MP11
COVID-19 Vaccine Handling and Management Policy

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Appendix 1 National standards of good practice in relation to this policy

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.

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 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 Service provides 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 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 Detail

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 should 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 policy documents marked as Classification: Official and annotated with a publication approval reference number.

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 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.

4.3.2 **Vaccination session set up and close down**

- Before the start of every vaccination clinic, the COVID-19 Vaccination session record (Procedure 10 Attachment 1) must be completed by the Clinical Lead.
- The document must remain live throughout the session and all sections must be fully completed.
- The close-down process must be completed before the clinic and the vaccination team leave each night.
- The supervision log must be kept with the vaccination worksheets completed on the same day.
- 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)

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

4.8 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 Trust incident reporting policies OP04 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.

4.9 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. .

4.10 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 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	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.	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	Governance Team	Review of Datix	Monthly	Living Well Group Governance Committee
Service Oversight by the medicine safety group	Clinical Lead – for each directorate providing the service	Report of annual 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: MP11 V3.0	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 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
	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
	2.5	April 2024	Clinical Lead – Living Well Group	Extension
	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
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 Trust Policy Group				

Name and date of Trust level group where reviewed	Trust Policy Group – June 2024
Name and date of final approval committee	Trust Management Committee – June 2024
Date of Policy issue	July 2024
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 **MP10 Medicine Cold Chain Policy** 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

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 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

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 Ordering

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

leaflets (PILs) will be provided with each vaccine delivery and sites may order more through Foundry.

3.2.2 Information about the supply can be found on the Supply Dashboard within Foundry.

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

3.2.3 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.

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

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

3.3 Mutual Aid and Internal Transfers

3.3.1 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.

3.3.2 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.

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

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

3.4 Supply of Vaccine to Trust Vaccine Services

3.4.1 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.

3.5 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 Foundry

5.0 Training

Designated 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	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 v2	**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
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) 04/2024 Trust Policy Group – June 2024			
Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)	Medicines Management Group (MMG) 04/2024 Trust Management Committee – June 2024			
Date of Procedure/Guidelines issue	July 2024			

Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	March 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

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) 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 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.

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

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 SOP09.

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 (Foundry 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 Foundry

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 v3.0	**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.
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) 04/2024 Trust Policy Group – June 2024			
Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)	Medicines Management Group (MMG) 04/2024 Trust Management Committee – June 0224			
Date of Procedure/Guidelines issue	July 2024			

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

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) 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 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. https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2021/09/position-statement-reducing-microbial-risk-when-transporting-covid-19-vaccines-v1.1.pdf
- Transport of vials for Mutual Aid. https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2021/01/C1424-mutual-aid-and-the-transfer-of-covid-19-vaccines-between-nhs-vaccination-sites-v2.pdf

If any of the three scenarios above are approved, the transport principles described in this SOP will remain generally applicable. If Spikevax vials are to be transported again, the total permitted transport time, including that already used by the Specialist Pharmaceutical Logistics (SPL) providers, must not be exceeded (Section 5.2.2).

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.

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

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

3.1.5 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 Select the minimum number of vials required for the planned session. This may be

- one or more vials.
- a full carton, where smaller cartons are available.

3.2.3 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 Spikevax only, record the journey time remaining. This will normally be 30 hours (of the total 36 allowed, assuming 6 hours for the original delivery). However, if the carton states that the vaccine has already been transported for more than 6 hours, the journey time remaining should be calculated as 36 hours minus the journey time already used.

3.2.4 Pack the labelled container into the cool box in such a way that it remains upright and minimises the movement of the vials. If frozen ice packs are recommended by the manufacturer, use packing material e.g. bubble wrap to ensure that the frozen ice pack does not come into direct contact with the vaccines.

3.3. Transport of vaccine to the end user location

3.3.1 Pack the cool box into the vehicle 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 time for which the cool box is validated (if applicable)
- the temperature inside box is between 2 and 8°C (if thermometer in use)
- for Spikevax vaccines only, that the journey time was less than the remaining journey time written on the vaccine container.

If not, the vaccine should be quarantined in the refrigerator and advice sought from the Clinical Lead

3.3.4 Use the vaccine immediately on arrival, or place it into the refrigerator and use as soon as possible.

3.3.5 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.

3.3.6 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:

- COVID-19 Vaccine Standard Operating Procedure 5 - Standard Operating Procedure for Preparation of Comirnaty 30 (XBB1.5) Ready to use 0.3mL Syringes for Administration

- COVID-19 Vaccine Standard Operating Procedure 6 - Standard Operating Procedure for Preparation of Comirnaty 10 (XBB1.5) Ready to Use 0.3mL Syringes for Administration
- COVID-19 Vaccine Standard Operating Procedure 7 - Standard Operating Procedure - Preparation of 0.2mL Syringes Using Comirnaty 3 Concentrate for Children 6 Months to 4 Years
- COVID-19 Vaccine Standard Operating Procedure 8 – Standard Operating procedure - Preparation of Spikevax (XBB.1.5) 0.5mL Syringes for Administration

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

3.3.8 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 Transferring Vaccine

3.4.1 **Mutual Aid**
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. COVID-19 Vaccine Standard Operating Procedure 1 - Ordering of COVID-19 Vaccine The approval for and record of transfers is completed within Foundry by SVOC.

3.4.2 Mutual aid paperwork (see appendix 1) must be in place and temperature records for vaccine received as mutual aid by the service must be kept for 2 years.

3.4.3 **Transfers within the same legal entity** (i.e between 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.

4.0 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.

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** Standard Operating Procedure for for the use of cool boxes to transport COVID-19 Vaccines to end user locations and for Mutual Aid	**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	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
	V5	April 2024	Clinical Lead – Living Well Group	Review
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: Trust Medicines Management Group (MMG)				
Name and date of group where reviewed	Medicines Management Group (MMG)			

	04/2024 Trust Policy Group – June 2024
Name and date of final approval committee (if trust-wide document)/ Directorate or other locally approved committee (if local document)	Medicines Management Group (MMG) 04/2024 Trust Management Committee – June 2024
Date of Procedure/Guidelines issue	July 2024
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	June 2027

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 Vaccine Vaccination Transporting 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) 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		

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**	**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 The number of vials used and doses wasted must be recorded on the daily vaccination session record (See MP11 SOP 11). This will enable reconciliation should it be needed if a discrepancy occurs and investigation need to be completed.

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 Foundry Stock Site Manager App.

3.4 A stock take must also be completed and submitted on Foundry 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 Foundry

3.6.1 Log on to Foundry 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 Foundry 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

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

4.0 Equipment Required

Foundry

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 v3.0	**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 Foundry 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 Foundry recording processes.
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) 04/2024 Trust Policy Group June 2024			
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)04/2024 Trust Management Committee – June 2024			
Date of Procedure/Guidelines issue	July 2024			
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	June 2027			

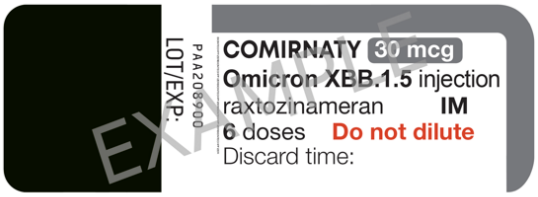
Training and Dissemination: All Vaccinators and Pharmacy Staff participating in the COVID-19 vaccine delivery programme are required to read this procedure.	
To be read in conjunction with: COVID-19 Vaccine handling and management policy and associated procedures Trust Policy MP10 Cold Chain Policy	
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 Procedure 5 Standard Operating Procedure for Preparation of Comirnaty 30 (XBB1.5) 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 Omicron XBB.1.5 30 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) raxtozinameran **(Comirnaty 30 (XBB.1.5))** 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 30 (XBB.1.5)** 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 10 – Preparation of Comirnaty 30 (XBB1.5) 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/department 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 Clean workstation with disinfectant wipes and discard into a clinical waste bin.

3.1.5 Following RWT or WHT Infection Prevention Policies respectively, wash hands thoroughly.

3.2 When ready to begin preparation select one vial of **Comirnaty 30 (XBB.1.5)** vaccine.

3.2.1 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.

N.B It is permissible to remove multiple vials from the refrigerator if local systems are in place to ensure segregation of punctured and unpunctured vials.

3.2.2 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.

3.2.3 Check the identity of the vial. This procedure is intended for use with the Comirnaty **Comirnaty 30 (XBB.1.5)** vaccine.

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

3.2.4 Assemble the following materials required to prepare syringes:

- Comirnaty **Comirnaty 30 (XBB.1.5)** vial X 1,
- 1mL syringe with integrated 23g (or finer) x 25mm needle x 6, and
- sterile single use 70% alcohol swab x 6.
- Comirnaty 30 (XBB.1.5) workstation log

3.2.5 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.

3.2.6 Remove the grey vial dust cover

3.3 Prepare the syringes

3.3.1 Check the label again, to ensure the label on the vial selected matches the image below:

3.3.2 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.

3.3.3 Complete the vaccine and practitioner information on the workstation log ready for use.

3.3.4 Confirm the **0.3mL** booster or primary course dose of **Comirnaty 30 (XBB.1.5)** is required by the patient

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

3.3.6 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.

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

3.3.8 Check volume withdrawn is **0.3mL**.

- Registered practitioners who have completed the Trust required training on oral drug administration and non-IV administration competency may administer without a second check
- All non-registered practitioners, and those registered practitioners without the required training must request a second check of volume. The person completed the second check must be familiar with this SOP and have been signed off as competent to complete the second check.

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

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

3.3.11 The vaccinator and person carrying out the second check (If applicable) must sign the workstation log.

3.3.12 After first dose withdrawal, use the vial as soon as practically possible and within 12 hours (stored at 2^0C to 30^0C).

3.3.13 Document the expiry date and time (24-hour format, e.g. 14:00) on the vial after first use.

N.B. from a microbiological point of view, the method of puncture does not preclude the risk of microbial contamination, so the vaccine should be used as soon as practically possible e.g. within one work session which would not normally be more than 6 hours.

3.3.14 Steps 3.3.1 to 3.3.11 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.

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.

3.3.16 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 punctured vaccine vial is physiochemically stable for 12 hours. However, from a microbiological point of view, the method of puncture does not preclude the risk of microbial contamination, so the vaccine should be used as soon as practically possible and within 6 hours.

3.3.17 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).**

3.3.18 Empty outer cartons must be disposed of in a secure manner which prevents theft. Score through the label text with a permanent marker and dispose in confidential waste.

3.4 Dealing with deviations from this procedure

3.4.1 Any deviations from this procedure must immediately be reported to the clinical lead on shift.

3.4.2 Where vaccine is discarded, this must be recorded on the workstation log

4.0 Equipment Required

Comirnaty **Comirnaty 30 (XBB.1.5)** Vaccine

Yellow lidded sharps bins

Indelible pen

Workstation logs

Appropriate personal protective equipment

Disinfectant wipes

Clinical waste bins

Plastic trays for assembly and preparation

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

Single use 70% alcohol swabs

Attachment 1 Comirnaty 30 (XBB.1.5) 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 5 V1.2	**Title of Procedure/Guidelines** Standard Operating Procedure for Preparation of **Comirnaty 30 (XBB.1.5)** Vaccine		**Status:** **FINAL**	**Author: Clinical Lead – Living Well Group** **Director Sponsor: Chief Medical Officer**
Version / Amendment History	Version	Date	Author	Reason
	1	28/09/2023	Clinical Lead – Living Well Group	New SOP
	1.2	23/03/2024	Deputy Clinical Director of Pharmacy	Re-numbering to SOP 5 in line with streamlined policy and minor amendment removing requirement of second check for registered staff with appropriate training.
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) 04/2024 Trust Policy Group – June 2024			
Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)	Trust MMG 06/2024 Trust Management Committee – June 2024			
Date of Procedure/Guidelines issue	July 2024			
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 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 Comirnaty 30 (**XBB1.5)** Vaccine	
Key words for intranet searching purposes	COVID-19 Vaccine Vaccination Comirnaty 30 (XBB.1.5)

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) 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		

Pfizer Comirnaty® 30 (XBB1.5) COVID-19 Vaccine GREY CAP

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® 30 (XBB1.5) 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):	

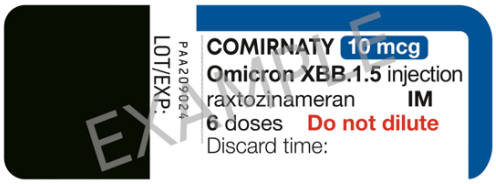
	0.3mL Doses drawn up & checked (first check by person drawing up and second check signed by person overseeing - if applicable)							
Dose	1	2	3	4	5	6	Issues identified (enter appropriate letter above)	Comments
Time:								
Patient's name:								
Delete as appropriate	Primary dose Booster	Primary dose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

COVID-19 Vaccine Procedure 6 Standard Operating Procedure for Preparation of Comirnaty 10 (XBB1.5) 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 Omicron XBB.1.5 10 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) raxtozinameran **(Comirnaty 10 (XBB.1.5) ready to use)** 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 10 (XBB.1.5)** 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 11 – Preparation of Comirnaty 10 (XBB1.5) Ready To Use Vaccine*

2.0 Accountabilities

2.1 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.

2.2 The Clinical Lead for the vaccination service/department 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.

2.3 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.

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

3.1.5 Following RWT infection Prevention Policies respectively, wash hands thoroughly.

3.2 When ready to begin preparation select one vial of **Comirnaty 10 (XBB.1.5)** vaccine.

3.2.1 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.

N.B It is permissible to remove multiple vials from the refrigerator if local systems are in place to ensure segregation of punctured and unpunctured vials.

3.2.2 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.

3.2.3 Check the identity of the vial. This procedure is intended for use with the Comirnaty **Comirnaty 10 (XBB.1.5)** vaccine.

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

3.2.4 Assemble the following materials required to prepare syringes:

- Comirnaty **Comirnaty 10 (XBB.1.5)** vial X 1,
- 1mL syringe with integrated 23g (or finer) x 25mm needle x 6, and
- sterile single use 70% alcohol swab x 6.
- Comirnaty 10 (XBB.1.5) Workstation log

3.2.5 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.

3.2.6 Remove the blue vial dust cover

3.3 Prepare the syringes

3.3.1 Check the label again, to ensure the label on the vial selected matches the image below:

3.3.2 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.

3.3.3 Complete the vaccine and practitioner information on the workstation log ready for use.

3.3.4 Confirm the **0.3mL** booster or primary course dose of Comirnaty **Comirnaty 10 (XBB.1.5)** is required by the patient

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

3.3.6 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.

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

3.3.8 Check volume withdrawn is **0.3mL**.

- Registered practitioners who have completed the Trust required training on oral drug administration and non-IV administration competency may administer without a second check
- All non-registered practitioners, and those registered practitioners without the required training must request a second check of volume. The person completed the second check must be familiar with this SOP and have been signed off as competent to complete the second check.

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

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

3.3.11 The vaccinator and person carrying out the second check (If applicable) must sign the workstation log.

3.3.12 After first dose withdrawal, use the vial as soon as practically possible and within 12 hours (stored at 2^0C to 30^0C).

3.3.13 Document the expiry date and time (24-hour format, e.g. 14:00) on the vial after first use.

N.B. from a microbiological point of view, the method of puncture does not preclude the risk of microbial contamination, so the vaccine should be used as soon as practically possible e.g. within one work session which would not normally be more than 6 hours.

3.3.14 Steps 3.3.1 to 3.3.11 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.

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.

3.3.16 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 punctured vaccine vial is physiochemically stable for 12 hours. However, from a microbiological point of view, the method of puncture does not preclude the risk of microbial contamination, so the vaccine should be used as soon as practically possible and within 6 hours.

3.3.17 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).**

3.3.18 Empty outer cartons must be disposed of in a secure manner which prevents theft. Score through the label text with a permanent marker and dispose in confidential waste.

3.4 Dealing with deviations from this procedure

3.4.1 Any deviations from this procedure must immediately be reported to the clinical lead on shift.

3.4.2 Where vaccine is discarded, this must be recorded on the workstation log.

4.0 Equipment Required

Comirnaty **Comirnaty 10 (XBB.1.5)** Vaccine

Yellow lidded sharps bins

Indelible pen

Workstation logs

Appropriate personal protective equipment

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 10 (XBB.1.5) 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 6 v1.2	**Title of Procedure/Guidelines** Standard Operating Procedure for Preparation of **Comirnaty 10 (XBB.1.5)** Vaccine		**Status:** **FINAL**	**Author: Clinical Lead – Living Well Group** **Director Sponsor: Chief Medical Officer**
Version / Amendment History	Version	Date	Author	Reason
	1	28/09/2023	Clinical Lead – Living Well Group	New SOP
	1.2	23/03/2024	Deputy Clinical Director of Pharmacy	Re-numbering to SOP 6 in line with streamlined policy and minor amendment removing requirement of second check for registered staff with appropriate training.
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) 04/2024 Trust Policy Group – June 2024
Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)	Trust MMG 06/2024 Trust Management Committee – June 2024
Date of Procedure/Guidelines issue	July 2024
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 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 Comirnaty 10 (**XBB1.5)** Vaccine	
Key words for intranet searching purposes	COVID-19 Vaccine Vaccination Comirnaty 10 (XBB1.5)

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) 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		

Worksheet: Pfizer Comirnaty® 10 (XBB1.5) Ready To Use COVID-19 Vaccine 5-11 Year Old BLUE CAP

Date		Service Location	

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® 10 (XBB1.5) 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:								
Signature of vaccinator:								
Signature of second checker:								

COVID-19 Vaccine Procedure 7 Standard Operating Procedure for Preparation of 0.2mL Syringes Using Comirnaty 3 (THREE) (XBB.1.5)Concentrate for Children 6 Months to 4 Years

1.0 Procedure Statement

This SOP describes the process for preparation of ready to administer **0.2mL** syringes of **Comirnaty XBB.1.5 3mcg Dose for 6 Months to 4 years COVID-19 mRNA Vaccine 3micrograms/0.2ml dose concentrate for dispersion for injection (Comirnaty 3 (THREE) (XBB.1.5) concentrate).**

Different strengths / formulations of Comirnaty vaccine are available. Ensure the correct procedure is selected for the strength / formulation required. This SOP is for use with Comirnaty 3 (THREE) (XBB.1.5) 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 9 – Preparation of 0.2mL syringes using Comirnaty 3 (THREE) (XBB.1.5) Concentrate*

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

NB 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 3 (THREE) (XBB.1.5) concentrate** presentation. Check label format on the vial selected matches the picture below:

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

3.1.5 Unless diluting immediately, 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 the 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 3 (THREE) (XBB.1.5) Concentrate

Concentrate Room Temperature 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 Take the vial/box to the vaccine preparation station.

3.2 Workstation preparation

3.1.4 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 the RWT Infection Prevention Policies respectively, 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

3.3.1 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 to refer to if required.

3.3.2 **When working under a PGD the entire process must be completed by a single person named on the PGD Records**

3.3.3 Assemble the following materials required to perform dilution:

- sodium chloride 0.9% ampoule 5mL X 1,
- 3mL Syringe X 1,
- 21g or finer needle X 1,
- sterile single use 70% alcohol swab x2, and
- Comirnaty 3 (THREE) (XBB.1.5) concentrate workstation log

3.3.4 When ready to begin the dilution process, bring a single vial of **Comirnaty 3 (THREE) (XBB.1.5) 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.**

3.3.5 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.

3.3.6 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.

3.3.7 Check the identity of the vial. This procedure is intended for use with **Comirnaty 3 (THREE) (XBB.1.5) concentrate** presentation.

- Check the vial has a maroon cap.
- Check label format on the vial selected matches the picture below:

3.3.8 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 maroon 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 Draw up **2.**2mL of sodium chloride 0.9% solution for injection:

- 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.
- Using aseptic technique, snap the top off the ampoule and use the 3mL syringe and a 21g or finer needle to draw up **2.2 mL** of sodium chloride 0.9% solution for injection.
- Self-check the volume of sodium chloride 0.9% drawn up is **2.2 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.
- Dispose of the remainder of the 5mL sodium chloride 0.9% ampoule into a yellow lidded sharps bin.

3.4.4 Dilute the concentrate vaccine vial by adding **2.2 mL** of 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 2.2mL 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 2.2 mL may therefore not be added to the vial.

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

3.4.6 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.

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

3.4.8 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.

3.5 Withdrawal into syringes

3.5.1 Assemble the following materials into a plastic tray:

- diluted **Comirnaty 3 (THREE) (XBB.1.5) 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 3 (THREE) (XBB.1.5) concentrate** presentation.

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

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.**

- Registered practitioners who have completed the Trust required training on oral drug administration and non-IV administration competency may administer without a second check
- All non-registered practitioners, and those registered practitioners without the required training must request a second check of volume. The person completed the second check must be familiar with this SOP and have been signed off as competent to complete the second check.

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 The vaccinator and person carrying out the second check (If applicable) must sign the workstation log.

3.5.12 Steps 3.5.3 to 3.5.11 may be repeated a further nine times to produce a total of ten 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.

3.5.13 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.

3.5.14 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.

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 (up to 6 hours transportation time post dilution).
- The punctured vaccine vial is physiochemically stable for 12 hours. However, from a microbiological point of view, the method of puncture does not preclude the risk of microbial contamination, so the vaccine should be used as soon as practically possible and within 6 hours.

