>Tbc<br>Trust Management Committee – January 2023 | | | |
| **Date of Procedure/Guidelines issue** | September 2022 | | | |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | August 2023 12 monthly | | | |

| | |
|---|---|
| **Training and Dissemination:**<br>This procedure will form part of the COVID-19 vaccine training programme which all new vaccinators are required to complete | |
| **To be read in conjunction with:**<br>COVID-19 Vaccine handling and management policy and associated procedures | |
| **Initial Equality Impact Assessment: Completed**<br>**Full Equality Impact assessment (as required): No** | |
| **Contact for Review** | Clinical Director of Pharmacy |
| **Monitoring arrangements** | Trust Medicines Management Group |
| **Document summary/key issues covered**<br>This Standard Operating procedure (SOP) describes the process for Nuvaxovid Vaccine | |
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination<br>Nuvaxovid |

**IMPLEMENTATION PLAN**
**To be completed when submitted to the appropriate committee for consideration/approval**

| | | |
|---|---|---|
| **Procedure/Guidelines number and version** | **Title of Procedure/Guidelines** | |
| **Reviewing Group** | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** | | |

| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
|---|---|---|
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | | |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | | |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | | |
| Financial cost implementation<br>Consider Business case development | | |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | | |

# Novavax Nuvaxovid® COVID-19 Vaccine

| Date | | Workstation identifier | |
|---|---|---|---|

| Issues identified codes | |
|---|---|
| A | Vial Dropped - do not use |
| B | Syringe dropped - do not use |
| C | Vial discoloured or contained particles |
| D | Syringe contained particles |
| E | Other (give detail) |

| | |
|---|---|
| Workstation cleaned and set up for session | |
| All unused vials removed from storage box and discarded | |
| Workstation cleared and cleaned | |

**Vials received at workstation**

| Product | Batch number | Expiry date | Date | Time | Confirm fridge temp | Vial check | Completed by | Checked by |
|---|---|---|---|---|---|---|---|---|
| Novavax Nuvaxovid® COVID-19 Vaccine 0.5ml Dose | | | | | | | | |

Maximum amount of Time for **unpunctured** vial to be stored outside of the fridge up to 25C is **12 hours**

| | |
|---|---|
| **Name of vaccinator :** | **Name of second checker:** |
| **Vaccination room temp: Must be below 25C** | |

## Vial Expiry Time (6 Hours after the first puncture):

| | 0.5ml Doses drawn up & checked (first check by person drawing up and second check signed by person overseeing | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Dose** | **1** | **2** | **3** | **4** | **5** | **6** | **8** | **9** | **10** | **Issues identified (enter appropriate letter above)** | **Comments** |
| **Time:** | | | | | | | | | | | |
| **Patient's name:** | | | | | | | | | | | |
| **Signature of vaccinator:** | | | | | | | | | | | |
| **Signature of second checker:** | | | | | | | | | | | |

The Royal Wolverhampton NHS Trust

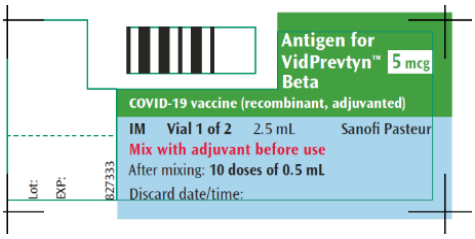
# COVID-19 Vaccine Procedure 15 Standard Operating Procedure for Preparation of VidPrevtyn Beta 0.5mL Syringes for Administration

## 1.0 Procedure Statement

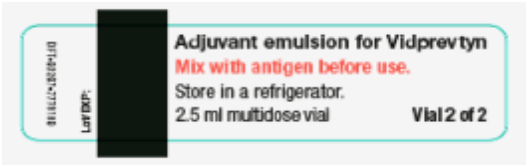
This SOP describes the process for preparation of ready to administer **0.5mL** syringes of **VidPrevtyn Beta Solution and emulsion (Concentrate) for Adults 75 years and over**

VidPrevtyn Beta is presented as two multidose vials (antigen vial and adjuvant vial) that must be mixed before use. After mixing, the vaccine vial contains 10 doses of 0.5 mL

Antigen vial label 2.5mL (10 doses after mixing)




Adjuvant vial label 2.5mL




This procedure covers the process from the removal of vials from the outer carton in the refrigerator, or removal of individual vials from a cool box, up until the point of administration. This includes assigning an expiry date and time after mixing, and the preparation of syringes for administration.

This procedure may be adapted to suit either of the following models:

- One person performing mixing and drawing up of syringes to administer by themselves.
- One person performing mixing, who passes the mixed vial to a vaccinator to draw up individual doses into syringes.
- One person both mixing the vials and drawing up individual doses into syringes and passing the syringe to the vaccinator. This model requires additional local risk assessment, and the introduction of local controls to reduce the risk of needle stick injuries on transfer between individuals.

