Vaccine Storage and Handling -

Cold Chain Policy

NHS England – East of England

Authors: East of England Screening and Immunisation Team

Date: March 2026

Version: 9.1

Date for Review: March 2028 (or when clinical advice is updated – whichever is sooner)

Change history

Version number	Change Details	Date
V06.00	Appendix 4 Vaccine Manufacturers Contact details: Addition to vaccines listed to include Engerix B (Hep B) to GSK section.	19/4/2022
V06.00	Public Health England (PHE) logo removed.	27/5/2022
V06.00	NHS improvement removed.	1/10/2022
V07.00	Manufacturer contact details amended and email contacts added.	11/04/2023
V07.00	Appendix 4 Vaccine Manufacturers Contact details: Addition to vaccines listed to include Vaxelis (Hexavalent) to Sanofi section.	11/04/2023
V08.00	Incident Pathway Process and Updated incident form Additional product changes flu/MenACWY/pertussis/RSV and manufacturer contact details	
V09.00	Electronic incident form linked and advised is preferred method of reporting incidents by providers	
V09.1	Correction to email address for RVOC, page 17; england.eoe-vacprg@nhs.net	13/5/2026

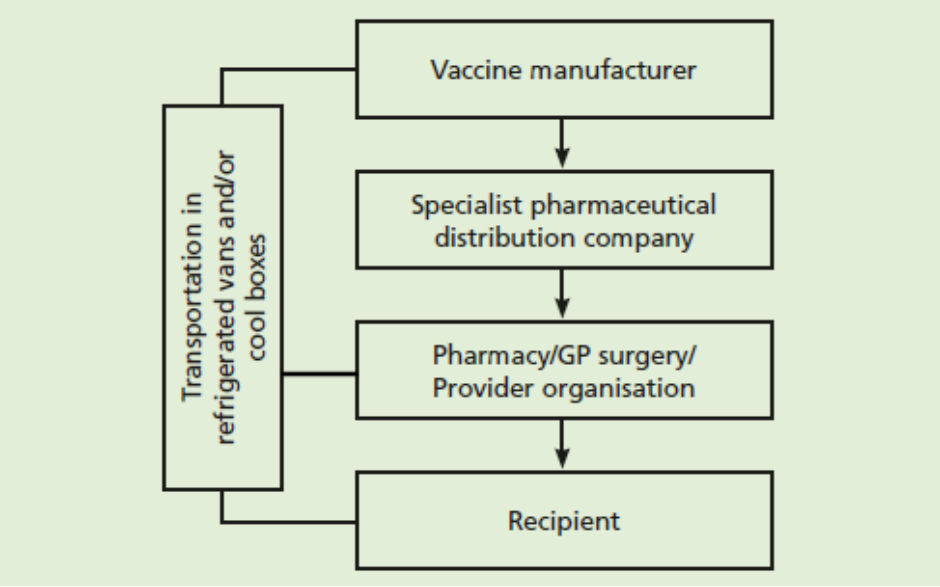
Contents

1. Introduction

1.1 Background

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 appropriate temperature range +2°C to +8°C[1]. Vaccines are sensitive biological substances that when too hot or too cold can quickly lose their efficacy. 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.

Chart 1[2]



This policy aims to support service providers to efficiently manage vaccine handling, storage, and the cold chain. Its purpose is to ensure that vaccines are stored and managed appropriately to allow vaccination to be carried out efficiently and safely. To achieve this, this policy provides clear and comprehensive information around cold chain storage and maintenance. This policy also advises on the correct procedure in the event of a cold chain breach and to mitigate the potential wastage

[1] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/833415/PHE_vaccine_incident_guidance.pdf

[2] https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3

of vaccines.

Service providers commissioned to deliver vaccinations should have at least two fully trained individuals who are accountable for the cold chain management. All staff should be aware of the importance of safe vaccine management. Maintenance of the cold chain should be part of all new staff inductions, as well as clinical staff annual immunisation training.