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 Where vaccine is discarded, this must be recorded on the workstation log

4.0 Equipment Required

Comirnaty 3 (THREE) (XBB.1.5) 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)

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 3 (THREE) (XBB.1.5) Workstation Log

Document Control

COVID-19 Vaccine Procedure 7 v1.2	**Title of Procedure/Guidelines** Standard Operating Procedure for Preparation of Comirnaty 3 (THREE) (XBB.1.5) Concentrate		**Status:** **FINAL**	**Author: Clinical Director of Pharmacy** **Director Sponsor: Chief Medical Officer**
Version / Amendment History	Version	Date	Author	Reason
	1	20/09/2022	Deputy Clinical Director of Pharmacy	New SOP
	1.2	23/03/2024	Deputy Clinical Director of Pharmacy	Re-numbering to SOP 7 in line with streamlined policy and minor amendment removing requirement of second check for registered staff with appropriate training.
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) 04/2024 Trust Policy Group – June 2024
Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)	Trust Management Committee – June 2024
Date of Procedure/Guidelines issue	July 2024
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 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 3 Concentrate Vaccine.	
Key words for intranet searching purposes	COVID-19 Vaccine Vaccination Comirnaty 3

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) 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		

Worksheet Workstation Log - Covid-19 Vaccine Comirnaty 3(THREE) (XBB.1.5) (Maroon Cap) concentrate for Children 6 Months – 4 years

Date	/ /	Workstation identifier/Site Name		Issues identified codes

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

A Vial Dropped - do not use
B Syringe dropped - do not use
C Vial discoloured or contained particles
D Syringe contained particles
E Vial not diluted before expiry
F Other (give detail)

Operator preparing vaccine doses

Name (Print)	Signature

Second check carried out by

Name (Print)	Signature

Removal from fridge - (expiry 12hrs at 8-30°C until diluted)

Date	Expiry Time (24hr clock)	Fridge Temperature	Completed by	checked by	
/ /	:	°C		Comirnaty 3 (THREE) (XBB.1.5) Maroon lid	

Vials received at workstation

Vaccine	Vaccine Batch number	Vaccine Reconstituted Expiry (24hr clock) NB 12hr expiry post dilution	Volume Sodium Chloride 0.9% drawn up (2.2 ml) and added to vial by:	Volume & Addition checked by:
Covid 19 Vaccine Comirnaty® 3 (THREE) (XBB.1.5) (Maroon cap)		date: / /		
		Time: :		
diluent	Diluent Batch Number	Diluent Expiry Date		
Sodium Chloride 0.9% injection		/		
Room Temperature when diluted	°C			

Name of vaccinator:	Name of second checker:

Vaccination room temp:	°C

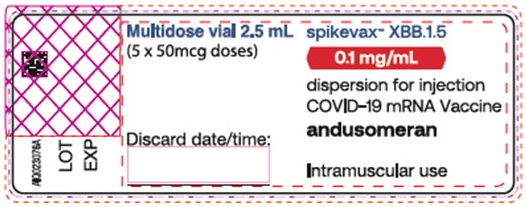
	0.2ml Doses drawn up & checked (first check by person drawing up and second check signed by person overseeing)										Issues identified (enter appropriate letter above)
Dose	1	2	3	4	5	6	7	8	9	10	
Time:											
Patient's name:											
Signature of vaccinator											
Signature of person second checking											

COVID-19 Vaccine Procedure 8 Standard Operating Procedure for Preparation of Spikevax (XBB1.5) 0.5mL Syringes for Administration

1.0 Procedure Statement

This SOP describes the process for preparation of **ready to administer** 0.5mL syringes of Spikevax XBB.1.5 (0.1mg/mL) dispersion for injection COVID-19 mRNA Vaccine andusomeran **(Spikevax (XBB.1.5))** prior to immediate administration.

Ensure the correct procedure is selected for the strength or formulation required. This SOP is for use with **Spikevax (XBB.1.5)** 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 13 – Preparation of Spikevax (XBB1.5) 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/department 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 Clean workstation with disinfectant wipes and discard into a clinical waste bin.

3.1.5 Following RWT Infection Prevention Policies respectively, wash hands thoroughly.

3.2 When ready to begin preparation select one vial of **Spikevax (XBB.1.5)** vaccine.

3.2.1 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.

N.B It is permissible to remove multiple vials from the refrigerator if local systems are in place to ensure segregation of punctured and unpunctured vials.

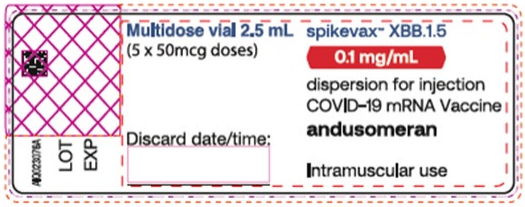
3.2.2 If working with vials from a cool box at 2-8^{O}C:

- 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.

3.2.3 Check the identity of the vial. This procedure is intended for use with the S**pikevax (XBB.1.5)** vaccine.

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



3.2.4 Assemble the following materials required to prepare syringes:

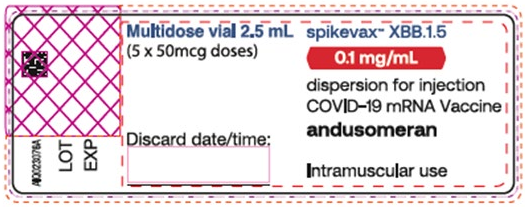
- **Spikevax (XBB.1.5)** vial X 1,
- 1mL syringe with integrated 23g (or finer) x 25mm needle x 5, and
- sterile single use 70% alcohol swab x 5.
- Spikevax (XBB.1.5) workstation log

3.2.5 Swirl the vial by gently rotating in a circular motion several times, DO NOT shake it.

3.2.6 Remove the dust cover

3.3 Prepare the syringes

3.3.1 Check the label again, to ensure the label on the vial selected matches the image below:



3.3.2 Gently swirl, then 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 (XBB.1.5)** is a white to off-white dispersion. It may contain white or translucent product related particulates.

3.3.3 Complete the vaccine and practitioner information on the workstation log ready for use.

3.3.4 Confirm the **0.5mL** dose of **Spikevax (XBB.1.5)** is required by the patient

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

3.3.6 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.

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

3.3.8 Check volume withdrawn is **0.5mL**.

- Registered practitioners who have completed the Trust required training on oral drug administration and non-IV administration competency may administer without a second check
- All non-registered practitioners, and those registered practitioners without the required training must request a second check of volume. The person completed the second check must be familiar with this SOP and have been signed off as competent to complete the second check.

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

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

3.3.11 The vaccinator and person carrying out the second check (If applicable) must sign the workstation log.

3.3.12 After first dose withdrawal, use the vial as soon as practically possible and within 6 hours (stored at 2^0C to 25^0C).

3.3.13 Document the expiry date and time (24-hour format, e.g. 14:00) on the vial after first use.
N.B. from a microbiological point of view, the method of puncture does not preclude the risk of microbial contamination, so the vaccine should be used as soon as practically possible.

3.3.14 Steps 3.3.1 to 3.3.11 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.

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.

3.3.16 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 25°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 punctured vaccine vial is physiochemically stable for 6 hours at temperatures between 2 and 25°C. However, from a microbiological point of view, the method of puncture does not preclude the risk of microbial contamination, so the vaccine should be used as soon as practically possible.
- **Unopened vaccine MUST be transported at a temperature between 2 and 8°C**

3.3.17 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).**

3.3.18 Empty outer cartons must be disposed of in a secure manner which prevents theft. Score through the label text with a permanent marker and dispose in confidential waste.

3.4 **Dealing with deviations from this procedure**

3.4.1 Any deviations from this procedure must immediately be reported to the clinical lead on shift.

3.4.2 Where vaccine is discarded, this must be recorded on the workstation log.

4.0 Equipment Required

Spikevax (XBB.1.5) Vaccine

Yellow lidded sharps bins

Indelible pen

Workstation logs

Appropriate personal protective equipment

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 **Spikevax (XBB.1.5) Workstation Log**

References:

Spikevax (XBB.1.5) 0.1 mg/mL dispersion for injection

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 8 v1.1	**Title of Procedure/Guidelines** Standard Operating Procedure for Preparation of **Spikevax (XBB.1.5)** 0.5mL Syringes for Administration		**Status:** **FINAL**	**Author: Clinical Lead – Living Well Group** **Director Sponsor: Chief Medical Officer**
Version / Amendment History	Version	Date	Author	Reason
	1	12/10/2023	Clinical Lead – Living Well Group	New SOP
	1.1	23/03/2024	Deputy Clinical Director of Pharmacy	Re-numbering to SOP 8 in line with streamlined policy and minor amendment removing requirement of second check for registered staff with appropriate training.
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) 04/2024 Trust Policy Group – June 2024
Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)	Trust Management Committee – June 2024
Date of Procedure/Guidelines issue	July 2024
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 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 Spikevax (**XBB1.5)** Vaccine	
Key words for intranet searching purposes	COVID-19 Vaccine Vaccination Spikevax (XBB1.5)

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) 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		

Spikevax (XBB.1.5) 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
Spikevax (XBB.1.5) COVID-19 Vaccine 0.5mL dose								

Name of vaccinator :		Name of second checker:	
Vaccination room temp: MAX 25C		Vial Expiry Date/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 - if applicable)						
Dose	1	2	3	4	5	Issues identified (enter appropriate letter above)	Comments
Time:							
Patient's name:							
Signature of vaccinator:							
Signature of second checker:							

COVID-19 Vaccine Procedure 9 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/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 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 9 v2.1	**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
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) 04/2024 Trust Policy Group – June 2024
Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)	Medicines Management Group (MMG) 04/2024 Trust Management Committee – June 2024
Date of Procedure/Guidelines issue	July 2024
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
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) 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 10
Identifying patients who have been in hospital over 21 days and offering them the current seasonal vaccines

1.0 Procedure Statement

This procedure provides the steps to take to identify patients who have been in hospital for more than 21 days who, if eligible, must be offered the opportunity to receive seasonal vaccines.

2.0 Accountabilities

Directorate manager is responsible for the implementation of this procedure and that staff follow the process

Seasonal Program Staff are responsible for ensuring that the procedure is followed and that all necessary checks are made to reduce the risk of double vaccination of identified patients.

3.0 Procedure/Guidelines Detail / Actions

3.1 Identifying eligible patients

There is a report provided by the Trust information services. To access the report, head to the Information Portal at http://rs2008/ReportServer_RS2008SERVER/Pages/ReportViewer.aspx?%2fInformation%2fInformationPortal%2fMainMenu

Then click on 'Performance Management' under the heading of 'Select Report Category', then click on 'Stranded Patients' once the Performance Management window opens.

Within this report, the first tab is called 'Stranded Patients Summary', and gives details of the numbers of stranded patients per ward. You'll need to go to the second tab, 'Stranded Patients Detail', then filter column I, 'Stranded Category' to 21+ Days.

3.2 Process:

3.2.1 Each Monday, identify the patients using the above process in 3.1. Save a copy of the spreadsheet in a local folder recording the date of the report. Using this saved report identify patients on your ward and review each patient to see if they meet the criteria to be offered the Covid-19 and/or influenza seasonal vaccinations.

3.2.2 Plan time to visit each eligible patient

3.2.3 Ensure you have the correct vaccines available in accordance with the Green Book. Order any vaccine required through pharmacy stores as needed.

3.2.4 Check that vaccination status, eligibility and consent is in place and follow the appropriate MP11 SOP for preparation and administration of Covid-19 vaccine

3.2.5 Patients who lack capacity to consent to receiving a vaccine must have a best interest discussion with nursing team, patient's consultant and if possible nearest relative/ next of kin. This should also be documented under a best interest discussion within the recording system

3.2.6 When vaccinating patients the vaccinations administered must be recorded on the National Immunisation and Vaccination System (NIVs) in accordance with training provided and must be recorded in the patients hospital administration record using EPMA (see appendix 1)

3.3 Claiming payment

Once the vaccination is entered into NIVS it will automatically trigger payment to the Trust.

4.0 Equipment Required

Computer to access NIVS, EPMA, and COVID-19 vaccine and Influenza vaccine and accompanying consumables.

5.0 Training

Vaccinators must be able to work under the national protocols. All must have completed or been assessed as competent for vaccination administration in accordance with MP11 Procedure 13 and have completed the e-lfh for core learning of both COVID-19 and influenza vaccinations and the vaccine specific training for the vaccines in use. Evidence of this must be held in the staff members training record, and where appropriate, they must have signed the national protocol.

6.0 Financial Risk Assessment (where assessed in the policy does not need to be repeated for the procedure)

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	

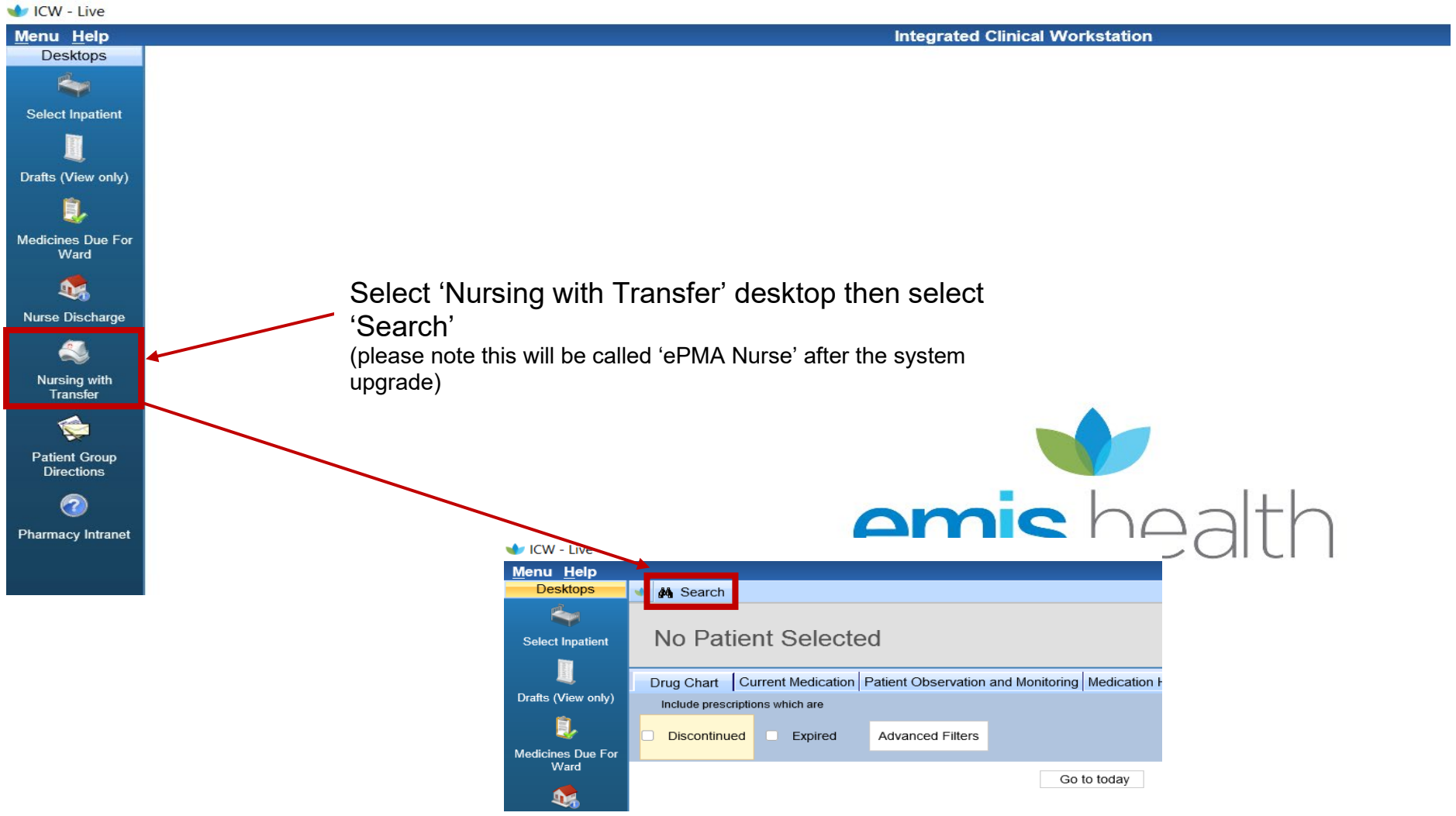
7.0 Document Control

COVID_19 Vaccine Policy Procedure 10 V1.0	**Title of Procedure** Identifying patients who have been in hospital over 21 days and offering them the covid-19 and influenza vaccine		**Status:** Final	**Author: Deputy Clinical Director of Pharmacy** **For Trust-wide Procedures and Guidelines Chief Officer Sponsor: Chief Medical Officer**
Version / Amendment History	Version	Date	Author	Reason
	1.0	23/03/2024	Deputy Clinical Director of Pharmacy	New SOP to support the vaccination of inpatients who are have stayed over 21 days

Intended Recipients: Doctors and clinical staff caring for inpatients who have stayed more than 21 days in hospital	
Consultation Group / Role Titles and Date: Div 2 & 3 senior nursing teams IP nurses, Chief Nursing Officer. EPMA Pharmacy Technician	
Name and date of group where reviewed	Trust Medicine Management Group (MMG) 04/2024 Trust Policy Group – June 2024
Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)	Trust MMG 06/2024 Trust Management Committee – June 2024
Date of Procedure/Guidelines issue	July 2024
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)	June 2027

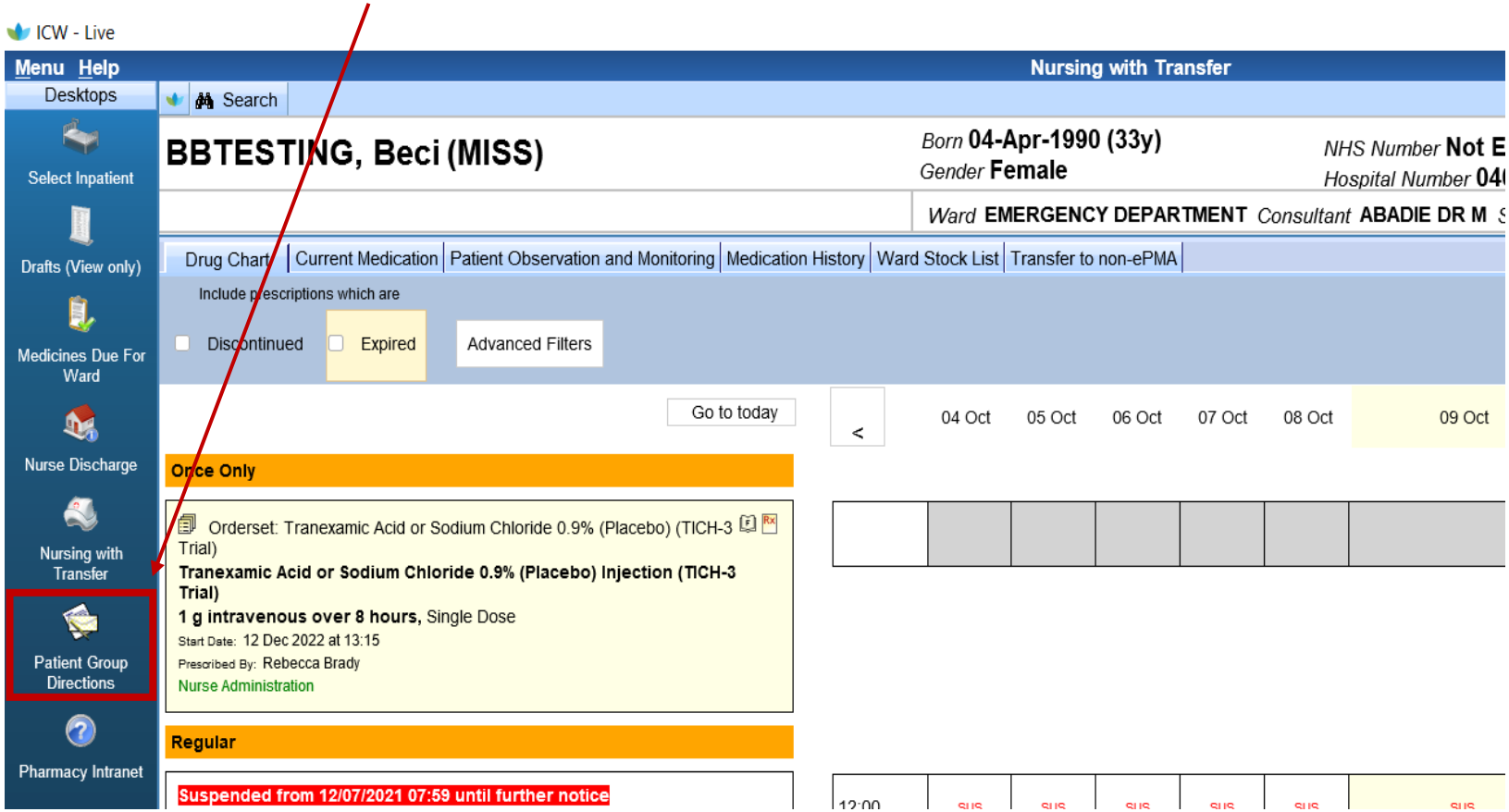
Training and Dissemination: This procedure will form part of the COVID-19 vaccine training programme which all new vaccinators are required to complete. All staff working in departments with long-stay inpatients will be required to read this procedure.	
To be read in conjunction with: MP 11 COVID-19 vaccine Policy	
Initial Equality Impact Assessment: Completed Yes **Full Equality Impact assessment (as required): No**	
Contact for Review	Deputy 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 identification and offer of seasonal vaccines to long-stay inpatients	
Key words for intranet searching purposes	COVID-19 Vaccine Vaccination Flu Influenza Inpatient

