

# Vaccine cold storage

January 2010

## Supporting Information

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## Background

The maintenance of the cold chain in the delivery of vaccines in the UK is subject to a very vigorous and robust procedure. In the unlikely event of a break in this cold chain during the delivery process, vaccines can be traced and recalled, and individual patients who have received them can be identified within a matter of hours using tested recall procedures. Once vaccines have been delivered to providers however, the maintenance of the cold chain and the storage of vaccines may, on occasion, fall short of manufacturers' recommendations. All vaccines supplied clearly display the recommended storage conditions on the label and on the Summary of Product Characteristics (SPC). It is good practice to physically check the labelled storage conditions for each delivery before it is put away.

For vaccines to be effective, it is important that they are stored within the temperature range recommended by manufacturers [ $+2^{\circ}\text{C}$  to  $+8^{\circ}\text{C}$ ] to ensure that they remain potent. The vaccination cold chain refers to all the materials, equipment and procedures involved in maintaining vaccines under the required storage conditions from manufacturer to administration<sup>1,2,3</sup>.

It is becoming increasingly important for those working in primary care to be able to communicate to patients and their carers the benefits of vaccination, the known side effects of vaccines, as well as the safety and efficacy of vaccines to allay fears.

## Vaccine stability

Whilst storage of vaccines outside of manufacturer's recommendations is clearly not best practice, some vaccines are particularly susceptible to becoming inactive if stored below  $+2^{\circ}\text{C}$ . Conversely, stability data suggests other vaccines stored outside recommendations may continue to be used in specific circumstances.

Details of the effect of temperature on vaccine stability have been investigated in detail and are published in the World Health Organization report *Temperature sensitivity of vaccines*<sup>4</sup>.

For practical day-to-day guidance on the use of UK-licensed medicines and vaccines when the cold chain has been broken, UK Medicines Information (UKMi) maintains a database that collates published and unpublished information from manufacturers. This is known as 'The Fridge Database', and is available at: [www.ukmi.nhs.uk/applications/fridge/](http://www.ukmi.nhs.uk/applications/fridge/). It recommends action designed to prevent wastage for 237 medicines and 50 vaccines. Access can be obtained by contacting your regional medicines information centre (contact details in Appendix 1 of this document and at the front of the *British National Formulary*).

Whilst product use following a break in the cold chain may be appropriate in certain circumstances for individual products, it will usually be outside the terms of the product licence and use remains at the discretion of individual practitioners.

Further comprehensive advice regarding the principles, practices and procedures relating to immunisation programmes in the UK, as well as information on the diseases, vaccinations and vaccines can be found in the Department of Health (DH) publication *Immunisation against infectious disease - 'The Green Book'*<sup>1</sup>.

Information can also be found on the NHS Immunisation Information website: [www.immunisation.nhs.uk](http://www.immunisation.nhs.uk)

## Scale of the patient safety issue

It should be noted that immunisation is one of the most important weapons for protecting individuals and the community from serious diseases. The number of incidents highlighted in this report represents a very small proportion of the vaccine doses given.

In June 2009, a clinical audit of vaccine storage in GP practices and NHS trusts was shared with the National Patient Safety Agency (NPSA). A routine infection control audit had showed that childhood vaccines had been stored incorrectly in a GP practice which had resulted in an extensive vaccination recall. Subsequently, similar findings were reported from other GP practices. A two-year retrospective audit (where records existed for that length of time) of 96 GP practices revealed that over 40 per cent of vaccines had been stored outside of the recommended temperature range. These audit findings were risk assessed using a risk assessment tool (Appendix 2), developed using Health Protection Agency (HPA) guidance for vaccine storage, and WHO guidance on the effectiveness of vaccines stored outside of manufacturer's recommended temperature ranges.

A local HPA consultant in communicable diseases discussed the vaccine risk with the Centre for Infections and confirmed that frozen vaccines were the ones most likely to be rendered ineffective. Each practice in that PCT was visited to complete the risk assessment. The HPA consultant then reviewed the findings for each practice on a case-by-case basis. Vaccines known to have been stored below -2°C were considered to be the highest risk and resulted in recall. Patients were recalled from two practices within the PCT.

