

VACCINE UPDATE

Protecting and improving the nation's health

Issue 254, October 2016

MenB success!



In September, 2015, the UK became the first country to introduce the multicomponent, protein-based meningococcal vaccine into a national, publicly funded infant immunisation programme.

The vaccine was offered to all infants born since July 1 2015, at 2 months, 4 months, and 12 months alongside their routine immunisations.

The current 2 dose infant schedule was found to be 83% effective against all cases

of MenB in vaccine eligible infants. In the first ten months of the programme, there has already been a 50% reduction in MenB cases in those who were eligible for the vaccination.

We would like to take this opportunity to congratulate all of the teams across the country that have contributed to the profound success of the programme so far. This level of collaborative partnership shows that world class public health initiatives can be fleet footed, flexible and tireless in their ambition and objectives. Giving the public the information that they need, complemented by access to healthcare advice and vaccine at the optimum time assures programme success. High levels of vaccine coverage have had such a major impact so quickly.

Last Friday a paper on this world class immunisation programme has been published in the Lancet. See weblink 1.

New Meningitis B and ACWY vaccine coverage estimates published

The latest MenB vaccine coverage report shows that the first two monthly cohorts to be routinely offered the vaccine achieved high coverage; 94.3% for one dose and 91.5% for two doses, when evaluated aged 12 months at the end of August 2016. Infants aged 6 months in August also achieved high coverage with 95.8% receiving at least one dose and 87.8% receiving both. The full coverage report can be found at weblink 2 and further immunisation information can be found in the "Immunisation against infectious disease" book (the green book – see weblink 3), chapter 22.

National MenACWY vaccine coverage has also been published for 18 to 19 year olds offered vaccine through a GP based catch-up programme (born between 01/09/1997 and 31/08/1998). 17.4% of this cohort have been vaccinated to the end of August 2016. Unvaccinated individuals in this cohort and the first priority catch-up cohort (born between 01/09/1996 and 31/08/1997, now aged 19 to 20 years) continue to be eligible for vaccination until they reach age 25.

Recent advice from PHE, the Meningitis Research Foundation (MRF) and Meningitis Now urge young people in the eligible cohorts, whether starting university or not, to get vaccinated against meningitis and septicaemia, signposting them to their GP, either at home or in their university town if they had not had the vaccine before the beginning of term. With further communications about receiving the vaccine at university fresher's fairs during September and October, we expect coverage to continue to increase.

The latest coverage report can be found at weblink 2 and further immunisation information can be found in the "Immunisation against infectious disease" book (the green book – see weblink 3), chapter 22.

Flu vaccine for pregnant women under the age of 18 years old

Pregnant women less than 18 years old should be offered the inactivated flu vaccine. Although there is no evidence of risk in pregnancy from live attenuated influenza vaccine (LAIV), inactivated influenza vaccines are preferred for those who are pregnant. Testing LAIV-eligible girls for pregnancy or advising avoidance of pregnancy in those who have been recently vaccinated with LAIV is not necessary.

The Community Pharmacy influenza immunisation service can only vaccinate those aged 18 years and above using inactivated influenza vaccine.

Interpretation of vaccine storage requirements

Many manufacturers' Summary of Product Characteristics (SPCs) and Patient Group Directions (PGDs) state that vaccines should be stored in a refrigerator between 2°C and 8°C. PHE have received a number of enquiries about the interpretation of such statements, particularly in relation to removing vaccines from refrigerators and placing them in cool boxes for off-site immunisations. The principle that should be followed is that vaccines should be stored between 2°C and 8°C. The device used to achieve these conditions may be a refrigerator, or a validated cool box capable of maintaining these temperatures.

Vaccines removed from a refrigerator and placed in cool boxes, but which are not administered to patients, should be returned to the refrigerator and used for subsequent immunisations, providing storage temperatures of 2°C and 8°C have been maintained.

Where an SPC allows for a vaccine to be removed from the refrigerator for a certain time period before it should be discarded, this should be interpreted as removal from the cold chain rather than removal from the refrigerator into an alternative container where the storage temperature remains between 2°C and 8°C.

Further information can be found in chapter 3 of the Green Book, with particular reference to section titled "Importance of the cold chain"; see weblink 13.

LAIV storage and cold chain

Last October, PHE published an information sheet titled "Responding to cold chain failures involving the live attenuated intra-nasal influenza vaccine (LAIV)". This was written to assist providers in taking prompt and appropriate action in the handling of live attenuated influenza vaccine (LAIV) (Fluenz Tetra®) that has been stored outside the recommended temperature range.

