17 May 2013

Dear Colleague

Important Changes to the National Immunisation Programme In 2013-14 and introduction of Rotavirus Vaccination for Babies at 2 and 3 Months Of Age

Following recent recommendations by the Joint Committee on Vaccination and Immunisation, a series of changes to the national immunisation programme in Wales will be introduced over the course of 2013-14.

This letter covers both an outline of planned changes to the national immunisation programme and details of the specific programme for rotavirus for babies at 2 and 3 months of age.
The National Immunisation Programme in 2013-14

A number of changes to the national immunisation programme are being made during 2013-14 to reflect the planned and phased implementation of a series of recommendations by the Joint Committee on Vaccination and Immunisation (JCVI) to improve the overall level of protection against vaccine preventable diseases. A table providing the full details of these changes is at Annex A but in summary they are as follows:

- **MenC:** From June 2013, changes will be made to the current schedule for administering the MenC conjugate vaccine. The second priming dose currently given at four months will be discontinued and replaced by a booster dose given in adolescence. The initial change will be to cease giving the four month dose from 1 June 2013.

- **Rotavirus:** From July 2013, the introduction into the childhood immunisation schedule of a vaccine to protect babies against rotavirus.

- **Shingles:** From September 2013, the introduction of a shingles vaccine for people aged 70 years and over to protect against herpes zoster.

- **Childhood Flu:** In autumn 2013, it is planned to extend the flu immunisation programme to include children in some age groups using a nasal spray vaccine. This is the first step of the phased introduction over a number of years of immunisation against flu for all children aged two to 16 years.

I will be writing to you soon about the changes to MenC programme. More detail on shingles and childhood flu will be issued prior to their implementation. Further detail about the introduction of the rotavirus vaccine is contained in this letter.

The introduction of rotavirus vaccination for babies at 2 and 3 months of age.

Rotavirus is a very common and potentially serious intestinal infection of young babies.

The rotavirus vaccine will be included in the programme from 1st July 2013.

The vaccine should be offered routinely to all babies at the age of 2 months and again at 3 months (that is, two doses, four weeks apart) when they attend for their first and second routine childhood immunisations.

Detailed clinical guidance for healthcare professionals is set out in Annex B to this letter.
A new chapter on rotavirus, including clinical advice and information about the vaccine, has been included in *Immunisation against infectious disease (the Green Book)* and is available to read at:


JCVI’s statement about rotavirus and rotavirus vaccine is available at:

The Welsh Government recognises the importance of immunisation in preventing disease and the consequent benefits to the people of Wales. Successful national immunisation programmes bring great benefits to the health of the population. We do not underestimate the additional work brought about by this change to the programme and we would like to take this opportunity to thank all involved in delivering the programme for their continuing hard work.

Yours sincerely

Dr Ruth Hussey OBE
Chief Medical Officer / Medical Director
**Summary of planned changes to the immunisation schedule in 2013/14**

<table>
<thead>
<tr>
<th>Programme</th>
<th>June 2013</th>
<th>July 2013</th>
<th>August 2013</th>
<th>Sept 2013</th>
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</thead>
<tbody>
<tr>
<td>MenC vaccine: remove one primary dose</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rotavirus vaccine introduced</td>
<td></td>
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<td>✓</td>
<td></td>
</tr>
<tr>
<td>MenC vaccine: adolescent dose introduced</td>
<td></td>
<td></td>
<td></td>
<td>✓*</td>
</tr>
<tr>
<td>Shingles vaccine: programme begins</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Flu vaccine for 2 and 3 year olds and Year 7 introduced</td>
<td></td>
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<td>✓</td>
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* This can take place at any point in the 2013/14 academic year. In practice, it is most likely to be administered alongside the teenage booster Td/IPV vaccination through a schools programme or through general practices, as applicable locally.
1. This guidance is based on advice from the Joint Committee on Vaccination and Immunisation (JCVI), the UK’s independent panel of immunisation experts. Full guidance can be found in the new chapter on rotavirus now included in *Immunisation against infectious disease* (‘the Green Book’) at: https://www.gov.uk/government/publications/green-book-the-complete-current-edition

