NHS
South West Collaborative Commissioning Hub

Cold Chain Management and Best Practice Toolkit

South West Immunisation Clinical Advice and Response Service (ICARS)
england.swicars@nhs.net

March 2026, Version 1.0

The Purpose of this Toolkit

NHS
South West Collaborative Commissioning Hub

Maintaining an effective cold chain is essential to ensuring that vaccines remain safe, potent and clinically effective from the moment they arrive in the practice to the point they are administered

Every member of the general practice team plays a crucial role in safeguarding vaccine integrity, protecting patient safety and supporting national immunisation programmes

A single break in the cold chain can reduce vaccine efficacy, result in avoidable waste and disrupt service delivery – highlighting the importance of robust systems, procedures and staff awareness

This Cold Chain Best Practice Toolkit provides clear, practical guidance for general practice staff involved in receiving, storing, handling and transporting vaccines. It brings together key principles, step-by-step processes and best practice recommendations to help ensure high-quality vaccine management in line with NHS standards.

Whether you are new to immunisations or an experienced practitioner, this toolkit will support you to:

- Understand the importance of maintaining the cold chain
- Apply consistent procedures for vaccine storage, temperature monitoring, and record-keeping
- Respond effectively and safely to cold chain incidents
- Maintain compliance with national guidance and practice policies
- Ensure reliable, safe, and efficient delivery of immunisation services

By strengthening cold chain practice across immunisation settings, we protect public confidence in vaccinations and contribute to the continued success of the national immunisation programmes.

Contents

South West Collaborative Commissioning Hub

Importance of maintaining the cold chain

What constitutes a cold chain breach?

Managing a cold chain breach

Using vaccines off-label

Reporting wastage on ImmForm

Best practice for cold chain management

Ordering and delivery

Stock management

The vaccine fridge

Temperature monitoring

Data loggers

Validated cool boxes

Learning from cold chain breaches

Avoidable breaches

Unavoidable breaches

Cold chain audit

Resources

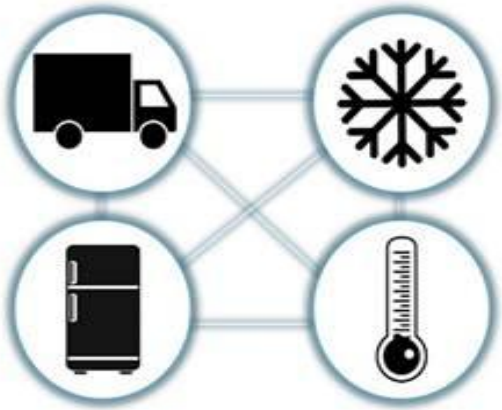
Contact Information

Importance of maintaining the cold chain

NHS
South West Collaborative Commissioning Hub

What is the cold chain?

The vaccine cold chain refers to the strict temperature conditions required to preserve vaccine potency throughout storage and distribution. For almost all vaccines used in the UK, this is between +2°C and +8°C, as defined in the vaccine's Summary of Product Characteristics (SPC). Compliance with these conditions is part of the product's licence and essential to ensuring its safety and effectiveness.



Why does maintaining the cold chain matter?

- **Preserves vaccine potency:** Vaccines are sensitive biological substances and must remain within their recommended temperature range; deviations can irreversibly reduce effectiveness.
- **Protects patient safety:** Compromised vaccines may may fail to create the desired immune response, increasing the risk of disease outbreaks and undermining public trust.
- **Prevents waste and financial loss:** Temperature breaches may result in vaccines being quarantined or destroyed, affecting service delivery and increasing costs.
- **Ensures compliance:** Cold chain adherence is a key requirement of UKHSA and NHS England immunisation programmes and is reviewed as part of CQC inspections.
- **Supports high-quality care:** Reliable vaccine stock and stable temperatures help maintain smooth clinic operations and safe, consistent immunisation practice.