This policy outlines pathways to help staff in the event of a cold chain breach. These pathways are based on National guidance[3]

> Pathway 1) actions 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.

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. An example of a Vaccine Storage Audit form can be found on our web pages.

1.2 Scope of Policy

This Cold Chain Policy supports the vaccination programmes carried out by service providers across East of England. This policy should be used in conjunction with the National Vaccine Incidence Guidance, UKHSA Protocols on Storage and Handling, and the Green Book[4].

2. Ordering and Receipt of Stock

2.1 Ordering Stock

Service providers should ensure that stock is ordered at **least every 1-2 weeks** according to need only. ImmForm allows users to place orders on a weekly basis so there is no need to order in bulk. Over-ordering can result in significant wastage and unnecessary costs to vaccination providers and the NHS.

[3] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/833415/PHE_vaccine_incident_guidance.pdf

[4] https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3

Please consider packaging sizes for the vaccines to ensure fridges are not overstocked as this can prevent air circulation.

Vaccine wastage cost £6.4 million of NHS funds in 2025, £5.4 million of which was avoidable (Vaccine update: issue 369, February 2026 - GOV.UK).

The nominated cold chain lead should ensure that vaccine stock is monitored on a weekly basis. This is to ensure that stock levels can be observed to prevent over-ordering, vaccine shortages and stockpiling. Vaccine fridges should be no more than 50% full. 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-stocked refrigerators, leading to poor air flow and potential freezing.
- Reduce the space in clinic refrigerators available for periods of high demand and outbreaks *e.g.,* flu season.

2.2 Receipt of Stock

All staff involved in vaccinations should be trained in line with the National Minimum Training Standards[5, 6]. The nominated cold chain lead is primarily responsible for receiving vaccines, deputies should also be identified to oversee receipt of stock when the lead is unavailable. When vaccines arrive at the designated venue, any staff accepting delivery should be aware of the need to certify that there is no damage to the vaccine packaging or any potential leakage of vaccines. This must be done before signing for the delivery. Manufacturers will not accept items for return once they are no longer under their control.

All members of staff to be aware that a vaccine delivery needs to be refrigerated immediately if the nominated cold chain lead is not available.

Once the vaccines have been signed for, it is recommended that the following information should be recorded in a separate stock control book / system:

- Vaccine type and brand
- Quantity
- Batch number and expiry date
- Date and time of receipt
- Running total of vaccines, including wastage
- Signature of person receiving delivery

[5] https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners
[6] https://www.gov.uk/government/publications/immunisation-training-of-healthcare-support-workers-national-minimum-standards-and-core-curriculum

While more sophisticated stock information systems are available, as a minimum, a paper-based record or simple spreadsheets could be used for stock management and monitoring. Stock information systems are most effective when updated immediately upon ordering and receipt of vaccines and at the end of clinical sessions where vaccines have been administered. Vaccine stock should be checked and records updated at least every month.

Ensure there is one stock control book for each vaccine fridge or clearly differentiate between vaccine fridges in a stock control system where there is multiple. Promptly transfer the stock of vaccines into the fridge, always maintaining the cold chain.

Vaccines must be kept within their original packaging when placed into the fridges to prevent damage to the vaccine. Keep vaccines away from the sides of the fridge or the floor to allow for air circulation and to avoid them freezing.

Freezing can irreversibly denature [affect/destroy] the proteins in the vaccine and significantly reduce the efficacy of the vaccine. In addition, hairline cracks can form in the vial/syringe which can contaminate the contents.

3. Vaccination Storage

3.1 Stock maintenance

The nominated cold chain lead is responsible for certifying there is good vaccine stock management and monitoring of stock on a regular basis. The temperature monitoring chart should be located near the vaccine fridge. Example of a temperature monitoring chart (**Appendix 2**).

