Cheshire and Wirral Partnership NHS
NHS Foundation Trust

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Immunisation and vaccination policy

Lead executive	Medical Director
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Type of document	Policy
Target audience	All CWP staff
Document purpose	The aim of this policy is to ensure core standards of good practice in immunisation and vaccination in line with Cheshire and Wirral Partnership NHS Foundation Trust (CWP) standards.

Document consultation		
AMH – Wirral	Yes	Business Support Manager (BSM)
AMH – West	Yes	Business Support Manager (BSM)
AMH – East	Yes	Clinical Support Managers (CSMs)
D&A services	Yes	Deputy Service Manager, Clinical Support Manager
CAMHS	Yes	CSM, Modern Matron
LD services	Yes	Senior Nurse - East
CCWC services	Yes	BSM, Head of Therapy
Corporate services	Yes	Compliance manager, Clinical Governance Manager, L&D Manager, Pharmacists, Security Manager, Health & Safety Advisor, Deputy Head of Facilities
Staff side	Yes	Staff side representatives - West
Other –	Yes	Research and Effectiveness Manager, Knowledge Manager, E&D Lead, IPC Team, Health Records Manager, First Aid and Life Support Trainer, MVA Co-ordinator/ Resuscitation Lead

Approving meeting	Patient Safety and Effectiveness Sub Committee	15-Aug-13
Original issue date	Aug-13	
Implementation date	Aug-13	

CWP documents to be read in conjunction with	HR6 IC1 GR29	Mandatory Employee Learning (MEL) policy Trustwide IPC operational policy Waste management policy

Training requirements	No - Training requirements for this policy are in accordance with the CWP Training Needs Analysis (TNA)

Financial resource implications	No

Equality Impact Assessment (EIA)

Initial assessment	**Yes/No**	**Comments**
Does this document affect one group less or more favourably than another on the basis of:		
• Race	No	
• Ethnic origins (including gypsies and travellers)	No	
• Nationality	No	

Initial assessment	Yes/No	Comments
• Gender • Culture • Religion or belief • Sexual orientation including lesbian, gay and bisexual people • Age • Disability - learning disabilities, physical disability, sensory impairment and mental health problems	No No No No No No	
Is there any evidence that some groups are affected differently?	No	
If you have identified potential discrimination, are there any exceptions valid, legal and/or justifiable?		
N/A		
Is the impact of the document likely to be negative? • If so can the impact be avoided? • What alternatives are there to achieving the document without the impact? • Can we reduce the impact by taking different action?	No No No No	
Where an adverse or negative impact on equality group(s) has been identified during the initial screening process a full EIA assessment should be conducted.		

If you have identified a potential discriminatory impact of this procedural document, please refer it to the human resource department together with any suggestions as to the action required to avoid / reduce this impact.

For advice in respect of answering the above questions, please contact the human resource department.

Was a full impact assessment required?	No	
What is the level of impact?	Low	

Document change history

Changes made with rationale and impact on practice
1.

External references

References
1. British National Formulary http://bnf.org/bnf 2. http://www.dh.gov.uk/en/Publichealth/Scientificdevelopmentgeneticsandbioethics/Consent/Consentgeneralinformation/index.htm 3. DH (2006) Immunisation against Infectious Disease London HMSO - Green Book http://www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/dh_4097254 4. Department of Health Records Management NHS Code of Practice Part 2 (2nd Edition) 5. http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_093024.pdf 6. NICE Guidance 160 Feverish illness in children http://www.nice.org.uk/nicemedia/live/14171/63908/63908.pdf 7. NMC Code of Professional Conduct: Standards for Conduct, Performance and Ethics (2006). 8. NICE (2013) Clinical guideline 160 guidance.nice.org.uk/cg160 Feverish illness in children 9. http://www.archive.official-documents.co.uk/document/doh/hinfo/

Monitoring compliance with the processes outlined within this document

Please state how this document will be monitored. If the document is linked to the NHSLA accreditation process, please complete the monitoring section below.	Patient Safety and Effectiveness Sub Committee will be responsible for monitoring the process detailed within this document.

Content

1. Introduction

The aim of this policy is to ensure core standards of good practice in immunisation and vaccination in line with Cheshire and Wirral Partnership NHS Foundation Trust (CWP) standards. The policy has been produced in accordance with the recommendations from Public Health England and the publication 'Immunisation against infection disease' generally known as and for the purposes of this guidance, 'the green book' (DH 2006).

To obtain the most up to date information the 'green book' should be accessed on-line at: https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book

2. Scope

The guidance is for all Provider Services staff who are involved in any way in vaccinations and immunisations. The guidance covers clinicians and non-registered staff such as; named designated persons and deputies assigned to take responsibility for the ordering, delivery, storage and monitoring of vaccines. Staff who carry out vaccinations should be familiar with the procedures to follow in case of needle stick injury.

3. Consent

Mental Capacity Act

When administering immunisations or vaccinations, the immunisers should be familiar with the principles of the Mental Capacity Act (2005). All immunisations must be given with reference to the Mental Capacity Act, ensuring that the five (5) main principals are adhered to:

1. A person must be assumed to have capacity unless it is established that s/he lacks capacity.
2. A person is not to be treated as unable to make a decision unless all practicable steps to help him to do so have been taken without success.
3. A person is not to be treated as unable to make a decision merely because He/she makes an unwise decision.
4. An act done or decision made, under this Act for or on behalf of a person who lacks capacity must be done, or made, in his/her best interests.
5. Before the act is done, or the decision is made, regard must be given to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action (OPSI 2005).