**Background to the introduction of rotavirus vaccine**

2. Nearly all children will have at least one episode of rotavirus gastroenteritis before reaching five years of age. An estimated 130,000 children with rotavirus gastroenteritis will visit their GP and approximately 12,700 of these children will be hospitalised in England and Wales every year. Although deaths from rotavirus in the UK are rare and are difficult to quantify accurately, there are likely to be up to three to four a year. Rotavirus infection in children leads to severe diarrhoea, vomiting, stomach cramps, dehydration and mild fever and the symptoms are likely to last approximately three to eight days.

3. In the UK there are several circulating strains of rotavirus, with G1P[8] the most abundant type, although distribution of the strains changes over time. Rotavirus is highly contagious and transmission by the faecal-oral route is most frequent, although respiratory transmission may also occur. Although good hygiene measures can help prevent spread of the disease, for example proper hand washing after going to the toilet or after nappy changing, the robustness of rotavirus and the low minimal infectious dose of 10 – 100 virus particles, renders rotavirus readily transmissible and makes standard sanitary measures to halt transmission of the virus relatively ineffective.

4. Rotavirus infection in the UK is seasonal, occurring mostly in winter and early spring (January to March). People of any age can be infected by rotavirus but most infections occur in infants and children between one month and four years of age, with a peak between 6-18 months of age. Infections are often recurrent, and many children experience infection on one or more occasions by three years of age. Infection in newborns is common but tends to be either mild or asymptomatic because of protection by circulating maternal antibodies. Once someone has had a rotavirus infection they usually develop immunity although it may be short lived.

5. JCVI advised in 2009 that the use of licensed rotavirus vaccines would have a significant impact on reducing gastroenteritis in young children and that the UK health departments should introduce the vaccines if they could be
procured at a cost effective price. This advice was reiterated in 2011 following consideration of a further cost-effectiveness study. As we are now able to procure a rotavirus vaccine at a cost effective price, the vaccine is to be added to the UK’s childhood immunisation programme.

6. Rotavirus vaccines, including the Rotarix® vaccine which will be used in the UK programme, are already used to routinely vaccinate children in the US and many other countries. In the US, studies have shown that rotavirus-related hospital admissions for young children have been cut by more than two thirds since rotavirus vaccination was introduced.

7. The rotavirus immunisation programme in the UK will prevent a significant number of young infants from developing this infection. A published study\(^1\) estimated that vaccinating a single annual birth cohort of infants in England and Wales may prevent around 90,000 infections, about 10,000 hospitalisations and around two deaths due to rotavirus in that cohort over the first five years of life. It may also provide some additional protection to the wider population through herd immunity.

**Timing**

8. The vaccine will be included in the childhood immunisation programme from 1\(^{st}\) July 2013. All children scheduled to receive their primary vaccines at ages 2 and 3 months should be offered the vaccine, to complete a course of two doses at least four weeks apart.

**Recommendations for use of the vaccine**

**Administration**

9. Rotarix® vaccine is given orally. **It must not be injected.**

10. If the infant spits out or regurgitates most of the vaccine, a single replacement dose may be given at the same vaccination visit. There are no restrictions on an infant’s consumption of food or drink before or after vaccination.

11. Full guidance on the administration technique is included in the relevant chapter of the Green Book.

**Dosage**

**Infants aged 6 weeks to under 15 weeks**

12. The minimum age for the first dose of Rotarix® is 6 weeks 0 days, the maximum age for the first dose is 14 weeks and 6 days.

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Infants aged 15 weeks to under 24 weeks

13. Vaccination with Rotarix® should not be initiated for infants aged 15 weeks and 0 days or older. Infants who have received their first dose of vaccine under 15 weeks and 0 days of age can receive their second dose of Rotarix®, which must be given with a minimum interval of 4 weeks and by 23 weeks and 6 days of age.