Vaccine stock checks should be carried out at least **once a week** with any updated information being recorded in the stock control book. When carrying out a stock check, ensure that stock is rotated regularly and vaccines with the shortest expiry date are placed at the front of the refrigerator and used first.

Any expired vaccines should be discarded immediately and appropriately in line with the recommended National and local policies[7]. **Discarded stock should be reported on the ImmForm website as a 'stock incident'**. This is to ensure that all vaccines within the fridge are safe and suitable for use, and to safeguard against inappropriate vaccinations being administered to patients.

If an expired vaccination is administered to a patient, the nominated cold chain lead should immediately contact the vaccine manufacturer and local Screening and Immunisation Team (SIT). The cold chain lead should gather all required information relating to the incident. Local SIT contact details can be found in **Appendix 3**.

Any vaccine that has been removed from the fridge and returned to the fridge having not been administered must be clearly marked. The time and date of its return should

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

be logged, and the vaccination must be placed at the front of the fridge to be used first at the earliest opportunity. This is applicable to vaccinations that have remained within the recommend +2°C to +8°C only.

Any vaccines involved in a potential cold chain breach should NOT be removed from the cold chain whilst investigation is under way.

Vaccines should always be kept within their original packaging. This protects the vaccines from light exposure and potential damage as well as maintaining a consistent temperature.

Vaccine stock should be stored across multiple fridges. This helps to prevent complete stock wastage should a single fridge fail.

3.2 The vaccine fridge

A validated medical / pharmacy vaccine fridge must be used to ensure that stored vaccines are maintained within the +2°C to +8°C temperature range. The ideal temperature for a vaccine fridge is 5°C, this ensures there is leeway of ±3°C. There are occasions when the fridge temperature may fluctuate *i.e.,* during stock rotation. If this occurs, then action as follows: note on the temperature monitoring chart and ensure that the temperature resumes to +2°C to +8°C range **within twenty minutes**.

The fridge temperature should be checked at **least once a day** and recorded on a temperature monitoring chart (**Appendix 2**). There is no requirement to keep paper copies of fridge monitoring charts, but electronic copies must be easily accessible and cover the full storage history of any products contained within the fridge. The Green Book Chapter 3 advises that retaining temperature records for 'five years will generally enable the full storage history of the vaccines be accounted for'.

If cool boxes are being used, they must be validated and ensure that the temperature is recorded and monitored. It is recommended that digital thermometers are used to record the temperature, as these allow for a more accurate reading. Ideally a thermometer that uses a probe in the centre of the stock. Service providers should ensure the thermometers are re-set and replaced as per the fridge manufacturer's guidance.

It is recommended that data loggers are used for monitoring fridge temperatures. Data loggers continuously monitor and record the temperature of the fridge which allows for accurate temperature readings. This is particularly useful in the event of a cold chain breach when staff are trying to establish how long the fridge temperature may have been compromised. If it is known exactly how long vaccines have been out of the appropriate range this can mitigate the amount of wastage caused from cold chain breaches. It is recommended that the data logger information be reviewed a minimum of weekly. If the data is not regularly downloaded the data logger may

become full and stop recording. When checking the fridge temperature ensure that the four '**R**'s are observed:

- **Read** Check temperature at the same time daily and sign the sheet when completed.
- **Record** Record temperature in standard fashion on a temperature monitoring chart.
- **Reset** Reset the temperature after each reading.
- **React** React if the temperature falls outside +2°C to +8°C

The vaccine fridge must only be used to store vaccines and medicines. Specimens and food should never be placed in the vaccine fridge. The fridge should always be kept clean and safeguarded against ice building up.

To avoid the possibility of vaccines freezing, vaccines should not be placed against the walls or the floor of the fridge.

