ADVISORY DOCUMENT

ON

ORDERING, STORAGE AND HANDLING OF VACCINES

7th Revision

September 2017

ADVISORY DOCUMENT ON ORDERING, STORAGE & HANDLING OF VACCINES

This is an All Wales document that provides guidance towards all ordering, storage and handling of vaccine products. It is recommended for Health Boards (HBs) to adapt and inform local policies and guidelines in practice and also be used as a resource in local immunisation training on the cold chain.

Health Boards (HBs) responsible for the delivery of vaccination programmes must ensure that local practice is in accordance with national policy and best practice.

It is a statutory requirement that vaccines are stored in accordance with manufacturer's instructions.

Current advice from the Green Book *Immunisation against Infectious Disease*[1] and Public Health Wales[2] should always be taken into account. Vaccine cold storage and supporting information, to include:

- Patient Safety Notice July 2015[3]
- Protocol for ordering, storage and handling medicines (PHE)[4]
- NHS Rapid Response Report 2010[5]

Welsh Government leads the vital role in identifying any significant safety risks and concerns across healthcare, and has developed Patient Safety Solutions[6] at a national level for issue to the NHS in Wales.

The original document was written by the Community Services Pharmaceutical Sub-Group of the Welsh Pharmaceutical Committee, and published by the Welsh Office in March 1994. This 7th revision has been completed by an advisory group of Vaccine Pharmacists, Health Board Immunisation Coordinators and Public Health Wales, endorsed by the All Wales VPDP business meeting in September 2017.
The information in this document is issued on the understanding that it is the best available from the resources at our disposal at the time of issue.

[1] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
[2] http://nww.immunisation.wales.nhs.uk/ordering-handling-and-storage-of-vaccine
[3] http://www.wales.nhs.uk/sites3/Documents/254/WHTM%2007-01.pdf
[4] http://immunisationsuk.co.uk/wp-content/uploads/2015/06/Protocol_for_ordering__storing_and_handling_vaccines_March_2014.pdf
[5] http://www.nrls.npsa.nhs.uk/alerts/?entryid45=66111
[6] http://www.patientsafety.wales.nhs.uk/safety-solutions

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Contents

1. Introduction

Vaccine quality is a shared responsibility of all parties, from the time the vaccine is manufactured to it being administered.

Vaccines may lose their effectiveness quickly if they become too hot or too cold, and therefore should be stored between +2°C to +8°C at all times. 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 required immune response and consequently provide poor protection. Inappropriate storage and transport also results in wastage and unnecessary costs to the NHS[7] [8].

Vaccine failures caused by the administration of a reduced-potency vaccine can affect a large number of people causing risk to patients, embarrassment, expense and possible liability. Patient confidence in vaccine products and the vaccination process is diminished if repeat vaccination is required.

The 'cold chain' is a term used to describe the cold temperature conditions in which certain products need to be kept during storage and distribution. Maintaining the cold chain ensures that vaccines are transported and stored according to the manufacturer's recommended temperature range of +2°C to +8°C until the point of administration.

Anyone handling vaccines should be up to date with local and national guidance to ensure cold chain compliance. Individual Summaries of Product Characteristics (SPCs) that are supplied by the manufacturers of the vaccines outline individual vaccine storage requirements.

Vaccines that have **not** been transported or stored accordingly are no longer within the terms of the marketing authorisation (product license). A risk assessment should be completed on a case-by-case basis to include time out of the cold chain, reference to the manufacturer and/or

[7] A research project to identify the causes of vaccine wastage in practices across Wales, assess compliance to guidelines, and make recommendations for future good practice. (Carys Jones, Welsh School of Pharmacy, Cardiff University, 2009)
[8] Vaccine update 242. Mar 2016: https://www.gov.uk/government/publications/vaccine-update-issue-242-march-2016

the UKMI Fridge Database[9] to determine the likely impact of the temperature variation on the vaccine and whether use of a specific vaccine under these circumstances is appropriate. In such cases any subsequent use will be considered “off label”. Unlicensed products cannot be administered or supplied through use of a Patient Group Direction (PGD). However, “off-label” products can be included under PGD provided that there is documented evidence to support its inclusion.