Infants aged 24 weeks or older

14. Rotarix® vaccine should not be given to an infant who is 24 weeks and 0 days of age or older.

15. It is preferable that the full course of two doses of Rotarix® be completed before 16 weeks of age, allowing at least four weeks between the first and second dose. Infants older than 14 weeks 6 days of age, who have not received a first dose of vaccine, should not be offered Rotarix®. Infants who receive the first dose before week 15 should complete the course before 24 weeks of age. If the course is interrupted, it should be resumed but not repeated, in line with the restrictions on timings above. Generally the first and second doses will be given at the scheduled 2 and 3 month immunisation visits. In practice the age restrictions mean that the first dose may be given at the 3 month visit and the second at the 4 month visit, but the first dose should not be given at the 4 month visit.

Contraindications

16. There are very few infants who cannot receive rotavirus vaccine. Where there is doubt, appropriate advice should be sought from an immunisation coordinator or consultant in health protection rather than withholding vaccination.

17. Rotarix® should not be given to:

- infants with a confirmed anaphylactic reaction to a previous dose of rotavirus vaccine;
- infants with a confirmed anaphylactic reaction to any components of the vaccine;
- infants with a previous history of intussusception;
- infants age 24 weeks or over;
- infants presenting for their first dose of Rotarix® at age 15 weeks or over;
- infants with Severe Combined Immunodeficiency (SCID) disorder;
- infants who have a malformation of the gastrointestinal tract that could predispose them to intussusception;
- infants with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.

18. Administration of rotavirus vaccine should be postponed in infants:
• suffering from acute severe febrile illness;
• suffering from acute diarrhoea or vomiting. This is to make sure that the vaccine is not regurgitated or passed through the intestines too quickly, which could reduce the effectiveness of the vaccine.

19. Other minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation.

Immunosuppression and HIV infection

20. Rotavirus vaccine should not be administered to infants known to have severe combined immunodeficiency (SCID). There is a lack of safety and efficacy data on the administration of rotavirus vaccine to infants with other immunosuppressive disorders. However, given the high risk of exposure to natural rotavirus, the benefits of administration is likely to outweigh any theoretical risks and therefore should be actively considered, if necessary in collaboration with the clinician dealing with child’s underlying condition.

21. The safety profile between Rotarix® and placebo is similar in infants with HIV infection and therefore vaccination is supported in HIV infected infants. Additionally, infants with unknown HIV status, but born to HIV positive mothers, should be offered vaccination.

22. There is a potential for transmission of live attenuated vaccine in Rotarix® from the infant to severely immunocompromised contacts through faecal material for at least 14 days (Anderson, 2008). However, vaccination of the infant will offer protection to household contacts from wild-type rotavirus disease and outweigh any risk from transmission of vaccine virus to any immunocompromised close contacts. Those in close contact with recently vaccinated infants should observe good personal hygiene.

Concomitant administration with other vaccines

23. Rotavirus vaccine can be given at the same time as the other vaccines administered as part of the routine childhood immunisation programme, including BCG, and so should ideally be given at the scheduled two month and three month vaccination visits (see above). Rotavirus and BCG can be given at any time before or after each other.

Consent

Pharmacy issues

Vaccine brand name and manufacturer


Presentation

26. Rotarix® is supplied as an oral suspension in pre-filled oral applicator.
27. The vaccine is presented as a clear, colourless liquid (a sucrose solution), free of visible particles, for oral administration.
28. The vaccine is ready to use (no reconstitution or dilution is required).
29. The vaccine is to be administered orally without mixing with any other vaccines or solutions.
30. The vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance. In the event of either being observed, discard the vaccine.
31. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Vaccine supply

32. The rotavirus vaccine should be ordered in the same way as other vaccines for the current national childhood vaccine programmes.
33. Vaccines for private prescriptions, occupational health use or travel are NOT provided through the national programmes and should be ordered from the manufacturers directly.

