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To:
General Practitioners
Chief Executives of Strategic Health Authorities
Chief Executives of Primary Care Trusts
Chief Executives of NHS Trusts
PCT Directors of Public Health
Medical Directors of NHS Trusts
Directors of Nursing
Chief Pharmacists/Pharmaceutical Advisers of PCTs
Chief Pharmacists of NHS Trusts
Lead Nurses at PCTs

Dear Colleague

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

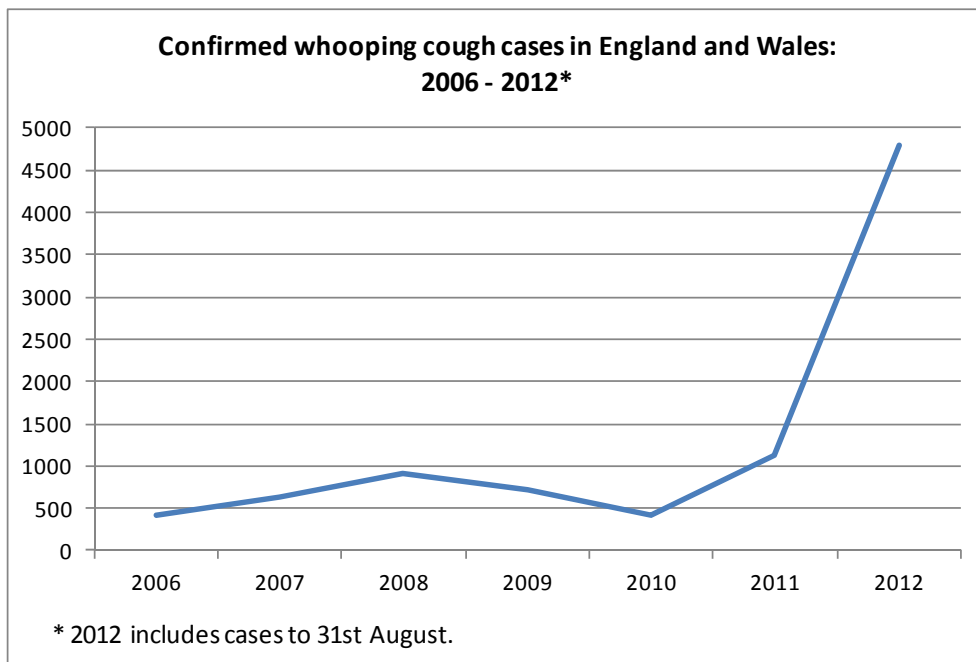
We are writing to you about the introduction of a temporary programme to vaccinate pregnant women against pertussis to protect their infants. This programme should be implemented quickly following receipt of this letter.

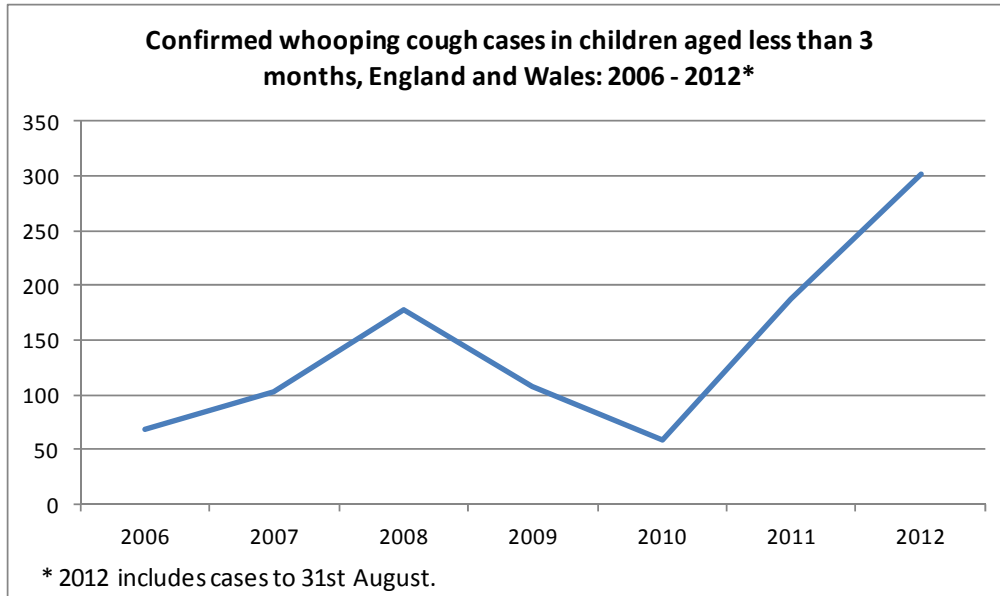
There has been a considerable increase in pertussis activity in the UK starting in mid-2011. The current national outbreak is the largest seen in the UK for over a decade with a total of 4791 cases confirmed so far this year in England and Wales. The greatest numbers of cases are in adolescents and young adults but the highest rates are in infants less than three months of age. The latter are at highest risk of complications and death and are too young to be protected through routine

