MP11
COVID-19 Vaccine Handling and Management Policy

ContentsMP11

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1.0 Policy Statement

The COVID-19 vaccination programme is part of the seasonal vaccination programme. 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.

COVID-19 Vaccination Programme
Refers to the government programme to give the COVID-19 vaccination. This is now part of the seasonal and year-round vaccination program.

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

Federated Data Platform (FDP) 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 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 Chief Pharmacist may delegate operational responsibility for oversight of ordering, receipt, storage and safe handling of vaccines and medicines to a suitably trained pharmacy team member.

3.2 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.

3.3 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.

3.4 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.

3.5 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

4.1 COVID-19 Vaccines

There are several COVID-19 vaccines that have received MHRA approval and are licensed for use. Regulation 174 of the Human Regulations 2012 should now only be used if there is a need to use an unlicensed vaccine due to 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

4.2.1 All activity is to be undertaken in accordance with the Human Medicines Regulations 2012 and Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020.

4.2.2 All new vaccination sites must be approved by the pharmacy lead for COVID-19 vaccines, infection prevention team, and be included in the Trust CQC registered locations following the Trust CQC registration process. You can do this by contacting the CQC Enquiry team rwh-tr.cqcenquiry@nhs.net. System assurance check may also be required.

4.2.3 Any vaccination sites that pause between seasonal programmes must check that they are still a Trust CQC registered location before re-starting activity.

4.2.4 If a vaccination site closes it must be removed from the Trust CQC registered locations.

4.2.5 All activity is also to be aligned with relevant COVID-19 Vaccination Programme NHS Schedules and contracts.

4.2.6 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

4.3.1 All Vaccination Sites must have received Site Assurance sign off from local System and Regional Vaccine teams. This process is completed through the Federated Data Platform (FDP) system.
All activities must be carried out in accordance with:

- This policy document;
- 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

4.4.1 Legal authorisation for vaccine administration must be in place e.g., Patient Specific Direction (prescription), National 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.

4.4.2 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 Preparation and Administration of Vaccine

4.5.1 Preparation of the vaccine must be completed in accordance with the Summary of Product Characteristics (SmPC) for the vaccine. Aseptic touch technique must be used.

4.5.2 Vaccine administration must be recorded in the appropriate system in accordance with NHS England guidance. In patient vaccinations must also be recorded on the patient administration record.

4.5.3 Multidose vials must have a vaccine worksheet in place and be fully completed. This provides traceability and a record of any wasted doses which are required to be submitted on to the FDP (attachment 5).

4.6 Safety and security of vaccines and related medicines

4.6.1 The 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.

4.7 Storage and transportation of vaccines

4.7.1 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.

4.7.2 Storage and transportation of vaccines must be undertaken in accordance with Trust Policy MP10 – Temperature management for medicines storage and manufacturers'

information.

4.7.3 Cold chain temperatures must be monitored correctly and any 'out of specification' recordings addressed promptly and appropriately, in accordance with MP10.

4.7.4 The appropriate vaccine SmPC must be referred to for specific conditions of handling and movement, and for the initial investigation of temperature excursions.

4.8 Transferring Vaccine

4.8.1 **Mutual Aid**

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

4.8.2 Mutual aid transfers can only happen with permission from the system and region in accordance with mutual aid ordering. COVID-19 Vaccine Standard Operating Procedure 1 - Ordering of COVID-19 Vaccine The approval for and record of transfers is completed within the FDP.

4.8.3 Mutual aid paperwork (attachment 3) must be used when transferring vaccine to or from a separate legal entity and must be kept for 2 years by the receiving site.

4.8.4 **Transfers within the same legal entity** (i.e. between internal Trust services)
It is the responsibility of the Clinical Lead of the site receiving the supply to organise transport and oversee and monitor the temperature of the vaccine. Cold chain transfer must be completed in accordance with MP10 and this SOP. The record of transfers is completed within Foundry by the nominated registered professional authorised within the Trust to do so.

4.9 Workforce and training

All staff undertaking duties at the vaccination site must meet the national minimum standards and core curriculum for vaccination training and have completed the vaccinator competency assessment tool workbook.

Staff must also have undertaken the latest e-LfH covid-19 vaccine training.

All training must be recorded in the staff personal file.

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

4.10 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:

- Intramuscular (IM) adrenaline 1:1,000;
- Oxygen;
- 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 Trust incident reporting policies GOP02 and OP10. Incidents must also be reported to the system vaccine oversight committee (SVOC). Any adverse effects from a vaccine must also be reported 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.