Training on the Mental Capacity Act is provided by the Trust to all employees. Further information on the Mental Capacity act can be downloaded at: www.legislation.gov.uk/ukpga/2005/9/contents.

Consent must be obtained before administering vaccines. Staff should refer to the CWP consent to treatment policy and guidance and the DH 'Immunisation against infection disease's (The Green Book, 2006). All communications with patients should give consideration to those people with communication problems i.e. visual or hearing loss or non-English speakers. Any information provided should be in a format which is understood to ensure compliance.

For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question (this will be the patient or someone with parental responsibility for a patient under the age of 18, someone authorised to do so under a Lasting Power of Attorney (LPA) or someone who has the authority to make treatment decisions as a court appointed deputy). Agreement where the person does not know what the intervention entails is not 'consent'.

Patients retain the right to change their mind, so consent can be withdrawn at any time. Written consent is not a legal requirement but does provide a permanent record and can provide evidence that informed consent took place. Further information on consent is available from the DH.

Staff who are immunising children should be aware of their responsibilities and knowledgeable about the legalities of consent (Frazer competent) https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition

4. Refusal of vaccination

The patient or carer should be informed of the potential consequences of not being vaccinated. Refusal should be documented on the patient's medical record. Information should also be passed to child health as appropriate.

5. Immunisation by healthcare staff

Vaccines are usually administered by health care staff following a Patient Specific Direction (PSD) or a Patient Group Direction (PGD) as defined below.

5.1 Patient Specific Direction

A Patient Specific Direction (PSD) is a written instruction from an independent prescriber i.e. doctor, dentist or non-medical prescriber, for medicines to be supplied or administered to a named patient. This means that the prescriber has assessed the patient for their suitability to be administered the medicines.

5.2 Patient Group Directions (PGD)

Patient Group Directions (PGDs) provide a legal framework for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment i.e. for certain vaccinations. This means that certain registered clinicians may undertake vaccinations, working to an approved PGD, without referring to a prescriber.

Both the registered clinician and their line manager/employer are required to sign the PGD prior to vaccination being administered. The registered clinician should ensure that they have the required training and competencies before signing and agreeing to practice under any PGD and must be able to provide evidence of their training and competence. PGDs do not remove inherent professional obligations or accountability.

5.3 Non registered staff

Within CWP Healthcare assistants or other non-registered clinicians may not give immunisations.

6. Training

Registered health professionals are professionally accountable for their practice. Registered health professionals, **new** to immunisations will be required to undertake the Trust two day training course on immunisations and vaccinations and be assessed as competent by experienced mentors or supervisors.

Staff will be provided with a yearly half day update (usually prior to the influenza immunisation programme) on an annual basis, and will ensure that they meet any specific training requirements listed on specific Patient Group Directions (PGD).

Practitioners who have undergone training and demonstrated competency in medicines administration (usually intramuscular into deltoid muscle) may administer vaccines in accordance with this Trust policy.

Assessment should include a formal medicines administration competency checklist demonstrating attainment against specified clinical competences.

- Recognition and treatment of anaphylaxis and basic life support (Cardio-Pulmonary Resuscitation) training must be completed annually;
- All registered health professionals who undertake immunisations must be familiar and competent with the following:
  - 'Immunisation against Infectious disease' (The Green Book, DH 2006);
  - Trust policies and procedures for immunisations, medicines, management of cardiac arrest and anaphylaxis;

- Product Information Sheets / Summary of Product Characteristics;
- Patient Group Directions (PGD);
- Patient Specific Directions (PSD);
- UK Guidance on Best Practice in Vaccine Administration (Royal College of Nursing 2001) (RCN 2001).

- Public Health England guidance.

Staff providing information on immunisation and vaccination should attend specific training.

7. Vaccine storage, monitoring and distribution

Vaccines are biological substances that may lose their effectiveness quickly if they become too hot or too cold at any time, especially during transportation and storage. The efficacy of vaccines depends on maintaining an unbroken cold chain for the vaccines from the point of manufacture, during transport and storage in a refrigerator until they are used. Incorrect storage of vaccine can be wasteful, costly, reduce vaccine effectiveness and cause vaccine failures. Vaccine should be stored in their original packaging at +2ºC to + 8ºC or in accordance to manufactures recommendations and protected from light, as exposure to ultraviolet light will cause loss of potency. All vaccines are sensitive to some extent to heat and cold. The effectiveness of vaccines cannot be guaranteed unless stored at the correct temperature. Heat speeds up the decline in potency of most vaccines, thus reducing its shelf life. Freezing of vaccines may cause increased reactogenicity and loss of potency for some vaccines. It can also cause cracks in the container leading to contamination of contents.

At every base where vaccines are stored there should be a named, designated nurse should take overall responsibility with a trained person and deputy assigned (1) to take responsibility for:

- Receipt and storage of vaccine;
- Monitoring of fridge temperatures;
- Management of a stock information system which keeps track of orders, expiry dates and running totals of vaccines;
- Maintenance of fridge and thermometer.

This applies to all areas where vaccines are stored. Regular audit (at least annually) of the cold chain should be undertaken.

7.1 The Cold Chain

Maintaining the cold chain ensures vaccines are transported and stored according to the manufacturer's recommended temperature range (+2ºC and + 8ºC) until the point of administration. Attention should be paid to vaccine temperature on receipt, storage, removal from fridges and distribution. Opening the fridge door and the length of time the fridge door is open should be kept to a minimum**.**

7.2 Vaccine fridges

Specialised refrigerators, not ordinary domestic refrigerators, should be used for vaccine storage. The refrigerator must be located in an area with restricted public access. The refrigerator must be dedicated to storing vaccine / pharmaceutical products only. Food, drink and clinical specimens must not be stored in the same refrigerator as vaccines.