If the cold chain is breached then advice should be sought from the supplying pharmacy or manufacturer. Vaccine Incident Guidance[10] provides useful information and a useful risk assessment tool is available[11].
Further reading and reference material is available[12] [13] [14] [15] [16]

Vaccine handling and storage mistakes are avoidable.
Freezing can cause the deterioration and denaturing of the vaccine rendering it useless. It can also lead to hairline cracks in the ampoule / vial / pre-filled syringe with the potential for contamination of the contents. Repeated warming and cooling of vaccines may lead to a shortened shelf life.
If you have any concerns about how a vaccine has been handled or stored you should seek advice.

Include Health Board immunisation/pharmacy leads/ roles here:

[9] http://www.ukmi.nhs.uk/
[10] https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors
[11] Causer K. When the Cold Chain is breached – a risk assessment tool to help decision making. SE London Vaccine Incident working Group May 2005

[12] Finn l Crook S. A district survey of vaccine cold chain protection in GP surgeries
[13] Communicable Disease and Public Health 1999;**2**:1:47-49

[14] Review of a vaccine related incident Vaccine incident

[15] *Rapid Response Report: Vaccine cold storage and supporting information* Jan 2010

[16] PHE leaflet: Vaccines temporarily stored outside recommended temperature range

2. General

2.1 Vaccines are Prescription Only Medicines.

The Medicines Act requires that within HBs, a pharmacist should have overall responsibility for their purchase and supply. In general practices this responsibility falls to the Lead GP. Practice staff ordering vaccines meet the legal requirements for the possession of vaccines as they are acting on behalf of the GP. In private clinics staff are authorised when acting on behalf of a registered medical practitioner with a license to practice. Vaccines can also be administered and/or supplied via a patient group direction (PGD).

2.2 There should be a named person (and deputy) responsible for the ordering, receipt, storage and monitoring of vaccines. In general practice the named persons should be one registered healthcare professional from the nursing team and one from the administration/management team.

2.3 Systems should be in place to ensure:

- vaccines are stored in a dedicated vaccine/medicine refrigerator
- cold chain maintained at all stages.
- good stock control and careful stock rotation (using vaccines with the shortest expiry dates first).
- regular monthly recording of the cold chain process
- damaged/out of date vaccines and vaccine related healthcare waste are disposed of appropriately.

2.4 Care must be taken when ordering, as excessive stocks can lead to waste and increased costs to the NHS. Stocks should be monitored by the designated person to prevent over-ordering and stockpiling. The Green Book states no more than 2-4 weeks stock.

2.5 Whenever vaccines are stored or distributed (including cool bags) it is essential that the temperature is monitored using electronic data recorders e.g. data loggers, or other temperature monitoring equipment. Maintaining recommended temperatures is essential to ensure the efficacy of vaccines and accurate recording of temperature data helps verify that vaccines have been stored correctly for the cold chain.

2.6 Training should be available to ensure there is an understanding of the importance of complying with processes and procedures.

2.7 There should be an annual self audit of ordering, storage and handling of vaccines to ensure compliance. Additional guidance is available[17]

2.8 Incidents, cold chain failure and waste recording.

- Any breaches of cold chain should be reported to the HBs Immunisation Coordinator or Pharmacy Lead.
- All cold chain incidents should be recorded on the Datix system.
- Any wastage must be recorded on an ImmForm Incident Form.
- All incidents should be reviewed by the HB's Strategic Immunisation Group (or equivalent).

