Public Health England

NHS England

Cumbria and North East Region

Safe and Secure Handling of Vaccines

OPERATIONAL GOOD PRACTICE GUIDANCE

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1. Key Points

These are the key points to note from the guidance. More detailed advice is available in the main document.

Essentials

- Ensure a policy and procedure is in place which is in line with national policy. You may adjust this guideline.
- Keep policy, procedures and temperature monitoring charts close to each refrigerator
- Ensure an appropriately trained named person is responsible for all vaccines including ordering, receipt and storage.
- Ensure you have easy access to 'The Green Book (on-line version), *Immunisation against Infectious Diseases*.' Available at: Green Book, Chapter 3 Storage, Distribution and Disposal of Vaccine

Delivery of vaccines

Whoever takes delivery of the vaccine must:

- Check the batch against the order. Do not accept leaking or damaged vaccines.
- Check that the dispatch time and date are clearly marked.
- Ensure "cold chain" has been maintained during transport.
- Store immediately in vaccine refrigerator
- Inform the named responsible person

Storage

- Store all vaccines in a refrigerator between +2°C to +8°C. **Aim for +5°C.**
- Keep them in their original packaging and protect from light. Never allow them to freeze
- Only use Medical / Pharmacy refrigerators for vaccine storage
- **Reset the thermometer if the** refrigerator **temperature exceeds +8˚C when the** refrigerator **is being restocked**
- Do not store food, drink or medical specimens in the same refrigerators as vaccines.
- Ensure refrigerator is not overfilled so there is plenty room for air to circulate and keep vaccine away from sides
- Record minimum, maximum and current refrigerator temperature every working day and always before and after an immunization clinic
- Always use the integral thermometer as the single monitoring device
- Use a 'back up' thermometer or data logger which does not need mains electricity in addition to the refrigerator integral thermometer. This will help if the refrigerator fails
- Reset thermometer after every reading
- Keep temperature logs for at least 12 months and up to 5 years from the last entry
- Ensure everyone monitoring refrigerator temperatures has been suitably trained to use the thermometer
- Always use switch-less sockets for refrigerators to stop them being accidentally turned off. Or use prominent notices placed over plugs
- Ensure refrigerators are serviced according to manufacturers recommended schedule, at least **annually**, including calibration and PAT testing. Stock rotation systems must prevent vaccine waste and stock running out.

- Only keep **two to four weeks of stock at any time**.
- Only take enough vaccine from the refrigerator for a particular session
- Always use reconstituted vaccines within the recommended time period.
- Label each refrigerator and corresponding logs

In the event of cold chain failure

- Ensure everyone knows what actions to take should the refrigerator reading be out of the range +2°C to +8°C
- Follow the actions detailed in the poster Take Action Now poster – Make sure its displayed clearly on the front of all refrigerators
- Have you got a contingency plan for a refrigerator failure?
- Record all incidents and report them to Public Health England via email **england.cane.screeningimms@nhs.net** or phone **Monday to Friday 1-5 pm 011382 53017**. You will receive a response within 2 working days.
- Any vaccine that has **not** been stored at a temperature of +2°C to +8°C according to the manufacturer's SPC is no longer within its product license.
- If in doubt do not use vaccines and seek information from PHE

2. Purpose & Scope

2.1. This document is primarily for use within Cumbria and North East (NHS England) and is intended to provide guidance to support immunisation providers in fulfilling contractual and statutory arrangement in relation to systems & procedures for storage and handling of vaccines.

2.2. The document is aimed at ensuring that the cold chain is maintained ensuring efficacy and safety of vaccines. Many of the principles and procedures outlined are good practice for all medicines requiring refrigeration.

2.3. The document may be further developed as practice specific standing operating procedures (SOPs).

2.4. The document should be read and used in conjunction with national policy on immunisation, recognised texts and standards for immunisation namely:

- Nurse & Midwifery Council (2007): Standards for Medicines Management (https://www.nmc.org.uk/standards/additional-standards/standards-for-medicines-management/

- Immunisation against Infectious Disease, (current on-line version). Also known as "*The Green Book*." (https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3)

- PHE standards and guidance
  https://www.gov.uk/government/collections/immunisation#immunisation-training-resources-for-healthcare-professionals
  - National Standards for Immunisation Training
  - Core Curriculum for Immunisation Training

3. Introduction

3.1. The safety and efficacy of vaccines depends on ensuring that vaccines are stored and transported in accordance with the manufacturers recommended storage conditions. This usually requires vaccines to be maintained between +2°C and +8°C and protected from light. The system of processes from manufacturer, though supply, storage and transportation to patient administration is known as the "Cold Chain."

3.2. It is vital that appropriate policies and procedures are implemented and monitored to ensure that vaccination programmes are effective as well as efficient.

3.3. Inadequate temperature control during storage and transport of vaccines can reduce the efficacy of the vaccine and compromise the attainment of a satisfactory level of immunity in both individual and population.

3.4. Freezing can cause deterioration of the vaccine and potentially produce hairline cracks in the ampoule/ via/ pre-filled syringe, potentially contaminating the contents. Glass splinters produced may also cause serious adverse local reactions.

4. Responsibility

4.1. Each healthcare professional is responsible for the implementation of the procedures for the safe storage and transport of vaccines in their practice.

4.2. All staff handling vaccines need to be aware of their responsibilities in maintaining correct storage, transport and disposal of vaccines.

4.3. A designated person and deputy should be appointed at each vaccine storage location that has overall responsibility for vaccines, ensuring the organisations procedures are followed and standards for safe and effective storage and transport are maintained and tasks and functions are appropriately delegated. The designated person must have successfully completed immunisation training in accordance with the national minimum standards described in the PHE training recommendations (https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards).