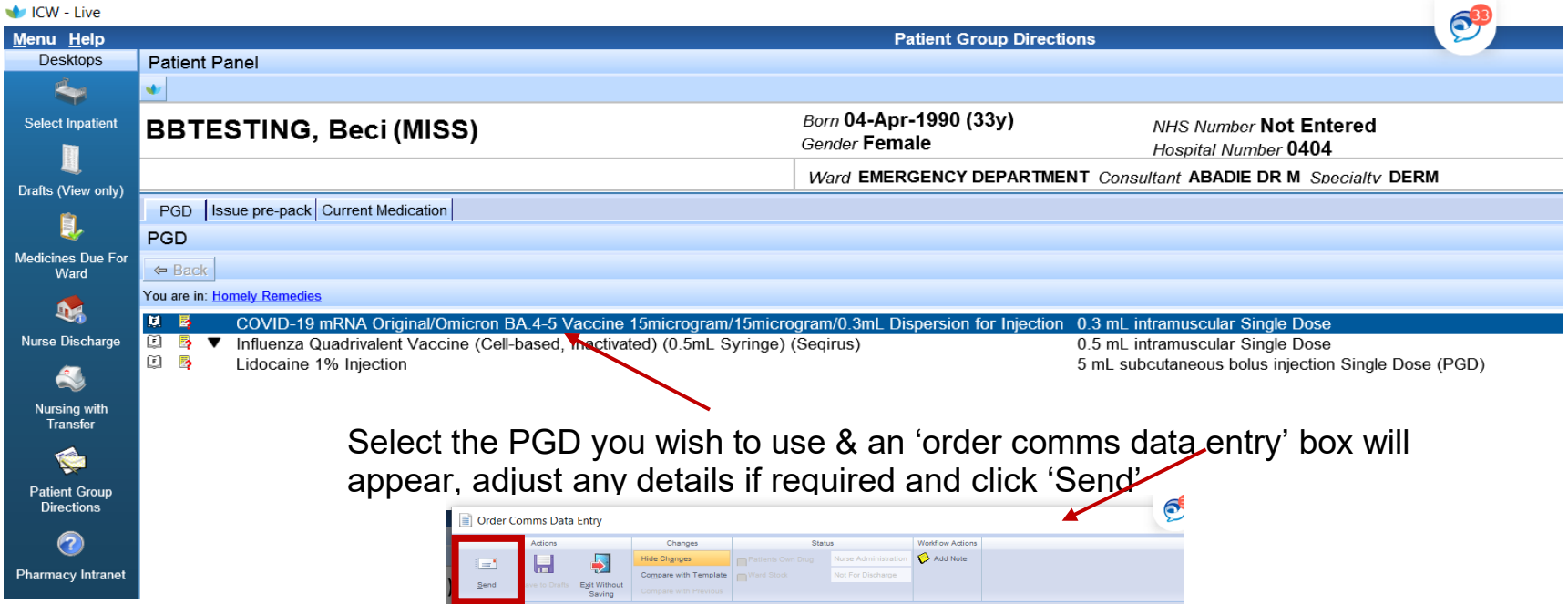
Appendix 1: Recording the vaccination in EPMA



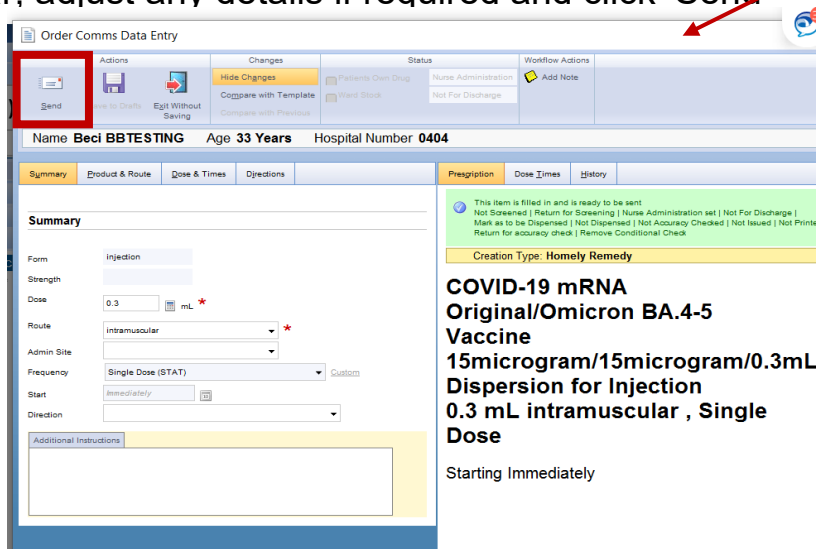
Search for the Patient using their NHS or Hospital number, and then select the appropriate inpatient episode and click ‘ok’

From there then select the ‘Patient Group Directions’ desktop

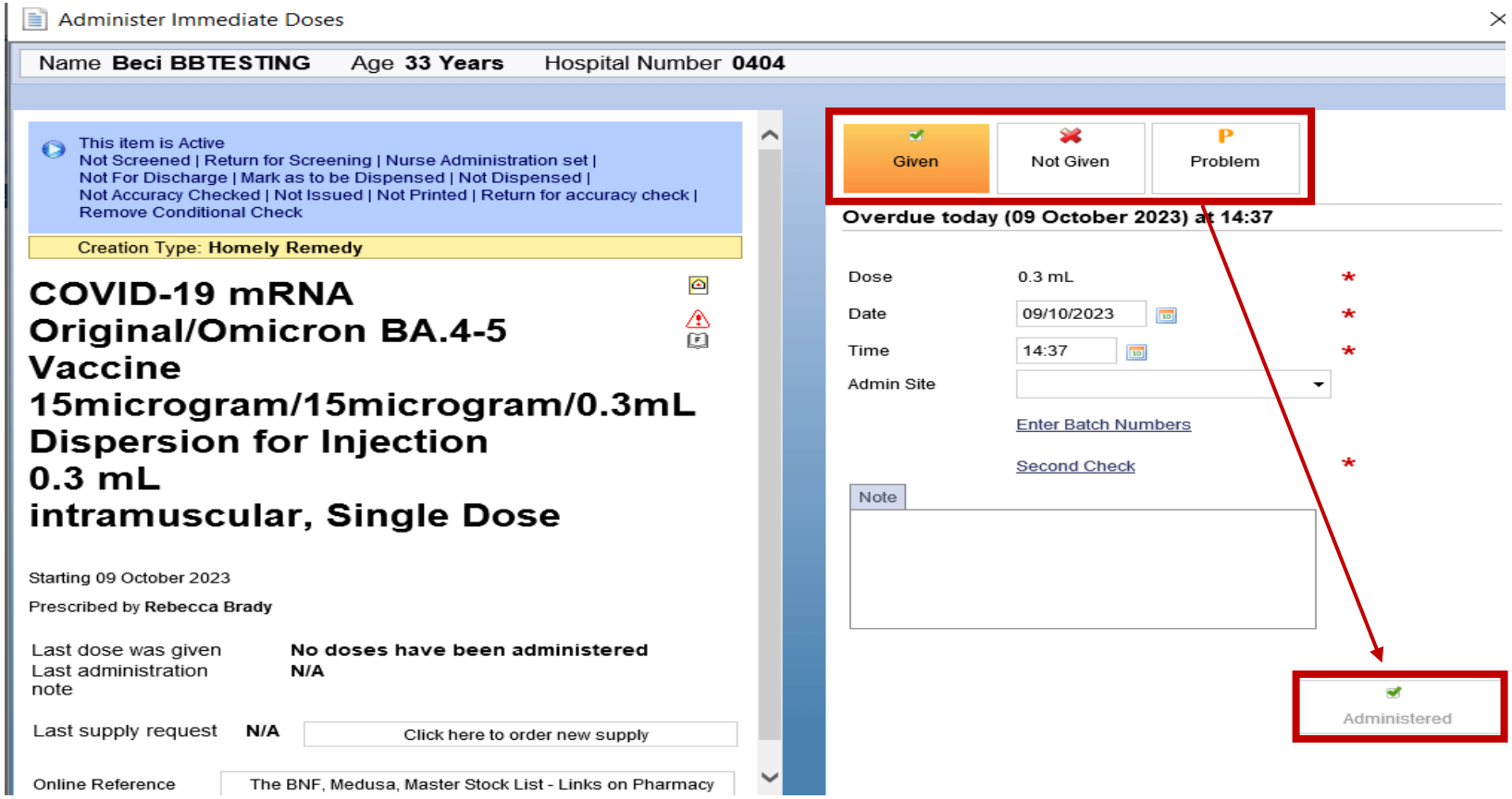




Select the PGD you wish to use & an 'order comms data entry' box will appear, adjust any details if required and click 'Send'



An administration box will appear, select the most appropriate action and then select ‘administer’.



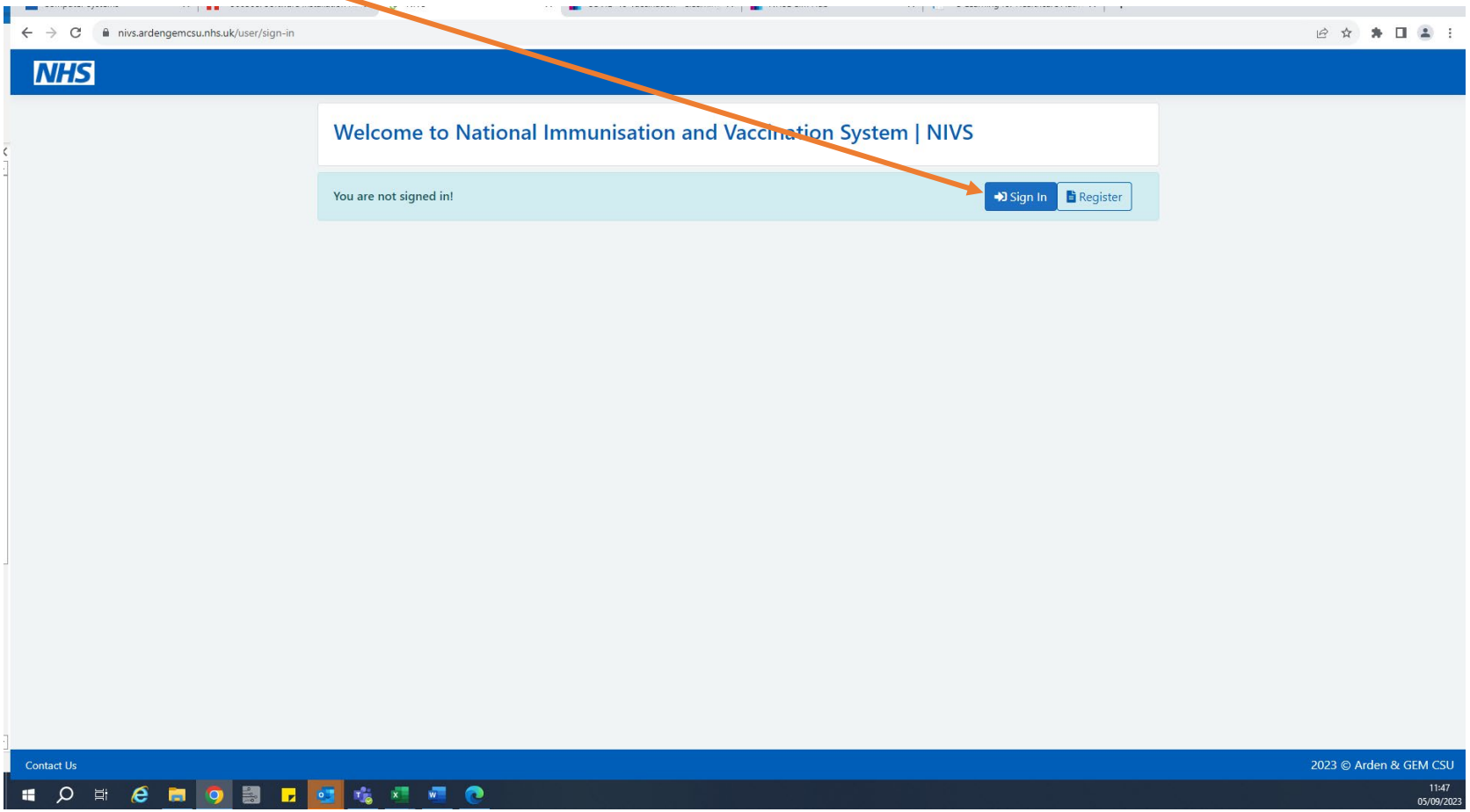
PLEASE NOTE: as this is an injection there may be a second check required before you can select the administer button

Appendix 2: NIV's How input Covid Vaccinations

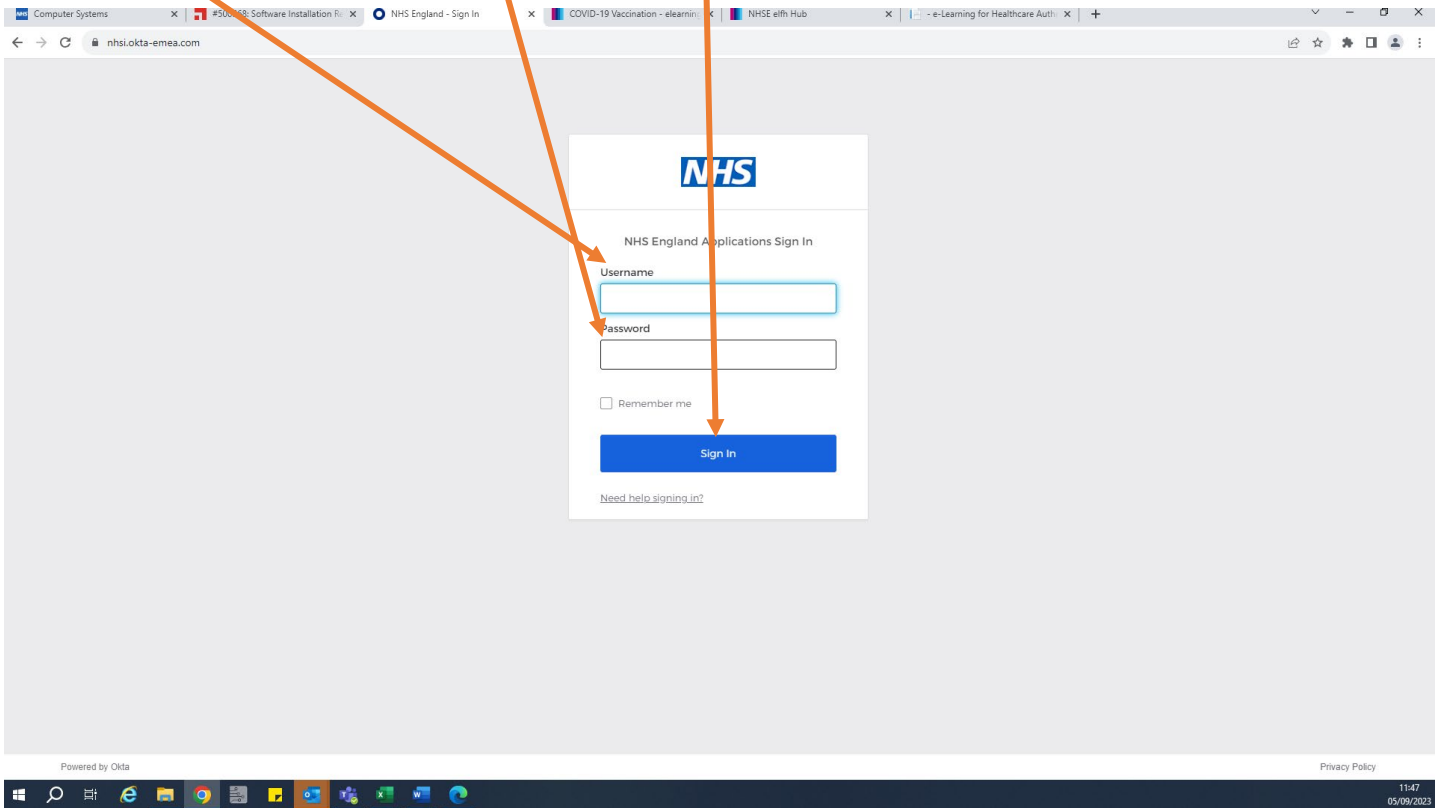
1. Use to link to open the Nivs sign in page:

https://nivs.ardengemcsu.nhs.uk/user/sign-in

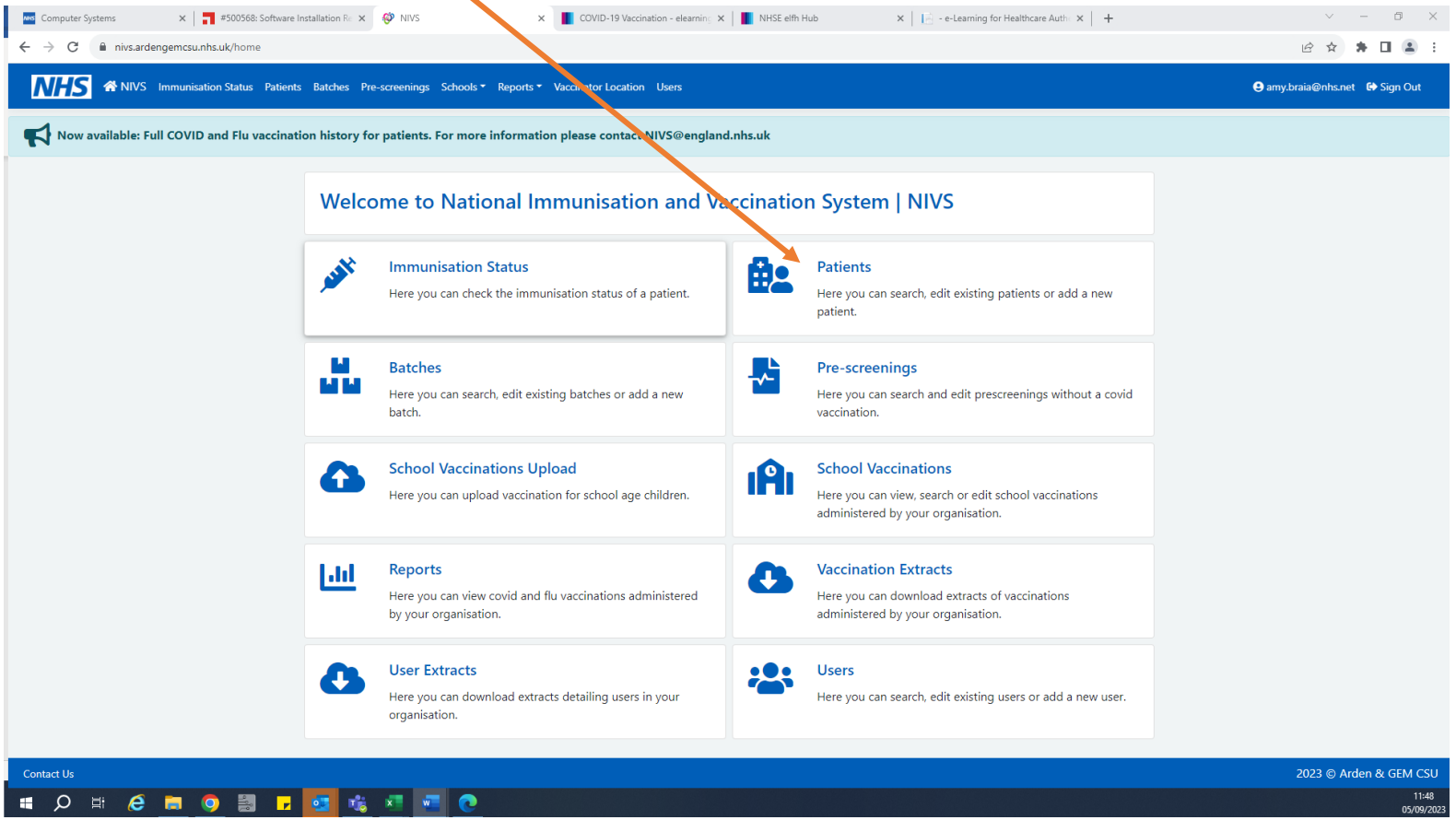
2. Select sign in



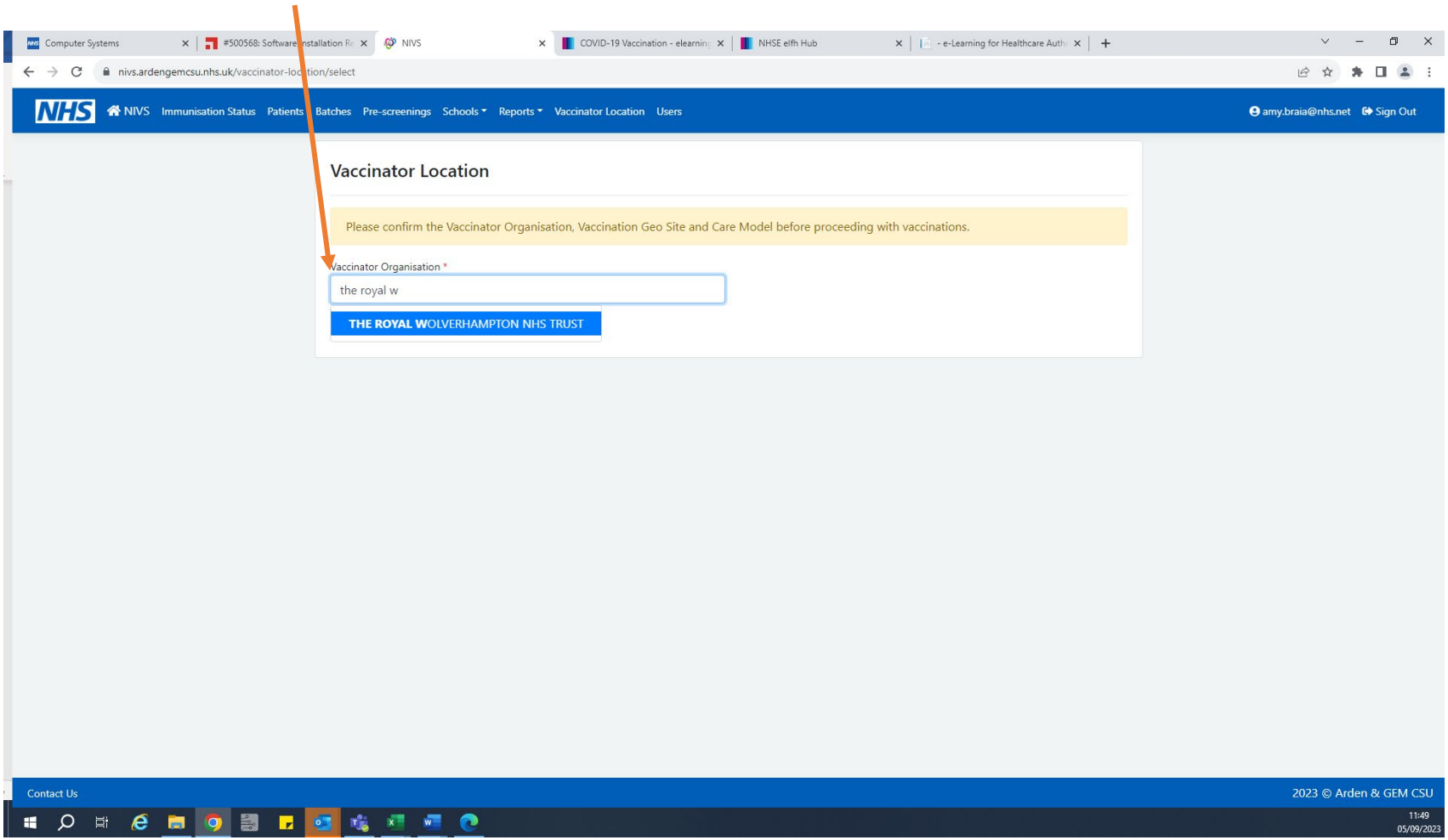
3. Enter username and password and select sign in



