Meningococcal ACWY programme for adolescents

HSC Public Health Agency

Information for healthcare professionals

These training resources have been prepared with reference to the version of UKHSA's "Immunisation against infectious disease: the Green Book" available at the time of publication. The resources have been made available at this time to allow the training to commence. It should be noted that whilst every effort has been made to ensure the accuracy of this training material and information at the time of publication, additions, updates, alterations and changes to the "Green Book" are likely to occur between the time of publication and the time the user views the training material, and so all healthcare professionals should also refer to and be familiar with any updates to the "Green Book".

Background

In 2015, Public Health England (PHE) reported a continued, year on year increase in meningococcal capsular group W (MenW) cases in England.[1] 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, compared to 18 cases in 2014 and nine cases in 2013 in the same period. In Northern Ireland there have been two cases in 2013 and three cases in 2014, giving an early indication of a similar increase of meningococcal W infection in Northern Ireland.

Although cases of meningococcal disease overall have been in decline since 2002, cases of meningococcal W were first observed in previously healthy adults in 2009 and by 2011 cases had extended across all age groups and across all regions in England, indicating that the strain had become endemic.[2] For the first time in a decade, meningococcal W related deaths have been observed in young children and an increase in meningococcal W cases among students attending universities across the country suggests that carriage and transmission of the bacteria has become established.[2]

In February 2015, the Joint Committee on Vaccination and Immunisation (JCVI) agreed that the increase in meningococcal W cases in England and Wales constituted an outbreak situation and recommended a vaccination programme aimed at protecting adolescents against meningococcal capsular groups A, C, W and Y strains.[3] This was felt to be the best option to generate population level herd protection, which should provide protection to all age groups.

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 capsular groups 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 capsular group C have reduced dramatically, with capsular group B now 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 meningococcal W have often presented with atypical clinical presentations with septic arthritis and severe respiratory tract infections (including pneumonia, epiglottis, and supraglottis) being over-represented among MenW cases compared with other meningococcal groups. Several adults with meningococcal W 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.

Vaccination against meningococcal disease for adolescents

What is the purpose of the routine programme?

From 1 September 2015 the routine MenC vaccine (meningococcal capsular group C) was directly replaced with the MenACWY conjugate vaccine to offer direct protection against meningococcal capsular group W to those in academic school year 11 (14–15 year olds). Offering protection to this age group prevents carriage of the meningococcus bacteria in the nose and throat before the age at 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 immunity, thus preventing transmission of the bacteria. Protection is best achieved across all age groups by **replacing** the adolescent MenC booster vaccine administered around 14 years of age with MenACWY conjugate vaccine. This vaccine will continue to offer protection against meningococcus capsular group C as well as offering additional protection against W, A and Y groups.

Why offer MenACWY conjugate vaccine to adolescents

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

- Transmission of meningococcal capsular group W has been seen across age groups and across all regions in England, indicating that the strain was endemic.

- The highest rates of carriage have been observed in the adolescent population with evidence of sustained transmission, particularly within students attending universities.

- Those at highest risk of complications are young children and for the first time in the past decade, meningococcal capsular group W related deaths have occurred in this age group.

- As an outbreak control measure, the JCVI has recommended the **replacement** of the MenC vaccine routinely administered around 14 years with MenACWY conjugate vaccine to prevent carriage and transmission within the adolescent population, thus ensuring protection against meningococcal W to all other age groups through herd immunity.

What is the recommended vaccine for the programme and why?

From 1 September 2015, a MenACWY conjugate vaccine replaced the MenC vaccine routinely administered around 14 years of age (adolescent booster).

The recommended vaccines for the programme are the MenACWY conjugate vaccines Menveo® or Nimenrix®. These two vaccines will continue to offer protection against meningococcal capsular group C, while offering additional protection against groups W, A and Y. Both vaccines are licensed for use in adolescents and adults and can be safely given with other routine adolescent vaccines.

Who is the vaccine recommended for?

The MenACWY immunisation programme is recommended for:

- all teenagers – this is usually administered in school year 11 (at ages 14 or 15 years) regardless of their intention to continue into further education
- anyone born after 1 September 1996 and until their 25th birthday if they have an unknown or incomplete MenACWY vaccination history
- anyone aged 10 years up to their 25th birthday if they have an incomplete or unknown MenC vaccination history
- first time university entrants up to 25 years (inclusive) Note: University is defined as any University or College that is a member of the University and Colleges Admissions Services (UCAS).