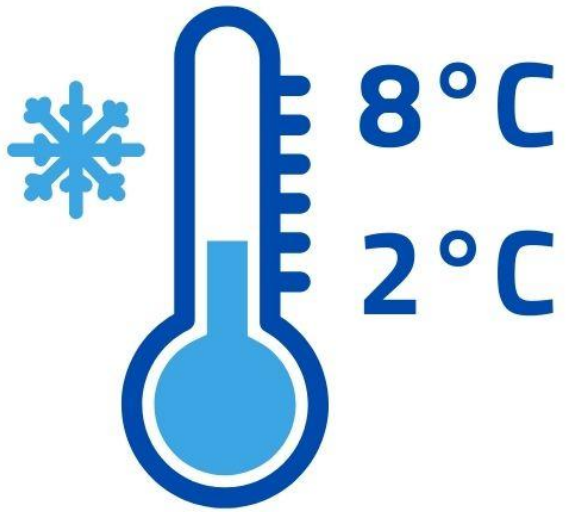
What constitutes a cold chain breach?

South West Collaborative Commissioning Hub

Generally, vaccines available for use in the UK are very stable and able to withstand short temperature excursions outside the recommended temperature range.

It is the length of time spent outside of the recommended cold chain conditions and the temperatures to which the vaccines were exposed that may compromise the potency of a vaccine and will determine the significance of the breach.

'One off' fluctuations rising above +8°C 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.



Any temperature excursion above +8°C for more than 20 minutes, or below +2 °C for any length of time, is considered a cold chain breach and should be reported to SW ICARS (england.swicars@nhs.net) so vaccine stability can be assessed.

Vaccines exposed to temperatures below +2°C (particularly temperatures below 0 °C) for any length of time are more likely to be affected and should be reported to ICARS.

Managing a cold chain breach

NHS
South West Collaborative Commissioning Hub

If a cold chain breach is identified, the following actions must be taken **immediately:**

Quarantine affected vaccines in a working fridge and clearly label them 'Not for Use'. Ensure the fridge remains powered and staff are informed not to access it. If the vaccines cannot be stored in a working fridge, keep the fridge closed and undisturbed. The vaccines must not be administered to patients until their stability is assessed.

Contact SW ICARS at england.swicars@nhs.net to report the incident. You will be asked to complete an incident form (latest version available here) and provide any available data logger readings covering the breach period.

Once SW ICARS have the required information, you will be provided with stability data confirming whether the vaccines can continue to be used. Do not discard any vaccines until appropriate guidance has been obtained from SW ICARS.

If you have previously received advice from SW ICARS and the same vaccines are involved in a new breach, please contact ICARS again. Stability guidance can change, and the assessment may differ when vaccines have been exposed to multiple breaches.

Please note: We can only advise on vaccines used for the routine immunisation programmes. For any vaccines outside of these e.g. travel vaccinations, you will need to contact the manufacturers directly for stability information.