The first recall involved approximately 200 children (75 per cent of these attended for revaccination). The second recall included 360 adults and children (60 per cent attended for recall, but some were travel vaccines). It took 15 days to audit 96 practices. Both recalls required a full-time person for one month, with administrative assistance and help from a data quality team to help track patients. The PCT provided media handling, a helpline and significant levels of support to the practices. There were around 50 additional recall clinics at local venues.

At the same time, the NPSA undertook a review of the Reporting and Learning System (RLS) for vaccination errors during the period 1 January 2005 to 1 April 2009. The search terms used included:

Vaccine, Vaccination, Immunisation, Inoculate/inoculation, Men C, Meningitis C, Hib, Pneumococcal/ pneumococcus/ streptococcus pneumoniae, DPT (Diphtheria, Pertusis, Tetanus), Diphtheria, Tetanus, Polio, Pertusis, Whooping cough, Jab/jabs, Immunise, booster, Hep A/B, Typhoid HPV, MMR (Measles, Mumps, Rubella), Measles, Mumps, Rubella, German measles, BCG, Tuberculosis, Pediacel, Infanrix-IPV, Prevenar, Meningitec, Menjugate, Neisvac-C, Priorix, MMR II, Revaxis:

Additional search terms:

Stor\*, Fridge, Refrigerat\*, Temperature, Froze, Freeze, Cold

During this period, the NPSA received 260 reports of incidents related to vaccination cold storage. All of these incidents (reviewed by NPSA staff) were reported as 'no harm'. While this is technically correct in terms of known harm to specific patients at the time of incident, it does not reflect the potential for future harm from possible vaccine failure.

## Identified themes

Themes identified in qualitative review of incidents which relate to breaking the cold chain once the vaccine has reached the practice are shown in Table 1, with example incidents below. Some of these example incidents may fall into more than one thematic category but have only been highlighted once:

**Table 1**

Theme	Number of reported incidents
Wrong storage of vaccines	80
Storage at wrong temperature range	74
Fridge being switched off	23
Broken fridge	22
Power cut	21
Poor storage conditions for vaccines	9
Fridge door left open	8
Lack of temperature monitoring	8
Other	7
Lack of, or inadequate, equipment	5
Use of a domestic fridge	3
<b>Total</b>	<b>260</b>

### **Wrong storage of vaccines (80 reported incidents)**

Of these 80, 39 happened following the delivery of vaccines where the vaccines were not stored appropriately immediately after delivery:

*'MMs were dropped off at 10:30am. Staff did not liaise with HV Team and consequently the vaccines were not stored in the fridge and had to be disposed of.'*

*'A package of vaccines was delivered to the surgery and taken over the counter and signed for. These vaccines were not put in the fridge and were forgotten about, hence they were ruined.'*

Of these 80, 12 were concerned with breaking the cold chain as the vaccines were transported to patients:

*'Patient was prescribed hepatitis B vaccine. Protocol is for drug to be given in 1st 24hrs of life. Drug dispensed by pharmacy and ward rung to say ready by 6.30pm not collected so rung again and told putting in their locker. Not collected by the next day when pharmacy reopened. Vaccine now expired as cold chain broken.'*

*'Influenza vaccine was dispensed for pt on. It was found in a patient locker drawer a few days later. It should have been stored in the fridge. There were fridge stickers on the bag and the box. I removed the vaccine and supplied the patient with a new one.'*

### **Storage at wrong temperature range (74 reported incidents)**

All 74 incidents in this category were 'no harm' incidents:

These incidents also highlight the problem of waste and costs due to inappropriate storage:

*'Vaccine fridge in practice (PCO property) failing to keep within 2-8 degree range - rendering vaccines unusable. Works department notified on several occasions but problem not dealt with. Pharmacy contacted who advised disposal of vaccine - estimated cost £150.00 Problems continue with cold chain - sometimes deliveries left in hospital and not delivered. New vaccine fridge needed. Medicines management team informed.'*

*'Fridge in Nurses room - temperature log shows temperatures out of range, i.e. outside 2-8°C . Older records show 0°C in March and July up to 13°C. Fridge stock including vaccines to be ineffective due to these temperatures. Flu stock found to be stored in the food fridge, no temperature records kept or available.'*

*'Refrigerator broke down, causing 1100 doses of an unlicensed MMR vaccine to be invalidated.'*

### **Fridge being switched off (23 reported incidents)**

All 23 incidents in this category were 'no harm' incidents:

*'Patient was given Hib and Men C jab before staff noticed that the fridge and temperature alarm was switched off. Fridge was 22°C.'*

*'Nurse arrived to conduct her BCG Clinic. On preparing for her clinic she discovered the fridge had been switched off at the mains, and the vaccines therefore ruined.'*

### **Broken fridge (22 reported incidents)**

All 22 incidents in this category were 'no harm' incidents:

These incidents are also an example of inconvenience to patients; cancellations of vaccination schemes and recall programmes.