All vaccine refrigerators must be lockable or located in a lockable room with no public access without a member of staff. The refrigerator must not be sited near a heat source i.e. in front of a radiator, and should be appropriately ventilated.

The refrigerator plug must be secured to avoid disconnection i.e. wired directly into the socket or labelled to prevent accidentally turning off of the power supply. Ideally the vaccine refrigerator should be fitted with an audio/visual alarm system to alert staff if the unit exceeds the operating temperature range.

To ensure the refrigerator remains within the safe operating temperature (+2°C and +8°C), one thermometer should be used per fridge. This should preferably be integral but if this is not available a calibrated digital external minimum / maximum thermometer may be used. Vaccine stocks should be monitored to avoid over-ordering or stockpiling.

7.3 Fridge maintenance and failures

Vaccines refrigerators are required to undergo annual maintenance checks and any external thermometers should have monthly calibration checks against an external thermometer. These checks should be recorded (2). Maintenance, servicing and calibration records should be kept for the lifetime of the equipment. A record should be maintained of defrosting and cleaning of the vaccine fridge, which should be undertaken as required if ice builds up unless a self -defrosting fridge. When cleaning or defrosting the fridge, vaccines should be stored in an alternative cool storage facility. The temperature of the vaccines should be monitored during this process.

If there is a fridge failure then unless temporary, the vaccines should be removed to an alternative suitable fridge and the temperature monitored.

The designated, trained person in each site should ensure this maintenance takes place and manage and store the records.

7.4 Fridge temperature monitoring and recording

The temperature within the vaccine fridge must be continually monitored with a maximum / minimum thermometer. A daily record log must be kept of the maximum, minimum and the actual temperature of the fridge on each working day. The fridge thermometer must be re-set after each reading is made (example - 2 Vaccine Refrigerator Monitoring Sheet).

A record of the fridge temperature should also be recorded after vaccine stocks are placed in or removed from the fridge. Record the temperature on the log sheet with the reason e.g. removal of stock.

If the fridge temperature exceeds the vaccine safe storage temperature limits (+2° and +8°C) this should be recorded together with the reason for the rise in temperature e.g. removal of stock (3) . If the fridge temperature exceeds the recommended vaccine storage temperature **for more than one hour** the designated staff member should be contacted and arrangements made to transfer the vaccine to a separate cold storage facility if appropriate. If necessary the vaccine should be quarantined. An investigation conducted, incident record completed and reflective learning undertaken (example - 3 process for reporting temperature problems). Temperatures records must be retained.

7.5 Stocking and removing refrigerator items

On delivery of vaccines, staff must check these against the order for discrepancies, leakage or damage before signing for them. Vaccine distributors and manufactures will not accept any vaccine for return once it has left their control. Once checked against the order the vaccine stock should be immediately placed under the required storage conditions.

Vaccines should be stored in their original containers so that brands, batch numbers and expiry date information is easily obtained. Vaccine stocks must be checked regularly and rotated according to expiry date with older stock positioned at the front of the fridge to be used first.

Any out of date stock should be clearly marked, removed from the refrigerator and destroyed in accordance with waste regulations as soon as possible. Vaccines must never be used when past their expiry date. Quarantined stock should be clearly marked and left in the fridge until the decision to waste the stock is made.

The vaccines should be evenly distributed within the refrigerator to allow air to circulate. The refrigerator must not be overfilled. Vaccine stocks should be stored in the main part of the fridge and not in fridge drawers or door or next to the freezer plate.

When stocking / removing items from the refrigerator the door must not be left open for prolonged periods of time as this causes the inside temperature to rise and may activate the refrigerator alarm. The fridge door may have to be opened and closed several times when stocking / removing stock from the fridge to ensure the safe operating temperature is maintained.

It is good practice that certain shelves are designated for different vaccines. A list may be kept on the outside of the fridge to identify where a particular vaccine is stored and therefore minimize the length of time the door is kept open when searching for a vaccine.

If the refrigerator temperature exceeds the manufacturer's advised limits follow 'process of reporting temperature problems' procedure (example 3). A record should be made of the action taken on the vaccine temperature monitoring chart (example - 2).

7.6 Transportation of vaccine

All practitioners should adhere to the Standards of good practice and operating procedures for the storage and transportation of vaccines (6). A validated insulated cool bag/box with the facility for measuring maximum and minimum temperature will be used for transporting vaccines requiring cold storage where vaccines are likely to be returned to stock. Community nurses must use the validated cool bags / box for transportation of vaccines to use in patients' homes. Cool bag / boxes and ice / gel packs should be purchased from a recognised medical/vaccine cool bag / box supplier.

Individual manufacturer's instructions on the use of the cool bag / box should be followed. NO vaccines may then be returned to fridges for re-use if an invalidated box / cool bag has been used.
If any vaccines are destroyed the service lead / senior manager should be made aware as to the type of vaccine the brand, number of vaccines the batch code and the reason why.

Vaccines should be transported in their original packaging. Ice / gel packs must not come into direct contact with the vaccine as this may cause the vaccine to freeze. Some vaccines are more unstable with temperature variations than others.

The time between removing vaccines from cool storage and use and the frequency of opening the cool bag / box to access vaccines should be kept to a minimum. The cold chain must be maintained throughout the movement of vaccines and a log should be kept of all movements and temperatures (example - 4).

On returning vaccines to the main storage fridge, any unused vaccines must be dated as to when they were removed from the fridge and placed at the front of the fridge to ensure they are used first on subsequent immunisation sessions. Vaccines must only be placed back into the refrigerator **once** for potential reuse. If this stock is taken out again and not reused, then the vaccine should be discarded in accordance with waste regulations.