This procedure is based on Specialist Pharmacy Services Procedure *CV 6 – Preparation of VidPrevtyn Beta 0.5mL syringes for Administration*

## 2.0 Accountabilities

The Clinical Director of Pharmacy is professionally accountable for the safe and secure handling and management of COVID-19 vaccine and related medicines on all vaccination sites operating within the jurisdiction of the Trust.

The Clinical Lead for the vaccination site is professionally accountable for ensuring that appropriate and formal authorisation for vaccine administration is in place (PSD, PGD or National Protocol), and that the staff groups who are supplied with, prepare, and administer the COVID-19 vaccine are those defined as eligible to do so in accordance with the authorisation being used.

When working under the National Protocol the Clinical Lead will ensure that a 'Clinical Supervisor' is present for the duration of the vaccination session and this person is clearly identifiable and competent in all stages of the vaccination pathway. The Clinical Lead is also responsible for ensuring that all staff undertaking duties at the vaccination site meet the training standards and competencies for the vaccination programme.

When working under a PSD, the prescriber is legally accountable for the safe and secure handling and management of the COVID-19 vaccine under The Human Medicines Regulations (2012) Regulation 3.

Registered healthcare professionals working under a PSD, PGD or the National Protocol and non-registered staff working under the National Protocol are responsible for ensuring the safe and secure handling requirements are met and must follow this procedure.

## 3.0 Procedure Detail / Actions

### 3.1 Workstation preparation

3.1.1 Confirm the preparation workstation is clear and free from any other vials of vaccine.

3.1.2 Ensure a yellow lidded sharps bin with sufficient free capacity is available.

3.1.3 Ensure an indelible pen is available and a workstation log with information completed for start of session.

3.1.4 Put on apron.

3.1.5 Clean workstation with disinfectant wipes and discard into a clinical waste bin.

3.1.6 Following the RWT Infection Prevention Policy, wash hands thoroughly. Put on disposable gloves and an apron (if not already wearing one) and ensure a face mask is worn.

## 3.2 Preparation

3.2.1 When ready to begin preparation select one vial of 5 microgram in 2.5mL Antigen for VidPrevtyn Beta and one vial of 2.5mL Adjuvant emulsion for VidPrevtyn Beta.

3.2.2 If working with vials stored in a refrigerator:

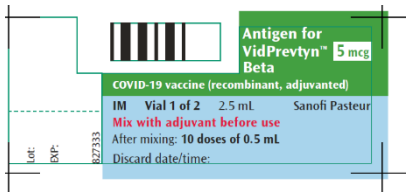
- If there is more than one batch of vaccine vials, use the one with the shortest expiry.
- Check the manufacturer's expiry on the carton has not been exceeded.
- Remove one vial of antigen and one vial of adjuvant.

3.2.3 If working with vials from a cool box at 2-8$^{O}$C:

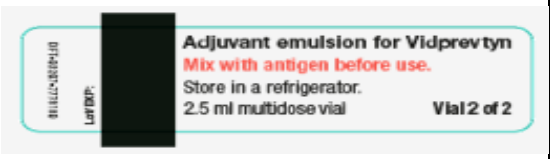
- Check the vials are within the manufacturer's expiry on the carton or vial.
- Refer to MP11 Procedure 3: *Standard operating procedure for the use of Cool-boxes to transport COVID-19 Vaccines to End User Locations*
- Remove one vial of antigen and one vial of adjuvant and close the lid of the cool box.

3.2.4 Check the identity of the vials. This procedure is intended for use with the VidPrevtyn Beta vaccine. Check the label on the antigen vial selected matches the image on the left, and the label on the adjuvant vial selected matches the image on the right below:

Antigen vial label 2.5mL (10 doses after mixing)




Adjuvant vial label 2.5mL




3.2.5 Allow the vials to come to room temperature
N.B. This aids patient comfort on administration and may take up to 15 minutes.

3.2.6 Invert (without shaking) each vial and inspect them visually for foreign particulate matter and/or discoloration prior to administration. If foreign particulate matter or discolouration are present, the vaccine should not be administered.

N.B. The antigen solution is a colourless, clear liquid, and the adjuvant emulsion is a whitish to yellowish homogeneous milky liquid.

3.2.7 Assemble the following additional materials required for mixing:

- 3mL syringe with 21g (or finer) needle x 1
- Sterile single use 70% alcohol swab x 1

### 3.3 Mixing the Vials

3.3.1 When ready to begin the mixing process, bring one vial of adjuvant and one vial of antigen into the centre of the workstation.

**N.B. Only one vial of adjuvant and one vial of antigen should be in use in the preparation workstation at any one time.**

3.3.2 Remove the flip off caps and cleanse both vial stoppers with a single use 70% alcohol swab, and discard swab in a clinical waste bin.

