

▶ **Page 53**  
Vaccines multiple  
choice questionnaire

▶ **Page 54**  
Read Lorna Young's  
practice profile on  
patient safety

▶ **Page 55**  
Guidelines on  
how to write a  
practice profile

# Safe storage and handling of vaccines

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## Abstract

Safe vaccine storage and handling is essential to ensure that the 'cold chain' that refrigerates the vaccine at a temperature between +2°C and +8°C is maintained from manufacture, through delivery and storage, to patient administration. This article considers the available literature on vaccine storage and handling. Although the UK provides significant guidance on the topic, global resources can increase understanding of areas that are not particularly clear for the practitioner undertaking cold chain management. It is hoped that readers will appreciate the importance of this subject not only within their own practice, but also on a global scale. The article aims to increase readers' confidence to review and enhance, or if necessary develop, a vaccine storage and handling protocol, thus ensuring the highest standard of care in this area.

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## Keywords

Cold chain, data loggers, protocols, vaccination, vaccine management, vaccine storage

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## Aims and intended learning outcomes

In the UK, vaccination programmes are undertaken predominantly in primary care although many vaccines are also administered in occupational health (private companies and NHS secondary care), private travel clinics, school and military settings. Vaccines and many medications such as insulin and chemotherapy require storage in the 'cold chain', which in this case involves maintaining a temperature range of between +2°C and +8°C. Therefore, the topic of cold chain storage is wide-reaching and important in vaccine management.

This article focuses on vaccine storage and handling in the healthcare setting, with minimal reference to ordering and disposal of vaccines. However, resources will also direct the reader to further information and perhaps evoke greater consideration for more unusual settings such as the home or travel abroad. After reading this article and completing the time out activities you should be able to:

- ▶ Define the cold chain and describe the importance of such knowledge.
- ▶ Identify the elements required to ensure safe vaccine storage and handling.
- ▶ Apply knowledge of safe vaccine storage and handling to practice and consider writing a protocol for your workplace.
- ▶ Evaluate the principles of vaccine storage and apply this knowledge, where appropriate, to more unusual settings.

## Introduction

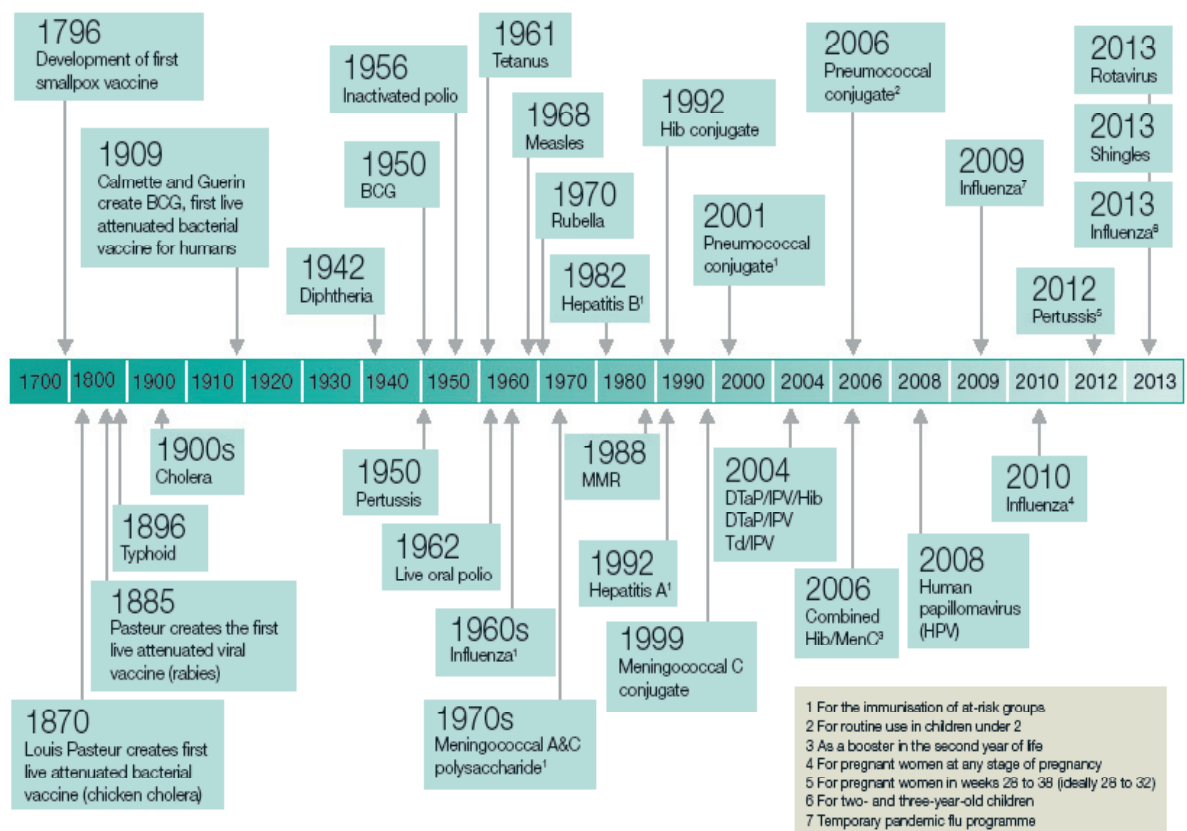
Vaccination is one of the most effective public health interventions worldwide, second