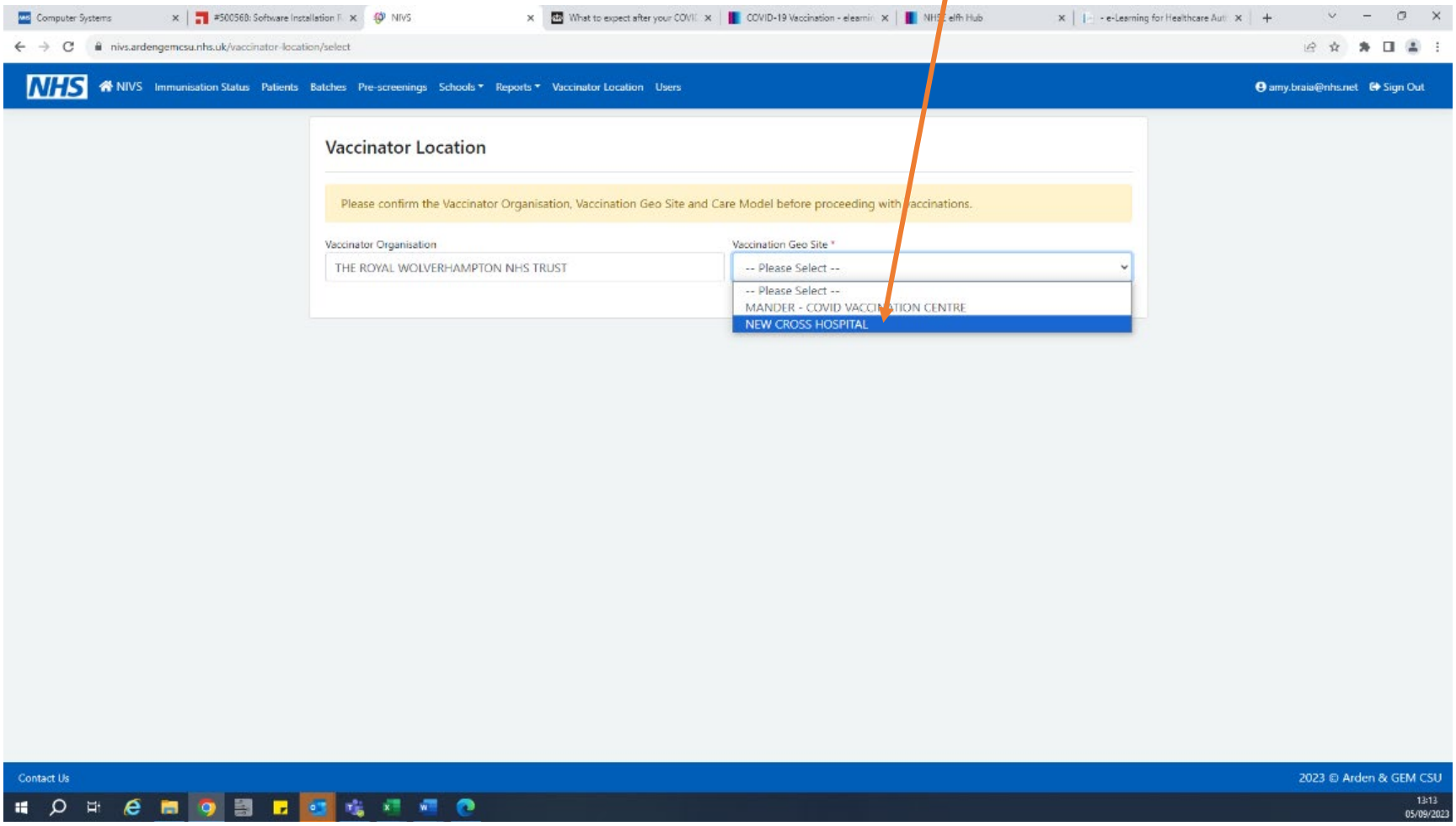
4. This screen will appear select patients.



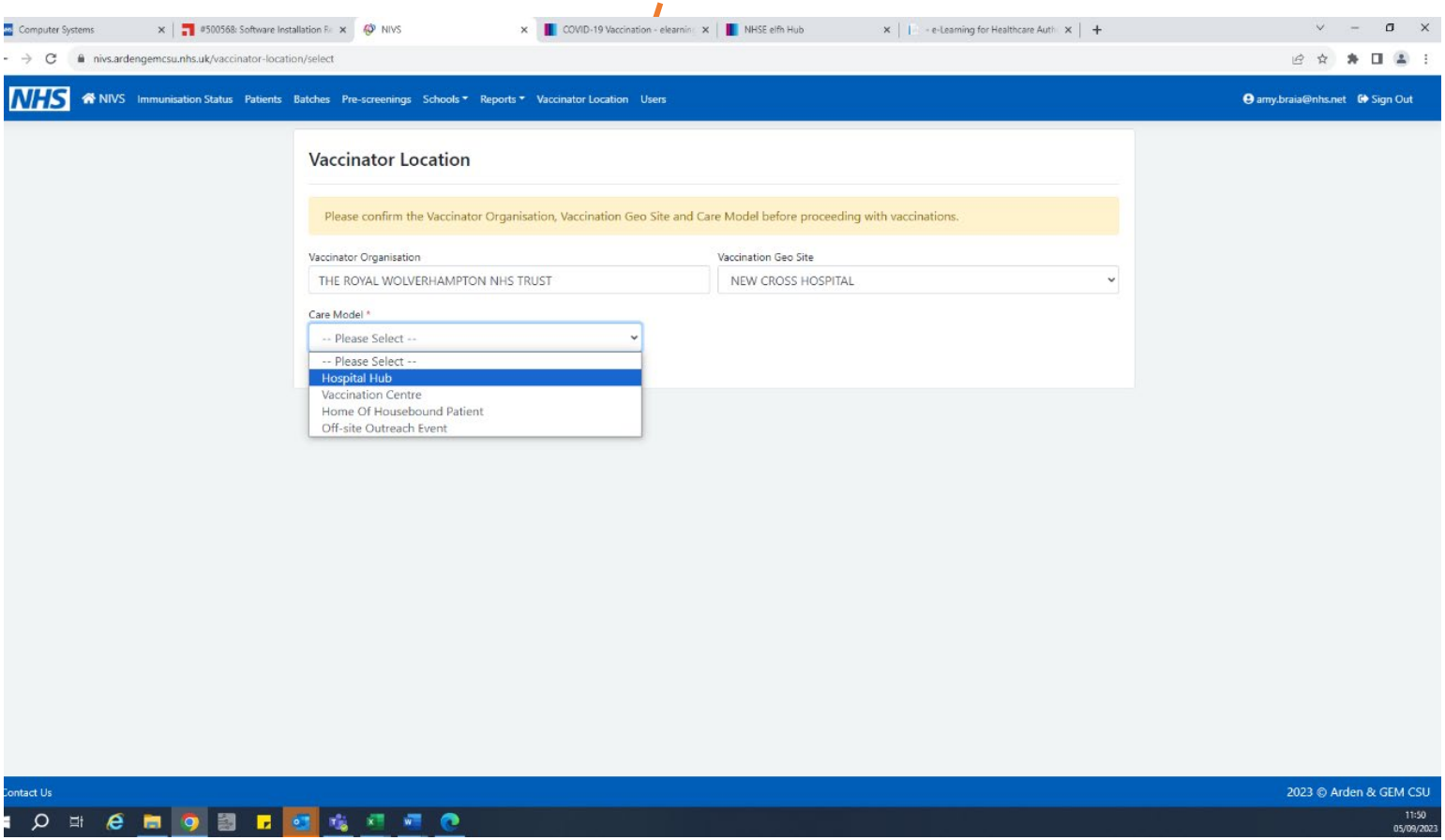
5. If you are logging in for the first time that day it will take you to the Vaccination Screen, please begin writing The Royal Wolverhampton and the drop down box will highlight in blue select the correct site. Click the blue box



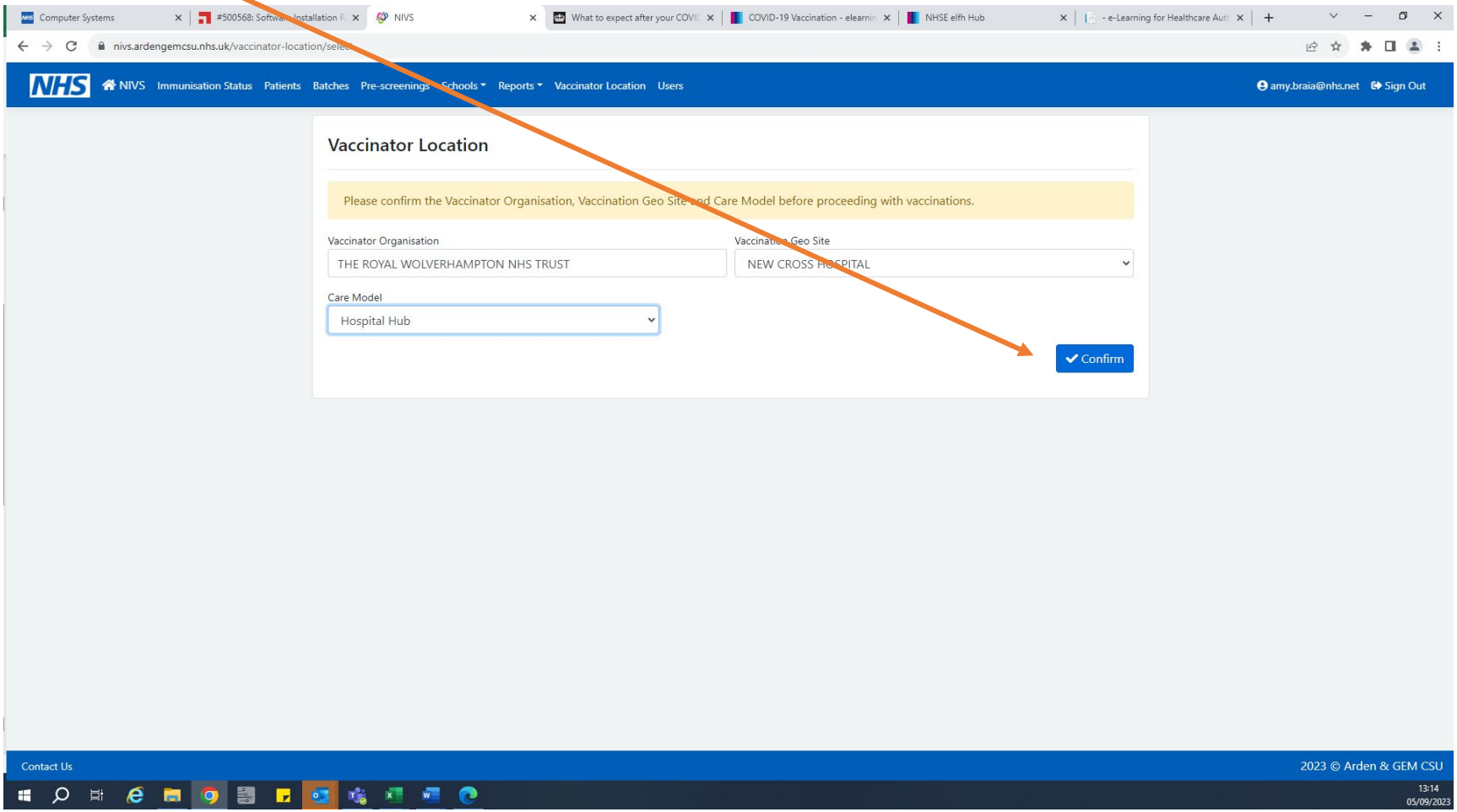
6. It will then ask for Vaccination Geo site, From the drop down box, select New Cross hospital



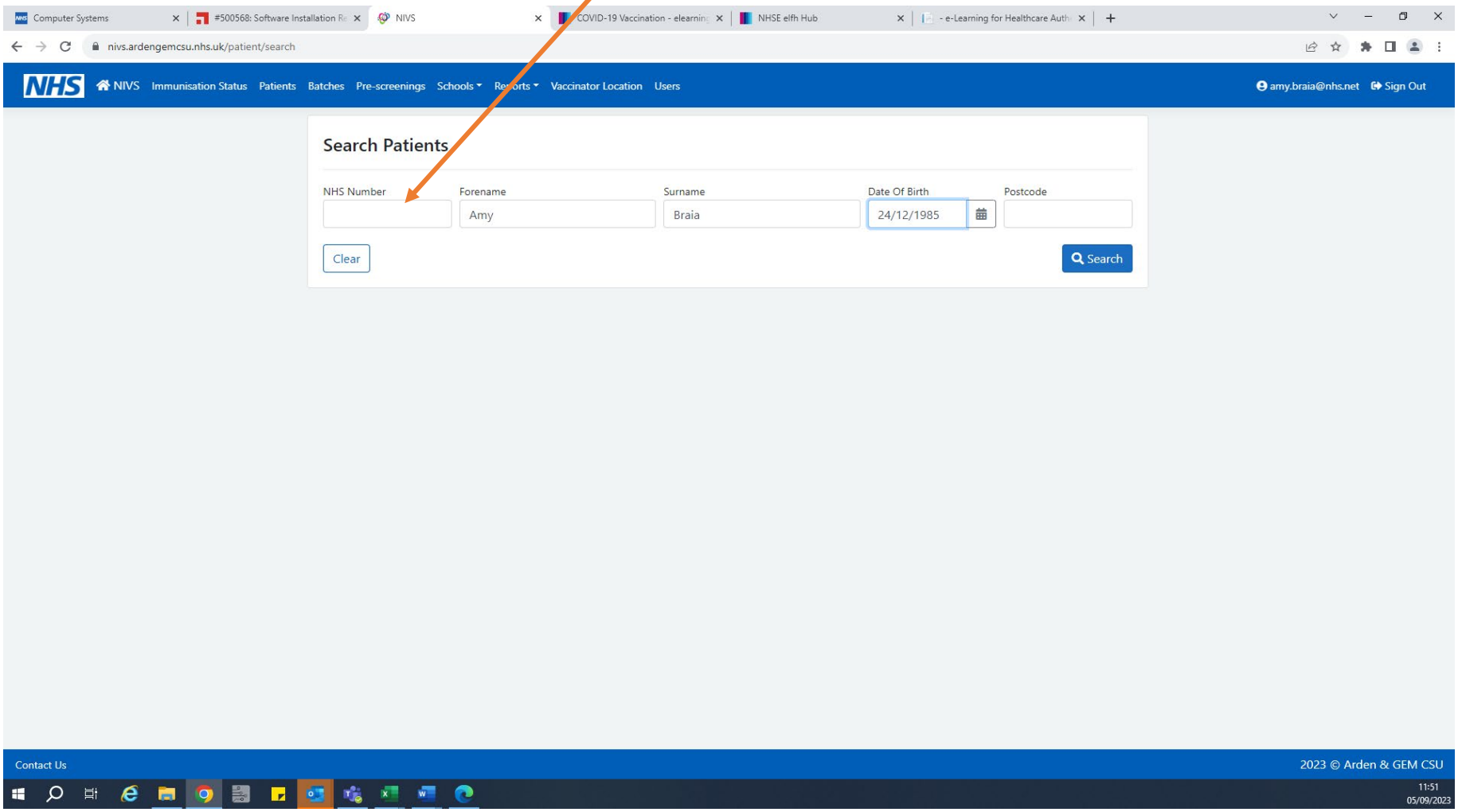
7. It will then ask you for a care model select Hospital Hub from the drop down box



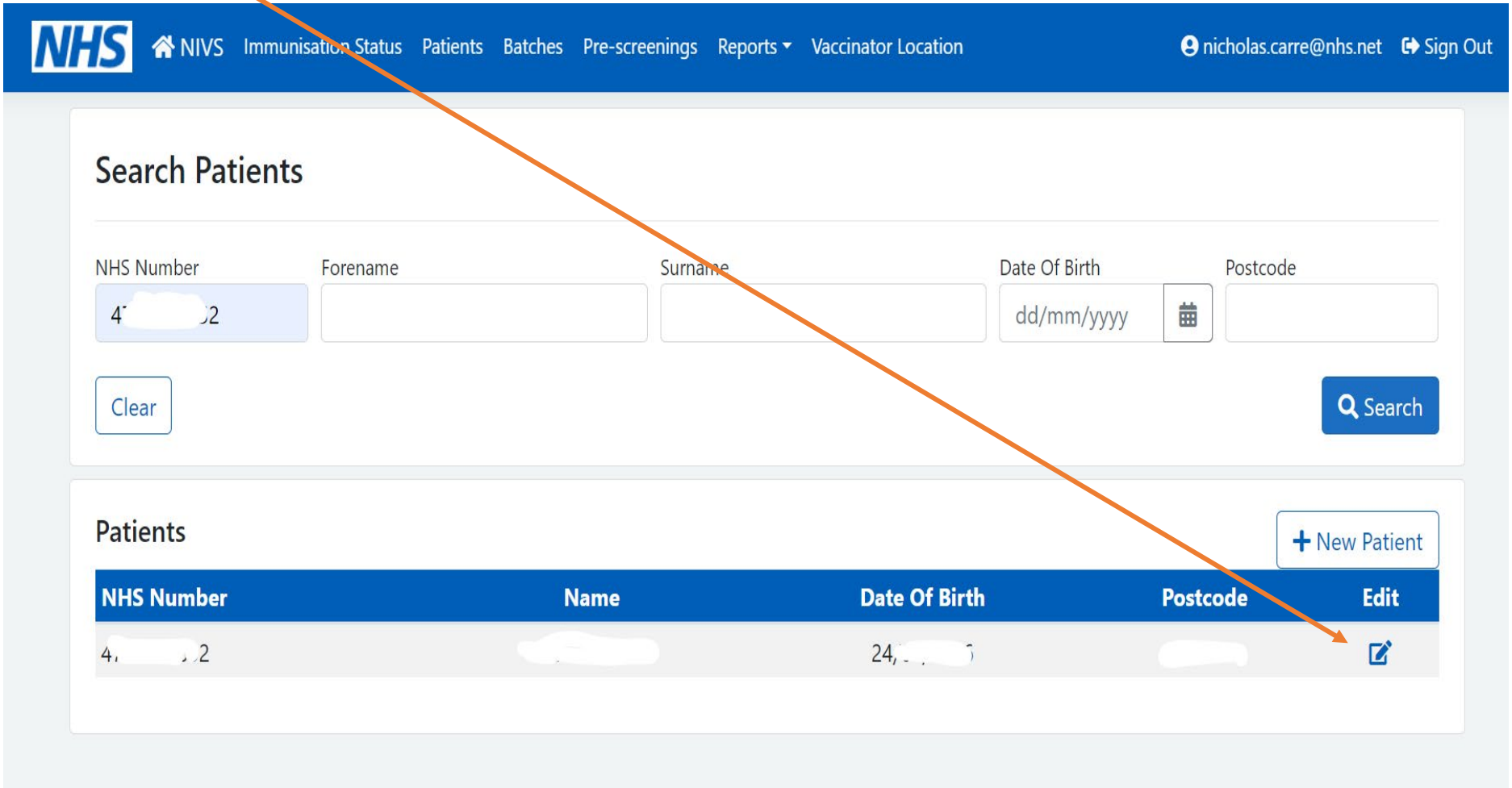
8. Check all the details are correct and click confirm.



