Background

In 2015, Public Health England (PHE) reported a continued increase in meningococcal serogroup W 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 5 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 relating to the recent epidemiology of meningococcal disease is available on the Health Protection Scotland website [http://www.hps.scot.nhs.uk](http://www.hps.scot.nhs.uk)

Although cases of meningococcal disease overall has been in decline since 2000, cases of meningococcal W 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, meningococcal W related deaths were 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.

In February 2015, the Joint Committee on Vaccination and Immunisation (JCVI)\textsuperscript{*}
agreed that the current increase in meningococcal W cases in England and Wales constituted an outbreak situation and recommended a vaccination programme aimed at protecting all adolescents aged 14-18 years against Meningococcal serogroups ACWY strains was the best option to generate population level herd protection, providing protection across all age groups.

*The Joint Committee on Vaccination and Immunisation (JCVI) is a statutory expert Standing Advisory Committee. Its purpose is to provide expert impartial advice to the Secretaries of State for Health for England, Scotland, Wales and Northern Ireland on matters relating to communicable diseases, preventable and potentially preventable through immunisation.

Rationale of resource

This resource is designed to support and inform registered healthcare practitioners around the importance of immunising adolescents against meningococcal serogroup W disease, providing evidence based information around the implementation and delivery of the meningococcal serogroup W programme in Scotland. **Note:** Meningococcal serogroup W is commonly referred to as MenW. For the purpose of this resource MenW is used throughout this document.

This resource does not cover the actual administration techniques involved in vaccination against MenACWY. Information on immunisation by registered healthcare practitioners is available in chapter 5 of *Immunisation against infectious disease*, Green Book available at [http://immunisation.dh.gov.uk/category/the-green-book/](http://immunisation.dh.gov.uk/category/the-green-book/).

**Please note:** These educational resources continue to be updated as required to support this programme but do not replace the clinical judgement of practitioners. Practitioners should refer to the Public Health England Green Book Chapter when administering the vaccine.
If a patient declines the vaccination, advice should be given about the protective effects of the vaccine, the risks of infection and complications. Document advice given and decision reached. In GP practice setting, inform or refer to GP.
In infants and young children carriage of the bacteria remains low.
Key roles of immunisers in relation to immunisation against meningococcal ACWY disease in adolescents

- **Advise** Patients or parents/carers of those who are eligible for the routine meningococcal ACWY immunisation programme that the vaccine is strongly recommended to ensure direct protection against meningococcal serogroups ACWY.
- **Explain** the risks and complications of invasive meningococcal disease in all age groups and in particular explain that up to 25% of adolescents can carry the bacteria in their nose and throat without showing any signs or symptoms of the disease. In being immunised against meningococcal ACWY, carriage of the bacteria will also be prevented.
- **Explain** what vaccine will be used, the contraindications and possible side effects of immunisation
Learning Outcomes
On completion of this resource registered healthcare practitioners will:

- **Know** that the most common types of meningococci in the UK and their relationship in causing invasive meningococcal disease
- **Describe** the aetiology and epidemiology of meningococcal disease
- **Understand** the registered healthcare practitioners role in supporting the implementation of the meningococcal Men ACWY immunisation programme
- **Administer** the Men ACWY vaccine safely
- **Identify** sources of additional information and resources
Contents

• What is meningococcal disease?
• Immunisation against meningococcal ACWY disease and the use of Menveo® and Nimenrix®
• The role of registered healthcare practitioners
• Resources
What is meningococcal disease?
Less commonly, individuals may present with pneumonia, myocarditis, endocarditis, pericarditis, arthritis, conjunctivitis, urethritis, pharyngitis and cervicitis.
What is meningococcal disease? (Contd.)

- Since the introduction of the routine meningococcal C conjugate immunisation programme, cases of invasive meningococcal disease (IMD) in the UK from group C have reduced dramatically.
- Serogroup B now accounts for approximately 69% of all laboratory confirmed cases reported to Health Protection Scotland.
- Although cases of meningococcal disease overall has been in decline since 2000, cases of serogroup W were first observed in previously health adults in 2009.
- In 2011, cases of meningococcal W had extended across all regions in England, indicating the strain is now endemic.
- In Scotland, there were five cases of W group disease reported in 2014, in the first 20 weeks of 2015 there had been six cases in group W disease in early indication of a similar increase in Men W infection in Scotland*

*Information relating to recent epidemiology of meningococcal disease is available on the Health Protection Scotland website.
Please note that some or all symptoms may appear, in any order, and this list is not exhaustive. Table contents based on Meningitis Now

https://www.meningitisnow.org/meningitis-explained/signs-and-symptoms/

Onset of disease varies from severe acute and overwhelming features, to insidious with mild prodromal symptoms. Symptoms may be harder to identify in young infants particularly, the onset may be insidious and the signs be non-specific without classical features of meningitis.

