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The Scottish Government

Dear Colleagues

TEMPORARY PROGRAMME OF PERTUSSIS (Whooping Cough) VACCINATION OF PREGNANT WOMEN

1. We are writing to you about the introduction of a temporary programme to vaccinate pregnant women against pertussis to protect their infants. The programme will begin on 15 October, however opportunistic immunisation should begin as soon as possible following receipt of this letter.

Background

2. As you will be aware, there has been a considerable increase in pertussis activity in the UK starting in mid-2011. The current national outbreak is the largest seen in the UK for over a decade. There have been 1037 laboratory confirmed cases, 65 of these cases have been in infants under 3 months of age. A table demonstrating the rise in pertussis cases in Scotland is attached at Annex B.

3. The highest morbidity and mortality occurs in infants too young to be protected through routine vaccination. There have been no reported deaths across Scotland to date in 2012. There have been 9 deaths so far this year in infants below 3 months in England and Wales.

4. A rise in pertussis with deaths in infants has also been seen in the United States where a similar

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For action
Chief Executives, NHS Boards
Medical Directors, NHS Boards
Directors of Nursing & Midwifery, NHS Boards
Directors of Pharmacy
Directors of Public Health
General Practitioners
Practice Nurses
Immunisation Co-ordinators
CPHMs
Scottish Prison Service
Scottish Ambulance Service

For information
Chairs, NHS Boards
Infectious Disease Consultants
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recommendation for routine vaccination of pregnant women has been made by the Advisory Committee on Immunisation Practices. For more information see: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6041a4.htm.

Key Points

5. The Joint Committee on Vaccination and Immunisation (JCVI) has agreed that a temporary programme of immunisation of women in later stages of pregnancy be implemented forthwith. The purpose of vaccinating women in the later stages of pregnancy is to transfer pertussis-specific antibodies from the mother to her baby to protect the infant before routine immunisation starts at 8 weeks of age. The temporary programme will last for 6 months in the first instance.

6. The committee has reviewed the epidemiology of the disease and the safety and effectiveness of the proposed approach. The committee is of the opinion that vaccinating pregnant women is likely to be the most effective strategy to provide protection to newborn infants and that there is no evidence of excess risk to the mother or her baby. JCVI will keep this temporary programme under review. The MHRA will monitor the safety of the programme.

7. The Committee's full advice will be published in due course on the following website: http://www.dh.gov.uk/health/about-us/public-bodies-2/advisory-bodies/jcvi/.

8. In Scotland, it is expected that vaccination will in most cases by provided through General Practice. Vaccination against pertussis should be provided for all pregnant women from 28 weeks onwards. Vaccination against pertussis can be given at the same time as vaccination against influenza that is also recommended for pregnant women.

9. If pregnant women attending for vaccination are at or over 28 weeks gestation, they should have both the pertussis and the flu vaccine.

10. The programme will be reviewed at the end of the six-month period and we will provide advice on whether it should be continued beyond that point. See **Annex A** for detailed clinical guidance.

Vaccine supply

11. The Department of Health has taken steps to ensure that sufficient stocks of **Repevax** are available to rapidly implement a six-month interim vaccination programme of pregnant women from week 28 of their pregnancy. The Department of Health has also identified options to secure further supplies if needed. Vaccine can be ordered from NHS Board vaccine holding centres. Holding centres can order vaccine in the usual way, via ImmForm.

Contractual Arrangements

12. Vaccination of pregnant women should be provided by General Practitioners in the same way as vaccination against seasonal flu. The existing seasonal flu DES will be updated to reflect that claims for payment can be made for pertussis vaccination. Payment rates have been agreed at a UK level by NHSE and GPC, based on the current Scotland rate for influenza for under 65s of £7.67 per vaccination.

Monitoring uptake and impact on incidence of pertussis

13. Every effort should be made by medical practitioners, midwives and others to encourage pertussis vaccination for pregnant women and maximise its uptake. It is also important that data on vaccination is shared between GPs and midwives timeously, ideally within 10 working days.

14. Arrangements are being put in place to ensure that we can monitor uptake of vaccination by pregnant women. GP practices will be required to provide Health Boards with immunisation data and will continue to collect data on the changes in pertussis epidemiology, by age.

Information materials

15. An information leaflet for pregnant women has been produced which gives full and comprehensive information about the programme and vaccine. Leaflets and posters are being distributed to GP Practices, Maternity Units, Pharmacies and Community Centres. Should you require a further supply of these materials, please contact: nhshealthscotland-publications@nhs.net. This information will also be available on the Immunisation Scotland website at http://www.immunisationscotland.org.uk/ from Monday 1 October 2012.