4.11 Management 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 Lead and reviewed in line with local governance procedures.

4.12 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.

4.13 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.

4.14 Business Continuity Planning

The business continuity plan of each service 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	No
2	Does the implementation of this policy require additional revenue resources	No
3	Does the implementation of this policy require additional manpower	No
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.	No
	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 an evolving service and as such new and updated information is being published regularly. 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.

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	Clinical Lead – for each directorate providing the service	Review of Datix	Monthly	Local Directorate Governance
Service Oversight	Clinical Lead – for each directorate providing the service	Report of annual audit results	Annually	Local Directorate Governance

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/.

11.0 Part A - Document Control

Policy number and Policy version: MP11 V3.2	Policy Title COVID-19 Vaccine handling and management policy	Status: Final		Author: Assistant Director of Pharmacy Director Sponsor: 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 2022	Angela Davis	Extension
	2.0	December	Nicholas	Updates to all

	2022	Carré	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
2.2	June 2023	Clinical Lead – Living Well Group	Addition of SOP 17
2.3	October 2023	Clinical Lead – Living Well Group	Addition of SOPs 18 & 19
2.4	November 2023	Clinical Lead – Living Well Group	Addition of SOP20
3.0	March 2024	Assistant Director of Pharmacy	Removal of NHSE processes that have stopped, 8 obsolete SOPs removed, and refresh of remaining SOPs. Addition of in-patient service SOP 10
3.1	October 2024	Assistant Clinical Director of Pharmacy	Minor update to reflect new national system (FDP) in main policy and SOP 1, 2 and 4) and update of SOP 5-8 vaccines with new JN.1 variant
3.2	October 2025	Assistant Clinical Director of Pharmacy	Full review, removing vaccine preparation SOPs. SOP 3, 5,6,7,8,10, 12 and 13 removed. Remaining SOPs updated and renumbered.

Intended Recipients: All staff involved in the handling and management of the COVID-19 vaccine	
Consultation Group / Role Titles and Date: Trust Medicines Management Group – September 2024	
Name and date of Trust level group where reviewed	Trust MMG (virtual review) – 30.09.25 Trust Policy Group (virtual review / approval via Sponsor) – 26.09.25
Name and date of final approval committee	Trust Policy Group – October 2025
Date of Policy issue	October 2025
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	June 2027
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 MP01 Prescribing, Storage and administration of Drugs, **MP10 Temperature management for medicines storage** and associated Standard Operating Procedures	
Initial Equality Impact Assessment (all policies): Completed Yes Impact assessment (as required): NA	
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 Vaccination COVID-19 Immunisation
High Risk Policy? Definition: • Contains information in the public domain that may present additional risk to the public e.g. contains detailed images of means of strangulation. References to individually identifiable cases. • References to commercially sensitive or confidential systems. 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

12.0 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

13.0 IMPLEMENTATION PLAN

MP11 V4.0	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) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.	N/A	
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form	N/A	
Development of Forms, leaflets etc; Consider 1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed	Consent forms in use	Already implemented
Strategy / Policy / Procedure communication; Consider 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 Vaccine from UK Health Security Agency (UKHSA)

This procedure is based on Specialist Pharmacy Services Guidance and Future NHS COVID-19 vaccination systems training and Guidance (When you first log on you will need to create 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.

The Clinical Lead responsible for the COVID-19 Vaccine programme is responsible for the ordering and purchasing tasks within this procedure.

3.0 Procedure Detail / Actions

3.1 All ordering and stock management procedures are completed within the Federated Data Platform (FDP).

3.2 All users of FDP must have accounts and be able to access all areas necessary for their role. For any queries relating to FDP access users must contact: ssd.nationalservicedesk@nhs.net

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

3.4 Stock Holding

3.4.1 Stocktake submissions are made on the Site Stock Manager module of FDP.

3.4.2 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.

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

3.5 Ordering

3.5.1 Adult Covid-19 vaccines and associated consumables will be supplied to vaccination sites automatically based on usage and stock levels.

3.5.2 Patient information leaflets (PILs) will be provided with each vaccine delivery and sites may order more through FDP.