All vaccine fridges should meet the National recommendations[8]. The nominated cold chain lead should ensure that:

- All fridges have a unique identifier *i.e.,* a serial number
- The refrigerator is safe. Carrying out regular visual checks and portable appliance testing (PAT) can safeguard this.
- The refrigerator is lockable or at least within a locked room. All vaccines are Prescription Only Medicines (POMs) and therefore must be locked away.
- There is a maintenance contract that allows for yearly servicing.
- Vaccine fridges are included in the practice capital replacement plans.
- There has been consideration for safeguarding against the possibility of interruption to the electrical supply *i.e*. installing a switchless socket.

As well as carrying out regular stock and temperature checks, service providers should have up to date records of regular servicing, electrical testing, cleaning, and defrosting of the fridges.

3.3 Auditing of stock

Regular audits of vaccine stock should be carried out as per the national recommendations[9] below:

- 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.

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

4. Transporting Vaccines

There may be instances when the service provider transports vaccines *i.e.* for a home visit or to care homes. When transporting vaccines, in order to reduce the possibility of damage during transit, validated cool boxes and cool packs from an appropriate medical supply company should be used. Different types and models of cool boxes have varying storage capacities and sizes of water packs.

It is vital to use the correct number and size of water packs, exactly as specified by the manufacturer.

Ensure that validated cool boxes/vaccine carriers are stored as per manufacturer's instructions. Vaccines should be removed from the fridge at the latest possible stage to minimise the length of exposure time out of the fridge and to ensure the cold chain is always maintained.

When transporting vaccines ensure they are kept in their original packaging and placed into the cool box/vaccine carrier with the cool packs according to the manufacturer's instructions. It is important to ensure there is no direct contact between the cool packs and the vaccine, as this could cause potential freezing and destabilize the vaccination. A data logger to continually monitor temperatures for transport is recommended.

On arrival at the designated centre, the vaccines should be placed in a vaccine fridge if possible. If not, then the vaccines should always be stored within the cool box/vaccine carrier with the lid closed until required. Similarly, with the vaccine fridge, certify that the cool box/vaccine carrier is placed in a secure location until the vaccines are to be administered.

Those vaccines not used during transport that can be returned to the service provider's base fridge, should be dated, and labelled as 'use first' to ensure minimum vaccine wastage.

5. Disruption of the Cold Chain

5.1 Immediate actions

In the event of a cold chain breach, ensure the following procedures are carried out:

1. Do not dispose of any vaccines or storage equipment.

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. 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. DO NOT remove from the cold chain whilst investigation takes place as this will result in stock being unusable.

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**).

6. Contact the manufacturers of the affected vaccines to assess which if any vaccines are still appropriate for use 'off label'. For a list of all manufacturers and their contact details **(Appendix 4).** Discard all vaccinations which have been confirmed as not stable according to National and local policy. 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.

7. Contact your local screening and immunisation team (SIT) to advise of the incident and confirm the action taken, this can be done by completing the electronic incident form (Vaccine Incident Reporting Form). Please note that outside of working hours (8am until 5pm Monday to Friday {not including bank holidays} any urgent advice can be sought from the UKHSA Health Protection Team Email: PHE.EoEHPT@nhs.net or Tel: 0300 303 8537

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.**

The East Screening and Immunisation Team have developed this policy which provides information on what to do in the event of a potential cold chain breach. All

guidance and resources can be found on the EoE Website NHS England — East of England » Vaccine and cold chain incident management

Pathway 1 **(Appendix 5)** should be followed in the event of a cold chain breach. Pathway 2 **(Appendix 6)** should be followed for Investigating serious cold chain breaches.

The local SIT should be informed of what happened and the electronic incident form (e-form) should be completed (Vaccine Incident Reporting Form). The e-form should be the first-line method to report all incidents. If the reporter is unable to access the e-form, the incident should be reported manually using the template provided in Appendix 7 and returned to the relevant e-mail address.

5.2 Formation of Incident Control team

In the event of a Cold Chain breach that affects patients, the formation of an Incident Control Team (ICT) should be undertaken. The SIT will usually lead on the incident but if outside of normal working hours (Monday to Friday 8am until 5pm) the UKHSA Health Protection Team may be able to provide advice. Contact the team on 0300 303 8537 or EastofEnglandhpt@ukhsa.gov.uk

The service provider and other key stakeholders will be invited to an incident meeting.