Following communication with the vaccine manufacturer, the information sheet on the thermo-stability of LAIV is no longer valid. Instead, immunisers should follow the text provided in the Summary of Product Characteristics which can be found at weblink 4.

Further information can be found in chapter 3 of the Green Book, with particular reference to section titled 'Importance of the cold chain'; see weblink 5.

MenACWY vaccination impact in England

MenACWY vaccination was introduced from last August with school leavers in 2015 (born between 1/9/96 and 31/8/97) the first cohort to be offered vaccination. Overall cases of MenW increased in 2015/16 when compared to the previous epidemiological year, rising by 19% from 176 to 210 cases, but cases are no longer doubling as in previous years.

In 2015/16, numbers of cases in all age groups were similar or higher than previous years, apart from 15-19 year-olds, many of whom will have become eligible for the MenACWY vaccination programme over the course of that year (see figure 1 below). So far we have not had a single case of MenW, A, C or Y in a vaccinated teenager.

Priority remains to get high vaccine coverage in all vaccine-eligible cohorts. This will not only provide direct protection for vaccinated teenagers themselves but is expected to provide indirect protection to the wider population in the coming years.

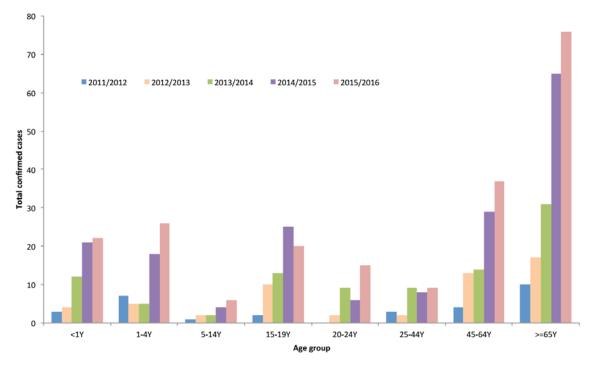


Figure 1: Age distribution of confirmed MenW cases in England, 2011/12 to 2015/16

Decrease in coverage for routine childhood vaccines

England has some of the highest vaccination rates in the world and in 2015-2016, coverage at 5 years was 94.8% for MMR1 and 95.6% for DTaP/IPV/Hib, close to or exceeding the World Health Organization 95% target.

However, vaccine coverage has fallen slightly in more recent cohorts. DTaP/IPV/ Hib Coverage at 12 months in 2015-16 was 93.6%, a 1.1% decrease since 2012-13. MMR coverage at 24 months was 91.9%, a 0.8% decrease since 2013-2014. This decreasing trend continued in the first 2016-17 quarter with 93% coverage for DTaP/ IPV/Hib Coverage at 12 months and 91.5% for MMR1 at 24 months and MMR2 at 5 years decreasing to 87.5%.

There are many factors which may have affected vaccination rates. We are working to understand the underlying factors and then, working with the NHS, on increasing uptake. This may focus on areas where uptake is low and could include improving training for local healthcare professionals, some data cleaning and addressing any access issues. The 2015-16 annual immunisation statistics report can be found at weblink 6 and the Q1 2016-2017 COVER report can be found at weblink 7.

Vaccinating and testing babies born to Hepatitis B infected mothers – reminder

Following recent queries about testing infants born to hepatitis B infected mothers, a reminder of the recommendations around vaccination and testing of infants born to hepatitis B infected mothers is provided below.

Infants born to hepatitis B infected mothers are at increased risk of infection through perinatal transmission and are routinely offered four doses of hepatitis B vaccine, which are administered at birth and at one, two and twelve months. Doses that coincide with other vaccines in the routine childhood vaccine schedule can be given concurrently. Testing infants for hepatitis B surface antigen (HBsAg) at the age of 12 months, (whilst administering the fourth dose of the hepatitis B vaccine at the same visit) will identify any infants for whom hepatitis B vaccination has not been successful and who have become chronically infected. Testing at risk infants at this age will allow early referral for specialist management of those who have developed persistent hepatitis B infection.

Testing can be done either using a venous sample, or using dried blood spot (DBS) in areas where it is available. PHE provides a national DBS testing service for these at-risk infants, with DBS kits and testing provided free of charge by PHE Colindale.

The DBS test uses a single-use safety lancet to prick the heel of the infant allowing healthcare professionals in GP surgeries, community hospitals and clinics to obtain several drops of blood, which is then applied to a filter paper with speed and little discomfort. Simple standard infection control precautions prevent any risk of cross-infection and allowing the blood to air dry onto the filter paper renders it safe for posting to the laboratory at Public Health England Colindale.

