3

Storage, distribution and disposal of vaccines

Introduction

Vaccines are both sensitive biological substances and Prescription-Only-Medicines (POMs). This chapter outlines:

- storage requirements for vaccines
- ways of obtaining centrally purchased vaccines
- restrictions on the use of centrally purchased vaccines
- recommendations for stock management
- handling spillages, and
- safe disposal of expired or damaged vaccines.

Vaccines may lose their effectiveness if they become too hot or too cold at any time. Vaccines naturally biodegrade over time, and storage outside of the recommended temperature range – including during transport – may speed up loss of potency, which cannot be reversed. This may result in the failure of the vaccine to create the desired immune response and consequently provide poor protection. Inappropriate storage and transport also results in wastage and unnecessary costs to the NHS.

Anyone handling vaccines should follow appropriate policies to ensure cold chain compliance. The guidance in this chapter should be used to define local policies, including patient group directions (PGDs) (see Chapter 5), and should be read in conjunction with the individual summaries of product characteristics (SPCs) that are supplied by the manufacturers of the vaccines.

Storage requirements are described in SPCs. Vaccines that have not been transported or stored accordingly are no longer within the terms of the marketing authorisation (product licence) and should not be used without a risk assessment based on a thorough understanding of the likely impact of the temperature variation on the vaccine. Any use of vaccines that have deviated from recommended storage or transportation conditions is the responsibility of the user. For specific guidance around considerations of when vaccines

may still be used, see 'Refrigerator failure or disruption of the cold chain' – page 30). Guidance on how to manage a situation where vaccines that have not been stored correctly have already been administered has been produced by the HPA (http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1267551139589).

Policies and procedures in primary care and immunisation clinics

Commissioner and provider organisations responsible for the delivery of vaccination programmes in England and equivalent bodies in Scotland, Wales and Northern Ireland should ensure that local practice is in accordance with national policy and best practice guidelines.

The Department of Health provides a protocol that covers the minimum standards expected of professionals responsible for vaccination. The protocol applies to all staff involved in immunisation, and covers:

- ordering and delivery
- storage
- auditing and monitoring of stock, including checking expiry dates
- maintenance of the cold chain, including frequent and regular monitoring of fridge performance, and
- incident reporting.

The protocol can be accessed at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_120010

Guidance on vaccine storage and handling is also available for NHS Boards in Scotland is at www.hps.scot.nhs.uk/Search/guidedetail.aspx?id=45674

Guidance on vaccine storage and handling is available in Wales from Public Health Wales at www.publichealthwales.org/vaccine-handling-and-storage

In Northern Ireland, guidance for general medical practices on the maintenance of vaccine cold chain is available at www.hscboard.hscni.net/medicinesmanagement/Prescribing%20Guidance/

Named individuals and legal authority to order vaccines

In organisations such as GP surgeries or community health service providers, at least two individuals need to be nominated, one from the nursing team and one from the administration/management team. These people will be responsible for ordering, receipt and care of vaccines. They should ensure vaccines are stored in a refrigerator promptly after delivery and that there is maintenance of the cold chain at all stages. They should understand the need for stock control and careful stock rotation (using those vaccines with the shortest expiry dates first). They will be responsible for ensuring there is regular recording throughout the cold chain and that damaged or out of date vaccines and vaccine related healthcare waste are disposed of appropriately.

Staff who order vaccines should ensure they meet all necessary legal requirements for the subsequent possession of vaccines, which are prescription-only medicines (POMs). This will be covered when they are acting on behalf of a registered medical practitioner with a licence to practice or because the use of the vaccine is authorised through a patient group direction (see Chapter 5).

Ordering stock

Vaccine stocks should be monitored regularly by the nominated staff members to avoid shortages, under or over-ordering or stockpiling (see monitoring and management of stock). Any other individual administering vaccines should also contribute to the monitoring in accordance with the appropriate national protocol (see above).

Vaccination providers should have no more than two to four weeks' supply of vaccines at any time. This will be sufficient for routine provision. Best practice is to order small quantities on a regular, scheduled basis. Ordering should be done in sufficient time to ensure that there is always an adequate supply for clinics.

