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Meningococcal ACWY immunisation programme for adolescents

Information for registered healthcare
practitioners
September 2018

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Updates for March 2017

- The inclusion criteria for vaccination against ACWY meningococcal disease are adolescents aged 13-18 years
- Valid consent must be given to receive the vaccine

Background

In 2015, Public Health England (PHE) reported a continued increase in meningococcal serogroup W (MenW) cases in England. The rise was initially recorded in 2009 and since this time, cases have steadily increased, rising from 11 cases in 2009 to 117 cases in 2014. In January 2015, 34 laboratory confirmed cases were notified to PHE, demonstrating a year on year increase compared to 18 cases in 2014 and 9 cases in 2013 of the same period. In Scotland, there were five cases of group W disease reported in 2014, in the first 20 weeks of 2015 there had been six cases of group W disease an early indication of a similar increase in MenW infection in Scotland. Information of recent epidemiology of meningococcal disease is available on the Health Protection Scotland website <http://www.hps.scot.nhs.uk>

Although cases of meningococcal disease overall has been in decline since 2000, cases of MenW were first observed in previously healthy adults in 2009 but by 2011, cases had extended across all age groups and across all regions in England, indicating that the strain had become endemic. For the first time in a decade, MenW related deaths were observed in young children and an increase in MenW cases among students attending universities across the country suggests that carriage and transmission of the bacteria has become established.

In February 2015, the Joint Committee on Vaccination and Immunisation (JCVI) agreed that the current increase in meningococcal W cases in England and Wales constituted an outbreak situation and advised that the replacement of MenC vaccine with Men ACWY conjugate vaccine for the adolescent and freshers vaccination programmes was likely to be beneficial in controlling invasive MenW disease and MenC. The JCVI recommended that the replacement should be implemented from academic year 2015/16. The committee also recommended that a catch-up vaccination programme for all 14-18 year olds using MenACWY conjugate vaccine should be offered as quickly as possible in order to generate population level herd protection, providing protection across all age groups. As the incidence of meningococcal W disease is also increasing in Scotland the same programme has been introduced in Scotland.

What is meningococcal disease?

Meningococcal disease is caused by invasive infection with the bacterium *Neisseria meningitidis*, also known as the meningococcus. There are 12 identified serogroups of which groups B, C, W and Y were historically the most common in the UK. Since the introduction of the routine MenC vaccination programme, cases of invasive meningococcal disease in the UK due to serogroup C have reduced dramatically, with serogroup B accounting for the majority of cases.

Meningococci colonise the nasopharynx of humans and are mostly harmless commensals. Between 5 and 11% of adults and up to 25% of adolescents carry the bacteria without any signs or symptoms of the disease. In infants and young children, the carriage rate is low.

Meningococcal disease is transmitted by respiratory aerosols, droplets or by direct contact with the respiratory secretions of someone carrying the bacteria. The incubation period is from two to seven days and the onset of disease varies from fulminant with acute and overwhelming features, to insidious with mild prodromal symptoms.

Meningococcal infection most commonly presents as either meningitis or septicaemia, or a combination of both. However, cases of MenW have often presented with atypical clinical presentations including septic arthritis and severe respiratory tract infections (including pneumonia, epiglottitis, and supraglottitis) being over-represented among MenW cases compared with other meningococcal groups. Several adults with MenW septicaemia have presented primarily with gastrointestinal symptoms without the characteristic rash making clinical diagnosis of the disease difficult.

Who does it affect?

Meningococcal disease can affect all age groups, but the highest rates of disease are in children under five years of age, with the peak incidence in those under one year of age. There is a second peak in incidence in young adolescents aged 15 to 19 years.

In the current outbreak in England and Wales, there has been a steady increase in MenW cases across all age groups, although for the first time in a decade MenW related deaths in young children have been observed. Additionally, an increase in cases among those attending universities suggest carriage and transmission of the bacteria are now established within this group.

The meningococcal ACWY Immunisation Programme

What is the purpose of the programme?