vaccination. There have been nine deaths in England up to 1st September this year – all in infants below the age of vaccination.

A recent rise in whooping cough has been reported from a number of other countries, including the USA where deaths in infants have also been seen. In June 2011, the US Advisory Committee on Immunisation Practices recommended that pregnant women who have not been previously boosted as adults are offered a dose of pertussis containing vaccine.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6041a4.htm>.





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 the programme is to boost antibodies in the vaccinated women in late pregnancy, so that pertussis specific antibodies are passed from the mother to her baby. This aims to protect the infant before routine immunisation can be started at eight weeks of age. The committee has reviewed the epidemiology of the disease and the safety and effectiveness of the proposed approach. The committee was convinced 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 risk to the mother or her baby. However, while providing vital protection for infants, this programme will not have any effect on transmission of pertussis across the population. The Health Protection Agency will continue to monitor the levels of whooping cough and JCVI will keep this temporary programme under review. As with all medicines and vaccines the MHRA will monitor the safety of the programme. The JCVI stated that: "The committee has no concerns about the safety of use of this vaccine at any stage in pregnancy."

The Committee's full advice will be available at <http://transparency.dh.gov.uk/category/minutes-2/jcvi-minutes/>

Advice to pregnant women on this vaccination programme can be provided wherever antenatal care is available. At present, antenatal care is provided by GPs and midwives in various community settings and in hospitals. Vaccination against pertussis, combined with tetanus, diphtheria and polio (Repevax®) should be provided for all pregnant women ideally between 28 and 38 weeks of pregnancy.

David Flory, Deputy NHS Chief Executive, is today writing simultaneously to commissioners to outline the commissioning arrangements for PCTs including details of a nationally agreed service specification with the General Practitioners Committee of the BMA, which PCTs should use locally with GP practices to establish vaccination services quickly. The agreement does not prohibit PCTs from making additional or alternative arrangements for vaccine services from other suitably qualified and experienced providers, for example, local midwifery services.

Vaccination against influenza is also recommended for all pregnant women and pertussis vaccination can be given at the same time. However, vaccination against influenza should not be delayed to be given alongside the pertussis vaccination. Where influenza vaccination has been given before 28 weeks of pregnancy, pertussis vaccine should be given separately after 28 weeks, in line with the clinical guidance in Annex A.

This programme will be kept under review and we will announce whether it will be continued or stopped.

See Annex A for detailed clinical guidance.

Vaccine supply

We have accepted the JCVI advice and accordingly have taken steps to ensure that sufficient stocks of **Repevax®** are available to rapidly implement an interim vaccination programme of pregnant women from week 28 of their pregnancy. We have also identified options to secure further supplies if needed.

Vaccination will need to be undertaken wherever antenatal care is provided. At present, antenatal care is provided by GPs and midwives in various community settings and in hospitals. Vaccine can be ordered for delivery to appropriate locations, such as GP practices and hospital pharmacies via ImmForm. See Annex B for more details about how to order the vaccines.

Monitoring uptake and impact on incidence of pertussis

We anticipate that uptake in pregnant women will be at least as high as that achieved for flu vaccination last year. Furthermore, we anticipate that uptake of flu vaccination will increase in 2012/13 compared to the previous year and that the rates of pertussis vaccination will match it. Every effort should be made by medical practitioners, midwives and others to maximise the uptake of pertussis-containing vaccine.