Standard Operating Procedures (SOPs) should include details of: -

- Person(s) responsible for performing specific tasks or functions
- why the task is important or relevant
- who they report to
- what tasks/functions need to be performed and how, when and where they are to perform the task/function.
- details of relevant stationary to be used (what, where stored etc.) or other facilities/equipment

4.4. It is the responsibility of the immuniser to ensure the cold chain is maintained prior to immunising. It is the clinician's responsibility for maintaining the cold chain. When administrative staff are used in this process, the clinician retains full responsibility.

4.5. Please note that within the NHS Standard Contract for primary or general medical services, storage of vaccines and ensuring that staff have appropriate training are contractual requirements.

5. Ordering of Vaccines

5.1. At least two individuals need to be nominated; one from the nursing/healthcare professional team and one, from the administration/management team to be responsible for ordering, receipt and care of vaccines in order to meet service and patient needs. NB: As vaccines have a fairly short shelf life care should be taken to avoid over ordering or stockpiling of vaccines. It is the responsibility of the clinical trained member of staff to oversee all aspects and training of administration / management team. This includes ensuring quantities ordered are appropriate and avoid overstock (more than 2-4 weeks supply)

5.2. Details of the responsible person(s) and their deputy are to be documented and made known to all relevant staff.

5.3. Vaccines are to be ordered in accordance with a **SOP for ordering vaccines** developed by and specifically for the service/location.

6. Receipt of Vaccines

6.1. Vaccines are to be received in accordance with an **SOP for the receipt of vaccines** developed by and specifically for the service/location.

6.2. A designated person, or named persons, in the absence of the designated person are to be responsible for receiving vaccines delivered to the location. Their details are to be documented and made known to all relevant staff.

6.3. All members of staff are to be aware of the importance of maintaining the cold chain. If any member of staff receives a delivery of vaccines, or notice a package containing vaccines, they are to inform one of the designated persons responsible for the receipt of vaccines.

6.4. On receipt of a delivery of vaccines, the person(s) responsible for receipt of vaccines is to: -

- Examine vaccines for leakage or breakages. If damaged, report immediately to person delivering and/or contact supplier.

- Check vaccines supplied against the delivery note using the original order as reference to ensure the correct type and numbers of vaccines have been supplied. In the event of discrepancies contact the supplier immediately. Retain the delivery note on file for a minimum period of 2 years.

- Record all vaccines received, including number of vaccines, batch numbers and expiry dates. Enter the date and time at which the vaccine was received in a vaccine log (Stock Control Forms) along with the time the vaccine spent outside of a refrigerator. (See Appendix 5 for example stock control from).

- Check expiry date to ensure that the vaccines are not date expired or have a shorter than expected shelf-life. If short-life vaccines (less than 6 months) have been supplied contact the manufacturer or supplier to ascertain the reason.

Vaccine Expiry Dates Explained

Date on Box	Actual Expiry Date
Use by Dec 05	01.12.2005
Exp. Dec 05	31.12.2005
Use Before Dec 05	30.11.2005

- Place the vaccines in the refrigerator(s) designated for the storage of vaccines. Stock is to be rotated by placing new stock behind existing stock. If short-life vaccines are supplied, and not returned to supplier, ensure that they are located in an appropriate place to ensure they are used before they expire.

7. Storage of vaccines

7.1. To ensure vaccines are safe and effective it is imperative that they are suitably stored and that temperature history is tracked and recorded appropriately. To do this there are many types of equipment available. Therefore, it is important to understand how and what should be used, the specifications they should have and what is considered as best practice relating to storing vaccines and monitoring temperatures.

Most vaccines are to be stored between +2°C and +8°C. (The vaccine packaging provides information on storage requirements). Medicines requiring refrigerated storage must be placed in a specially designated medicines refrigerator as soon as possible after receipt.
All vaccines and medicines requiring strict adherence to recommended storage temperatures, must be stored and handled in accordance with procedures for maintaining the cold chain and the safe and secure handling of vaccines/medicines.

7.2. Maintain the temperature of the refrigerator between +2°C and +8°C (see section 9 and 10). **Aim for +5°C.** Storage outside of the recommended range may result in loss of product quality, safety and efficacy. In addition, temperatures on or below freezing point (0°C and below) may cause hairline cracks to develop in glass ampoules or vials resulting in a loss of sterility. Please note that vaccine stability data outside of the recommended range (+2°C to +8°C) may not have been reviewed by the licensing agencies, e.g. Medicines Healthcare Regulatory Agency (MHRA).

7.3. It is important to separate and segregate vaccines so that childhood and adult vaccines are not mixed together or with other vaccines of similar name. This helps to avoid confusion and risk.

7.4. Always ensure vaccines are stored in line with these requirements:

- Package vaccines to allow complete air circulation around them.
- Do not overfill the refrigerator (fill to no more than 75% capacity)
- Keep stock in original packaging and keep neat and tidy. Many are sensitive to light and thus will deteriorate if taken out of boxes for any length of time.
- Use breathable mesh baskets (allows cold air to circulate around vaccine)

- Ensure stock is rotated whenever new stock is placed into the refrigerator - oldest used first
- Remove expired stock.
- Segregate vaccines in refrigerator to reduce risk of selection error
- Avoid storing vaccines in any part of the refrigerator that may not provide stable temperature or sufficient air flow, e.g. directly under cooling vents, in drawers, or in shelves on the door.
- If other medications or biological products must be stored in the same refrigerator as vaccines, never store these in the same container as vaccines. Always store them below vaccines and on a different shelf. This prevents contamination and reduces the likelihood of medication errors.

Example of good vaccine storage

Place vaccines in breathable plastic mesh baskets and clearly label baskets by type of vaccine.

Place vaccines by paediatric, adolescent and adult types.