Meningococcal infection most commonly presents as either meningitis or septicemia, 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 septicemia have presented primarily with gastrointestinal symptoms without the characteristic rash making clinical diagnosis of the disease difficult.
It is important to note that an absence of a rash does not preclude the illness of meningitis.
Transmission, infectivity, incubation and carriage

- Transmission is through person to person spread from respiratory droplets or by direct close contact with respiratory secretions of someone who is carrying the bacteria
- Infectivity of meningococci is relatively low and requires prolonged close contact, for example those living in the same household or through direct contact with nose and respiratory secretions such as intimate “wet” kissing
Transmission, infectivity, incubation and carriage (contd.)

- Incubation period ranges from 2 to 7 days with the onset of disease ranging from severe with overwhelming features to insidious mild prodromal symptoms.
- Carriage in the nose and throat (without any signs or symptoms) is uncommon in infants and young children but increases to 25% in adolescents.
Potential complications of meningococcal disease

- Meningococcal disease is associated with significant case-fatality, ranging from around 5% in infants and young children to 25% in older adults.
- Around a quarter of survivors of meningococcal disease will suffer serious long-term complications after recovering from the infection.
- It is estimated that approximately one quarter of those diagnosed with meningococcal disease caused by Neisseria meningitidis will suffer complications as a result.
Potential complications of meningococcal disease (contd.)

- Complications can vary in severity and can either be temporary or permanent. The more severe the disease, the greater the risk complication

  Complications can include:
  - Loss of hearing, loss of vision, loss of memory and/or concentration, difficulties in coordination and balance, epilepsy, cerebral palsy, limb amputations and may result in death
Immunisation against Meningococcal ACWY disease
The recommended vaccine(s)

- Two vaccines are used in the programme
  - Menveo®
  - Nimenrix®
The recommended vaccine(s)

- **Brand name**: Menveo®
- **Generic Name**: Meningococcal group A, C, W135 and Y conjugate vaccine
- **Marketed by**: GlaxoSmithKline
- **Licensed** for use in children from 2 years, adolescents and adults at risk of invasive disease from Neisseria meningitidis A, C, W and Y
- **Recommended** for adolescents as part of a routine immunisation programme
The recommended vaccine(s)

- Menevo® is one of two vaccines recommended for the catch up Men ACWY vaccination programme for adolescents

- Menevo® will be centrally supplied through NHS Board vaccine holding centres

- It is important immunisers familiarise themselves with the vaccine and its product information to avoid administration errors
The recommended vaccine(s) Menveo®

Active ingredients
- Meningococcal group A oligosaccharide 10 micrograms
  - Conjugated to Corynebacterium diphtheria CRM 197 protein 16.7 to 33.3 micrograms
- Meningococcal group C oligosaccharide 5 micrograms
  - Conjugated to Corynebacterium diphtheria CRM 197 protein 7.1 to 12.5 micrograms
- Meningococcal group W135 oligosaccharide 5 micrograms
  - Conjugated to Corynebacterium diphtheria CRM 197 protein 3.3 to 8.3 micrograms
- Meningococcal group Y oligosaccharide 5 micrograms
  - Conjugated to Corynebacterium diphtheriae CRM 197 protein 5.6-10.0 micrograms

Excipients
- Sucrose, potassium dihydrogen phosphate, sodium dihydrogen phosphate monohydrate, Disodium phosphate dehydrate, sodium chloride, water for injection
Menveo® will be centrally supplied by Vaccine Holding Centres in packs containing 5 doses (10 vials).

For the composition and full list of excipients of the vaccine, please refer to the manufacturer’s Summary of Product Characteristics http://www.medicines.org.uk/EMC/medicine/27347/SPC/Menveo+Group+A,C,W135+and+Y+conjugate+vaccine/

Registered healthcare practitioners should chose the correct needle size to ensure intramuscular administration.

All meningococcal-containing vaccines are given intramuscularly into the upper arm. This is to reduce the risk of localised reactions, which are more common when the vaccine is given subcutaneously.

However, for individuals with a bleeding disorder, vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding. Registered practitioners should refer to the Green Book Chapter for further details.

After reconstitution, the medicinal product should be used immediately. However, chemical and physical stability after reconstitution was demonstrated for 8 hours below 25°C.
Administration of Menveo® (contd.)

- After reconstitution, the solution should be clear, colourless to light yellow and free from visible foreign particles.
- Prior to administration, registered healthcare practitioners should change the needle for a suitable needle for IM administration into the deltoid muscle.
- The vaccine should not be administered where there are variations in physical appearance or signs of foreign particulate are observed after shaking.
- Menveo® can be safely given with other routine adolescent vaccines.
The recommended vaccine(s) Nimenrix®

- **Brand names: Nimenrix®**
- Nimenrix® is one of two vaccines recommended for the catch up Men ACWY vaccination programme for adolescents

- Nimenrix® will be centrally supplied through NHS Board vaccine holding centres

- It is important immunisers familiarise themselves with the vaccine and its product information to avoid administration errors
Brand names: Nimenrix®

- **Generic Name:** Meningococcal group A,C,W 135 and Y conjugate vaccine
- **Marketed** by GlaxoSmithKline
- **Licensed** for use in children from 6 weeks, adolescents and adults at risk of invasive disease from Neisseria Meningitidis A,C W and Y
- **Recommended** for adolescents as part of a routine and catch-up immunisation programme
Nimenrix®

Active ingredients
- Neisseria meningitidis group A polysaccharide 5 Micrograms
- Neisseria meningitidis group C polysaccharide 5 Micrograms
- Neisseria meningitidis group W-135 polysaccharide 5 Micrograms
- Neisseria meningitidis group Y polysaccharide 5 Micrograms
- Conjugated to tetanus toxoid carrier protein 44 micrograms

Excipients
- Sucrose, trometamol, sodium chloride, water for injections
Nimenrix® will be centrally supplied by NHS Board Vaccine Holding Centres.