The purpose of this programme is to offer all those aged 13-18 years direct protection against meningococcus serogroup W. Offering protection to this age group prevents carriage of the meningococcus bacteria in the nose and throat before the age of which the highest rates of carriage have been observed.

Offering protection and preventing carriage of the meningococcus bacteria in the adolescent population also provides indirect protection to all other age groups by generating population level herd protection, thus preventing transmission of the bacteria.

Why offer MenACWY conjugate vaccine to adolescents aged 13-18 years?

In 2015, the JCVI reviewed all the available evidence and advised:

- MenW has been seen across age groups and across all regions in England indicating that the strain is now endemic.
- The highest rates of meningococcal carriage are usually observed in the adolescent population with evidence of sustained transmission, particularly within students attending universities.
- Those at highest risk of complications are young children who for the first time in the past decade, have observed meningococcal serogroup W related deaths.

What is the recommended vaccine for the programme and why?

The recommended vaccines for the programme are either Menveo[®] or Nimenrix[®]. The two recommended vaccines will continue to offer protection against meningococcal serogroup C, whilst offering additional protection against serogroups W, A and Y. Both vaccines are licensed for use in adolescents and adults and can be safely given with other routine adolescent vaccines.

Both Menveo[®] and Nimenrix[®] vaccines can be ordered from NHS board vaccine holding centres which supply other childhood vaccines.

Who is the vaccine recommended for?

The inclusion criteria for the vaccination against group ACWY meningococcal disease are adolescents aged 13-18 years.

How often should Men ACWY vaccine be administered?

Men ACWY vaccine should be administered as a single dose only. The need for, and the timing of a booster dose of Men ACWY vaccine in individuals has not yet been determined and therefore is not currently recommended.

What should you do if a person has already received the MenC conjugate vaccine at age 10 years or over?

Those who have previously received a MenC vaccine over the age of 10 years should continue to be offered MenACWY conjugate vaccine to ensure protection against the additional serogroups A, W and Y. A minimum interval period of four weeks should be observed between the administration of the two vaccines.

What should you do if a person has previously received MenACWY vaccine over the age of 10 years?

Those who have previously received a MenACWY conjugate vaccine over the age of 10 years, for example, for travel purposes, do not require an additional dose as part of the catch-up MenACWY immunisation programme. However it is not a contraindication if a person has already received a previous dose of MenACWY conjugate vaccine and if there is any doubt then a dose of MenACWY conjugate vaccine should be given. If a dose of MenACWY polysaccharide vaccine has been given over the age of 10 years a dose of MenACWY conjugate vaccine as part of the programme is required.

Vaccine administration

What are the recommended vaccines?

Two vaccines are used in the programme- **Menveo**[®] and **Nimenrix**[®]

How are the vaccines administered?

Menveo[®] should be administered via **intramuscular** injection (IM) into the upper arm (deltoid muscle). The vaccine is supplied containing two separate vials- one vial containing Men A (powder) and the second vial containing MenCWY (solution). The entire contents of the vial of solution should be added to the vial of powder. This vial should be inverted and shaken vigorously. A dose of 0.5 ml of reconstituted product can then be drawn up for administration. It is normal for a small amount of liquid to remain in the vial following withdrawal of the dose. Individuals with a bleeding disorder should have the vaccine given by deep subcutaneous injection to reduce the risk of bleeding.

Nimenrix[®] should be administered via **intramuscular** injection (IM) into the arm (deltoid muscle). The vaccine is supplied containing one vial of powder and one pre-

filled syringe. The entire contents of the pre-filled syringe should be added to the vial. After the addition of the solvent to the powder, the mixture should be well shaken until the powder is completely dissolved in the solvent. A dose of 0.5ml of reconstituted product can then be drawn up for administration. Individuals with a bleeding disorder should have the vaccine given by deep subcutaneous injection to reduce the risk of bleeding.

Registered healthcare practitioners are encouraged to familiarise themselves with the manufacturers Summary of Products Characteristics (SmPC) to ensure vaccines are reconstituted correctly.