3.3.3 Draw up the full contents of the adjuvant emulsion:

- Using aseptic technique, use a 3mL syringe and 21g or finer needle to draw up **the full contents** of adjuvant emulsion vial.
- Invert the adjuvant vial to facilitate the withdrawal of **the full contents**.
- Check **the full contents** of the adjuvant emulsion vial has been drawn up**.**
- Dispose of the empty vial into a yellow lidded sharps bin.

3.3.4 Transfer the full syringe contents into the antigen vial

- To minimise the risk of stopper coring and particles entering the vial:
  - Insert the needle vertically through the centre ring of the vial stopper.
  - Do not twist or rotate the needle once inserted

- During the addition, keep the needle tip in the air space of the vial at all times. Equalise the pressure by adding the adjuvant emulsion in gradual steps and allowing air to vent back into the syringe repeatedly until all of the adjuvant emulsion has been added and there is 2.5 mL air in the syringe.

N.B. If using a syringe with an auto retracting needle depressing the plunger fully will cause the needle to retract prematurely. If the above technique is not used the full 2.5mL may therefore not be added to the vial.

3.3.5 Dispose of syringe and needle into a yellow lidded sharps bin.

3.3.6 Mix the contents by inverting the vial 5 times, DO NOT shake. One inversion requires the vial to be fully rotated back to an upright position.

3.3.7 Inspect the vial. The mixed vaccine should present as whitish to yellowish homogeneous milky liquid emulsion. Discard the mixed vaccine if particulates or discolouration are present.

3.3.8 Calculate and write the time / date of post-mixing **expiry** on the vial label as shown in red below. Use 24-hour clock format.


N.B. The expiry is 6 hours from the point of mixing, but the vial should be used as soon as practically possible.

### 3.4 Withdrawal into syringes

3.4.1 Assemble the following materials required to prepare syringes:

- Mixed VidPrevtyn Beta emulsion vial X 1
- 1mL syringe with integrated 21g (or finer) x 25mm needle X 10
- Sterile single use 70% alcohol swab x 10

3.4.2 Check the identity of the vial. Check label on the vial selected matches the picture below:


3.4.3 Check the vial is within the hand-written post-mixing expiry time on the label.

3.4.4 Prior to each administration, mix the contents by inverting the vial 5 times, DO NOT shake. One inversion requires the vial to be fully rotated back to an upright position.

3.4.5 Cleanse the vial stopper with a single use 70% alcohol swab, and discard swab in a clinical waste bin.

3.4.6 Using aseptic technique, draw up **0.5mL** of the mixed vaccine using a new 1mL syringe with integrated 21g or finer x 25mm needle.
N.B. A 21g or finer x 38mm needle and 1mL syringe should be used for administering the vaccine to morbidly obese patients.

3.4.7 Adjust to remove air bubbles with the needle still in the vial to avoid loss of diluted vaccine.

3.4.8 Check volume withdrawn is **0.5mL**. Request a second check of volume. The vaccinator and person carrying out the second check must sign the workstation log

3.4.9 Visually inspect the syringes for particles and leaks. Discard if these are observed.

3.4.10 The newly filled syringe must be used for immediate administration.

3.4.11 Steps 3.4.2 to 3.4.10 may be repeated a further nine times to produce a total of ten syringes from each mixed vaccine vial. Each time the vial bung is punctured, this should be in a different location to previous points of puncture on the bung.

If the amount of vaccine remaining in the vial cannot provide a full 10th dose of 0.5 mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

3.4.12 Once empty, or no longer needed, immediately discard the used vaccine vial into a yellow lidded sharps bin.

N.B. Vials should not be stored between sessions:

- During the in-use period, when doses are being withdrawn from the vial and administered, the vial may remain at room temperature (up to 25°C according to SPC). This may include the time it takes to move short distances between patients e.g. in a care home, or the time between patients in a clinic.
- If within the work session there is no immediate need to withdraw further doses, the vial should be returned to storage between 2-8°C in a container which protects the vial from light and maintains segregation from the un-mixed vials.

3.5 Dispose of outer cartons by defacing using permanent black marker pens and placing in the general waste stream. Note: the packaging can be flattened easily. For mass vaccination centres packaging must be stored in a secure container(s) and shredded on-site.