3.5.3 Information about the supply can be found on the Supply Dashboard within FDP.

3.5.4 Vaccine volumes and delivery dates will be visible in the supply dashboard. Site managers must review their supply dashboard to understand when their delivery will be made. Further vaccine orders will also be visible in the supply dashboard

3.5.5 Exceptional vaccine requests can be made directly in the supply dashboard. These requests require approval by the ICB and regional teams before being confirmed as orders.

3.5.6 Requests for children and young people's vaccines throughout the programme must be made through this exceptions process.

3.5.7 Hospital Hubs will not receive dynamic replenishment and must request any additional vaccine through the exceptions process

3.6 Mutual Aid and Internal Transfers

3.6.1 If you have too much or not enough vaccine for any reason, a mutual aid request can be made. The Transfer Tool module in FDP 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.

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

3.6.3 All mutual aid transfers must be recorded on the Transfer Tool module in FDP, and any stock received must be a fully auditable in accordance with SOP 3: The use of cool boxes to transport COVID-19 vaccines

3.6.4 All internal transfers between RWT services with separate FDP accounts must be recorded in the Transfer Tool module in FDP. This must be completed by the Lead Pharmacist for COVID-19 vaccine services.

3.7 Supply of Vaccine to Trust Vaccine Services

3.7.1 Each service must manage their supply of vaccine to ensure 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, this must be escalated immediately to the Lead Pharmacist for COVID-19 Vaccine who in turn will work with the Clinical Lead to resolve the situation.

3.8 Cancelling Orders

Orders can only be cancelled by 11am of the day before the scheduled delivery. To do this you would need to contact the SVOC by emailing covidsystemsvacsinfo@nhs.net

4.0 Equipment Required

Access to FDP

5.0 Training

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

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	Yes
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	

Document Control

COVID-19 Vaccine Procedure 1 v3.2	**Title of Procedure/Guidelines** Standard Operating Procedure for Ordering COVID-19 Vaccine		**Status:** **Final**	**Author: Clinical Director of Pharmacy** **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.
	V3.0	April 2024	Deputy Clinical Director of Pharmacy	Updated process for ordering and stock take using Foundry
	V3.1	September 2024	Assistant Director of Pharmacy	Update process to reflect change from Foundry to Federated Data Platform
	V3.2	September 2025	Assistant Director of Pharmacy	Review and check of links no changes made
Intended Recipients: Pharmacy Procurement staff, Designated pharmacy staff working in vaccination sites.				
Consultation Group / Role Titles and Date: Trust Medicines Management Group (MMG)				
Name and date of group where reviewed			Medicines Management Group (MMG) September 2025 Trust Policy Group (virtual review / approval via Sponsor) – 26.09.25	
Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)			Medicines Management Group (MMG) September 2025 Trust Policy Group – October 2025	
Date of Procedure/Guidelines issue			October 2025	

Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	June 2027
Training and Dissemination: This procedure will form part of the COVID-19 vaccine training programme	
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 ordering COVID-19 Vaccine	
Key words for intranet searching purposes	COVID-19 Vaccine Vaccination

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 program.

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

3.1 Accepting Deliveries

3.1.1 Process the vaccine delivery immediately to maintain the cold chain.

3.1.2 Check:

- 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
- whether the transit time Spikevax vaccines has exceeded 6 hours. This information will be provided by the delivery driver.
  N.B there are no transit restrictions for any other COVID-19 vaccines

3.1.3 If any part of the delivery is damaged, already opened, missing or otherwise not as expected report without delay to the pharmacy stores Chief Pharmacy Technician or in a vaccine hub, the Clinical Lead.

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

3.2 Physical Examination of Delivery

3.2.1 Check:

- the tamper evident seal is intact
- there is no evidence of any damage
- the identity, batch number, expiry date and quantities against the delivery note.

and

- endorse the delivery note to confirm

3.2.2 For Spikevax, if the transit time exceeded 6 hours (see 3.1.2) 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.

3.2.3 If there is any damage or discrepancy, quarantine the stock at the correct storage temperature (refrigerated at 2-8°C) and report without delay to pharmacy stores Chief Pharmacy Technician or in a vaccine hub, the Clinical Lead. If any vials are broken, deal with the spillage following MP11 SOP006.

3.2.4 Put the vaccines into a refrigerator (at 2-8°C) immediately

3.3 Logging Receipts on the Stock Control System

3.3.1 For each order, receive the goods on to the stock control system (Federated data platform (FDP) and pharmacy stock management system)

3.3.2 Forward completed delivery documentation to pharmacy procurement team or if delivery is at a vaccination hub, retain records for 2 years.