1. **Menveo**[®] summary of product characteristics (SmPC)
2. **Nimenrix**[®] Summary of Product Characteristics (SmPC).

What action should be taken if registered healthcare practitioners forget to reconstitute the MenA component of the Menveo[®] vaccine and only administers the MenCWY solution?

Registered healthcare practitioners should inform the patient of the administration error and reassure them that no further action is required. The purpose of the routine adolescent programme is to ensure protection against meningococcal capsular groups C and W. In the UK, meningococcal capsular group A infections are extremely rare and therefore, they do not require an additional dose of vaccine. If in the future the patient plans to travel to a country where protection against meningococcal capsular group A is required, then they should be advised to be immunised with a further dose of MenACWY conjugate vaccine at that time.

Registered healthcare practitioners should report the administration error via their local governance system(s), so that appropriate action can be taken, lessons can be learnt and the risk of future errors minimised.

How many doses are required to ensure Protection?

Men ACWY vaccine should be administered as a single dose only. The need for, and the timing of, a booster dose of Men ACWY vaccine has not yet been determined and is therefore not currently recommended.

What is the shelf life of Menveo[®] OR Nimenrix[®],

Menveo[®] has a shelf life of three years when stored in its original packaging in a refrigerator at the recommended temperatures of +2°C and +8°C.

Nimenrix[®] has a shelf life of three years when stored in its original packaging in a refrigerator at the recommended temperatures of +2°C and +8°C

Healthcare practitioners must check the expiry date of all vaccines being administered.

Registered healthcare practitioners should place small regular orders with their supplying vaccine holding centre.

What are the contraindications for receiving MenACWY vaccines?

There are very few individuals who cannot receive meningococcal vaccines. Where there is doubt appropriate advice should be sought from your local Immunisation Co-ordinator rather than withholding immunisation.

MenACWY vaccines should not be administered to those who have had:

1. A confirmed anaphylaxis to a previous dose of the vaccine OR
2. A confirmed anaphylaxis to any constituent or excipient of the vaccine

For the composition and full list of excipients of the vaccine, please refer to the manufacturer's Summary of Product Characteristics (SmPCm).

What are the precautions?

Minor illness without fever or systemic upset are not valid reasons to postpone immunisation. Meningococcal vaccines may be given to pregnant women when clinically indicated. Individuals with Human Immunodeficiency virus (HIV) should be given meningococcal vaccine in accordance with the routine schedule.

What are the possible adverse reactions for MenACWY vaccines?

For both vaccines there can be pain, tenderness, swelling or redness at the injection site. For Menveo[®] a very common reaction includes headache, nausea, rash fever, joint aches and malaise. For Nimenrix[®] common reactions include fever, irritability, tiredness, drowsiness, headache, nausea and loss of appetite.

Does Menveo[®] or Nimenrix[®] contain any preservatives such as thiomersal?

No, they do not contain thiomersal. For a full list of excipients, registered healthcare practitioners should read the manufacturers Summary of Products Characteristics (SmPC).

Does Menveo[®] or Nimenrix[®] contain any porcine gelatin?

No, they do not contain porcine gelatin. For a full list of excipients, registered healthcare

practitioners should read the manufacturer's Summary of Products Characteristics (SmPC).

Does Menveo[®] or Nimenrix[®] contain latex?

Neither Menveo[®] nor Nimenrix[®] contain latex.

Can Menveo[®] or Nimenrix[®] be given with other routine vaccines?

Menveo[®] and Nimerix[®] can be safely given with other routine adolescent vaccines.

Where can I get further information

NHS Inform

Joint Committee on Vaccination and Immunisation:

<https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation>

Chapter 22 Immunisation against infectious disease

<https://www.gov.uk/government/publications/meningococcal-the-green-book-chapter-22>

NHS Inform <https://www.nhsinform.scot/healthy-living/immunisation/vaccines/meningitis-acwy-menacwy-vaccine> Meningitis Research Foundation <http://www.meningitis.org/>

Meningitis Now <http://www.meningitisnow.org>