2.9 Wherever vaccines are stored e.g. pharmacy departments, NHS or private clinics and wards, GP practices, community pharmacies the following reference documents should be available:

- Local and national guidance on vaccine storage and handling
- Patient Safety Notice: Storage of medicines: Refrigerators July 2015[18]
- *Rapid Response Report: Vaccine cold storage and supporting information* National Patient Safety Agency January 2010 [19]
- On line access to Immunisation against Infectious Disease Department of Health to ensure use of current version [20]
- Local policy for disposal of vaccines e.g. post vaccination waste (sharps/clinical/non-clinical), out of date stock etc.
- Vaccine Incident Guidance (Mar 2012)[21] provides structured support for health professionals involved in immunisation on actions to take in response to vaccine errors.
- Revised GMS contract [22] to ensure all vaccines are stored in accordance with the manufacturer's instructions and guidance contained in The Green Book

<u>Supporting documents to also include:</u>

- Current monthly e-bulletin for Wales[23]

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[17] http://nww.immunisation.wales.nhs.uk/ordering-handling-and-storage-of-vaccine

[18] http://www.patientsafety.wales.nhs.uk/sitesplus/documents/1104/PSN015%20The%20storage%20of%20medicines%20-%20refrigerators.pdf

[19] NPSA alert

[20] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

[21] www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

[22] http://www.gpone.wales.nhs.uk/gp-contract

3. Ordering

3.1 Vaccine stocks should be monitored by the named staff members to avoid over-ordering or stockpiling.

3.2 Vaccination providers should usually 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 an adequate supply.
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, potential freezing of stock (especially near the fridge walls)
- cause poor stock rotation
- delay the introduction of new vaccines until local supplies have been used
- increase the cost of replacement of stocks if the vaccine refrigerator fails
- reduce the space in vaccine refrigerators available for periods of high demand, such as the autumn, when flu immunisation takes place.

3.3 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.

3.4 Vaccines for the routine NHS immunisation programmes are ordered through ImmForm by GP practices and HB pharmacies. Vaccines for other immunisation programmes such as influenza are also ordered direct with manufacturer. There are restrictions on the use of centrally purchased vaccines these are detailed in Chapter 3 of the Green Book. Information on the supply of the majority of centrally purchased vaccines is available from the ImmForm vaccine supply page[24](registration is required). Information on supply for vaccines not purchased centrally is available direct from the vaccine provider.

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[23] Public Health Wales

[24] https://portal.immform.dh.gov.uk/Logon.aspx?returnurl=%2fVaccineSupply%2fVaccineSupply%2fHome%2fVaccine-Supply-Home.aspx

4. Receipt

4.1 All vaccine deliveries should be clearly labelled ‘Vaccines - refrigerate on receipt’ (or similar).

4.2 Goods received should be checked against the order and/or delivery note and any discrepancies reported to the supplier **before** accepting and signing for them.

4.3 Deliveries should be inspected for leakages and damage. Defective products should be reported to the supplier and dealt with as they recommend.
Pharmaceutical distributors and manufacturers will not accept any vaccine for return once it has left their control.

4.4 Vaccines must be refrigerated **immediately** on receipt and must not be left at room temperature.

4.5 It is the responsibility of the named individuals to ensure there is adequate recording of stock ordering and receipt of vaccines. Records should be kept of manufacturers name, batch numbers and expiry dates. This is to allow for the event of any batch recall or if any becomes out-of-date.

4.6 Standard date-checking procedures should be in place.

5. Storage[25,26,27,28]

5.1 Vaccine effectiveness cannot 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 SPC, usually at +2 to +8˚C, and protected from light. Prolonged exposure to ultraviolet light will cause loss of potency.

5.2 Vaccines should be stored in a cold store or a vaccine refrigerator which should be lockable or in a room which is locked when not in use. There should be restricted public access to the area.

Domestic refrigerators are not designed for the storage of vaccines and must not be used.

5.3 Refrigerators must be the right size to meet 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 e.g. seasonal 'flu' vaccine stocks.

5.4 Refrigerators should not be sited near a heat source e.g. radiator, hot pipes, which will adversely affect their working. There should be sufficient space for air to circulate freely around the back of the refrigerator.