*'Vaccinating pupils with Revaxis - Diphtheria, Tetnus, Polio. Vaccine - pre-filled syringes. Contacted by school health that the fridge storing the vaccine had been malfunctioning and told to cease vaccination session. 109 pupils had already received Vaccine. 12 children remaining - not given vaccine. The vaccine had been collected at 08:30 and transferred as recommended per protocol, and stored in school in storage box in line with cold chain guidelines. Contacted pharmacy who contacted manufacturers, also contacted district immunisation coordinator for local health protection agency. Contacted manufacturers' medical information department, and followed their recommendations and informed head teacher.'*

*'Refrigerator broke down, causing 1100 doses of an unlicensed MMR vaccine Farillon to be invalidated.'*

### **Cold chain because of power cut (21 reported incidents)**

One incident here was categorised as 'low harm'. The remaining 20 incidents were 'no harm' incidents:

*'Power failure occurred over the weekend leading to fridge temperature being unregulated and vaccines spoiled.'*

*'Power failed on drug fridge over weekend. Fridge contained childhood immunisation vaccines - temperature rose above 21°C. Reported by Health Visitor. 9 Paediacel, 19 infanrix, 18 MMR, 20 Meningitis C vaccine required destruction.'*

### **Poor storage conditions for vaccines (nine reported incidents)**

All nine incidents in this category were 'no harm' incidents:

*'Whilst carrying out infection control ward competencies in A&E department , checking A&E staff room fridges , found that the fridge belonging to the out of hours GP service ( Food Fridge ) contained drugs ( Flu vaccine , Eye drops , Hypostop + 1 box IV Med as well as food and drink. Items of food included tub of soft cheese - 6 months out of date!'*

*'I was informed that the school age immunisations had been removed from their boxes of 50 and put into the drug fridge. The problem was not removing them from the original box but the fact that they were against the back and the sides of the fridge. The fridge was jam packed with single boxes. Local policy states fridge should not be filled to more than 50% capacity.'*

*'Son took his father to the practice - A to receive the flu vaccine. When they took the vaccine out of the fridge he thought he saw other items being stored in the fridge including urine samples. Gentleman also mentioned that the fridge was jam packed with items. He asked whether they had vaccines anywhere else they could use and was told there were some in their kitchen fridge at which point he decided he was not happy for his father to be vaccinated by the practice so took him elsewhere.'*

### **Fridge door being left open (eight reported incidents)**

All eight incidents in this category were 'no harm' incidents:

*'Large drugs fridge left open. Therefore all stored vaccines had to be disposed of. The fridge is lockable but key has been missing for several months. The fridge was last used by PCT staff at 12 noon. Fridge alarm sounded 16.40.'*

### **Lack of monitoring of temperature (eight reported incidents)**

All eight incidents in this category were 'no harm' incidents:

*'Vaccine fridge temperature check not done as per audit / procedure requirements.'*

### **Lack of, or inadequate, equipment (five reported incidents):**

All five incidents in this category were 'no harm' incidents:

*'Flu vaccinations not having ' cold chain ' maintained. 1x vaccine fridge has no thermometer 2nd vaccine fridge thermometer not working. Fridge records not maintained, overcrowding in fridge.'*

### **Use of a domestic fridge (three reported incidents).**

All three incidents in this category were 'no harm' incidents:

*'A section of the infection control audit conducted in GP Practices requires inspection of vaccine management and storage. I found vaccines stored in domestic refrigerator in doctors exam room also storing drink water and juice. On looking at the pharmacy fridge in the nurses room the fridge thermometer read 10°C and was filled to capacity allowing insufficient air supply. Daily recordings of the fridge temperatures had not taken place.'*

Other themes identified in the qualitative analysis, not directly related to breaking the cold chain once the vaccines has reached the practice:

### **Other potential risks identified from RLS reports include the risk of infection due to failure to store vaccine appropriately:**

*'Asplenic patient who requires vaccines. On [date] pneumococcal vaccine + hiberix vaccine supplied to ward in appropriately labelled bag. Label on bag stated: 'Vaccines to be refrigerated immediately'. When ward Pharmacist visited ward on [date] - vaccines found in patient locker. Ward staff informed of error & re-supply made. A new supply was made, unfortunately of pneumovax II only - as Pharmacy has no hiberix in stock. Again - in an appropriately labelled bag. Ward Pharmacist visit on [date] - the vaccines were again in the patient locker & not in the fridge. Cost implication = approx 10 per vaccine. Patient at risk of pneumococcal & haemophillus infection as a result of not being able to have vaccines.'*

### **Related evidence**

Discussions with NHS Nottinghamshire County/HPA incident team have indicated that the problem of inappropriate storage of vaccines is widespread. In 2009, a routine clinical audit of vaccine storage in GP practices and NHS trusts was shared with the NPSA. The audit revealed that around 40 per cent of vaccines were stored outside of the recommended temperature range.

The literature also suggests that this is a well-known and reoccurring problem. Vaccination storage problems are believed to be underreported as a patient safety issue, and the literature suggests that the administration of vaccines with suboptimal potency because of cold chain failure and the extent of the wastage are much greater than reflected by RLS data<sup>5</sup>.

Incorrect storage of vaccines is not only wasteful and costly to the NHS, but the failure to store vaccines correctly can reduce vaccine effectiveness and cause undue vaccine failures. In this way, failure to store vaccinations appropriately represents a threat to patient safety.

Though the RLS is yet to receive any reports of harm due to the administration of wrongly stored vaccines, it is important to note that vaccine potency is recognised by the World Health Organization as being directly related to storage conditions for many vaccines<sup>4</sup>. An Australian study in 2008 monitoring the temperature in vaccine refrigerators in 28 general practices, revealed that compared with purpose built vaccine refrigerators, all other refrigerators were significantly less likely to keep temperatures within the recommended range<sup>6</sup>.

Further risk reduction strategies cited in the literature include the following, although not all may be appropriate for the UK:

- Use electronic monitoring with feedback of storage temperatures to correct adverse storage<sup>7</sup>.
- Educate staff on correct storage conditions<sup>8</sup>.
- Use reimbursement schemes to ensure that purpose built refrigerators are put in place, or sanctions for repeated temperature violations, including losing access to subsidised vaccines<sup>6</sup>.
- Have public health staff conduct regular onsite inspections of the cold chain management in clinics and provide education and ensure safe handling of vaccines<sup>5</sup>.
- Ensure that local public health unit should have a vaccine-preventable disease team available to assist when problems with temperature maintenance, power loss and possible spoilage arise<sup>5</sup>.

### International Guidance

A variety of guidance on safe vaccine storage and handling exists including the following publications:

- World Health Organization – *Temperature sensitivity of vaccines*<sup>4</sup>.
- Department of Health – *Immunisation against infectious disease*<sup>1</sup>.
- Health Canada – *Canada Communicable Disease Report*<sup>9</sup>
- Centers for Disease Control and Prevention – *Vaccine storage and handling*<sup>10</sup>.
- Local government initiatives such as Ontario Ministry of Health and Long-Term Care - *Vaccine storage and handling guidelines*<sup>2</sup>.

In addition to these publications, the guidelines are summarised in clinical research outlets such as *Canadian Family Physician*<sup>11</sup>, *Paediatrics*<sup>3</sup>, and *Practice Nurse*<sup>12</sup>, and similar recommendations are presented in variety of clinical research articles, for example 'Managing the vaccination cold chain'<sup>13</sup> and 'Vaccination do's and don'ts'<sup>14</sup>.

- The summary of the existing recommendations provided by DH<sup>1</sup> are listed in Appendix 3.
- Nottinghamshire County PCT have also issued *Revised Practice Guidance for Vaccine Cold Chain Storage* as stated in Appendix 4

It should be noted that markers such as 'the number of days a fridge temperature is recorded as below 0°C' may be very important in assessing risk.