If the storage criteria (+2° to +8°C) have not been met during the immunisation session, vaccine stock should be marked and returned to the appropriate cold chain conditions separating this stock from other vaccines (quarantined). Refer to 3 or seek advice from the vaccine manufacturer whether the stock is suitable for use. To reduce waste, a minimum amount of stock should be removed from the fridge or cool box at each session.

Vaccines should not be destroyed without first seeking advice.

8. General guidance for administration of vaccines

Staff providing the vaccination should ensure that they have the required training and competencies to do so. There should be a clinician trained in the management of anaphylaxis immediately available at all times when vaccines are being administered.

Adrenaline should be available (shock pack) at all times when immunisations are being undertaken. Staff will attend their yearly mandatory training such as Basic life support.

The identity of the vaccine must be checked to ensure the correct product is used in the appropriate way.

The date of immunisation, the brand, name of the vaccine, batch/lot number and expiry date must be recorded on the patient's medical record. When two vaccines are given together, the relevant sites should be recorded to allow for any reactions to be related to the causative vaccine. If the vaccination is administered as part of the national childhood vaccination programme, information on the brand, type of vaccine, batch / lot number and expiry date should be sent to child health in a timely manner. Vaccinators should ensure that:

- There are no contraindications to the vaccines being given;
- The recipient or carer is fully informed about the vaccine;
- The recipient or carer is aware of possible adverse reactions and how to treat them.

8.1 Reconstitution of vaccines

Vaccines should be reconstituted if required following the manufacturer's instructions. Each vaccine should be reconstituted and drawn up when required in order to avoid errors and maintain vaccine efficacy and stability. Vaccines should not be drawn up in advance of an immunisation session.

Before injection, the colour and appearance of all components of the vaccine must be checked with that stated in the manufacturer's package insert. Vaccines must not be mixed in syringes unless specifically licensed for this purpose.

8.2 Cleaning of skin

If the skin is clean, no further cleaning is necessary. Visible dirt may be washed with soap and water. It is not necessary to disinfect the skin. Using alcohol to disinfect the skin increases the risk of deactivating live vaccines. If used there should be sufficient time left for the evaporation of the alcohol.

8.3 Route of administration

Vaccines should be given via the route suggested on the vaccine information sheet. Most vaccines should be given intramuscularly. Individuals with a bleeding disorder should receive their vaccines by deep subcutaneous injection to reduce the risk of bleeding.

The antero-lateral aspect of the thigh or the deltoid area of the upper arm should be used. In infants under one year, the antero-lateral aspect of the thigh is preferred as this provides a large muscle mass into which the vaccines can safely be injected.

8.4 Needle size

For intramuscular and subcutaneous injections, the needle needs to be sufficiently long to ensure that the vaccine is injected into the muscle or deep into subcutaneous tissue. For IM injections a 25mm 23-gauge (blue) or 25-gauge (orange) needle should be used. Only in pre-term or very small infants is a 16mm needle suitable for intramuscular injection. In larger adults, a longer length (e.g. 38mm) may be required, and an individual assessment should be made (see 'green book').

8.5 Injection technique

Intramuscular injections should be given with the needle at a 90º angle to the skin and the skin should be stretched, not bunched. Deep subcutaneous injections should be given with the needle at a 45º angle to the skin and the skin should be bunched, not stretched. It is not necessary to aspirate the syringe after the needle is introduced into the muscle, however if blood does back track into the syringe the vaccine should not be given as it may be in a blood vessel. If this occurs withdraw the needle change the needle for a clean one and give again. For further information see the 'green book'.

Documentation

Accurate documentation should include the immunisation given, the practitioners name who gave the immunisation the site of injection brand, batch number and expiry date

9. Adverse reactions

Recipients of vaccines should be observed for immediate adverse reactions but need not be kept for longer observation. Side effects are rare but some patients may be a little feverish, aching, nauseous or have a headache.

Paracetamol should be recommended for the treatment of fever and pain (see British National Formulary). The area of the vaccination may become red, swollen and painful but if induration occurs then the patient should seek a doctor's opinion. For advice about specific vaccinations see advice given in the 'Green Book', the authorised leaflet included with the vaccine, the Specific Product Characteristics, or the PGD if used.

9.1 Post-immunisation pyrexia in infants

The parent should be advised that if pyrexia develops after childhood immunisation, the infant can be given a dose of paracetamol and, if necessary, a second dose given 4-6 hours later; ibuprofen may be used if paracetamol is unsuitable. The parent should be warned to seek medical advice if the pyrexia persists. For post-immunisation pyrexia in an infant and children, see NICE guidance on managing feverish illness (http://www.nice.org.uk/nicemedia/live/14171/63908/63908.pdf). An oral syringe can be obtained from any pharmacy to give the small volume required.

10. Adverse Reaction Reporting (ADR)

The Medicines and Healthcare products Regulations Agency (MHRA) encourages reporting of suspected adverse drug reactions (ADRs) even if there is uncertainty as to whether the vaccine or drug played a causal role. The Yellow Card scheme should be used for reporting.

Any ADR that is suspected to be linked to an established vaccine should only be reported if it is a serious ADR. For newly licensed vaccines labelled with a black triangle, ALL suspected adverse reactions should be reported.