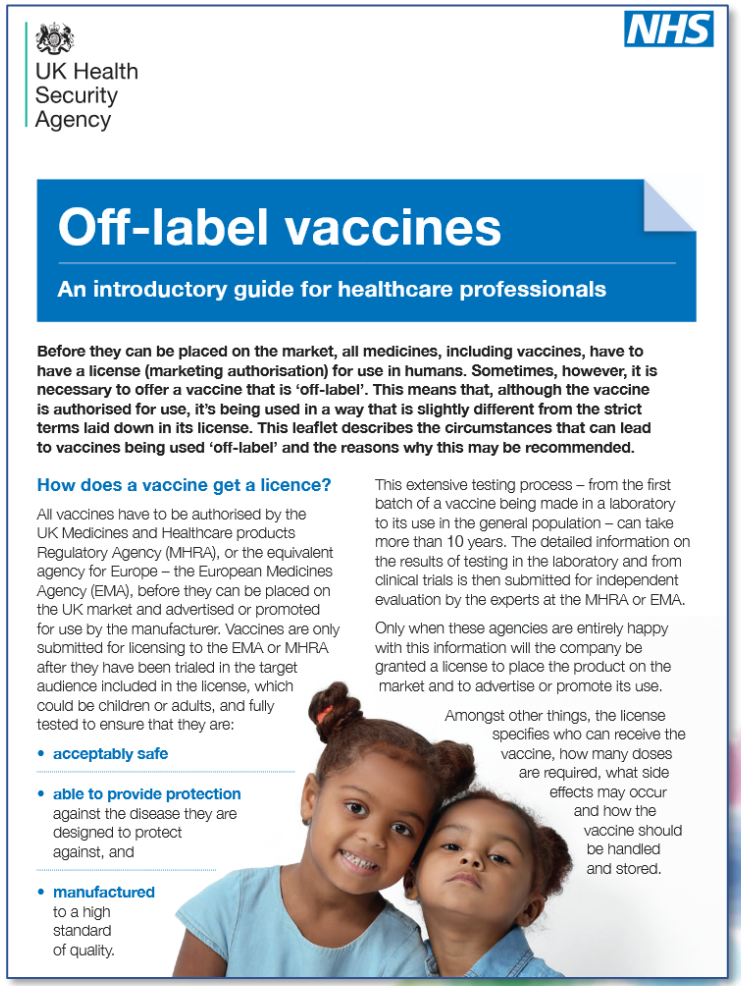
Using vaccines off-label

South West Collaborative Commissioning Hub

If vaccines are confirmed as stable by SW ICARS using the stability data included in the SPC, they may continue to be used on-label.

If stability is confirmed based on the manufacturer's internal (in-house) stability data, the vaccines may still be used, but this will be considered off-label use. This means that administration will be outside the terms of the marketing authorisation and the prescribing practitioner or provider assumes responsibility for using the vaccine:

- Whilst any decision to use affected stock off-label rests with the GP practice, NHSE firmly supports the use of stock involved in temperature excursions where robust risk assessment has been carried out and there is data to support stability.
- Vaccine that has been fully assessed as stable following a breach can continued to be administered under a PGD (see section 7.4 Vaccine Incident Guidance). Best practice would be for these vaccines to be labelled as having been involved in a breach so they are clearly identifiable in the case of any future breaches and used first.
- The decision on whether to inform patients that the vaccine they're receiving is being given off-label rests with the practice (see pages 37 and 38 of Vaccine Incident Guidance.
- In using vaccines off-label, there are leaflets to support healthcare professionals and patients available here: Off-label vaccine: leaflets.



UK Health Security Agency

NHS

Off-label vaccines

An introductory guide for healthcare professionals

Before they can be placed on the market, all medicines, including vaccines, have to have a license (marketing authorisation) for use in humans. Sometimes, however, it is necessary to offer a vaccine that is 'off-label'. This means that, although the vaccine is authorised for use, it's being used in a way that is slightly different from the strict terms laid down in its license. This leaflet describes the circumstances that can lead to vaccines being used 'off-label' and the reasons why this may be recommended.

How does a vaccine get a licence?

All vaccines have to be authorised by the UK Medicines and Healthcare products Regulatory Agency (MHRA), or the equivalent agency for Europe – the European Medicines Agency (EMA), before they can be placed on the UK market and advertised or promoted for use by the manufacturer. Vaccines are only submitted for licensing to the EMA or MHRA after they have been trialed in the target audience included in the license, which could be children or adults, and fully tested to ensure that they are:

- **acceptably safe**
- **able to provide protection** against the disease they are designed to protect against, and
- **manufactured** to a high standard of quality.

This extensive testing process – from the first batch of a vaccine being made in a laboratory to its use in the general population – can take more than 10 years. The detailed information on the results of testing in the laboratory and from clinical trials is then submitted for independent evaluation by the experts at the MHRA or EMA.

Only when these agencies are entirely happy with this information will the company be granted a license to place the product on the market and to advertise or promote its use.

Amongst other things, the license specifies who can receive the vaccine, how many doses are required, what side effects may occur and how the vaccine should be handled and stored.

Reporting wastage on ImmForm

NHS
South West Collaborative Commissioning Hub

Please report all cold chain breaches to ICARS at england.swicars@nhs.net **before** discarding any vaccines, as some vaccines may still be usable. ICARS can review on-file stability data and contact manufacturers on your behalf, to assess the stability of vaccines involved in a breach.

Vaccines that have been quarantined…

- Vaccine wastage should only be reported to ImmForm when vaccines have been discarded.
- For vaccines that have been **quarantined and are still in a fridge**, please contact ICARS for further guidance.
- Quarantined vaccines do not need to be reported to ImmForm unless they are subsequently discarded.