3.3.3 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
- Post thaw expiry date

4.0 Equipment Required

Access to FDP

5.0 Training

All staff involved in the receipt of COVID-19 vaccine 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 V3.2	**Title of Procedure/Guidelines** Standard Operating Procedure for Receipt and Storage of COVID-19 Vaccines at 2°C – 8°C		**Status:** **Final**	**Author: Clinical Director of Pharmacy** **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.
	V3.0	April 2024	Deputy Clinical Director of Pharmacy	Update to SPS SOP, minor change to Foundry process. Removal of reference to frozen vaccine.
	V3.1	September 2024	Assistant Clinical Director of Pharmacy	Replace reference to Foundry with federated data platform
	V3.2	September 2025	Assistant Clinical Director of Pharmacy	Review of MP11 no changes
Intended Recipients: Designated staff in COVID-19 vaccine services and pharmacy department				
Consultation Group / Role Titles and Date: Trust Medicines Management Group (MMG)				
Name and date of group where reviewed			Medicines Management Group (MMG) Trust Policy Group (virtual review / approval via Sponsor) – 26.09.25	

Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)	Medicines Management Group (MMG) Trust Policy Group – October 2025
Date of Procedure/Guidelines issue	October 2025
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	June 2027

Training and Dissemination:
Published on Trust Intranet and staff briefing to ensure it is read by relevant staff.

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 Receipt and Storage of refrigerated COVID-19 Vaccine

Key words for intranet searching purposes	COVID-19 Vaccine Vaccination

MP11 Attachment 3:

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**	**Vaccination centre**	**Hospital Hub**	
Donor Site Clinical Lead:	Name		Designation		
Mutual Aid Agreed by BCICB SRO and SVOC?	**Yes**	**No**	Mutual Aid Agreed by Place ICB 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					
Quantity (Number of vials) being transferred (as per Mutual aid agreement)					
Vaccine Batch Number (if Pfizer please include V number)					
Vaccine expiry date					
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.
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 recording a stock count, wastage and deliveries 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 Clinical Lead for each service has operational responsibility for ensuring stock takes are submitted in a timely manner in accordance with this SOP.

3.0 Procedure Detail / Actions

3.1 Access to the Federated Data Platform (FDP) is required to undertake the activities in this SOP. Set up and user guides can be found here

3.2 Wasted doses/vials must be recorded the same day or within 24 hours.

3.3 After each delivery a stock take must be submitted on the FDP Stock Site Manager App.

3.4 A stock take must also be completed and submitted on FDP Stock Site Manager at least every 7 days. If this is not completed orders will not be approved.

3.5 Completing a Stock Count

3.5.1 For each different batch number and vaccine type:

- Complete a physical count of the number of vials. Where a pack is sealed do not open it to count, but assume it is full.
- Check and record the expiry dates and note the batch number
- Ensure there is appropriate stock rotation (shortest dated stock is foremost).

3.5.2 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.

3.6 Submitting the Stock take on FDP

3.6.1 Log on to FDP and open the Site Stock Manager App. This can be accessed from the LVS Workspace.

3.6.2 Select the Stock Tab and click add new record

3.6.3 Complete the record including the Date, vaccine type, batch number, quantity of vials and expiry date click add record

3.6.4 Review the summary page and if correct click submit.

3.6.5 Repeat for each different batch and vaccine type.

3.7 **Recording waste**

3.7.1 Log on to FDP and open the Site Stock Manager App. This can be accessed from the LVS Workspace.

3.7.2 Select the Waste Tab and click add new record

3.7.3 Complete the record including the Date, vaccine type, waste category, waste reason, quantity, units you are recording the waste in (doses or vials), batch number and expiry date click add record

3.7.4 Review the summary page and if correct click submit.

3.7.5 Repeat for each different batch and vaccine type.

3.8 **Resolution of any discrepancies**

Any discrepancies identified must be investigated and escalated immediately to the Clinical Lead.