16. NHS Education for Scotland and Health Protection Scotland have produced training slides to help support midwives and other health professionals involved in raising the issue of vaccination against pertussis with pregnant women. These slides will be available shortly at:

http://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-protection/immunisation/pertussis-(whooping-cough).aspx

Clinical Guidance

17. Annex A to this letter provides clinical guidance for professionals on the vaccination of pregnant women against pertussis. This should be read in conjuction with the existing advice provided within the Green Book.

Yours sincerely

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Annex A

Clinical guidance on immunisation of pregnant women against pertussis

This guidance is based on advice from the Joint Committee on Vaccination and Immunisation[1] and supplements existing guidance in the chapter on pertussis in *Immunisation against infectious disease* ('the Green Book')[2]. The guidance should be read in conjunction with the existing guidance in the Green Book. Recommendations regarding vaccines given in Green Book chapters may differ from those in the Summary of Product Characteristics (SPC) and Patient Information Leaflet. When this occurs, the recommendations in the Green Book are based on current expert advice received from the JCVI and should be followed. These Green Book recommendations and/or further advice from the Scottish Government should also be reflected in Patient Group Directions (PGDs).

The aim of the temporary programme is to provide indirect protection against pertussis to infants by offering immunisation to their pregnant mothers such that they pass pertussis-specific antibodies to their babies while in the womb. During the course of the temporary immunisation programme the following guidance should be followed.

Recommendations for use of the vaccine

Immunisation with a single dose of Repevax® vaccine (dTaP/IPV) should be offered to pregnant women, ideally at a routine antenatal visit, in the period weeks 28 to 38 (inclusive) of pregnancy; the optimal time is in the period weeks 28 to 32 (inclusive). Immunisation during weeks 28 to 38 of pregnancy is likely to maximise transplacental transfer of anti-pertussis antibodies from the pregnant woman to foetus. Pregnant women who are now beyond week 38 of pregnancy should also be offered immunisation up to the onset of labour so that some direct protection may still be provided to the infant. Vaccination may be offered to new mothers who have never previously been vaccinated against pertussis, up to when their child receives their first vaccination. A single dose of Repevax® is recommended in these circumstances and should ideally be given as soon as possible following the birth.

The advice from JCVI differs from that in the SPC and Patient Information Leaflet for Repevax® which states that its use is not recommended during pregnancy. This statement follows the routine exclusion of pregnant women from clinical trials, and not because of any specific safety concerns or evidence of harm in pregnancy. The advice from JCVI should be followed. There is no

[1]The advice from JCVI can be found in the minute of JCVI August 2012 teleconference at: http://transparency.dh.gov.uk/category/minutes-2/jcvi-minutes/
[2]The pertussis chapter can be found at: http://immunisation.dh.gov.uk/green-book-chapters/chapter-24/

evidence of risk to pregnancy or the infant with inactivated vaccines such as Repevax®. Use of Repevax® is not contraindicated in pregnancy and does not affect breast-feeding.

A single 0.5ml dose of Repevax should be given irrespective of the number of fetuses in the pregnancy.

Women who become pregnant again while the programme is in place should be offered immunisation during each pregnancy to maximise transplacental transfer of antibody.

Pregnant women who have received immunisation against pertussis, tetanus, diphtheria and/or polio relatively recently (for example, within the last few months) should also be offered immunisation, but with a gap of at least one month between immunisations. Although cumulative doses may increase the likelihood of injection site reactions or fever, this is far outweighed by the expected benefit.

At present, the emphasis of this programme is on the vaccination of pregnant women as it is believed this will provide the maximum protection for vulnerable neonates. It is not currently recommended that other family members are vaccinated at the same time as the priority for currently available vaccine stocks is pregnant women.

Contraindications

There are very few medical reasons why Repevax® should not be given. Repevax® should not be given to pregnant women who have had:

- a confirmed anaphylactic reaction to a previous dose of pertussis, diphtheria, tetanus or polio vaccines;
- a confirmed anaphylactic reaction to any component of the vaccine or to any substances carried over from manufacture (formaldehyde, glutaraldehyde, neomycin, streptomycin, polymyxin B or bovine serum albumin);
- an encephalopathy (brain disorder) of unknown origin within 7 days of previous immunisation with pertussis-containing vaccine.

If the pregnant women is acutely unwell and has a fever, immunisation should be postponed until the patient has recovered. This is to avoid wrongly associating any cause of fever, or its progression, with the vaccine and to avoid increasing any pre-existing fever. Having a minor illness without a fever (e.g. a cold) is not a reason to delay immunisation.

Concomitant administration with influenza vaccine or anti-D treatment

There are no reasons why Repevax® cannot be administered at the same time as influenza vaccine. However, influenza immunisation should not be delayed until week 28 or after of pregnancy in order to give Repevax® at the same visit. Pregnant women are at risk of severe illness at any stage of pregnancy from influenza. There are no reasons why Repevax® cannot be administered at the same time as anti-D treatment.

Annex B