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For Action by:

General Practitioners
Immunisation Leads, Health Boards
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British Medical Association
GPC(Wales)
Royal College of GPs
Royal College of Nursing
Royal Pharmaceutical Society
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Enclosure(s): None

Dear Colleague,

Meningococcal ACWY conjugate vaccination (MenACWY)

1. I am writing to advise you of the introduction of MenACWY vaccination into the national immunisation programme this year following advice from the Joint Committee on Vaccination and Immunisation.
2. This programme is being implemented to respond to an outbreak situation which has seen a sudden, rapid and accelerating increase in cases of meningococcal group W (MenW). The introduction of MenACWY immunisation will have a significant effect on reducing carriage. I do not underestimate the additional work brought about by the addition of this catch up programme and I would like to take this opportunity to thank all involved in delivering the programme for their continuing hard work.
3. The programme will include:
 - An urgent catch-up campaign for all current (Sep 2014 – Aug 2015) school year 13 age adolescents through general practice.
 - Replacing the MenC vaccine routinely offered to adolescents at around 14 years (year 9) with the MenACWY vaccine.
 - A catch up campaign for those in school year 11, from September 2015 onwards, through schools.
 - Replacing the MenC vaccine offered to new university entrants up to 25 years of age with the MenACWY vaccine.
4. Annex A contains a table showing details of eligible age groups and when they should be invited for vaccination. The programme will be delivered by primary care and in schools.

Primary Care Programme

School year 13

5. From August 2015 to March 2016, the programme will offer MenACWY vaccine to all adolescents in the current school year 13 age group (academic year 2014 - 15) i.e. with a date of birth between 01/09/1996 and 31/08/1997.
6. General practices should invite all eligible adolescents for vaccination in this date range on a call and recall basis. Vaccination should be offered to all young people in the cohort whether in education or not.
7. The aspiration is to vaccinate this cohort by 14 September 2015 in order to ensure that those who are starting university in October are protected. I appreciate the difficulties this raises because GPs are unable to individually identify university entrants.
8. There will be a further two year catch up programme in primary care for adolescents currently in school years 11 and 12 (academic year 2014-15) as they reach school year 13:
 - From April 2016 to March 2017.
 - Date of birth between 01/09/1997 to 31/08/1998.

 - From April 2017 to March 2018.
 - Date of birth between 01/09/1998 and 31/08/1999.
9. These adolescents will remain eligible for vaccination on presentation or an opportunistic basis until they reach the age of 25 years if they are attending university.

University entrants

10. Additionally, from August 2015, MenACWY should be offered in place of Men C to first time university entrants aged under 25 years who have not previously been vaccinated as part of the existing time limited programme announced in June 2014 (Ref: CMO 2014/11). General practice is not required to issue invitations for this group. Vaccination should be offered opportunistically or on request.

School Programme

11. The school programme will begin from the start of the new academic year in September 2015.

Routine programme

12. MenACWY should be offered in place of the current routine MenC vaccine given to school year 9 adolescents alongside the Td/IPV vaccine. Where the current routine MenC programme is not provided through a school programme, health boards should make alternative local arrangements.

Catch up programme

13. There will be a catch up programme delivered over two years. MenACWY should be offered to the following cohorts:
- From September 2015 - School year 11.
 - Date of birth between 01/09/1999 and 31/08/2000.

 - From September 2016 - School year 11.
 - Date of birth between 01/09/2000 and 31/08/2001.
14. Health boards should also consider opportunities to offer catch-up vaccination to those who miss a scheduled vaccination.
15. Further information is provided in Annex A.
16. A revised chapter on Meningococcal disease will be included in *Immunisation against Infectious Disease (the Green Book)* at:
- <https://www.gov.uk/government/publications/meningococcal-the-green-book-chapter-22>
17. JCVI advice about MenW and the MenACWY quadrivalent conjugate vaccination is at:
- [JCVI advice on meningococcal disease](#)

Yours sincerely



DR RUTH HUSSEY OBE
Chief Medical Officer / Medical Director NHS Wales

Timelines for the implementation of the MenACWY programme.

