Investigation of a Cold Chain Incident

Check list for responding to an adverse storage incident/ cold chain breach where vaccines have been given

1. Embargo Fridge

- When a cold chain breach has been identified at any level it is important that all the vaccines exposed to temperatures outside those stated in their SPC are labeled and isolated and wherever possible maintained in a functioning monitored fridge.
- Vaccines should not be discarded until directed to do so by PCT or vaccine manufacturers as they may still be viable.
- All staff within the organization should be advised the fridge is embargoed until further notice, ensuring the vaccines are not used.
- The incident should be reported and documented according to local PCT guidelines

2. Confirm and Define the Incident

- The refrigerator temperature records should be checked and the cold chain practice prior to this event discussed with staff. Are there any explanations for temperature discrepancies? E.g. stock delivery, evidence thermometer was not being re-set, untrained staff monitoring fridge.
- The accuracy of current thermometer/s in use should be confirmed with the supplier if this has not already been done prior to use.
- Depending on the severity of the incident, a site visit may need to be carried out by an appropriately trained professional, (usually community pharmacist)
- The general condition of the fridge should be documented. Is it purpose built vaccine fridge? Are there any obvious signs of freezing? Is it placed in a well ventilated area? Is it used for any other purpose than vaccine storage?
- A check of the fridge service history may give some indication when the fridge was last working properly if the incident is over an extended period of time. No service history may give a concerning indication of how vaccines have been managed prior to this incident.
- The current fridge temperatures should be confirmed and where possible continuous temperature logging using a data logger should be carried out for a 48 hour period to establish temperature patterns of the fridge.

3. Collect as much information as possible

- To include:
  - What monitoring has taken place? (max/min/current thermometer readings)
  - When was the cold chain last guaranteed?
  - What time period/s are involved? (hours/days/months)
  - What is the temperature range during this period?
  - Identify all vaccines stored in the fridge, the time they have been stored there, usual stock turn over and expiry dates
- Identify whether vaccine potency is likely to have been affected by the storage conditions identified. (May need to contact vaccine manufacturers)
- Vaccines against the same disease but from different manufacturers must be considered individually.

- Identify which vaccines are given at the facility. Does the clinic administer National Schedule Vaccines, Travel vaccines, and Annual Flu vaccines? This may give an indication of time scale involved and draw attention to those at immediate risk.
- How many patients are registered at the facility and what is the catchment area it serves? This may give you an indication of the extent of the situation.

When all the above information has been collated an Incident team meeting should be convened. The incident Team should include all relevant Practice and PCT staff (for example; Pharmacy lead, clinical governance, immunisation lead, communications lead) A representative from the local HPU should also be included.

Informed decision making by incident team

Ideally a summary of the investigation report should be drawn up and circulated for discussion prior to the meeting.

The team must review the key findings of this report and consider if they have got enough information in order to make an informed risk assessment of the compromised vaccines. They will also need to review what information is not known and consider how this may influence the decision making process.

From the evidence available the team must make a judgement on whether the cold chain breach investigated was sufficient to consider the vaccines given to patients sub-potent and if so what action now needs to be taken.

Identify recipients of affected vaccines

- Identify patients who have been given affected vaccines from facility records/vaccination database and compile a patient list for possible revaccination identifying patients with specific risk factors, patients given vaccines as part of a course, patients given vaccines for travel.
- Consider, if necessary, how you might trace/contact those who may require revaccination but have moved on since the incident has been identified. It is important that every effort is made to identify those at risk.
- Formulate revaccination schedules for each vaccine recipients taking into account appropriate intervals between vaccines and the potential risk of side effects.

Identify Resources/manpower required.

- Consideration needs to be given to how, where, and in what timescale revaccination will take place. Is there a need to offer special clinics in the evening or at the weekend or identify other key vaccine providers in the area who can help?
- Depending on the scale of the incident, additional staff may be temporarily required to council, advise and/or revaccinate patients

Identify Training needs

- Rapid training may be required for all staff involved with the cold chain incident prior to the re-commencing of clinics and the arrival of a new vaccine fridge or vaccine stock.
- Staff involved in the revaccination clinics must be clear about the objectives and confident about the rationale for revaccination programme prior to advising patients.
- They should be able to explain the risks and benefits to patients of being re-immunised and know who to contact if they are unable to answer any questions/are unsure how to proceed with re-immunisation.

Develop a communication plan and identify resources

- Communication with the public must be open and honest; the whole process should be as transparent as possible to avoid distress, confusion or misinterpretation.

- Effective means of communication should be established and maintained between all parties involved with the incident to date so that everyone is kept informed of the progress and developments of the incident as they occur. It is important not to forget people who may have been involved early on in discussions but who subsequently become less involved during the final stages.

- Consideration should be given to the most appropriate medium for informing the patients involved. If the incident only involves a small number of people this may be best done on an individual basis by writing to patients via the GP practice/immunisation centre. If larger numbers are involved additional support may be needed from local radio, TV or newspapers, adverts in local pharmacy or community centre. Consider targeted communications mediums (i.e. local churches/temples etc, community groups/centres) to get messages out to local ethnic, cultural and/or religious groups in the area. It may also be beneficial to set up a telephone helpline.

- A lead spokesperson must be chosen from the PCT or SHA to liaise with the media. Both reactive and proactive press briefings should be drafted in the event of media interest. A ‘Questions and Answers’ briefing should be drafted and agreed by all members of the incident team for use in response to the media.

- Support needs to be in place prior to informing the individuals involved. Information resources should be identified or developed for patients, taking into consideration the language needs of the local population. Translation of this information may be essential to the community response. Accessibility needs should also be factored in i.e. mobility, speech, hearing or eyesight

Re-immunise patients and record any adverse events

- It is important to follow up on patients who have been revaccinated. Any adverse event should be documented in the patient notes and reported to the MHRA through the yellow card reporting system.
- Any adverse events should also be documented in the final report of the incident as this information may be valuable to future management of vaccine incidents.

Document and evaluate

- The incident should be fully documented at every stage. This should include: the cause of incident, reason for decisions made, who advice was sought from and where relevant, the action taken to prevent future incidents.
- A final report at the conclusion of the incident should evaluate the management of the incident, patient response and lessons learned for the future.
- Incidents such as these rarely occur in isolation and often reflect other problems in the practice. It is recommended a full audit of the whole immunisation service is carried out to ensure that all processes and training of staff are in place and satisfactory.