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Dear Colleague,

Changes to the schedule for meningococcal serogroup C conjugate vaccine

You will be aware from our letter dated 30 April regarding changes to England's national immunisation programme and details about the rotavirus vaccination programme that, following recent advice and recommendations by the Joint Committee on Vaccination and Immunisation (JCVI), and in line with our standing commitments on patient rights under the NHS Constitution on implementing such recommendations, a series of changes will be introduced over the course of 2013-14.

This letter covers the changes to the schedule for meningococcal serogroup C conjugate (MenC) vaccination.

We will be writing separately, in the near future, about:

- new vaccination programmes for shingles and childhood flu;
- with information about the continuation of pertussis vaccination for pregnant women; and
- details of the next annual flu immunisation programme.

These changes have the support of the Department of Health's Chief Medical Officer, Chief Pharmaceutical Officer and Director of Nursing.

The changes to the MenC vaccination schedule will commence from 1 June 2013.

In summary, these changes are:

- the removal of the second dose at age 16 weeks (four months) from the routine schedule for infants (from 1 June 2013); and,
- the introduction of an adolescent booster dose at around 14 years (school year 10) for the academic year 2013 -14. Colleagues should note that JCVI has recommended that the adolescent booster dose, together with Td/IPV, should be given routinely at age 13-14 years and it is our intention that, over time, there will be a planned, coordinated, country wide approach to enable areas to move towards giving these vaccines between the ages of 13-14 years (school year 9).. Further information regarding this will follow.

From mid-August 2014, there will also be a catch-up programme of limited duration to offer the vaccine to first time university entrants under the age of 25 years, i.e. those who will not have been vaccinated under the revised schedule at around age14 years.

The JCVI has advised that these changes will make the MenC vaccination schedule more effective and offer greater overall public health protection. The background to these changes, together with detailed information for healthcare professionals on how to implement them, is set out in ***Annex B*** of this letter.

A revised chapter on Meningococcal vaccination, including clinical advice and information about the new MenC vaccination schedule, has been included in *Immunisation against Infectious Disease 2006*, ("the Green Book") available at:
Revised chapter on Meningococcal Vaccination

The JCVI's statement about the revised MenC vaccination schedule and subsequent discussions, with details about the changed schedule are available at:
JCVI statement on revised MenC vaccination

and

JCVI minutes October 2012 & February 2013

Responsibility for the national immunisation programme has changed from 1 April 2013. The letter issued by the Department of Health on 23 August 2012 sets out the roles and respective accountabilities of the Department, Public Health England, NHS England and local authority Directors of Public Health with regard to immunisation in the reformed system.

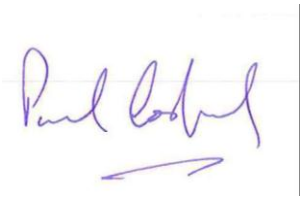
Future operations for Screening and Immunisation

The UK's successful national immunisation programme brings great benefits to the health of the whole population. We do not underestimate the additional work brought about by these changes to the programme and we would like to take this opportunity to thank all involved in delivering the programme for their continuing hard work.

If you have any queries about the content of this letter please email: england.immunisation@nhs.net

Yours sincerely

Dame Barbara Hakin
NHS England, Chief Operating Officer and Deputy Chief Executive



Dr Paul Cosford
Public Health England, Medical Director and Director of Health Protection

Dr Felicity Harvey
Department of Health, Director General, Public Health

Annex A

Summary of planned changes to the immunisation schedule in 2013/14

Programme	June 2013	July 2013	August 2013	Sept 2013
MenC vaccine: remove one primary dose	√			
Rotavirus vaccine introduced		√		
MenC vaccine: adolescent dose introduced through schools				√ *
Shingles vaccine: programme begins (including catch-up)				√
Flu vaccine for some pre-school aged children introduced				√

* This can take place at any point in the 2013/14 academic year. In practice, it is most likely to be administered in schools in the spring 2014 term.

