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The Scottish Government
Riaghaltas na h-Alba

LEGACY 2014
XX COMMONWEALTH GAMES
SCOTLAND

Dear Colleague

IMPORTANT CHANGES TO THE SCOTTISH IMMUNISATION PROGRAMME IN 2013-14 – ROTAVIRUS IMMUNISATION PROGRAMME

1. This letter provides details of the rotavirus immunisation programme which will be introduced into the routine childhood immunisation programme from 1 July 2013 for infants aged 2 and 3 months.

2. Rotavirus is a very common and potentially serious infection of the gut in young babies. The vaccine will be offered routinely to all infants aged 2 months, and again at 3 months (that is, 2 doses 4 weeks apart) when they attend for their first and second routine childhood immunisations.

3. A new Green Book chapter on rotavirus, including clinical advice and information about the vaccine has been included in *Immunisation against infectious disease 2006 (*'the Green Book'*)*, available to read at http://immunisation.dh.gov.uk/category/the-green-book/.

From the Chief Medical Officer
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1 May 2013

SGHD/CMO(2013) 4

For Action
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Medical Directors, NHS Boards
Directors of Nursing & Midwifery, NHS Boards
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Directors of Public Health
General Practitioners
Practice Nurses
Immunisation Co-ordinators
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For Information
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FURTHER CHANGES TO THE SCOTTISH IMMUNISATION PROGRAMME

4. The Joint Committee on Vaccination and Immunisation (JCVI) has published a statement in relation to rotavirus and the vaccine, which is available at:

http://immunisation.dh.gov.uk/tag/httpwww-dh-gov-ukabjcvidh_128726/

The introduction of the rotavirus programme is part of a wider programme of changes to the routine immunisation programme in Scotland and across the UK. They are:

- From June 2013, changes to the current schedule for administering the Men C vaccine, including the removal of the second dose, given at 4 months and the addition of a dose at the S3 booster appointment.
- From September 2013, the introduction of a shingles vaccine for people aged 70 years (routine cohort) and 79 years (catch-up cohort) this year to protect against herpes zoster
- From Autumn 2013, phased implementation of the seasonal flu programme to extend to healthy children aged 2 to less than 17 years will begin. Vaccination will be offered to some pre-school children, accompanied by a limited pilot programme involving primary school children.

5. The JCVI has endorsed each of these changes to the national immunisation programme, and we will be writing to you separately about each of the changes prior to their implementation. Timings for the introduction of these changes are set out at **Annex D**.

6. Scotland's successful immunisation programme brings great public health benefits. We do not underestimate the additional work required to implement the forthcoming changes to the programme and we would like to take this opportunity to thank you all very much for your efforts in delivering these programmes.

Yours sincerely

Harry Burns *Ros Moore* *Bill Scott*

SIR HARRY BURNS
Chief Medical Officer

ROS MOORE
Chief Nursing Officer

PROFESSOR BILL SCOTT
Chief Pharmaceutical Officer

ANNEX A

CLINICAL GUIDANCE ON IMMUNISATION OF INFANTS AGAINST ROTAVIRUS

1. The Joint Committee on Vaccination and Immunisation (JCVI) statement about rotavirus and rotavirus vaccine is available at:

http://immunisation.dh.gov.uk/tag/httpwww-dh-gov-ukabjcvidh_128726/

This guidance is based on advice from the 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') http://immunisation.dh.gov.uk/category/the-green-book/

Background to the introduction of rotavirus vaccine

2. An estimated 55,000 episodes of rotavirus induced gastroenteritis occur each year in children of less than 5 years in Scotland and approximately 1200 of these children are hospitalised. Although deaths from rotavirus in the UK are rare and are difficult to quantify accurately, there are likely to be approximately 3 to 4 a year (the 3 to 4 are based on a study for England and Wales by Jit *et al)* . Rotavirus infections in children and adults leads to severe diarrhoea, vomiting, stomach cramps, dehydration and mild fever and is likely to last approximately 3 to 8 days.

3. 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 4 years of age. Infections are often recurrent, and many children experience infection on one or more occasions by 3 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. The JCVI advised in 2009 that the licensed rotavirus vaccines would have a significant impact in 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.

Timing

6. The vaccine will be included in the childhood immunisation programme from 1 July 2013. All babies scheduled to receive their primary vaccines at ages 2 and 3 months should be offered the vaccine, that is, 2 doses, 4 weeks apart. This will apply to babies born on or after 1 May 2013.

Recommendations for use of the vaccine

Administration

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

8. 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.

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

Dosage

- First dose of 1.5 ml of Rotarix® vaccine at 2 months (approximately 8 weeks) of age.
- Second dose of 1.5 ml at least 4 weeks after the first dose.

10. It is preferable that the full course of 2 doses of Rotarix® be completed before 16 weeks of age, allowing at least 4 weeks between the first and second dose. Infants older than 15 weeks of age (i.e older than 14 weeks and 6 days), who have not yet received their first dose of vaccine, should not be commenced on Rotarix®. Infants who receive the first dose before week 15 should complete the course by 24 weeks of age (i.e. by 23 weeks and 6 days). If the course is interrupted, it should be resumed but not repeated, provided that the second dose can be given before the 24 week cut-off.

Contraindications

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

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 older than 15 weeks of age (i.e. older than 14 weeks and 6 days), who have not yet received their first dose of vaccine, should not be commenced on Rotarix®. Infants who receive the first dose before week 15 should complete the course by 24 weeks of age (i.e. by 23 weeks and 6 days)
- infants with severe combined immunodeficiency (SCID) disorder
- infants who have a malformation of the gastrointestinal tract that could predispose them to intussusception; and
- infants with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency

Administration of rotavirus vaccine should be postponed in infants:

- suffering from acute severe febrile illness
- suffering from acute diarrhoea or vomiting. This is to ensure that the vaccine is not regurgitated or passed through the intestines too quickly, which could reduce the effectiveness of the vaccine.

Immunosuppression and HIV infection

12. Rotavirus vaccine should not be administered to infants known to have severe combined immunodeficency (SCID). There is a lack of safety and efficacy data on the administration of rotavirus vaccine to infants with other immuno-suppressive disorders. Given the high risk of exposure to natural rotavirus, however, the benefits of administration are likely to outweigh any theoretical risks and therefore should be actively considered, if necessary in collaboration with the clinician dealing with the child's underlying condition. The safety profile between Rotarix® and placebo is similar in infants with HIV infection and therefore vaccination is advised in HIV infected infants. Additionally, infants with unknown HIV status, but born to HIV positive mothers, should be offered vaccination.

13. There is a potential for transmission of live attenuated vaccine in Rotarix® from the infant to severely immuno-compromised 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 risks from transmission of vaccine virus to any immunocompromised close contacts. Additionally, those in close contact with recently vaccinated infants should observe good personal hygiene. In cases where an infant may come into contact with severely immunocompromised contact, the vaccine should be considered in discussion a with relevant specialist physician.

Concomitant administration with other vaccines

14. 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 2 month and 3 month vaccination visits (see above).

Consent

15. See Chapter 2 of *Immunisation against infectious disease* ('the Green Book')

https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book

Vaccine issues

Vaccine brand name and manufacturer - Rotarix® – manufactured by GlaxoSmithKline.

Presentation

16. Rotarix® is supplied as an oral suspension in pre-filled oral applicator. The vaccine is presented as a clear, colourless liquid, free of visible particles, for oral administration. The vaccine is ready to use (no reconstitution or dilution is required). The vaccine should be administered orally without mixing with any other vaccines or solutions. 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. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Vaccine supply

17. The rotavirus vaccine should be ordered in the usual way from NHS Board vaccine holding centres

Storage

18. 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. 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.

Vaccine stock management

19. Please ensure sufficient fridge space is available for the new vaccine. Each site holding vaccine is asked to review current stocks of all vaccines. No more than 2 to 4 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. 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.

Reporting of adverse reactions

20. 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 about which ADRs to report and how to do so. Additionally, Chapter 8 of the Green Book provides detailed advice on managing ADRs following immunisation.

Intussusception

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

http://www.who.int/vaccine_safety/committee/topics/rotavirus/rotarix_and_rotateq/Dec_2010/en/index.html

Research from some countries[1],[2] 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 effects. The benefits of vaccination in preventing the consequences of rotavirus infection outweigh this small potential risk in young children. Because of the potential risk, and to reduce the likelihood of a temporal association with rotavirus, the first dose of vaccine should not be given after 15 weeks of age.

Health Information Systems (SIRS and GP)

22. The Scottish Immunisation Recall System (SIRS) will be adapted to provide full functionality for the new rotavirus vaccination and discontinue invitations for the second MenC dose at 4 months of age. NHS boards should ensure vaccine batch numbers are entered into the SIRS system, to enable rapid identification of specific children who have been given a particular batch. GP IT systems will also be adapted to accommodate the new vaccine programme changes.

Patient group directives

23. The requirement for Patient Group Directions is described in HDL(2001)7 available from http://www.sehd.scot.nhs.uk/mels/HDL2001_07.HTM. The use of PGDs for administration of vaccines is described in detail in chapter 5 'Immunisation against Infectious Disease' http://media.dh.gov.uk/network/211/files/2012/07/Chapter-5.pdf

A specimen Patient Group Direction (PGD), for administration of Rotarix® is under development and will shortly be available on the Health Protection Scotland website.

Contractual Arrangements

24. We ask Boards to ensure that practice attached staff are appropriately engaged in assisting practices to deliver immunisations.

The existing Childhood Immunisation DES will be updated to reflect that claims for payment can be made for rotavirus vaccination. Payment rates have been agreed with SGPC at £7.67 per dose within the course of 2 immunisations.

As previously notified, SGHSCD is meeting the vaccine purchase costs associated with this programme and Boards are meeting the delivery costs, including GP costs, from their baseline resources.

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

[2] 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.

ANNEX B

COMMUNICATIONS AND INFORMATION FOR PARENTS AND HEALTH PROFESSIONALS

Further information about the full range of immunisations and vaccines in Scotland is available on the public information website: www.immunisationscotland.org.uk

The public information leaflet "Rotavirus – help protect your baby against severe diarrhoea and vomiting" will be distributed locally, and can also be accessed here: http://www.immunisationscotland.org.uk/vaccines-and-diseases/rotavirus.aspx.

It will also soon be available in Polish, Chinese, Urdu and easy read format here: http://www.immunisationscotland.org.uk/vaccines-and-diseases/rotavirus.aspx

This resource is available in Urdu, Chinese and Polish, and in Easy Read format, NHS Health Scotland is happy to consider requests for other languages and formats. Please contact 0131 536 5500 or email nhs.healthscotland-alternativeformats@nhs.net

ANNEX C

EDUCATIONAL TOOLS FOR HEALTH PROFESSIONALS

NHS Education for Scotland in partnership with Health Protection Scotland has produced a number of educational resources to support registered healthcare practitioners involved in this programme. The resources include training slides (with accompanying notes) and a 'questions and answers' leaflet. These are available on the NHS Education for Scotland website at:

http://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-protection/immunisation/rotavirus.aspx

ANNEX D

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

Programme	June 2013	July 2013	August 2013	Sept 2013	Oct 2013	Nov 2013	Dec 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 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.