STANDARD OPERATING PROCEDURES FOR IMMUNISATIONS OF PATIENTS AT HUMBER TEACHING NHS FOUNDATION TRUST GP SURGERIES

Document Reference	SOP18-004
Version Number	1.02
Author/Lead **Job Title**	Marian Opoku-Fofie Deputy Chief Pharmacist
Date Last Reviewed	September 2021
Date of Next Review	October 2024
Consultation:	Drugs and Therapeutics Group
Ratified and Quality Checked by: **General Manager/Clinical Lead/Committee** **Date Ratified:**	Drugs and Therapeutics Group 30 September 2021
Name of Trust Strategy/Policy/Guidelines this SOP refers to	Safe and Secure Handling of Medicines Procedures Immunisation Guidelines

VALIDITY – All local SOPS should be accessed via the intranet

CHANGE RECORD

Version	Date	Change details
1.00	October 2018	New SOP
1.01	December 2018	Addition of Appendix 7, Completing Immunisation and Vaccination e-Learning in ESR
1.02	September 2021	Review and minor changes.

Contents

1. INTRODUCTION

These procedures supersede all previous policies and procedures for the management of the cold chain for vaccines for Humber Teaching NHS Foundation Trust GP surgeries.

These procedures describe the standard operating procedures for the safe and secure handling of vaccines including: Receipt, Storage, Stock Management, Distribution, Administration, Returns and Waste in accordance with the current Trust Safe and Secure Handling of Medicine Procedures (SSHMP) and the Department of Health's 'Green Book'.

2. SCOPE

These procedures must be adhered to by Trust GP surgeries.

3. DUTIES AND RESPONSIBILITIES

The practice manager/clinical lead has overall responsibility for the effective implementation of this standard operating procedure.

The prescriber (GP) must ensure that there is a specific direction of each patient who is to be administered a vaccination by a healthcare assistant.

The prescriber (GP) is responsible for ensuring the vaccination is appropriate for the patient.
The practice nurse/healthcare assistant will be responsible for:

- Practice nurses will offer vaccinations at immunisation clinics and at home for housebound patients.
- Will assemble the vaccinations required for each session in accordance with this protocol, and the Department of Health's Green Book.
- Will adhere to the EasyLog USB Data Temperature Logger guidelines.
- Will be responsible for implementation of and management of the EasyLog USB Data Temperature Loggers.
- Any unused vaccinations refer to 4.8.
- Trust staff carrying out the procedure must be competent in immunisation and have completed the specific training and updates to ensure effectiveness and patient safety.
- Trust staff must ensure they have Trust anaphylaxis equipment with them when administering immunisation and have completed Trust anaphylaxis training.
- Practice nurses will use a Trust Patient Group Direction (PGD) to administer the vaccine. The nurse will be competent in this specific PGD and follow the Trust's PGD policy.
- Healthcare Assistants will follow the Patient Specific Direction (PSD – see the example in Appendix 6) to administer for each patient.
- Before administration of the vaccination, Trust staff will use a checklist to ensure the immunisation is not contraindicated. If it is contraindicated the immunisation must not be given and this must be reported to the prescriber (GP) through SystmOne.
- Consent must be obtained from the patient or their carers. The patient must be given both verbal and written information to help them make an informed decision. Where the patient does not have the capacity to give consent a best interest meeting should be considered.
- Patients should be made aware of any side effects and contraindications.

4. PROCEDURES

This section includes the order process, accepting a delivery, dealing with damaged/unwanted vaccines, stock management, distribution, returns.

4.1. Order Process

The practice manager is responsible for ordering the immunisations required for each session

4.2. Check of Delivery Consignment

Please note: This is an inspection of the outer carton only.

Staff accepting the vaccine delivery consignment must check the following:

- The consignment appears to be in good condition and all boxes are sealed.
- There are no signs of leakage on the packaging.
- Each box delivered is addressed to the surgery accepting the consignment.
- If a consignment is not expected, damaged or the delivery driver has not got identification inform the practice manager immediately.
- The consignment must be transferred immediately into the immunisation refrigerators.
- The consignment must not be unpacked until it has been checked.

