



Vaccine Storage and Handling - Cold Chain Policy

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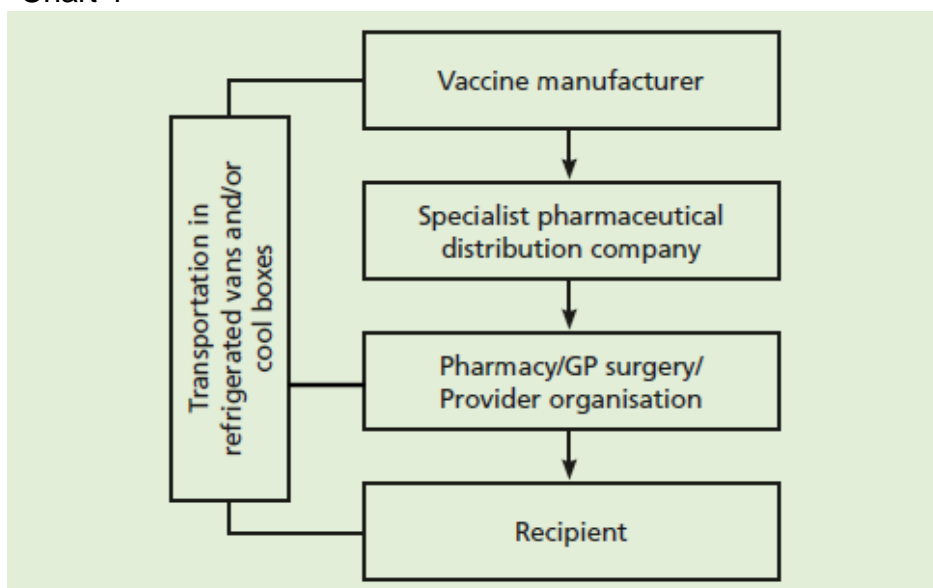
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1. Introduction

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°C¹. 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 1²



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 of vaccines.

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>



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 guidance³

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 occurring.

1.2 Scope of Policy

This Cold Chain Policy supports the vaccination programmes carried out by service providers across East. This policy should be used in conjunction with the National Vaccine Incidence Guidance, PHE Protocols on Storage and Handling, and the Green Book⁴.

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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>



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, Public Health England and the NHS.

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 Standards⁵.⁶ The nominated cold chain lead should be responsible for receiving vaccines. When vaccines arrive at the designated venue, nominated staff should 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.

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

- 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>



Ensure there is one stock control book for each vaccine fridge. Promptly transfer the stock of vaccines into the fridge, maintaining the cold chain at all times.

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. It is recommended that the fridge temperature monitoring chart is kept within the stock control book. This ensures all information is kept in one place. Ideally, this should be located near the vaccine fridge. Example of a temperature monitoring chart (**Appendix 1**).

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 policies⁷. 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 (**Appendix 2**).

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

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



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 $\pm 3^\circ\text{C}$. 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 up to twice a day and recorded on a temperature monitoring chart (**Appendix 1**).

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.

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 safeguard 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 recommendations⁸. 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 recommendations⁹ 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.

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.



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.
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 3**). Discard all vaccinations which have been confirmed as not stable according to National and local policy.
7. Contact your local SIT to advise of the incident and confirm the action taken. You will be asked to complete a Significant Event form (**Appendix 6**). For contact details of your local SIT see **Appendix 2**.
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 has developed this policy which provides information on what to do in the event of a potential cold chain breach.

Pathway 1 (**Appendix 4**) should be followed in the event of a cold chain breach. Pathway 2 (**Appendix 5**) should be followed for Investigating serious cold chain breaches.

The local SIT should be informed of what happened and a significant event form should be completed (**Appendix 6**).

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 should be undertaken. The SIT will usually lead on the incident. 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 revaccination¹⁰ and actions for the ICT (**Appendix 5**).

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. 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.

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



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 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 authorisation¹¹. The practice should offer patient information leaflets on 'off label' use of vaccines¹².

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 2

Contact information for local Screening and Immunisation Teams

Screening and Immunisation Team	Contact No.	Email
East Anglia		England.ea-phsi@nhs.net England.eaimms@nhs.net
Essex	0113 824 9101	England.essexatimms@nhs.net
Herts/Beds/Luton	07899 064484	England.immsqu@nhs.net

Note: Service providers should put all immunisation and cold chain queries in writing to the appropriate email address.