The incident control team will analyse all the information related to the Cold Chain breach and make recommendations. This may include re-calling patients for re-vaccination. Further guidance on revaccination[10] and actions for the ICT **(Appendix 6).**

5.3 Follow up actions

A discussion should be held with all staff involved in the Cold Chain breach. This provides an opportunity for the team to confirm that the relevant protocol has been followed as well as discussing any lessons learnt.

Service providers should keep an internal record of Cold Chain incidents, actions taken and dates, and any significant lessons learnt if applicable, which would be useful for CQC inspections See below links to the CQC's guidance for further helpful information: https://www.cqc.org.uk/guidance-providers/gps/how-we-monitor-inspect-regulate-gp-practices

5.4 Patient Communication

The service provider should be able to explain the risks and benefits of being re-vaccinated to their patients. The service provider should know who to contact (*e.g.*

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

local Screening and Immunisation Team, Health Protection Team, or Community Paediatrician) if they are unable to answer any questions.

It is the professional duty of candour to be open and honest with patients.

Example of patient/carer/parent letter (**Appendix 9**).

Patients' consent needs to be obtained before the administration of any vaccine. Patients should be provided with enough information to ensure they are able to make informed decisions and give informed consent.

Patients' 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[11] The practice should offer patient information leaflets on 'off label' use of vaccines[12].

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.

[11] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/833415/PHE_vaccine_incident_guidance.pdf
[12] https://www.gov.uk/government/publications/vaccines-stored-outside-the-recommended-temperature-range-leaflet

Appendix 1

Vaccine Storage Incident Checklist

- ✓ Do not dispose of any vaccines or storage equipment
- ✓ Isolate potentially compromised vaccines clearly labelling ‘not for use’, these vaccines should be maintained between +2°C to +8°C and moved to an alternative monitored environment that is able to maintain recommended +2°C to +8°C temperature range
- ✓ Ensure vaccine fridge involved remains switched on and that the main electrical supply that thermometer and thermometer probe are undisturbed, and staff are aware they should not be accessing fridge
- ✓ Do not remove vaccines from the cold chain whilst investigation takes place
- ✓ Refer to algorithm (Appendix 5) and cold chain checklist (Appendix 8)
- ✓ Inventory of all exposed vaccines stored in fridge recording quantity, expiry date, position in fridge
- ✓ Contact local Screening and Immunisation Team (Appendix 3)

Appendix 2

Example of Temperature Record Chart[13]

[13] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/223753/Green_Book_Chapter_3_v3_0W.pdf

A sample refrigerator temperature record chart

Name of health facility: .....

Fridge identifier: .....

Month and Year: .....

The temperature should be between +2°C and +8°C. Check each working day. If the temperature is outside the recommended range, take appropriate action as indicated in the written procedure.

Remember: Read, Record, Reset and React.

Date	Time	Current temp	Min temp	Max temp	Checked by (signature)	Thermo-meter reset (tick)	Comments

Monthly review by: ..... (name) ..... (date).

Appendix 3

Contact information for local Screening and Immunisation Teams

Screening and Immunisation Team	Email

East Anglia (Cambridge & Peterborough, Norfolk, Suffolk)	england.eaimms@nhs.net
Essex	england.essexatimms@nhs.net
Herts/Beds/Luton/Milton Keynes West Essex	england.immsqa@nhs.net
Regional Vaccination Operations Centre (please send incident forms here if not using the electronic incident form and instead using Appendix 7)	england.eoe-vacprg@nhs.net

Note: Service providers should put all immunisation and cold chain queries in writing to the appropriate email address. Incidents should be reported using the electronic incident form (link: Vaccine Incident Reporting Form), you will receive an automatic acknowledgement and if the SIT requires any further information they will contact you within two working days.