Vaccines that have been lost, mislaid, or discarded…

- All vaccines that were ordered via ImmForm which are discarded, lost or mislaid should be reported to ImmForm as a stock incident.
- If the incident has already been reported to ICARS, please include the ICARS reference number (beginning SID00…) in the supporting comments. This ensures we can align ImmForm stock wastage notifications with already reported breaches.

Best Practice for Cold Chain Management

Ordering and delivery

South West Collaborative Commissioning Hub

In GP practices at least **two individuals must be nominated**, one from the nursing team and one from the administration / management team. These individuals will be responsible for ordering, receipt and care of vaccines, and maintenance of the cold chain at all stages (p19, Green Book Chapter 3). However, all members of the primary care team should understand the importance of good vaccine management.

When ordering and taking delivery of vaccines…

- Place orders every two-four weeks according to need. Do not stockpile vaccines.
- Place orders in time so there is an adequate supply for clinics.
- Check there are no leakages, damage or discrepancies in the delivered vaccine before signing, as manufacturers will not accept returns once they've been signed for.
- Vaccines must be refrigerated immediately and must not be left at room temperature.
- Vaccines should be stored according to the manufacturer's SPC (usually between +2˚C and +8˚C) and protected from light. They should be stored in their original packaging.

The VaST have produced an A4 poster that you can print and display in your reception or office area (or other location where vaccine deliveries are received) to remind staff that vaccine deliveries need to be placed immediately into a working pharmaceutical fridge. A PDF of this poster can be accessed here: 20260129 SW Vaccine Cold Chain Poster for Reception v1.0 - South West Vaccination & Screening Team - Futures

Stock management

South West Collaborative Commissioning Hub

The nominated individuals at the practice are responsible for ensuring there is good stock management and monitoring of stock.

Best practice for stock management

- Keep a stock information system to keep track of orders, expiry dates and running totals of vaccines (including wastage). Records should be updated at least every month.
- Aim for +5°C, the midpoint in the +2°C to +8°C range.
- Designate areas within the refrigerator for different vaccines so that all staff know where specific vaccines are stored. Glass doors or labels on the outside of fridges can reduce the time the door needs to be open.
- Make checks at least once a week to:
    - Rotate stock so that those with the shortest expiry date are moved to the front of the fridge and used first.
    - Remove any expired vaccines from the refrigerator, destroy promptly and report on ImmForm.

Stock records

- A stock information system could be a simple paper-based record or spreadsheet, but as a minimum should record the following:
    - **Orders**, e.g. order date, vaccine name and brand, quantity, date/time received, person receiving the delivery, notes of any discrepancies/damage on delivery
    - **Batch-specific information,** e.g. batch number, expiry date, storage requirements, manufacturer
    - **Stock levels and movement,** including running totals (stock received, stock used)
    - **Wastage,** e.g. number of doses wasted, batch/expiry involved, reason for wastage

The vaccine fridge

NHS
South West Collaborative Commissioning Hub

Best practice for the vaccine fridge

- Store vaccines in a validated fridge specifically designed for pharmaceutical products. Do not use a domestic fridge.
- Only use it to store pharmaceutical products. Do not store food and clinical specimens alongside vaccines.
- Maintain the temperature between +2 and +8ºC. Keep the vaccine fridge secure. It should only be accessible to authorised practice staff. Therefore, keep it locked or in a locked room.
- Reduce the possibility of accidentally interrupting the electricity supply. For example, install a switchless socket or clearly label the plug with a cautionary notice: 'Do not unplug/switch off'.
- Use a large enough fridge to allow enough space around the vaccine packages for air to circulate.
- Further detailed guidance can be found in the Green Book Chapter 3.

Routine maintenance

- Make sure that the fridge is maintained in a clean condition
- There is a maintenance contract that allows for at least yearly servicing and calibration of temperature gauge.
- A routine vaccine management review is performed quarterly
- The temperature is calibrated at least every month against an independently powered external thermometer

Records should be kept of regular servicing, defrosting and cleaning, calibration and electrical testing. All maintenance actions should be recorded on a log sheet, which should be kept with the vaccine fridge.