Annex B

CHANGES TO THE VACCINATION SCHEDULE FOR MenC VACCINE

1. The changes to the MenC vaccination schedule are based on advice from the Joint Committee on Vaccination and Immunisation (JCVI)[1], the UK's independent committee of immunisation experts. Full guidance can be found in the revised chapter on meningococcal vaccination now included in *Immunisation against infectious disease* ('the Green Book')[2].

Background to the changes

2. The objective of the routine MenC vaccination programme is to protect those under 25 years of age and individuals outside this age range who may be at increased risk from meningococcal serogroup C disease.

3. Recently published studies show that vaccination against meningococcal serogroup C disease in early childhood provides a short-term protective immune response (Borrow *et al*., 2010; Kitchen *et al*., 2009; Perret *et al.,* 2010), that vaccination later in childhood provides higher levels of antibodies that persist for longer (Snape *et al*., 2008), and that Men C vaccination significantly reduces nasopharyngeal carriage of serogroup C meningococci providing indirect protection through herd protection (Ramsay *et al*., 2003; Maiden *et al*., 2008). Full references are included in the relevant chapter of *Immunisation against Infectious Disease*.

4. Following consideration of these studies, the JCVI has advised that an adolescent booster dose at age 13-14 years (school year nine) be added to the routine vaccination schedule. The booster dose should be given at the same time as the Td/IPV vaccine booster dose. The Td/IPV vaccine is currently offered, in most areas at a later age, e.g. 14-15 years (school year 10). Our intention is that in the future there will be a planned approach to enable areas to move towards giving the vaccines between the ages of 13–14 to align the programmes across the country. It is important that local arrangements are made to ensure that children do not miss the offer of the Td/IPV booster vaccination because the age at which this offer is made is being lowered.

5. Additionally, following a study that showed a single dose of some varieties of MenC vaccine at three months of age would be sufficient to prime infants against meningococcal serogroup C disease, and provide protection for the first year of life until the first booster at 12-13 months of age when Hib/MenC vaccine is offered (Findlow *et al.,* 2012), the JCVI has advised that the second dose at four months of age be removed from the routine vaccination schedule.

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[1] JCVI statement: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_132443.pdf

[2] The Meningococcal chapter can be found at: Meningococcal chapter

6. The table below sets out the routine MenC vaccination schedule, as revised from 1 June 2013:

Revised Routine MenC Vaccination Schedule from June 2013:

Age	Primary/Booster	Dose
Three months	Primary‡	one dose - Men C vaccine* (Neisvac C® or Menjugate Kit ® only)
12-13 months	Booster	one dose - Hib/MenC vaccine*
Around 14 years	Booster	one dose – Men C vaccine*

‡ Although the Summary of Product Characteristics for available MenC vaccines state that two doses should be given at least two months apart in those less than one year of age, evidence from a UK study shows that the immune response is adequate following a primary course of a single dose in infants (Findlow *et al*., 2012).
*If no doses of MenC vaccine have been received, follow the 'Individuals with unknown or incomplete vaccination histories' table.

(Reproduced from Immunisation against infectious disease) Green Book chapter 22

Vaccination of individuals with uncertain or incomplete immunisation status.
7. For those children who have not been immunised according to the UK routine schedule, please see the advice at:
http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1194947406156

and the Green Book chapter: Meningococcal chapter

Vaccination of infants
8. JCVI has advised that the second dose at four months of age be removed from the routine vaccination schedule. The new infant vaccination schedule should commence from 1 June 2013 and from that date infants should only be offered MenC vaccine at age three months (one dose).

9. **Colleagues should note the following:**

- **That Neisvac C® and Menjugate Kit® are the only Men C vaccines which should be used for the priming dose for infants from 1 June 2013.**

- **Infants who have received a first priming dose of Meningitec® but not received a second dose by 1 June 2013, must receive a second dose of vaccine, which should preferably be either Meningitec® or Menjugate Kit®. This may be after 1 June 2013.**

- **Infants who have received a first priming dose of Menjugate Kit® but not received a second dose by 1 June 2013, will not need a second dose after 1 June 2013.**

  See the Green Book Chapter 22 for further information.