Further information on the service and a video demonstrating how to use the DBS test is available at weblink 8. lease contact your Screening and Immunisation Team or Health Protection Team. Screening and Immunisation leads and managers in local area teams who feel this free of charge service could help to increase the uptake of testing of at risk infants at 12 months of age are encouraged to express their interest in the service by emailing hepatitisbbabies@phe.gov.uk

A timely reminder for GP based programmes for meningococcal vaccines...

... due to range of enquiries regarding eligibility. Explanation of the GP based programmes for meningococcal vaccines – which contract and which vaccine should be used for catching up children who missed vaccination at their allotted time.

The MenACWY programme

The current ACWY programme is being undertaken as a replacement for the MenC booster programme targeted at teenagers in school (normally given in year 9 or 10 at school), with a catch-up programme for young adults.

The GP based components of the programme are outlined below:

- In financial year, 2015/16 there was a MenACWY programme targeted at 17/18 year olds (born between 01/09/1996 and 31/08/1997) who were leaving school in summer 2015 and for freshers starting university in Autumn 2015. These groups were eligible for MenACWY vaccine regardless of their prior MenC status, and practices were reimbursed by an Enhanced Service payment.
- For financial year 2016/17, the MenACWY programme is again targeted at 17/18 years olds (born between 01/09/1997-31/08/1998) who are leaving school in summer 2016 and for freshers (born between 1/4/1991-31/08/1997) who start university/further education in Autumn 2016.
- The new specification also allows for catch-up with MenACWY vaccine for those who were school leaving age in summer 2015 (as above) but did not receive vaccination during 2015/16. These individuals will remain eligible up until the age of 25 years. Again this vaccine should be given regardless of prior MenC status, but vaccination is not required for those who have already received a dose of MenACWY conjugate vaccine after the age of 10 years.
- The General Medical Service (GMS) Statement of Financial Entitlement (SFE) also makes provision for GP practices to offer vaccine opportunistically to children who miss out on the routine school based MenACWY vaccination programme usually given in year 9/10. Any patient born on or after the 1 April 2001, who has missed the school based dose, will remain eligible for this vaccine up to the age of 25 years.

The MenC programme

MenC vaccine was introduced in 1999 as a three dose infant programme, with catch-up to 25 years of age. The routine schedule changed in 2006 and in 2013.

From July 2016 no single MenC vaccine will be part of the routine UK schedule. Hib-MenC will continue to be routinely offered at one year of age, and MenACWY offered in school year 9/10.

The GMS Statement of Financial Entitlement (SFE) makes provision for GP practices to opportunistically catch-up anyone aged six years or over who presents up to the age of 25 years who is unimmunised or partially immunised against MenC. The purpose of this payment is to ensure protection against MenC and so vaccination with any of the MenC containing vaccines (MenC, Hib-MenC or ACWY vaccine) would offer this protection.

From 1 July this year, single MenC is no longer be supplied for the UK programme and so catch-up would normally be conducted with a combination vaccine as follows:

- For those aged between six and nine years, children should have received at least one dose of MenC (normally given as combined Hib-MenC) above the age of one year. Those who have missed this dose may also require catch-up for Hib, and so it makes sense to offer a Hib-MenC (Menitorix) vaccine to any children who are incompletely immunised against MenC. These children will become eligible for ACWY vaccine at school.
- For those aged 10 years or over, these individuals may also be eligible, or will shortly become eligible, for MenACWY. Therefore it makes sense to offer anyone aged over 10 years who has NEVER received a MenCcontaining vaccine a single dose of ACWY vaccine. In patients who are also eligible under the MenACWY programme (above), practices should only claim once for the vaccine administration.

Children under six years should have received at least one dose of MenC (normally given as combined Hib-MenC) above the age of one year. The vaccination of these children with Hib-MenC (Menitorix) is covered by the additional services funded under the global sum within the SFE.

Resources

What do you get for free? Spread the word!

Our immunisation stand travels round the country promoting the visual resources and publications that we produce to health care practioners, screeening and immunisation teams, midwives, practice nurses, GPs and we are keen to remind you all that the DH order line is where you go to order copies of the leaflets and posters free of charge.

You will notice from the pages on .Gov.UK that all of our resources are available to download (see weblink 9) but we do not expect you to download and print posters and leaflets for promotion where we provide hard copies free of charge. The download facility should only be used if necessary if you have run out of hard copies, need single copy or wish to familiarise yourself with the publication. There are a limited amount of patient facing leaflets which are download only but they are rare and infrequent use leaflets.