4.3. Checking Vaccine Order

- Printed copies of the order confirmation email from MASTA will be given to all nursing staff.

All vaccine deliveries must be checked as follows:

- Open the consignment and remove any paperwork. The consignment must contain a delivery note and or invoice. If a delivery note and invoice is supplied staple together with the invoice on top.
- Check the supplier details and the receiver details on the paperwork.
- Check the paperwork against the order confirmation email to ensure the order received corresponds with the order placed.
- Remove the stock from the delivery box and check the products match the paperwork (ensure the accuracy of the item, e.g. quantity, pack size, form, strength etc.)
- Check stock is in good condition.
- Tick against each line on the invoice/delivery note as the items are checked.
- For each product listed write down the batch number and expiry date on the paperwork (if not already recorded).
- Sign and date the paperwork (if a delivery note and an invoice has been supplied the invoice must be signed and dated) – delivery notes and or invoices must be kept for two years from the date of issue. Refer to section 4.5.4.
- The information must be inputted into the Vaccine Stock Record refer to section 4.5.4.

4.3.1. Discrepancies/Damaged stock

If there is a discrepancy with the order, stock is visibly damaged or the innermost container has been compromised the effected stock must be quarantined awaiting a decision from the practice manager. Refer to section 4.4.

4.4. Quarantining Stock

- Contact the practice manager to alert them of the need to quarantine.
- Segregate the quarantined stock. Quarantine the affected vaccines as follows:
  Orders delivered to the surgery
  - Retain in the box in which the order was delivered.

  Following an immunisation session
  - Retain in the returned vaccine porter.

  Current stock held in immunisation refrigerator
  - Place the quarantined stock in clear plastic bag.
- Complete quarantine stock notice(s) in Appendix 2 and attach to the relevant container or clear plastic bag holding the quarantined stock.
- **Please note**: One quarantine notice must be completed for each product quarantined.
- If the quarantined stock is to be stored in the immunisation refrigerator it must be stored in a clear plastic bag with a quarantine stock notice attached. See Appendix 2.
- Empty clear plastic bags are housed in the clean utility room.

- If the immunisation refrigerator needs to be quarantined attach an Immunisation Refrigerator Quarantine Notice to the refrigerator door. See Appendix 3.
- Practice Manager to take appropriate action and advise the team accordingly.
- Following assessment by Practice Manager any quarantined vaccines that are deemed unsuitable to be returned to stock, will be disposed of in accordance with Trust SSHMP, section 16. Refer to section 4.7.2 regarding stock deemed suitable for use following a temperature excursion.

4.5. Stock Management

4.5.1. Storage of received orders

- Checked stock must be stored in the designated immunisation refrigerator(s).
- All vaccines of the same type must be stored together and in original packaging.
- Vaccines with the shortest expiry dates must be stored so they are selected first.

4.5.2. Stock rotation:

- Vaccines with the shortest expiry dates must be stored so they are selected first.
- Returned vaccines that have been assessed as appropriate for use must be used at the earliest opportunity. These returned vaccines will be identified by a red dot sticker.

4.5.3. Stock checks of the immunisation refrigerators

Stock checks should be carried out when an order is placed and the stock balance confirmed with the Vaccine Stock Record. Any discrepancies must be reported to the Practice Manager.

4.5.4. Completion of Vaccine Stock Record

The Vaccine Stock Record accounts for vaccine activity. The information required can be obtained from the delivery/invoice or the vaccine porter cold chain compliance form (Appendix 1). All records must be completed in a timely manner to ensure a true reflection of stock held.

- Date
- Time
- Name of vaccine
- Batch number
- Expiry date
- Delivery Note and or Invoice number (where applicable)
- Quantity received
- Quantity returned
- Quantity destroyed
- Sign and date the delivery note and or invoice to confirm the information has been inputted in to the Vaccine Stock Record.
- File the paper invoice and or delivery note in the vaccine order folder

4.6. Vaccine Distribution

4.6.1. Collating Immunisation Session Information

The Practice Nurse/Health Care Assistant administering the vaccination will be responsible for completing/updating the patients SystmOne record using the vaccination template.