4.0 Equipment Required

FDP

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 v3.2	**Title of Procedure/Guidelines** Standard Operating Procedure for recording a stock count, wastage and deliveries of COVID-19 Vaccine	**Status:** **Final**		**Author: Clinical Director of Pharmacy** **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 FDP recording and reconciliation frequency changes. Removal of SPS reference as no longer available
	V3	April 2024	Deputy Clinical Director of pharmacy	Removal of the need for a stock book and update to FDP recording processes.
	V3.1	September 2024	Assistant Clinical Director of Pharmacy	Minor updates to remove references to Foundry and replace with FDP
	V3.2	September 2025	Assistant Clinical Director of Pharmacy	Minor updates to remove use of session worksheet
Intended Recipients: All Vaccinators and Pharmacy Staff participating in the COVID-19 Vaccine delivery programme				
Consultation Group / Role Titles and Date: Trust Medicines Management Group (MMG)				
Name and date of group where reviewed	Medicines Management Group (MMG) Trust Policy Group (virtual review / approval via Sponsor) – 26.09.25			

Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)	Medicines Management Group (MMG) Trust Policy Group – October 2025
Date of Procedure/Guidelines issue	October 2025
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	June 2027

Training and Dissemination:
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:
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 Director of Pharmacy
Monitoring arrangements	Trust Medicines Management Group

Document summary/key issues covered
This Standard Operating procedure (SOP) describes the process for Stocktaking and Reconciliation of COVID-19 Vaccine

Key words for intranet searching purposes	COVID-19 Vaccine Vaccination

COVID-19 Vaccine Pre-Mixed Multi Dose Vial

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 name	**Batch number**	**Expiry date**	**Date**	**Time**	**Confirm fridge/Cool Box temp**	**Vial check**	**Completed by**	**Checked by**

No of Doses in Vial:	Dose: mL		
Name of vaccinator :		**Name of second checker:**	
Maximum Room temperature allowed for product:		**Actual Room temperature:**	**Vial Expiry Date/Time):**

	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 (if applicable):								

COVID-19 Vaccine Procedure 6 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.

2.0 Accountabilities

The shift Clinical/Department 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 RWT or WHT Trust Waste 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 6 V3.0	**Title of Procedure/Guidelines** Standard Operating Procedure for Handling of Spillages and Breakages of COVID-19 Vaccine		**Status:** **FINAL**	**Author: Clinical Director of Pharmacy** **Director Sponsor: Chief Medical Officer**
Version / Amendment History	Version	Date	Author	Reason
	v1	29/12/2020	Clinical Director of Pharmacy	New SOP
	v2	22/09/2022	Deputy Clinical Director of Pharmacy	Updated to include reference to all COVID-19 vaccines
	V2.1	23/03/2024	Deputy Clinical Director of Pharmacy	SOP Number change as part of rationalisation. No changes, re-issued following expiry
	V3.0	19/9/25	Assistant Director of Pharmacy	SOP Number change as part of rationalisation. No changes.
Intended Recipients: All staff delivering the COVID-19 vaccination programme				
Consultation Group / Role Titles and Date: Trust Medicines Management Group (MMG)				
Name and date of group where reviewed			Medicines Management Group (MMG) Trust Policy Group (virtual review / approval via Sponsor) – 26.09.25	
Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)			Medicines Management Group (MMG) Trust Policy Group – October 2025	

Date of Procedure/Guidelines issue	October 2025
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	June 2027

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 RWT HS10 or WHT-IPC924 respectively

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 method to be used to safely deal with a spillage of COVID-19 vaccine.

Key words for intranet searching purposes	COVID-19 Vaccine Vaccination

IMPLEMENTATION PLAN

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) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.		
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form		
Development of Forms, leaflets etc.; Consider 1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed		
Procedure/Guidelines communication; Consider 1. Key communication messages from the policy / procedure, who to and how?		
Financial cost implementation 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
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 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 does not apply to inpatient services which should only have one vaccine type in their location

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 regular (minimum monthly) assurance visits to each active vaccination site.

3.0 Procedure Detail / Actions

VACCINE ASSURANCE VISITS

3.1 The COVID-19 Lead pharmacist must complete regular assurance visits to each site and complete the pharmacy supervision of COVID-19 Vaccine Checklist (attachment 1). This can be delegated to an appropriately trained pharmacist.

SAFETY BRIEF

3.2 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.

3.3 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 that day, and the coloured tray for each different vaccine.
- 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.

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. All staff members must be aware that the colours may vary at different vaccination sites.

3.13 Using the poster in Appendix 1, 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 in 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 Only **one** type of COVID vaccine can be in the vaccination workstation at any time.

3.17 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.

3.18 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.

3.19 Where this is not possible and a different vaccine is required, the current vaccine must be moved to a clearly separated area and the alternative vaccine taken to the vaccination workstation

3.20 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

3.21 The patients' demographics will be requested. These will be cross checked using a Vaccination Software (e.g. RAVS/pharmoutcomes).