only to providing clean water, to help save people's lives and improve their health (Public Health England 2013a). Vaccination has been part of the UK's public health programme for many years as the latest historical timeline illustrates (Public Health England 2013b) (Figure 1). Figure 1 is a useful reference tool for all healthcare professionals involved in immunisation. However, when the first vaccine was developed, the smallpox vaccine in 1796, vaccine storage and management would not have been a topic for consideration. Figure 1 also illustrates the importance of vaccination for individuals of all ages in UK childhood and adult immunisation programmes, in addition to some travel vaccines. Complete time out activity 1

For a vaccination programme to be effective and provide maximum protection, it is essential for vaccines to be stored in optimum conditions. If vaccines become too hot or too cold, their effectiveness may be compromised. Vaccines naturally biodegrade over time and this process may be accelerated if they are stored outside the recommended temperature range. Vaccines must never be frozen because in addition to vaccine deterioration, this increases reactogenicity by irreversible denaturing of the proteins in the vaccine. This causes the emulsions in the vaccine to become unstable and produces hairline cracks in the ampoule, vial or prefilled syringe, potentially contaminating the contents. Any glass spicules produced may also cause serious local adverse reactions. These factors may result in the failure of the vaccine to stimulate the

FIGURE 1

Historical vaccine development and introduction of vaccines in the UK



BCG – Bacillus Calmette-Guerin; DTaP – diphtheria, tetanus and pertussis; Hib – *Haemophilus influenzae*;  
 IPV – inactivated polio vaccine; MenC – meningitis C; MMR – measles, mumps, rubella; Td – tetanus and diphtheria

(Public Health England 2013b)

intended immune response, therefore providing poor protection to the individual (Department of Health (DH) 2013), which in turn may also affect herd immunity and have wide-reaching public health implications.

**Complete time out activity 2**

## Global need for effective vaccine management

Worldwide, conditions are such that it is difficult for the cold chain to be maintained, for example if power is non-existent or power cuts occur regularly in a particular area. Vaccination programmes may need to be performed in remote areas, where road and transport problems may make them difficult to access.

**Complete time out activity 3**

*The History of Vaccines* (Hammond *et al* 2013) explain that the eradication of smallpox was, in part, a success because the smallpox vaccine remained viable for reasonable lengths of time even when stored at relatively high temperatures. However, some of the newer vaccines cannot withstand such temperatures. In 2010, a volcanic ash cloud in Iceland brought air traffic to a standstill. Some of the aeroplanes involved were transporting 15 million doses of polio vaccine, destined for West Africa. There was significant concern that the cargo hold temperatures of the grounded planes would increase and render the vaccines ineffective.