**3.6 Dealing with deviations from this procedure**

3.6.1 Any deviations from this procedure must immediately be reported to the Clinical Lead on Shift.

3.6.2 An audit worksheet (the workstation log) must be completed for each vial at each stage throughout the process by the vaccinators and the team overseeing stock control. Where vaccine is discarded, this must be recorded on the work station log and one of the following codes documented:

| ID | Name | Description | Vaccine/ Medical | Consumables | PPE |
|---|---|---|---|---|---|
| 1 | Contamination | The item (e.g. vaccine, diluent) has been contaminated | x | | X |
| 2 | Site Fridge/Freezer Malfunction | The item was stored in a temperature controlled environment that failed | X | | |
| 3 | Transport Breakdown | The item was in transit between locations when the vehicle it was in broke down, resulting in a temperature excursion | X | | |
| 4 | Excess Stock | Where a vaccination team reach the end of an allotted shift or job, and have surplus vaccines that cannot be returned to stock | X | | |
| 5 | Expired shelf-life | Where the expiry date for the product in its current state has been exceeded | X | | X |
| 6 | Waste at Point of Care | Where the prepped dose was refused by the patient | X | | |
| 7 | Improper Storage | The item had not been stored in accordance with instructions (e.g. left out of fridge) | X | X | X |
| 8 | Damaged/Dropped | The item is broken (e.g. vial dropped onto concrete floor) | X | X | X |
| 9 | Lost/ Stolen | The item has gone missing and is assumed lost or stolen | X | X | X |
| 10 | Refused at Delivery | The item has been delivered in a form that is unusable (e.g. temperature excursion or damaged item) | X | X | X |
| 11 | Reconstitution/ dilution /prep error | A mistake was made when drawing up the vaccine, making the dose unusable | X | | |

## 4.0 Equipment Required

Antigen for VidPrevtyn Beta vial

Adjuvant Vial for VidPrevtyn vial

Yellow lidded sharps bins

Red & Black Indelible pen

VidPrevtyn Beta Workstation logs

Appropriate personal protective equipment including:

- Apron
- face mask
- Disposable gloves

Disinfectant wipes

Clinical waste bins

3mL Syringes with 21g (or finer) needles

Plastic tray

1ml syringes with integrated 23g (or finer) x 25mm needle (supplied with vaccine)

Single use 70% alcohol swabs

## 5.0 Training

All staff operating under this procedure must meet the training standards and competencies for the COVID-19 vaccination programme.

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | Yes – No |
| 2 | Does the implementation of this document require additional revenue resources | Yes – No |
| 3 | Does the implementation of this document require additional manpower | Yes – No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | Yes – No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | Yes – No |
| | Other comments | |

## Attachment 1 VidPrevtyn Beta Workstation Log

## Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 15 v1 | **Title of Procedure/Guidelines**<br><br>Standard Operating Procedure for Preparation of Vidprevtyn Beta syringes | **Status:**<br><br>**FINAL** | | **Author: Clinical Director of Pharmacy**<br><br>**Director Sponsor: Chief Medical Officer** |
| Version / Amendment History | Version | Date | Author | Reason |
| | 1 | 29/03/2023 | Clinical Lead – Living Well | New SOP |
| **Intended Recipients:** All staff delivering the COVID-19 vaccination programme | | | | |
| **Consultation Group / Role Titles and Date:**<br>Trust Medicines Management Group (MMG) | | | | |
| **Name and date of group where reviewed** | Medicines Management Group (MMG) 04/2023<br>Trust Policy Group – VA – April 2023 | | | |
| **Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Trust Policy Group – Virtual Review – April 2023 | | | |
| **Date of Procedure/Guidelines issue** | April 2023 | | | |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | April 2026 | | | |

| | |
|---|---|
| **Training and Dissemination:**<br>This procedure will form part of the COVID-19 vaccine training programme which all new vaccinators are required to complete | |
| **To be read in conjunction with:**<br>COVID-19 Vaccine handling and management policy and associated procedures | |
| **Initial Equality Impact Assessment: Completed**<br>**Full Equality Impact assessment (as required): No** | |
| **Contact for Review** | Clinical Lead – Living Well |
| **Monitoring arrangements** | Trust Medicines Management Group |
| **Document summary/key issues covered**<br>This Standard Operating procedure (SOP) describes the process for preparation of Comirnaty 10 Concentrate Vaccine. | |
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination<br>VidPrevtyn Beta |

**IMPLEMENTATION PLAN**
**To be completed when submitted to the appropriate committee for consideration/approval**

| **Procedure/Guidelines number and version** | **Title of Procedure/Guidelines** | |
|---|---|---|
| **Reviewing Group** | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** | | |

| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
|---|---|---|
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | | |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | | |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | | |
| Financial cost implementation<br>Consider Business case development | | |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | | |

# Workstation Log - VidPrevtyn Beta® COVID-19 Vaccine

| Date | | Workstation identifier | |
|---|---|---|---|

| | |
|---|---|
| Workstation cleaned and set up for session | |
| All unused vials removed from storage box and discarded | |
| Workstation cleared and cleaned | |

| Issues identified codes | |
|---|---|
| A | Vial Dropped - do not use |
| B | Syringe dropped - do not use |
| C | Vial discoloured or contained particles |
| D | Syringe contained particles |
| E | Other (give detail) |

