# East of England Cold Chain Toolkit 2024

Produced by the East of England Screening and Immunisation Team

NHS England, East

## Contents


This document is intended for use alongside the East of England Cold Chain Policy and will be subject to amendments and changes with legislation and guidance.

Please ensure that this document is being accessed through the EoE Website for the most up to date information.

## The East of England Cold Chain Policy

The purpose of the vaccine cold chain is to maintain vaccine product quality from the time of manufacture until the point of administration. This is fulfilled by ensuring that vaccines are handled, stored, and transported appropriately within the recommended temperature range +2°C to +8°C. Vaccines are sensitive biological substances that can quickly lose their efficacy when too hot or too cold. If vaccines are stored outside of the recommended range this may result in the failure of the vaccine to create the desired immune response and inadequate protection against vaccine preventable disease.

The East of England Cold Chain policy outlines pathways to help staff in the event of a cold chain breach.

These pathways are based on National Guidance

Pathway 1): actions to take when the temperature of a fridge has been found outside the +2°C to +8°C temperature range for more than 20 minutes.

Pathway 2): actions to manage more serious breaches of the cold chain. These more serious breaches may occur when compromised vaccines have been administered to patients, prior to the breach being identified.

For all cold chain breaches, it is expected that the provider will be able to demonstrate to the commissioners that the appropriate measures have been put in place to reduce the risk of a further cold chain breach or serious incident occurring.

In the event of a cold chain breach the following procedures should be carried out **immediately**:

1. Embargo affected fridge but **do not immediately remove vaccines from the fridge or dispose of any vaccines or storage equipment.**

- It is important that vaccines involved in a cold chain breach are **NOT** discarded before appropriate advice has been sought. Not all temperature excursions will affect the vaccines efficacy. Stability data for many vaccines supports efficacy at higher temperatures for long periods of time. PGD's also support the use of these vaccines that have been involved in temperature excursions.
- UKHSA report that in 2022 vaccine wastage accounted for 5.7 million pounds of NHS funds. 50% of the reported wastage was due to a cold chain breach. This level of wastage adds to the cost pressure upon the NHS and whilst some breaches cannot be avoided many of these vaccines are safe and effective for off-label use.
- The risk of discarding vaccines can also pose a risk to patients as clinics may need to be cancelled if a vaccine is not available. This will leave a part of the population unprotected and risk they do not return to another planned clinic.

2. Ensure that all affected vaccines are quarantined from unaffected vaccines (maintaining the cold chain). Clearly label these as quarantined and 'not for use'. Under NO circumstances should these vaccinations be administered to patients until confirmation that they are safe for use.

3. Ideally move the affected vaccine stock to an alternative environment [fridge/validated cool box] that is monitored and able to maintain recommended temperature of +2°C to +8°C. If this is not possible then keep the vaccines in the affected fridge closed until further advice has been sought.

4. Ensure vaccine fridge involved in cold chain breach, remains switched on at main electrical supply and the thermometer and probe are undisturbed and staff are aware not to access fridge.

5. Take an inventory of all exposed vaccines, quantity, batch number/expiry date, and position in fridge. Investigate whether any patients have been vaccinated by stock