Incidents such as this are a stark reminder of the need for vaccines to be easily and safely transported in a range of conditions to ensure their effectiveness. In 2010, research at the Jenner Institute, University of Oxford in the UK, involved coating a small filter-like membrane with an ultra thin layer of sugar glass, with viral particles trapped inside it. This enabled viruses to be stored at temperatures of up to 45°C for six months without compromising their potential to provoke an immune response (Hammond *et al* 2013). Such research and development will help to improve the effectiveness of immunisation programmes globally.

## Vaccine management in resource-wealthy countries

Resource-wealthy countries have the facilities to ensure vaccines are always available in optimum conditions, but poor practice means this is not always the case. In June 2009, a UK primary care trust shared data with the

National Patient Safety Agency (NPSA) on its two-year retrospective audit of 96 practices, which revealed storage of vaccines outside the recommended temperature range, resulting in 560 patients from two practices having to be recalled for repeat vaccination (NPSA 2010).

Vaccine storage may be perceived as a tedious area. However, all staff involved in immunisation should be aware of training requirements and be compliant with the storage and handling of vaccines as detailed in published core curriculum guidance to ensure best practice (Health Protection Agency (HPA) 2005a, 2005b, 2012a).

## UK policy and resources

In the UK and abroad, guidance on vaccines and vaccination procedures is provided from a variety of sources. The main resource on this topic *Immunisation Against Infectious Disease*, also known as the *Green Book* (DH 2013), should now only be accessed online. Chapter 3 of this publication focuses on storage, distribution and disposal of vaccines, and was last updated in June 2013. It includes links to the processes undertaken for the ordering of centrally purchased vaccines in England, Scotland, Wales and Northern Ireland, as well as provision for immunoglobulins and antitoxins. It should be noted that processes in the four countries vary slightly. The chapter also addresses spillage and disposal of vaccines, indicating the need for locally written policies and procedures in this area (DH 2013).

## Policy for vaccine storage

Emphasis on optimum protection from correctly stored vaccines is paramount, but in addition, inappropriate storage and transport also results in wastage and unnecessary costs to the NHS. Many vaccines are expensive and whether they are supplied centrally or purchased directly from the manufacturer as is the case with travel vaccines, the financial burden of wastage should be avoided at all times.

A protocol for ordering, storing and handling vaccines should be available in the workplace that provides detailed information on the roles and responsibilities of all those involved. The aim of such a protocol is to ensure that vaccines are stored and managed appropriately, thus reducing the risk of compromising the quality, efficiency and safety of the vaccine, and improving the service for



**1** Access and print a copy of the vaccine development timeline (Public Health England 2013b). Consider laminating it and placing it on a noticeboard in the clinical area of your workplace, making it available for all to study.

**2** Look at slides for core topic 8: storage and handling of vaccines available at [tinyurl.com/mfruh7a](http://tinyurl.com/mfruh7a). From these slides, identify which vaccines are heat-sensitive, which are cold-sensitive and which are light-sensitive.

**3** Watch UNICEF ambassador Ewan McGregor illustrating how operationally difficult it is to maintain the cold chain and transport much-needed vaccines to protect vulnerable children at [tinyurl.com/ok86sg6](http://tinyurl.com/ok86sg6). Reflect on the difficulties encountered.