Operator preparing vaccine doses

| Name (Print) | Signature |
|---|---|
| | |

Second check carried out by

| Name (Print) | Signature |
|---|---|
| | |

**TRANSFER FROM FRIDGE TO COOL BOX (IF APPLICABLE)**

| Date | Time (24hr clock) | Fridge Temperature | Quantity of Vials transferred from Fridge to Cool Box | | Completed by |
|---|---|---|---|---|---|
| / / | : | | Antigen for VidPrevtyn Beta 2.5mL in 10mL vial GREEN CAP | | |
| | | | Adjuvant emulsion for VidPrevtyn beta 2.5mL in 3mL vial GOLD CAP | | |

Removal from fridge/cool box -

| Date | Time (24hr clock) | Fridge/ cool box Temperature* | Completed by | Correct Vials selected & checked by | |
|---|---|---|---|---|---|
| / / | : | | | Antigen for VidPrevtyn Beta 2.5mL in 10mL vial GREEN CAP | |
| | | | | Adjuvant emulsion for VidPrevtyn beta 2.5mL in 3mL vial GOLD CAP | |

*Delete as applicable

Vials received at workstation

| Product | Batch number | Vial Expiry date | Vial Check | Dilution Completed By | Diluted vial Checked by |
|---|---|---|---|---|---|
| **Antigen** for VidPrevtyn Beta 2.5mL in 10mL vial | | | | | |
| **Adjuvant** emulsion for VidPrevtyn beta 2.5mL in 3mL vial | | | | | |

| Diluted Vial Expiry Date: | | Diluted Vial Expiry Time (6 Hours after dilution): | |
|---|---|---|---|

| Name of vaccinator : | Name of second checker: | Vaccination room temp: 25C or less | Y / N |
|---|---|---|---|

**0.5mL Doses drawn up & checked (first check by person drawing up and second check signed by person overseeing**

| Dose | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Issues identified (enter appropriate letter above) | Comments |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Time: | | | | | | | | | | | | |
| Patient's name: | | | | | | | | | | | | |
| Signature of vaccinator: | | | | | | | | | | | | |
| Signature of second checker: | | | | | | | | | | | | |

# COVID-19 Vaccine Procedure 15 Standard Operating Procedure for Preparation of Comirnaty Bivalent Original/Omicron BA.4-5 0.3mL Syringes for Administration

## 1.0 Procedure Statement

This SOP describes the process for preparation of ready-to-administer 0.3mL syringes of Comirnaty Original/Omicron BA.4-5 COVID-19 mRNA Vaccine 15micrograms/15micrograms/0.3mLdose dispersion for injection (**Comirnaty Original / Omicron BA.4-5)** prior to immediate administration.

Different strengths and formulations of Comirnaty vaccine are available. Ensure the correct procedure is selected for the strength or formulation required. This SOP is for use with **Comirnaty Original / Omicron BA.4-5** with the following label format:


This procedure covers the process from the removal of vials of thawed vaccine from the outer carton in the refrigerator, or removal of individual vials from a cool box, up until the point of administration. This includes assigning an expiry date and time after the first dose withdrawal and the preparation of syringes for administration.

This procedure may be adapted to suit either of the following models:

- one person to both draw up individual doses into syringes and administer the vaccine or
- One person to draw up individual doses into syringes and pass the syringe to a vaccinator. This model requires additional local risk assessment, and the introduction of local controls to reduce the risk of needle stick injuries on transfer between individuals.

This procedure is based on Specialist Pharmacy Services Procedure *PCV 7 – Preparation of Comirnaty Bivalent BA.4-5 Vaccine.*

## 2.0 Accountabilities

The Clinical Director of Pharmacy is professionally accountable for the safe and secure handling and management of COVID-19 vaccine and related medicines on all vaccination sites operating within the jurisdiction of the Trust.

The Clinical Lead for the vaccination site is professionally accountable for ensuring that appropriate and formal authorisation for vaccine administration is in place (PSD, PGD or National Protocol), and that the staff groups who are supplied with, prepare, and administer the COVID-19 vaccine are those defined as eligible to do so in accordance with the authorisation being used. When working under the National Protocol, the Clinical Lead will ensure that a clinical supervisor is present for the duration of the vaccination session and this person is clearly identifiable and competent in all stages of the vaccination pathway. The Clinical Lead is also responsible for ensuring that all staff undertaking duties at the vaccination site meet the training standards and competencies for the vaccination programme.

When working under a PSD, the prescriber is legally accountable for the safe and secure handling and management of the COVID-19 vaccine under The Human Medicines Regulations (2012) Regulation 3.

Registered healthcare professionals working under a PSD, PGD or the National Protocol and non-registered staff working under the National Protocol are responsible for ensuring the safe and secure handling requirements are met and must follow this procedure.

## 3.0 Procedure Detail / Actions

### 3.1 Workstation preparation

3.1.1 Confirm the preparation workstation is clear and free from any other vials of vaccine.

3.2.2 Ensure a yellow lidded sharps bin with sufficient free capacity is available.

3.2.3 Ensure an indelible pen is available and a workstation log with information completed for start of session.

.