### Audit

The risk assessment tool in Appendix 2 may be adapted locally as an audit tool to provide baseline data for organisations wishing to document improvement and change following the implementation of this Rapid Response Report. By undertaking such an audit before and after implementation, a measure of change could be determined.

## Summary and conclusion

Vaccination programmes in the UK are well developed and have led to a large reduction, and in some cases eradication, of disease. It is important therefore that confidence in the immunisation programme is not compromised. It is however also important to ensure that immunisation programmes remain effective, and so the issues highlighted in the document need to be addressed at both national and local level.

This document demonstrates the issue of incorrect storage of vaccines, in all healthcare settings, that could potentially lead to ineffective vaccination leaving patients more susceptible to disease. The nature of this problem means it is very difficult to absolutely demonstrate direct harm as a result of ineffective vaccination, although the evidence brought together in this document demonstrates the potential for this to happen.

Evidence supplied by a single region in the UK suggest that the issue of incorrect vaccination storage and lack of rigour in monitoring that storage is substantial, and can lead to both financial waste of resource (vaccinations), worry for patients and their families, potential recall programmes being instigated and a potential increase in disease. It is likely that similar problems could be found across the UK. Experience from one PCT shows the cost implications of poor vaccine management, including a recall of over 500 patients from just two practices.

Advice does exist on this issue, although it is clear that this is not always followed. In this respect the NPSA is well placed to issue a Rapid Response Report to address some of these issues and highlight a requirement to comply with existing guidance.

## References

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2. Ontario Ministry of Health and Long-Term Care (2005). *Vaccine storage and handling guidelines*. Available at: [http://pcchu.peterborough.on.ca/VPD/images/PDF/MOH\\_Vaccine\\_StorageGuide\\_E\\_19Jan06%5B1%5D.pdf](http://pcchu.peterborough.on.ca/VPD/images/PDF/MOH_Vaccine_StorageGuide_E_19Jan06%5B1%5D.pdf)
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11. Anon. National guidelines for vaccine storage and transportation. Laboratory Centre for Disease Control. *Can Fam Physician*. 1995; 41: 1221-1222.
12. Anon. Practicalities of vaccination: The cold chain. *Practice Nurse*. 2006; 31: Supplement.
13. Diggle L. Managing the vaccination cold chain. *Practice Nurse*. 2006 32: 39.
14. Parini S. Vaccination do's and don'ts. *Nursing*. 2003; 33: 58-63

## Appendix 1: Medicines information services contact details

### Medicines information services

Information on vaccine stability can be obtained from regional and district medicines information services. Details regarding the local services provided within your region can be obtained by telephoning the following numbers.

#### England

Birmingham (0121) 424 7298

Bristol (0117) 342 2867

Ipswich (01473) 704 431

Leeds (0113) 392 3547

Leicester (0116) 255 5779

Liverpool (0151) 794 8113/4/5/7 and (0151) 794 8206

London:

Guy's Hospital (020) 7188 8750 and (020) 7188 3849 and (020) 7188 3855

Northwick Park Hospital (020) 8869 2761 and (020) 8869 3973

Newcastle (0191) 260 6198

Southampton (023) 8079 6908/9

#### Wales

Cardiff (029) 2074 2979 and (029) 2074 2251

#### Scotland

Aberdeen (01224) 552 316

Dundee (01382) 632 351 and (01382) 660 111 Extn 32351

Edinburgh (0131) 242 2920

Glasgow (0141) 211 4407

#### Northern Ireland

Belfast (028) 9063 2032 and (028) 9063 3847

**Appendix 2: Risk Assessment Tool**

**Name:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Risk assessment of vaccine storage in fridges**

**Supporting information**

Vaccines should be stored at 2-8°C, but evidence has shown that vaccines are often stored above or below these temperatures. Vaccines are considered to be heat stable, but their potency is affected by freezing.

**Number of patients registered at the practice:**

	<b>Risk identified</b>	<b>Question</b>	<b>Answer</b>	<b>Risk score</b>
1	Use of non – vaccine fridge	1. Vaccine fridge (s) in use (how many) 2. Non-vaccine fridge(s) in use (how many) 3. Name of manufacturer used (list)	1. 2. 3.	
2	Temperature in fridge fall below 2°C	1. Min and max data not recorded 2. Number of times recorded at 1°C 3. Number of times recorded at zero 4. Number of times below zero	1. 2. 3. 4.	