Any significant ADR that occurs in children should be reported. Yellow cards can be downloaded from the Medicines and Healthcare products Regulatory Agency website (www.mhra.gov.uk) and reports can be submitted electronically (www.yellowcard.gov.uk). Yellow cards are also available in the back of the *British National Formulary (BNF), BNF for Children*, the *Nurse Prescribers formulary*, *Mims for Nurses* as well as the *ABPI Compendium of Data Sheets and summaries of Product Characteristics.*
Any adverse reactions should also be documented in the patient's health record.

11. Management of anaphylaxis

Anaphylaxis is typically rapid and unpredictable with variable severity and clinical features. Adverse reaction is usually immediate. See CWP policy for anaphylaxis treatment. All staff who are involved in the administration of immunisations should have received anaphylaxis training and basic life support. An anaphylaxis kit should be available at any immunisation session.

11.1 Emergency assistance

Ensure there is a telephone to hand and/or another colleague is close within the vicinity that could summon assistance or assist in an emergency. Vaccines should not be administered without immediate access to a shock pack containing adrenaline which must be available. Staff should have undertaken annual updates on anaphylaxis and basic life support. They are also responsible for ensuring their shock packs are in date.

12. Spillage and disposal

Sharps handling and appropriate disposal is vital to prevent the risk of blood borne virus transmission. All staff should comply with the infection control policy and waste management policy.

12.1 Spillage

Vaccine spillages should be dealt with as quickly as possible and gloves should be worn. The spillage should be soaked up with paper towels or other disposable absorbent material taking care to avoid skin puncture from glass or needle. If appropriate and the surface will withstand the use of Hypochlorite the area should be cleaned with 10,000 PPM solution of Hypochlorite if available.

On surfaces where this is not appropriate a soap and water solution should be used and the area left to dry. All gloves, towels etc, should be sent for incineration following the organisations waste management policy.

Spillages onto skin should be washed with soap on water. Splashes into the eye should be rinsed with sterile 0.9% sodium chloride or if not available, water and medical advice sought.

12.2 Disposal of vaccines

Any prepared or partially used vaccines must be destroyed at the end of each session, by placing directly into a yellow lidded 'sharps' disposal container (UN-approved, BS 7320) in accordance with waste regulations. The 'sharps' container should be replaced once it is two-thirds full and should not be accessible to any unauthorised individual.

Appendix 1 - Responsible persons list

Date		Vaccine location	

Named of designated person assigned to take responsibility for the following activities in relation to vaccines at the above site:

Nurse with overall responsibility	

Ordering and tracking	
Ordering	
Deputy	
Receipt and storage of vaccine	
Deputy	
Tracking orders, expiry dates and running totals	
Deputy	

Monitoring	
Monitoring of fridge temperatures	
Deputy	
Fridge and thermometer maintenance checks	
Deputy	
Maintenance check of fridge and thermometer carried out annually	Date:

Appendix 2 - Vaccine refrigerator monitoring sheet

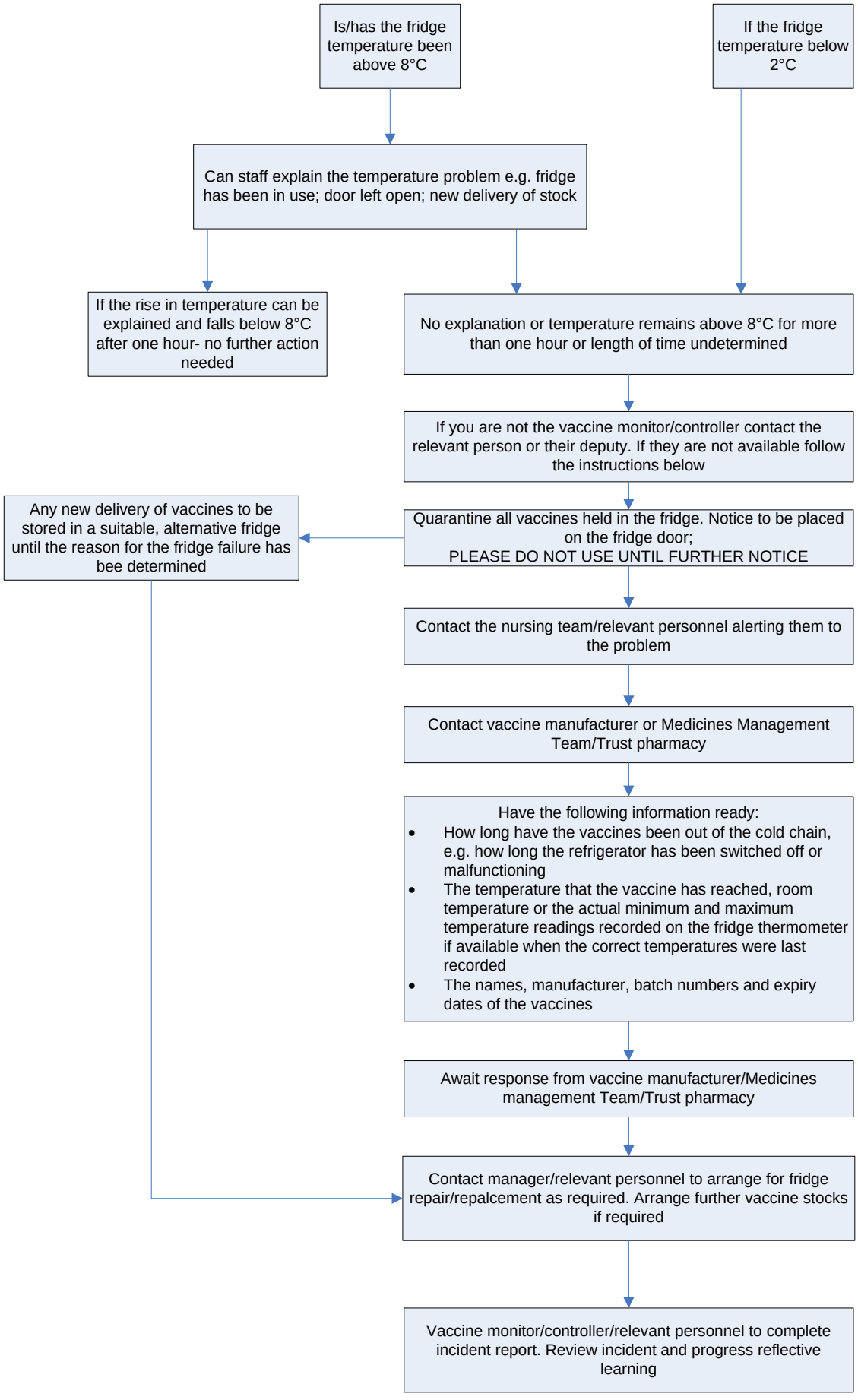
Temperature records must be filed for a minimum of 11 years. A record of the fridge temperature (min-max and actual) should be recorded on each working day. If the fridge temperature falls outside the recommended +2ºC to +8 ºC refer to the organisations process for reporting temperature problems.