3.2.4 Put on apron.

3.2.5 Clean workstation with disinfectant wipes and discard into a clinical waste bin.

3.2.6 Following RWT Infection Prevention Policy, wash hands thoroughly. Put on disposable gloves and apron (if not already wearing one) and ensure a face mask is worn.

3.3 When ready to begin preparation select one vial of Comirnaty **Original / Omicron BA.4-5** vaccine.

3.3.1 If working with vials stored in a refrigerator:

- if there is more than one batch of vaccine vials, use the one with the shortest expiry,
- check the post thaw expiry on the carton has not been exceeded, and
- Remove a single vial and close the carton.

3.3.2 If working with vials from a cool box at 2-8$^{O}$C:

- check the vial is within the post-thaw expiry date by checking the label on the vial transport container (refer to SOP 3: *Use of cool boxes to transport COVID-19 vaccines to end user locations), and*
- remove a single vial and close the lid of the cool box.

3.3.3 Check the identity of the vial. This procedure is intended for use with the Comirnaty **Original / Omicron BA.4-5** vaccine.

- Check the vial has a grey cap.
- Check label format on the vial selected matches the image below:


3.3.4 Assemble the following materials required to prepare syringes:

- Comirnaty **Original / Omicron BA.4-5** vial X 1,
- 1mL syringe with integrated 23g (or finer) x 25mm needle x 6, and
- sterile single use 70% alcohol swab x 6.

3.3.5 Gently mix by inverting the vial 10 times, DO NOT shake it. One inversion requires the vial to be fully rotated back to an upright position. Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.

3.3.6 Inspect the vial visually for foreign particulate matter and, or discoloration prior to administration. If particulate matter or discolouration is present, the vaccine should not be administered.

N.B. After mixing the vaccine should present as a white to off-white dispersion with no particulates visible.

3.3.7 Confirm the **0.3mL** booster or primary course dose of Comirnaty **Original / Omicron BA.4-5** is required by the patient

3.3.8 Remove the grey vial dust cover and cleanse the vial stopper with a single use 70% alcohol swab, and discard swab in a clinical waste bin.

3.3.9 Using aseptic technique, draw up **0.3mL** of the vaccine using a new 1mL syringe with integrated 23g or finer x 25mm needle.

N.B.

- a 21g or finer x 38mm needle and 1mL syringe should be used for administering the vaccine to morbidly obese patients, and

- if using a syringe with an auto retracting needle, depressing the plunger will cause the needle to retract prematurely.

3.3.10 Adjust to remove air bubbles with the needle still in the vial to avoid loss of vaccine.

3.3.11 Check volume withdrawn is **0.3mL**. Request a second check of volume. The vaccinator and person carrying out the second check must sign the workstation log.

3.3.12 Visually inspect the syringes for foreign particulate matter and leaks. Discard if these are observed.

3.3.13 The newly filled syringe must be used for immediate administration.

3.3.14 After first dose withdrawal, use the vial as soon as practically possible and within 12 hours (stored at $2^0$C to $30^0$C). Document the expiry date and time (24-hour format, e.g. 14:00) on the vial after first use.

3.3.15 Steps 3.3.3 to 3.3.13 may be repeated a further five times to produce a total of six syringes from each vial. Each time the vial bung is punctured, this should be in a different location to previous points of puncture on the bung.

N.B. to minimise the risk of stopper coring and particles entering the vial:

- Insert the needle through a fresh point in the inner ring of the vial stopper each time,
- each time the vial bung is punctured, it should be in a different location to previous points of puncture working methodically around the inner ring of the vial stopper tracking previous puncture points, and
- do not puncture the stopper outside of the inner ring as this may increase the risk of coring.

3.3.16 If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

3.5.13 After the final dose has been taken from the vial or if expiry has been exceeded, remove the label from the vial and attach to the workstation log. Discard the used diluted vaccine vial into a yellow lidded sharps bin.

N.B. Vials should not be stored between sessions:

- During the in-use period, when doses are being withdrawn from the vial and administered, the vial may remain at room temperature (up to 30°C). This may include the time it takes to move short distances between patients e.g. in a care home, or the time between patients in a clinic.

- The vaccine should be used as soon as practically possible and within 12 hours.
- The opened vial of vaccine can have a transportation time of up to 6 hours.

3.5.14 At the end of the session, discard any remaining part vials. Vials must not be stored between sessions or returned to the refrigerator. **Note that every reasonable effort must be made to safely use all available vaccine and therefore not waste doses; before discarding unused vials or doses permission must be sought from the Clinical Lead (senior nurse).**

3.5.15 Empty outer cartons must be disposed of in a secure manner which prevents theft. Score through the label text with a permanent marker and cut the box up into pieces before disposal in confidential waste.