Downloading and printing multiple copies locally in full colour is difficult and expensive which is why we provide the service. Please check regularly for updates or new resources and keep a stock of the publications you and your patients need.

Thinking about getting pregnant

This leaflet is aimed at women considering pregnancy and advises them on the need to have their measles, mumps and rubella (MMR) jab one month before attempting to get pregnant. It has been revised due the cessation of rubella screening. Copies of this leaflet are available to download or order free of charge from the DH orderline, using product code 14423. See weblink 10.

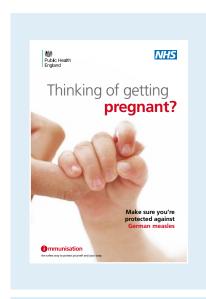
Whooping cough leaflet and poster

The leaflet provides in-depth information on:

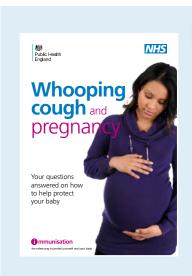
- why the vaccine is needed
- how maternal pertussis vaccination helps to protect babies from whooping cough
- when expectant mothers can have the vaccine
- vaccine safety and efficacy.

The poster has been designed to promote the need for maternal pertussis vaccination which is now recommended from week 20 of each pregnancy. It is suitable for GP surgeries, hospitals, maternity units, nurseries, child care centres and libraries.

The leaflet (product code: 3235344) and poster (product code is 54263393) are available to order free of charge from the DH health and social care order line. See weblink 11.



Thinking about getting pregnant leaflet



Whooping cough and pregnancy leaflet



Whooping cough and pregnancy poster

Vaccine supply

All vaccines for the childhood flu immunisation programme are now available to order on ImmForm

The following vaccines are available for the 2016/17 influenza season, and are supplied for the following cohorts:

Vaccine	Pack size	Туре	Age indication	Cohort
Fluenz Tetra (LAIV), AstraZeneca UK Ltd	10 dose	Quadrivalent live attenuated	From 24 months to less than 18 years of age	 All 2, 3 and 4 year olds All children of school years 1, 2 and 3 age All primary school-aged children from previous pilot areas¹ All children from 2 years to less than 18 years old in clinical risk groups
Fluarix Tetra, GSK	Single dose	Quadrivalent inactivated	From 3 years of age	Children in the above cohorts aged from 3 years who are contraindicated for Fluenz Tetra and in a clinical risk group
Inactivated influenza vaccine (split virion) BP, SPMSD	Single dose	Trivalent inactivated	From 6 months of age	 Children aged 6 months to less than 2 years in a clinical risk group Children aged less than 3 years who are contraindicated for Fluenz Tetra and in a clinical risk group

 $^{^{\}mbox{\tiny 1}}$ Bury, Gateshead, Leicester City and Rutland, Havering and South East Essex

Controls on LAIV (Fluenz Tetra®) ordering

For the 2016/17 season, ordering controls are in place for General Practice providers. These controls work by allocating an amount of vaccine to each practice, based on individual requirements. These allocations are being regularly reviewed and updated as the season progresses.

Current allocations are set at a level which allows practices to order enough vaccine to achieve last year's uptake (%), without needing to submit a request for more.

If your current allocation of vaccine is insufficient to allow you to complete planned activity in the next 2 weeks, you should contact the ImmForm helpdesk directly to discuss your requirements.

Requests for additional vaccine are being considered on a case by case basis but please note that it is important that vaccine already allocated to each practice is being used, before determining your requirement for more and remember to order in good time. Practices will need to make a strong case for ordering proportionately large volumes on top of that which is already allocated to them.

These measures have been taken to ensure that vaccine is available for those that need it and to help the NHS save a significant amount of money.

At present there are no plans to implement similar controls on school based providers as last years' data suggests that vaccine ordered was well matched to the vaccine uptake data. However there will be a high level cap on orders for schools, set at 300 packs (or 3,000 doses) per order per week to prevent accidental over-ordering. We recognise that there will be some instances in which school teams require more than this. Where this is the case, you can contact the ImmForm helpdesk directly to discuss your requirements. This cap will also be kept under review throughout the season and changes communicated through the ImmForm news item.

Please note that these controls are for ENGLAND ONLY. For information on supply of influenza vaccines in Scotland, Wales and Northern Ireland, please refer to guidance from your respective health departments.

Controls on inactivated flu vaccine ordering

Inactivated influenza vaccine (split virion) BP has a cap of 5 doses per order per week. Fluarix Tetra® has a cap of 30 doses per order per week. These controls are also being regularly reviewed and updates provided through the ImmForm website.