Site address inc postcode			
Department		Designated staff	

Photocopy sheet as required and store in the appropriate loose-leaf binder on top of or close by the fridge.

Date and time of reading	Thermometer Reading	Thermometer Reset	Action Taken	Actual Minimum	Maximum & Sign	Print Name	Sign

Appendix 3 - Process for reporting temperature problems



Appendix 4 - Maintaining the Cold Chain for use when transporting vaccines to an immunisation session

A validated cool bag / box must be used for transporting vaccines requiring cold storage. The internal temperature of bags used to transport the vaccine should be kept between +2^{o}C to +8^{o}C. The frozen ice packs should not come in direct contact with the vaccine. The bag should not be overfilled and air spaces kept to a minimum.

Storage site address including postcode			
Type of vaccine			
Batch No		Expiry date	
(Re-packaging reference as appropriate)			
Date and time vaccine removed from vaccine fridge			
No of doses / vials taken		Fridge temperature	
Signed		Print name	
Position		Organisation	

This part of the form should be completed at the delivery site:

Vaccine delivery address including postcode			
Date and time vaccine delivered into fridge			
No of doses/vials received		Stock temperature	
Signed		Print name	
Position		Organisation	

Checks made throughout the session

Date	Time	Thermometer reading	Print name	Sign

Maintaining the cold chain

Returned vaccine stock					
Date and time vaccine delivered into fridge					
Type of vaccine					
Batch No		Expiry date			
(Marked to indicate has been out the fridge - date as appropriate)					
Doses used		Doses wasted		Doses returned to stock	
Stock temperature					

If above 8ºC Action taken			
Signed		Print name	
Position		Organisation	

Appendix 5 - General Principles for the use of vaccine cool bag / box

- A log should be kept of all movements of vaccines;
- Vaccines should be transported in their original packaging;
- Cool blocks / packs must not come into direct contact with the vaccine;
- Cool blocks / packs should be placed in fridge for 24hours *(or see manufacturer's recommendations*) together with the vaccine thermometer prior to use;
- The time between removing vaccines from cool storage and use must be kept to a minimum;
- The frequency of opening the cool box should be kept to a minimum;
- Vaccine stocks should be transported directly to site;
- It is recommended that vaccines are not stored in cool boxes prior to their use for more than 4 hours *(unless the cool box specifically states otherwise - see manufacturer's guidance);*
- It is difficult to keep within the required temperature (+2ºC to +8ºC) when transporting or storing vaccines in a cool bag / box;
- The maximum / minimum temperature should be monitored and recorded at regular intervals.

The following advice may be helpful.

Packing of the cool bag / boxes

1. The cool box/bag should be filled immediately prior to transit.
2. Place the cool blocks / packs on the bottom of the cool bag / box.
3. Cover the cool blocks / packs with the insulating material (foil covered polystyrene sheets / bubble wrap etc).
4. Place the vaccine (original packs) on top of the insulating layer.
5. Place the thermometer / thermometer probe in the centre of the bag / box at this level.
6. Cover the vaccine stock with the insulating material.
7. Place the cool blocks / packs on the top of the insulating material layer.

Repeat 4, 6 and 7 as required. Use insulating material (i.e. bubble wrap) to fill any spaces within the cool bag/ box

Cold Chain

When the cool bag/box is in use and the temperature rises above 8ºC but below 25 ºC, most vaccines will still be viable and the stock may be used at that vaccination session.

If the storage criteria (+2° to +8°C) have not been met during the immunisation session, vaccine stock should be marked (date/time removed/returned) and returned to the appropriate cold chain conditions separating (quarantining) this stock from other vaccines.

Advice should be obtained from the vaccine manufacturer if the stock is suitable for use. Once returned vaccines have been assured for reuse they should be placed at the front of the fridge to ensure they are used first on subsequent immunisation sessions. Vaccines must only be placed back into the refrigerator once for potential reuse. If this stock is taken out again and not reused, then the vaccine should be discarded in accordance with waste regulations.

Vaccination of individuals in their own home

Nurses may be requested to vaccinate a patient on their list in their own home or a care home (i.e. influenza vaccination). If a cool bag/box without a min-max thermometer is used to transport the vaccine this must be taken to the patient's home without delay and nurses should be aware of temperatures during the transport e.g. do not sit the vaccine box in warm areas - next to heaters or in direct sunlight. To reduce waste, a minimum amount of stock should be removed from the fridge or cool box at a time.

