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Title: PERTUSSIS (WHOOPING COUGH) VACCINATION FOR PREGNANT WOMEN – EARLIER TIMING FOR VACCINATION.

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For Action by:

General Practitioners and Practice Nurses Immunisation Leads, Health Boards Chief Executives, Health Boards/Trusts Medical Directors, Health Boards/Trusts Nurse Executive Directors, Health Boards/Trusts Chief Pharmacists, Health Boards/Trusts Directors of Public Health, Health Boards Directors of Workforce and Organisational Development, Health Boards/Trusts Directors of Primary, Community and Mental Health, Health Boards Chief Executive, Public Health Wales Executive Director of Public Health Services. Public Health Wales Nurse Director. Public Health Wales Head Vaccine Preventable Disease Programme, Public Health Wales Consultants in Communicable Disease Control. Public Health Wales

For information to:

Welsh NHS Partnership Forum British Medical Association GPC(Wales) Royal College of GPs Royal College of Nursing Royal Pharmaceutical Society

Sender:

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Enclosure(s): The Primary Medical Services (Pertussis Immunisation for Pregnant and Post-natal Women) (Directed Enhanced Services) (Wales) Directions 2016

Dear Colleague,

PERTUSSIS (WHOOPING COUGH) VACCINATION FOR PREGNANT WOMEN EARLIER TIMING FOR VACCINATION.

I am writing to inform you of a change to the pertussis vaccination programme for pregnant women. This change reflects guidance from the Joint Committee on Vaccination and Immunisation (JCVI) that **immunisation should take place from week 16 of pregnancy onwards**.

The Green Book Chapter on pertussis has been updated in line with JCVI's advice. "The Green Book: Immunisation against infectious disease" can be viewed at: https://www.gov.uk/government/publications/pertussis-the-green-book-chapter-24

Background

Since October 2012, a temporary programme of pertussis vaccination for pregnant women has been in place. This was introduced in response to increased levels of pertussis activity across the UK since mid 2011. (See CEM/CMO/2012/16 and CMO2013/13).

The purpose of the programme is to boost antibodies in vaccinated women in pregnancy, so that pertussis specific antibodies are passed from mother to baby. The aim is to protect the baby from birth before routine immunisation can be started at eight weeks of age.

Cases of pertussis in infants born to vaccinated mothers have reduced by over 90% as a result of the programme¹. In light of the success of the temporary pertussis vaccination programme in saving infant lives and the continued increase in pertussis incidence, the Joint Committee on Vaccination and Immunisation (JCVI) recommended in June 2014 that the programme should be extended for a further five years.

In 2012, the available evidence indicated that vaccination would be most beneficial if administered early in the 3rd trimester. The JCVI, therefore, recommended that the vaccine should be offered to women between 28 and 32 weeks of pregnancy.

Since that time, new research has emerged² showing that maternal immunisation earlier in pregnancy (i.e. the 2nd trimester) is safe and increases antibody transfer to the infant. The earlier timing will also help to ensure protection for babies who may be delivered prematurely. This is particularly important as premature infants are over represented in cases of whooping cough occurring at this time.

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¹ Amirthalingam G., Andrews N., Campbell H., Ribeiro S., Kara E., Donegan K., Fry N.K., Miller E. and Ramsay M. (2014) Effectiveness of maternal pertussis vaccination in England: an observational study. The Lancet, Volume 384, Issue 9953: 1521-1528. http://www.sciencedirect.com/science/article/pii/S0140673614606863

^{1521-1528.} http://www.sciencedirect.com/science/article/pii/S0140673614606863

Eberhardt CS, Blanchard-Rohner G, Lemaître B, Boukrid M, Combescure C, Othenin-Girard V, Chilin A, Petre J, de Tejada BM, Siegrist CA. (2016) Maternal Immunization Earlier in Pregnancy Maximizes Antibody Transfer and Expected Infant Seropositivity Against Pertussis. Clin Infect Dis. Volume 62, Issue 7: 829-36. http://cid.oxfordjournals.org/content/62/7/829.full.pdf

Vaccination arrangements

Pregnant women should be offered a single 0.5ml dose of dTaP/IPV vaccine between gestational weeks 16 and 32 to maximise the likelihood that the baby will be protected from birth. Vaccine should be offered to women in every pregnancy. Women may still be immunised after week 32 of pregnancy but this may not offer as high a level of passive protection to the baby. Vaccination late in pregnancy may, however, directly protect the mother against disease and thereby reduce the risk of exposure to her infant.

This change offers more opportunities for pregnant women to be offered the pertussis vaccine during pregnancy.

Programme delivery and vaccine supply

The pertussis programme should continue to be delivered (in most cases) through General Practice. The General Practitioners' Committee (Wales) has been made aware of the proposed change.

General Practices should ensure that all pregnant women are contacted regarding vaccination, particularly those who are solely in the care of a midwife or hospital consultant. Midwives should ensure that pregnant women are informed of the programme and advised to contact their GP surgery to arrange to be vaccinated.

All health professionals should ensure that appropriate information and advice about the pertussis vaccine is given to each pregnant woman who attends an immunisation session and reasonable opportunity is given to discuss any concerns before being immunised.

Vaccination against pertussis can be given at the same time as vaccination against influenza during the winter months.