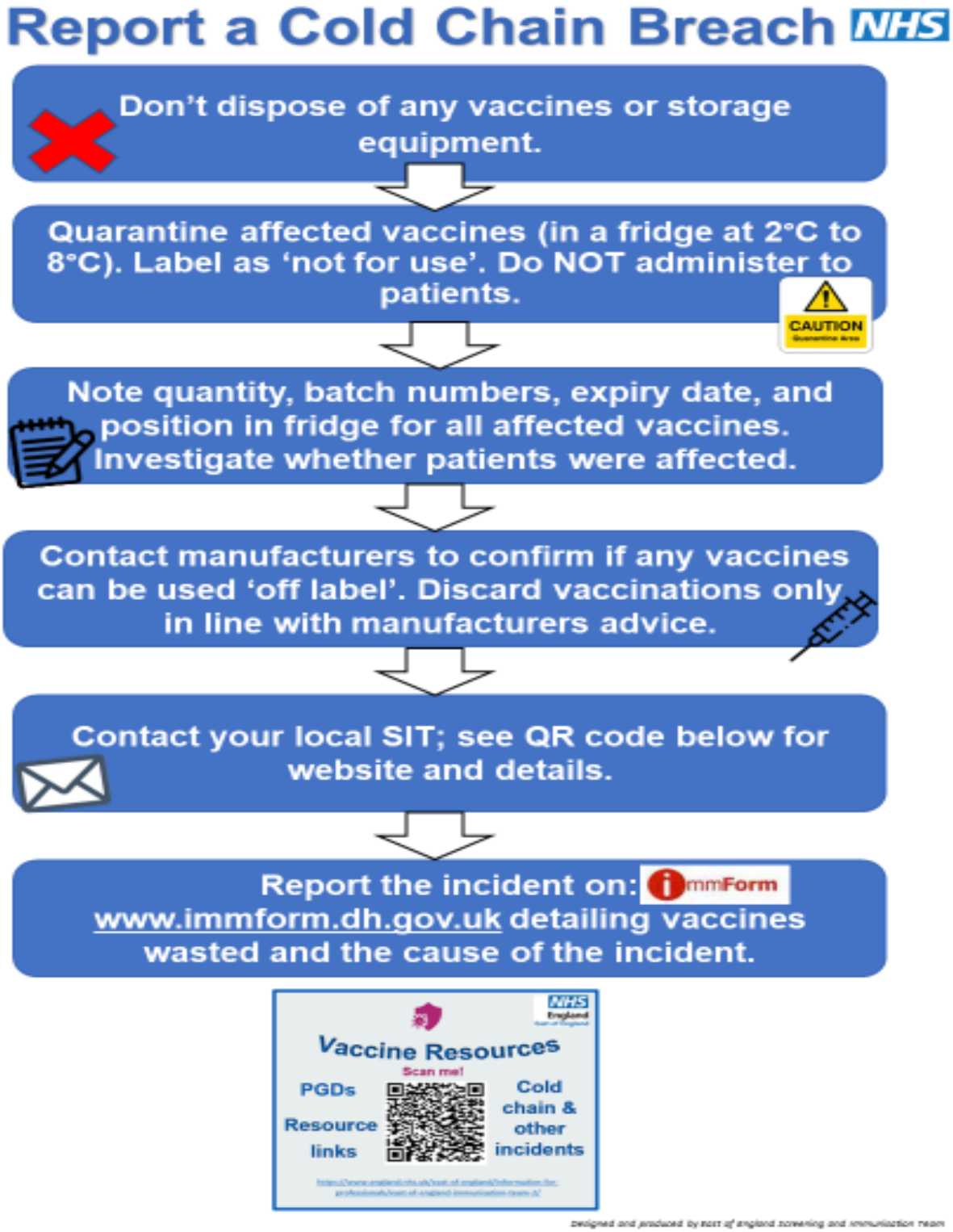
compromised by the cold chain breach. Complete Vaccine Incident checklist form (Appendix 8 of the EoE Cold chain Policy).

6. Contact the manufacturers (see table below) of the affected vaccines to assess which, if any, of the vaccines are still appropriate for use ‘off label’. Discard all vaccinations which have been confirmed as not stable according to national and local policy.

7. Contact your local screening and immunisation team (SIT) to advise of the incident and confirm the action taken. You will be asked to complete a Significant Event form (Appendix 7). For contact details of your local SIT see Appendix 3.

8. Report the incident on ImmForm www.immform.dh.gov.uk detailing all disposed vaccines and the causes of the incident.

A poster has been produced for use in the event of a cold chain breach. Printable version on resources page.