Stability Data
If you are in any doubt of vaccine stability advice should always be obtained from the vaccine manufacturer.

Influenza vaccines
As this group of vaccines change at each influenza season, information on the stability of the individual product should be obtained from the manufacturer (see list below).

Medical Information:

Sanofi Pasteur (Revaxis, Pediacel,mmr vAXpro,Repavax,infanrix) medinfo@spmsd.com
Medical Information44 (0)1628 587 693
Wyeth Pharmaceuticals (Prevenar)

GlaxoSmithKline UK –Rotarix, menitorix, priorix
Telephone: (0)800 221 441

Merk Gardasil
Novartis Vaccines -Menjugate
Telephone: +44 (0)1276 694 490
http://www.novartis.com
Medical Information Direct Line: +44 (0)8457 451 500

Appendix 6 - Standards of Good practice and operating procedures for refrigerator monitoring

Standards of good practice

Standards of best practice:

- CWP practice should be in accordance with national policy for ordering, storage, stock control, distribution, transport and disposal of pharmaceutical products and vaccines;
- Procedures in place to alert staff to breaches of the cold-chain before administration;
- Incidents and near misses should be reported via the datix system;
- Review cold chain practices.

	Expected outcome
1.1	Refrigerator temperature readings are recorded daily to identify if pharmaceutical products including vaccines have been stored outside of manufacturers temperature ranges, **before** they are administered to patients
1.2	Refrigerator records are retained for 6 months for pharmaceutical fridges and 12 months for vaccine fridges
1.3	Any pharmaceutical fridge storage incidents and near misses to be recorded on the datix system and procedures reviewed accordingly
1.4	In case of interruption to power supply or out of range fridge temperatures recorded, remedial procedure for dealing with the incident see fridge temperature recording document

Staff training and competencies

Standards of best practice:

- Each vaccine fridge should have a designated person and deputy responsible for the management of pharmaceutical products requiring storage in a refrigerator;
- Designated person responsible for receipt of vaccines and recording the relevant information;
- Fridge monitors taking temperature readings should understand how to read and reset the thermometer and why this is necessary (See 1 for monitoring sheet and 2 or vaccine fridge monitoring procedure;
- Monitoring sheet provides information on the action to take when readings are out of the desired range of +2ºC to +8ºC (see 1, for summary of required action).

	Expected outcome
2.1	A designated person with at least one trained deputy to be identified as vaccine fridge controllers
2.2	The designated person will have received training and be able to demonstrate competency in the needs for: a) Appropriate storage conditions; b) Stock rotation; c) Receipt and management of vaccine stock; d) Monitoring arrangements; e) Action to take in the event of temperature fluctuations and power supply interruptions; f) Maintenance schedule.

Storage conditions

Standards of best practice:

- Specialised refrigerators are available for the storage of pharmaceutical products, and must be used for products requiring storage between +2ºC to +8ºC. Ordinary domestic refrigerators **MUST** not be used for storage of pharmaceutical products **under any circumstances**. Food, drink, and clinical specimens must never be stored in the pharmaceutical refrigerators;
- The majority of pharmaceutical products and all vaccines are Prescription Only Medicines (POMs) and must be stored under locked conditions. Refrigerators must be lockable. Vaccines should never be left unattended at outlying clinics;
- The refrigerator should be set between +2ºC to +8ºC;

- Vaccines should be stored in the original packaging and protected from light;
- Follow the manufacturer's guidance on appropriate storage of medication in refrigerators. Pharmaceutical products should not be stored in the door, bottom drawers or adjacent to the freezer plate or the ice box of the refrigerator. These areas are more likely to show temperature variations outside the recommended range;
- Pharmaceutical products should be stored in neat piles to allow air circulation and should not touch the walls, floor, or roof of the fridge, or shelf above;
- Pharmaceutical products should be placed within the refrigerator so that expiry dates are visible and those with shorter expiry dates are used first. It is important not to assume the most recent deliveries will have a longer expiry period;
- Check expiry dates, highlight any short dated stock and ensure this is used first.

	Expected outcome
3.1	Specialised fridges are used for the storage of pharmaceutical products
3.2	Food, drink and clinical specimens will not be stored in the same refrigerators as pharmaceutical products
3.3	Refrigerator operating temperature will be set between +2ºC and +8ºC
3.4	Vaccines are stored in the original packaging and protected from light
3.5	Pharmaceutical products should not be stores in the door, in the bottom drawers or adjacent to the freezer plate of the refrigerator
3.6	Pharmaceutical products to be neatly stored in the refrigerator
3.7	Pharmaceutical products arranged in the refrigerator so that those with shorter expiry dates are used first.
3.8	Refrigerators must be lockable

Receipt of medication

Standards of best practice:

- The vaccines should be received by the designated fridge controller. On receipt, the delivery should be checked for leakage or damage;
- Pharmaceutical products requiring storage between +2ºC to +8ºC must be refrigerated **immediately on receipt** and must not be left at room temperature for any reason;
- Vaccine types, brand, quantities, batch numbers and expiry dates should be recorded with the date and time at which the vaccines were received.

Monitoring

Standards of best practice:

- Daily monitoring of the refrigerator with recording of maximum, minimum and actual refrigerator temperatures in Degrees Centigrade (ºC) on the chart (see 1);
- Only ONE thermometer per refrigerator to be used preferably integral but if not available a calibrated digital external thermometer can be used;
- Refrigerator records to be retained as advised for refrigerated medication for 6 months but retain vaccine refrigerator records for the life of products stored in therein (usually 1 year);
- See 1 for information on remedial action if temperature is recorded as out of the range +2ºC to +8ºC.

