Cold chain incidents

Learning Objectives

- To update colleagues about the consequences of cold chain failure
- To review cold chain guidelines and promote consent (best) practice
- To understand the legal implications on practice when things go wrong
- To clarify education and standards connected to administration of vaccines and medicines

Learning Outcomes

- Prevent future patient harm by applying effective cold chain management policies and procedures
- Know how to respond to a breach in the cold chain, including when and who to escalate concerns to
- All colleagues will know:

    They have a duty of candour and legal responsibility to protect the public

    When not to use a PGD

    When and how vaccines must be wasted/when and

    how they can be used after an excursion from the cold chain

Where, at what level and how frequently to access education and how to document confirmation of competence

Introduction

To avoid a cold chain breach, all staff within the practice need to be aware of the importance maintaining a robust cold chain. This includes reception personal through to the clinical team that administer the immunisations and vaccinations.

Do you know how to manage all these situations?

Incident Description

1. Vaccines stored in the basket on the bottom of the fridge or fridge door. Why is this a no no!!!

2. There is a power cut that last 5min/ 3 hours/ all weekend?

3. Fridge temperature recorded at 13 degree

Response

1. Vaccine's may freeze rendering them inactive and unusable. Vaccines should be stored with space between the vaccine and the refrigerator sides/top/bottom/back/front to allow for cold air circulation around the vaccine and ensure the correct temperature is maintained

Response

2. Establish time frame of failure and fridge min/max temperature for this duration.

   Isolate stock in another fridge if possible

   Contact the manufacturer for further information on use/destruction of vaccines

Response

3. Manufacturer's recommend temperature range is +2 C to +8 C. Being exposed to higher temperatures can cause loss of potency.

The Vaccine Fridge

- Vaccines cost the NHS around £200 million a year.
- The loss of only one dose of Pediacel vaccine a month in each general practice would cost an estimated £4 million a year.
- Specialised vaccine fridges cost £600 – £1200
- A validated carrier costs around £300

Some ‘musts’ about the fridge

A validated vaccine fridge must be:

- suitable for the storage of vaccines between +2 and +8 C – a mid range of +5C is good practice
- locked or kept in a locked room
- used only to store vaccines and medicines, i.e. food or specimens must not be stored alongside vaccines
- large enough to hold the stock and allow sufficient space around the vaccine packages for air to circulate
- wired into switch-less sockets to avoid them being turned off accidentally
- safe – for example, by carrying out visual inspections and P&T testing.
- Vaccines stored in validated vaccine fridges must be kept in their original packaging

Thermometers

- All fridges should ideally have two thermometers, one of max/min thermometer independent of mains power
- If only one thermometer is used, then a monthly check should be considered to confirm that the calibration is accurate.
- Care should be taken that the thermometer probe cable does not interfere with the door seal, causing the temperature to fall outside the permitted range.

DATA LOGGERS

Are a must!!!

They will confirm the exact length of time the fridge temperature has been out of range and at what temperature.

However, ensure these do not make the team complacent about daily fridge monitoring.

Temperature monitoring

Do observe the four Rs

Read Record Reset React

Do make sure that the person making the recording:

- does it at the same time every day during the working week and signs the sheet
- records it in a standard fashion and on a standard form
- ACTS if the temperature falls outside +2 to +8 C
- resets the thermometer after each reading.

Note: any vaccine that has not been stored at +2 to +8 C as per its licensing conditions is no longer a licensed product.

Freezing- do not freeze vaccines

- Freezing vaccines causes deterioration and can give rise to increased adverse reactions by:
  - irreversibly denaturing the proteins in the vaccine
  - reducing the efficacy of the vaccine causing the in the vaccines to become unstable
  - producing hairline cracks in the ampoule/vial/prefilled syringe, potentially contaminating the contents. The glass spicules (small sharp pointed fragments) produced may also cause serious local adverse reactions.

Stock management

Do:

- keep all vaccines in their original packaging during storage
- make checks at least once a week to:
- rotate stock so that those with the shortest expiry date are moved to the front of the refrigerator and used first
- remove any expired vaccines (there should be none) and discard in appropriate waste stream
- mark clearly any vaccine returned to the fridge with the date and time of its return and place it at the front of the fridge so it is used first at the next session – this should only be done with vaccines that have remained in the cold chain.