If the fridge is not to capacity, store water bottles in the fridge to stabilize the temperature. This also helps maintain temperature longer in a power outage

8. Refrigerators

8.1. **Your vaccine** refrigerator **should:**

- be kept in a secure room that is maintained at room temperature (i.e. not exceeding 25°C or kept within the manufacturer's recommended operating temperature)
- be validated for vaccine storage, dedicated and lockable
- be wired into a switch-less socket to avoid it being turned off accidentally
- be of adequate size, i.e. large enough to hold the stock and allow sufficient space around the vaccine for air to fully circulate
- serviced in line with the manufacturers recommendations at least annually (including thermometer calibration) & PAT tested.
- be capable of maintaining and storing vaccines between +2°C to +8°C
- be capable of having a set point temperature set to 5°C
- have an integrated & calibrated thermometer fitted, with a minimum accuracy of ± 1°C (lower is better – acceptable levels range from ± 0.1°C to ± 1°C). You should also have in place a backup max/min thermometer independent of mains power.
- Kept away from heating source eg –radiator
- Ensure the key to the refrigerator or room is retained by the either the person designated responsible for vaccines, their deputy or the person in charge who is responsible for medicines.
- SOPs developed specifically for the location/service are to include details of responsibilities and arrangements for keys and security and should be kept close to each refrigerator.
- Label each refrigerator and its associated documents to ensure a clear audit trail

8.2. **A refrigerator is only as good as the temperature monitoring system inside.**

- In some vaccine refrigerators the integrated thermometer only reads the air temperature around the vaccines. (Air temperature can vary within the refrigerator and can change quickly when refrigerator doors are opened).
- There are vaccine fridges in which the fridge thermometer monitors both the air and the "load" temperatures*****. These types of refrigerators usually have the thermometer probe placed within a sealed glycol bottle, which mimics the vaccine liquid. (Load temperature measures more accurately vaccine temperature and is less prone to air temperature variations. Air temperature changes much more rapidly than product or load temperature). **Refrigerators that measure "Load" temperature are therefore preferred.**
- Some vaccine refrigerators also include a data logger function, allowing the collected data to be downloaded and viewed on a computer. It is important to be able to understand and interpret the data and graphs produced by such devices. It is recommended that data logger functions are only used as a back up to the main integrated refrigerator thermometer readings. When carrying out daily monitoring record the refrigerator integral thermometer display readings (min, max & current). The data logger function may be checked occasionally or if issues arise.

- Where a backup thermometer is in place it is essential it is calibrated as per manufactures instructions. A data logger may be used as the back-up thermometer.

8.3 Load temperature:

The Load temperature refers to the actual temperature of the vaccine ("load") placed in the vaccine fridge. The load temperature more accurately reflects the temperature of the load as it is not the temperature of the air within the refrigerator surrounding the vaccines. Air temperature can vary very quickly, but load temperature takes much longer to change. (Some manufacturers refer to load temperature as "True temperature" by LEC

9. Maintenance, Monitoring and Recording of Refrigerator Temperatures

9.1. Maintain the temperature of the refrigerator between +2^{o}C and +8^{o}C. Aim for +5^{o}C to allow for fluctuations of +/- 3^{o}C

9.2. **All staff who use the refrigerator are responsible for maintaining the temperature of the refrigerator between +2^{o}C and +8^{o}C. To minimise fluctuations in temperature the refrigerator door is to be opened only when necessary and is to be left open for as little time as practically possible.**

If the thermometer reading goes above +8°C while the refrigerator **door is open, i.e. during the stocking of the** refrigerator**, then the thermometer should be reset. Recheck the temperature and record once the temperature is within range. Then reset**

All staff that use vaccines are responsible for visually checking the refrigerator and contents every time they add or remove a vaccine from the refrigerator and reporting any concerns or incidents.

9.3. Refrigerator temperatures are to be monitored and recorded in accordance with a **SOP** developed by, and specifically for, the location of the immunisation provider.

9.4. A member of staff, designated by the clinical lead or person in charge must record the minimum and maximum temperatures, preferably twice a day in the "Temperature Monitoring Log" (see appendix 1) located by the medicines refrigerator. The assigned member of staff must re-set the monitoring device after each reading.

The person in charge must seek immediate advice from the clinical lead/person in charge or the manufacturers of the medicine in the event of either the minimum or maximum temperatures being breached.

Staff who may access the refrigerator must be trained in the use and storage of refrigerated medicines. Details of the person(s) responsible for monitoring and recording refrigerator temperatures is to be documented and made known to all relevant staff..

9.5. Monitor and record the temperature preferably twice a day (as early and as late as possible), but once daily as a minimum, at the same time of day on each day the location is staffed. The following is to be recorded.

- The date and time
- The actual temperature

- The minimum and the maximum temperature
- Signature/initials of person taking the readings
- A tick to indicate that the thermometer has been reset
- Comments to explain any out of range temperatures and actions taken thereof.

9.6. Irrespective of whether daily or twice daily readings are taken, the refrigerator must be checked as late as possible prior to the department being closed for a weekend or public holiday.

Record the above details on the refrigerator temperature monitoring log (see model template in Appendix A). Keep the log next to the refrigerator in a bound format so that all staff using vaccines can check temperature conditions and history and records cannot be mislaid or misappropriated. Keep the records for at least 2 years from the last entry.

9.7. Reset the thermometer after each reading is taken and recorded. Visually check the refrigerator and contents when the refrigerator temperature is checked and recorded.

9.8. If the temperature is, or has been outside the desired range immediately contact the lead person (or their deputy) responsible for vaccines (see section 3). Establish reason(s) for break in cold chain and carry out the procedures outlined in section 12 to ensure the cold chain is reinstated and/or appropriate actions are taken regarding the efficacy of the vaccines.

9.9. Thermometers should be reset and replaced according to the manufacturer's guidance.

9.10. **Understanding temperatures:**

Refrigerator temperature is NOT a single point measurement. It can be affected by several factors, including:

- Refrigeration cycle (cooling down and warming up)
- Air circulation patterns (temperature variations within refrigerator)
- Use patterns
    - **frequency and duration of door opening**. The greater number of times the refrigerator door is opened and the longer it is kept open, then the more likely the refrigerator temperature will be affected.
    - **loading density**, i.e. how much stock is stored. More stock provides a greater load density, so reducing the rate at which the vaccine stock temperature changes.
- Environmental conditions - room temperature variation, power failures
- The defrost cycle
- Thermometer sensor/probe location – what are you measuring?
- (The thermometer sensor/probe or device (e.g. USB data logger) should be placed in the centre of the refrigerator with the vaccines).