Academic Year 14-15 (Sep 2014 to Aug 2015)	Academic Year 15-16 (Sep 2015 to Aug 2016)	Academic Year 16-17 (Sep 2016 to Aug 2017)	Details
			Primary care
			School – routine
			School – catch up
School Year 13			<p>Primary care</p> <p>From August 2015 - to be offered to all adolescents of School Year 13 age on a call and recall basis.</p> <p>From August 2015 – to be offered to all first time university entrants* aged up to 25 years, opportunistically or on request, as a replacement for MenC.</p>
	School Year 9		<p>School routine programme</p> <p>From September 2015 – to be offered routinely alongside Td/IPV vaccine in schools (or through an alternative where there is no school based provision for Td/IPV) as a direct replacement for MenC.</p>
	School Year 11		<p>School catch-up programme.</p> <p>From September 2015 – to be offered to all in School Year 11 (or through an alternative where there is no school based provision for Td/IPV).</p>
	School Year 13		<p>Primary care</p> <p>From April 2016 - to be offered to all adolescents of School Year 13 age on call and recall basis.</p> <p>From April 2016 – to be offered to all first time university entrants* aged up to 25 years, opportunistically or on request, as a replacement for MenC.</p>

		School Year 9	<p>School routine programme</p> <p>From September 2016 - to be offered routinely alongside TD/IPV in schools (or through an alternative where there is no school based provision for Td/IPV as a direct replacement for MenC.</p>
		School Year 11	<p>School catch up programme</p> <p>From September 2016 – to be offered in to all in School Year 11 (or through an alternative where there is no school based provision for Td/IPV).</p>
		School Year 13	<p>Primary care</p> <p>From April 2017 - to be offered to all adolescents of School Year 13 age.</p> <p>From April 2017 – to be offered to all first time university entrants* aged up to 25 years, opportunistically or on request, as a replacement for MenC.</p>

*University entrants to include only those not already vaccinated through school year 13.

CLINICAL GUIDANCE ON IMMUNISATION WITH MENACWY QUADRIVALENT CONJUGATE VACCINES

1. This guidance is based on advice from the Joint Committee on Vaccination and Immunisation (JCVI), the UK's independent committee of immunisation experts. A revised chapter on meningococcal disease, including clinical advice and information about the vaccines, is in *Immunisation against infectious disease* ('the Green Book') available to read at:

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

Background to the introduction of MenACWY vaccination

2. England and Wales are experiencing a significant increase in invasive MenW disease. In England, MenW cases have continued to increase since 2009 and this rise has accelerated in recent years, with 42 cases in 2012, 76 in 2013 and 117 in 2014. In the current epidemiological year (running from 1 July 2014 to 30 June 2015), there have been 155 cases (provisional) in England to the end of April compared to 80 cases to the end of April in the 2013/2014 epidemiological year and the increased activity continues. In Wales there have been 6 MenW cases confirmed in the first five months of 2015, against a background of 0-4 cases a year for the previous five years. MenW cases, which were previously reported mainly in older adults, are now being diagnosed across all age groups and, for the first time in over a decade, are causing deaths in infants, toddlers and adolescents, including university students. Characterisation of the MenW isolates revealed that the increase was nearly all caused by MenW serotype 2a strains associated with the cc11 complex. This clonal complex was associated with the increase in incidence and case fatality of meningococcal serogroup C infections in the UK in the late 1990s, and has been associated with prolonged periods of high incidence of both MenC and MenW disease in other countries.
3. The highest carriage rates for meningococcal bacteria are in adolescents and young adults who are believed to drive most transmission of MenW infection amongst them and to other age groups. PHE's advice is that this may be the start of a rise in incidence which could continue for several years, as happened with MenC in the mid-1990s, and the situation could get worse if early action is not taken to protect the population by interrupting transmission through immunisation.
4. JCVI advised at its meeting on 4 February 2015 that a programme to vaccinate all adolescents aged 14-18 years of age with MenACWY conjugate vaccine should be undertaken as soon as practicable, in order to protect them and generate herd protection against MenW for the rest of the population, including infants. This course of action is based upon substantial evidence that adolescents in this age range are the most likely to carry meningococcal

bacteria and to spread it to other groups within the population, and that meningococcal conjugate vaccination has a significant impact on the acquisition of meningococcal carriage in adolescents.

5. The quadrivalent conjugate meningococcal ACWY vaccines Menveo® and Nimenrix® will be used in the UK national immunisation programme. These vaccines have been used previously as travel vaccinations for travellers to areas of sub-Saharan Africa and areas of Saudi Arabia or any areas where outbreaks from vaccine-preventable capsular groups are reported.
6. The MenACWY vaccination does not offer protection against meningococcal serogroup B (MenB) infection.

Timing

7. The programme will start in August 2015 and will prioritise the immunisation of all school year 13 adolescents and any older first time university entrants up to the age of 25 years old. After completion of this priority cohort, the MenACWY programme will focus on the routine and catch up programmes as outlined in Annex A.