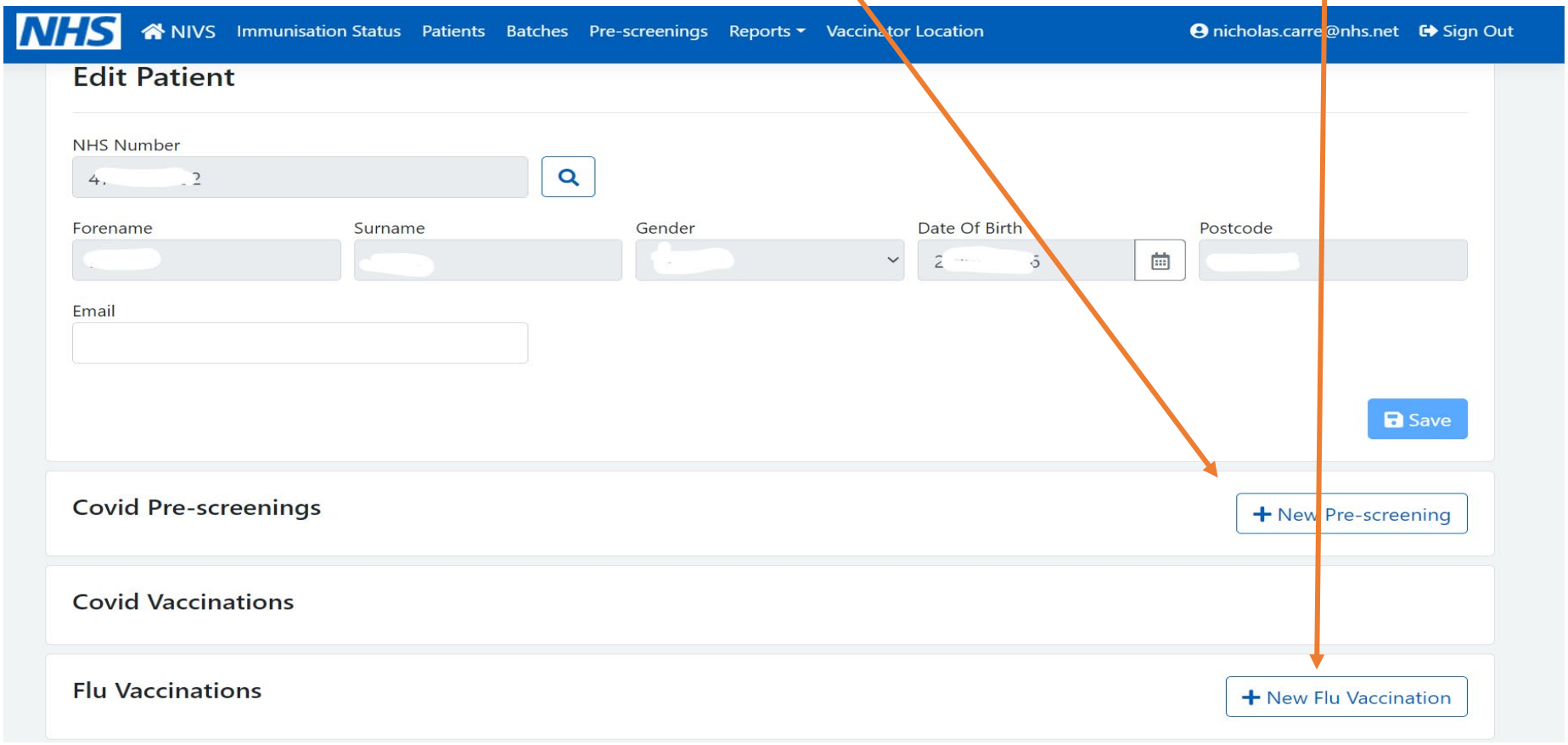
9. You will be taken to this screen add the patients NHS Number. If the patients NHS number is'ne available to you can search by name, date of birth and post code.



10. Patients will appear matching the details entered confirm the patients identify by checking the name and date of Birth and if correct select edit

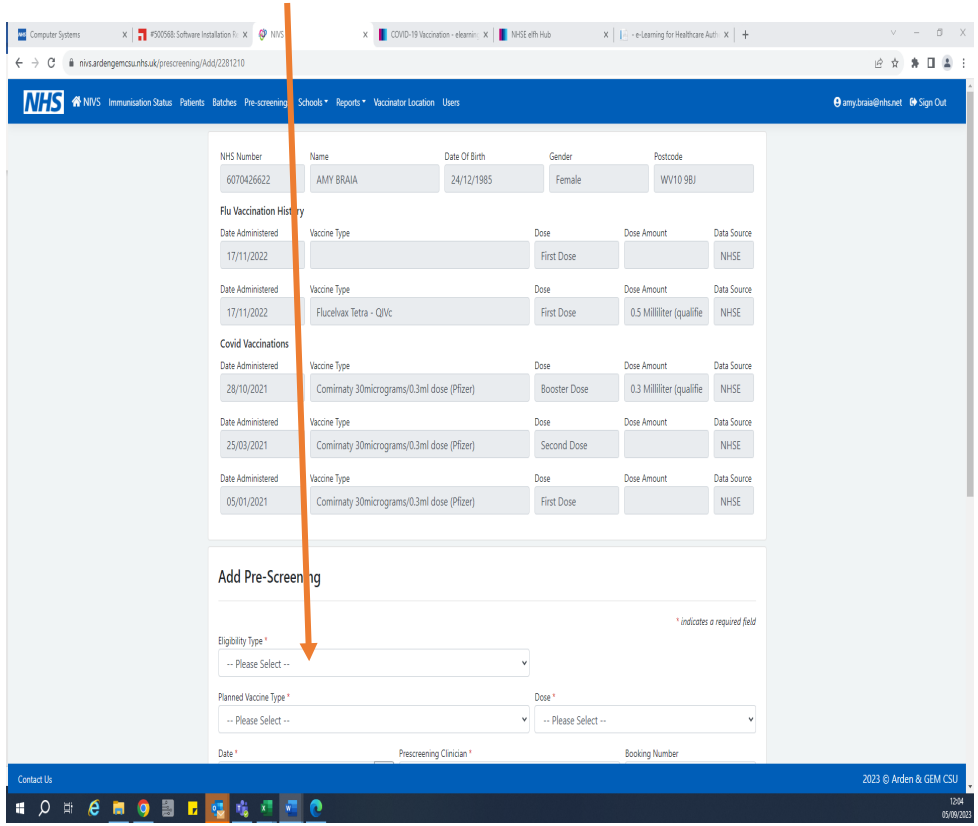


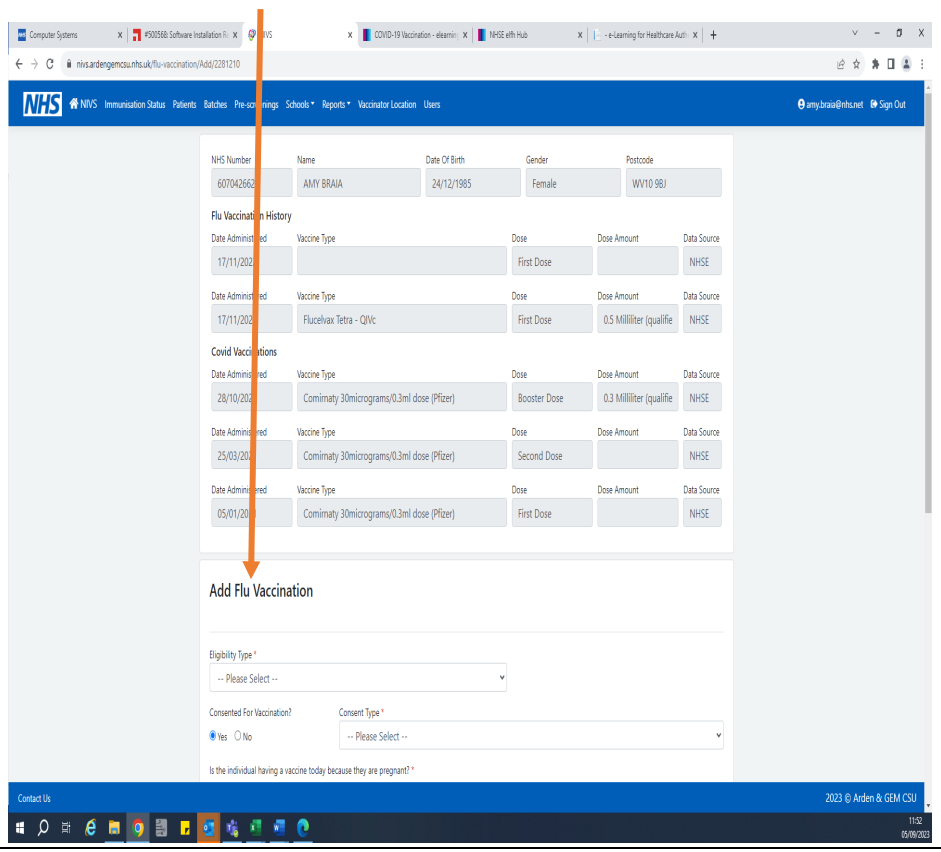
11. Select the vaccine you are giving and click either +New Pre-screening (or Covid-19 vaccine) or +New Flu Vaccination



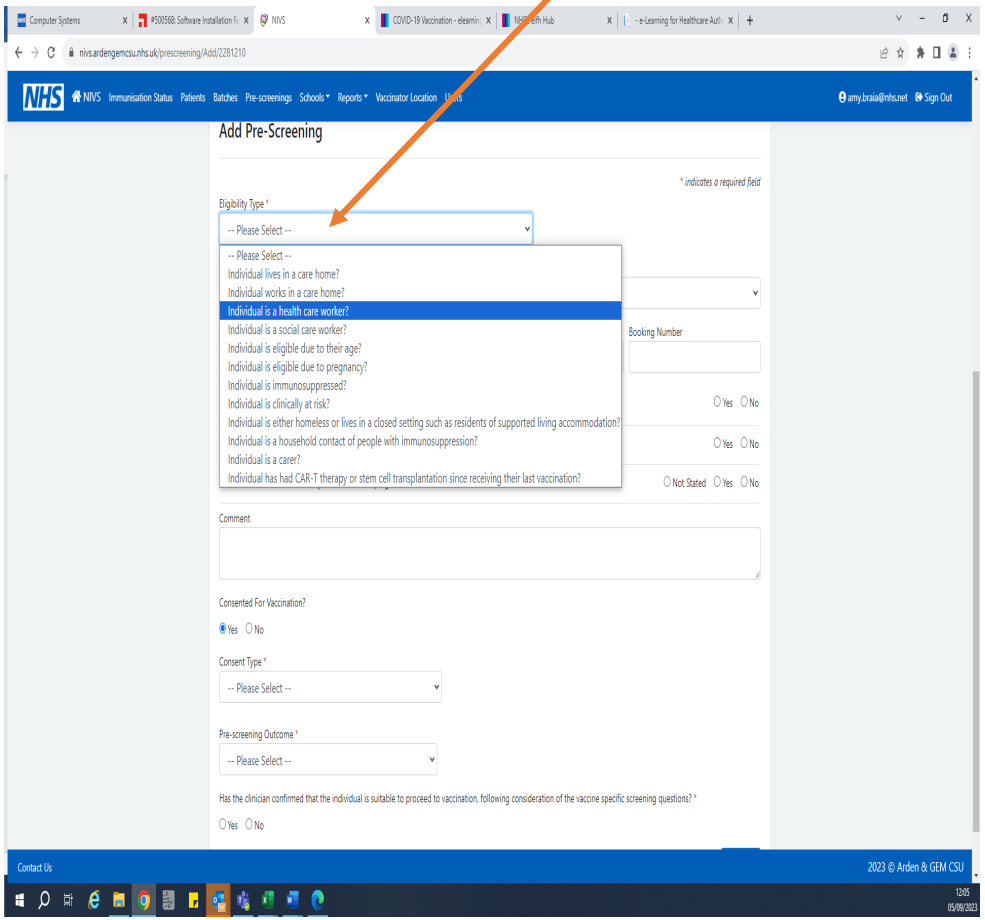
12. In both instances this will bring up the patients records of previous vaccinations. For Covid-19 Vaccine, check that the most recent dose was given at least 90 days ago. For the Flu vaccine check that the previous dose was before April of the current year Then:

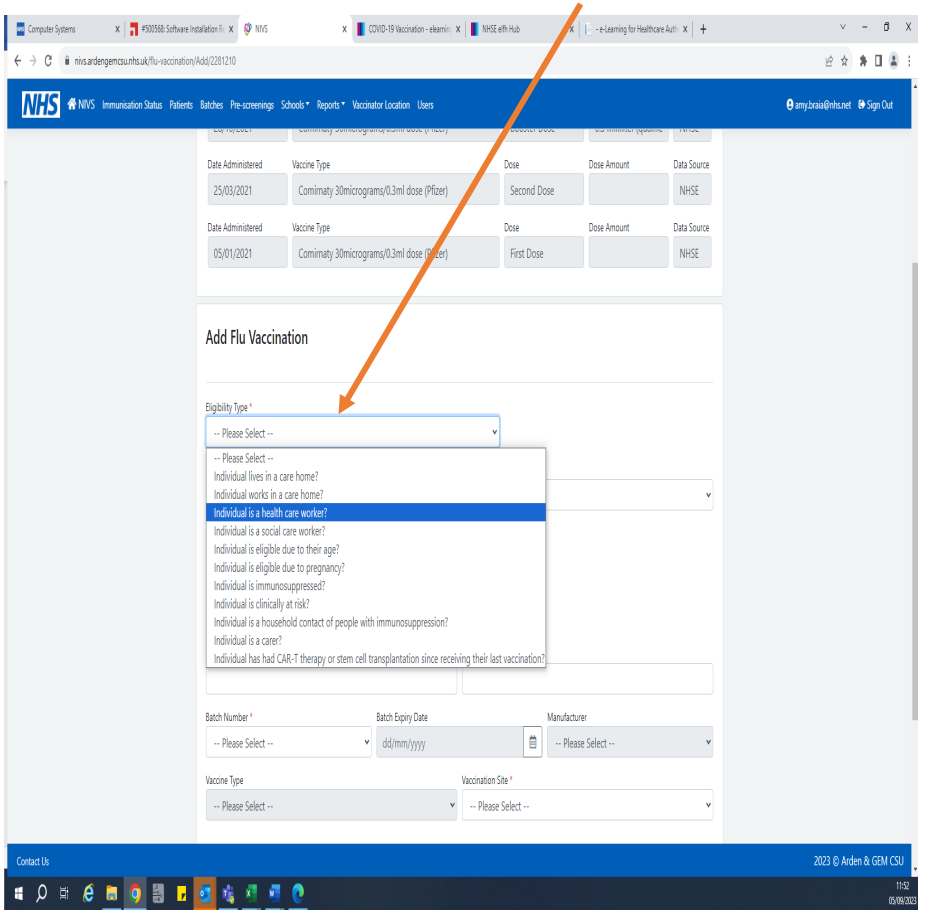
COVID-19 Vaccine	Flu Vaccine
1. scroll down to Add Pre-Screening	1. Scroll down to Add Flu Vaccination



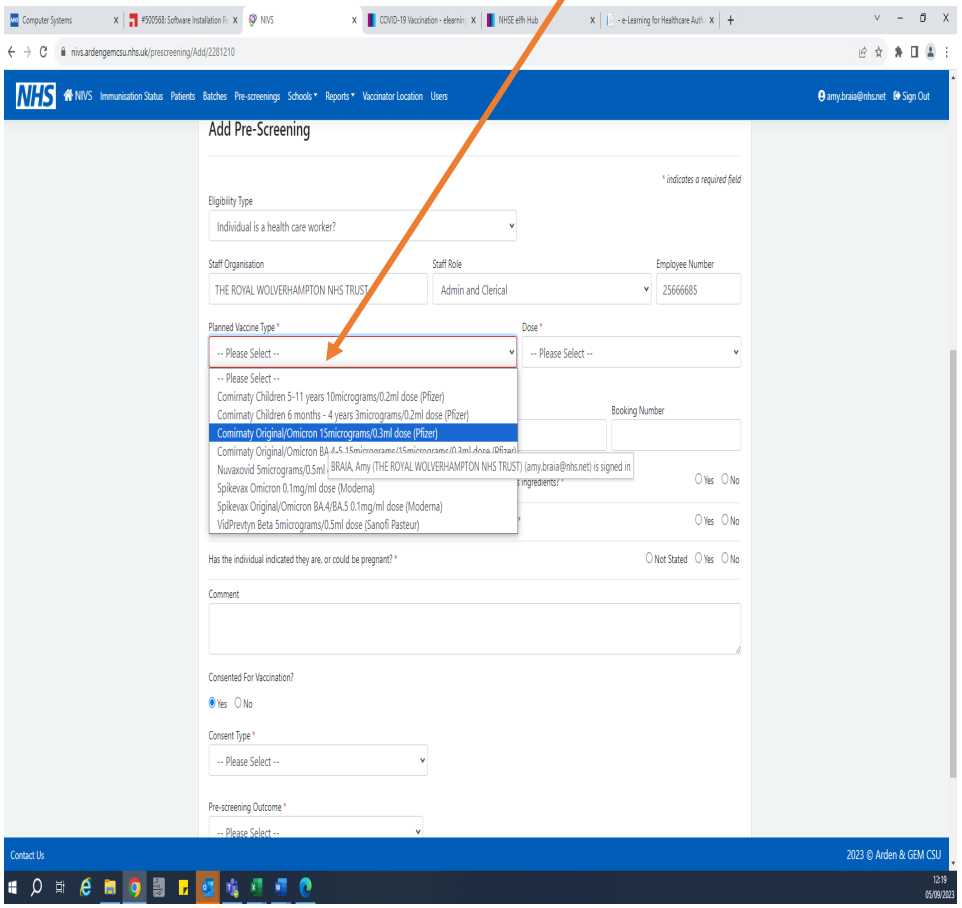


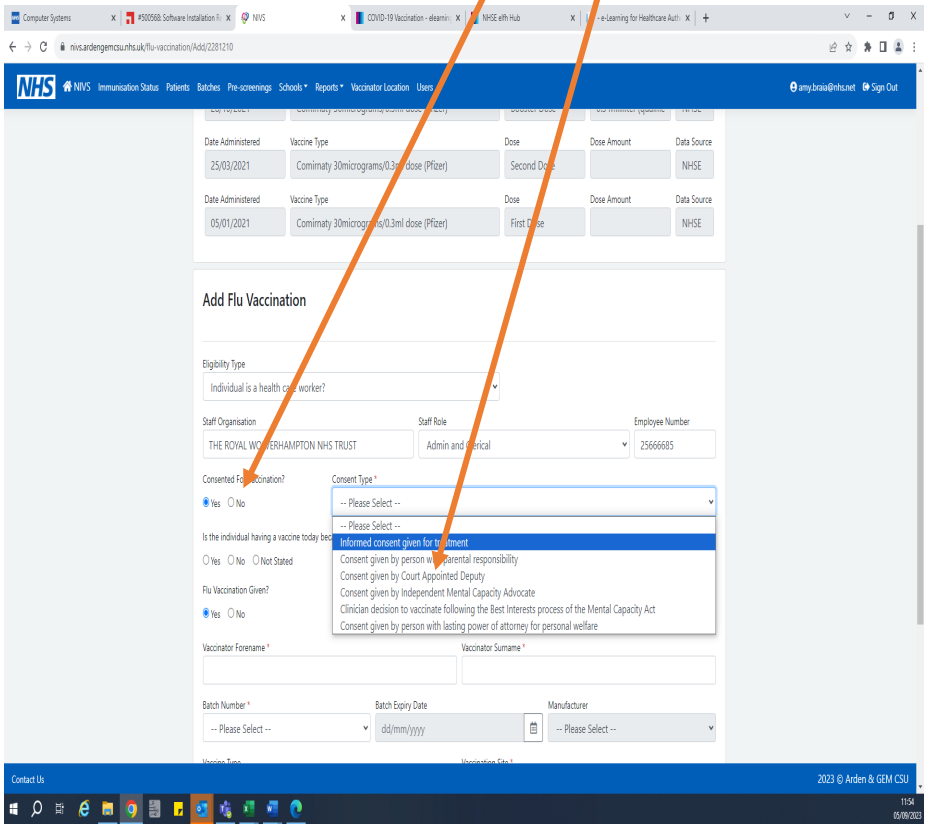
COVID-19 Vaccine	Flu Vaccine
2. For eligibility type select the appropriate category for the patient e.g. “eligible due to age” from the drop down list	2. or eligibility type select the appropriate category for the patient e.g. “eligible due to age” from the drop down list