4.6.2. Vaccine Porter Preparation

- Prior to vaccine porter preparation download each immunisation refrigerator EasyLog data logger and check all temperature readings have remained between 2-8°C.
- Any deviation outside of the recommended temperature range must be reported to the Practice Manager and the immunisation fridge quarantined. An immunisation refrigerator quarantine notice must be applied. Refer to Appendix 3 and Section 4.5.

- If the temperature readings have remained between 2 to 8°C, the vaccine porters can be prepared.
- Calculate the number of vaccine porters and cool packs required for the immunisation session.
- Check each vaccine porter and cool pack for visible damage – damage should be reported to the Practice Manager.
- Select the EasyLog data logger assigned to each specific vaccine porter
- Prepare the Vaccine Porter Cold Chain Compliance form (Appendix 1). Place in the clear window on the outside of the vaccine porter; one Vaccine Porter Cold Chain Compliance Form per porter.

Ensure any special instructions are added to the Vaccine Porter Cold Chain Compliance Form, e.g. use this porter first.

Vaccine Porters 9:

- Add one Medicool 28 cool pack to the bottom of the porter, add one Medicool 28 cool pack to each side of the porter (five packs in total)
- Pack the vaccines in their original packaging into the porter as per manufacturer's instructions.
- Leave enough space at the top of the porter for one further Medicool 28 cool pack (making a total of six cool packs in accordance with manufacturer's guidance) and the lid.
- Start the Easylog data logger and place in the centre of the vaccine porter – update the Vaccine Porter Cold Chain Compliance Form.
- Re-set the digital thermometer and place the glycol vial in the centre of the vaccine porter. The digital thermometer should be placed in the clear window at the front of the vaccine porter.
- Any voids must be filled with bubble wrap.
- Securely fit the lid.
- The outer casing must be fastened in place.
- Vaccine porter must not be stacked.

More information regarding packing Vaccine Porters can be found at
VaccinePorter Carrier Systems

4.7. Immunisation Sessions

4.7.1. Cold chain compliance within immunisation sessions

- Vaccine porters are to be used in numerical order.
- The digital thermometer temperature reading must be checked before administration to ensure that the vaccine porter temperature has remained within the recommended temperature range (2-8◦c). If the temperature has not remained within range the Practice Manager must be notified immediately.
- Immunisation staff are responsible for recording on the Vaccine Porter Cold Chain Compliance Form how many times the vaccine porter has been opened.
- Immunisation staff are responsible for recording the time the Vaccine Porter is emptied on the Vaccine Porter Cold Chain Compliance form, if emptied at the immunisation session.

4.7.2. Broken Cold Chain following Immunisation Session

Vaccines that have been removed from the Vaccine Porter during the Immunisation Session and not used and must be destroyed.

- Record the destruction on a 'Record for the Destruction of Pharmacy Waste' form Appendix 4 and dispose of in accordance with the Pharmaceutical Waste Flowchart section 16 of the SSHMP.

- A Datix must be completed
- Inform the Practice Manager.
- Practice Manager to record on the MASTA website.

4.8. Returned Vaccine Porters and Vaccines Following Immunisation Session

- Vaccine porters must be returned to the GP surgery, immediately following the immunisation session completion.
- Vaccines will be transferred immediately into the refrigerators in the clean utility room, other treatment rooms.
- Remove and complete the Vaccine Porter Cold Chain Compliance form (Appendix 1) for each vaccine porter
- Remove and download the data logger; review the data and inform the Practice Manager immediately if there have been any temperature excursions.
- The EasyLog data logger temperature graph must be printed for each porter and stapled to the relevant Vaccine Porter Cold Chain Compliance form.
- Returned vaccines must remain within the vaccine porter segregated from all other stock, until the EasyLog data logger temperature record has been reviewed by the Practice Manager.
- The Practice Manager will advise appropriate action to be taken.