10. **Meningitec® vaccine should not now be used to immunise infants as a single priming dose**, because it does not provide adequate protection against meningococcal serogroup C disease when administered as a single dose in infancy. It is not, therefore, recommended for use in those less than 12 months of age in this programme. If, following the introduction of the changed programme, an infant receives **Meningitec**® at three months of age, a second dose of MenC (preferably one containing a CRM conjugate such as Meningitec® or Menjugate Kit® should be offered at four months of age.

11. Full information on administration, dosage, contraindications, concomitant administration with other vaccines, consent and reporting of adverse reactions are set out in the relevant chapter of Immunisation against Infectious Diseases- the Green Book

12. Arrangements for vaccine supply and other vaccine issues for the MenC vaccine for use by GPs in infants remain unchanged.

13. Children should also continue to receive one dose of Hib/MenC vaccine at 12-13 months.

Arrangements for adolescent vaccination

14. The JCVI recommends that the new adolescent booster dose should be given routinely at 13-14 years to be delivered though the schools' immunisation programme and ideally at the same time as the routine Td/IPV vaccine booster. Adolescents will be able to receive the MenC vaccine from the next Spring term (academic year 2013-14) that is, January to March 2014 as that is when most children may be offered the Td/IPV vaccine booster currently.

15. Currently most local vaccination programme arrangements offer the Td/IPV vaccine at 14-15 years (school year 10), and we are recommending for this academic year that the MenC booster dose should, for a period of time, be offered at that age. Local areas will be encouraged to offer these vaccinations at age 13-14 years (school year nine) and further information about this will follow. Funding to support this will be reflected in future funding agreements between the Department of Health and NHS England. However, it is important that when changing to the new routine schedule, local arrangements are made to ensure that children do not miss the offer of the Td/IPV booster vaccination as a result of the age being lowered.

16. All the available MenC vaccines are appropriate for the booster vaccination of adolescents. However, to ensure there is sufficient stock of MenC vaccines available for infants, it is preferable for Meningitec® and Menjugate Kit® to be used for this age group until current stocks of these vaccines are exhausted.

17. Full information on administration, dosage, contraindications, concomitant administration with other vaccines, consent and reporting of adverse reactions is set out in the relevant chapter of Immunisation against Infectious Diseases- the Green Book.

18. Arrangements for vaccine supply and ordering are set out in this letter at paragraphs 28 to 33.

Arrangements for the catch-up programme for first time university entrants

19. Studies suggest that older adolescents may be at a higher risk of contracting meningococcal C disease when they go to university, particularly if they are in accommodation such as halls of residence.

20. From mid-August 2014, there will be a catch-up programme of limited duration – possibly up to five years - to offer the vaccine to first time university entrants under the age of 25 years, i.e. those who will not have been vaccinated at around 14 years under the revised schedule.

21. This programme will be delivered mainly through primary care.

22. To ensure time for a full immune response, young people should be vaccinated no later than two weeks before departing for university. Starting the programme in mid-August 2014 will ensure that young people are immunised before they leave for university.

23. When young people have not been vaccinated before leaving for university, they should be offered the vaccine as soon as possible once they arrive at university.

24. All the available MenC vaccines are appropriate for this age group.

25. Full information on administration, dosage, contraindications, concomitant administration with other vaccines, consent and reporting of adverse reactions is set out in the relevant chapters of Immunisation against Infectious Diseases- the Green Book.

26. Colleagues will be reminded of the introduction of the university entrants' catch-up programme nearer the time of implementation.

Vaccine ordering (including ImmForm registration)

27. Menjugate Kit® is currently available to order through ImmForm. Many GPs and hospital pharmacies already have an ImmForm account. The national programme vaccines will be distributed by Movianto.

28. For organisations which have a NHS Movianto account they can self-register on ImmForm by going to the following URL: www.immform.dh.gov.uk and by clicking the 'Register for an Account' option on the ImmForm welcome page. They will need their NHS Movianto account number and a NHS or gov.uk email address. This process should take less than one day.