5.5 The refrigerator should be wired directly into the socket or appropriate steps should be taken to ensure the refrigerator is not accidentally switched off e.g. labelled '**do not switch off'**.

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[25] Rapid Response Report: Vaccine cold storage
National Patient Safety Agency January 2010 NPSA alert

[26] Control and monitoring of storage and transportation temperatures
Mail No131 May/June 2002; 2

[27] Medicines Management and the Cold Chain – Issues in the changing NHS for Pharmacy. Pharmacy Management Supplement Oct 2002

[28] Taylor J. Recommendations on the control and monitoring of storage and transportation temperatures of medicinal products. Pharm J 2001; 267:128-131

5.6 The temperature of the vaccine refrigerators or cold stores should be monitored at regular times each day and recorded, preferably first thing in the morning and at the end of the day before leaving the premises especially prior to weekends and bank holidays. This should be done by a named designated person who knows what action to take if the temperature is outside the +2 to +8°C range. Training to be provided as necessary.

Temperatures in the refrigerator must be monitored and recorded at least once each working day, and documented on a chart for recording temperatures. The records should be readily accessible and be retained for at least one year. 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.[29]

5.7 Digital recording systems that log temperature and alarm if out of range are the preferred monitoring method especially where large stocks are stored (this does not replace the requirement for daily recording by named individual). The Green Book also advises that temperature can be monitored in the event of electricity loss for example by use of a maximum-minimum thermometer (independent of mains power) or data logger. The maximum-minimum thermometer should be calibrated annually to confirm that it is giving accurate readings.

The thermometer or probe should be placed towards the back of the refrigerator at the level of the middle shelf.

5.8 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:** 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

[29] Immunisation against Infectious Disease 'Green Book' available via link

- **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 to +8˚C and document this action.

5.9 There should be an emergency storage procedure should the refrigeration fail. Ideally the cold store / refrigerator should have an alarm which is activated when the temperature exceeds +8^{o}C or falls below +2^{o}C. Arrangements should be in place for back-up facilities to be available in the event of the refrigerator failing or breaking down.

5.10 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 a lower temperature.
- informing 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
- separating all quarantined vaccines affected by an incident and maintaining them in the cold chain (ensuring temperature is monitored). Clearly label as quarantined.
- recording all details of the incident.
- implementing actions agreed and further follow-up of the incident after discussion with the immunisation coordinator. This may include re-immunising patients who potentially have been given sub potent vaccines. Expert advice should be sought from the HB leads (see p.3)
- safely disposing of the vaccines as appropriate, if considered unusable, according to local protocols

5.11 Freezing may render vaccines inactive and unusable. Further specific risk assessment is required, aligned with other breaks from cold chain processes (see section 1 Introduction).

5.12 Refrigerators should be defrosted and cleaned at least monthly – unless self-defrosting fridge. Records of regular servicing, defrosting and cleaning, calibration, electrical testing should be kept. All maintenance actions should be recorded on a log sheet, which should be kept with the vaccine refrigerator.

5.13 Special care should be taken during defrosting to ensure that vaccines do not exceed the specified temperature range for significant periods of time. Alternative refrigerators or cool boxes should be used.

5.14 Items other than medicines, e.g., food and drink, specimens and blood samples **must not** be stored in the vaccine refrigerator.

5.15 Vaccines should not be too tightly packed. Room should be left for the circulation of cold air between vaccine products[30]. Vaccines should be kept away from the side and back walls of the refrigerator.

5.16 Vials or ampoules should not be removed from their original packaging so as to retain information on whole vaccine product batch number and expiry dates and to ensure protection from light.

5.17 Stocks should be stored tidily. Vaccines should only be stored on the shelves of the refrigerator and not on the floor of the unit or in storage compartments of the refrigerator door. They should not be stored in trays with solid walls, if necessary use baskets which allow the air to circulate.