TABLE 1

## Topics for consideration when developing a protocol for ordering, storing and handling of vaccines

Topic	Action	Comment
Staff involved	All staff, but at least two named trained people – one from the nursing team and one from administration or management – need to be responsible for ordering, receipt and care of vaccines.	Delegated persons to be named in the protocol.
Vaccine ordering	No more than 2-4 weeks supply of vaccines should be stored at any time. Small quantities should be ordered on a regular basis. Ordering needs to be done in sufficient time to ensure adequate supply of the vaccine. Details of various ordering methods for England, Scotland, Wales and Northern Ireland are detailed in the <i>Green Book</i> .	Care should be taken regarding bank holiday periods, ensuring advance planning. Central stock should be used appropriately and legally.
Vaccine delivery	Vaccines should be checked: correct order supplied against the delivery note and that there is no damage or leakage before accepting and signing for them. Vaccines should be put into the validated vaccine fridge immediately to ensure the cold chain is maintained. New stock details should be entered on the stock inventory. It is the responsibility of the named individuals to ensure this process takes place.	The delivery check needs to be well managed as delivery personnel have little time to wait and damaged stock cannot be claimed after signing for receipt.
Equipment	<ul style="list-style-type: none"> <li>▶ A validated fridge must be used to store the vaccines between +2°C and +8°C. Aiming for +5°C is considered good practice. A domestic fridge is not suitable for storing vaccines.</li> <li>▶ A validated cool box or carrier, such as a portable vaccine fridge, must be used if vaccines are to be administered in a separate place to where the vaccine fridge is situated. Domestic cool boxes should not be used.</li> <li>▶ Two maximum/minimum thermometers should be available per fridge, one being independent of mains power.</li> </ul>	See further details regarding equipment in the main text of this article. The <i>Green Book</i> provides comprehensive information about the vaccine fridge. Consider investing in a portable vaccine fridge for greater reliability.
Stock rotation and storage	Stock should be properly rotated using stock with the shortest expiry date first. Vaccines should be left in their original packaging and storing boxes against the back or side walls of the fridge should be avoided. Prolonged exposure to ultraviolet light causes loss of potency.	Use of a marking system on vaccine packaging can be useful for 'use first' identifiers.
Stock monitoring and management	A system needs to be in place to keep track of records; keep track of expiry dates; and keep a running total of vaccines, including wastage. Such systems are most effective when kept up to date on ordering, delivery and after administration. Vaccine stock should be checked and records updated at least every month. The named persons are responsible for ensuring this task is undertaken.	The <i>Green Book</i> states that sophisticated stock information systems are available, but as a minimum, a paper-based record or a spreadsheet could be used.
Routine maintenance	Regular maintenance should be arranged to ensure the vaccine fridge is clean, annual contract for servicing and calibration of the temperature gauge. Vaccine management review should be performed quarterly and maintenance of the cold chain should form part of the immunisation training update.	A record of calibration certification should be kept.
Incident reporting	In the event of vaccine fridge failure, the protocol should have explicit documentation of all procedures to be followed.	See the <i>Green Book</i> for full details, and <i>ImmForm Helpsheet 18</i> .
Audit	<ul style="list-style-type: none"> <li>▶ Daily vaccine fridge temperatures should be recorded as a minimum and this task could be allocated to any staff member as long as he or she understands the process of the 'four Rs': read, record, reset and react, in addition to regular downloading of the USB or SD card recordings.</li> <li>▶ Content of the vaccine fridge should be checked weekly.</li> <li>▶ Review of vaccine stock should be undertaken monthly.</li> </ul>	Guidance states that audit of stock and temperature management should be shared with the clinical commissioning group every three months. See also <i>ImmForm Helpsheet 21</i> .

(Adapted from Department of Health 2010, 2012b, 2013, Public Health England 2013c, 2013d)

patients. Table 1 outlines some of the topics that might be covered in such a protocol.

#### Complete time out activity 4

### Effects of vaccine storage outside the recommended temperature range

The summary of product characteristics for a vaccine will provide details of the storage conditions required, between +2°C and +8°C. If vaccines have not been stored at the recommended temperature range, they are no longer covered by the terms of the marketing authorisation or product licence. It is essential that the cold chain is maintained from the point of manufacturing, through delivery and storage, to patient administration. If this cannot be guaranteed:

- ▶ The vaccine should not be used without a risk assessment based on a thorough understanding of the likely effect of the temperature of the vaccine.
- ▶ The vaccine cannot be administered within a patient group direction for that product.
- ▶ Use of the vaccine becomes the responsibility of the user and/or prescriber.
- ▶ Full details should be provided to the recipient of the vaccine since it would be administered outside the licence use.