All emails received out of office hours will be responded to on the next working day, in the interim please follow all actions as specified in Pathway 1,

Appendix 5

UKHSA Health Protection Team (out of hours incidents involving patients)	**Email: EastofEnglandhpt@ukhsa.gov.uk** **Tel: 0300 303 8537**

Appendix 4

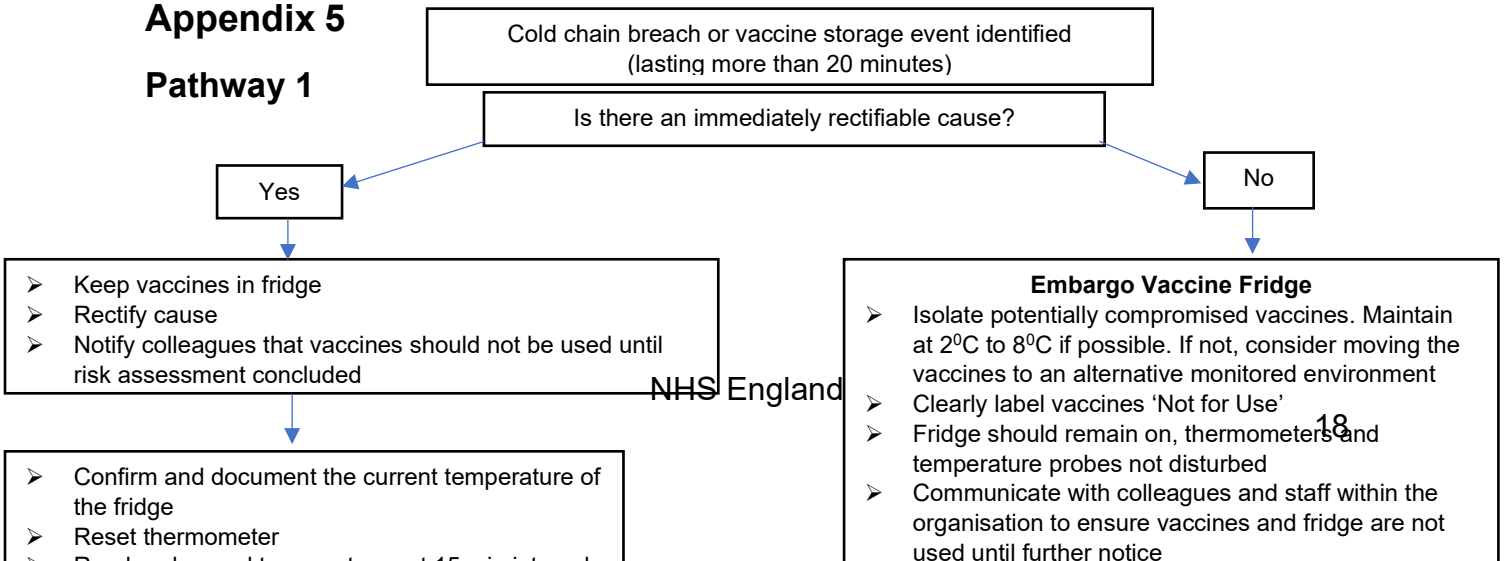
Vaccine Manufacturers' Contact Details

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) / Priorix Tetra® (MMRV)			
Boostrix©-IPV			
Bexsero© (MenB)			
Menevo© (MenACWY)			
Engerix B© (HepB)			
Shingrix© (shingles)			
Prevenar 13© (PCV) / Prevenar®20 (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**	**0208 154 8000**	**medicalinformationuk@msd.com**
Pneumococcal polysaccharide vaccine (PPV)			
MMRvaxPro© (MMR) / ProQuad® (MMRV)			
Zostavax (Shingles)			
QIVc aQIV	Seqirus UK Limited	01748 828816	SeqirusGB@eu.propharmagroup.com
QIVe	**Viatrus**	**01707 853000**	**reception@viatris.com**
			For Covid-19 vaccinations please contact england.eoe-vacprg@nhs.net for further information