For the composition and full list of excipients of the vaccine, please refer to the manufacturer’s Summary of Product Characteristics https://www.medicines.org.uk/emc/medicine/26514 Registered healthcare practitioners should choose the correct needle size to ensure intramuscular administration.

All meningococcal-containing vaccines are given intramuscularly into the upper arm. This is to reduce the risk of localised reactions, which are more common when the vaccine is given subcutaneously.

**However, for individuals with a bleeding disorder, vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding.**

After reconstitution: After reconstitution, the vaccine should be used promptly. Although delay is not recommended, stability has been demonstrated for 8 hours at 30°C after reconstitution. If not used within 8 hours, do not administer the vaccine.
How many doses?

- MenACWY vaccine should be administered as a single dose only
- The need for, and the timing of a booster dose of MenACWY vaccine has not yet been determined and is therefore not currently recommended
- 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
- The MenACWY conjugate vaccine can be administered at any interval after MenC vaccine and at any interval before, after or at the same time as other vaccines eg Td/IPV, MMR, travel vaccines
- Those who have already received a MenACWY conjugate vaccine at the age of 10 years or over do not require an additional dose (with the exception of close contacts of a confirmed case of MenACWY infection)
Administration of Menveo® or Nimenrix®

Menveo® or Nimenrix® should only be administered:

- Against a prescription written manually or electronically by a registered medical practitioner or other authorised prescriber
- Against a Patient Specific Direction
- Against a Patient Group Direction
For the composition and full list of excipients of the vaccine, please refer to the manufacturer’s Summary of Product Characteristics

https://www.medicines.org.uk/emc/medicine/26514

There are very few individuals who cannot receive meningococcal vaccines. Where there is doubt, appropriate advice should be sought from NHS board immunisation co-ordinator or from your local health protection team rather than withholding immunisation.

For further information on contraindications and precautions, please refer to the meningococcal Green Book chapter online at
Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have recovered fully. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine.

**Pregnancy and breast-feeding**

Meningococcal vaccines may be given to pregnant women when clinically indicated. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated virus or bacterial vaccines or toxoids.

**Immunisation and HIV infection**

Individuals with immunosuppression and human immunodeficiency virus (HIV) infection (regardless of CD4 count) should be given meningococcal vaccines in accordance with the routine schedule.

For further information on contraindications and precautions, please refer to the meningococcal Green Book chapter online at...
Possible adverse reactions (adolescents)

For both MenACWY vaccines: pain, tenderness, swelling or redness at the injection site

For Menveo®: very common or common reported reactions include headache, nausea, rash, fever, joint aches and malaise

For Nimenrix®: very common or common reactions include fever, irritability, tiredness, drowsiness, headache, nausea, and loss of appetite

Reports of all adverse reactions can be found in the summary of product characteristics for Menveo® and Nimenrix®

For the composition and full list of excipients of the Nimenrix® vaccine, please refer to the manufacturer’s Summary of Product Characteristics
https://www.medicines.org.uk/emc/medicine/26514

For the composition and full list of excipients of the Menveo® vaccine, please refer to the manufacturers Summary of Product Characteristics
Registered Healthcare practitioners and patients are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the yellow card reporting scheme.
The role of registered healthcare practitioners

- To promote clear, concise and accurate information to patients, parents or carers of those receiving the Men ACWY vaccine
- Every effort should be made by registered healthcare practitioners to maximise the uptake of the meningococcal ACWY vaccine in adolescents and to ensure that patients, parent or carers are fully informed about the importance of ensuring protection against meningococcal ACWY disease
Key Messages

- Meningococcal disease is caused by infection with the bacterium Neisseria meningitidis also known as meningococcus.
- There are 12 serogroups of meningococcus of which group B, C, W and Y were historically more common in the UK.
- Invasive meningococcal disease most commonly presents as meningitis or septicaemia and can affect all age groups, particularly children under 2 years, particularly aged 5 months and older adolescents.
- The meningococcal bacteria colonises the nasopharynx of humans. Between 5-11% of adults and up to 25% of adolescents carry the bacteria without any signs or symptoms.
- Offering MenACWY vaccine to adolescents offers them direct protection against capsular groups A, C, W and Y and prevents carriage of these bacteria in this age group, thereby potentially offering protection through herd immunity to other age groups.
Resources

- NHS Inform
- CMO Letter
- Green Book
- Meningitis Research Foundation
  www.meningitis.org
- Meningitis Association Scotland
  www.menscot.org
- Meningitis Now
  www.meningitisnow.org
- Immunisation Scotland
  www.immunisationscotland.org.uk