3	The thermometer and therefore the documented temperature reading does not reflect the true temperature in fridge	<ol style="list-style-type: none"> <li>1. How many thermometers are in use per fridge?</li> <li>2. What type(s) of thermometer are in use? (list)</li> <li>3. Is the integral thermometer being used correctly?</li> <li>4. Have the thermometers been PAT tested?</li> </ol>	<ol style="list-style-type: none"> <li>1.</li> <li>2.</li> <li>3.</li> <li>4.</li> </ol>	
4	Lack of documentation to evidence action taken in response to a rise or fall in temperature, and daily reset of thermometer	<ol style="list-style-type: none"> <li>1. Are 'resets' documented daily?</li> <li>2. Are 'resets' documented occasionally?</li> <li>3. Are there any other comments on the log sheets?</li> </ol>	<ol style="list-style-type: none"> <li>1.</li> <li>2.</li> <li>3.</li> </ol>	
5	Lack of knowledge about vaccines contained in the fridges	<ol style="list-style-type: none"> <li>1. What vaccines were stored in the fridge(s) that had temperatures at zero?</li> <li>2. What vaccines were stored in the fridge(s) that had temperatures at 1°C?</li> <li>3. Can the practice provide details of the delivery dates of the vaccines?</li> <li>4. Can the practice describe a stock rotation process?</li> <li>5. Does the practice monitor stock rotation each month?</li> </ol>	<ol style="list-style-type: none"> <li>1.</li> <li>2.</li> <li>3.</li> <li>4.</li> <li>5.</li> </ol>	

**Appendix 3: A summary of the existing recommendations provided by DH<sup>1</sup>**

- Local practice should be in accordance with national policy for the ordering, storage, stock control, distribution, transport and disposal of vaccines.
- 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.
- Vaccines should be stored in the original packaging at +2°C to +8°C and protected from light.
- Vaccine stocks should be monitored by the designated person(s) to avoid over-ordering or stockpiling.
- Surgeries should have no more than two to four weeks' supply of vaccines at any time.
- Vaccines must be refrigerated immediately on receipt and must not be left at room temperature.
- Specialised refrigerators are available for the storage of pharmaceutical products, and must be used for vaccines and diluents. Ordinary domestic refrigerators must not be used. Food, drink, and clinical specimens must never be stored in the same refrigerators as vaccines.
- The accidental interruption of the electricity supply can be prevented by using a switchless socket or by placing cautionary notices on plugs and sockets.
- An approved cool box or alternative refrigerator should be used to store vaccines during defrosting of the main refrigerator.
- The temperature with the vaccine refrigerator must be continually monitored with a maximum-minimum thermometer.
- Temperatures in the refrigerator must be monitored and recorded at least once each working day, and documented on a chart for recording temperatures.
- Arrangements should be in place for back-up facilities to be available in the event of the refrigerator failing or breaking down.

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<sup>1</sup> Department of Health. *Immunisation against infectious disease – 'The Green Book'*. Third edition. DH, London. (2006). Available online at: [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_079917](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917)

#### Appendix 4: Local guidance issued by Nottinghamshire County PCT

Nottinghamshire County PCT have issued the following revised practice guidance for vaccine cold chain storage:

- Vaccine fridge **must** be used for storing vaccinations and domestic fridges must not be used for the storage of vaccines **under any circumstances**.
- Only **use one thermometer** for each fridge preferably integral but if not available a calibrated digital external thermometer can be used.
- Electrical and calibration tests must be completed on **all** vaccine fridges **annually**.
- The temperature readings must be taken on **every working day**.
- The temperature readings must be recorded to include:
  - current temperature;
  - maximum and minimum;
  - time of reset;
  - signature of individual taking reading;
  - comment box to include what actions are taken if reading recorded out with the range 2–8°C.
- Ensure that the individuals taking the readings understand how to **read and reset the thermometer** and why this is necessary.
- Ensure that individuals understand **when and how to take action** when readings are out with the range 2–8°C:
  - record on the log any known reasons for fluctuations in temperature, e.g. when stocking up the fridge;
  - quarantine any exposed stock until assurance received;
  - contact each manufacturer for advice giving details of temperatures and time exposure;
  - ensure manufacturers responses are documented;
  - if issue with temperature control cannot be resolved promptly, then vaccines must be moved to another suitable location.
- Individuals responsible for receipt and management of vaccine stock must understand the need for **close stock control and careful stock rotation**. Practices should have **no more than two to four weeks of stock at any time**. This will be sufficient for routine provision.
- All practices must ensure that they have access to and refer to Chapter 3 of 'The Green Book, *Immunisation against Infectious Diseases*.'