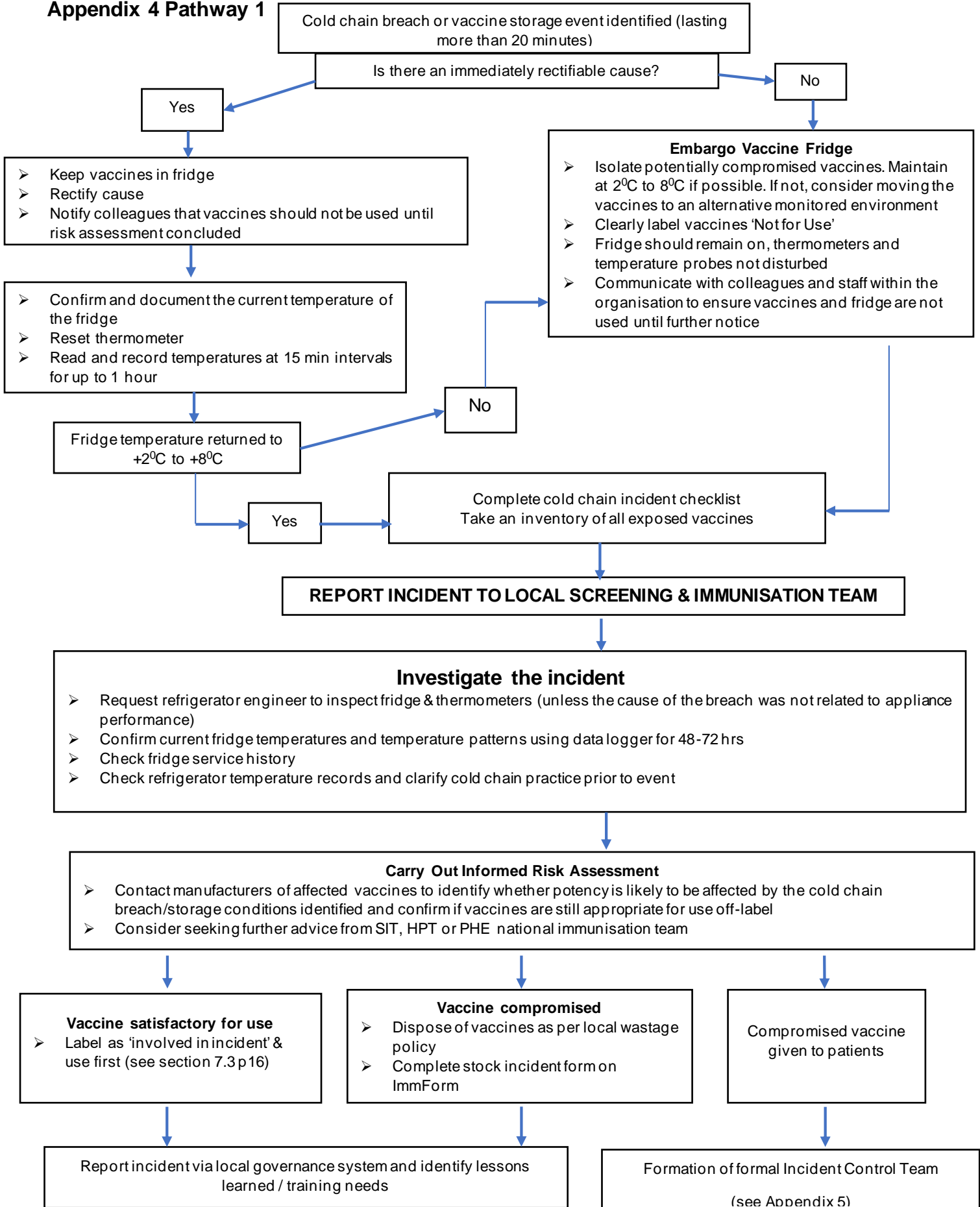
Appendix 3

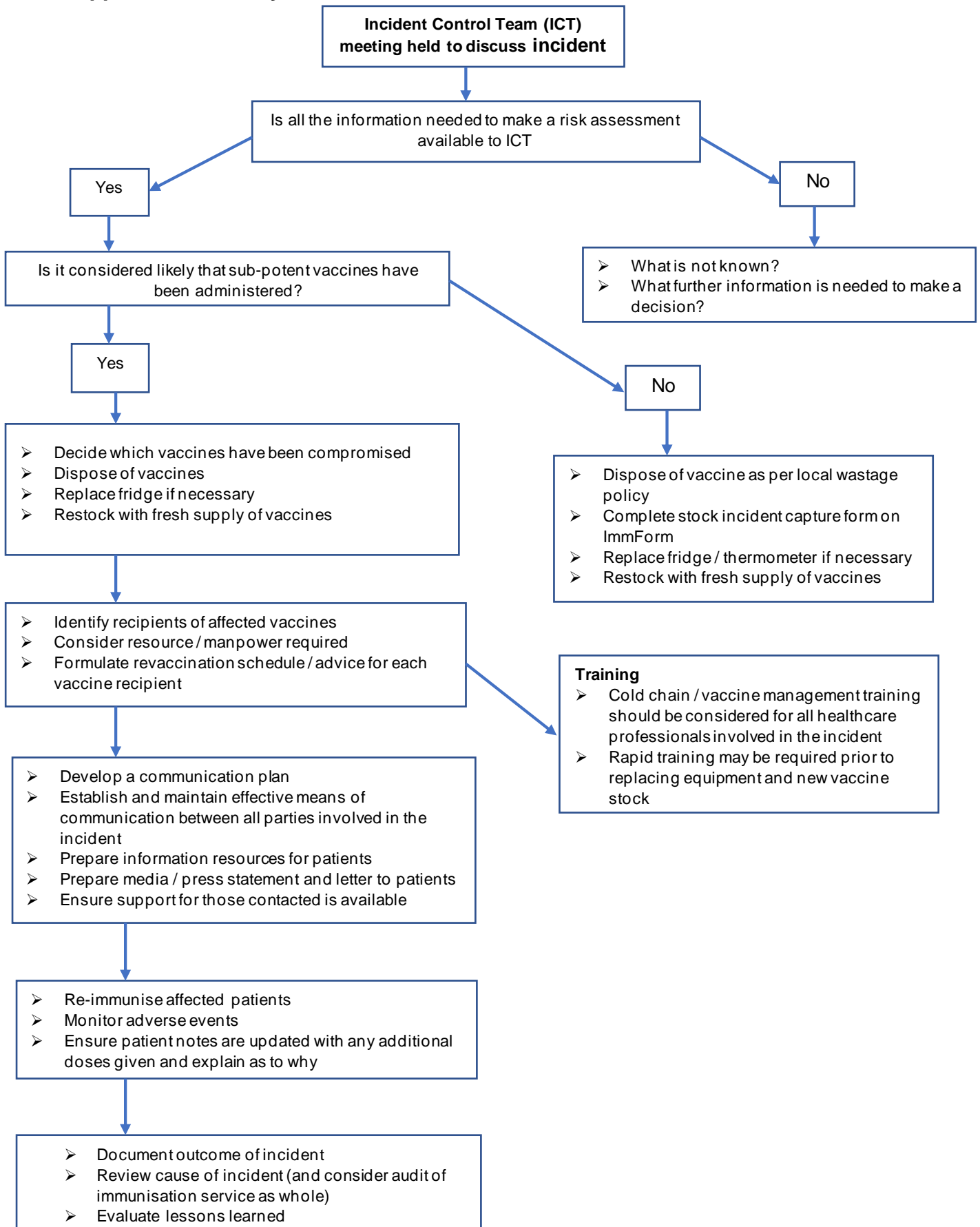
Vaccine Manufacturers' Contact Details

Vaccine	Manufacturer	Telephone Number
Infanrix hexa (DTaP/IPV/Hib/HepB)	GlaxoSmithKline UK	0800 221 441
Rotarix (Rotavirus)		
Menitorix (Hib/MenC)		
Priorix (MMR)		
Boostrix-IPV		
Bexsero (Men B)		
Menveo (MenACWY)		
Prevenar 13 (PCV)	Pfizer Limited	01304 616 161
Nimenrix (MenACWY)		
Fluenz Tetra (Flu nasal spray)	AstraZeneca UK	0800 783 0033
Repevax (DTaP/IPV)	Sanofi Pasteur MSD Limited	0800 035 2525
Revaxis (Td/IPV)		
Gardasil (HPV)	MSD	01992 467 272
MMR VaxPRO (MMR)		
Pneumococcal polysaccharide vaccine (PPV)		
Zostavax (Shingles)		
Flucelvax Tetra aTIV	Seqirus	01748 828 816
<p>For any other vaccines, including travel vaccinations, the manufacturer details are located on the vaccine box and contact details of the relevant company are listed at the back of the BNF. Alternatively, the EMC website can be used to find manufacturer and contact details: www.medicines.org.uk/emc</p>		



Appendix 4 Pathway 1







Appendix 6

Example of NHS England and NHS Improvement - East) Cold Chain Breach Form (practice significant event forms can be used instead if they include all the below)

Brief description of what happened

(Please give a brief description of how the incident was discovered with times and dates)

What root causes contributed to the breach in the cold chain?

- Equipment failure?
- Unable to ascertain the amount of time outside temperature range?
- Individual error?

What contingencies have been put in place to prevent further cold chain breaches?



Appendix 7 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
- ✓ Complete cold chain checklist
- ✓ Inventory of all exposed vaccines stored in fridge recording quantity attach number expiry date position in fridge
- ✓ Contact local Screening and Immunisation Team



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 <i>(e.g. thermometer reading, fridge alarming, data logger)</i>	
8. Is there an alarm fitted on fridge? If so <i>Are parameters set</i> <i>After how long outside +2°C to +8°C</i> <i>Does the alarm sound</i>	
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 From

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? <i>(e.g. re-stock/power failure/busy clinic)</i>	
22. Any obvious signs of freezing? <i>(e.g. frosting sides or back of fridge, or wet or damaged boxes)</i>	
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

The Green Book:

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

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

<https://www.gov.uk/government/publications/vaccines-stored-outside-the-recommended-temperature-range-leaflet>

Vaccine Incident Guidance:

<https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors>

World Health Organization:

http://www.who.int/immunization/documents/IIP2015_Module2.pdf

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:

<https://portal.immform.dh.gov.uk/>

Immform fridge failure helpsheet:

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



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