NHS England and NHS Improvement – South West

Integrated South West Public Health Team

Flu Season 2020/21 Update

We appreciate how challenging the flu season can be and that is even more true this year. We would like to say a big thank you and well done to all GP practice staff for the hard work and effort seen so far this season. We know that this will continue into the rest of the season and look forward to seeing a continued, positive picture of uptake and response in GP practices.

Flu Vaccine Storage and Cold Chain Information

The credibility and success of any immunisation programme is highly dependent on the administration of safe, quality vaccines. **This quality is only assured through strict adherence to vaccine storage, handling and preparation procedures**.

Errors in the administration, storage or handling of vaccines cause concern both for the patient/parent/carer and immuniser. Whilst it is accepted that cold chain breaches and administration errors can occur in even the most meticulously run organisations/clinics, when they do occur, an informed decision needs to be made as to whether the vaccine has been compromised and if so, whether it presents a risk to patients. The effective management of errors is essential to ensure patient safety, to maintain public confidence in immunisation programmes and to minimise vaccine wastage.

The costs associated with loss and replacement of compromised vaccines should not be underestimated. Healthcare professionals have a responsibility to minimise financial risk and to help sustain supplies, whilst still ensuring the safety of patients and the continuing success of the national immunisation programme.

Maintaining vaccines within the cold chain between the recommended temperature range minimises the risk of compromising the effectiveness of the vaccine and ensures compliance with the manufacturer's product license.

Vaccines should be stored in their original packaging at +2°C to +8°C and protected from light. All vaccines are sensitive to some extent to heat and cold. Heat speeds up the decline in potency of most vaccines, thus reducing their shelf life. Efficacy, safety and quality may be adversely affected if vaccines are not stored in the temperatures specified in the license.

Freezing may also cause increased reactogenicity and a loss of potency for some vaccines and can also cause hairline cracks in the container, leading to contamination of the contents.

Exposing vaccines to any temperature outside the manufacturer's recommended range is considered a breach of the cold chain and may invalidate the product license.

It is, however, the length of time spent outside of the recommended cold chain conditions and the temperatures to which the vaccine(s) were exposed that may compromise the potency of a vaccine and as such, will determine the significance of the breach. While there are varying degrees of significance, each breach of the cold chain should be immediately acted upon and specialist advice should be sought in order to ascertain what action, if any, is required. Increasingly, the SPCs for some vaccines will contain information on vaccine stability outside the normal +2°C to +8°C temperature range. Where this information is available, providers can use this to determine whether or not a single temperature excursion is likely to have affected vaccine quality.

'One off' fluctuations in fridge temperatures rising above +8°C but lasting less than 20 minutes, such as may occur when stock taking or restocking, are not likely to have breached the vaccine cold chain and as such do not require further action. The cause of the 'excursion' should be documented on the

temperature recording chart, the maximum/minimum thermometer reset, and vaccines continued to be used to their expiry date. This pragmatic approach is based on studies from the U.S National Institute of Standards and Technology which demonstrated vaccine vials can maintain temperatures below +8°C for a minimum of 20 minutes despite the continuous influx of ambient air to the fridge. Vaccines must be stored in their original packaging to preserve this temperature stability and providers should be confident that vaccines have been stored appropriately prior to this event.

As a general rule, live attenuated vaccines are more sensitive to heat exposure than inactivated vaccines. However, when stored within the recommended cold chain conditions, most vaccines are very stable.

Fluenz Tetra (LAIV)

Fluenz Tetra is particularly sensitive and there have been several reported cold chain incidents involving this vaccine recently.

Key facts:

- Fluenz Tetra needs to be stored in a fridge (between 2–8°C) and protected from light; it must not be frozen.
- In order to calculate how much fridge space is needed, please note each pack of 10 vaccine applicators is 106 mm by 176 mm by 29 mm (length by width by depth).
- Please remember Fluenz Tetra has a maximum shelf life of 18 weeks that starts at the point of release from the manufacturer. This is a shorter shelf life than other influenza vaccines and some of this time will have passed when the vaccine reaches the place where it is to be administered. It is important that the expiry date on the nasal spray applicator is checked before use. If the expiry date has passed, arrangements should be made to have the vaccine disposed of safely.
- Always check the expiry date (day, month, year) on individual sprayers before administration.
- Discard any unused vaccine at the end of the vaccination season to prevent use of expired vaccine.
- Fluenz Tetra® may be left out of the refrigerator/removed from the cold chain for a maximum period of 12 **hours** at a temperature **not above 25°C** as indicated in the SPC. **If the vaccine has not been used after this 12 hour period, it should be disposed of.**
- If expired Fluenz Tetra is administered, this should be reported as an adverse event. The primary concern with administering expired Fluenz Tetra vaccine is that the vaccine strains may lose their effective potency. A clinical decision will need to be made as to whether to re-administer another unexpired.
- We would recommend vaccines are not out of the fridge for longer than 20 mins and if considering having a supply of flu vaccines in each consulting room, a portable cold storage container (suitable for vaccine storage) should be used, to maintain the temperature of 2-8 degrees.

Cold Chain Incident Reporting

In the event of a potential cold chain incident, an email should be sent to england.swscreeningandimms@nhs.net detailing the following:

- Name and type of vaccine.
- Reason for cold chain breach (e.g. power failure to fridge).
- Which vaccines were affected (including batch numbers and quantity)?