Recommendations for the use of the MenACWY vaccines (Menveo® and Nimenrix®)

Administration

8. Menveo® and Nimenrix® are given intramuscularly in the deltoid region of the upper arm.
9. Full guidance on the administration is included in the relevant chapter of the Green Book.

Dosage

10. Those vaccinated in these programmes should receive a single dose of 0.5ml.

Contraindications

11. There are very few individuals who cannot receive meningococcal vaccines. When in doubt, appropriate advice should be sought from a consultant paediatrician, immunisation co-ordinator or consultant in communicable disease control, rather than withhold immunisation.
12. The vaccines should not be given to those who have had:
 - A confirmed anaphylactic reaction to a previous dose of the vaccine, or
 - A confirmed anaphylactic reaction to any constituent or excipient of the vaccine.

Immunosuppression and HIV infection

13. Individuals with immunosuppression and human immunodeficiency virus (HIV) infection (regardless of CD4 count) should be given meningococcal vaccines in accordance with the routine schedule. These individuals may not make a full antibody response. Re-immunisation should be considered after treatment is finished and recovery has occurred. Specialist advice may be needed.

Concomitant administration with other vaccines

14. Meningococcal vaccines can be given at the same time as other vaccines such as pneumococcal conjugate vaccine, measles, mumps and rubella (MMR), diphtheria, tetanus, pertussis, polio, Hib and HPV. Other vaccines should be given at a separate site, preferably in a separate limb. If given in the same limb, they should be given at least 2.5cm apart.

Consent

15. See Chapter Two of *Immunisation against infectious disease* ('the Green Book'):

<https://www.gov.uk/government/publications/consent-the-green-book-chapter-2>

Pharmacy issues

Vaccine brand names and manufacturer

16. Menveo® and Nimenrix® are manufactured by GlaxoSmithKline.
17. It is likely that both Menveo® and Nimenrix® will be provided for this programme. A single dose of either vaccine is considered adequate to help provide protection to most adolescents. A certain volume of Nimenrix® will be supplied in general export packs rather than a UK pack.

Presentation

18. Vaccinators should note that the two vaccines are presented in similar packaging. Care is required to identify the correct product.
19. Menveo® will be supplied in a five dose pack as a powder in a vial and a solution in a vial (10 vials per pack). The vaccine must be reconstituted by adding the entire contents of the MenCWY solution vial to the vial containing the powder (MenA).
20. No needles are supplied with this product. Additional Patient Information Leaflets (PIL) will be supplied with each pack of five vaccines ordered, as there is only one PIL in each pack.
21. Nimenrix® will be supplied in a single pack as powder in a vial (MenACWY) and 0.5ml solvent in a pre-filled syringe. Two needles are included in the pack. The vaccine must be reconstituted by adding the entire contents of the pre-filled syringe to the vial containing the powder.
22. After reconstitution of either vaccine, the entire 0.5ml should be drawn up into the syringe and used immediately, but Menveo® is stable at or below 25°C for

up to eight hours, and chemical and physical in-use stability has been demonstrated for 8 hours at 30°C for Nimenrix®

23. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Vaccine supply

24. Due to the speed with which the MenACWY programme is being implemented, centrally held stocks of vaccine will be less than would usually be the case for a national programme. This increases the risk that **ordering restrictions may be applied for temporary periods**, or vaccines may become temporarily unavailable for ordering while further stocks are delivered. For this reason, and because **initial stocks may be relatively short-dated**, it is important that vaccines are not over ordered or stockpiled. (Note that Menveo is supplied in packs of five). Regular updates on vaccine availability will be provided.
25. We anticipate that ordering of the MenACWY vaccines for **general practice** for the current school year 13s and older university entrants will open in July 2015.
26. We anticipate that the vaccine for the **school routine programme** will be available from October 2015 and further supplies to enable the **school catch up programme** (i.e. school year 11 from September 2015) will be available from November 2015.
27. The MenACWY vaccines should be ordered online via the ImmForm website:

www.immform.dh.gov.uk

Vaccines are distributed by Movianto UK (Tel: 01234 248631) as part of the national childhood immunisation programme. Vaccines for private prescriptions, occupational health use or travel are NOT provided free of charge and should be ordered from the manufacturers. For outbreaks and contacts, vaccine should be procured locally directly from the manufacturer. Further information about ImmForm is available at:

[ImmForm Helpsheet](#)

or from the ImmForm helpdesk at:

helpdesk@immform.org.uk

or Tel: 0844 376 0040.