10 Temperature Monitoring Devices

These are a critical part of good storage and handling practice. Therefore, we recommend that you only use thermometers and data loggers that are currently certified as calibrated.

- A calibrated thermometer or data logger is one that has been calibrated and certified by a United Kingdom Accreditation Service (UKAS) certified organisation.
- All temperature monitoring devices, through normal use, drift over time, which affects accuracy. Because of this, thermometer devices should undergo periodic calibration testing.
- Calibration may or may not be part of the routine servicing of the vaccine refrigerator.This should be clarified with the manufacturer.

10.1. Temperature data loggers:

Ensure data loggers are correctly set-up according to manufacturer's instructions. Monitor refrigerator temperature at regular intervals (e.g. every 5 minutes) 24 hours a day 7 days a week. Once set, they will record the temperature automatically with no more intervention. The temperature data can be downloaded onto a computer and viewed as a report, usually in a graph and table format. It is important to record the refrigerator thermometer display temperatures during daily monitoring. The data logger information may be checked occasionally as a safeguard or when issues arise. Different types of data loggers are available and these should be considered as the backup thermometer.

- USB data logger (place whole unit in the centre of refrigerator) - monitors air temp.

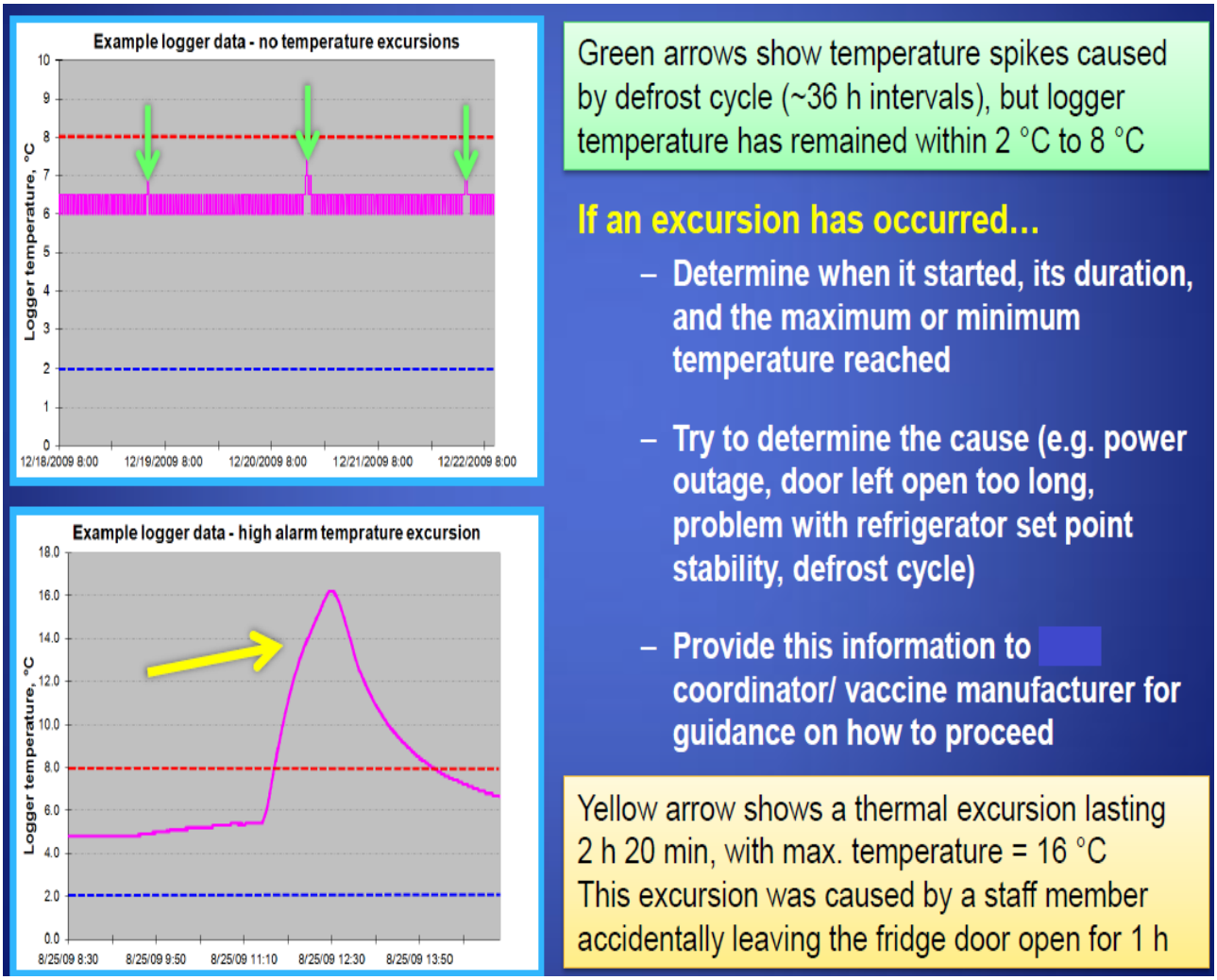
- USB data logger with separate air temperature probe
- USB data logger with separate "load" temperature probe

10.2. How to interpret data logger information

It is important to determine if any thermal excursions (temperatures outside the +2°C to +8°C range) have occurred. Manufacturers need accurate information in helping to determine viability of vaccine. Data loggers can be helpful in determining how long vaccines have been out of temperature range.

Data loggers typically produce a graph showing variation of temperature with time. Example below:

Example of graph produced by data logger



11. Refrigerator Maintenance

11.1. Defrost the refrigerator regularly in accordance with the manufacturer's recommendations if required. Record the date on the temperature record log, (see Appendix 1).