## Manufacturer Contact Details

| Vaccine | Manufacturer | Telephone Number | E-mail |
|---|---|---|---|
| Infanrix hexa© (DTaP/IPV/Hib/HepB) | GlaxoSmithKline UK | 0208 047 5000 | cUK.Ireland-CPA@gsk.com |
| Rotarix© (Rotavirus) | | | |
| Menitorix© (Hib/MenC) | | | |
| Priorix© (MMR) | | | |
| Boostrix©-IPV | | | |
| Bexsero© (MenB) | | | |
| Menevo© (MenACWY) | | | |
| Engerix B© (HepB) | | | |
| Shingrix© (shingles) | | | |
| Prevenar 13© (PCV) | Pfizer Limited | 0800 0327907 or 0345 608 8866 | Use the chat function online at Contact Us \| Pfizer UK |
| Nimenrix© (MenACWY) | | | |
| Abrysvo© (RSV) | | | |
| Fluenz© (Flu nasal spray) | AstraZeneca UK Limited | 0800 783 0033 | medical.informationuk@astrazeneca.com |
| Repevax© (DTaP/IPV) | Sanofi Pasteur | 0800 035 2525 | uk-medicalinformation@sanofi.com |
| Revaxis© (Td/IPV) | | | |
| QIV/QIVe (Flu) | | | |
| QIV-HD | | | |
| Vaxelis■ (DTaP/IPV/Hib/HepB) | | | |
| Adacel■ (Tdap) | | | |
| Men Quadfi© (MEN ACWY) | | | |
| Gardasil■ (HPV) | MSD | | |

| | | | |
|---|---|---|---|
| **Pneumococcal polysaccharide vaccine (PPV)**<br>**MMRvaxPro©**<br>**Zostavax (Shingles)** | | **0208 154 8000** | **medicalinformationuk@msd.com** |
| **QIVc**<br>**aQIV** | **Seqirus UK Limited** | **01748 828816** | **SeqirusGB@eu.propharmagroup.com** |
| **QIVe** | **Viatrus** | **01707 853000** | **reception@viatris.com** |
| | | | **For Covid-19 vaccinations please contact england.vacprg@nhs.net for further information** |

We have produced an email template to assist with contacting specific manufacturers for advice following a breach.

Email Template:

Dear

The following vaccines have been exposed to a maximum / minimum (delete as appropriate) temperature of _____°c, for a maximum time period of _____hours_____mins.

| Vaccine | Expiry date | Batch number |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

Please can you provide the stability data for the vaccines under these conditions.

Thank you.

Yours sincerely,

**Vaccine Inventory Template (for each manufacturer) detailed below.**

| Manufacturer: GlaxoSmithKline UK 208 047 5000 | | | | |
|---|---|---|---|---|
| Vaccine type | Number of vaccines | Expiry date(s) | Batch number(s) | Summary of incident (e.g. length of time/temp of vaccines during breach) |
| Rotarix (Rotavirus | | | | |
| Infanrix hexa (DTaP/IPV/Hib/HepB) | | | | |
| Menitorix (Hib/MenC) | | | | |
| Priorix (MMR) | | | | |
| Boostrix-IPV | | | | |
| Bexsero (Men B) | | | | |
| Menveo (MenACWY) | | | | |
| Engerix B (Hep B) | | | | |
| Shingrix (shingles) | | | | |

Pfizer Limited 0800 032 7907

| Vaccine type | Number of vaccines | Expiry date | Batch number | Summary of incident (e.g. length of time/temp of vaccines during breach) |
|---|---|---|---|---|
| Prevenar 13 (PCV) | | | | |
| Nimenrix (MenACWY) | | | | |
| Abrysvo (RSV) | | | | |

AstraZeneca UK 0800 783 0033

| Vaccine type | Number of vaccines | Expiry date | Batch number | Summary of incident (e.g. length of time/temp of vaccines during breach) |
|---|---|---|---|---|
| Fluenz (Flu nasal spray) | | | | |

Sanofi Pasteur (Merck) Limited 0800 035 2525

| Vaccine type | Number of vaccines | Expiry date | Batch number | Summary of incident (e.g. length of time/temp of vaccines during breach) |
|---|---|---|---|---|
| Repevax (DTaP/IPV) | | | | |
| Revaxis (Td/IPV) | | | | |
| QIV/QIVe (Flu) | | | | |
| QIV-HD | | | | |
| Vaxelis (DTaP/IPV/Hib/HepB) | | | | |
| Adacel (Tdap) | | | | |
| Men Quadfi (MEN ACWY) | | | | |