Storage

35. 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. Do not freeze. 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.
36. The vaccine should be used immediately after opening.

Vaccine stock management

37. Please ensure sufficient fridge space is available for the vaccine. Container dimensions are 42mm x 24mm x133mm. Each site holding vaccine is asked to review current stocks of all vaccines. 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.

38. 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.

39. Any cold chain failures must be documented and reported to the local immunisation co-ordinator. All cold chain incidents are considered a patient safety issue and should be reported to the National Patient Safety Agency as well as being reported through the local incident reporting scheme and the Health Board Immunisation Co-ordinator.

**Reporting of adverse reactions**

40. Suspected adverse reactions (ADR) to vaccines should be reported via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard). Chapter 9 of the Green Book gives detailed guidance which ADRs to report and how to do so. Additionally, Chapter 8 of the Green Book provides detailed advice on managing ADRs following immunisation.

41. 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.

**Intussusception**

42. Intussusception is a naturally-occurring condition, with a background annual incidence of around 120 cases per 100,000 children aged under one year (ref: https://extranet.who.int/aim_elearning/en/vaccines/rota/pdf/Acute_intussusception_WHO.pdf)

43. Research from some countries suggests that Rotarix® may be associated with a very small increased risk of intussusception, possibly 2 cases per 100,000 first doses given. The Rotarix® prescribing information includes this as a possible side effect. Even with this small potential risk, the benefits of vaccination in preventing the consequences of rotavirus infection outweigh any possible side effects.

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**Surveillance**

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

**Patient Group Directions**

45. The usual method for the supply and administration of vaccines in the routine childhood immunisation programme is via a Patient Specific Direction (PSD). 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. Where a PSD exists, there is no need for a PGD.

46. A template PGD is available for amendment by Health Boards to authorise appropriate health professionals to administer the vaccine where a PSD is not available: [http://howis.wales.nhs.uk/immunisation](http://howis.wales.nhs.uk/immunisation)

**Vaccine uptake data collection**

47. Collection of data needed to calculate uptake figures for rotavirus immunisation will take place, in the same way as all other routine childhood immunisation, through the Public Health Wales COVER reporting scheme. Quarterly and Annual COVER reports use data provided by the National Community Child Health Database, which is comprised of records from each Health Board Local Child Health administration database in Wales. Uptake figures for rotavirus immunisation will be reported for children reaching their first birthday each quarter.

**Child Health Information Systems**

48. Health Boards will be responsible for the commissioning of Child Health Information Systems (CHIS) and associated Child Health Records Department activities. Infants will be called for their immunisation against rotavirus at the same time as for their other immunisations offered at two and three months via the local CHIS or their GP surgery (whichever is the usual method of call/recall used in the area).

49. Healthcare professionals administering the vaccine must ensure that information on vaccines administered is documented in the general practice record and parent held record.

50. The healthcare professional must ensure that information on vaccines administered is submitted directly to the local Child Health Office within 7 days. In the initial stages of the programme this may require manual addition
of the rotavirus vaccine given to sheets returned to the local Child Health Records Department.

51. 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 and service arrangements

52. Changes confirmed to the GP contract for 2013/14 introduce a new item of service fee of £7.67 for a completed course of rotavirus vaccine for infants. The Directions to Local Health Boards as to the Statement of Financial Entitlements Directions, to be published shortly, contains the provisions (Section 8) on eligibility for payment to GMS contractors to commence from 1 July 2013.

53. A top-up funding allocation for the rotavirus 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.

Communications and information for parents and health professionals

54. An information leaflet for parents has been produced to support the introduction of the vaccine. This will be available on the Welsh Government web site at:

http://wales.gov.uk/topics/health/protection/immunisation/leaf/?lang=en

Hard copies can be ordered from the PHW Health Protection Library at: hplibrary@wales.nhs.uk or by telephone: 0845 606 4050.

55. In addition to the new Green Book chapter, materials for health care professionals e.g. training slides, FAQ’s can be accessed here:

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