Excess stock can:

- increase the risk of administering an out-of-date vaccine
- increase wastage and the cost of disposal
- increase the dangers of over-packed refrigerators, leading to poor air flow and potential freezing of stock (especially near the fridge walls)

- prolong the use of vaccines no longer supplied and/or delay the introduction of new vaccines potentially leading to inappropriate mixed schedules
- increase the cost of replacement of stocks if the refrigerator fails
- reduce the space in clinic refrigerators available for periods of high demand, such as the autumn, when flu immunisation takes place.

Care must be taken in ordering vaccines. Some vaccines are packaged in multiple quantities or multi-dose vials. Over-ordering can result in wastage and unnecessary costs to vaccination providers and the NHS.

Ordering centrally purchased vaccines in England

In England, vaccines for the routine immunisation programmes are ordered and delivered from a specialist pharmaceutical distribution company via the Department of Health's ImmForm website www.immform.dh.gov.uk (see Chapter 11 and ImmForm helpsheet 13 immunisation.dh.gov.uk/immform-helpsheets).

To register for an ImmForm account, please register online at www.immform.dh.gov.uk/registration.

You will need to provide:

- NHS organisation code (e.g. GP practice code)
- the distributor account number(s)
- name, email and phone details (of the key individual responsible for placing vaccine orders)

For further information and helpsheets on how to use ImmForm, please see immunisation.dh.gov.uk/immform-helpsheets

Ordering centrally purchased vaccines in Scotland

In Scotland, vaccines are ordered by the vaccine holding centres (VHCs) in each NHS board for onward distribution as required. Orders are placed by the VHCs using ImmForm.

Ordering centrally purchased vaccines in Wales

In Wales, vaccines for the routine immunisation programme are also ordered through ImmForm, however, there are different storage arrangements in North and South Wales. In South Wales, vaccines are stored and distributed by health

board pharmacies whilst in North Wales vaccines are distributed directly to GP practices and health board pharmacies.

Ordering centrally purchased vaccines in Northern Ireland

In Northern Ireland, vaccines for the routine immunisation programmes are ordered from a specialist pharmaceutical distribution company by local health and social care (HSC) trust pharmacy departments for onward distribution as required.

Centrally purchased influenza vaccines can be ordered directly by GP practices and hospitals from a specialist distribution company.

Ordering immunglobulins

Please refer to the specific disease chapter for details on how to order immunoglobulin.

Approved uses of centrally purchased vaccines and immunoglobulins

The Department of Health (England) buys vaccines on behalf of the NHS for use in routine national immunisation programmes. This central purchasing allows the UK to negotiate better prices with manufacturers, enabling the introduction and maintenance of vaccine programmes that may otherwise be unaffordable or available to fewer patient groups. Specialist immunoglobulins and antitoxins are also purchased for post-exposure prophylaxis and/or treatment of rare infections. Other vaccines are ordered directly from the manufacturer or through pharmacies and wholesalers. Details of manufacturers are shown throughout this book, at the end of each chapter.

Centrally purchased vaccines should only be used for purposes approved by the Department of Health and the devolved administrations. Healthcare professionals should ensure they are using appropriately sourced vaccines for the particular clinical circumstances. Using centrally purchased vaccines for incorrect purposes could prevent NHS patients who require immunisation from being able to access it. If centrally purchased vaccines are knowingly used for non-approved circumstances, particularly private health services, this may also be considered fraudulent.

Centrally purchased vaccines **can** be used for:

- **the national routine immunisation programmes**, including universal and targeted programmes, as specified in Chapter 11.
- **catch-up vaccination** of older children and adults to complete their immunisations as part of the routine immunisation programme, including people coming to live in the UK. This includes both national catch-up campaigns and opportunistic catch-up of individual patients, in accordance with recommendations in Chapter 11.
  It is good practice for general practice teams to review patients' records on a regular basis to identify patients with incomplete immunisation courses. These patients should be offered catch-up vaccinations. Opportunistic catch-up also includes ensuring tetanus protection is up to date following wounds (see Chapter 30). GPs should use centrally purchased stock in conjunction with clinical records. For hospitals offering vaccination against tetanus for patients with uncertain immunisation histories, stocks of tetanus-containing vaccine should be obtained through other sources, such as the DH Commercial Medicines Unit hospital framework agreement in England.