Policies and procedures should be in place to deal with a breach in the cold chain and incorporated into the protocol for ordering, storing and handling of vaccines. *Vaccine Incident Guidance* (HPA 2012b) not only addresses all aspects of errors in vaccine storage, but also covers topics such as responding to errors in vaccine preparation and administration. This document should be read in its entirety and would make a useful addition to the protocol for vaccine storage.

#### Complete time out activity 5

### Equipment details

While advice is given to use specific equipment for vaccine storage, limited information is provided and there is no longer a document advising on recommended suppliers. Some policies recommend contacting the local health organisation for information (Health Protection Scotland (HPS) 2013), however, with significant changes in the NHS, the most appropriate person to provide advice in this area, for example an immunisation manager, may be difficult to identify. For the purpose of this article, the author has

reviewed the available information to detail the practicalities of such equipment.

### Vaccine fridge

Specialised vaccine fridges are indicated for the storage of pharmaceutical products – ordinary domestic fridges cannot be used. Food, drink and clinical specimens must not be kept in the vaccine fridge under any circumstances. These fridges have no storage compartments on the door and are available with glass front doors for easy viewing, and to minimise the length of time the fridge remains open. The fridge should be lockable because vaccines are prescription-only medicines. Vaccine fridges are more expensive than domestic fridges, but they are purpose-built and designed with the following features (Ontario Ministry of Health and Long-Term Care 2013):

- ▶ Internal temperatures are regulated by a temperature regulation mechanism, which ensures minimal tolerance for any deviation.
- ▶ Air is circulated continuously ensuring the temperature is distributed evenly throughout the fridge.
- ▶ The internal temperature is maintained between +2°C and +8°C.
- ▶ An evaporator operates at +2°C to prevent vaccines from freezing.
- ▶ The temperature recovery system works quickly.
- ▶ The forced air which is circulated helps to ensure the temperature inside the fridge is kept between +2°C and +8°C, even when the temperature outside the fridge fluctuates.

Consideration must be given to the size of the fridge. It should be large enough to store products required for immunisation programmes at any time of the year, while ensuring there is sufficient space for air to circulate around the products – ideally, the fridge should never be more than two thirds full. Having a plan in the fridge for storage of specific items is good practice to minimise the time the door needs to be kept open. A glass door or labelling systems on the door can also speed up the selection of vaccines required. The fridge should not be positioned near a heat source and there should be adequate ventilation space around the fridge. The power supply to the fridge should be secure so that accidental interruption of electricity does not occur, for example by installing a switchless socket (DH 2013). A vaccine fridge will have an integrated thermometer and newer models will also have standardised internal data loggers.



4 Before you look at Table 1, consider the topics that you would include in a protocol for ordering, storing and handling of vaccines. Now compare your findings with the information in Table 1.

5 Read *Vaccine Incident Guidance* (HPA 2012b). Identify information that is relevant to your area of practice and arrange a session to discuss this with your colleagues.

**Vaccine transporter**

To transport vaccines, UK guidance recommends the use of a validated cool box costing around £300 and validated cool packs to be obtained from a recognised medical supplier and used according to manufacturers' instructions (DH 2010, 2013). Monitoring temperature throughout use is essential – the transporter should contain only sufficient vaccines for the required session and any unused vaccines can be returned to the vaccine fridge as long as the cold chain has been maintained (DH 2013).

The Ontario Ministry of Health and Long-Term Care (2013) provides further information that might be useful before purchase of a vaccine transporter. The vaccine transporter is in an insulated solid-walled container with a tight lid. The required temperature inside the container is maintained by using ice packs or gel packs, but should only be used for short storage periods because most containers can only maintain the required temperature for up to three or four hours. Preparation of the container involves placing it in the vaccine fridge until its temperature is between +2°C and +8°C before use, which will take a few hours, or pre-chilling the container with icepacks for at least one hour before use. If this method is used, the ice packs or gel packs must be pre-conditioned.