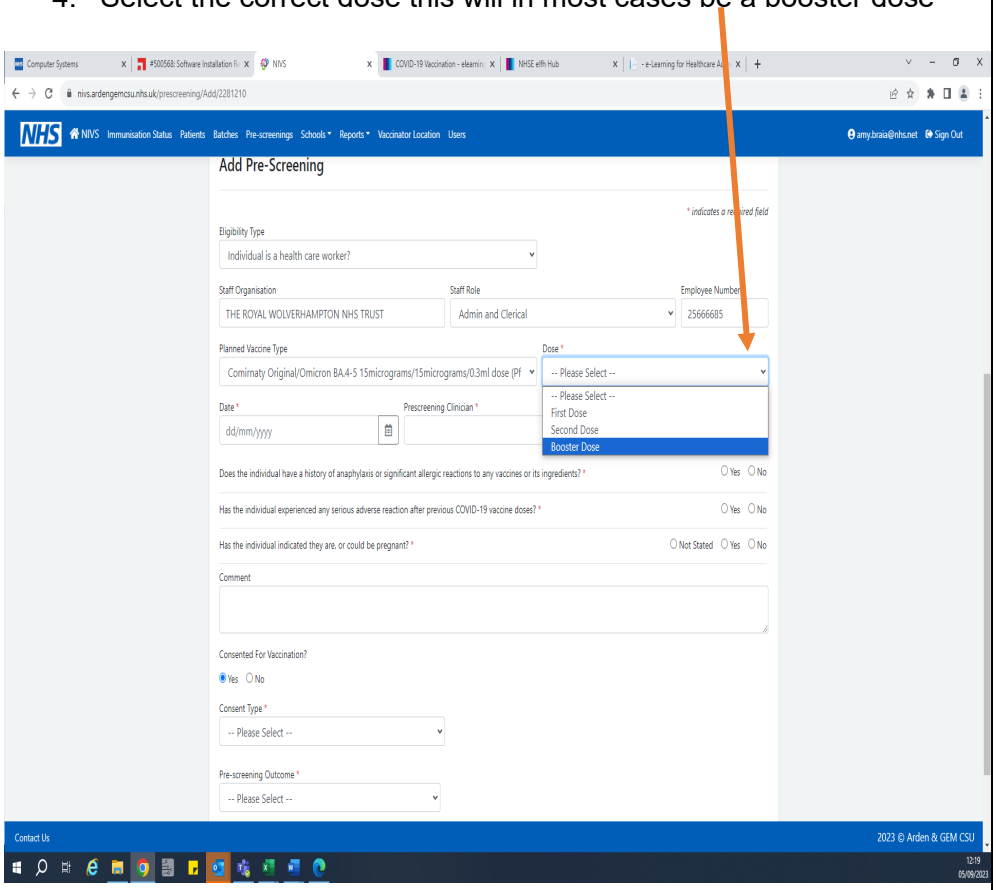
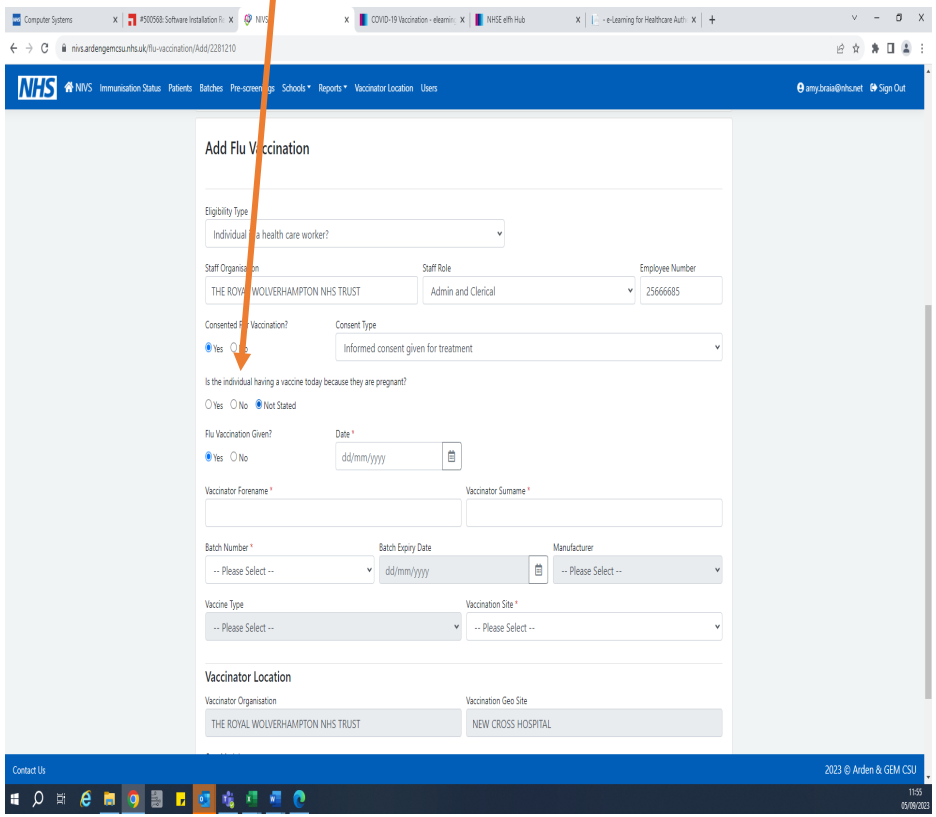




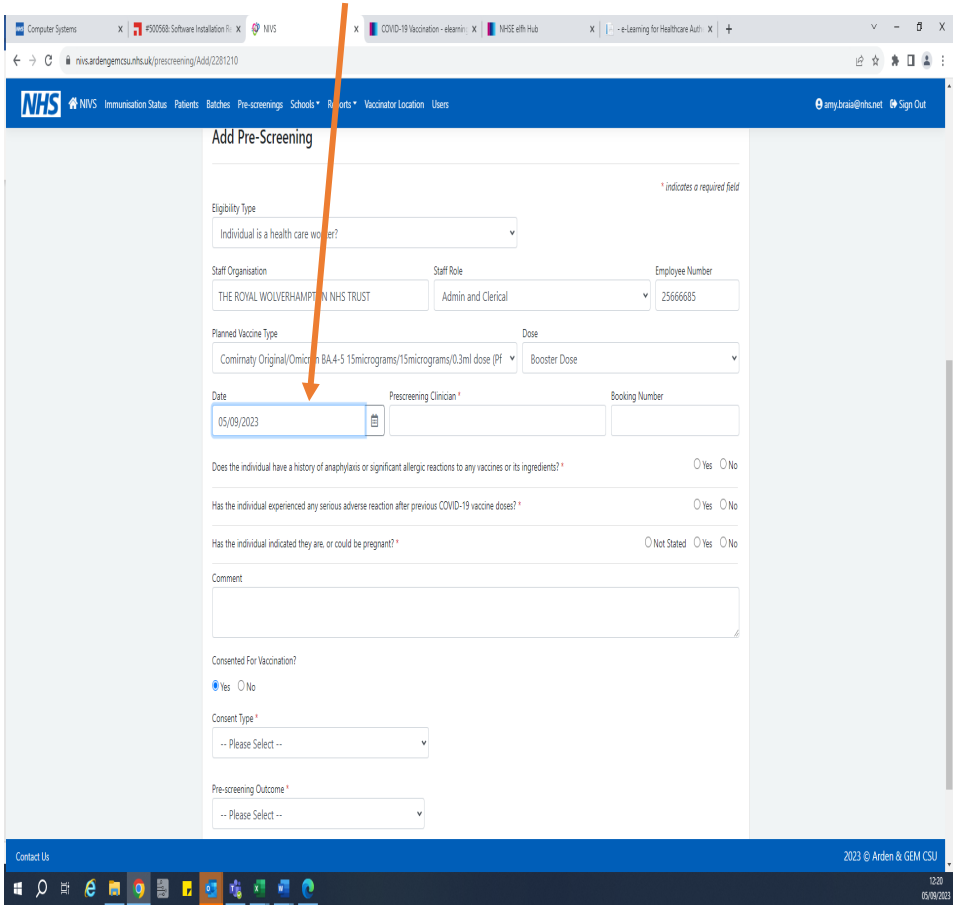
COVID-19 Vaccine	Flu Vaccine
3. Select the correct vaccine from the drop down list	3. Complete the consent process clicking the button to confirm if the patient has consented for vaccination or not and then select from the drop down box, the type of consent given by or on behalf of the patient

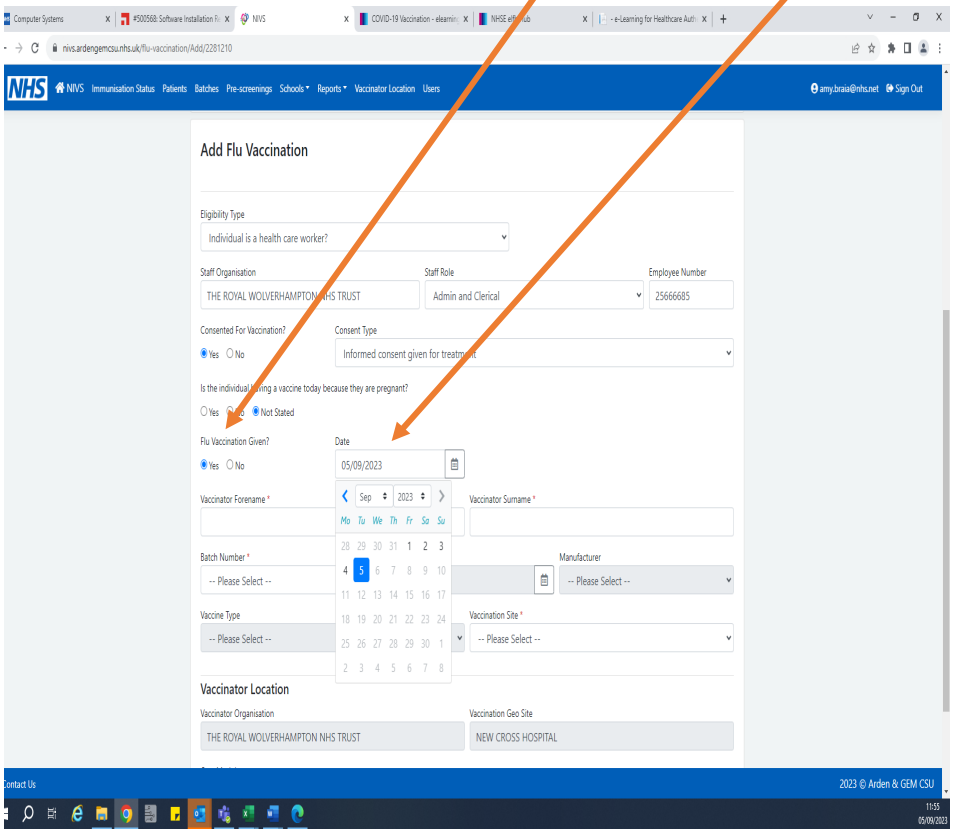




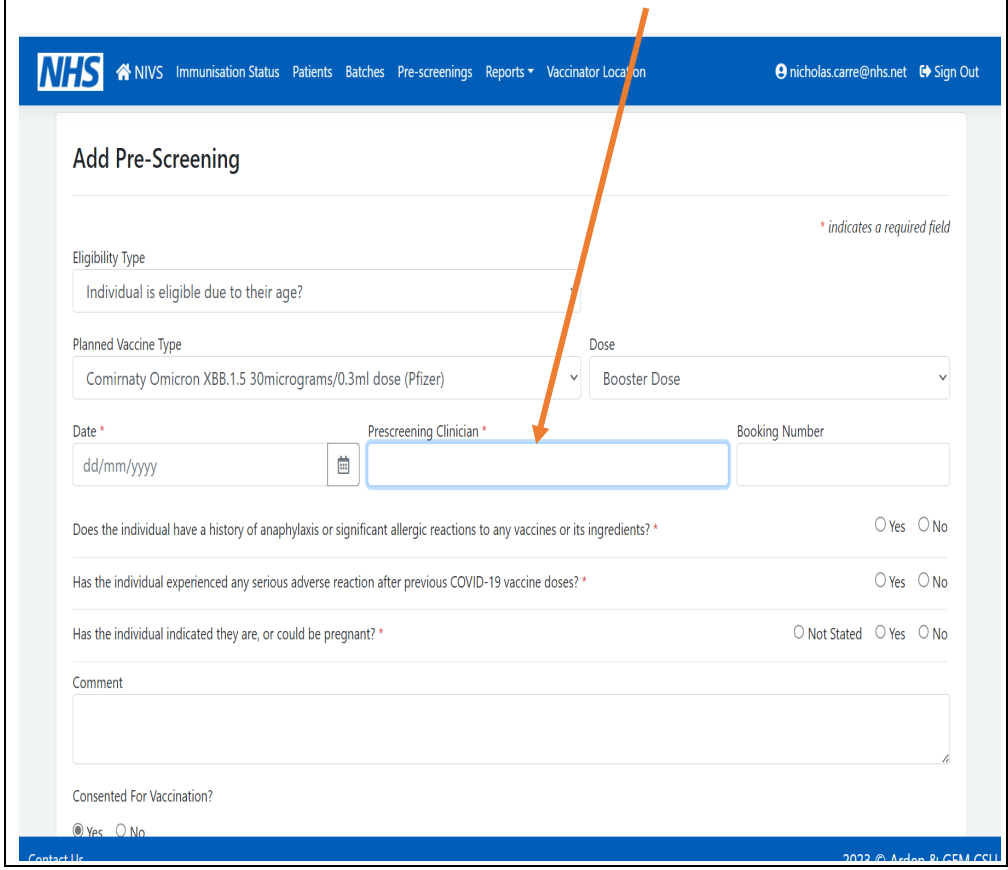
COVID-19 Vaccine	Flu Vaccine
4. Select the correct dose this will in most cases be a booster dose 	4. Confirm if the patient is having a vaccine today because they are pregnant. 

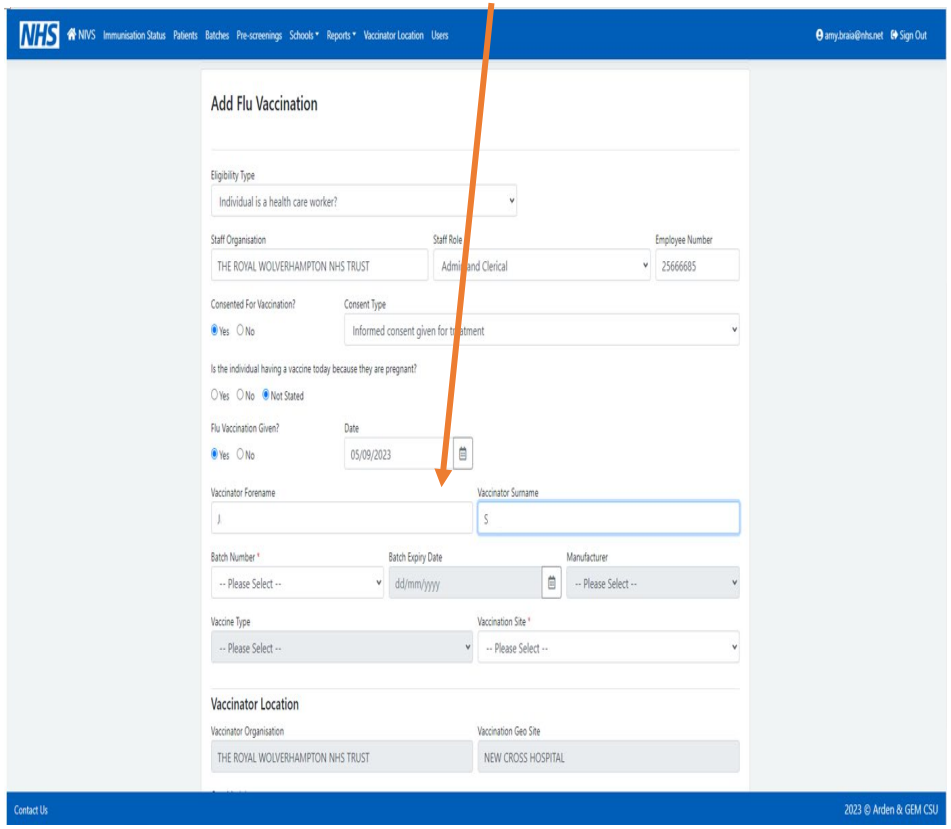
COVID-19 Vaccine	Flu Vaccine
5. Select the Correct Date	5. Select if the vaccination has been given and record the date of the vaccination



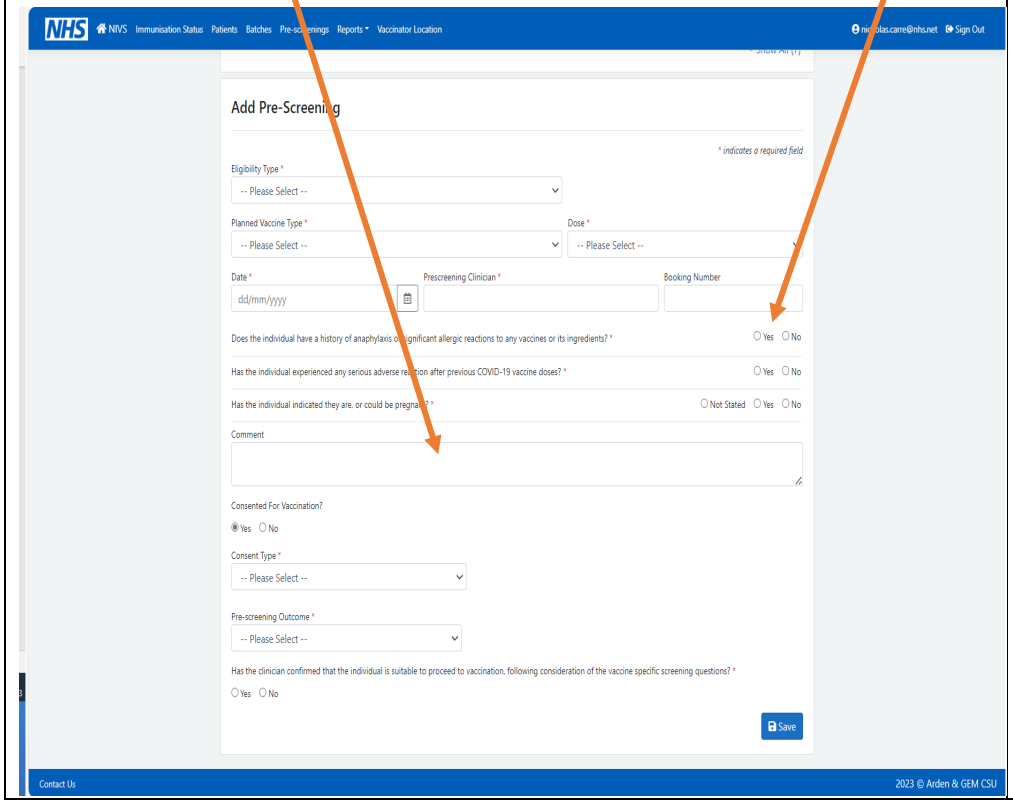


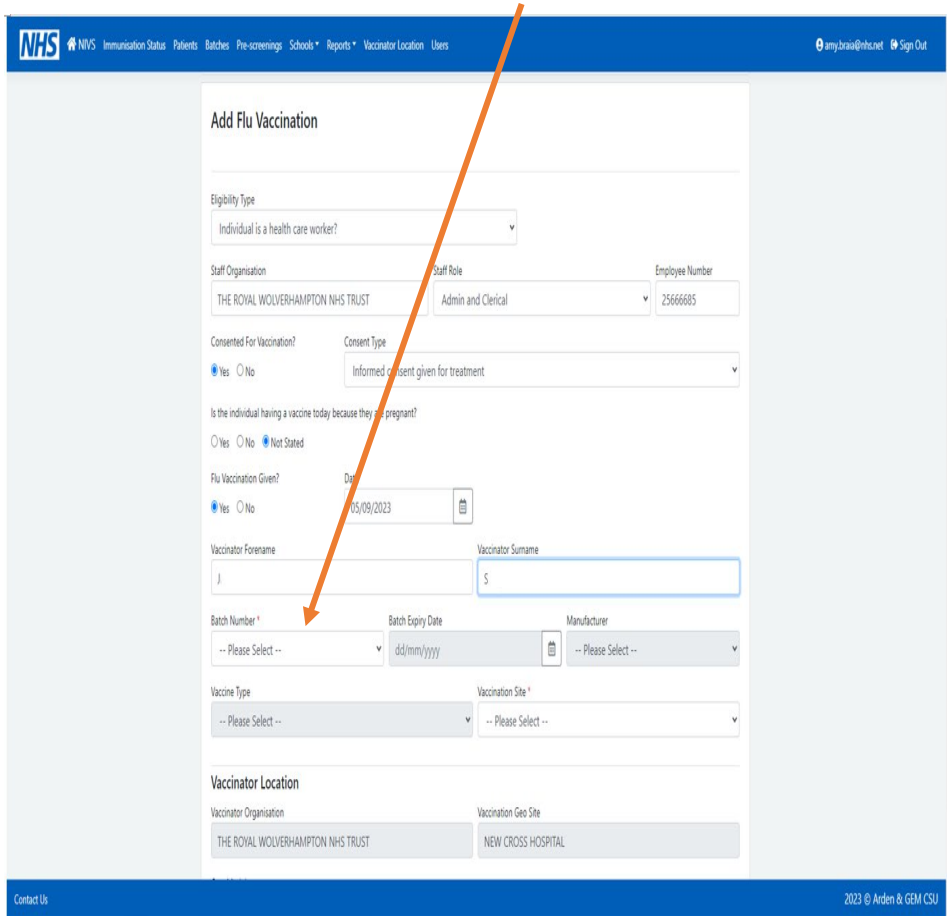
COVID-19 Vaccine	Flu Vaccine
6. Type in the name of the pre-screening Clinician	6. Type in the name of the vaccinator