11.2. An alternative refrigerator or insulated container should be used for vaccines storage during defrosting of refrigerators. The temperature of the vaccines must not go outside the temperature range.

11.3. After defrosting turn the refrigerator back on, reset the maximum / minimum thermometer and when the temperature reaches between +2°C and +8°C replace the vaccines and recheck the temperature after 30 minutes to ensure the refrigerator is working correctly.

11.4. The refrigerator should be cleaned regularly and immediately in cases of vaccine spillage or visible spoiling.

11.5. Ensure the refrigerator is serviced in accordance with the manufacturers recommended schedule, at least annually, and when a fault develops or when there is suspicion or concern that the refrigerator is not working efficiently. Keep records of maintenance and repairs carried out for the lifetime of the refrigerator.

12. Stock Management

12.1. Stock monitoring will be carried out by use of stock control sheets for each specific vaccine or component of vaccine stored.

12.2. Formally check stock on a monthly basis (at the end of each month) for expiry dates and overall condition of vaccines and storage conditions. This is in addition to regular visual checks when daily temperatures are logged.

12.3. Rotate stock according to expiry dates and place older stock at the front of the refrigerator so that it can be used first.

12.4. Remove out of date stock from the refrigerator (out of date stock must not be kept in the refrigerator).

12.5. Check stock in response to alerts issued by MHRA and action in accordance with instructions in the alert e.g. quarantine affected vaccines, return to supplier.

13. Transport of Vaccines

13.1. Vaccines require strict adherence to recommended storage temperatures. Vaccines needed for sessions outside of the location where vaccines are stored (e.g. outlying clinics, home visits or care homes etc.) should be transported in a validated cool box/bag.

13.2. Validated Cool boxes/bags or cool packs should be stored either in a cold room or a refrigerator overnight before use. Commercial, **not** domestic packs must be used. The use of frozen ice packs should be avoided where possible. Where frozen ice packs must be used they should only be used in cool boxes designed to keep ice packs from touching from the vaccines. Insulating filler material should be used to fill spaces in incomplete loads.

13.3. If possible, pre cool the bags internally with cool packs. This will reduce the transfer and equalisation of temperature when taking product out of the refrigerator at +5°C and putting into a thermal bag which is +16°C. The product will end up in-between the refrigerator and bag temperature.

13.4. Vaccines should only be assembled immediately prior to dispatch and it should be confirmed that correct storage conditions have been adhered to.

13.5. Only the quantity of vaccine required for the immunisation session should be removed and the date and time of assembly should be recorded in **the vaccine log**. The time between removing vaccines from cool storage and use must always be kept to a minimum.

13.6. If a refrigerator is not available in the remote setting the vaccines must remain in the closed cool box until they are required. To minimise constant opening of the cool box, and hence frequent exposure to room temperature, remove sufficient vaccines to cover a reasonable number of patients.

13.7. Be sensitive to where you are keeping the cool bags in ambient conditions. Try to avoid warm areas and aim to site in cool shaded areas.

13.8. Any unused vaccine may be returned to the central refrigerator as soon as possible after the session, marked USE FIRST, so that this will be the first stock used at the next session, providing storage criteria have been maintained.

13.9. Where storage criteria have not been met, stock must not be returned to the refrigerator for reuse unless product specific guidance is in place for use within a defined time frame. In the latter case stock may be return to refrigerator marked USE FIRST with amended expiry date clearly marked. See also section 14 for disposal of vaccines.

14. Breaks in the cold chain

14.1. A vaccine cold chain failure can be defined as when vaccines storage has been determined to have fallen outside of the licensed allowable storage temperature range +2°C to +8°C. Advice should immediately be sought from the screening and immunisation team as to whether further action is required: Public Health England (contact telephone: 01138 253017)

Record all incidents involving breaks in the cold chain.
The NHS England Screening and Immunisation Team (SIT) can be contacted for help to interpret national policy and guidelines regarding Screening and Immunisations programmes.

Contact the team via email or phone. You will receive a response within 2 working days.

Email **england.cane.screeningimms@nhs.net**

Or Telephone **Monday to Friday 1-5 pm 011382 53017**

Temporary breaks in cold chain (Please also refer to Appendix 3 - “Take Action Now” poster)

14.2. If the maximum or minimum thermometer indicates that the temperature has been outside of range (+2°C and +8°C) but the actual (current) temperature is within range:

- Ensure refrigerator is functioning properly.
- Refer to temperature log to ascertain when refrigerator was last monitored and if there have been recent problems with temperatures.
- Establish possible reasons for break in cold chain since the refrigerator temperature was last monitored.
- Download data logger report where available
- Contact screening and immunisation team for advice

NB: Without constant temperature readout it is difficult to estimate how long the temperature was outside of range.

14.3. If the current temperature is outside of range, check the power supply to the refrigerator and follow the procedure outlined in section 15.

Accidental and temporary disconnection of the electricity supply

14.4. Note the refrigerators current (actual) temperature and the maximum and minimum temperatures (since the last reading). Refer to log to ascertain when refrigerator was last monitored and if there have been recent problems with temperatures. Download data logger report where available

14.5. If temperature is still within range (+2°C and +8°C):

- Reconnect power supply if possible to do so and take no further action.
- If power supply cannot be immediately reinstated, regularly monitor refrigerator temperature, keep refrigerator door closed and make alternative arrangements for vaccine storage for if or when the temperature approaches +8°C. If alternative arrangements cannot be made follow procedure below if temperature falls outside of range.