5.18 There should be established stock rotation and expiry date check systems. Out of date stock should be clearly labelled, removed from the refrigerator immediately and sent for safe disposal in line with the local waste policy.

5.19 The refrigerator door should be checked to make sure it is shut at the end of a session and at night.

[30] Grassby P F. Safe storage of vaccines: Problems and solutions. Pharm J 1993; 251:323-327

6. Packing of vaccines for distribution[31,32]

6.1 There should be standard procedure for the packing of vaccines for onward distribution, to include documentation, checking policy and loading patterns used.

6.2 Orders should be assembled in a designated area within easy access to the storage refrigerator/cold store.

6.3 A validated cool box has evidence from the manufacturer (or pharmacy that supports its usage) of being compliant with maintaining cold chain temperatures when used in accordance with manufacturer (or pharmacy) directions.
Validated cool boxes and cool packs from a recognised medical supply company must be used. Usual monitoring of temperatures apply. Where practicable all transportation of vaccines should be monitored by the use of electronic data recorders or other temperature validating equipment. Monitoring of vaccine deliveries and recording by data-loggers provide assurance of cold chain compliance.

6.4 Packing components e.g. cool boxes, filler materials, should be stored in the coolest available area, preferably a cold room. Whenever possible, cool boxes should be chilled prior to use.

6.5 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.
If ice/cool packs are used they should be stored in accordance with the manufacturer's instructions to ensure they maintain the cold chain at the right temperature. Some form of staging or insulating material should be used to separate the vaccines from the ice pack (not necessary with gel packs).

6.6 Any spaces within the load should be filled with insulating material to prevent temperature variations.

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[31] Brown D R, Samsum C J. The transportation of vaccines: Is the cold chain integrity maintained? Pharm J 1992; 249:267-269

[32] Steward M, Brown P W, Allwood M C. An assessment of insulated carriers for transport of vaccines. Int J Pharm Pract 1991; 1:27-2

6.7 The time that vaccines are exposed to room temperature during packing should be kept to a minimum.

6.8 Orders should be clearly marked '**VACCINES – URGENT**. Refrigerate on receipt' or similar.

6.9 For school sessions, a requirement to highlight 'use first' if some vaccines have been previously returned to avoid opening the box to see which ones to use first.

6.10 Distribution should be by carrier, hospital transport or personal collection with the minimum delay in transportation.

6.11 For distribution records and audit purposes documentation should include: -
order details
manufacturer's name and batch numbers
date and time of assembly, despatch and receipt
signature of persons assembling, transporting and receiving the order

7. Transportation of vaccines

7.1 Persons responsible for transporting vaccines should sign to accept the delivery when the orders are collected.

7.2 All deliveries should be completed within an allotted time.

7.3 If deliveries other than vaccines are transported then priority should be given to the vaccine delivery.

7.4 Receipt of vaccines at destination should ensure cold chain is maintained. Vaccines must not be left at unattended delivery points.

7.5 Where appropriate, the signed receipt should be returned to the dispatcher and kept for future reference

7.6 Deliveries should never be made to unattended clinics.

7.7 If vaccines are being transported for a vaccination session e.g. school, request only enough vaccine for the session

8. Vaccination session

8.1 Adrenaline (Epinephrine) must be available during an immunisation session. Advice on symptoms and management of anaphylactic shock should also be available.

The expiry date should be checked at the start of each session.

8.2 Vaccines should only be removed from the base refrigerator/coolbox at the beginning of the session when they will be used.

8.3 Work flow should be organised so that the opening of the refrigerator door or cool box is kept to a minimum.

8.4 Vaccines should be out of a refrigerator/coolbox for as short a time as possible.

8.5 When transporting vaccines to an outside clinic, school or for a domiciliary visit, the named individuals are responsible for ensuring that only the amounts of vaccines necessary for each session are removed from the refrigerator. These should be placed immediately into the validated cool box as stated in Section 6 and the opening and closing must be kept to a minimum,

8.6 On arrival at the outside clinic or school the vaccines should be transferred to a designated refrigerator if available, otherwise they should be left in the **closed** cool box until required. The latter also applies for a domiciliary visit. Take care not to place the cool box near a heat source or in direct sunlight.

