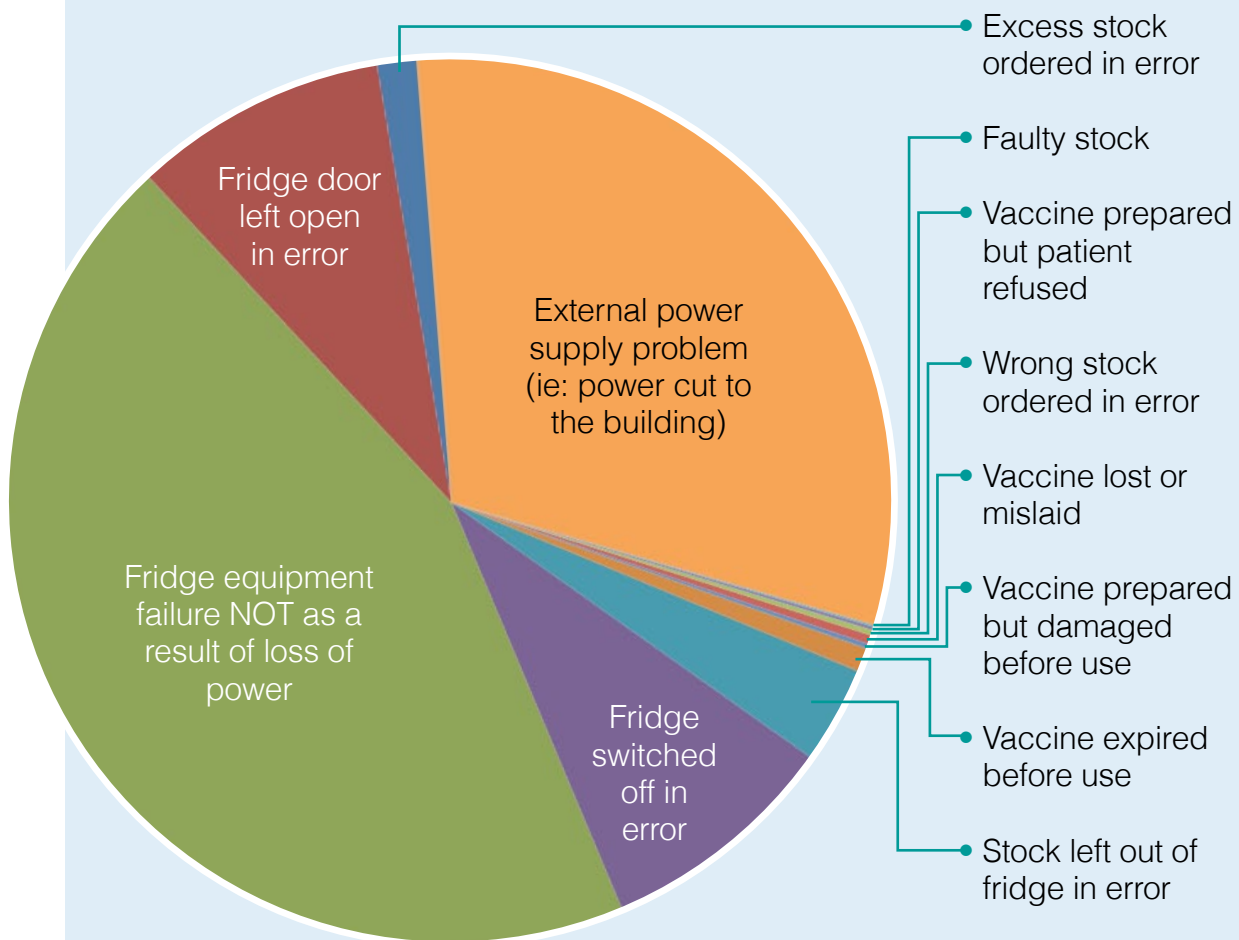




Cold chain – How are we doing?

During 2015, vaccines wasted through incidents in primary care reported through ImmForm had a value at list price of roughly £3.4 million. Although some of this wastage was due to non-avoidable incidents such as external power failures, most of the wastage occurred as a result of avoidable incidents.

Causes of vaccine wastage incidents
1st January 2015 – 31st December 2015



Common **avoidable** incidents can be summarised as being due to either:

The storage conditions and fridge:

- fridge door being left open
- fridge being switched off or broken
- equipment failure (not as a result of power failure)
- wrong temperature range
- lack of temperature monitoring
- lack of, or inadequate, equipment
- stock left out of fridge or prepared but damaged before use

The vaccine stock ordering process:

- wrong vaccine being ordered
- vaccine expiring before it could be used

If vaccines are not stored correctly, it is not only wasteful and expensive for the NHS but vaccines may lose their effectiveness, and this could result in a failure of the vaccine to provide the required immune response.