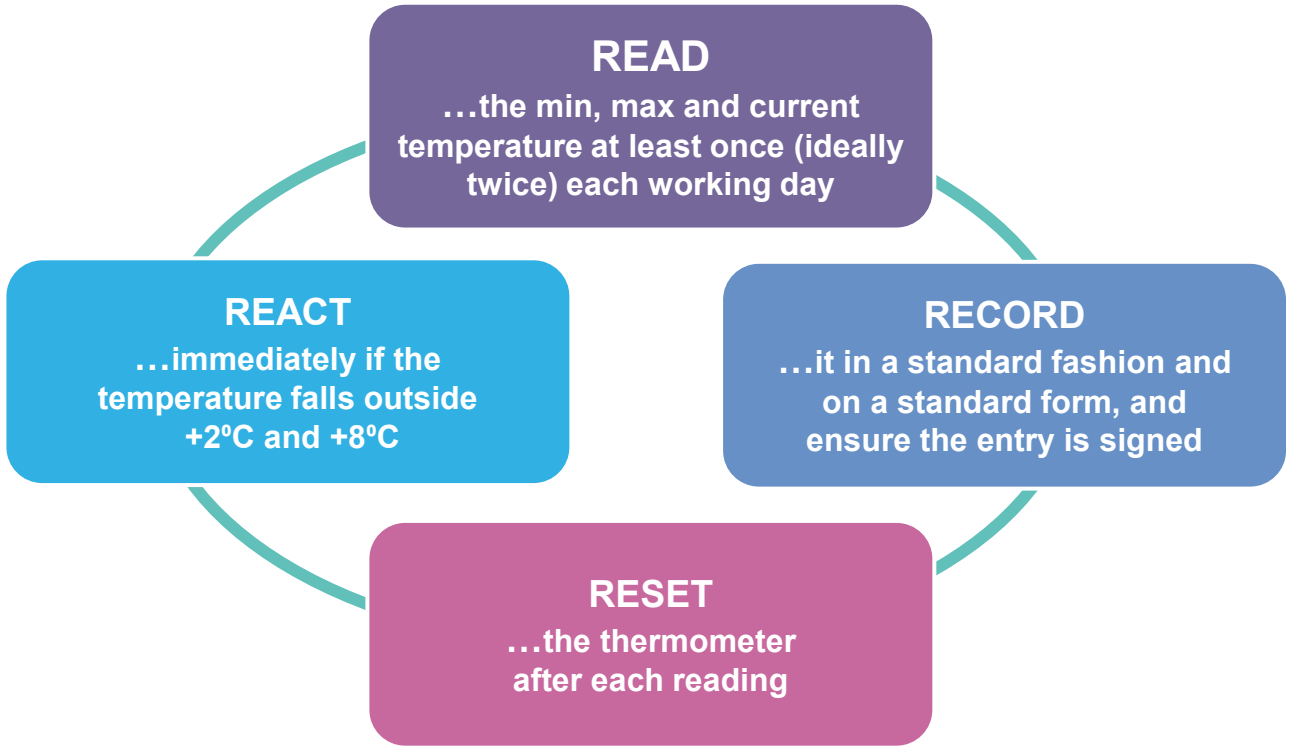
When cleaning the vaccine refrigerator, vaccines should be transferred to another refrigerator with appropriate temperature monitoring or validated cool box.

Temperature monitoring

South West Collaborative Commissioning Hub

Temperature monitoring should follow the Green Book Chapter 3 guidance which gives details of the four Rs: Read, Record, Reset, React.

The person making the recording of the fridge temperature should:



Fridge thermometers

All fridges should ideally have two thermometers, one of which is a max/min thermometer independent of mains power. If only one thermometer is used, then a monthly check should be considered to confirm that the calibration is accurate. Care should be taken that the thermometer probe cable does not interfere with the door seal, causing the temperature to fall outside the permitted range.

Ideally, use a second thermometer independent to the integral thermometer in the vaccine fridge. This second reading cross-checks the accuracy of the temperature and monitors the temperature if the electricity supply to the vaccine fridge is interrupted.

Data loggers

South West Collaborative Commissioning Hub

Data loggers are useful to gain more detailed information about the fridge temperature if there is a cold chain breach, for example during a power cut. Although you can use a data logger in the vaccine fridge, each working day you must still:

- read and record temperatures on the integral fridge thermometer (minimum, maximum and current)
- reset the min/max thermometer.