8.7 The temperature of cool boxes should be monitored when in use. Temperatures should be recorded, as a minimum, at the start and end of each session. See section 6.3

8.8 Freeze-dried vaccines should be reconstituted according to the manufacturer's instructions immediately prior to use and used within the manufacturer's recommended period.

Vaccines should not be drawn up in advance of a session.

8.9 The ACIP[33] recommends as best practice that the individual administering the vaccine prepares the vaccine for administration to avoid error.

8.10 Different vaccines should not be mixed in the same syringe unless the manufacturer's information indicates that they can.

8.11 The identity of the vaccine and expiry date should be checked prior to administration. The appearance of the vaccine should also be checked to ensure that it meets the manufacturer's requirements.

8.12 Check that the correct storage conditions have been observed.
e.g. check Cold Chain Record

8.13 The following information should be recorded accurately:

●vaccine name, product name, batch number and expiry date

●dose administered

●site(s) used – including, clear description of which injection was administered in each site, especially where two injections were administered in the same limb

●date immunisation(s) were given

●name and signature of vaccinator.

8.14 Once opened, multi-dose vials must be disposed of at the end of the session, or if the manufacturer's recommended period has expired, whichever is soonest.

8.15 If there are any unused vaccines (in original packaging) left over at the end of a vaccination session, provided 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 clearly marked, dated and should be used at the earliest opportunity.

[33] https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

9. Disinfection and spillages

9.1 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.

9.2 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

9.3 Spillages on skin should be washed with soap and water.

9.4 Affected eyes should be washed with sterile 0.9% Sodium Chloride solution and medical advice sought.

10. Disposal of vaccines

10.1 There should be a local policy for the disposal of vaccines, including out-of-date stock, that comply with current waste regulations.

10.2 Vaccines should only be disposed of by incineration at a suitability authorised site.

10.3 Equipment used for vaccination, including used vials, ampoules, syringes or partially discharged vaccines should be disposed of at the end of a session by placing in a proper, puncture-resistant 'sharps' box according to local authority regulations and national guidance[34]
The 'sharps' container should be sealed and replaced once it is two-thirds full, or 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.

[34] Safe Management of Healthcare Waste: http://www.wales.nhs.uk/sites3/Documents/254/WHTM%2007-01.pdf

11. Hazard and Incident reporting

11.1 There should be a policy for the cascading of hazard warnings and recall notifications. This should specify who needs to be contacted and must be kept up to date.

11.2 There should be a policy specifying the contact number to report any hazard, serious defects or cold chain incidents. The policy will vary depending on the local system.

11.3 Any disruption to the cold chain should be considered an adverse event and must be reported in line with the HB policy.

11.4 Suspected Adverse Drug Reactions (ADRs) should be reported via the 'Yellow Card Scheme' access and completed on line available at the back of the BNF or at Yellow Card Scheme website[35]

Only report serious ADRs for established vaccines.
All ADRs should be reported for new vaccines (BNF black triangle▼)
All ADRs in children should be reported.

11.5 Patient safety incidents should be reported through to the National Reporting and Learning System (NRLS) via Patient Safety Wales[36] as well as being reported through the local incident reporting scheme. Cold chain incidents are considered a patient safety issue.

11.6 Any stock incident which results in vaccines being wasted should be documented on ImmForm and a Datix form completed (if a Datix form is completed, Immunisation Coordinators should be automatically informed). All incidents to be available to the Health Board's Strategic Immunisation Group for oversight and review. Specific reports can be run from ImmForm.

[35] https://yellowcard.mhra.gov.uk/
[36] http://www.patientsafety.wales.nhs.uk/patient-safety-incidents