- **pre and post exposure prophylaxis of rabies** (authorised or issued by the HPA or PHE following risk assessment), **and tetanus**.

Centrally purchased specialist immunoglobulins and antitoxins can be used for:

- **post exposure prophylaxis of a limited range of infections (measles, mumps, rubella, hepatitis A, hepatitis B, varicella-zoster, polio, rabies)** (authorised or issued by the HPA or PHE following risk assessment). http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Immunoglobulin/
- **treatment of rare infections (diphtheria, botulism).**

Centrally purchased products **can not** be used for:

- **clinical indications or patient groups not described above.** Centrally purchased vaccines can only be used in the situations described above. If the patient is not in one of the clinically indicated groups listed for the vaccine, but the clinician believes it should be given as it would be beneficial for the patient, then it should instead be ordered from pharmacies, wholesalers or manufacturers, or prescribed.

- **occupational health immunisations.** It is the responsibility of the employer to fund the purchase and administration of vaccines for occupational health purposes. Vaccines should be purchased from manufacturers, pharmacies or wholesalers. BCG and Tuberculin Purifed Protein Derivative (PPD) for occupational health can be purchased through DH/ImmForm using a private account.
  The exceptions are anthrax vaccine and rabies vaccine, which can be given for occupational health use from centrally purchased stock. See Chapter 13 Anthrax and Chapter 27 Rabies for details of how to obtain central stock.
  Centrally purchased vaccines can be used to 'catch-up' routine and targeted immunisation courses if incomplete vaccination histories are identified when patients attend for occupational health screening.
- **travel immunisations.** These should be purchased privately from the manufacturers, pharmacies or wholesalers. This includes vaccines which are offered free on the NHS (cholera, hepatitis A, polio and typhoid) which should be purchased by the GP practice, who can claim reimbursement.
  Centrally purchased vaccines can be used to 'catch-up' routine and targeted immunisation courses if incomplete vaccination histories are identified when patients attend for travel vaccination.
- **national outbreaks and health protection incidents,** such as influenza pandemics, for population groups defined by the DH, Health Protection Agency (HPA), Public Health England (PHE), Health Protection Scotland, Public Health Wales, the Northern Irish Public Health Agency or the devolved administrations. However, if stock is unavailable from the manufacturer, central stock may be available to cover outbreaks, but will need to be paid for.

BCG for travel or occupational health

BCG for travel or occupational health use is not available directly from the manufacturer and should be purchased through ImmForm using a private account.

A limited exception to the restriction on the use of centrally purchased vaccine is made for BCG to reduce vaccine wastage of the multi-pack, multi-dose vials. Providers who infrequently provide BCG for travel or occupational health but hold centrally-purchased stock can use this for travel or occupational vaccinations. This usage should not be a significant proportion of BCG immunisations offered; if it is, then private stock should be ordered.

Centrally purchased BCG should not be charged to the patient/employer or claimed from the commissioning organisation, though fees for administration may be chargeable/claimable.

To apply for a private ImmForm account, healthcare providers can contact the ImmForm helpdesk at ImmForm@dh.gsi.gov.uk or 0844 376 0040. They will need to have their distributor account number available (currently Movianto) if an account already exists. For further information on ImmForm, please see www.dh.gov.uk/en/Publichealth/Immunisation/immform/index.htm

What if centrally purchased stock has been used for an unauthorised purpose?

If centrally purchased stock is used for a purpose not authorised by the Department of Health, then it should be replaced by privately purchasing the equivalent amount of stock, and this replacement stock made available for approved uses, such as the routine immunisations programme. Failure to do this may constitute fraud or theft. Vaccine misuse should be referred to the NHS Counter Fraud Service or equivalent in devolved administrations. This does not apply to vaccine used before 12 March 2013 when this update was released.

Receipt of vaccines

On receipt of vaccines, staff should check them against the order for discrepancies and leakage or damage before accepting and signing for them. Pharmaceutical distributors and manufacturers will not accept any vaccine for return once it has left their control.

Vaccines must be refrigerated immediately and must not be left at room temperature.

The receipt of vaccines should be recorded on a stock inventory (see monitoring and management of stock). It is the responsibility of the named individuals to ensure there is adequate recording of stock ordering and receipt of vaccines.