29. Organisations without a Movianto account or if the Movianto account number is not known should email the following information to: helpdesk@immform.org.uk mailbox.

- The full address of the NHS Organisation
- The full delivery address (if different)
- The NHS organisation code
- Contact telephone number
- First Name
- Surname
- NHS or gov.uk email address

30. Arranging a Movianto account number takes two to four working days and login details will be emailed as soon as the account is set up.

31. Please note all delivery addresses should have suitable cold storage facilities for vaccines and have local procedures for ensuring the vaccines are stored appropriately immediately after delivery. See the Green Book Chapter Three for more information on the storage, distribution and disposal of vaccines (www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3)

32. For more information on ImmForm, including a number of help sheets, please see www.gov.uk/government/organisations/public-health-england/series/immform.

Funding implications

Removing the four month dose

33. Childhood immunisations are classified as additional services in the GP contract and the infrastructure costs of delivering these are covered by GP practices core funding (global sum payment or baseline PMS funding). GP practices are also eligible for target payments if they have vaccinated 70% or 90% of their two-year old patients with the recommended vaccines, including currently two doses of MenC vaccine.

34. NHS England plans an adjustment to those target payments to reflect the change from two to one dose of MenC in the infant scheme. However, this adjustment will not be made until 2015/16 reflecting that vaccination status is not assessed until children reach two years of age (i.e. children aged four months by 31 May 2013 receiving two doses will still need to be assessed when they reach two years of age).

Catch-up for first time university entrants

35. Further information will follow relating to the funding and vaccine supply arrangements for the catch-up for first time university entrants.

Adolescent booster dose

36. Further information will follow relating to the funding for the adolescent booster dose

Patient Specific Directions and Patient Group Directions

37. The usual method for the supply and administration of vaccines in the routine childhood immunisation programme is via a Patient Specific Direction. The authorisation for this is usually the responsibility of the GP or an independent nurse prescriber at the six to eight-week check and is recorded as an instruction in the Personal Child Health Record (PCHR or Red Book). This agreement allows immunisations to be given in GP surgeries or clinics.

38. The use of Patient Group Directions, where this is appropriate and there are the necessary governance arrangements in place, can continue for the immediate future. However, arrangements for the development and authorisation of Patient Group Directions may be reviewed in the light of the new system architecture.

Communications and information for parents and health professionals

39. Information flyers and leaflets for parents and young people are being produced to support the introduction of the vaccine. These will be available from the Publications Orderline in the usual way. The existing immunisation information booklets will be amended to bring them into line with the new schedule. In addition to the new Green Book chapter, there will be a Q&A factsheet for health professionals.

40. Materials for health care professionals will be available at: https://www.gov.uk/government/organisations/public-health-england/series/immunisation

41. Materials for parents and young people will be available at: https://www.gov.uk/government/organisations/public-health-england/series/immunisation

Vaccine uptake data collection

42. Coverage of one dose of MenC vaccine at 12 months of age will be assessed as part of the routine quarterly COVER programme from July 2014, replacing the current assessment of two doses of MenC at 12 months of age. An annual assessment of coverage of the adolescent booster dose of MenC vaccine is also planned.

43. This collection is subject to review of central returns (ROCR) approval. Further details will be issued in due course.

Personal Child Health Record (the "Red Book")

44. Arrangements have been made for the Red Book record of childhood vaccinations to be amended to reflect the changes to the childhood schedule, including MenC vaccination. It is important that information about vaccinations that have been given are recorded in the Red Book, when it is available. Further information on the details to be recorded is given in Chapter Four of the Green Book

Disease Surveillance

45. Public Health England will continue to monitor the incidence of invasive meningococcal disease and investigate cases in the same way as currently. See: Meningococcal Disease Epidemiological Data

Reporting and management of cases of meningococcal disease

46. Current guidance should continue to be followed. See: hpa.org.uk - current guidance