## Appendix 5: Implementation checklist

This checklist gives examples of what should have happened before the Central Alerting System (CAS) (formerly SABS) can be updated to signal 'Action Complete'.

NHS organisations should:

No	Recommendation	Action	Compliance Y/N
1	Ensure that all departments and providers (including independent contractors) holding vaccine stocks are aware of relevant policy on safe storage, for example as given in Appendices 3 and 4 of the supporting information. Local policies should include having a designated person and deputy/ies responsible for receipt and storage of vaccines.	Records of guidance being issued and disseminated are complete and available, along with a copy of that guidance. <i>Note: no need to repeat this, if appropriate guidance already issued earlier.</i>	
2	Have procedures in place to assure themselves that all relevant departments and providers adhere to relevant policy for vaccine cold chain storage. This includes reviewing refrigerator temperature readings in a manner that will identify if vaccines have been stored outside of manufacturers' recommended temperature ranges before they are administered to patients.	A copy of relevant procedures is available and signed off by relevant committee.	
3	Have procedures in place for remedial action where vaccines are stored outside manufacturers' recommended temperature ranges, and ensure departments and providers are aware of these. Actions may include initial reference to the UKMi fridge database ( <a href="http://www.ukmi.nhs.uk/applications/fridge">www.ukmi.nhs.uk/applications/fridge</a> ) with subsequent advice sought from NHS medicines information services or the vaccine manufacturer.	A copy of relevant procedures is available and signed off by relevant committee, and evidence of dissemination of those procedures to providers and contractors.	

**Appendix 6: Summary of rationale for recommended actions**

This table provides a summary of how the incident reports, local policy review, and literature explored above informed our recommended actions.

NHS organisations should:

Action	Summary of rationale
<p>Ensure that all departments and providers (including independent contractors) holding vaccine stocks are aware of relevant policy on safe storage, for example as given in Appendices 3 and 4 of the supporting information. Local policies should include having a designated person and deputy/ies responsible for receipt and storage of vaccines.</p>	<p>Guidance already exists for vaccine cold chain storage and so it is important that providers and contractors holding vaccine stocks are aware of that guidance. This may be adapted locally by PCOs but should cover salient points. Allowing for more than one deputy designated person should help in respects of departments and providers that rely on temporary staff and staff working shifts.</p>
<p>Have procedures in place to assure themselves that all relevant departments and providers adhere to relevant policy for vaccine cold chain storage. This includes reviewing refrigerator temperature readings in a manner that will identify if vaccines have been stored outside of manufacturers' recommended temperature ranges before they are administered to patients.</p>	<p>Organisations need to satisfy themselves that good practice guidance is being adhered to. Evidence stated in this document highlights the potential problems that can occur if vaccines are not stored at the correct temperature. Organisations must assure themselves that temperature readings are being monitored and recorded and that vaccines stored and administered by their providers or departments have been stored under safe conditions. This needs to be done in a way that ensures any potentially compromised vaccines are identified before affected vaccines are offered to patients. Note that the RRR does not give recommended time periods for review (daily, weekly, monthly etc) as this will differ according to the clinical setting. Intervals should be set locally according to need and use.</p>
<p>Have procedures in place for remedial action where vaccines are stored outside manufacturers' recommended temperature ranges, and ensure departments and providers are aware of these. Actions may include initial reference to the UKMi fridge database (<a href="http://www.ukmi.nhs.uk/applications/fridge">www.ukmi.nhs.uk/applications/fridge</a>) with subsequent advice sought from NHS medicines information services or the vaccine manufacturer.</p>	<p>If it is discovered that vaccines have been stored incorrectly then it is important that procedures are in place to identify, and if necessary, recall affected patients. If such vaccines have not been administered then it is also important that holders of those vaccines understand what procedures they need to undertake to establish the efficacy of those vaccines and any action that must be taken.</p>