Monitoring and management of stock

The nominated persons are responsible for ensuring there is good stock management and monitoring of stock. Any system should:

- keep track of orders
- keep track of expiry dates, and
- keep a running total of vaccines, including wastage.

While more sophisticated stock information systems are available, as a minimum, a paper-based record or simple spreadsheets could be used for stock management and monitoring. Stock information systems are most effective when updated immediately upon ordering and receipt of vaccines and at the end of clinical sessions where vaccines have been administered. Vaccine stock should be checked and records updated at least every month.

Expired vaccines

Any out-of-date stock should be clearly labelled, removed from the refrigerator immediately and disposed of according to local policies.

Vaccines must never be used past their expiry date. If this does occur, it should be reported to the relevant provider or commissioning organisation immediately, using the local untoward incident reporting procedure. Expert advice should be sought – it is often necessary to re-administer the vaccine dose. The local health protection team or immunisation lead will be able to provide or direct to the relevant expert advice. Occasionally, MHRA may grant an extension to an expiry date on the product. In this instance, a letter from the manufacturer or supplier should be sent or accompany the product to indicate that the expiry date has been extended – stock accompanied by such literature should not be destroyed.

Damaged vaccines

Where the vial or syringe containing the vaccine, diluent or the immunoglobulin is damaged or not intact, the vaccine should not be used. These should be removed from use immediately, labelled as damaged and either disposed of according to the local policy or reported as a product defect.

Importance of the cold chain

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 (Figure 3.1). Maintaining the cold chain ensures that vaccines are transported and stored according to the manufacturer's recommended temperature range of +2˚C to +8˚C until the point of administration.

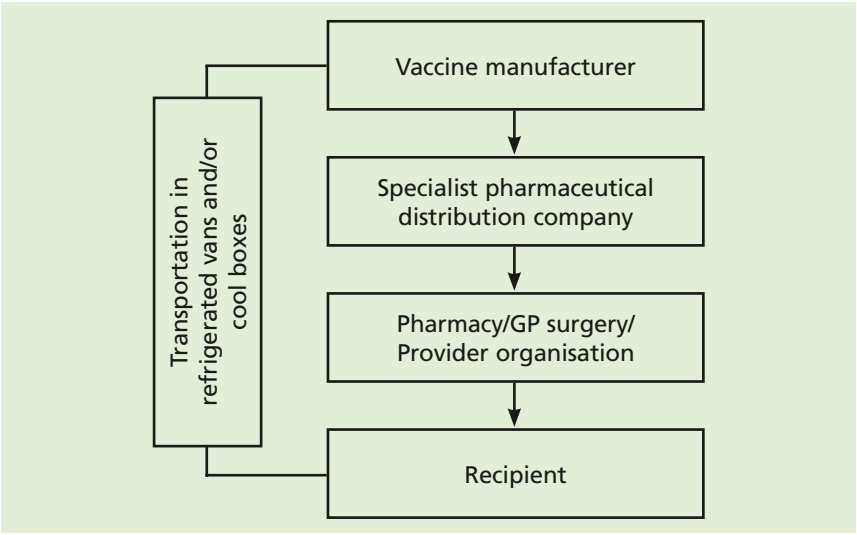

Figure 3.1 A typical cold chain system for vaccines

Vaccines must **never** be frozen. This causes deterioration of vaccines and may give rise to a loss of potency and an increase in reactogenicity by:

- irreversibly denaturing the proteins in the vaccine
- causing the emulsions in the vaccines to become unstable
- producing hairline cracks in the ampoule/vial/pre-filled syringe, potentially contaminating the contents. The glass spicules (small sharp pointed fragments) produced may also cause serious local adverse reactions.

Storage of vaccines and immunoglobulins

Storage of vaccines

Vaccine effectiveness can not be guaranteed unless the vaccine has been stored correctly. Vaccines should be stored in the original packaging, retaining batch numbers and expiry dates. Vaccines should be stored according to the manufacturer's summary of product characteristics (SPC) – usually at +2˚C to +8˚C and protected from light. Prolonged exposure to ultraviolet light will cause loss of potency. Within the refrigerator, sufficient space around the vaccine packages should be left for air to circulate. Vaccines should be kept away from the side and back walls of the refrigerator; otherwise the vaccines may freeze rendering them inactive and unusable.