The vaccine should also be offered to first time entrants to further or higher education (UCAS registered establishments, up to 25 years of age, that have not previously had a dose of MenACWY conjugate vaccine over the age of 10 years. This includes both UK born and international students. This includes those who may have previously received the MenC vaccine at 10 years or over. Young people aged 16 or 17 years old attending CAFRE agricultural college residentially for the first time are also included in the programme as this is a member of UCAS.

First time university entrants aged less than 25 years who have previously received a dose of MenACWY conjugate vaccine aged 10 years or over do not require an additional dose of vaccine.[1]

How often should MenACWY vaccine be offered?

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

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

Those who have already received a MenC vaccine over the age of 10 years should still be offered MenACWY conjugate vaccine as part of a catch-up programme to ensure protection against the additional capsular groups A, W and Y. If the MenC vaccine has recently been administered, they should also be offered the MenACWY vaccine as soon as possible to provide protection against Men W.

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

Those who have already received a MenACWY conjugate vaccine at the age of 10 years or over (with the exception of close contacts of a confirmed case of MenACWY infection), for example, for travel purposes, do not require an additional dose as part of the MenACWY immunisation programme.

Are individuals under 25 years of age who are going to university for the first time and who have never previously received a dose of MenC conjugate vaccine previously eligible to receive MenACWY vaccine?

Yes, MenC conjugate vaccine is recommended for all individuals under the age of 25 years who have never received a dose of MenC previously. These individuals should now receive the MenACWY conjugate vaccine, replacing the dose of MenC while the immunisation programme is in place.

Vaccine administration

How are the vaccines administered?

Menveo® should be administered via **intramuscular** injection (IM) into the arm (deltoid muscle). The vaccine is supplied in a box containing two separate vials - one vial containing MenA (powder) and the second vial containing MenCWY (solution). The MenCWY solution should be injected into the MenA powder and should be vigorously mixed together prior to administration. Each dose contains **0.5mls**. It is normal for a small amount of liquid to remain in the vial following withdrawal of the dose.

Menveo® is supplied in a five-dose pack as a powder in a vial and a solution in a vial (10 vials per pack). Additional patient information leaflets (PILs) will be supplied with each pack of five vaccines ordered. Please discard the PIL in the pack and use only the additional PILs which have been provided.

Please note that no needles are supplied with this product, so needles will have to be ordered in the usual way.

Nimenrix® should be administered via **intramuscular** injection (IM) into the arm (deltoid muscle). The vaccine is supplied containing one vial of menACWY powder and one pre-filled syringe of solvent. The contents of the pre-filled syringe should be vigorously mixed with the contents of the vial prior to administration providing one dose **(0.5mls)**.

Healthcare professionals are encouraged to familiarise themselves with the manufacturers Summary of Products Characteristics (SPC) to ensure vaccines are reconstituted correctly.

1. Menveo® Summary of product characteristics (SPC)
2. Nimenrix® Summary of Product Characteristics (SPC)

What is the shelf life of Menveo® and Nimenrix®?

Menveo® has a shelf life of two 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

At the start of the programme the vaccine supplied may have a shorter shelf life and 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 the Public Health Agency duty room (0300 555 0119) rather than withholding immunisation.

MenACWY conjugate 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 (SPC).

Do Menveo® or Nimenrix® contain latex?

Neither Menveo® nor Nimenrix® contains latex.

What should I do if less than the recommended dose of vaccine is inadvertently administered?

In the event that MenACWY vaccines are administered at less than the recommended dose, the vaccination will need to be repeated because the dose that the individual received may not be sufficient to evoke a full immune response. Where possible, the dose of MenACWY vaccine should be repeated on the same day or as soon as possible after.

What action should be taken if health professionals forget to reconstitute the MenA component of the Menveo® vaccine and only administers the MenCWY solution?

Health professionals 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.

Health professionals 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.

What action should be taken if health professionals forget to reconstitute the MenACWY component of the Nimenrix® vaccine and only administer the contents of the pre-filled syringe?