Storage

28. Vaccines should be stored in the original packaging at +2°C to +8°C and protected from light. All vaccines may be sensitive to some extent to heat and cold. Heat speeds up the decline in potency of most vaccines, thus reducing their shelf life. Effectiveness of vaccines may be impaired if not stored at the correct temperature. Freezing may cause increased reactogenicity and loss of potency for some vaccines. It can also cause hairline cracks in the container, leading to contamination of the contents.

Vaccine stock management

29. Please ensure sufficient fridge space is available for the vaccines. Each site holding vaccine is asked to review current stocks of all vaccines. A maximum of two to four weeks of stock is recommended, and higher stock levels should be reduced to this level. A review of available fridge space will be necessary to ensure adequate storage capacity at the start of the programme.
30. Effective management of vaccines throughout the supply chain is essential to reduce vaccine wastage. Local protocols should be in place to reduce vaccine wastage to a minimum. Even small percentage reductions in vaccine wastage will have a major impact on the financing of vaccine supplies.
31. Any cold chain failures must be documented and the incident reported to the local health board immunisation co-ordinator as appropriate.

Reporting of adverse reactions

32. Suspected adverse reactions (ADR) to vaccines should be reported via the Yellow Card Scheme:

<https://yellowcard.mhra.gov.uk/>.

33. Chapter Nine of the Green Book gives detailed guidance on which ADRs to report and how to do so. Additionally, Chapter Eight of the Green Book provides detailed advice on managing ADRs following immunisation.
34. Any reported adverse incidents, errors or events during or post vaccination must follow determined procedures. In addition, teams must keep a local log of reports and discuss such events with the local immunisation co-ordinator.

Surveillance

35. The programme will be carefully monitored by Public Health Wales and the Medicines and Healthcare products Regulatory Agency (MHRA).

Patient Group Directions

36. The usual method for the supply and administration of vaccines is via a Patient Specific Direction (PSD). The authorisation for this is usually the responsibility of the GP or an independent nurse prescriber. Where a PSD exists, there is no need for a Patient Group Direction (PGD).
37. In school situations where a PSD is not available, a PGD may be used. A PGD is a written instruction that allows for the supply and/or administration of medicines to groups of patients who present for treatment where it offers an advantage to patient care without compromising safety. Template PGDs are available for amendment by health boards to authorise appropriate health professionals to administer the vaccine where a PSD is not available. More information is available from the Public Health Wales Vaccine Preventable Disease Programme NHS Wales intranet site at:

<http://howis.wales.nhs.uk/immunisation>

Vaccine uptake data collection

38. Practices are required to provide data to Public Health Wales (PHW) sufficient to carry out surveillance and monitoring of the MenACWY vaccination programme. Data to monitor vaccine uptake will be collected automatically in the same way that data for influenza immunisations delivered through General Practices are collected.

Child Health Information Systems

39. Health boards will be responsible for the commissioning of Child Health Information Systems (CHIS) and associated Child Health Records Department activities.
40. Healthcare professionals administering the vaccine must ensure that information on vaccines administered is documented appropriately as outlined in Green Book Chapter 4 – Immunisation Procedures.

<https://www.gov.uk/government/publications/immunisation-procedures-the-green-book-chapter-4>

41. The healthcare professional must ensure that information on vaccines administered is submitted directly to the local Child Health Office within seven days (for young people up to and including 18 years of age).
42. Arrangements continue to be required to inform neighbouring areas when children resident in their area are immunised outside their local area through the CHIS system

Funding

Primary Care

43. A practice will receive an item of service (IOS) payment of £7.80 per dose in respect of each child in an eligible cohort who is vaccinated.
44. An additional fee of £2.12 per dose in respect of each child in an eligible cohort who is vaccinated will be paid to GPs from the start of the programme until 31 March 2016 in recognition of the urgency of implementation and delivery of the programmes and the additional workload this short lead in timeframe will mean for practices.
45. A top-up funding allocation for the MenACWY programme will be made to health boards' block allocations. The top-up allocation will be calculated on the full practice registered population for the health board, adjusted to take into account implementation part way into the financial year.

Health Boards

46. Health boards will be paid the standard vaccination, pharmacy and Child Health monies and it is expected to see the funds translated into appropriate resources in the respective service areas.

Information materials

47. Leaflets will be made available on the NHS Direct (Wales) web site at:

<http://www.nhsdirect.wales.nhs.uk/encyclopaedia/m/article/meningitis/55>.

48. Further information for healthcare professionals, are available from the Public Health Wales Vaccine Preventable Disease Programme, NHS Wales intranet site at:

<http://howis.wales.nhs.uk/immunisation>