MSD 0208 154 8000

| Vaccine type | Number of vaccines | Expiry date | Batch number | Summary of incident (e.g. length of time/temp of vaccines during breach) |
|---|---|---|---|---|
| Gardasil (HPV) | | | | |
| MMR VaxPRO (MMR) | | | | |
| Pneumococcal polysaccharide vaccine (PPV) | | | | |

Sequiris 01748 828 816

| Vaccine type | Number of vaccines | Expiry date | Batch number | Summary of incident (e.g. length of time/temp of vaccines during breach) |
|---|---|---|---|---|
| QIVc | | | | |
| aQIV | | | | |

Viatrus 01748 828816

| Vaccine type | Number of vaccines | Expiry date | Batch number | Summary of incident (e.g. length of time/temp of vaccines during breach) |
|---|---|---|---|---|
| QIVe | | | | |

## Off Label Vaccine Use

Information sourced from UKHSA "The use of vaccines that have been temporarily stored outside the recommended temperature range" Leaflet

"Vaccines, like all medicines, should always be stored in accordance with the manufacturer's instructions. If they have been inadvertently frozen or have fallen outside the 'cold chain' for a long period, they may not be as effective and so should not be used. Sometimes however, the storage temperature has varied only a little and most vaccines can tolerate being above the recommended range for a short period of time. For example, vaccines in a fridge that breaks down during the night are likely to still be usable the following day if they are quickly placed back into the recommended cold chain temperature range. Although small temporary changes are not likely to affect the safety of the vaccine, nor the way in which it works, it means the vaccine is referred to as being used 'off-label' because it has been stored in a way other than that described in its licence".

Key points re off-label vaccine use:

- As part of the manufacturer's licensing conditions, it is recommended that vaccines are kept cool at all stages of their production, distribution and storage.
- Sometimes, however, this 'cold chain' as it is called, is interrupted and the vaccines may get warmer or colder than recommended.
- For many vaccines there is good evidence that minor or short-term temperature changes do not affect how well the vaccine works. So, as long as the vaccine is used within its shelf life, it will still be effective.
- Although small temporary changes are not likely to affect the safety of the vaccine, nor the way in which it works, it means the vaccine is referred to as being used 'off-label' because it has been stored in a way other than that described in its licence.

- The decision to allow the vaccine to be used ‘off-label’ will only be taken if the vaccine is still considered to be safe and effective.

- This may be the only way the vaccine is available at an appointment and refusal may delay protection against serious infections.

- The PGD’s cover off-label vaccine use for example:

| | |
|---|---|
| **Off-label use** | Administration of a two-dose primary series of Prevenar®13 to pre-term infants <37 weeks gestation is contrary to the three-dose primary schedule detailed in the SPC but is in accordance with the recommendations for the Vaccination of premature infants and Chapter 25 of the ‘Green Book’.<br><br>Administration of a one-dose primary series of Prevenar®13 is contrary to the two or three dose primary schedule detailed in the SPC but is in accordance with the recommendations and Chapter 25 of the ‘Green Book’.<br><br>A single dose schedule for previously unvaccinated individuals between 12 months and up to 2 years of age is contrary to the 2-dose schedule detailed in the SPC but is in accordance with the national recommendations for the Vaccination of individuals with uncertain or incomplete immunisation status and Chapter 25 of the ‘Green Book’.<br><br>A single dose schedule for partially immunised individuals between 12 months and up to 2 years of age is not consistent with the SPC but is in accordance with the national recommendations for the vaccination of individuals with uncertain or incomplete immunisation status and Chapter 25 of the ‘Green Book’.<br><br>Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.<br><br>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence. |

The Specialist Pharmacy Service (SPS)

Specialist Pharmacy Service (SPS) have a Regulated Medicines stability tool that can be used to assess viability of vaccines stored outside of the cold chain. UKHSA advise in the first instance that the manufacturers are contacted to assess viability and this tool is used as part of the process.

Studies have shown that if fridge air temperatures exceed 8°C for less than 20 minutes, this will not have warmed the medicine itself above 8°C.