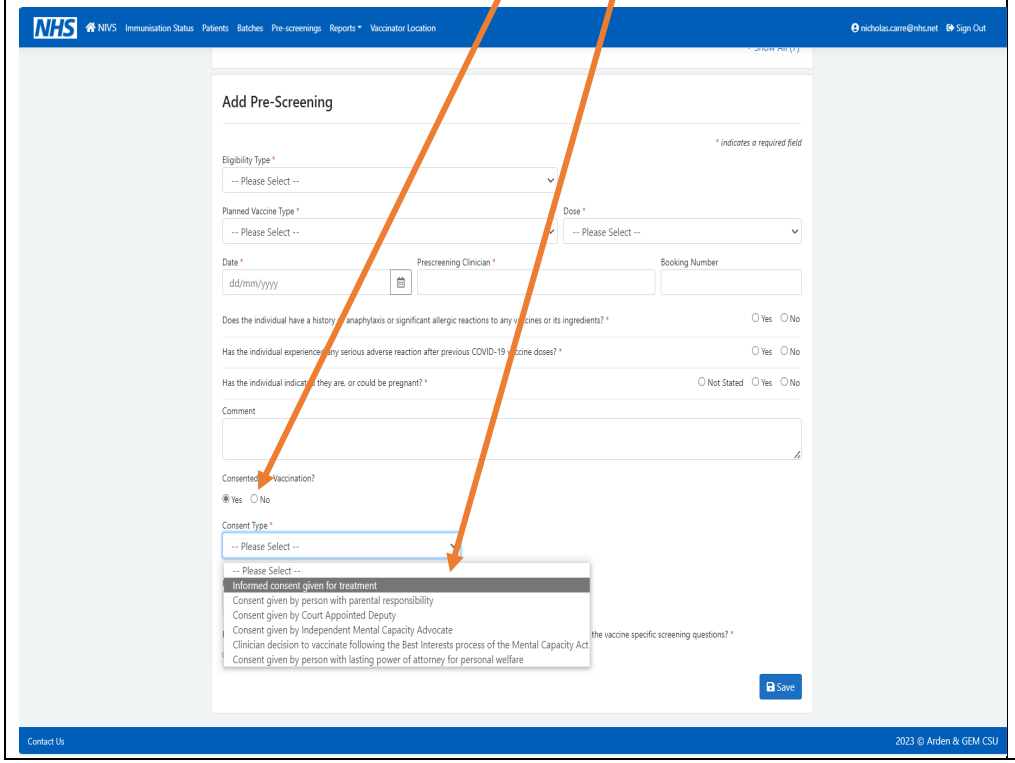


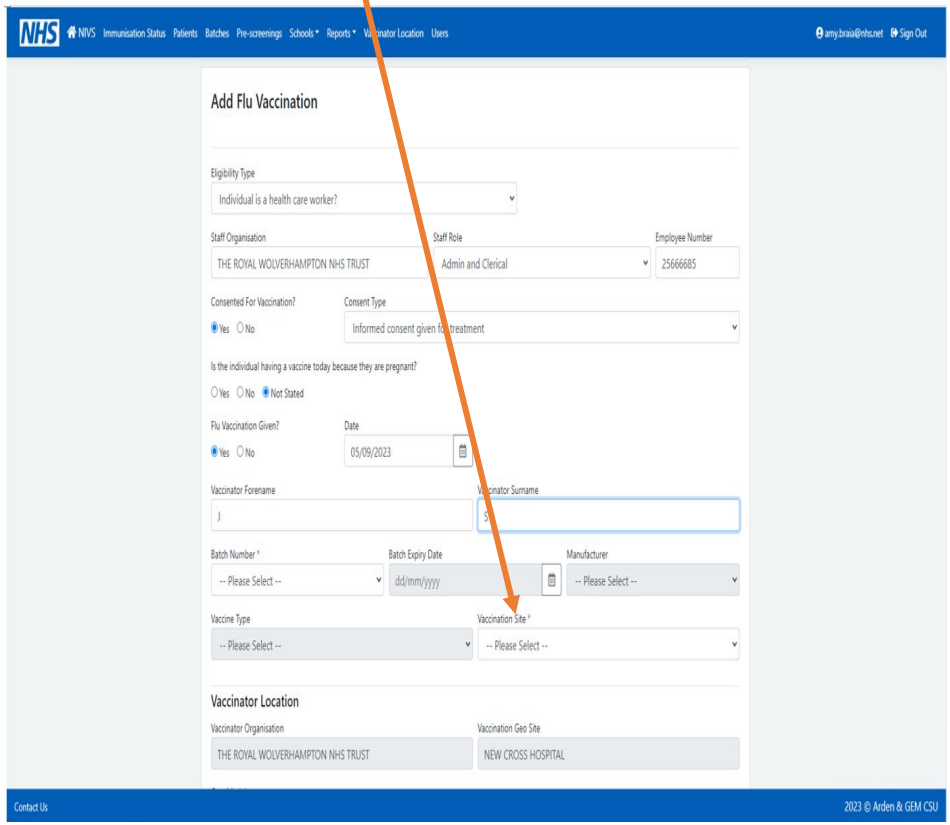
COVID-19 Vaccine	Flu Vaccine
7. Ask the Prescreening Questions and click the appropriate button to record their yes/no responses to each question. Record any relevant information in relation to the patient and their responses in the comment box.	7. Select the correct vaccine used, including batch number



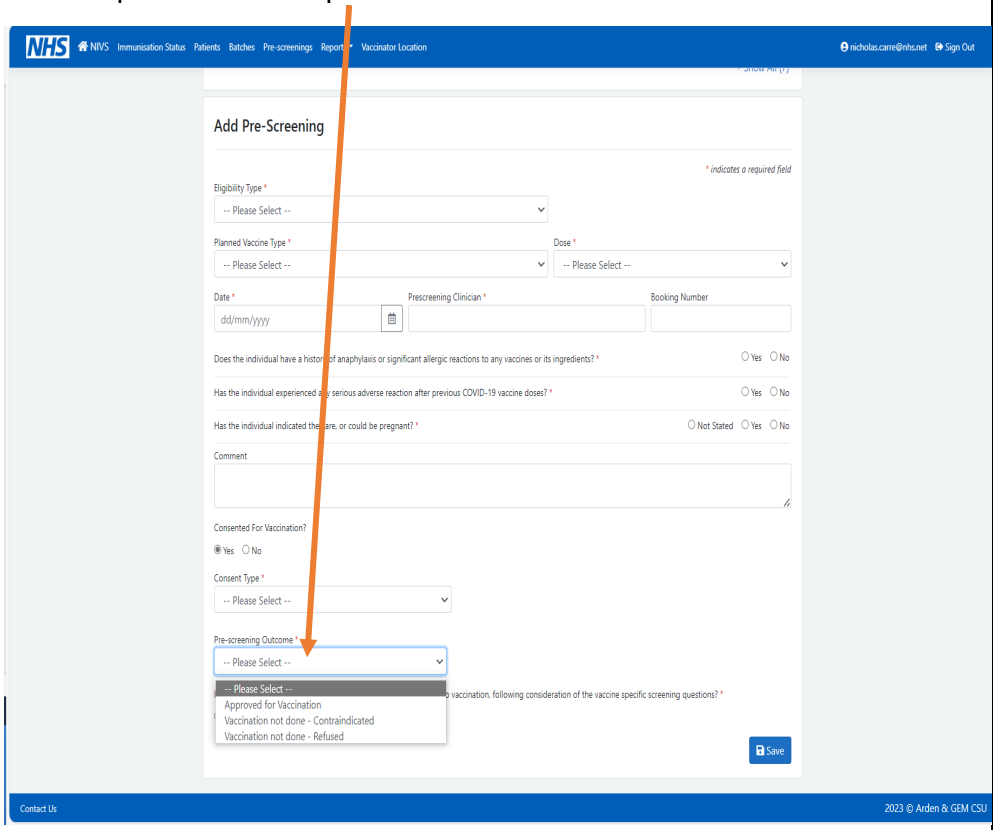


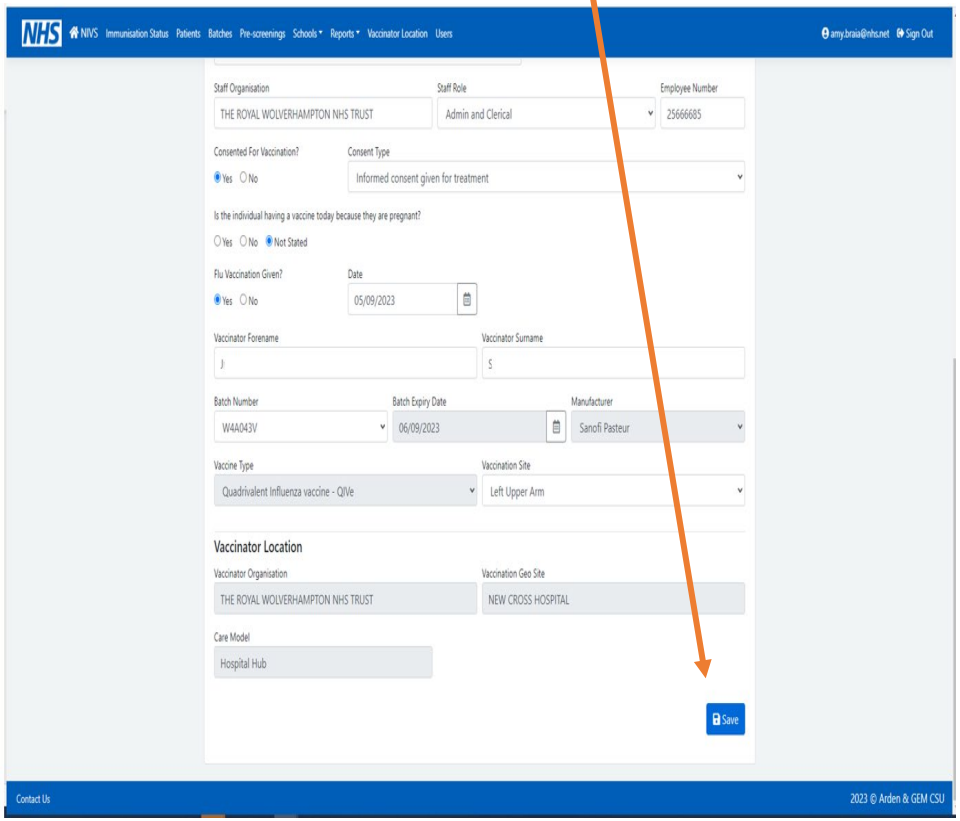
COVID-19 Vaccine	Flu Vaccine
8. Complete the Consent process clicking the button to confirm if the patient has consented for vaccination or not and then select from the drop down box, the type of consent given by or on behalf of the patient	8. Record the location site of the vaccination (e.g. Left upper arm)

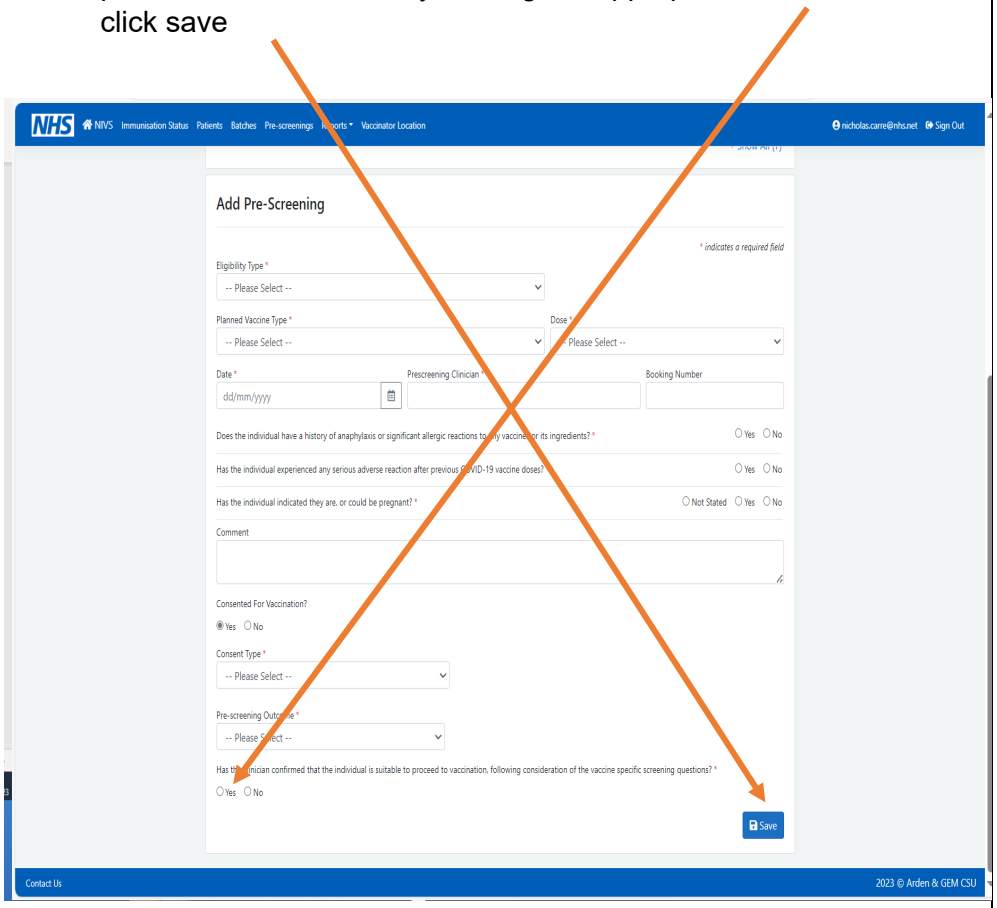


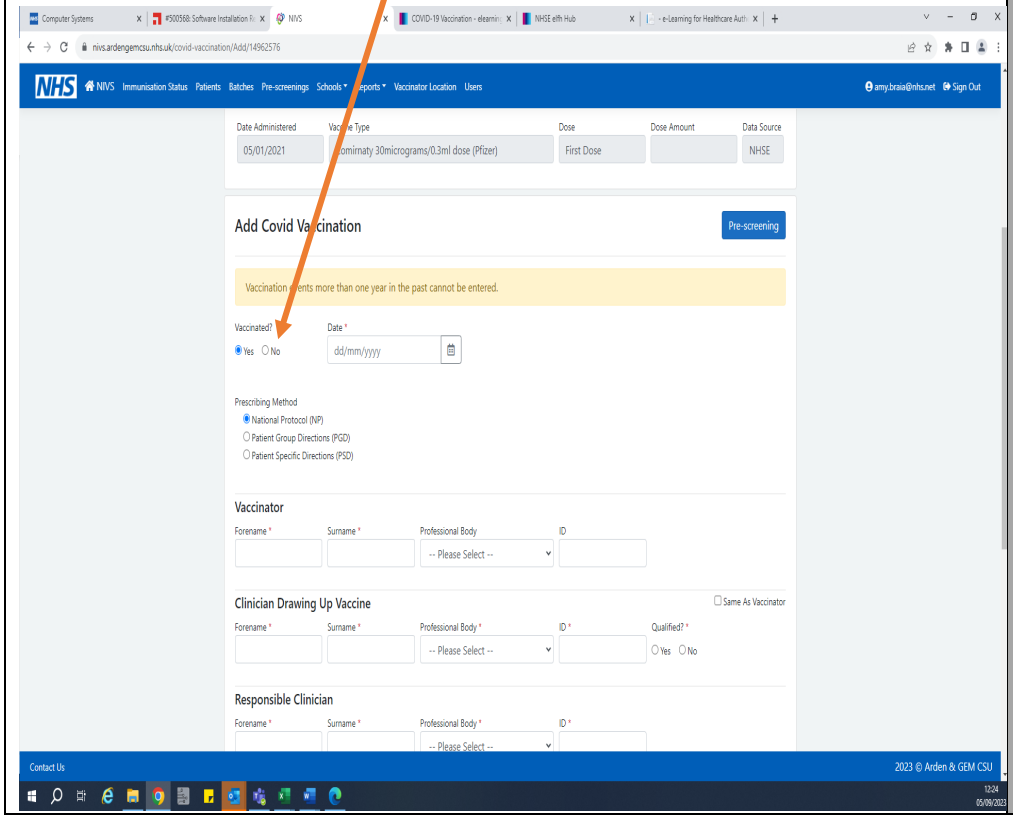


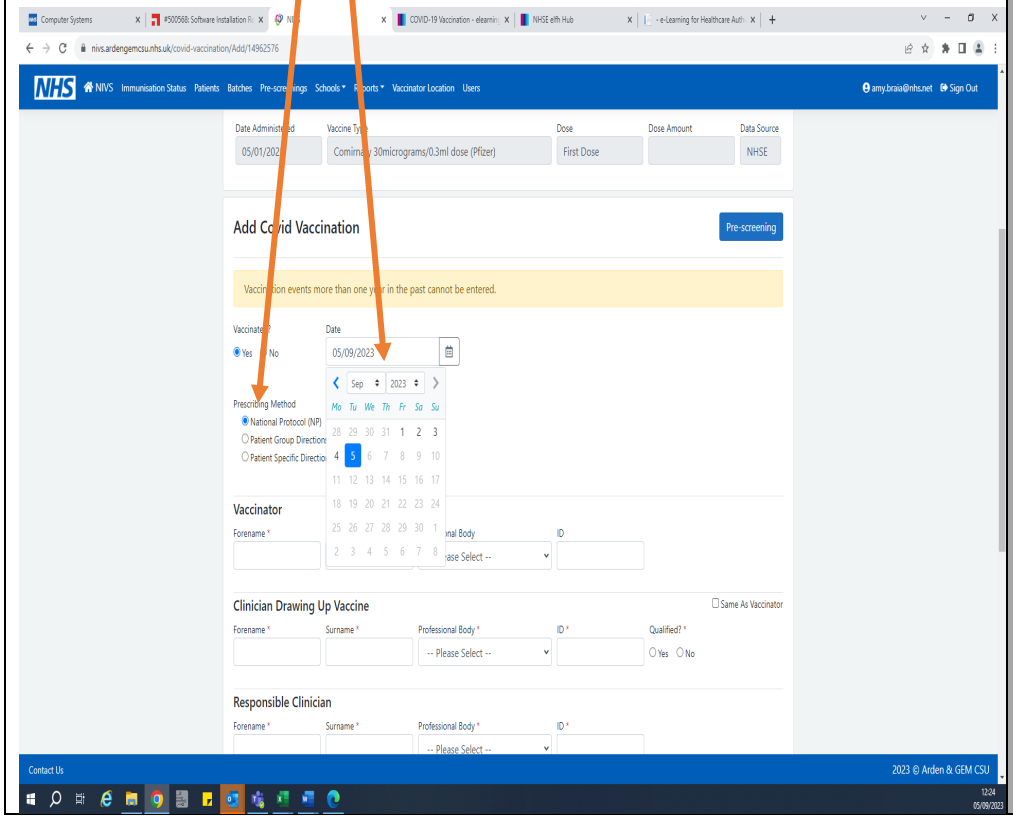
COVID-19 Vaccine	Flu Vaccine
9. The clinician must record their clinical decision regarding administration of the vaccine and record the outcome from the options in the drop down box.	9. Review the information for accuracy, confirm the location is correct and once satisfied click save