3.22 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.

3.23 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.

3.24 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.

3.25 Consent will be documented on the relevant consent forms available on the computerised system for all vaccines. A parental consent must be recorded 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.

3.26 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.

3.27 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.

3.28 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.

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

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

3.31 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.

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

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

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

3.35 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 – 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 7 V4.0	**Title of Procedure/Guidelines** Standard Operating Procedure for the administration of multiple vaccines in a single vaccination clinic setting		**Status:** Final	**Author: Nicholas Carré** For local procedures and guidelines Lead Sponsor: 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
	V3.1	23/03/2024	Deputy Clinical Director of Pharmacy	Updated appendix 2 to reflect current COVID-19 vaccines for Spring Booster 2024. Change to timeframe for assurance checks
	V4.0	22/09/2025	Assistant Clinical Director of Pharmacy	Updated to reflect current processes, appendix 1 removed, appendix 2 renamed appendix 1 and renamed to procedure 7 as part of MP11 update.

Intended Recipients: All staff working in Trust 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	Medicines Management Group (MMG) Trust Policy Group (virtual review / approval via Sponsor) – 26.09.25
Name and date of final approval committee	Medicines Management Group (MMG) Trust Policy Group – October 2025
Date of Procedure/Guidelines issue	October 2025
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	June 2027

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 providing vaccination services will be required to read this procedure this includes vaccinators, pharmacy and admin staff.

To be read in conjunction with
MP 11 COVID-19 vaccine Policy

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

Contact for Review	Assistant 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 Vaccine Vaccination

APPENDIX 1 - Vaccine Colour identifier

Vaccine	Tray Colour
Comirnaty 30 Ready to use	
Comirnaty 10 for Children 5-11 years Ready to use	
Comirnaty 3 (THREE) Concentrate	
Vaccine name:	
Vaccine name:	
Vaccine name:	

COVID-19 Vaccine Procedure 7 Attachment 1
Assurance Check for COVID-19 Vaccines Service

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

1. Workforce	Signature	
Identify the Clinical Lead and introduce yourself. Ensure the name of the Clinical Lead on shift 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	**Signature**	
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 Huddle time: 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. SOPS and Protocols	**Pass**	**Fail**
Check the protocols are the latest version and signed by everyone working that day Check the protocols have been signed by the authorising clinician Check all necessary Policy and SOPs are in place and staff have signed the SOPs Check there is an operational SOP for managing multiple vaccines in place		

Observe on 3 occasions (if possible) that vaccine handling is in accordance with policy If applicable, observe each second checker on 2 occasions to confirm that the draw up second check is being followed correctly. Record any missing protocols and SOPs here and who has been asked to update them		
3. Equipment & Facilities	**Pass**	**Fail**
Check the fridges are working within range (2-8°C) and there have been no excursions. Confirm that any temperature excursions have been documented correctly and reported, stock is quarantined pending an outcome on stability and if still safe to use. Confirm that fridge temperatures are being recorded and the thermometer has been reset Confirm that data loggers are in place and operational. Download the latest data and check temperature stability. Attach a copy to this record. Confirm any temperature excursions have been appropriately managed (If applicable). 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 all areas where vaccine is stored and used. Confirm that ambient temperatures are being recorded and the thermometer has been reset. Confirm that ambient temperatures are within the required range. Confirm any temperature excursions have been appropriately managed (If applicable).		

Ensure the vaccine preparation station is clear and cleaned ready for the session. **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.		
Agree action for Clinical lead to order any additional medicines required from Pharmacy		
4. Vaccine and Consumables	**Pass**	**Fail**
Ensure that the vaccine vials are in date. Ensure vaccine vials currently in use by vaccinators have not expired. Confirm the vaccinators have the latest worksheets and are completing them correctly (check 10 sheets). 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. 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		
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: • confirm that the fridge door is firmly closed and locked and the temperature is within range (2-8°C),		

• confirm that drug cupboards are locked, and • 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 sharps bins currently being used have the correct information documented on them and are secure when not in use.		
Confirm all full sharps bins are sealed, signed and stored in a secure location until collection.		
Ensure any empty vaccine boxes are defaced and disposed of as confidential waste.		

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

Print Name:

Actions Communicated to Service Lead

Service Lead name:

Date:

MP11 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