

Standard Operating Procedure For: Safe Handling of Vaccines

Name of Discipline and Clinic : PCT Wide	
Objectives	To ensure vaccines are stored in accordance with manufacturers' recommended temperatures and conditions, in order to ensure that their potency is maintained.
Scope	The purpose of this document is to inform all PCT staff and primary care contractors of the correct procedure for the safe handling of vaccines
Target Group (Staff who are authorised to follow standard operating procedure)	All PCT employed staff and primary care contractors, who handle vaccines
Cross reference related policies	Safe Handling and Administration of Medicines Policy NHS Wirral
Evidence to support procedure	Immunisation Against Infectious Disease. Chapter 3 Storage, Distribution and Disposal of Vaccines. <i>Department of Health August 2006</i>

Procedure		
Activity	Rationale	Responsibility
1. Staff Training		
1.1 A suitably trained person and at least one deputy must be nominated for each clinic area to be responsible for the receipt, safe storage of vaccines and recording of refrigerator temperatures	The procedure will be adhered to and records kept up to date	Department / Practice Manager
1.2 The temperatures recorded must be audited regularly at least annually	The procedure will be adhered to	Department / Practice Manager
2. Receipt of Vaccines		
2.1 On receipt of vaccines, check the vaccines against the order for leakage, damage, expiry date and discrepancies, before signing for them	The pharmaceutical distributor will not accept any returned vaccines once they have left their control	Nominated staff member
2.2 Vaccines must be refrigerated immediately on receipt and not left out at room temperature	To maintain cold chain	Nominated staff member
2.3 Vaccine type, brand, quantity, batch number and expiry date must be recorded together with the date and time received	To maintain an audit trail	Nominated staff member

Standard Operating Procedure For: Safe Handling of Vaccines

3 Maintenance of Correct Storage Conditions		
3.1 Manufacturers' recommendations on storage must be adhered to. Vaccines must be kept in their original containers issued by the manufacturer and stored between +2 to +8 °C	The potency of vaccines can only be guaranteed if manufacturer's recommended storage conditions are maintained.	Nominated staff member
3.2 A maximum / minimum thermometer must be used in refrigerators, where vaccines are stored. The thermometers must be reset and placed according to manufacturers' guidance. Resets should be documented daily on all working days.	To ensure the thermometer is recording correct temperatures	Nominated staff member
3.3 The calibration of the thermometer must be checked annually and the record of this check must be kept at least until the next audit	To ensure the thermometer is recording correct temperatures	Department / Practice Manager
3.4 Maximum and minimum temperatures reached within the refrigerator must be recorded each working day.	Extremes of temperature will be noted.	Nominated staff member
3.5 In the event of temperatures going outside the recommended range, contact the Medicine Management Team at Old Market House (tel 643 5338) for advice as to whether the vaccines are fit for use. Do not administer any vaccines until you have received confirmation. Document any advice given for audit purposes.	A Pharmacist will advise whether the vaccines are fit for use.	Immuniser or Department / Practice Manager
3.6 Vaccines must never be kept below 0 degrees centigrade. Any vaccines exposed to these temperatures must be discarded.	Freezing causes significant deterioration of the vaccine rendering it useless and may break down the container.	Nominated staff member in conjunction with the Immuniser or Department/ Practice Manager
3.7 Vaccines must be stored in the main body of the refrigerator, allowing air to circulate around the packages and ensuring there is no obstruction to the refrigerator fan. Vaccines must not be stored in the door of the refrigerator or in the bottom drawers or adjacent to the freezer plate.	Storage in the main body of the refrigerator will minimise any variations in storage temperatures	Nominated staff member
3.8 Vaccines must be protected from light	Vaccines are very sensitive to strong light and exposure will cause loss of potency	Nominated staff member
3.9 Domestic refrigerators are not designed for storage of vaccines and must not be used.	Medicine fridges ensure the reliable	Department / Practice

Standard Operating Procedure For: Safe Handling of Vaccines
--

	maintenance of temperature	Manager
4 Maintenance of vaccine refrigerators		
4.1 Vaccine refrigerators must be defrosted regularly and a record maintained of when the fridge was defrosted	Ice should not be allowed to build up as this reduces the effectiveness of the refrigerator	Nominated staff member
4.2 Vaccines must be transferred to an alternative drug refrigerator or stored in an approved cool box with appropriate monitoring	Vaccines will be maintained at the correct temperature.	Nominated staff member
4.3 Vaccine refrigerators must not be situated near a radiator or other heat source. They must also be appropriately ventilated	Sources of heat or inappropriate ventilation could alter the effectiveness of the refrigerator	Nominated staff member
4.4 Fixed spur wiring should be fitted for vaccine fridges. If this is not practical, refrigerator plugs and sockets must be covered with tape which reads "DRUG REFRIGERATOR - DO NOT SWITCH OFF"	Refrigerators will not be unplugged accidentally.	Nominated staff member
4.5 Refrigerators used for vaccine storage should be lockable and used exclusively for medicines.	Vaccines are medicines therefore; access should be limited to authorised staff.	Nominated staff member
4.6 The door of the refrigerator must not be opened unnecessarily and should not be left open any longer than absolutely necessary.	This will avoid affecting the effectiveness of the refrigerator	Nominated staff member
4.7 Arrangements must be in place for back up facilities in the event of the refrigerator failing or breaking down. In unforeseen circumstances when alternative storage arrangements are needed urgently, contact the Professional Development Nurses for Primary Care (tel 643 5454 or 643 5318)	Vaccines to be maintained at the correct temperature	Department / Practice Manager
5. Ordering and Monitoring of stock		
5.1 Vaccines should be ordered by the designated person(s)	To avoid stockpiling or over ordering	Nominated staff member
5.2 Care must be taken to avoid over ordering or stock piling vaccines. No more than 2-4 weeks stock should be maintained.	Excess stock could lead to: increased cost of replacement stock, an increased risk of out of date vaccines, poor air	Nominated staff member

Standard Operating Procedure For: Safe Handling of Vaccines

	flow of over packed fridge, potential freezing and delays in the introduction of new stock	
5.3 Vaccine stocks must be placed within the fridge to ensure vaccines with shorter dates are used first, (i.e. stock rotate). Regular weekly checks must be made to remove time expired vaccines.	Expired vaccines are not used.	Nominated staff member
6 Disposal of unused vaccine		
6.1 All reconstituted vaccines and opened single and multi-dose vials must be used within the period recommended by the manufacturer and disposed of at the end of a session	To ensure vaccines are used within the terms of their product licenses.	Immuniser
6.2 Expired and partly used vaccines must be disposed of in a bin for incineration, together with used ampoules and vials. The outer cardboard packaging should be removed prior to disposal.	Incineration is the recommended method of disposal for all vaccines.	Immuniser
7. Batch number and expiry date		
7.1 The batch number of the vaccines, the manufacturer used and the expiry date must be recorded on whatever system is in place.	The vaccine may be traced in the event of an adverse reaction.	Immuniser
8 Vaccines removed from the refrigerator for use		
8.1 Vaccines must only be removed from the refrigerator immediately prior to immunisation sessions. Only one box should be removed at a time.	To reduce the time vaccines are out of the refrigerator	Immuniser
8.2 All unused vaccines which have been out of the refrigerator must be marked with a cross and dated and then replaced immediately in the refrigerator, or appropriately destroyed, if the vaccine has been exposed to a higher than average room temperature or a long clinic session.	Re-warming and re-cooling of vaccines may make them unsafe for use.	Immuniser
8.3 Vaccines that have been marked with a cross and dated must be used at the next immunisation session or appropriately destroyed	This will prevent repeated exposure to room temperature.	Immuniser
9. Vaccine spillage		
9.1 Vaccine spillages must be cleared up in accordance with any advice given in the Control of Substances Hazardous to Health (COSHH) data sheets. Spillages must be cleared quickly whilst wearing gloves, mop up excess with paper towels, avoiding skin puncture from glass or needles and discard soiled paper towels, gloves and vials in a bin for incineration. Clean surface with Titan Sanitizer powder. Splashes on the skin must be washed with soap and water. Eyes must be washed	Some vaccines are live and may be a potential source of infection. All vaccines are chemicals which need to be cleared up appropriately.	Immuniser

Standard Operating Procedure For: Safe Handling of Vaccines

with copious amounts of 0.9% sodium chloride and medical advice sought		
10. Use of Insulated Cool Boxes		
10.1 Domestic cool boxes should not be used to distribute, or transport vaccines. Validated cool boxes should be used. It is strongly recommended that the cool box is monitored with a maximum minimum thermometer.	Vaccines need to be maintained at +2 to +8 °C	Immuniser
10.2 If ice packs are used, they must be obtained from a recognised medical supplier and the vaccines kept in their original containers and wrapped in bubble-wrap (or a similar insulating material)	This prevents direct contact with the ice pack and therefore prevents the vaccines freezing and being rendered useless	Immuniser
10.3 Place vaccines in cool box in accordance with the manufacturer's instructions		Immuniser
10.4 Vaccines must not be returned to stock after being stored in a cool box unless the immuniser is certain that the vaccines were maintained at temperatures between +2 and +8°C. Alternatively a pharmacist from the Medicine Management Team must be contacted if there is any doubt as to whether vaccines are fit for use. Any advice given must be documented for audit purposes	Any time vaccines are out of the fridge is accumulative. Vaccines returned to the fridge may lose their potency.	Immuniser

Training	
Continuing education & training	Training on Safe Handling of Vaccines Training on How to Use Maximum/ Minimum Thermometer
Risk Assessments	Vaccines are biological substances that may lose their effectiveness quickly if they become too hot or too cold at any time, especially during transport and storage.

Organisation	Wirral PCT
Department (If applicable)	PCT Wide