Summary of Product Characteristics (SmPC)

For a number of products the SPC information includes stability data to enable the product to be used on license following a cold chain breach. **The products listed below are licensed for storage at temperatures outside of the 2 – 8 degree celsius range and would therefore not be considered off-label in certain cirumstances.**

Summary of Product Characteristics (SPC) – Further information can be accessed at emc (electronic medicines compendium)

**Prevenar 13**

**Infanrix Hexa**

**Gardasil 9**

## Why do we offer vaccines 'off-label'?

"All routine vaccines currently used in the UK are licensed to be placed on the market. So, as well as having the data to support their safety and efficacy in accordance with the license, it means they have been manufactured to a high standard and have undergone

independent batch testing before release. Sometimes, however, clinical experts on JCVI recommend that the vaccine should be used in people who were not included in the initial trials or recommend that the number or timing of the doses is different from that used in the trials. As these situations were not specified in the license this would mean the vaccine was being used 'off-label'. This recommendation is normally based on additional evidence presented to the committee that may have been obtained by a research group independent from the manufacturer. Sometimes it reflects the expert clinical judgement of the members based on their understanding of how vaccines work in different patient groups. When a vaccine is being used 'off-label', it means that experts have advised that there are clear benefits of using the vaccine in this way and that the vaccine is still considered to be safe and effective. 'Off-label' use of vaccines does not mean they are unlicensed – they are licensed for use in different people or to be used in a slightly different way from the license recommendation. Often, the information gained from off-label use is then used by the manufacturer to apply to modify the license to include these different uses."

## Examples of 'off-label' vaccines being used successfully in practice

"One example is the use of a whooping cough vaccine in pregnant women. In the years running up to 2012, the UK experienced an increase in the number of whooping cough cases – many in babies too young to be vaccinated themselves. An urgent decision on how best to prevent deaths and serious illness in these babies was required. In 2012, JCVI agreed that the best way to protect these very young babies was by vaccinating pregnant women with pertussis (whooping cough) vaccine. This would ensure that babies were born with high levels of antibody from their mothers.

There were 2 vaccines suitable for boosting whooping cough protection in adults but neither had been tested on pregnant women because such women are excluded from most clinical trials. However, data on the extensive use of vaccines with similar components was available and suggested that the vaccine would be safe and effective. One of the vaccines was therefore offered 'off-label' to pregnant women and around 70% of mothers now receive the vaccine.

This vaccine programme quickly resulted in a significant fall in the number of whooping cough cases and deaths in babies and detailed analysis has shown that the vaccine is safe for the mother and the pregnancy. Based on the success of this vaccination programme, and particularly the important data on safety and effectiveness in pregnant women generated in the UK, regulators should now be able to determine if use in pregnancy will be 'within label' in the future"

Patient Consent

**The Green Book Chapter 2** details the principles of consent for immunisations.

## 12.2 Patient consent

Patients' consent needs to be obtained before the administration of any vaccine. Patients should be provided with sufficient information so as to provide valid consent and all questions should be answered fully and openly. It is at the discretion of the healthcare professional as to whether to inform patients, when obtaining consent, that a vaccine to be supplied or administered has been stored outside the terms of the marketing authorisation.

It is at the discretion of the healthcare professional whether to discuss 'off-label' vaccine use with patients/parents when administering a vaccine 'off-label'. This discretion to inform patients only applies to those vaccines that have not been compromised. If compromised vaccines have been administered the practice have a professional duty to inform their patients.

Parent guides can be accessed here

The GMC guidance (Prescribing unlicensed medicines - ethical guidance - GMC (gmc-uk.org)) also helpfully confirms that unlicensed medicine may be necessary to use if:

"A suitably licensed medicine that would meet the patient's need is not available. This may arise where, for example, there is a temporary shortage in supply."

**Resoures**

Managing temperature excursions – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice)

Stability outside the fridge – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice,

Prescribing unlicensed medicines - ethical guidance - GMC (gmc-uk.org)

The use of vaccines that have been temporarily stored outside the recommended temperature range - A brief guide for parents, carers and patients (publishing.service.gov.uk)

The use of vaccines that have been temporarily stored outside the recommended temperature range - A brief guide for parents, carers and patients (publishing.service.gov.uk)

Off-label vaccine: leaflets - GOV.UK (www.gov.uk)

Printable Poster