Don’t:

- stock pile vaccine (no more than four weeks’ stock)

Audit

- Every week: fridge contents should be checked at least once
- Every month: vaccine stock should be audited and recorded
- Every three months: audit records of stock and temperature management can
- be shared with your local screening and immunisation teams

Routine maintenance

Make sure that:

- the fridge is maintained in a clean condition
- there is a maintenance contract that allows for at least yearly servicing and calibration of temperature gauge
- a routine vaccine management review is performed quarterly
- the temperature is calibrated at least every month against an independently powered external thermometer
- maintenance of the cold chain forms part of all immunisation training updates.

Validated cool boxes (carriers)

Do:

- use a validated medical grade cool box and cool packs
- monitor max/min temperature while the box is in use
- keep vaccines in their original packaging
- take only enough vaccine for a particular session and minimise exposure of the vaccines to room temperatures
- mark vaccines removed for an external session before returning to the fridge and then use at the earliest opportunity
- choose appropriate sizes of cool box for the amount of vaccine needed.

Don’t:

- freeze cool packs

Incident reporting

In the event of a fridge failure:

- inform the local NHS England screening and immunisation team
- quarantine all vaccines affected by an incident from others (but maintain in the cold chain)
- record all details of the incident
- implement any follow-up of the incident after discussion with the SIT
- implement and share lessons learned from the incident
- make sure written procedures for the disposal of vaccines are available locally
- report the incident on the ImmForm website www.immform.dh.gov.uk

‘Off- License’Vaccines

An ‘Off Licence’ vaccine is:

- A vaccine that for what ever reason has breached its licence, for example: was stored in a fridge that went out of normal/safe storage range (+2 to +8 Degrees C) but deemed safe and effective from clinical trials performed by the manufacturer.
- It should never be administered under PGD
- It should be administered under a PSD or individual prescription

The patient receiving the vaccine should always be made aware it is an off licence vaccine but still safe to use and given the choice to decline/accept an off licence vaccine

PSD Vs PGD

- **Patient Group Directive – PGD**
- Used only by registered health care professionals enabling them to administer vaccines to a group of patients meeting specific criteria.
- Cannot be used for administration of ‘Off licence’ products.
- **PSD**

Duty of Candour

It means be open and honest when things go wrong

https://www.nmc.org.uk/standards/guidance/the-professional-duty-of-candour/

Openness and honesty

when things go wrong:

the professional duty of candour

Ordering and delivery

At least two named, trained people need to be responsible for ordering, receipt and care of vaccines (one from the nursing team and one from management).

All members of the primary care team should be aware of the importance of good vaccine management.

Ordering and delivery

Staff should ensure that:

- orders are placed every 2-4 weeks according to need
- vaccine is promptly stored in a fridge after delivery, maintaining the cold chain at all stages
- there are no leakages, damage or discrepancies in the delivered vaccine stock is properly rotated – shortest expiry date used first
- a stock information system keeps track of orders, expiry dates and running total of vaccines
- ordering is done in sufficient time to ensure that there is an adequate supply for clinics

ImmForm

- Vaccines are only available for ordering through the ImmForm website. This ensures ordering is easier and more effective and efficient.
- To register on ImmForm please go to

  https://www.immform.dh.gov.uk/registration/
- You will need to supply your:

  NHS code (e.g. practice code)

  delivery address

  name, email and phone details (of the key contact responsible for placing orders)

Useful Links

- Chapter 3 of the Green Book ‘Storage, distribution and disposal of vaccines’

www.gov.uk/government/collections/immunisation-against-infectiousdisease-the-green-book

- National Patient Safety Agency advice on vaccine cold storage:

www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=66111

- PHE guidance on dealing with an incident

http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1267551139589

References

Public Health England

Protocol for ordering, storing and handling vaccines (2014)

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300304/Protocol_for_ordering__storing_and_handling_vaccines_March_2014.pd