4.8.1. Vaccine Porter Data Logger Data within Range 2-8°C

- Before vaccines can be returned to stock a visual check must be carried out to ensure that the stock is in good condition i.e. there are no signs of leakage on the packaging.
- A red dot sticker must be applied to all vaccines returned into immunisation stock.
- The returned vaccine should be placed on top of existing stock and used first at the next immunisation session.
- Record how many vaccines are returned to stock from each vaccine porter on the appropriate Vaccine Porter Cold Chain Compliance form.
- Update the vaccine stock record.
- Damaged stock refer to section 4.4.

4.8.2. Vaccine Porter Data Logger Data out of Range below 2°C above 8°C

- The practice manager is responsible for investigating any breach in the cold chain involving storage or administration of vaccines. The Practice Manager must inform Trust Pharmacy and will be responsible for implementing any action to be taken. A Datix must be completed.
- **Vaccine porters returned empty**: Check the exact time the vaccine porter was emptied; refer to the Vaccine Porter Cold Chain Compliance Form. If the temperature excursion has occurred after the vaccine porter was emptied, no further action is needed.
- If the temperature excursion has occurred during the immunisation session or whilst the vaccines are being stored in the vaccine porter the Practice Manager must inform Trust Pharmacy who will advise on appropriate action. Any affected vaccines must be quarantined. Refer to 4.5.
- Trust Pharmacy will instruct upon the safe handling of any vaccines that are approved for return to stock following a temperature excursion.
- Following instruction from Trust Pharmacy any quarantined vaccines that are deemed unsuitable to be returned to stock will be recorded on a ‘Record for the Destruction of Pharmacy Waste’ and dispose of in accordance with the Pharmaceutical Waste Flowchart section 16 of the SSHMP.
- The Practice Manager will inform MASTA of any vaccines that have been destroyed.

4.9. Immunisation Equipment

4.9.1. EasyLog Data Loggers

- When not in use the EasyLog data loggers must be stored within the immunisation refrigerators.
- Data Logger batteries must be changed annually. A message will appear on screen when the battery is running low; the data logger will have an amber flashing light.
- Refer to the data logger user guide
- Data logger batteries are available from Trust Pharmacy, email HNF-TR.pharmacysshm@nhs.net to request new batteries.

4.9.2. Medicool cool packs

- must be chilled for a minimum of 24 hours before use
- must not be stored more than three cool packs high and have 50mm of free air circulation when normalising
- must be stored flat
- must be replaced if they are visibly damaged or fall outside of the manufactures recommended weight.
- must be weighed every three months and the information recorded on the Medicool Weight Record Chart. Refer to Appendix 5
- Medicool 28 (MC034B) manufacturer's weight 600g with a +/-20g allowance Medicool 28 more/less than the +/-20g allowance must be destroyed.
- A visual and squeeze check of each Medicool must be undertaken before use.

4.10. Training

Training will be provided by the Trust's Pharmacy Department. See Appendix 7, Completing Immunisation and Vaccination e-Learning in ESR.

5. REFERENCES

- Safe and Secure Handling of Medicines Procedures
- Immunisation Guidelines
- Immunisation against infectious disease: The Green Book

Appendix 1: Vaccine Porter Cold Chain Compliance Form

Appendix 1

NHS
Humber Teaching
NHS Foundation Trust

Vaccine Porter Cold Chain Compliance Form

Date of Immunisation Session		Location	

Vaccine Porter Number			Vaccine Porter Packed			Date:	Time:
Data Logger Number			Data Logger Started			Date:	Time:
Data Logger Current Status?	Logging / Stopped (Delete as appropriate)	Warning Lights Visible?	Y / N (Circle)	Battery Replaced?	Y / N (Circle)	Date:	Time:
Name of Staff packing Vaccine Porter		Sign:		Print:			

Details of Vaccine (Include Batch) Number and Expiry Date	Quantity Released	Quantity Returned	Comments:

Number of time the vaccine porter is opened during the immunisation session (Record as simple tally e.g 𝍸)	
Vaccine Porter emptied at the session	Time:

Returned Vaccine Porter Information				
Data Logger downloaded. Data Logger temperature graph printed and stapled to the relevant vaccine porter cold chain compliance form.	Yes/No	Time:	Sign:	Print:
Downloaded data logger temperatures within the recommended 2 to 8◦c Range	Yes/No		Sign:	Print
• If the Data Logger readings are not within the recommended 2 to 8◦c range, contact the Practice Manager immediately				
Red Dot applied to authorised returned stock	Sign:		Print:	Comments:
Returned to the vaccine fridge by	Sign:		Print:	Comments:

Practice Manager use only.				
Datix Completed:	Yes/No	Date:	Time:	Datix Web Number

Completed Vaccine Porter Cold Chain Compliance Forms must be kept on the unit for 2 years from the last entry date. All forms must be scanned and stored in;

Appendix 2: Quarantined Stock

Quarantined Stock

Medication quarantined (Name, Form, Strength, Quantity):	
Date:	Time:
Invoice Number:	Delivery Note Number:
Batch Number:	Expiry Date:

Reason for Quarantine:			
Incorrect Stock Delivered	☐	Delivered Stock Damaged	☐
Damaged stock found at stock check	☐	Temperature Excursion	☐
Drug Recall	☐	Other (Please state)	☐

Action Taken:			
Line Manager Contacted: If no state reason:	Yes	☐	No ☐

Signature:

Print Name:

Quarantined stock must not be used unless authorised by the Practice Manager.
(only one medication per sheet)

Quarantined Stock

Medication quarantined (Name, Form, Strength, Quantity):	
Date:	Time:
Invoice Number:	Delivery Note Number:
Batch Number:	Expiry Date:

Reason for Quarantine:			
Incorrect Stock Delivered	☐	Delivered Stock Damaged	☐
Damaged stock found at stock check	☐	Temperature Excursion	☐
Drug Recall	☐	Other (Please state)	☐

Action Taken:			
Line Manager Contacted: If no state reason:	Yes	☐	No ☐

Signature:

Print Name:

Quarantined stock must not be used unless authorised by the Practice Manager.
(only one medication per sheet)

Appendix 3: Immunisation Refrigerator Quarantine Notice

Appendix 4: Record for Destruction of Pharmacy Waste

RECORD FOR DESTRUCTION OF PHARMACY WASTE
(Retain completed sheet on Unit 2 years from date of last entry)
Refer to Disposal of Medicines Section 16, Safe and Secure Handling of Medicine Procedures (SSHMP)

NHS Humber Teaching NHS Foundation Trust

UNIT / TEAM NAME:.....

DATE	PATIENT ID OR STOCK (S)	**DRUG, FORM, AND STRENGTH:** refer to SSHMP 16.10 for disposal of CDs i.e.: - • Schedule 2&3, Midazolam, Temazepam, Tramadol • Medicines handled as Schedule 2&3 :- ○ Potassium chloride concentrate solutions (potassium chloride content equal to or greater than 10%, i.e. 1g in 10ml, in ampoules/vials or greater than 40mmol/L in IV bags) ○ Solutions of potassium hydrogen phosphate and potassium dihydrogen phosphate in ampoules and vials • Schedule 4 part 1: all other benzodiazepines (e.g. Diazepam, Lorazepam etc.), Chlordiazepoxide, Zalepion, Zolpidem , Zopiclone,	Quantity	Non-Hazardous Waste	Hazardous Waste	REASON (See Codes)	SIGNATURES (2 x SIGNATURES REQUIRED)	

CODES:

A= PATIENT'S OWN DRUGS (Brought into Unit)	**G**= DECLINED/WASTED INDIVIDUALLY PREPARED DOSES FROM MEDICINES ROUND. **NOTE**: **PATIENT ID, DRUG, FORM & STRENGTH does not have to be noted. Record as 'Medicine Round Waste' (MRW) + time of medicine round**		
B= WARD STOCK – EXPIRED	**H**=	ENTER SPECIAL MEANING	
C= NON-STOCK MEDS (NSM) / SELF ADMINISTRATION MEDS (SAM) – EXPIRED	**I**=		
D= NSM/SAM – NOT REQUIRED	**J**=		
E= NSM/SAM – NOT TRANSFERRED WITH PATIENT	**K**=		
F= DISCHARGE / LEAVE (TTOs)	**L**=		

RecordPharmacyWasteForm PWR6

Appendix 5: Medicool 28 (MC033B) Weight Record Chart

NHS
Humber Teaching
NHS Foundation Trust

MEDICOOL 28 (MC033B) WEIGHT RECORD CHART

Medicool Number:.....