When an ice pack is removed from a freezer, its temperature is approximately -20°C so it needs to be kept at room temperature for a period of time to allow its core temperature to rise to 0°C. This process is called conditioning and beads of water will cover the surface of the ice pack when adequately conditioned – a process that can take 20-30 minutes. Conditioning is essential, particularly for gel packs because they can remain colder than 0°C for even longer. Packing of the insulated container is critical because freezing episodes can occur, particularly in the first two hours of use. The ice pack needs to be placed at the bottom of the container followed by a pre-conditioned (between +2°C and +8°C) vaccine blanket then the vaccine boxes, placing the maximum/minimum thermometer sensor in the centre of these packages, then another layer of the vaccine blanket followed by the ice pack on top. Newspaper or bubble wrap can be placed to fill the vertical void and the lid should be placed on top. The maximum/minimum thermometer should be read frequently to ensure the cold chain is maintained at all times and records of this

should be kept. The container should not be transported in the boot of a car because of the extremes of temperature that can occur in this environment (Ontario Ministry of Health and Long-Term Care 2013).

**Portable vaccine fridge**

Several portable vaccine fridges are available and are a sensible option if working outside the regular workplace frequently. They come in a variety of sizes and are designed to work on a normal 12 Volt DC (fitted with a car cigarette lighter connection for mobile operation) or 100-240 Volt AC (fitted with a three-pin plug for mains power operation). The fridge then works like a normal vaccine fridge with a calibrated maximum/minimum thermometer to keep the temperature between +2°C and +8°C (Ellis Spencer, national accounts manager, Shoreline (UK), Littlehampton, 2013, personal communication). Although a portable vaccine fridge is an expensive option, it is possibly easier to operate and there may be more confidence in its temperature stability than in that of a validated cool box.

**Temperature monitoring devices**

UK guidance advises continual monitoring of the temperature inside a vaccine fridge using a maximum/minimum thermometer and suggests that digital thermometers are the most reliable (DH 2013). The thermometer should be independent of mains power so that temperatures can be measured in the event of electricity disruption (DH 2013). New vaccine fridges have integral probes connected to a digital display. A calibration certificate should be supplied by the manufacturer and retained as evidence of calibration. The thermometer should have an accuracy of at least +/-1°C (HPS 2013). If the fridge is older, a calibrated independent maximum/minimum digital thermometer should be used, but if only one device is in place, then a monthly check should be carried out to confirm that its calibration is accurate (DH 2010). The probe should be positioned in the middle of the fridge among the vaccines and recordings should be read from outside the door if possible (HPS 2013).

Data loggers are devices that are used to record the fridge temperature continuously and can provide a historical record of the temperature. The frequency of temperature recordings can be set as often as every minute if desired. Data loggers are typically battery-operated and last up to ten years, depending on the device. The information can

be downloaded to a computer via software supplied, preferably on a regular basis, for example weekly and ideally at the same time each week. Data loggers will display information about temperature recordings and log the length of time a storage unit has been operating outside the recommended temperature range (Centers for Disease Control and Prevention (CDC) 2012), unlike a maximum/minimum thermometer that will only provide the warmest and coolest temperatures reached.

There are different data loggers available, ranging from simple ones starting at about £70, to more technologically advanced systems that can be monitored remotely. As a minimum, the data logger chosen should be capable of displaying the current temperature as well as the maximum/minimum temperatures and should have an alarm that can be set to ring at a specified temperature (CDC 2012). The *Green Book* (DH 2013) now includes consideration of the use of a data logger. New vaccine fridges often come with an integrated system and memory card, which stores the same information as a standalone data logger.

### Importance of temperature records and summary of cold chain disruption

The DH (2013) advises that temperature within the vaccine fridge is recorded at least once each working day, with emphasis placed on the 'four Rs': read, record, reset and react (Box 1).

#### Complete time out activity 6

Records of temperature readings should be kept for at least one year and cover the full storage history of products kept in the vaccine fridge. Since the shelf life of a vaccine can be up to four years or longer, it is recommended that records are kept for five years (DH 2013, HPS 2013).