Fridge Maintenance

Standards of best practice

Regular maintenance:

- Electrical tests and thermometer calibration tests must be completed on **ALL** fridges **annually**. Records should include pre-and post- calibration readings and details of any adjustments made or corrections to be applied;
- Records should be readily accessible for easy reference and retained until the next audit;
- Alarms should be checked at least annually for correct functioning;

- All newly purchased should be electrically tested by Estates and temperature in the expected working range having followed the manufacturers guide before any medication can be stored in it. The Trust has a legal duty to ensure that electrical circuits (Installation) and any hardwired appliances are checked in accordance with the electricity at Work Regulations 1989.

Defrosting

- Defrost the pharmaceutical regularly. Ice should not be allowed to build up within the refrigerator, as this reduces effectiveness;
- An alternative monitored refrigerator should be used to store vaccines and other pharmaceutical that require refrigeration during defrosting of the main refrigerator;
- Pharmaceutical products especially vaccines, should only be replaced once the refrigerator has returned to the correct temperature after defrosting.

Procedure in case of interrupted power supply

Standards of best practice:

- Accidental interruption of electricity supply can be prevented by using a switchless socket or placing a cautionary notice on plugs and sockets;
- In case of interruption in power supply, or in the event of a refrigerator failing or breaking down, alternative fridge facilities should be identified for storage of the refrigerated pharmaceutical medication.

Transport of Vaccines

Standards of best practice

Vaccine Transportation

- All vaccine being collected and returned by local immunisers must be transported in an appropriate vaccine porter in order to maintain the vaccine at an acceptable temperature;
- The validated vaccine porters should be packed with 6 ‘medicool’ packs to maintain the internal temperature. The medicool packs should have been refrigerated for a minimum of 24 hours at + 5°C as recommended by the manufacturer;
- Direct contact between vaccines and the medicool packs MUST be avoided to protect the vaccines from any damage. Vaccines should be wrapped in bubble wrap or another suitable insulating material. Any surrounding area should be filled with bubble wrap; this will prevent temperature variations due to shifting of the load within the vaccine porter;
- If the vaccine porters are used correctly, the manufacturer states that the correct temperature range (+2°C to +8°C) should be maintained for approximately 8 hours;
- Vaccines must not be issued to immunisers for transportation in the absence of these arrangements above;
- See 3 for embedded vaccine receipt and return spreadsheet.

Appendix 7 - Medicine fridge daily temperature recording sheet

Ward/Clinic Name:								
Date	Time	Min Temp °C	Max Temp °C	Actual Temp °C	Thermometer Reset (Tick)	Checked by (Signature)	Room Temp °C	Comments

1. Fridge temperature should be a **minimum of +2^{o}C** and a **maximum of +8^{o}C.**
2. After the daily fridge temperature information is recorded, the thermometer **MUST** be reset according to the manufacturers instructions.
3. If Fridge is not working or temperature is out of range (**+2^{o}C** to **+8^{o}C**), please report urgently to the Estates department on Helpline 01244 397737.
4. As a matter of urgency, contact your local clinical pharmacist for advice on fridge contents in the event of temperature being out of the range **+2^{o}C** to **+8^{o}C**.
5. Keep fridge monitoring records for 6 months **(12 months for vaccine fridges).**

Appendix 8 - Temperature recording procedure (Vaccine Fridges – RLDF0505)

1) Check the temperature on the fridge digital display. This screen is best visualised by cupping your hand above the display or putting the light out in the room.

2) Single unit temperature is displayed on the screen as 0**X**°C. (Where **X** is a number). Press the set button ONCE and record the temperature reading in the column "Current Temperature" on the monitoring sheet provided at the location.

3) Once current temperature has been recorded, press the HI/LO button ONCE

4) The digital display will read "HI" and then display the maximum temperature that has been reached. Record this temperature in the "Max Temp" column of the monitoring sheet.

5) This will be followed by "LO" and the minimum temperature will be displayed on the digital screen. Record this temperature in the "Min Temp" column of the monitoring sheet

6) The digital display screen will then return to the normal operating display showing the preset fridge temperature

7) If the displayed "HI/LO" temperatures are missed on attempting to record, they can be viewed again by pressing the HI/LO button ONCE when the display screen has returned to the preset fridge temperature.

8) Once the current and "HI/LO" temperatures have been recorded, press and hold down the HI/LO button for 10 seconds then release it.

9) The operation in No. 8 resets the thermometer facilitating an accurate reading of Hi/LO for the next maximum and minimum temperatures to be recorded.

NOTE: If the fridge door has been opened for an extended period i.e. vaccines being taken out or going in and out of the fridge regularly, do NOT perform the reset procedure. Close the fridge and leave for 30 minutes before undertaking the maximum/minimum temperature reset procedure.

Appendix 9 - Vaccine receipt and return forms

Seasonal flu 201__ - Vaccine audit trail

Vaccinator name		Locality	☐ Wirral ☐ West ☐ East
Date vaccine removed		Number of vaccine taken	

A) Administered vaccine				
No	Names	DOB	Department	Batch Number / Expiry Date
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				

Total given	

B) Returned vaccine	Number
Total returned	

C) Discarded vaccine	Number
Total discarded	

Total vaccine accounted for:	

Signed		Date	

Return of consent forms

Return of Consent Forms to OHD	
Date of Clinic	
Immuniser	
Numbers of consent forms returned	
Vaccine Batch Number(s):	

Return of Consent Forms to OHD	
Date of Clinic	
Immuniser	
Numbers of consent forms returned	
Vaccine Batch Number(s):	