In addition, if a vaccine is not stored or transported within the required temperature range of 2°C to 8°C then it is no longer within the terms of its product licence.

Everyone who handles vaccines should ensure that there are local policies in place to make sure that vaccines are stored, handled, and disposed of correctly, and that these local policies reflect national policy and best practice recommendations which can be found in Chapter 3 of the Green book (see [weblink 1](#)). There is also a 'Protocol for ordering, storing and handling vaccines' available on the Public Health England website which sets out the minimum standards expected of healthcare professionals working with vaccines (see [weblink 2](#)).

To protect your patients, you need to protect your vaccines so remember to:

Read:

take a daily reading of the thermometer's maximum, minimum and current temperatures at the same time every day during the working week

Record:

record temperatures in a standard fashion, on a standard form and sign each entry on the recording sheet

Reset:

reset the thermometer after each reading. The thermometers should also be reset when temperatures have stabilized after periods of high activity e.g. restocking

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

Reassuring parents on administering multiple injections and vaccines to infants in one session

Some parents have expressed concerns about the number of injections administered in one session, particularly at 12 months of age when four injections are given in one visit. Studies have demonstrated that there are no harmful effects from administering multiple injections or vaccines in one session. Parents can also be reassured that offering multiple vaccines in this way is a routine occurrence around the world with no harmful effects being identified. Equally, there is no evidence to support arguments of “overloading” the immune system.

From the moment a child is born, they are exposed to a huge number of bacteria and viruses on a daily basis which the immune system is able to cope with and, as a result, become stronger. Immunisation helps to improve our protection against harmful diseases at the very earliest opportunity.

Parents should not be encouraged to have these vaccines separately because delaying immunisation inevitably delays protection. The immunisation schedule has been designed to ensure optimal protection against diseases that are most common in the very young such as whooping cough, pneumococcal, Hib and meningococcal disease.

These diseases can be life-threatening and it is important for children to receive protection at the earliest possible opportunity. It is important to make parents aware that a delay in protection caused by separate immunisations could increase the risk of disease.

Pertussis vaccination in pregnancy – change to guidance from 1 April 2016

From 1 April 2016, PHE guidance on the timing of pertussis immunisation for pregnant women is being updated to reflect JCVI advice that immunisation can take place from week 16 of pregnancy. A recent study (see [weblink 3](#)) showed that maternal immunisation against pertussis in the second trimester significantly increased neonatal antibodies. Offering maternal immunisation earlier than the current 28 week recommendation should not only improve infant protection, it will also provide more opportunity for pregnant women to be offered the pertussis vaccine during pregnancy.

In practice, the most appropriate time to offer pertussis immunisation will be after the foetal anomaly scan, (also known as the 20-week scan) which usually takes place between 18 and 20 weeks gestation. Pertussis immunisation can be offered at any time after the scan.

This extension of the timing should be introduced throughout 2016/17 and fully implemented by April 2017.

The maternal pertussis immunisation programme has been highly effective at preventing cases and deaths from pertussis in infants. However, levels of pertussis remain at heightened levels in the population. It is therefore critically important that women are offered the pertussis-containing vaccine in each and every subsequent pregnancy.

Rubella susceptibility screening in pregnant women is stopping from 1 April 2016

To provide direct protection against rubella infection in pregnancy, single antigen rubella vaccines for teenage girls and women of child bearing age were first introduced in the UK in 1970. Complementing immunisation, antenatal rubella susceptibility screening and postnatal immunisation of susceptible women was also introduced. However, neither of these strategies was designed to provide population level immunity to rubella, instead they were intended to increase the proportion of women immune to rubella through vaccination.

In 1988 the combined measles, mumps and rubella (MMR) vaccine was introduced into the routine childhood immunisation programme in the UK for boys and girls. This programme not only provides direct protection to vaccinated individuals, but also interrupts transmission of rubella virus circulating in young children, thus providing additional indirect protection to rubella susceptible pregnant women.

In 2011, a review by the UK National Screening Committee (UK NSC) found that the UK incidence of congenital rubella syndrome is below the WHO criteria of elimination (less than 1 case of congenital rubella per 100,000 live births) and that rubella susceptibility is most effectively addressed prior to pregnancy through the MMR immunisation programme. The UK NSC therefore recommended the screening programme should cease (further information is available at [weblink 4](#)).

Therefore rubella susceptibility screening in pregnancy in England will cease from 1 April 2016.

GPs should continue to offer MMR to women of child bearing age (excluding those who are pregnant) who are unvaccinated or partially vaccinated for rubella and other adults and children who have no history of MMR vaccination, or incomplete immunisation status. The MMR section 7A service specification already sets out the service that providers are required to give (see [weblink 5](#)).

All opportunities should be taken for checking the status and administration of MMR vaccination to ensure 2 doses of MMR have been received for:

- all children and young adults who have not received 2 doses of MMR; for example at school entry, transition to secondary school, teenage immunisation sessions and school leaver checks
- new entrants to the UK at GP registration consultation
- postnatal women through health visiting assessments and six week GP maternal checks
- women accessing pre-conceptual; fertility or miscarriage and termination services.

Leaflets and resources

The routine immunisation schedule from Spring 2016			
Age due	Diseases protected against	Vaccine given and trade name	Usual site
Right after birth	Diphtheria, tetanus, pertussis (whooping cough), polio, Hib, pneumococcal conjugate vaccine	DTaP/IPV	Upper arm
8-12 weeks	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
13-15 weeks	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
16-18 weeks	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
19-21 weeks	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
22-24 weeks	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
25-27 weeks	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
28-30 weeks	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
31-33 weeks	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
34-36 weeks	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
37-39 weeks	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
40-42 weeks	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
1-2 years	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
3-5 years	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
11-13 years	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
16-18 years	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
65 years and over	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
75 years and over	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
80 years and over	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm
90 years and over	Polio, Hib, pneumococcal conjugate vaccine	IPV, Hib, Hib/TD	Upper arm

The complete routine schedule has been updated to reflect the change in recommendations for pregnant women to be able to have the Pertussis (whooping cough) vaccine from 20 weeks – usually after the foetal anomaly scan.

You can download this complete schedule via [weblink 6](#).

Please can you make sure that you have a good supply of the leaflets and or posters and that they are displayed so that patients and colleagues can see them and read them. They are produced to help patients to understand which immunisations are important for them and evidence shows that they fulfil a fundamental role in uptake of vaccines.

Please go to The Health and Social Care Orderline (via [weblink 7](#)) and register, which is a quick process and then you can order all the resources that you need or alternatively, you can call the following number: 0300 123 1003.

Vaccine Supply

All LAIV (FluMist® Quadrivalent) supplied for the Childhood Flu Programme has now expired

All FluMist Quadrivalent supplied for the 2015/16 season (batches FL2113 & FL2118) expired on 24 February 2016.

Due to required changes in the planned supply schedule of LAIV to the UK, there was a mismatch between the actual expiry date and that printed on the packaging and labelling of the two batches of FluMist® Quadrivalent that were supplied in the UK (FL2113 & FL2118) in the 2015/16 flu season. These have now expired (on 24 February) and must not be administered.

Withdrawal of unused FluMist® Quadrivalent.

In agreement with the MHRA, a pre-planned withdrawal of any unused stock of FluMist® Quadrivalent commenced on the 25 January to help ensure that expired vaccine is removed from circulation. AstraZeneca's logistics provider Movianto has contacted all providers individually to arrange for any leftover vaccine to be collected, however not all have responded. If you still have FluMist® Quadrivalent that needs to be returned, please contact Movianto as soon as possible. Alternatively if you have disposed of FluMist® Quadrivalent locally, or have no remaining vaccine to return, please could you notify Movianto so that they can update their records and complete the product withdrawal.

All Fluenz Tetra® supplied for 2015/16 has also expired. If you are still holding any Fluenz Tetra® then please ensure that it is disposed of in line with local policies. Please record any stock that is disposed of due to expiry through the ImmForm website.

Providing a second dose of flu vaccine after the FluMist® Quadrivalent expiry date/withdrawal

In cases where you still need to give a second dose of flu vaccine (for example, for children in clinical risk groups aged two to under nine years who have not received influenza vaccine before), then it is safe and effective to give inactivated vaccine as a second dose where LAIV was given initially.

Primary infant vaccine

Ordering for Pediacel is currently restricted to 3 doses per order, per week in England. Restrictions are also in place for Wales and Scotland. Infanrix IPV Hib is available to order, with no restriction on volume. Where possible and if local stock allows, it is preferable that the same DTaP/ IPV-Hib containing vaccine be used for all three doses of the primary course. However, vaccination should never be delayed because the vaccine used for previous doses is not known or unavailable. If using Infanrix IPV+Hib please remember to reconstitute and administer the separate freeze-dried Hib component.