14.6. If is **outside range (+2°C and +8°C):**

- Reconnect power supply, if possible to do so, noting the time the power was reconnected. Attempt to establish how long vaccines have been outside the required temperatures. Download data logger report where available
- Check for any evidence of previous exposure of vaccines to breaks in the cold chain and establish the approximate number and type of vaccines, including any marked USE FIRST, currently in stock.
  - NB: may need to check delivery notes and batch numbers to ascertain how long individual vaccines have been in the refrigerator and hence relevance of any previous break in the cold chain.
- Contact Public Health England screening and immunisation team (contact telephone: 01138 253017
  - NB: Due to the number of variables that may be involved when vaccines are exposed to temperatures above the specified ranges, the circumstances relating to each situation will need to be assessed individually. It is therefore not possible to provide specific guidelines that will cover all situations.
- The Screening and Immunisation team may advise contacting the manufacturer for advice regarding the safety of the vaccines. If the manufacturer advises that it is safe to continue to use the vaccines that have been exposed to higher than normal temperatures, mark the stock "TO BE USED FIRST".
  These vaccines are classed as un-licensed/off-label and are no longer safe to use. Many are still safe to use, but the patient must be informed that the vaccine is now off label. Patients, Parents or carers should be given a leaflet explaining the reasons for 'off label' use of vaccines available at:
  https://www.gov.uk/government/publications/off-label-vaccine-leaflets

You can use this dialogue when explaining to a patient about the use of the vaccines outside of the recommendations.

"***The vaccine(s) that are being used have been stored outside of the recommended temperature for a short period of time and are therefore being offered 'off label'. This does not mean that they are unsafe and they will continue to offer protection. Expert advice has been given by Public Health England, NHS and the manufacturers of the vaccines who have advised that they can be used."***

Further information about 'off label' vaccine usage is available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/384581/9037_OffLabel_Healthcare_workers_03_Web.pdf

Refrigerator breakdown

14.7. Note the refrigerator current, maximum and minimum temperatures.

14.8. If temperature is **within range, i.e. between +2°C and +8°C:**

- Transfer the items to another refrigerator if possible, keeping them separate from the contents of the latter.
- If it is not possible to transfer vaccines to another refrigerator regularly monitor refrigerator temperature and keep refrigerator door closed. Alternatively transfer as much of the vaccine as possible in to a pre cooled cool bag and place bag into refrigerator, to minimise temperature rise.
- Contact the appropriate person to organise an urgent repair.

14.9. If maximum or minimum temperature is **outside range (+2°C and +8°C):**

- Transfer the items to another refrigerator if possible, keeping them separate from the contents of the latter.
- If transfer to another refrigerator is not possible then transfer as much of the vaccine as possible in to a pre cooled Cool Bag and place bag into refrigerator. Keep the door of the malfunctioning refrigerator closed and monitor.
- See procedures for dealing with accidental and temporary disconnection for details about using these vaccines.

15. Preparation and administration of Vaccines

15.1. Only remove vaccines from refrigerator when required. Check refrigerator temperature and temperature log prior to preparing/ administering a vaccine or commencing a clinic to ensure vaccines have been stored correctly.

15.2. Check identity, colour, and expiry date of vaccine prior to use. Ensure the correct named vaccine is selected, as some vaccines have similar names.

15.3. Once prepared, vaccines should be administered immediately and should not leave the hand of the person who prepared the vaccine. Only one vaccine should be prepared at a time. Ensure the vaccine has been prepared correctly before administration. Several vaccines have multiple components that require mixing.

16. Disposal of vaccines

16.1. Following administration syringes and needles should be placed in a sharps bin and marked pharmaceutical waste. Partly used vials (i.e. multi-dose vials) should be placed in the appropriate pharmaceutical waste container.

16.2. Unused vaccines that have expired or are unwanted should be placed in an appropriate pharmaceutical waste container and disposed of as per practice policy. Please ensure you notify Immform and declare appropriate waste at https://portal.immform.dh.gov.uk

17. Untoward incidents

17.1. Document all incidents relating to handling and administration of vaccines and report via organisational incident reporting processes, including Public Health England: (Contact telephone: 01138 253017 / email: england.cane.screeningimms@nhs.net) GP practices are also required document incidents using (Safeguard Incident & Risk Management System (SIRMS). Other providers may also need to use their own internal systems, such as DATIX.

17.2. Document adverse reactions to vaccines in patient's notes and report if appropriate to do so via "Yellow Card Scheme" (www.mhra.gov.uk)

17.3. Report incidents and concerns regarding the quality of a vaccine to the manufacturer / supplier and the MHRA.

17.4. Respond accordingly to MHRA alerts and safety notices

18. Monitoring and audit

18.1. The immunisation provider's clinical lead/manager has responsibility for the implementation of the procedures for the safe storage and transport of vaccines in their teams and ensuring that the training needs of their staff are met. Vaccine training must meet the minimum requirements as set out by Public Health England (https://www.gov.uk/government/publications/immunisation-training-core-curriculum)

18.2. Evidence of named responsible person(s) for vaccine handling should be available along with SOPs and all relevant documentation relating to the ordering, receipt and storage of vaccines.

18.3. Annual audits of vaccine handling should be carried out and the results fed back to the responsible persons.

18.4. A template audit tool is included to support the audit of the cold chain process.

19. References

1. National Minimum Standards for Immunisation Training. Available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/362171/National_Immun_Train_Stand1.pdf
2. Public Health England: Immunisation Against Infectious Disease - The “Green Book” Chapter 3: Storage, distribution and disposal of vaccines Available at https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3.
3. Health Protection Training. Available at https://www.gov.uk/government/collections/health-protection-training
4. ***NS731 Chiodini J (2014)*** Safe storage and handling of vaccines. Nursing Standard. 28, 25, 45-52. Date of submission: October 13 2013; date of acceptance: December 2 2013
5. Records Management: NHS Code of Practice Part 1(20 March 2006): Gateway Ref: 6295.
6. Records Management: NHS Code of Practice Part 2 Second Edition; (January 2009): Gateway Ref: 10678
7. Nursing and Midwifery Council (NMC),: Standards for Medicines Management. https://www.nmc.org.uk/standards/additional-standards/standards-for-medicines-management/
8. Nursing and Midwifery Council (NMC), 2015: The Code for Nurses and midwives https://www.nmc.org.uk/standards/code/.