### 3.6 Dealing with deviations from this procedure

3.6.1 Any deviations from this procedure must immediately be reported to the clinical lead on shift.

3.6.2 An audit worksheet (the workstation log) must be completed for each vial at each stage throughout the process by the vaccinators and the team overseeing stock control. Where vaccine is discarded, this must be recorded on the workstation log and one of the following codes documented:

| ID | Name | Description | Vaccine/ Medical | Consumables | PPE |
|---|---|---|---|---|---|
| 1 | Contamination | The item (e.g. vaccine, diluent) has been contaminated | x | | X |
| 2 | Site Fridge/Freezer Malfunction | The item was stored in a temperature controlled environment that failed | X | | |
| 3 | Transport Breakdown | The item was in transit between locations when the vehicle it was in broke down, resulting in a temperature excursion | X | | |
| 4 | Excess Stock | Where a vaccination team reach the end of an allotted shift or job, and have surplus vaccines that cannot be returned to stock | X | | |
| 5 | Expired shelf-life | Where the expiry date for the product in its current state has been exceeded | X | | X |
| 6 | Waste at Point of Care | Where the prepped dose was refused by the patient | X | | |
| 7 | Improper Storage | The item had not been stored in accordance with instructions (e.g. left out of fridge) | X | X | X |
| 8 | Damaged/Dropped | The item is broken (e.g. vial dropped onto concrete floor) | X | X | X |
| 9 | Lost/ Stolen | The item has gone missing and is assumed lost or stolen | X | X | X |
| 10 | Refused at Delivery | The item has been delivered in a form that is unusable (e.g. temperature excursion or damaged item) | X | X | X |
| 11 | Reconstitution/ dilution /prep error | A mistake was made when drawing up the vaccine, making the dose unusable | X | | |

## 4.0 Equipment Required

Comirnaty **Original / Omicron BA.4-5** Vaccine

Yellow lidded sharps bins

Indelible pen

Workstation logs

Appropriate personal protective equipment including apron and face mask

Disposable gloves

Disinfectant wipes

Clinical waste bins

Plastic trays

1ml syringes with integrated 23g (or finer) x 25mm needle (supplied with vaccine)

Single use 70% alcohol swabs

**Attachment 1** **Comirnaty Bivalent Original / Omicron BA.4-5 Workstation Log**

## 5.0 Training

All staff operating under this procedure must meet the training standards and competencies for the COVID-19 vaccination programme.

## 6.0 Financial Risk Assessment

| | | |
|---|---|---|
| 1 | Does the implementation of this document require any additional Capital resources | Yes – No |
| 2 | Does the implementation of this document require additional revenue resources | Yes – No |
| 3 | Does the implementation of this document require additional manpower | Yes – No |
| 4 | Does the implementation of this document release any manpower costs through a change in practice | Yes – No |
| 5 | Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff. | Yes – No |
| | Other comments | |

## Document Control

| | | | | |
|---|---|---|---|---|
| COVID-19 Vaccine Procedure 16 v1 | **Title of Procedure/Guidelines**<br><br>Standard Operating Procedure for Preparation of Comirnaty **Original / Omicron BA.4-5** Vaccine | **Status:**<br><br>**FINAL** | | **Author: Clinical Director of Pharmacy**<br><br>**Director Sponsor: Chief Medical Officer** |
| Version / Amendment History | Version | Date | Author | Reason |
| | 1 | 30/03/2023 | Clinical Lead – Living Well Group | New SOP |
| **Intended Recipients:** All staff delivering the COVID-19 vaccination programme | | | | |
| **Consultation Group / Role Titles and Date:**<br>Trust Medicines Management Group (MMG) | | | | |
| **Name and date of group where reviewed** | Medicines Management Group (MMG) 04/2023 | | | |
| **Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)** | Trust MMG<br>04/2023 | | | |
| **Date of Procedure/Guidelines issue** | April 2023 | | | |
| **Review Date and Frequency** (standard review frequency is 3 yearly unless otherwise indicated) | April 2026 | | | |

| | |
|---|---|
| **Training and Dissemination:**<br>This procedure will form part of the COVID-19 vaccine training programme which all new vaccinators are required to complete | |
| **To be read in conjunction with:**<br>COVID-19 Vaccine handling and management policy and associated procedures | |
| **Initial Equality Impact Assessment: Completed**<br>**Full Equality Impact assessment (as required): No** | |
| **Contact for Review** | Clinical Director of Pharmacy |
| **Monitoring arrangements** | Trust Medicines Management Group |
| **Document summary/key issues covered**<br>This Standard Operating procedure (SOP) describes the process for preparation Comirnaty Bivalent **Original / Omicron BA.4-5** Vaccine | |
| **Key words for intranet searching purposes** | COVID-19<br>Vaccine<br>Vaccination<br>Comirnaty Bivalent<br>Original / Omicron BA.4-5 |