If a vaccine fridge is large, for example to store seasonal influenza vaccines, but has periods when it is not as full and it is harder to stabilise the internal temperature, then bottles of water can be placed in the fridge, ensuring they are labelled 'not for drinking', to keep the temperature more even, particularly if the fridge is opened frequently (CDC 2012).

Arrangements need to be in place for back-up facilities to be available in the event of the vaccine fridge failing or breaking down. A protocol explicitly outlining the action to be taken can be helpful when this type of event occurs (DH 2010, 2013). The DH (2012a) has

## BOX 1

### The four Rs of vaccine fridge temperature recordings

**Read:** Daily reading of the thermometer's maximum, minimum and current temperature at the same time every day, during the working week.

**Record:** Recording temperatures in a standard fashion and on a standard form, including signing each entry on the recording sheet.

**Reset:** Resetting the thermometer after each reading. Thermometers should also be reset when temperatures have stabilised after periods of high activity.

**React:** The person making the recording should take action if the temperature falls outside the +2°C to +8°C range and document this action.

required reporting of details of vaccine fridge failures, vaccine wastages and other stock incidents since January 2012. The *ImmForm Helpsheet 18* (DH 2012b) also outlines what to do in such an event, including isolating or quarantining the affected vaccines within the cold chain, which should then not be used or destroyed until advice has been obtained. The guidance advises that pharmacists at regional medicines information centres can provide NHS staff and contractors with access to the UK Medicines Information database, which collates published and unpublished information from manufacturers (DH 2012b).

#### Complete time out activity 7

### Cold chain issues in travel health

Travel vaccines can be purchased from individual vaccine manufacturers, although some surgeries will buy stock from a medical wholesaler or chemist, which may secure a reasonable wholesale price. The cost of the NHS vaccine is then claimed back in a variety of ways depending on where in the country the surgery operates. However, some surgeries simply issue a prescription (FP10 or GP10) and the patient goes to the chemist to obtain the drug before its administration. If a system is set up with a pharmacy on site or next door to the surgery or if it is known that the pharmacy can deliver the vaccine maintaining the cold chain, this would be satisfactory. However, many will leave the delivery of the drug up to the patient, with some keeping it at home possibly in their domestic fridge until the appointment time. DH (2013) advise that patients should not normally be asked to store vaccines or immunoglobulins, but if this need



6 Consider recreating Box 1 for the four Rs and place it in a suitable place near your vaccine fridge in your workplace to remind your colleagues of the process.

7 Access the *ImmForm Helpsheet 18* (DH 2012b) and ensure you and all relevant personnel in your clinical area are familiar with the guidance.



**8** Obtain a copy of the current vaccine storage and handling protocol in your workplace if you have one and review its content. Consider updating this document if required, or if you do not have one, consider developing such a document.

**9** Now that you have completed the article, you might like to write a practice profile. Guidelines to help you are on page 55.

should arise, advice on appropriate storage must be given to the patient or parents or carers. In a travel context, since such vaccines can be ordered, giving patients responsibility in this way would not seem sensible or advisable.

Those travelling overseas may attend appointments with insufficient time to complete a vaccine course before departure. It is not advisable to give these individuals a vaccine to take with them for administration when overseas. The cold chain, in this instance, cannot be guaranteed and would put the person responsible for prescribing that vaccine in a tenuous position. Instead, these individuals should be advised to seek completion of their vaccine course if necessary at a travel clinic abroad. Those who travel abroad with other medications such as insulin that are required for health conditions can obtain equipment to help keep products cool.

**Complete time out activity 8**

## Conclusion

Safe vaccine handling and storage is an important area of practice. It is essential to ensure that processes are in place to provide maximum protection to patients. UK guidelines have improved in recent years, but further and clearer guidance is needed to help practitioners develop good protocols and ensure their equipment and processes comply with best practice **NS**

**Complete time out activity 9**

## USEFUL RESOURCES

**www.janechiodini.co.uk**

A travel health website that offers healthcare professionals access to specifically designed tools to use in travel health care.

**www.istm.org**

A travel medicine website that contains a travel clinic directory for overseas destinations.

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