Appendix 1: Model Template for Daily Refrigerator Temperature Log

Location: _____. Room: _____ Month _____ Year_____

Date / day	Time	Actual temperature	Minimum temperature	Maximum temperature	Thermometer Reset (tick)	Checked by (Signature)	Comments
1st	am						
	pm						
2nd	am						
	pm						
3rd	am						
	pm						
4th	am						
	pm						
5th	am						
	pm						
6th	am						
	pm						
7th	am						
	pm						
8th	am						
	pm						
9th	am						
	pm						
10th	am						
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19th	am						
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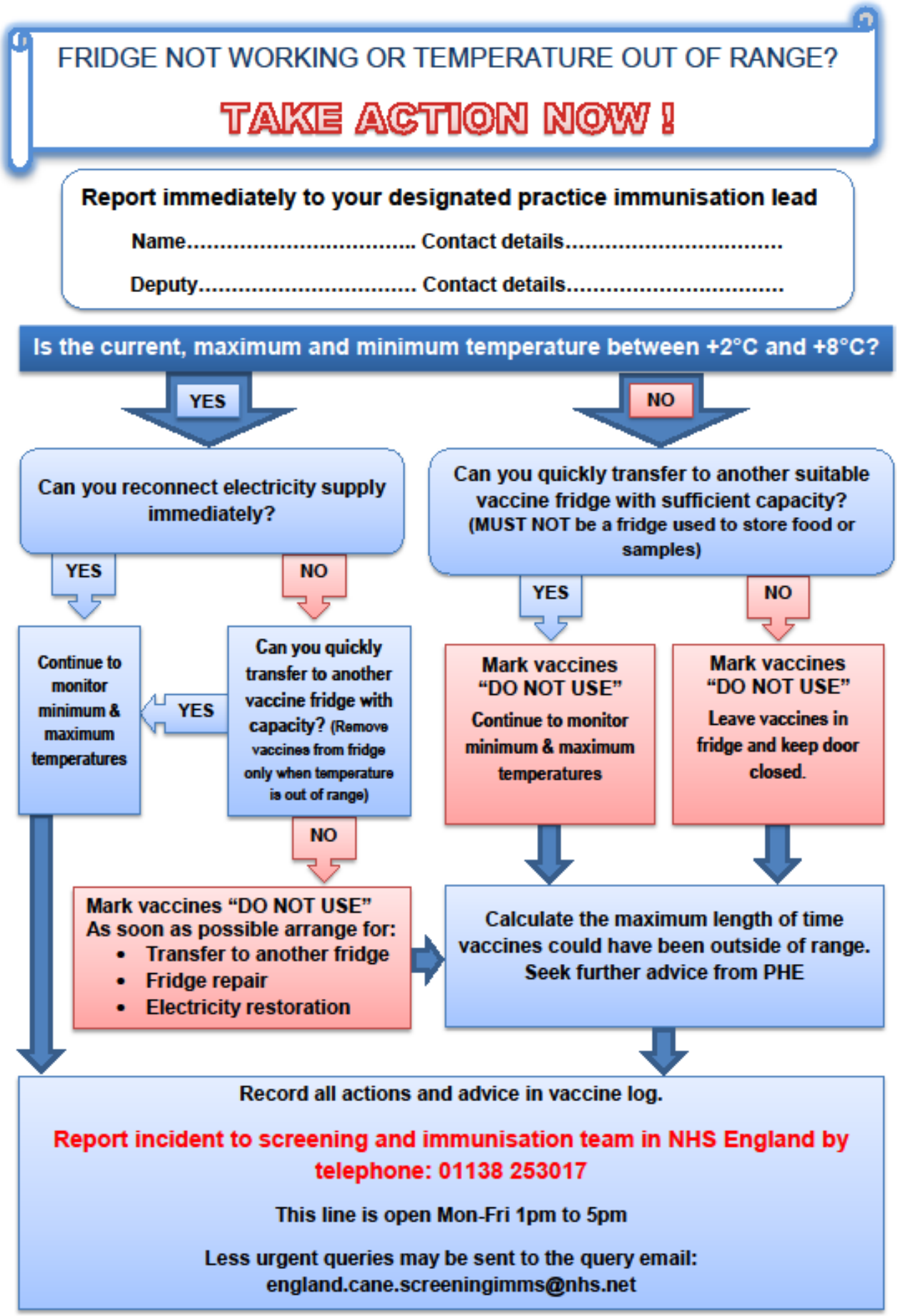
20th	am						
	pm						
21st	am						
	pm						
22nd	am						
	pm						
23rd	am						
	pm						
24th	am						
	pm						
25th	am						
	pm						
26th	am						
	pm						
27th	am						
	pm						
28th	am						
	pm						
29th	am						
	pm						
30th	am						
	pm						
31st	am						
	pm						

Appendix 2: - Model Template for Recording Refrigerator Maintenance

Date	Details of maintenance	Signature

Appendix 3: - Take Action Now Poster



Appendix 4: - Cold Chain & Refrigerator Storage Self Audit Tool - Example Template

Cold Chain & Fridge Storage – Risk Assessment Self Audit Tool for GP practices in Cumbria and North East

Question (Please answer each question by ticking YES or NO as appropriate). If your answer is No, please detail any remedial action being taken in the comments section.		YES	NO	Comments / Remedial actions
1	Is there a Vaccine Fridge(s) in use?			
2	Is the fridge appropriately ventilated & situated away from any heat source?			
4	Is the refrigerator being used exclusively for medicines & vaccines?			
5	Does the vaccine fridge have a service contract (Thermometer calibration and PAT test)?			
6	Is the fridge kept locked or in a room that's locked, when not in use?			
7	Is your fridge connected to the electricity supply using a switchless socket?			
8	If an ordinary socket is used, is there a label on the fridge plug saying "DO NOT SWITCH OFF"?			
9	Is a maximum/minimum thermometer used to monitor fridge temperature?			
	If YES, is this integrated [ ] or separate [ ] to the fridge (please tick) (NB Integral thermometers should always be the primary temperature monitoring device where available)			
	If an integrated thermometer is used, is a separate one or data logger used as a back-up?			
10	Are all thermometers and data loggers calibrated regularly according to manufacturer's advice			
11	Is a validated cool box [ ] or alternative fridge [ ] used during cleaning			
12	Are vaccines stored with sufficient space to allow air to circulate freely?			
13	Are all vaccines stored on the fridge shelf?			
14	Are all vaccines in your vaccine fridges in date (i.e. within their expiry date)?			
15	Is stock rotated so that vaccines with shorter expiry dates are used first?			
16	Is out-of-date stock, labelled clearly & then promptly removed & disposed of?			
17	Is the cold chain maintained when transporting vaccines for home visits or to outlying clinics? If so, how? Please describe in the comment box			
18	Are vaccines disposed of in accordance with waste regulations?			