**IMPLEMENTATION PLAN**
**To be completed when submitted to the appropriate committee for consideration/approval**

| **Procedure/Guidelines number and version** | **Title of Procedure/Guidelines** | |
|---|---|---|
| **Reviewing Group** | | **Date reviewed:** |
| **Implementation lead: Print name and contact details** | | |
| **Implementation Issue to be considered (add additional issues where necessary)** | **Action Summary** | **Action lead / s (Timescale for completion)** |
| Strategy; **Consider** (if appropriate)<br>1. Development of a pocket guide of strategy aims for staff<br>2. Include responsibilities of staff in relation to strategy in pocket guide. | | |
| Training; Consider<br>1. Mandatory training approval process<br>2. Completion of mandatory training form | | |
| Development of Forms, leaflets etc.; Consider<br>1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out.<br>2. Type, quantity required, where they will be kept / accessed/stored when completed | | |
| Procedure/Guidelines communication; Consider<br>1. Key communication messages from the policy / procedure, who to and how? | | |
| Financial cost implementation<br>Consider Business case development | | |
| **Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation** | | |

# Pfizer BIVALENT Comirnaty® Original/Omicron BA.4-5 COVID-19 Vaccine

| Date | | Workstation identifier | |
|---|---|---|---|

| | |
|---|---|
| Workstation cleaned and set up for session | |
| All unused vials removed from storage box and discarded | |
| Workstation cleared and cleaned | |

| Issues identified codes | |
|---|---|
| A | Vial Dropped - do not use |
| B | Syringe dropped - do not use |
| C | Vial discoloured or contained particles |
| D | Syringe contained particles |
| E | Other (give detail) |

**Vials received at workstation**

| Product | Batch number | Expiry date | Date | Time | Confirm fridge/Cool Box temp | Vial check | Completed by | Checked by |
|---|---|---|---|---|---|---|---|---|
| Comirnaty® Bivalent Original / Omicron BA.4-5 COVID-19 Vaccine 0.3mL dose | | | | | | | | |

| Name of vaccinator : | | Name of second checker: | |
|---|---|---|---|
| Vaccination room temp: MAX 30C | | Vial Expiry Date/Time (12 Hours after the first puncture): | |

| | 0.3mL Doses drawn up & checked (first check by person drawing up and second check signed by person overseeing - if applicable) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Dose | 1 | 2 | 3 | 4 | 5 | 6 | Issues identified (enter appropriate letter above) | Comments |
| Time: | | | | | | | | |
| Patient's name: | | | | | | | | |
| Delete as appropriate | Primary Course / Booster | Primary Course / Booster | Primary Course / Booster | Primary Course / Booster | Primary Course / Booster | Primary Course / Booster | | |
| Signature of vaccinator: | | | | | | | | |
| Signature of second checker: | | | | | | | | |

*Written by: SPS/Nicholas Carre*
*Approved by: Trust MMG*
*Authorised by: Trust MMG*

**Appendix 1**

## National standards of good practice in relation to this policy

**CQC Regulation 12: Safe Care and Treatment**
https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-12-safe-care-treatment

The intention of this regulation is to prevent people from receiving unsafe care and treatment and prevent avoidable harm or risk of harm. Providers must assess the risks to people's health and safety during any care or treatment and make sure that staffs have the qualifications, competence, skills and experience to keep people safe.
• Providers must make sure that the premises and any equipment used is safe and where applicable, available in sufficient quantities. Medicines must be supplied in sufficient quantities, managed safely and administered appropriately to make sure people are safe.
• Providers must prevent and control the spread of infection. Where the responsibility for care and treatment is shared, care planning must be timely to maintain people's health, safety and welfare.

The CQC understands that there may be inherent risks in carrying out care and treatment, and we will not consider it to be unsafe if providers can demonstrate that they have taken all reasonable steps to ensure the health and safety of people using their services and to manage risks that may arise during care and treatment.'

**NICE Clinical Guideline QS61: Infection Prevention and Control**
https://www.nice.org.uk/guidance/qs61

This quality standard covers preventing and controlling infection in adults, young people and children receiving healthcare in primary, community and secondary care settings.

**The Green Book - Immunisation against infectious disease (Public Health England)**
https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book#the-green-book

The latest information on vaccines and vaccination procedures, for vaccine preventable infectious diseases in the UK. The COVID-19 vaccine chapter is available on: https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a

**Specialist Pharmacy Service – COVID-19 Guidance**
COVID-19 – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

**FutureNHS COVID-19 Vaccination Programme**
COVID-19 Vaccination Programme - FutureNHS Collaboration Platform

**UK Health Security Agency COVID-19 Vaccination Programme**
COVID-19 vaccination programme - GOV.UK (www.gov.uk)

**NHS England COVID-19 Vaccination Programme**
Coronavirus » COVID-19 vaccination programme (england.nhs.uk)

**Professional guidance on the safe and secure handling of medicines (Royal Pharmaceutical Society of Great Britain)**
Available on https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines