Department of Health

Public Health England

NHS England

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NHS England Area Directors
Accountable Officer of Clinical Commissioning Groups
General Practitioners
Screening and Immunisation Leads
Directors of Public Health
Local Authority Chief Executives

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Dear Colleague,

Important changes to the national immunisation programme in 2013-14, and introduction of rotavirus vaccination for babies at two and three months

Following 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 to England's national immunisation programme 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 two and three months. It is the first in a new series of joint letters on public health issues from NHS England, Public Health England and the Department of Health, replacing the former series of letters from the Chief Medical Officer.

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 preventable diseases. A table providing the full details of these changes is at ***Annex A*** but, in summary they are as follows:

- **Meningitis C:** From June 2013, changes to the current schedule for administering the MenC conjugate vaccine. The second priming dose currently given at four months will be 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 (routine cohort) and 79 years (catch-up cohort) to protect against herpes zoster.

- **Childhood Flu:** The existing flu immunisation programme will be extended over a number of years to include all children aged two to 16 inclusive. In autumn 2013, immunisation will be offered to a limited age range of pre-school-aged children. Full details will be given in the annual flu immunisation letter.

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

We will be writing to you separately about the changes in England in relation to MenC, shingles and childhood flu 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 two and three months

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

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

The vaccine should be offered routinely to all babies at the age of two months and again at three 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:

New chapter for Rotavirus

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

JCVI Rotavirus Statement

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.

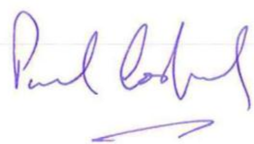
Future operations for Screening and Immunisation

The UK's successful national immunisation programme brings great benefits to the health of the 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.

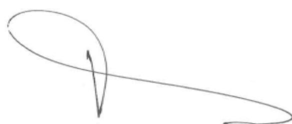
If you have any queries about the content of this letter please contact **Kate Davies, Head of Public Health, Armed Forces Health and Offender Health, NHS England** on kate.davies12@nhs.net .

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

CLINICAL GUIDANCE ON IMMUNISATION OF INFANTS AGAINST ROTAVIRUS

1. This guidance is based on advice from the Joint Committee on Vaccination and Immunisation (JCVI)[1], 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')[2] at the following generic link:

New chapter for Rotavirus

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 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 may be up to three to four a year. Rotavirus infection in children leads to severe diarrhoea, vomiting, stomach cramps, dehydration and mild fever and 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. 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 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

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[1] JCVI statement: JCVI advice on Rotavirus

[2] The rotavirus chapter can be found at: "The Green Book" reference

effective price. This advice was reiterated in 2011 following consideration of a further cost-effectiveness study.

6. In England, the NHS Constitution obliges health ministers to introduce new national vaccination programmes recommended by JCVI that are cost effective. 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.

7. Rotavirus vaccines, including the Rotarix® vaccine which will be used in the UK, 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.

8. The rotavirus immunisation programme in the UK will prevent a significant number of young infants from developing this infection. A published study[3] estimated that vaccinating a 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

9. The vaccine will be included in the childhood immunisation programme from 1 July 2013. All children scheduled to receive their primary vaccines at ages two and three months should be offered the vaccine, that is, two doses, four weeks apart.

Recommendations for use of the rotavirus vaccine (Rotarix®)

Administration

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

11. 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.

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

Dosage

Infants aged six weeks to under 15 weeks

13. The minimum age for the first dose of Rotarix® is six weeks 0 days, the maximum age for dose one is 14 weeks and six days.

Infants aged 15 weeks to under 24 weeks

14. 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

[3] Jit M, Edmunds WJ. Evaluating rotavirus vaccination in England and Wales. Part II. The potential cost-effectiveness of vaccination. Vaccine. 2007 May 16;25(20):3971-9. Epub 2007 Mar 13.

weeks and 0 days of age can receive their second dose of Rotarix®, which must be given with a minimum interval of four weeks and by 23 weeks and six days of age.

Infants aged 24 weeks or older

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

16. 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 15 weeks 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 by 24 weeks of age. If the course is interrupted, it should be resumed **but not repeated**, in line with the restrictions on timings above.

Contraindications

17. 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.

18. 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 over 24 weeks of age;
- 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.

19. 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.

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

Immunosuppression and HIV infection

21. 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. Given the high risk of exposure to natural rotavirus, however, 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.

22. However, 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.

23. 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. 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

24. 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

25. See Chapter Two of *Immunisation against infectious disease* (‘the Green Book’)

"The Green Book" - Chapter Two

Pharmacy issues

Vaccine brand name and manufacturer

26. Rotarix® – manufactured by GlaxoSmithKline.

Presentation

27. Rotarix® is supplied as an **oral** suspension in pre-filled **oral** applicator.

28. The vaccine is presented as a clear, colourless liquid, free of visible particles, for **oral** administration.

29. The vaccine is ready to use (no reconstitution or dilution is required).

30. The vaccine is to be administered **orally** without mixing with any other vaccines or solutions.

31. 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.

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

Vaccine supply (including ImmForm registration)

33. The rotavirus vaccine should be ordered online via the ImmForm website (www.immform.dh.gov.uk) and is distributed by Movianto UK (Tel: 01234 248631) as part of the national childhood immunisation programme.

34. Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm and are provided free of charge to NHS organisations. The vaccine will be available to order from June. Vaccines for private prescriptions, occupational health use or travel are NOT provided free of charge and should be ordered from the manufacturers. Further information about ImmForm is available at ImmForm Helpsheet or from the ImmForm helpdesk at helpdesk@immform.org.uk or Tel: 0844 376 0040.

35. For further information about vaccines available via ImmForm, please see ImmForm Helpsheet 13 (ImmForm Helpsheet)

Storage

36. 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.

37. The vaccine should be used immediately after opening.

Vaccine stock management

38. Please ensure sufficient fridge space is available for the new vaccine. 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.

39. 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.

40. Any cold chain failures must be documented and reported to the local immunisation co-ordinator and PHE/ImmForm as appropriate.

Reporting of adverse reactions

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

42. 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

43. Intussusception is a naturally-occurring condition, with a background annual incidence of around 120 cases per 100,000 children aged under one year (ref:

WHO Intussusception information

44. Research from some countries[4],[5] suggests that Rotarix may be associated with a very small increased risk of intussusception, possibly 2 cases per 100,000 first doses given, and 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.

Surveillance

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

Personal Child Health Record (the "Red Book")

46. Arrangements have been made for the Red Book record of childhood vaccinations to be amended to reflect the changes to the childhood schedule, including rotavirus vaccination. It is important that information about vaccinations 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.

Patient Group Directions

47. 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.

48. There are no plans to issue a national Patient Group Direction template for rotavirus vaccination as PSDs are the usual delivery method for childhood immunisations.

Vaccine uptake data collection

49. Monthly automated surveys from GP systems will run from the start of the programme (1 July 2013) so that July data (1/7/13 to 31/7/13 inclusive) will be collected in early August 2013 on ImmForm. A review will be conducted in March 2015 on continuing this sentinel collection. As a GP based collection, there should be little disruption caused by the new organisational structures that formally come into place in April 2013. The automated collection allows the collection of monthly

[4] Intussusception risk and health benefits of rotavirus vaccination in Mexico and Brazil. Patel MM, López-Collada VR, Bulhões MM, De Oliveira LH, et al. N Engl J Med. 2011 Jun 16;364(24):2283-92.

[5] Velázquez FR, Colindres RE, Grajales C, et al. Pediatr Infect Dis J. 2012 Jul;31(7):736-44. doi: 10.1097/INF.0b013e318253add3. Postmarketing surveillance of intussusception following mass introduction of the attenuated human rotavirus vaccine in Mexico.

data with minimal or no burden to the NHS and also gives quick and timely uptake figures.

50. A scope for a temporary ImmForm uptake data collection is attached at ***Annex C***. Clearance from the review of central returns (ROCR) has been applied for.

51. This data collection will run in parallel with the routine quarterly and annual COVER data collections which will evaluate rotavirus vaccine coverage for children at 12 months of age.

Child Health Information Systems

52. NHS England 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).

53. The provider must ensure that information on vaccines administered is documented in the general practice record.

54. The provider must ensure that information on vaccines administered is submitted directly to any relevant population immunisation register, in most areas the CHIS.

55. Following an immunisation session/clinic or individual immunisation, local arrangements should be made for the timely transfer of data onto the relevant CHIS. Where possible this should aim to be within two working days.

56. Arrangements will also 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

57. Changes confirmed to the GP contract for 2013/14 introduce a new item of service fee of £7.63 for a completed course of rotavirus vaccine for infants. The Statement of Financial Entitlements published 28 March contains the provisions (Section 12) on eligibility for payment to GMS contractors to commence from 1 July 2013. NHS England will be working to agree equivalent arrangements with PMS and APMS contractors who provide childhood immunisation services. NHS England intends to support the calculation of payments for rotavirus vaccination using the new Calculating Quality Reporting Service (CQRS) wherever possible to minimise the reporting requirements for GP practices. Further guidance on the GP contract changes and role of CQRS was published by NHS Employers on 2 April 2013.

Communications and information for parents and health professionals

58. Information flyers and leaflets for parents have been 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.

59. Materials for health care professionals can be accessed here: Professional Rotavirus Information

60. Materials for parents can be accessed here: Parents Rotavirus Information

Annex C

Scope of Temporary sentinel rotavirus immunisation coverage survey

This paper sets out the scope for the temporary sentinel data collections that will be undertaken as part of the rotavirus vaccination programme starting in 2013.

Aim

1. To automatically collect monthly uptake data from sentinel GP practices (i.e. GP practices that have automated data extraction facilities) to:

- regularly monitor the progress of the vaccination programme by Department of Health (DH), NHS England and Public Health England (PHE);
- support assessment by DH, NHS England and PHE of the delivery of the programme;
- potentially identify areas where coverage of first or second dose is low,
- provide epidemiological data to allow assessment of the impact of the programme;
- provide data for vaccine safety assessment;
- provide information to the public and ministers.

Data to be collected

2. Data will be collected on the following:

- Denominator: the number of infants in a GP practice who, in the survey month, reach 25 weeks of age;
- Numerators: number of infants in the denominator who received a) a first dose and b) a second dose of Rotarix® from six weeks of age up to 24 weeks of age, including vaccinations given by other healthcare providers.

3. Denominator and numerator data will allow uptake rates to be calculated. The count of doses given will help in validating GP payments and help in vaccine supply and efficiency analysis. The possibility of including denominator and numerators (dose one and dose two), broken down by gender and ethnicity will also be explored with suppliers.

4. Monthly automated surveys will run from the start of the programme (1 July 2013), so that July data (1/7/13 to 31/7/13 inclusive) will be collected in early August 2013. A review will be conducted in March 2015 on continuing the sentinel collection. As a GP practice-based collection, there should be little disruption caused by new organisational structures that formally come into place in April 2013. The automated collection allows us to collect monthly data with minimal or no burden to the NHS and giving quick and timely uptake figures. This data collection will run in parallel to a proposed COVER data collection.

5. Data will be extracted automatically for each monthly survey as follows:

Survey Month	Data from Date (inclusive)	Data to Date (inclusive)
August 2013	01 July 2013	31 July 2013
September 2013	01 August 2013	30 August 2013
October 2013	01 September 2012	31 September 2012
November 2013	01 December 2012	30 December 2012
etc	Etc	etc

NOTES

1. *All surveys are from the **start of the calendar month** (inclusive)*
2. *Each survey includes **data up until the survey month end** (inclusive)*

6. Collecting these data will allow monthly assessment of rotavirus immunisation coverage.

7. The source of data will be automated collections from GP practices to ImmForm and will be sentinel i.e. data will only be collected from practices with automated data extraction facilities. Data from GP practices included within the sentinel scheme can be aggregated by NHS England structures (Clinical Commissioning Groups (CCGs) and Area Teams (ATs)), through the ImmForm website, to:

- see coverage rates at local, regional and national levels;
- compare uptake with other anonymous CCGs and ATs;
- view data and export data into Excel, for further analysis.

8. The survey will comprise of:

- Monthly data collections from the start of the programme (July 2013) to provide complete data at the GP level. These data will allow DH, NHS England and PHE to assess the progress of the vaccination programme.

End of the Survey

9. The continuation of the sentinel collection will be reviewed in March 2015.