We will monitor vaccine uptake of Repevax® for pregnant women with a monthly data collection from PCTs through ImmForm. See Annex C for more details.

Communications

Informal research conducted recently among pregnant women indicated that there is little awareness of the current outbreak and limited knowledge of the potential severity of pertussis in neonates. We will run a communications campaign to inform pregnant women about the need for vaccination and to stimulate take up. The campaign will run from the end of October until February (with a break at Christmas) and will include advertising in women's and pregnancy magazines and on appropriate websites. We will also run feature-led PR to inform women about the potential severity and complications of pertussis for infants, and to underline the importance of maternal vaccination as a preventative measure. We will also circulate content to relevant private and voluntary sector organisations and outlets, eg NCT, Mumsnet,

Netmums, Bounty and Babycentre, for distribution via their own channels to broaden the reach of our messaging.

For healthcare professionals we will use DH and NHS channels and heads of profession to convey key messages and clinical information about pertussis. We will also work closely with professional stakeholder organisations and use their channels to signpost medical practitioners, midwives and others to relevant information.

Information materials

A range of printed materials is being published to support the programme. These materials will be available initially as downloadable pdfs via <http://immunisation.dh.gov.uk/> . Printed copies, which will be made available as soon as possible, can be pre-ordered from <http://www.orderline.dh.gov.uk> or by calling 0300 123 1002 Minicom 0300 123 1003.

The materials comprise:

- a flyer that provides the information that most expectant mothers will need to know before having the vaccination
- a leaflet that goes into more detail on the programme in a question and answer format
- a factsheet that gives the scientific background to the need for and the development of the programme, and
- a poster that aims to raise awareness of the vaccination.

A set of power point training slides will be made available through the Department of Health website.

Finally, a short video by Professor David Salisbury, Director of Immunisation at the Department of Health, describing the vaccination programme will be available at

<http://immunisation.dh.gov.uk/>

Yours sincerely

A handwritten signature in black ink that reads 'Sally C Davies'. The signature is fluid and cursive, with the first name 'Sally' being more prominent.

**PROFESSOR DAME SALLY C DAVIES
CHIEF MEDICAL OFFICER
CHIEF SCIENTIFIC ADVISER**

A handwritten signature in black ink that reads 'Vivienne J Bennett'. The signature is written in a cursive style with a large, sweeping initial 'V'.

**MRS VIVIENNE J BENNETT
DIRECTOR OF NURSING
PRINCIPAL ADVISOR ON PUBLIC HEALTH NURSING**

A handwritten signature in black ink that reads 'K.W. Ridge'. The signature is written in a cursive style with a large, sweeping initial 'K'.

**DOCTOR KEITH WILLIAM RIDGE
CHIEF PHARMACEUTICAL OFFICER**

Annex A – Clinical guidance

Clinical guidance on immunisation of pregnant women against pertussis

This guidance is based on advice from the Joint Committee on Vaccination and Immunisation¹ 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. 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 DH should also be reflected in PGDs.

The aim of the temporary programme is to provide indirect protection against pertussis to infants by offering immunisation to their pregnant mothers to boost antibody levels such that they pass more pertussis specific antibodies to their babies through the placenta. 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 levels of anti-pertussis antibodies in the mother in time for optimal transplacental transfer from the pregnant woman to foetus. Pregnant women who are now beyond week 38 of pregnancy should be offered immunisation up to the onset of labour so that some

¹The 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/>

direct protection may still be provided to the infant. In addition, vaccination of pregnant women, even after 38 weeks, will reduce the risk of the mother contracting pertussis in the post-partum period and therefore prevent her from infecting her 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.

The advice from JCVI differs from that in the Summary of Product Characteristics 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 evidence of risk to pregnancy or the infant with inactivated viral or bacterial vaccines or toxoids such as those against diphtheria, tetanus, polio and pertussis in Repevax®. Use of Repevax® in pregnancy is not contraindicated and breast-feeding should continue if that is the mother's wish.

A single 0.5ml dose of Repevax should be given irrespective of the number of foetuses 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 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 outweighed by the expected benefit to the infant.