Date	Weight Recorded (Please refer to notes below)	Signature/ print name:	Comments:

Please Note:

- All Medicool 28 (MC034B) must be weighed every 3 months
- Medicool 28 (MC034B) manufacturers weight 600g with a +/-20g allowance
  Medicool 28 more/less than the +/-20g allowance must be destroyed.
- A visual and squeeze check for damage must be conducted each time the Medicool 28's are weighed.

Appendix 6: Patient Specific Direction (PSD) for Humber Teaching NHS Foundation Trust Surgeries

Patient Specific Direction (PSD) for Humber NHS Foundation Trust GP Surgeries

Name of Patient	Date of Birth		Name of Patient	Date of Birth

I authorise for the above named patients to receive the following vaccination:

Name of Medication:	
Dose	
Frequency	
Site of injection/method of administration	
Additional Instructions/Information	

This can be administrated by the Practice Nurse/Health Care Assistant who is competent and is employed by Humber NHS Foundation Trust

Prescriber Signature .....

Print Name .....

Date .....

Expiry date of this PSD .....

Administration of Vaccination, Batch No, Expiry Date, Dose and site of injection to be recorded on named patients SystmOne record by Practice Nurse/Health Care Assistant upon administration of medication.

Medication administered by:

Signed _____

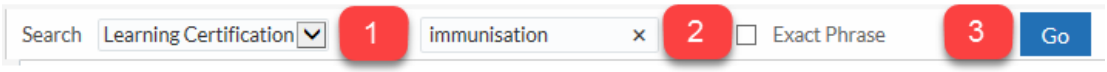
Print Name _____

Appendix 7: Completing Immunisation and Vaccination e-Learning in ESR

To support registered nurses in the trust new to immunisations and vaccinations, a new e-learning certification has been made available in ESR. This user guide illustrates how to access this e-learning using Employee Self-Service (ESS).

Accessing the Certification

After logging into ESR via ESS and selecting the '**MyLearning**' option, you will be taken to your learner homepage. At the top of the screen select '**Learning Certification**' from the Search drop down box, enter '**immunisation**' and click '**Go**'.



From the results select the '**338 Immunisation and Vaccination (e-learning)**' link and then click 'Subscribe' and then 'Finish'.

This will subscribe you to the learning certification and allow you to complete the attached e-learning modules.

Completing the Certification

Upon subscribing to the certification you will be presented with the list of components (courses) to complete as shown below:

Course	Component Status	Enrolment Details	Choose or Enrol in class	Performance Status	Play
000 Communicating with Patients, Parents and Carers	Planned			Not Attempted	
000 Immunology	Planned			Not Attempted	
000 Legal Aspects	Planned			Not Attempted	
000 National Immunisation Policy and Programmes	Planned			Not Attempted	
000 Vaccine Administration	Planned			Not Attempted	
000 Vaccine Storage	Planned			Not Attempted	
000 Vaccine Preventable Diseases	Planned			Not Attempted	

To fully pass the certification you will need to complete all of the e-Learning modules, although you are able to do this in multiple sittings (progress expires after 90 days). If the '**Play**' button is grey and unavailable (as above), you will need to click the yellow '**Enrol**' button first and then click '**Apply**'. This will enable the '**Play**' button.

Please note to be fully compliant for immunisations and vaccinations, you must also have received up-to-date basic life support and anaphylaxis training. You must also receive an annual, classroom-based Immunisation update from the Trust's immunisation co-ordinator.