BCG vaccine availability and use of batch 114022A beyond expiry (29/02/2016)

Due to supply delays from the manufacturer, the Serums Staten Instiut (SSI), BCG vaccine orders through ImmForm are restricted to 1 pack of BCG vaccine, per account, per fortnight. More detailed information about prioritisation and administration of the vaccine can be found in the Vaccine Update special edition published in September (see [weblink 8](#)).

Please note that the BCG vaccine manufactured by the SSI currently being distributed (batch 114022A) has an expiry of 29 February 2016. As further BCG vaccine supply from SSI is delayed the MHRA has agreed that it is acceptable to use batch 114022A for up to six months past its current expiry date, based on the known stability of the SSI BCG vaccine and on review of additional information provided by the manufacturer.

SSI BCG vaccine from batch 114022A ordered via ImmForm should therefore be retained and can be used past the labelled expiry date, outside of the marketing authorisation, until 31 August 2016. Batch 114022A of SSI BCG vaccine will not be re-labelled and a letter explaining the extension is being sent out with deliveries and should be kept with the BCG vaccine. The letter is available at [weblink 9](#).

Organisations may continue to supply and administer BCG vaccine by existing mechanisms, including via Patient Group Direction, as they deem appropriate. The administration of SSI BCG vaccine batch 114022A between 29 February 2016 and 31 August 2016 will be outside of the marketing authorisation (off-label) but there is no licensed alternative in the UK. MHRA have advised that a medicine which is for use outside its licenced indications can be included in a PGD. This use should be formally noted by the organisation but there is no requirement to amend existing PGDs for administration of the product.

As there is a global shortage of BCG, this batch may represent the only suitable UK supply for some months, and therefore BCG vaccine from Batch 114022A must not be discarded after February 2016.

PPD10TU

Due to manufacturing delays, PPD10TU (Mantoux) ordering through the ImmForm web portal is currently closed. If you require PPD10TU, please contact the ImmForm helpdesk. PPD2TU remains available.

Bank Holiday deliveries

Due to the Easter Bank Holiday, there will be no deliveries or order processing by Movianto UK on Friday 25 March and Monday 28 March 2016.

For customers with delivery dates of Friday or Monday, please be aware that after the 18 and 21 of March, your next available delivery day will be the 1 and 4 of April respectively.

For customers requiring a scheduled delivery on the 29 and 30 March, orders will need to be placed before the Easter Bank Holiday by 11:55AM on 23 and 24 March respectively.

You are reminded to be prepared for the break in deliveries and to order accordingly. Please make sure you have sufficient room in your fridge for any additional vaccine you wish to stock over this holiday period, bearing in mind the recommendation that only two to four weeks of vaccine stock be held at any one time.

Please see the table below for revised order and delivery dates.

Easter Bank Holiday orders and deliveries – revised table

Easter Bank holiday – 2016		
Delivery date	Order cut-off date	Order cut-off time
Friday 18 March	Wednesday 16 March	11:55 AM
Monday 21 March	Thursday 17 March	11:55 AM
Tuesday 22 March	Friday 18 March	11:55 AM
Wednesday 23 March	Monday 21 March	11:55 AM
Friday 25 March	CLOSED – NO DELIVERIES	
Monday 28 March	CLOSED – NO DELIVERIES	
Tuesday 29 March	Wednesday 23 March	11:55 AM
Wednesday 30 March	Thursday 24 March	11:55 AM
Thursday 31 March	Tuesday 29 March	11:55 AM
Friday 1 April	Wednesday 30 March	11:55 AM
Monday 4 April	Thursday 31 March	11:55 AM

Please be advised that Emergency or “Out of Schedule” deliveries cannot be arranged for failure to place orders in good time.

Web links

- web link 1 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/223753/Green_Book_Chapter_3_v3_0W.pdf
- web link 2 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300304/Protocol_for_ordering__storing_and_handling_vaccines_March_2014.pdf
- web link 3 <http://www.ncbi.nlm.nih.gov/pubmed/26797213>
- web link 4 <https://www.gov.uk/government/news/rubella-susceptibility-screening-in-pregnancy-to-end-in-england>
- web link 5 <https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/02/serv-spec-10.pdf>
- web link 6 <https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule>
- web link 7 https://www.orderline.dh.gov.uk/ecom_dh/public/contact.jsf
- web link 8 <https://www.gov.uk/government/publications/vaccine-update-issue-233-september-2015>
- web link 9 <https://www.gov.uk/government/collections/immunisation>