²The pertussis chapter can be found at: <http://immunisation.dh.gov.uk/green-book-chapters/chapter-24/>

Contraindications

There are very few medical reasons why Repevax® should not be given. The vaccine is suitable for those with an egg allergy. 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 seven days of previous immunisation with pertussis-containing vaccine.

If the pregnant woman is acutely unwell and has a fever, immunisation should be postponed until she 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 – Vaccine ordering (including ImmForm registration)

Repevax® for the vaccination of pregnant women will be available to order through ImmForm. PCTs will decide locally how they will implement this programme (see David Flory's letter). Some vaccine may be ordered by hospital pharmacies in order to allow access to the vaccine for midwives. Many hospital pharmacies already have ImmForm accounts (e.g. for ordering of HPV vaccine). If hospital pharmacies do not have an ImmForm account, this will need to be set up by emailing the ImmForm Helpdesk at ImmForm@dh.gsi.gov.uk. GP practices will also be able to order Repevax® through ImmForm as part of this programme. Most GP practices already have an ImmForm account and stocks of Repevax.

National programme vaccines are distributed by Movianto. For organisations which have a NHS Movianto account they can self-register on ImmForm by going to the following URL: <https://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 at hand and a NHS email address. This process should take less than one day.

If we do not have a NHS Movianto account number for the organisation (a private Movianto account number is not suitable, as these are for billable private purchases only) or if the Movianto account number is not known, please email the following information to the immform@dh.gsi.gov.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 email address

If we are unable to find a Movianto account number for an organisation we will need to arrange one. This takes 2-4 working days to arrange and we will email login details as soon as the account is set up.

Please note all delivery addresses should have suitable cold storage for vaccines and have local procedures for ensuring the vaccines are stored appropriately immediately after delivery. See the Green Book Chapter 3 for more information on the storage, distribution and disposal of vaccines (<http://immunisation.dh.gov.uk/category/the-green-book/>).

For more information on ImmForm, including a number of help sheets, please see <http://immunisation.dh.gov.uk/immform-helplets>.

Annex C – Vaccine uptake data collections

Because PCTs will decide how to implement this programme locally, the most appropriate data collection is a collection from PCTs (including PCT-based Care Trusts), similar to HPV.

Surveys will be monthly and will be collected via ImmForm. We aim to start collecting data from November onwards and carry on until the end of February. As PCTs will cease to exist from 1 April 2013 onwards, we will review the need for further data collections as part of the on-going review of the programme.

The proposed surveys and their collection schedules are as follows:-

Survey Month	Data from Date (inclusive)	Data to Date (inclusive)	Survey Collection Start Date	Survey Collection End Date
October 2012	01 October 2012	31 October 2012	01/11/2012	07/11/2012
November 2012	01 November 2012	30 November 2012	03/12/2012	07/12/2012
December 2012	01 December 2012	31 December 2012	02/01/2013	08/01/2013
January 2013	01 January 2013	31 January 2013	01/02/2013	07/02/2013
February 2013	01 February 2013	28 February 2013	01/03/2013	07/03/2013

NOTES

1. Each survey includes data from the **start of the calendar month** (inclusive) up until the **end of the calendar month** (inclusive).
2. The Survey Collection Start Date starts on the **first working day** of the month following the Survey Month
3. The Survey Collection End Date is **five working days** after the Survey Collection Start Date

The denominator is "The number of women delivering a live infant (28 weeks and over) in the survey month" in the PCT. The numerator is "The number of women delivering a live infant (28 weeks and over) in the survey month who received a dose of Repevax®"

A user guide will be issued to PCT Immunisation Coordinators in due course.

The data collection is subject to ROCR approval.

All PCT Immunisation coordinators already registered with an ImmForm account will be able to access the survey and provide data. If a PCT needs to register additional individuals to provide the uptake data, they should apply for an ImmForm account (see Annex B for how to register).

During the data collection period PCTs and SHAs are able, through the ImmForm website, to:

- see their coverage data;
- compare themselves with other anonymous PCTs and SHAs;
- validate the data on point of entry and correct any errors before data submission;
- view data and export data into Excel, for further analysis.

These tools can be used to facilitate the local and regional management of the pertussis vaccination programme for pregnant women.