Examples of good practice include:

- aiming for +5°C, the midpoint in the +2°C to +8°C range
- designating areas within the refrigerator for different vaccines so that all staff know where specific vaccines are stored. Glass doors or labels on the outside of fridges can reduce the time the door needs to be open, and
- rotating vaccine stocks within the refrigerator so that those with shorter expiry dates are at the front and used first

Storage of reconstituted vaccines

For some vaccines, there is a need to reconstitute the vaccine using a diluent. Storage requirements for the reconstituted vaccines vary and the SPC or packaging insert should be consulted to identify the specific requirements for these vaccines. Generally, it is not good practice to reconstitute vaccines in advance, although in some cases, such as using multi-dose vials, it can be considered. If a vaccine is reconstituted but not used immediately, it is good practice to label the vaccine with date and time of reconstitution and the initials of the person reconstituting the vaccine. These reconstituted vaccines should be stored in line with the guidance given in the SPC or packaging insert and any local policies.

Storage of immunoglobulins

Immunoglobulins should be stored in the original packaging, retaining batch numbers and expiry dates. Immunoglobulins should be stored at +2˚C to +8˚C and protected from light. Although these products have a tolerance to ambient temperatures (up to 25˚C) for up to one week, they should be refrigerated immediately on receipt. They can be distributed in sturdy packaging outside the cold chain to an end-user (such as the GP or hospital caring for a patient). They should not be frozen. See Chapters 17 (Hepatitis A), 18 (Hepatitis B), 21 (Measles), 27 Rabies and 34 (Varicella) for specific information about administering immunoglobulins.

Storage by patients or parents/carers

Patients or parents/carers should not normally be asked to store vaccines or immunoglobulins. Exceptionally, patients or parents/carers may be asked to transport and/or to store them for short periods of time. Should this need arise, advice on appropriate storage must be given to the patient or parents/carers.

The vaccine refrigerator

Specialised refrigerators are available for the storage of pharmaceutical products and must be used for vaccines and diluents. Ordinary domestic refrigerators must not be used. Food, drink and clinical specimens must never be stored in the same refrigerator as vaccines. Opening of the refrigerator door should be kept to a minimum in order to maintain a constant temperature. The fridge temperature gauge should be clearly visible to read without needing to open the fridge door.

As a minimum for providing adequate refrigerator conditions, the named individuals should ensure that:

- all fridges have a unique identifier, such as a serial number
- the refrigerator is safe, for example by undertaking regular visual inspections and portable appliance testing (PAT). The Electricity at Work Regulations (1989) require electrical systems to be 'maintained'.
- the refrigerator is lockable or within a locked room. All vaccines are Prescription Only Medicines (POMs) and must be stored under locked conditions.
- the refrigerator is the right size to meet the vaccination storage needs, i.e. there is sufficient space around the vaccine packages for air to circulate and there is sufficient capacity for vaccines for seasonal/ additional programmes such as the annual influenza vaccination campaign
- the refrigerator is placed in a suitable position (ventilated and away from heat sources)
- the refrigerator is maintained in a clean condition
- ice is not building up in the fridge. If defrosting is necessary, vaccines should be stored temporarily in a suitable alternative refrigerator or in a validated medical-grade cool box, but for the minimum possible time
- there is a maintenance contract that allows for at least yearly servicing and calibration of the temperature gauge
- steps have been taken to reduce the probability of accidental interruption of electricity supply, such as installing a switchless socket or clearly labelling the vaccine refrigerator plug.

Records should be kept of regular servicing, defrosting and cleaning, calibration and electrical testing. All maintenance actions should be recorded on a log sheet, which should be kept with the vaccine refrigerator.

Refrigerator thermometers

The temperature within the vaccine refrigerator must be monitored continually with a maximum–minimum thermometer. This will identify when the temperature may have been outside the recommended range. Digital thermometers are the most reliable. More sophisticated temperature-recording devices are now available, including alarmed digital maximum–minimum thermometers and data loggers.

At least one maximum-minimum thermometer that is independent of mains power should be used (as well as any integrated thermometer), so temperatures can be measured in the event of electricity loss. The maximum-minimum thermometer should be calibrated annually to confirm that it is giving accurate readings.

If checks suggest the thermometer is faulty, the following actions should be taken:

- consideration as to whether this has implications for the cold chain storage of current and recently administered vaccine stock
- the provider or commissioning organisation needs to be informed
- the servicing of the refrigerator should be a priority.

Monitoring of the refrigerator temperature

Temperatures in the refrigerator must be monitored and recorded at least once each working day, and documented on a chart for recording temperatures. An example can be found on page 36. The records should be readily accessible, be retained for at least one year, and cover the full storage history of any products contained in the fridge (NHS East of England Senior Pharmacy Managers Network 2008; Department of Health 2009). As shelf lives specified by vaccine manufacturers can be up to four years or longer, retaining records for five years will generally enable the full storage history of the vaccines be accounted for.

Temperatures of cool boxes should be monitored when in use, using maximum-minimum thermometers. Temperatures should be recorded at the start and end of each session (further information on cool boxes is given below).

Named staff can delegate the monitoring of refrigerator to other staff, but should ensure that staff undertaking this task understand all aspects of the process. This can be facilitated by using the ‘four Rs’:

- read
- record
- reset
- react

Read: daily reading of the thermometer's maximum, minimum and current temperatures at the same time every day during the working week

Record: recording temperatures in a standard fashion and on a standard form, including signing each entry on the recording sheet

Reset: resetting the thermometer after each reading. The thermometers should also be reset when temperatures have stabilized after periods of high activity

React: the person making the recording should take action if the temperature falls outside +2˚C to +8˚C and document this action.

Fridge failure or disruption of the cold chain

Arrangements should be in place for back-up facilities to be available in the event of the refrigerator failing or breaking down.

In the event of a refrigerator failure, the named individuals should take responsibility for the necessary actions. Local protocols should outline these actions, to include:

- keeping the vaccine refrigerator door closed until a rapid assessment of the situation has been undertaken and an action plan formed. Keeping the door closed will help to maintain the temperature
- informing the relevant provider or commissioning organisation and their local immunisation coordinator/lead via the local incident reporting scheme
- assessing the incident, establishing the last reliable temperature recording, the timing and cause of any temperature fluctuation (e.g. power loss or staff leaving the refrigerator door open). This will help to assess whether the cold chain has been broken
- quarantining all vaccines affected by an incident separately from unaffected vaccines (but maintain them in the cold chain and ensuring temperature is monitored) and clearly label as quarantined
- recording all details of the incident

- implementing any further follow-up of the incident after discussion with the immunisation coordinator/lead of the provider/commissioning organisation. This may include re-immunising patients who have been given unsuitable vaccines. Expert advice should be sought from the local immunisation lead or health protection team
- safely disposing of the vaccines as appropriate, if considered unusable, according to local protocols.

Vaccine stability data outside of the registered range (for example +2˚C to +8˚C) may not have been reviewed by the Medicines and Healthcare products Regulatory Agency (MHRA) or European Medicines Agency (EMA) who give the marketing authorisation for the vaccine. Product quality, safety or efficacy may have been adversely affected as a result of the temperature excursion.

Any use of vaccines that have deviated from recommended storage or transportation conditions is the responsibility of the user. The risk assessment and decision to use the vaccine after it has been stored at an incorrect temperature must be made on a case-by-case basis. Consideration must be given to the level of evidence available regarding the stability of the vaccine outside the correct temperature range over the relevant duration of time. Users must ensure that they have sufficient information to make an informed assessment and decision. Pharmacists in the local provider or commissioning organisation (e.g. medicines management team) may be able to advise on temperature stability.

Guidance is available from UK Medicines Information (UKMi). NHS pharmacists at UKMi collate published and unpublished information from manufacturers in *The fridge database*, which is available at www.ukmi.nhs.uk/applications/fridge. It recommends action designed to prevent wastage of refrigerated medicines and vaccines. Access for NHS staff and contractors can be obtained by contacting the regional medicines information centre – telephone numbers are in the British National Formulary (BNF). The UKMi fridge database also summarises the relevant sections of the manufacturers' summaries of product characteristics (SPC). SPCs are also available at www.medicines.org.uk/emc. Manufacturers' medical information departments can also be contacted for information.

The Health Protection Agency (HPA) also has detailed guidance on responding to errors in vaccine storage available at: http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1267551139589

Validated cool boxes (carriers) and transporting vaccines

Domestic cool boxes should not be used to store, distribute or transport vaccines. Validated cool boxes and cool packs from a recognised medical supply company should be used in conjunction with validated maximum–minimum thermometers. Cool packs should be stored in accordance with the manufacturers instructions, usually at +2˚C to +8˚C (not a freezer compartment) to ensure they maintain the cold chain at the right temperature. In general, ice packs and frozen cool packs should not be used as there is a danger of these freezing some vaccine doses during transit. The exception to this is when the cool box manufacturer's instructions specifically state that ice packs should be used. Individual manufacturer's instructions should be strictly adhered to.

A validated cool box provides ongoing assurance that the vaccines will be maintained within the cold chain temperature range during transport. With time and use, cool boxes may no longer be able to maintain this temperature range for extended periods so monitoring is always required. The cool box manufacturer should also provide sufficient evidence for assurance that a stable temperature within the range of the cold chain can be maintained for several hours.

Vaccines must be kept in the original packaging, wrapped in bubble wrap (or similar insulation material) and placed into a cool box with cool packs as per the manufacturer's instructions. This will prevent direct contact between the vaccine and the cool packs and will protect the vaccine from any damage.

When transporting vaccines, the named individuals are responsible for ensuring that only the amounts of vaccines necessary for each session are removed from the vaccine refrigerator. These should be placed quickly into the validated cool boxes and opening must be kept to a minimum. If there are any unused vaccines left over at the end of a vaccination session, providing there is evidence from the temperature monitoring that the cold chain has been maintained, the vaccines can be returned to the vaccine refrigerator. Returned vaccines should be used at the earliest opportunity. If the cold chain cannot be guaranteed, a risk assessment should be done, as described in the previous section.

Spillage

Locally written procedures should be used in conjunction with manufacturers' Control of Substances Hazardous to Health (COSHH) safety data sheets. COSHH safety data sheets are usually supplied with the product but can also be requested directly from the manufacturer. Spillages must be cleared up quickly and gloves should be worn. The spillage should be soaked up with paper towels, taking care to avoid skin puncture from glass or needles. The area should be cleaned according to the local chemical disinfection policy or COSHH safety data sheets. Gloves, towels, etc. should be sent for incineration.

Spillages on skin should be washed with soap and water. If a vaccine is splashed in the eyes, they should be washed with sterile 0.9% sodium chloride solution and medical advice should be sought.

Disposal of vaccines

There should be locally written policy and procedures for the disposal of vaccines by incineration at a suitably authorised facility. These procedures must be followed.

Equipment used for vaccination, including used vials, ampoules or syringes should be disposed of by placing it in a proper, puncture-resistant 'sharps' box according to local authority regulations and guidance in the technical memorandum 07-01 (Department of Health, 2006).

The 'sharps' container should be sealed and replaced once it is two-thirds full, or at the level indicated on the box by the manufacturer. The container should not be accessible to any unauthorised individual and disposed of as per local contractual procedures.

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Vaccine Update is the vaccine supply newsletter, published by Public Health England.

The monthly edition can be signed up to by going to https://public.govdelivery.com/accounts/UKHPA/subscribers/new?preferences=true

Previous issues can be accessed via https://www.gov.uk/government/organisations/public-health-england/series/vaccine-update

The Northern Ireland Vaccine Update Newsletter is available monthly from the Regional Pharmaceutical Procurement Service, Tel 028 9442 4089 Email: rphps.admin@northerntrust.hscni.net

A sample refrigerator temperature record chart

Name of health facility: .....

Fridge identifier: .....

Month and Year: .....

The temperature should be between +2°C and +8°C. Check each working day. If the temperature is outside the recommended range, take appropriate action as indicated in the written procedure.

Remember: Read, Record, Reset and React.

Date	Time	Current temp	Min temp	Max temp	Checked by (signature)	Thermo-meter reset (tick)	Comments

Monthly review by: ..... (name) ..... (date).