Appendix 5

Pathway 1



REPORT INCIDENT TO LOCAL SCREENING & IMMUNISATION TEAM
(see Contact Information- Appendix 3)

Investigate the incident

- Request refrigerator engineer to inspect fridge & thermometers (unless the cause of the breach was not related to appliance performance)
- Confirm current fridge temperatures and temperature patterns using data logger for 48-72 hrs
- Check fridge service history
- Check refrigerator temperature records and clarify cold chain practice prior to event

Carry Out Informed Risk Assessment

- Contact manufacturers of affected vaccines to identify whether potency is likely to be affected by the cold chain breach/storage conditions identified and confirm if vaccines are still appropriate for use off-label
- Consider seeking further advice from SIT, HPT or NHS national immunisation team

Vaccine satisfactory for use

- Label as 'involved in incident' & use first (see section 7.3 of National Vaccine Incident Guidance)

Vaccine compromised

- Dispose of vaccines as per local wastage policy
- Complete stock incident form on ImmForm

Compromised vaccine given to patients

Report incident via local governance system and identify lessons learned / training needs

Formation of formal Incident Control Team (see Appendix 6)

Appendix 6

Pathway 2

Incident Control Team (ICT) meeting held to discuss incident

Is all the information needed to make a risk assessment available to ICT

Yes

No

- What is not known?
- What further information is needed to make a decision?

Is it considered likely that sub-potent vaccines have been administered?

- Document outcome of incident
- Review cause of incident (and consider audit of immunisation service as whole)
- Evaluate lessons learned

Appendix 7

Example of NHS England - East Vaccine Incident Reporting Form to only be used if the e-form is unavailable. Practice significant event forms can be used instead if they include all the required information.

East of England – Vaccine incident reporting form

This template may be adapted for local system use. You can also use/share your usual incident report forms. It is not a requirement to use this form.

National and local incident guidance is available on the East of England immunisation website - EoE Immunisation Website

Please send all vaccine incident reporting forms to - england.eoe-vacprg@nhs.net

Reporting organisation details	
Name of person completing form & position/role	**Contact details for person completing form (Email/Phone number)**
Name: Position/Role:	Email: Phone Number:
ICB name:	**Date/Time of incident**
☐ Bedfordshire, Luton and Milton Keynes ICB ☐ Cambridgeshire and Peterborough ICB ☐ Hertfordshire and West Essex ICB ☐ Mid and South Essex ICB ☐ Norfolk and Waveney ICB ☐ Suffolk and North East Essex ICB	Date: Time: Vaccine type(s) if applicable:
Organisation name / Incident site name & ODS code / Provider code	
Organisation name/ Incident site name: ODS / Provider Code:	
Full address of site where incident occurred	
Type of incident	
☐ Licensed vaccine given outside legal mechanisms or Green Book (JCVI) guidance ☐ Cold chain / Expired stock	

☐ Additional doses given incorrectly ☐ Wrong cohort / Age ☐ Incorrect administration ☐ Other
Description of incident / Near miss
Vaccine incident guidance or cold chain policy referred to?
Actions taken
Vaccine manufacturer contacted if necessary? Duty of Candour?
Root causes and mitigation
Individual error/ knowledge gap/ time pressures? Recommendation or actions taken/required to prevent or reduce the risk of reoccurrence.
Lessons learned and how these will be shared

Has MHRA Yellow Card been completed	Did this incident occur in the context of an outbreak response
Yes☐ No☐	Yes☐ No☐