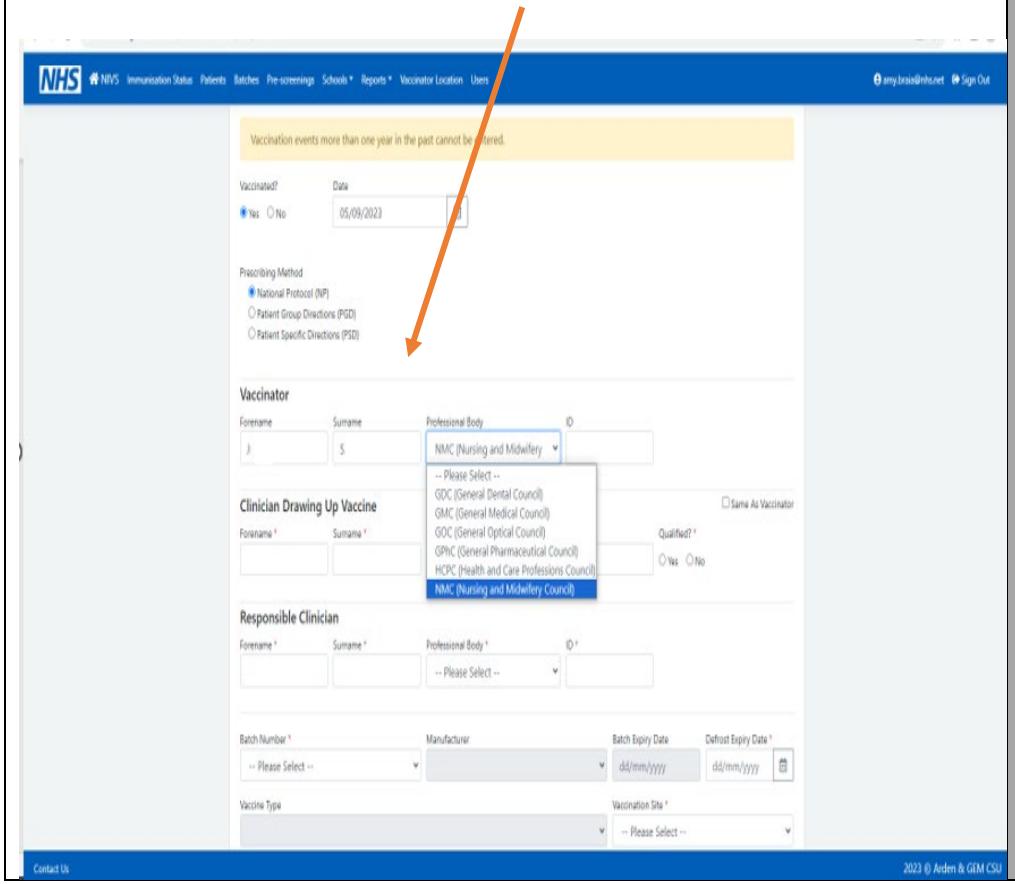


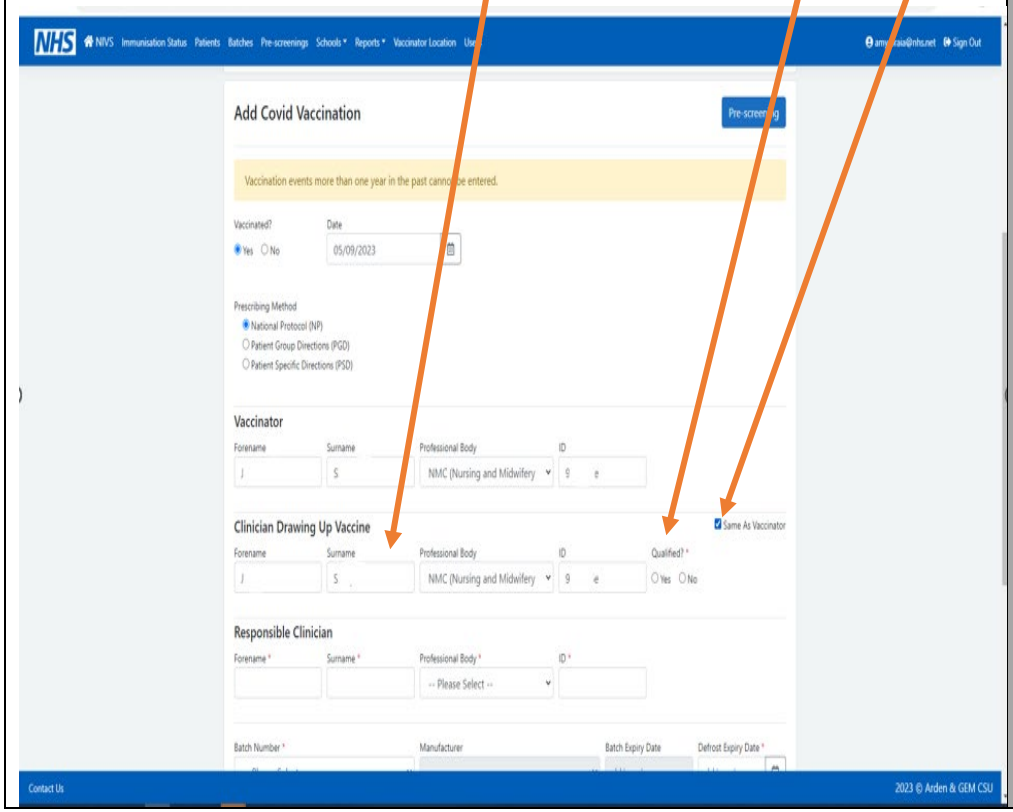


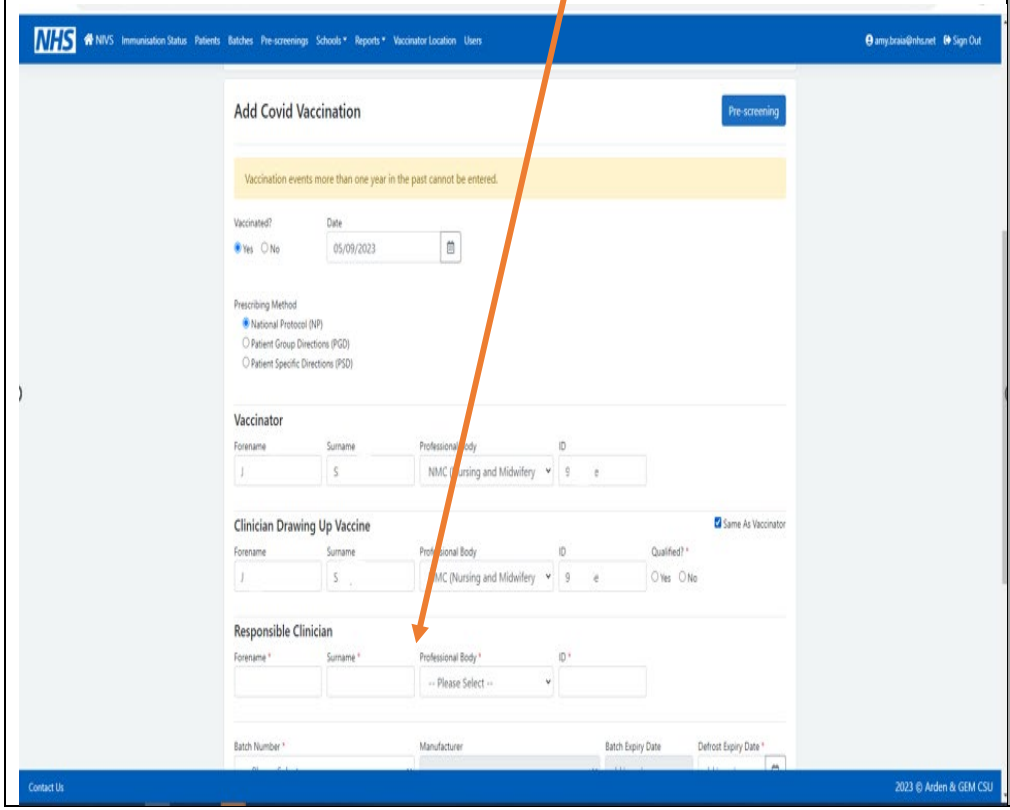
COVID-19 Vaccine	Flu Vaccine
10. The clinician must confirm whether the patient is suitable to proceed to vaccination by clicking the appropriate button and then click save 	10. Once saved the system will automatically go back to the vaccination information for the patient. Review the updated record to ensure that the vaccination you have just recorded appears on this page.

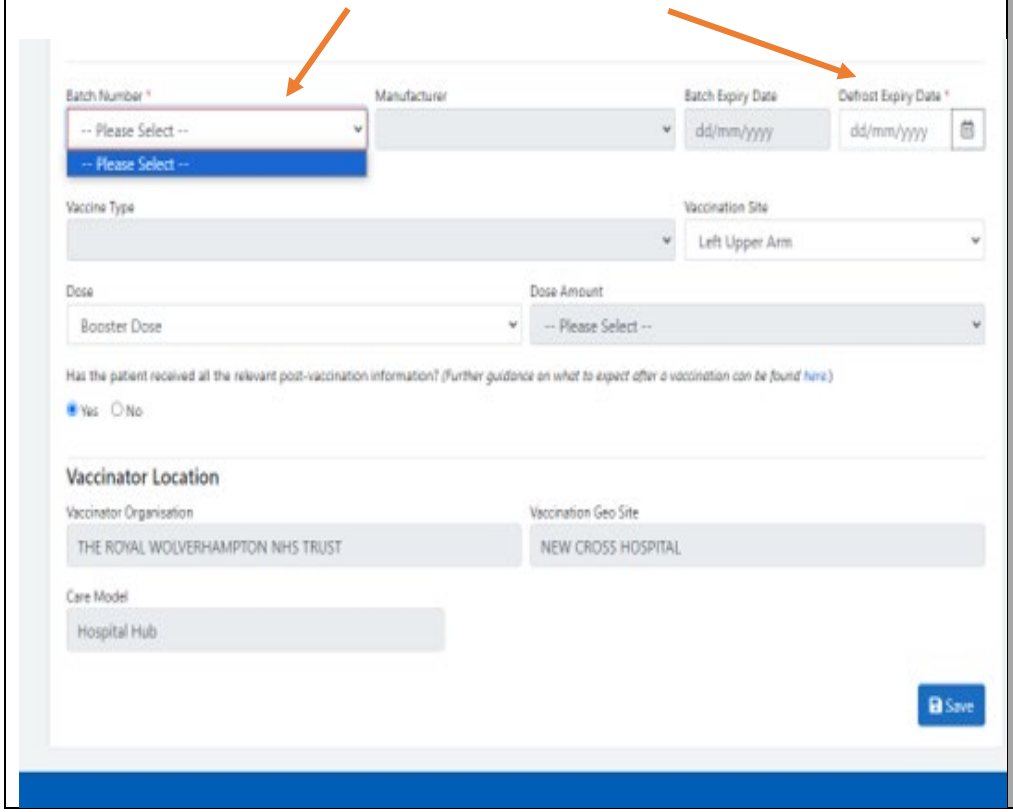
COVID-19 Vaccine	Flu Vaccine
At this point the vaccination will be given then the following is recorded 11. Select the correct button to confirm if vaccianted yes/no 	

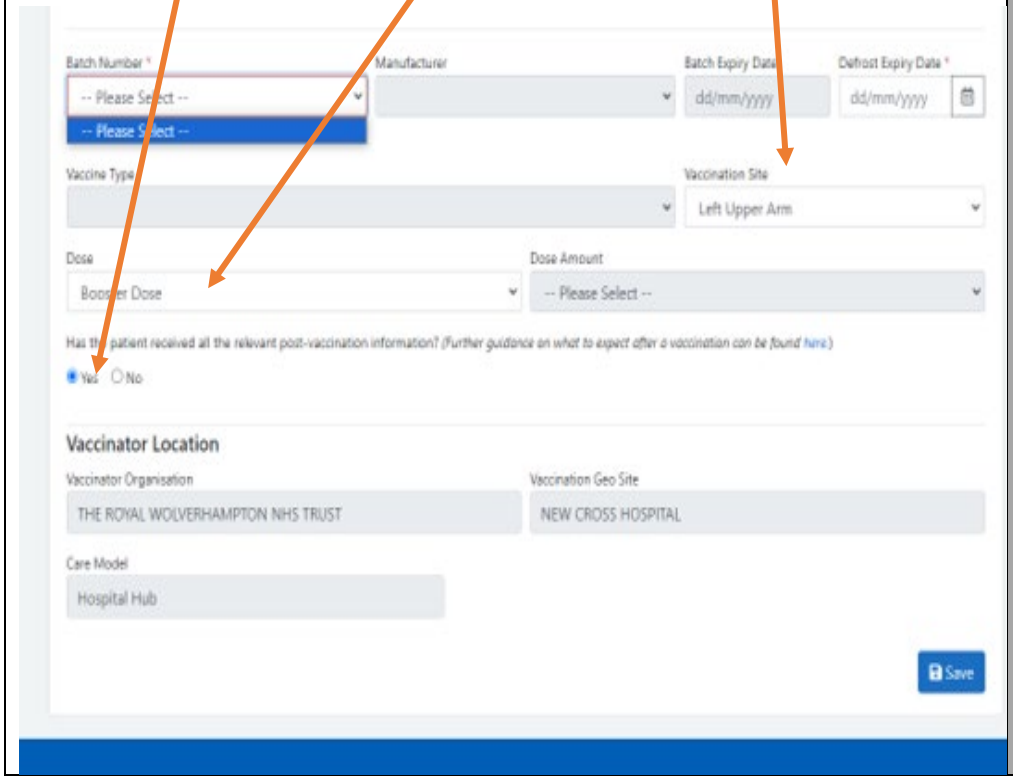
COVID-19 Vaccine	Flu Vaccine
11. Select the legal framework used to vaccine e.g. National Protocol and the correct date 	

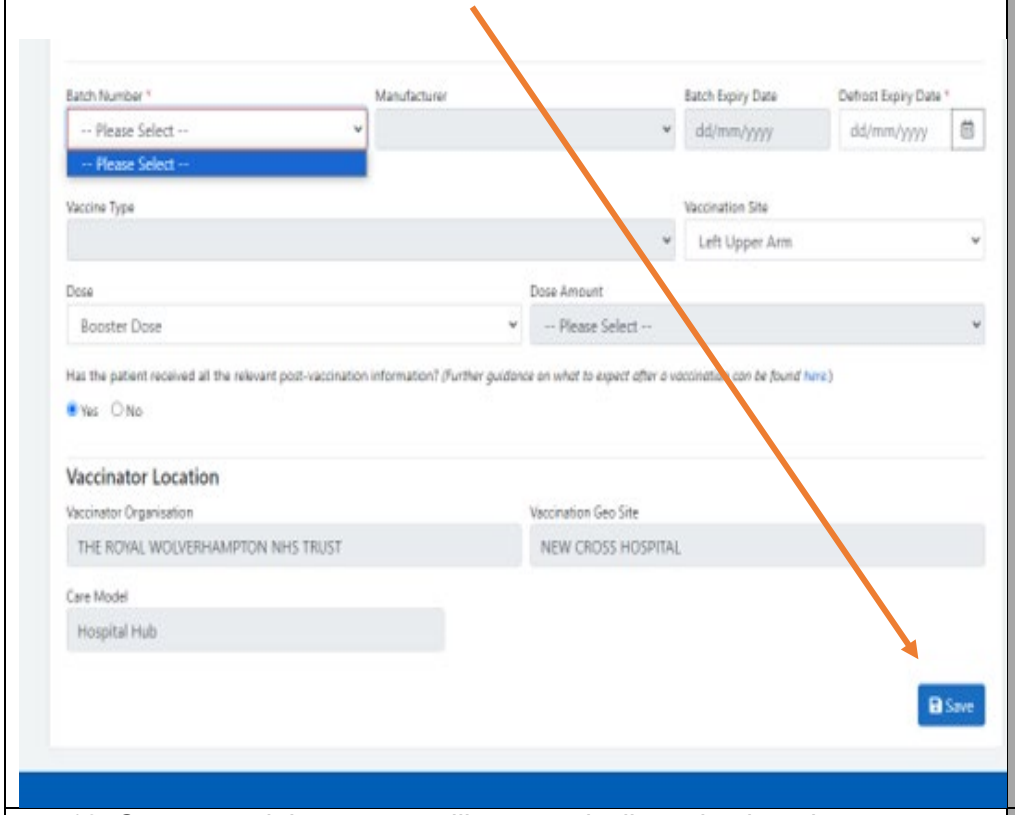
COVID-19 Vaccine	Flu Vaccine
12. Input the vacciantors name, professional body and registration number 	

COVID-19 Vaccine	Flu Vaccine
13. Input the details of the Clinician drawing up the vaccine. If it is the same person as the vaccinator, click the “same as vacciantor” box and the details will auto-populate. Select Yes or No button to confirm if the clinician drawing up is qualified – All clinicians drawing up vaccine for inpatient vacciantions should be registered. 	

COVID-19 Vaccine	Flu Vaccine
14. Input the details of the responsible clinician. This person is the clinical nursing lead for the ward on shift at the time of vaccination. They must be familiar with the eligiblity criteria and national protocol as well as the vaccine being used. 	

COVID-19 Vaccine	Flu Vaccine
15. Select the batch number and **defrost** expiry date of the vaccine used 	

COVID-19 Vaccine	Flu Vaccine
16. Record the dose type (e.g. Booster), vaccination site (e.g. left upper arm) and confirm whether the patient was given the relevant post-vacciantion information. 	

COVID-19 Vaccine	Flu Vaccine
17. Review the information for accuracy, confirm the location is correct and once satisfied click save 	
18. Once saved the system will automatically go back to the vaccination information for the patient. Review the updated record to ensure that the vaccination you have just recorded appears on this page.	

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 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 2). This can be delegated to an appropriately trained pharmacist.

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 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 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. All staff members must be aware that 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 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 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

<table>
<tr><td>COVID-19 Vaccine Procedure 11 V3.1</td><td colspan="2">Title of Procedure/Guidelines
Standard Operating Procedure for the administration of multiple vaccines in a single vaccination clinic setting</td><td colspan="2">Status:
Final</td><td>Author: Nicholas Carré
For local procedures and guidelines Lead Sponsor:
Clinical Director of Pharmacy</td></tr>
<tr><td rowspan="5">Version / Amendment History</td><td>Version</td><td>Date</td><td>Author</td><td colspan="2">Reason</td></tr>
<tr><td>v1</td><td>23/3/22</td><td>Deputy Clinical Director of Pharmacy</td><td colspan="2">New SOP</td></tr>
<tr><td>V2</td><td>20/09/2022</td><td>Deputy Clinical Director of Pharmacy</td><td colspan="2">Updated to allow use of additional vaccines outside influenza and COVID-19</td></tr>
<tr><td>V3</td><td>30/03/2023</td><td>Clinical Lead – Living Well Group</td><td colspan="2">Updated appendix 2 to reflect current COVID-19 vaccines for Spring Booster 2023</td></tr>
<tr><td>V3.1</td><td>23/03/2024</td><td>Deputy Clinical Director of Pharmacy</td><td colspan="2">Updated appendix 2 to reflect current COVID-19 vaccines for Spring Booster 2024. Change to timeframe for assurance checks</td></tr>
<tr><td colspan="6">Intended Recipients: All staff working in RWT COVID-19 Vaccination sites</td></tr>
<tr><td colspan="6">Consultation Group / Role Titles and Date: One Wolverhampton Living Well Group Manager, Clinical Director of Pharmacy, Clinical Lead, Alfred Squire Vaccination Hub</td></tr>
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Name and date of group where reviewed	Trust Medicine Management Group (MMG) 04/2024 Trust Policy Group – June 2924
Name and date of final approval committee	Trust MMG 06/2024 Trust management Committee – June 2024
Date of Procedure/Guidelines issue	July 2024
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 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 vaccine 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 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 - Checklist for clear-down of current vaccine dilution area

Name of Person completing checklist	
Date & Time of changeover	
[redacted]	
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
Comirnaty 30 (XBB.1.5) Ready to use	
Comirnaty 10 (XBB.1.5) for Children 5-11 years Ready to use	
Comirnaty 3 (THREE) (XBB.1.5) Concentrate	
Spikevax (XBB.1.5) Ready to Use	
Vaccine name:	
Vaccine name:	
Vaccine name:	

Date	/ /

Vaccination Site/Location	

Start of Session Approval	
Fridge temperatures checked, in range and reset	
Work stations clear	
Anaphylaxis kits given out to each room/roving team	
Vaccine types(s) in use this session	

Issues identified during session (confirm reported to Clincial Lead)

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	
Vaccination logs returned, completed and counted	
No. of vials used (record for each vaccine type)	
No of doses wasted (record for each vaccine type)	
Workspace cleared and disinfected	
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 secure location	
Vaccination session closed - ensure storage room door locked as you leave	

COVID-19 Vaccine Procedure 11
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 the relevant SOP Observe each vaccinator and second checker on 2 occasions that the draw up and second check SOP is being followed correctly. Record any missing protocols and SOPs here and who has been asked to update them		
Confirm there is a COVID-19 Vaccination session record completed for every day the site was operational.		
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:

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 Make a list of all the vaccines affected and isolate stock within the refrigerator so it cannot be inadvertently used. Follow MP10 Medicine Cold chain policy and do not use any vaccine that has been out of the cold chain until advice has been sought from the manufacturer or the Trust Medicines Information. Advice can also be sought from the COVID-19 Lead pharmacist.

- Check the plug. Ensure it has not been disconnected.
- Check whether the failure is due to a short-term electricity failure. Do you have a backup facility such as a generator and is it working?
- Inform the person designated to be in charge of all the refrigerators or a manager, in their absence, so that a repair engineer can be called.

3.2 Complete the stock take Wastage process on Foundry in accordance with MP11 Procedure 4

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 v2.0	**Title of Procedure/Guidelines** Standard Operating Procedure for managing Temperature Excursions 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	Deputy Clinical Director of Pharmacy	New SOP
	V2.0	29/12/2020	Deputy Clinical Director of Pharmacy	Update, removing the national reporting requirement Addition of the requirement to report in foundry
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) 04/2024 Trust Policy Group – June 2024	
Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)			Trust Management Committee – June 2024	
Date of Procedure/Guidelines issue			July 2024	
Review Date and Frequency			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 managing temperature excursions of COVID-19 Vaccine	
Key words for intranet searching purposes	COVID-19 Vaccine 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) 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 13 Using the COVID-19 Vaccinator Competency Assessment Tool

1.0 Procedure Statement

This Standard Operating Procedure provides the process to document and record competency using 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. Or by the Matron/Training Lead for a ward or department.

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 v1.1	**Title of Procedure/Guidelines** Using the COVID-19 Vaccinator Competency Assessment Tool	**Status:** **Final**		**Author: Deputy Clinical Director of Pharmacy** **Director Sponsor: Chief Medical Officer**
Version / Amendment History	Version	Date	Author	Reason
	v1	30/09/2022	Deputy Clinical Director of Pharmacy	New SOP
	V1.1	23/03/2024	Deputy Clinical Director of Pharmacy	Review and minor update to reference inpatient services oversight.
Intended Recipients: Pharmacy Procurement staff, Designated 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) 04/2024 Trust Policy Group – June 2024			
Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)	Trust Management Committee June 2024			
Date of Procedure/Guidelines issue	July 2024			
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 the assessment of vaccinators	
Key words for intranet searching purposes	COVID-19 Vaccine Vaccination Competency Assessment

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