This will assure you the fridge contents have been stored correctly and are safe to use.

Setting the data logger to record at 5-minute intervals will ensure that the duration of cold chain breaches can be accurately determined, reducing the potential for wastage

Data loggers should be downloaded once a week and checked to ensure temperatures have remained between the +2°C to +8°C range. Ideally, this should be on first entering the premises after the weekend and before administering the first vaccines of the week. This will allow a rapid additional check of the fridge function during the period when no staff member has been on the premises and mean that if there are discrepancies these can be more easily and quickly investigated before vaccine is administered.

Validated cool boxes

NHS
South West Collaborative Commissioning Hub

Validated cool boxes can be used to quarantine vaccines in the event of a fridge failure, or to move stock to a working fridge.

Best practice for validated cool boxes

- Only use validated medical grade cool boxes and cool packs from a recognised medical supply company and used in conjunction with validated min/max thermometers. Domestic cool boxes should not be used to store, distribute or transport vaccines.
- Keep vaccines in their original packaging.
- Take only enough vaccine for a particular session and minimise exposure of the vaccines to room temperatures.
- The cool box should be opened as little as possible to maintain the correct temperature and monitor max/min temperature while the box is in use.
- Temperatures should be recorded at the start and end of each session.
- If there are any unused vaccines left over at the end of a vaccination session, providing there is evidence that the cold chain has been maintained, the vaccines can be returned to the vaccine refrigerator. Returned vaccines should be labelled and used at the earliest opportunity.
- Choose appropriate sizes of cool box for the amount of vaccine needed.

Learning from Cold Chain Breaches

Avoidable breaches

NHS
South West Collaborative Commissioning Hub

A significant proportion of cold chain breaches are due to preventable system and process issues within practices. Understanding the most common avoidable causes and the learning that follows can help practices strengthen their processes and reduce future breaches.

Commonly reported reasons for avoidable breaches and associated learning are included below:

Fridge switched off or power supply accidentally interrupted

Learning:

- Use a switchless socket or clearly label plugs ‘Do not switch off’
- Ensure all staff understand that the vaccine fridge must never be unplugged or switched off
- Include fridge checks in opening and closing procedures, particularly before weekends and bank holidays

Lack of temperature monitoring or missed checks

Learning:

- At least daily min/max temperature checks and weekly review of data logger downloads
- Clear escalation processes if temperatures are out of range
- Named staff with clear responsibility for completing, recording and reviewing checks
- Cross-cover arrangements so checks continue during staff absence

Use of inappropriate or domestic fridges

Learning:

- Use a validated pharmaceutical vaccine fridge
- Ensure the fridge is exclusively used for vaccines and medicines (no food or specimens)
- Ensure the fridge is appropriately sized to allow adequate air circulation and prevent over-stocking

Avoidable breaches

NHS
South West Collaborative Commissioning Hub

Poor stock arrangement inside the fridge

Learning:

- Store vaccines centrally on shelves in original packaging
- Avoid over-stocking to allow air circulation on all sides and prevent fluctuations in temperatures
- Do not store vaccines in the fridge door, bottom baskets or against cooling plates

Data loggers not used, not reviewed or faulty

Learning:

- Use a calibrated data logger in all vaccine fridges
- Set clear expectations for regular review and documentation of readings
- Ensure staff know what constitutes an excursion and when to escalate
- Ensure data loggers remain powered (e.g. batteries replaced promptly if low) and are downloaded at least weekly to prevent memory capacity issues

Lack of training or unclear roles

Learning:

- Maintain at least two trained staff with responsibility for vaccine management
- Provide regular refresher training for all staff involved in vaccinations, including non-clinical staff
- Use incidents and near-misses as learning opportunities, not blame.

Avoidable breaches

NHS
South West Collaborative Commissioning Hub

Faulty vaccine fridge equipment

Learning:

- Arrange regular servicing of vaccine fridges in line with manufacturer and local policy recommendations.
- Keep up to date with fridge maintenance
- Ensure any emerging faults are addressed promptly.
- Maintain clear records of servicing, repairs, defrosting and cleaning.