A downloadable version of this form is available here

Appendix 8

Vaccine storage incident checklist form

Vaccine Storage Incident Checklist	
Item	Comments
1. Date and time of incident form completion	
2. Fridge Location /Identifier	
3. Date and time of cold chain breach identified	
4. What were the temperature readings when the breach was noticed?	Min Max current
5. Date and time of last guaranteed temperature between +2°C and +8°C	
6. Total duration of excursion	Hours Minutes
7. What alerted you to excursion *(e.g. thermometer reading, fridge alarming, data logger)*	
8. Is there an alarm fitted on fridge? If so *Are parameters set* *After how long outside +2°C to +8°C* *Does the alarm sound*	
9. If the alarm had gone off would anyone have heard it?	
10. Type of fridge Make and Model?	
11. How old is the fridge?	
12. When was fridge last serviced?	
13. Has an engineer checked fridge since incident? What did their report say?	

Appendix 8

Vaccine storage incident checklist form (cont.)

14. How often temperatures recorded	
15. What type of thermometer is in use (integral to fridge, battery operated independent, data logger)	
16. Is there a thermometer probe in the fridge, what is its position in fridge?	
17. When was thermometer last reset?	
18. When was thermometer last calibrated?	
19. Has continuous temperature monitoring 48 hrs with data logger been performed since incident identified?	
20. Result of 48 hr continuous temperature recording with data logger	
21. Possible reason for temperature excursion? *(e.g. re-stock/power failure/busy clinic)*	
22. Any obvious signs of freezing? *(e.g. frosting sides or back of fridge, or wet or damaged boxes)*	
23. Any vaccines against side or back of fridge or pushed against cooling plate or air inlet?	
24. Have any of the vaccines been exposed to previous cold chain breach outside +2°C to +8°C?	
25. What is current vaccine stock, quantity, location, expiry date?	
26. Has anybody been vaccinated with potentially affected vaccines?	
27. Has the cause of the breach been rectified and / or steps taken to prevent problem reoccurring?	
28. Form completed by name/signature/date	

Appendix 9
Example of letter to patient/carer/parent offering re-vaccination

Dear *(patient/carer's name)*

Re: Vaccines received at *(insert name of clinic/vaccination provider)*

I am writing to inform you that we have recently become aware of a problem with the storage/administration *(delete as appropriate)* of the vaccine/vaccines you/your child *(delete as appropriate)* received at *(clinic/vaccination provider name)*.

As a result of this problem, you/your child may not gain full protection from this vaccination, and we would therefore recommend you/your child as a repeat vaccination as soon as possible.

I understand you may have some questions regarding this incident and would ask that you call the practice/clinic on *(insert telephone number)* and make an appointment with *(provide name of GP or immuniser).*

At this appointment we will address any questions you may have regarding the incident and you/your child may/will *(delete as appropriate)* offered repeat vaccination.

I would like to apologise for any inconvenience/concern this may cause you/your family. Please be assured this incident has been fully investigated and every step will be taken to ensure this does not happen again.

Yours Sincerely,

(*Name of GP/Practice Manager)*

Further information and resources

East of England Immunisation Website

https://www.england.nhs.uk/east-of-england/information-for-professionals/east-of-england-immunisation-team-2/

The Green Book:

https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent

National protocol for ordering, storing and handling vaccines: https://www.gov.uk/government/publications/protocol-for-ordering-storing-and- handling-vaccines

Keep your vaccines healthy poster
https://www.gov.uk/government/publications/keep-your-vaccines-healthy-poster

Off label use
https://www.gov.uk/government/publications/off-label-vaccine-leaflets

Vaccines outside of recommended temperature range
Vaccines stored outside the recommended temperature range - GOV.UK (www.gov.uk)

Vaccine Incident Guidance:
https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

World Health Organization:

WHO | World Health Organization

CQC Guidance:
https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour#guidance

CQC Guidance on vaccine storage:
https://www.gov.uk/government/publications/vaccine-storage-management-care-quality-commission-inspection

Immform:
Intranet Portal - Logon

Immform fridge failure help sheet:

https://www.gov.uk/government/publications/fridge-failures-immform-helpsheet-18

Acknowledgements

East of England Screening and Immunisation Teams