Fluenz Tetra shelf life

Fluenz Tetra is a live attenuated vaccine and as such has a **very short shelf life**. Please bear this in mind when ordering. You will be able to place an order **every week** and deliveries will be made weekly alongside your usual deliveries of vaccines. Where possible do not order more than you will need for the next two weeks. This is to minimise vaccine wastage due to the vaccine passing its expiry date before it can be administered to patients. The vaccine will be available to order throughout the entire flu season to ensure there is in date stock available into the New Year. Subsequent deliveries of vaccine will have later expiry dates.

REMEMBER the General Principles for LAIV ordering

- LAIV is supplied in a 10-dose pack: 1 pack = 10 doses
- Order small amounts weekly and receive weekly deliveries
- Be realistic about the amount of vaccine that you expect to need
- Spread your orders over the course of the flu vaccination season later ordered stock will have a later expiry date and will last longer
- Hold no more than 2 weeks stock in your fridge; local stockpiling can cause delays or restrictions on stock being released to the NHS, and increases the risk of significant loss of stock if there is a cold chain failure in your practice

Pre-School Booster vaccine

The pre-school booster vaccine given to infants from three years four months has switched from Infanrix IPV to Repevax.

Ordering for Repevax is open on ImmForm, and ordering for Infanrix IPV is closed.

Whilst stocks of Infanrix IPV remain available locally, these should be used first and both Repevax and Infanrix-IPV are suitable for the pre-school booster vaccination regardless of the vaccine used for primary vaccination.

Repevax is not for use in the maternal pertussis programme, for which Boostrix IPV continues to be available.

As a reminder, Repevax is supplied as a prefilled syringe without needles and manufactured by Sanofi Pasteur MSD. Please note, the current Repevax pack will be changing to a smaller version around November. Please see images below.



Current pack



New smaller pack

MenACWY vaccine ordering controls

There are two types of MenACWY vaccine (Menveo and Nimenrix).

One is currently restricted, but the other isn't; **BOTH** are suitable for vaccinating teenagers and freshers against meningitis and both are available to order through ImmForm.

In England and Wales, Menveo is available without restriction to all ImmForm accounts, and is available in a 5 dose pack.

In order to balance central stocks, ordering for Nimenrix is currently restricted to 5 doses per order per week (Nimenrix is presented in a single dose pack).

Menveo can be used instead of Nimenrix to vaccinate teenagers and freshers against meningitis.

Use of SSI BCG vaccine batch 114022A

SSI BCG vaccine batch 114022A with a labelled expiry of 29 February 2016, which was extended to 31 August 2016, should no longer be used and any remaining stock of SSI BCG vaccine from 114022A should be disposed of in line with local policies and recorded on ImmForm.

Primary infant vaccine

Ordering for Pediacel remains 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.

PPD10TU

Due to manufacturing delays PPD10TU is not currently available to order. As per the Green Book guidance (see weblink 12) PPD 10TU is recommended if a second Mantoux test is required for clinical diagnostic purposes, and alternative testing may be available.

PPD2TU

Due to manufacturing delays, orders for PPD2TU (Mantoux) are currently restricted to 1 pack per account per fortnight for NHS customers and closed for private customers. Please note that each pack of PPD2TU contains ten multi-dose vials and efforts should be made to ensure efficient use of existing stocks to avoid wastage.

Web links

web link 1	http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31921-3/fulltext
web link 2	https://www.gov.uk/government/publications/meningococcal-b-immunisation-programme-vaccine-coverage-estimates
web link 3	https://www.gov.uk/government/publications/meningococcal-the-green-book-chapter-22
web link 4	https://www.medicines.org.uk/emc/medicine/29112
web link 5	https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/223753/Green_Book_Chapter_3_v3_0W.pdf
web link 6	https://www.gov.uk/government/publications/cover-of-vaccination-evaluated-rapidly-cover-programme-annual-data
web link 7	https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/556895/HPR_COVER_Q1617_1_April_to_June_2016_v4.pdf
web link 8	https://www.gov.uk/guidance/hepatitis-b-dried-blood-spot-dbs-testing-for-infants
web link 9	https://www.gov.uk/government/collections/immunisation
web link 10	https://www.gov.uk/government/publications/thinking-of-getting-pregnant-make-sure-you-re-protected-against-german-measles
web link 11	https://www.gov.uk/government/publications/resources-to-support-whooping-cough-vaccination
web link 12	https://www.gov.uk/government/publications/tetanus-the-green-book-chapter-30
web link 13	https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/223753/Green_Book_Chapter_3_v3_0W.pdf