Nimenrix® vaccine must be reconstituted by adding the entire content of the pre-filled syringe of solvent to the vial containing the ACWY powder. In the event a health professional administers the contents of the prefilled syringe without reconstituting the vaccine powder, the vaccination will need to be repeated as the solvent alone will not offer any protection against meningococcal capsular groups ACWY.

Where possible, the dose of MenACWY vaccine should be repeated on the same day or as soon as possible after. Health professionals 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.

What action should be taken if an individual has received a MenACWY polysaccharide vaccine?

University freshers up to 25 years who have received MenACWY polysaccharide vaccine in the last 12 months should have sufficient immunity against MenACWY infection to cover their university student years. Therefore, vaccination with MenACWY conjugate vaccine is not necessary, unless the polysaccharide vaccine was administered more than 12 months ago, in which case they should receive a MenACWY conjugate vaccine as soon as possible.

For all other adolescents being offered the vaccine as part of the routine or catch-up programme (excluding year 14 and university freshers) who have received either MenC conjugate or MenACWY polysaccharide vaccine should continue to receive the MenACWY conjugate vaccine as part of the national programme. The benefits of immunisation with conjugate vaccine outweigh any potential or theoretical harm associated with re-vaccination. Therefore, MenACWY conjugate vaccine should be given irrespective of the time interval between MenC conjugate or MenACWY polysaccharide vaccines.

Can the vaccine be offered to those outside of the immunisation programme?

Both Nimenrix® and Menveo® vaccines are licensed for use in children (from 12 months and two years respectively), adolescents and adults at risk of invasive disease from Neisseria meningitidis A, C, W and Y (see Green Book Chapter 7). Those not eligible to receive the vaccine as part of the routine or catch-up programmes, but who wish to receive the vaccine, should speak to their GP to discuss the possibility of obtaining the vaccine directly (privately) from the manufacturer. Parents/patients who request the vaccine privately will be liable for the costs of the vaccine and any additional administration charges. GP's should not use centrally procured stock for the national programme.

Why do the initial supplies of Nimenrix® look different to vaccines usually supplied?

In order to secure as much menACWY vaccine as possible at the start of the programme Nimenrix® will be delivered in 'general export packs' with multi-lingual packaging (English, French and Spanish). These packs will gradually be phased out and replaced by UK specific packs. Please note that the vaccine contained in the general export packs is compliant with all specifications and standards for the UK market. A single copy of the UK approved Patient Information Leaflet (PIL) will be provided with each pack of the vaccine distributed, but the pack itself does not contain a PIL for each dose. GSK has produced a letter to provide additional information about the use of the general export packs of Nimenrix®, which has been sent to all practices.

The general export packs of Nimenrix® will not include a detachable sticker for use in record keeping, and so this information will have to be transcribed manually.

What should I do if I have administered Menitorix® rather than Nimenrix® to a teenager?

Extreme care must be taken in practices not to confuse Menitorix® (the HiB/Men C vaccine for babies just after their first birthday) with Nimenrix® (the MenACWY vaccine for teenagers) as the boxes look very similar.

If Menitorix® is inadvertently given to a teenager, then they must be recalled for the MenACWY vaccine on the same day or as soon as possible. If Nimenrix® is inadvertently administered to a baby just after their first birthday, they must also be recalled for the HiB/MenC vaccine on the same day or as soon as possible afterwards.

Health professionals 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.

Useful links

- Public Health Agency leaflet *Are you aged 14–18 years old? Protect yourself against meningitis and septicaemia* https://www.publichealth.hscni.net/publications/teenage-immunisations-ages-14-18-english-and-translations
- Public Health England. Immunisation against infectious diseases: meningococcal chapter 22. www.gov.uk/government/publications/meningococcal-the-green-book-chapter-22
- Meningitis Research Foundation: www.meningitis.org/
- Meningitis Now: www.meningitisnow.org/
- NHS: www.nhs.uk/conditions/meningitis
- Joint Committee on Vaccination and Immunisation: www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation

References

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2. Public Health England (2015) Health Protection Report: Continuing increase in meningococcal group W (MenW) disease in England. Weekly report. Vol 9. No.7. Published 27 February 2015. [internet]. Accessed 15 June 2015. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/407865/hpr0715_men-w.pdf

3. Joint Committee on Vaccination and Immunisation (2015). Minutes of the meeting 4 February 2015. [internet] accessed 15 June 2015. www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation

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