- Length of time vaccines were out of the cold chain (if the combined period that vaccines were outside of the cold chain is less than 20 minutes then this is NOT a cold chain incident).
- Maximum temperature the vaccines were exposed to.
- Who was involved?
- Have the manufacturers been contacted?
- Have the vaccines been quarantined and labelled not for use?
- Were any of the implicated vaccines administered?
- Were the vaccines held in a vaccine grade fridge(s)?
- When was the vaccine fridge(s) purchased and last serviced?
- How many digital thermometers were in the fridge(s)?
- How many data loggers were in the fridge(s)?

Reporting wastage and reordering on ImmForm

Reporting wastage and reordering stock on ImmForm is a two-step process. Please see below for details:

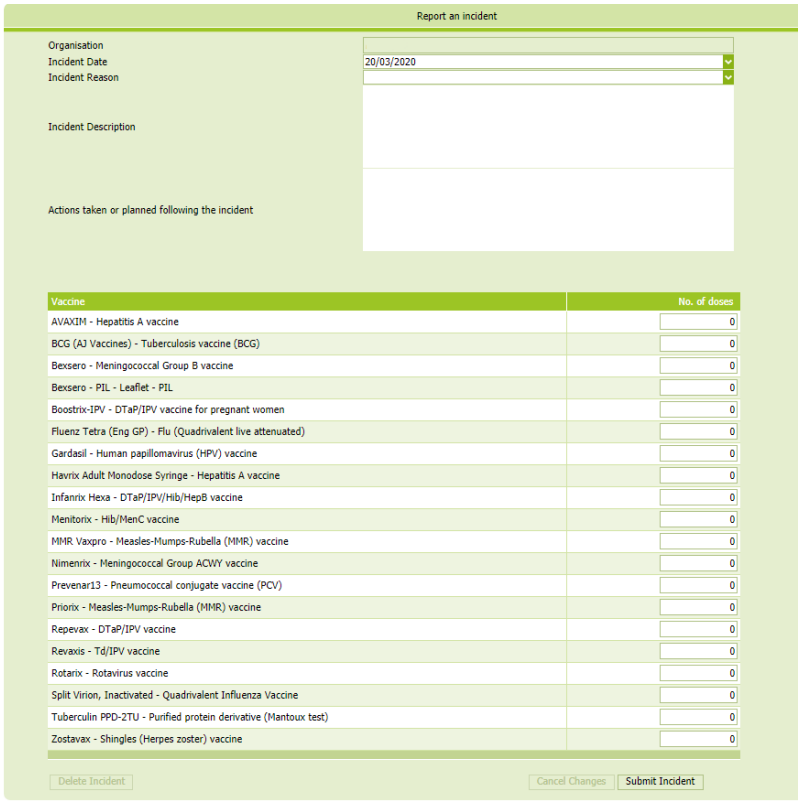
Step 1 – reporting wastage

In cases where vaccines have been ordered through ImmForm and need to be disposed of, a 'Stock Incident Form' on the ImmForm website must be completed.

Please see below for step-by-step instructions on how to fill in a 'Stock Incident' form:

1. From the ImmForm home page click on 'Product Ordering'
2. Navigate to the 'Stock Incident' tab and select 'Add Stock Incident'.

3. The following form allows you to enter, in doses, the lost vaccines.
4. You can select the Incident reason from the dropdown box and if required you can add further information in the Incident description.



5. Once completed click the 'Submit' button.

Please note, in order to receive new stock to replace any wastage, additional stock must be reordered via ImmForm in a separate process (detailed below).

Step 2 – re-ordering vaccine

Place a replacement order as normally via the ImmForm website, but only if a suitable replacement / repaired cold chain storage capacity is in place.

Replacement products can be delivered on their next usual scheduled delivery day provided you have ordered by the usual deadline, two working days before your scheduled delivery date.

Due to the risk of fridge failures and with expiry dates on products we recommend that only enough products are ordered to cover clinics for two weeks.

Out of schedule delivery requests

For urgent replacement products, an expedited delivery may be requested. Please note out of schedule deliveries disrupt the distribution company's delivery logistics and will normally only be considered in the event of an incident. Only consider applying for an out of schedule delivery if it is essential.
Please ensure the following is done prior to contacting the helpdesk:

• Place your replacement order on ImmForm as normal recording the account number and order reference of the new order.

• Complete a 'Stock Incident' on ImmForm to record the stock wastage.

• Ensure you have a fridge temperature log, clearly showing your organisation name or organisational code and where the temperature has gone out of range if you need an expedited delivery.

Once this is done email the ImmForm helpdesk at helpdesk@immform.org.uk with:

• Your Replacement Order number and your Ordering Account number

• Date you would like the order delivered

• Attach the fridge log where temperature deviation is shown.

The out of schedule delivery will only be authorised once the 'Stock Incident' report is completed and once ImmForm have received the Fridge temperature record chart.

The following links provide more detailed instructions:

Vaccine Incident Guidance:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/859773/PHE_vaccine_incident_guidance_January_2020.pdf

Wastage reporting and stock reordering guidance:

https://portal.immform.phe.gov.uk/IntranetPortal/files/ef/ef8e538c-22d0-4f1e-98c5-a29b649b7e68.pdf

If you have any queries relating to cold chain incidents and vaccine storage please contact england.swscreeningandimms@nhs.net