Policy & Procedures				
19	Does the practice have an up to date Cold Chain/Vaccine Storage Policy?			
20	Is there a procedure available specifying what action to take if the fridge fails?			
21	Have all staff that order/handle/administer vaccines been trained in this policy?			
22	Is there a designated person for receipt of vaccine on delivery?			
23	Are all staff aware that vaccines must be placed in the vaccine fridge immediately on receipt and the designated person informed?			

24	Is there a designated person(s) & deputy responsible for monitoring stock ordering and checking & monitoring fridge temperatures?			
25	Is there an up to date log/record of vaccine stock for each vaccine fridge?			
26	Is there a designated named individual within the practice responsible for vaccine ordering, receipt and storage?			
27	Who provides immunisation within the practice (please tick) :(i) Nurse [ ] (ii) GP [ ] or (iii) HCA [ ]			
28	Have all staff who administer immunisation trained to the HPA standards, i.e. (i) Basic training (2 days) plus (ii) An annual update			
29	Does your practice have an incidents policy?			
30	Are all immunisation incidents reported?			
	If so to whom / which organization? Please tick all that apply Screening and Immunisation Team ( ) North East Commissioning Support Team ( ) ImmForm ( ) Other ( )			
Looking at the last month of recorded fridge temperature logs				
31	Are fridge temperatures recorded onto a temperature log or chart?			
32	If YES to question 31, is the maximum and minimum fridge temperature recorded?			
	- is the "current" fridge temperature recorded?			
	- is the thermometer reset after each recording?			
33	Does the log contain the signature of individual taking reading?			
34	Does the log contain a "comment box" to record what actions were taken if the reading is recorded out with the range +2°C to +8°C and the reasons why this occurred			
35	Are fridge temperatures consistently recorded at least once each day?			
36	Excluding the days the practice is closed, how many gaps are there in the daily temperature recording log?	No. of gaps =		
37	Looking at the last month of recorded logs, are all fridge temperatures recorded in range i.e. between +2 to +8°C			
38	If you answer No to question 37, please state what action was taken.			
	Was this action documented?			
39	Do the recorded reasons/actions adequately explain the temperature fluctuations			

Additional Information for cold chain storage

- Each practice should have one trained individual, with at least one trained deputy, responsible for the receipt and storage of vaccines and the recording of refrigerator temperatures.
- A specifically designed fridge, with a service contract, is the minimum recommended standard.
- Vaccines should never be stored in a domestic fridge.
- Foodstuffs or medical specimens should never be stored in the same fridge as vaccines.
- Allow enough room for air to circulate between packages.
- The fridge door should not be used to store any medication requiring refrigeration.
- A maximum/minimum thermometer should be used in all vaccines fridges.
- Fridge temperatures must be monitored and documented at least daily. Preferably each morning and evening and when the fridge is opened for receipt of vaccines or when an immunization session starts.

- The fridge must be defrosted regularly if appropriate, as recommended by the manufacturers.

Further information
Public Health England: Immunisation against Infectious Disease "Green Book", Chapter 3 (June 2013); Storage, Distribution and Disposal of Vaccines, online version. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/223753/Green_Book_Chapter_3_v3_0W.pdf

Vaccination Cold Chain Audit Tool

It is recommended that each organisation commissioned by NHS England to deliver vaccination programmes undertakes this audit every 12 months, to ensure best practice. An important part of the audit is to ensure that any remedial actions are **recorded, reviewed and acted upon** within timescales which reflect the urgency of the necessary action.
NHS England Cumbria and North East region may request copies of most recent audits during vaccine incident investigations and following CQC inspections.

Why is this important for your practice? Vaccines are biological substances that may lose their effectiveness quickly if they become too hot or too cold at any time, especially during transport and storage. It is essential that all those handling vaccines follow polices to ensure cold chain compliance.

Who should complete this audit tool? The person responsible for storage of vaccines and is the designated responsible person as stated in the cold chain policy.

What information should be included? It is expected that the person conducting the audit should seek evidence of compliance (for example, reviewing the content of the refrigerator or viewing maintenance records) as well as reviewing the Cold Chain Policy and/or your local procedure documents.

Further information: Guidance on the urgency of remedial actions may be sought from NHS England Team by telephone on 01138 253 017, or email: england.cane.screeningimms@nhs.net

Date Audit Completed	
Name person completing the Audit	
Signature of person completing Audit	
Designation of person completing Audit	
Name of Practice immunisation lead (if different from above)	
Address of Clinic / Surgery	
Who is accountable for ensuring that the Remedial Actions are addressed?	

Vaccine Name: ..... **Brand Name:** ..... **Dose size (ml):** .....

Location of Stock: .....

Date	Obtained / Received					Administered / Supplied				
	From	Order number (if applicable)	(QTY) No. of doses	Batch No. & Expiry date	Name and signature of staff receiving	No. of doses supplied for clinic	No. of doses wasted	Batch No. & Expiry date	Name and signature of staff supplying	**Stock Balance**

Vaccine Stock Control Form (April 2015) (Public Health England - Cumbria and North East, supported by NECS Medicines Optimisation)