Repeated or prolonged fridge door opening

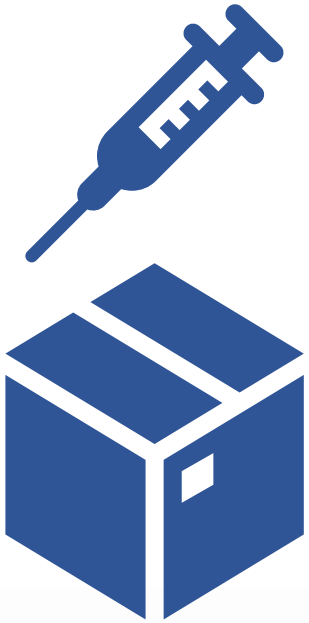
Learning:

- Ensure good internal fridge organisation to reduce the time the fridge door remains open
- During stock checks, check vaccines in small batches or place vaccines in validated cool boxes, reducing the time the fridge door remains open.
- Undertake stock checks outside of clinic times where possible to reduce competing demands on fridge access and minimise door opening

Vaccines not stored immediately after delivery

Learning:

- Ensure all staff are aware of the importance of checking and storing deliveries immediately.
- Nominated staff members with oversight of deliveries.



Unavoidable breaches

NHS
South West Collaborative Commissioning Hub

Some cold chain breaches are outside the direct control of GP practices, for example:

- Power cuts caused by stormy weather
- Wider electrical supply failures
- Infrastructure issues affecting the whole building

While these incidents may be unavoidable, effective preparation and monitoring can significantly reduce vaccine wastage:

Alarmed vaccine fridges
Vaccine fridges with audible or remote alarms alert staff promptly to excursions, enabling faster response and reducing the duration of exposure.

Use of data loggers
Independently powered data loggers (i.e. battery powered) will continue recording temperatures during power outages. Setting loggers to 5-minute intervals allows the exact duration and extent of the breach to be determined, which can reduce wastage.

Clear 'do not open' response during outages
If a power cut is identified, keep the fridge closed and undisturbed and ensure staff are aware not to access the fridge. This helps maintain internal temperatures for longer and limits further excursions.

Back-up storage planning
Contingency arrangements for alternative monitored storage (e.g. another vaccine fridge or validated cool box). Knowing in advance where vaccines can be moved reduces delays during an incident.

Accurate and timely temperature recording
Continue daily min/max/current temperature checks using the integral thermometer and reset after each reading, even when data loggers are in place.

Prompt escalation and advice
Early contact with ICARS and provision of clear information (completed incident form, data logger readings) enables timely stability advice. Do not discard vaccines without advice, as many remain stable following excursions.

Cold chain audit

South West Collaborative Commissioning Hub

ICARS would like to request sites storing vaccines to complete our annual audit tool is available here

This audit tool was adapted from the Oxford Vaccine Group (Vaccine storage audit) and should be used in conjunction with:

- The Green Book: Storage, distribution and disposal of vaccines (chapter 3).
- The Protocol for ordering, storing and handling vaccines.
- The standards required by CQC standard 4: medicines management (healthcare services) -vaccine storage in GP practice.

Please direct any queries to the South West Immunisation Clinical Advice and Response Service (ICARS) at england.swicars@nhs.net

Useful resources

NHS
South West Collaborative Commissioning Hub

Guidance

- Green Book Chapter 3 – Storage, distribution and disposal of vaccines (UKHSA)
- Vaccine incident guidance – Responding to errors in vaccine storage, handling and administration (UKHSA)
- GP mythbuster 17 – Vaccine storage and fridges in GP practices (Care Quality Commission)
- ICARS – South West Immunisation Clinical Advice & Response Service (NHS England)
- Sign in | ImmForm | UKHSA

Leaflets and Posters

- Off-label vaccine: leaflets - GOV.UK
- Vaccines stored outside the recommended temperature range - GOV.UK
- Keep your vaccines healthy poster and magnet - GOV.UK

Contact Information

NHS
South West Collaborative Commissioning Hub

If you have any questions regarding this toolkit, please get in touch with us at england.swvast@nhs.net

For clinical queries and incidents relating to the routine immunisation programmes, please contact us via england.swicars@nhs.net

This toolkit was produced by: Vaccination and Screening Team, NHS England South West

Last reviewed: March 2026