There will be a small rise in the number in eligible women at first but this will not impact on vaccine supply and sufficient stocks of vaccine are available.

The vaccine should be ordered through ImmForm in the same way as other vaccines used in national programmes. Providers should order the vaccine recommended on ImmForm. Where there is no Boostrix® IPV (dTaP/IPV) vaccine available, Repevax® (dTaP/IPV) is a suitable alternative. In those exceptional circumstances when a woman attends and neither Boostrix®-IPV nor Repevax® (dTaP/IPV) is available, rather than delay vaccination, Infanrix®-IPV (DTaP/IPV) should be given.

Uptake Rates

Current uptake of the pertussis vaccine in pregnant women Wales is high. A survey undertaken by Public Health Wales at the start of 2016 across all health boards areas indicated 72.4% of pregnant women in Wales recalled receiving the pertussis vaccine. Making the vaccine available earlier in pregnancy will increase the opportunity for women to have the vaccine and will provide the option to offer vaccination at the same time as the routine 20 week ultrasound anomaly scan or during other scheduled or opportunistic contacts. Every effort should be made by

medical practitioners, midwives and others to encourage pregnant women to take up the offer of the pertussis vaccination.

Implementation

The Primary Medical Services (Pertussis Immunisation for Pregnant and Post-natal Women) (Directed Enhanced Services) (Wales) Directions 2016 are attached which formally enforce this vaccination programme to commence on 17 June 2016. The fee for GPs administering this vaccine is in line with the current rate of £7.80. However a review is currently underway of the "Item of Service" fee which we hope to conclude by the end of June 2016. Any change there may be to the IOS fee will be applied to all vaccination programmes with an IOS fee currently of £7.80, including this programme, and backdated to 1 April 2016.

Information materials

Resources for health practitioners are being updated and will be available through Public Health Wales at:

http://nww.immunisation.wales.nhs.uk/pertussis-vaccination-in-pregnancy

The leaflet "Whooping Cough and Pregnancy" will be replaced by a combined leaflet for vaccination in pregnancy which will be available in due course by emailing hplibrary@wales.nhs.uk or telephoning 0845 606 4050.

The leaflet, together with other information will also available at NHS Direct Wales: http://www.nhsdirect.wales.nhs.uk/encyclopaedia/w/article/whoopingcough/

I would like to take the opportunity to thank you and your staff for continuing to promote and deliver this important vaccination programme.

Yours sincerely

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Dr Chris Jones

Acting Chief Medical Officer/Medical Director NHS Wales

2016 No. 13 (W.13)

THE NATIONAL HEALTH SERVICE (WALES) ACT 2006

The Primary Medical Services (Pertussis Immunisation for Pregnant and Post-natal Women) (Directed Enhanced Services) (Wales) Directions 2016

Made 16 June 2016

Coming into force 17 June 2016

The Welsh Ministers, in exercise of the powers conferred by sections 12(3), 203(9) and (10) and 204(1) of the National Health Service (Wales) Act 2006(³) give the following Directions:

Title, commencement and application

- **1.**—(1) The title of these Directions is the Primary Medical Services (Pertussis Immunisation for Pregnant and Post-natal Women) (Directed Enhanced Services) (Wales) Directions 2016.
 - (2) These Directions come into force on 17 June 2016.
 - (3) These Directions are given to Local Health Boards(4) and apply in relation to Wales.

Interpretation

2. In these Directions—

"the Act" ("v Ddeddf") means the National Health Service (Wales) Act 2006;

"financial year" ("blwyddyn ariannol") means the period from 1 April to 31 March;

"general practitioner" ("ymarferydd cyffredinol") means a medical practitioner whose name is included in a medical performers list prepared by a Local Health Board under regulation 3 of the National Health Service (Performers Lists) (Wales) Regulations 2004(5);

"GMS contractor" ("contractwr GMS") means a person with whom a Local Health Board is entering or has entered into a general medical services contract;

"healthcare professional" ("gweithiwr gofal iechyd proffesiynol") means a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002(⁶);

"PMS contractor" ("contractwr PMS") means a person with whom a Local Health Board is entering or has entered into arrangements in accordance with section 50 of the Act which require the provision by that person of primary medical services;

"primary medical services contractor" ("contractwr gwasanaethau meddygol sylfaenol") means—

(a) a GMS or PMS contractor, or

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⁽⁴⁾ Local Health Boards established pursuant to section 11 of the National Health Service (Wales) Act 2006.

⁽⁵⁾ S.I. 2004/1020 (W. 117) as amended.

^{(&}lt;sup>6</sup>) 2002 c. 17.

(b) a person with whom a Local Health Board is making or has made contractual arrangements for the provision of primary medical services under section 41(2)(b) of the Act; and

"Statement of Financial Entitlement" ("Datganiad ar Hawlogaeth Ariannol") means any directions given by the Welsh Ministers under section 45 of the Act.

Establishment of a Pertussis Immunisation for Pregnant and Post-natal Women Scheme

3. Each Local Health Board must exercise its functions under section 41 of the Act of providing primary medical services within its area, or securing the provision of such services within its area, by (as part of its discharge of those functions) establishing (if it has not already done so), operating and, as appropriate, revising a Pertussis Immunisation for Pregnant and Post-natal Women Scheme, the underlying purpose of which is to extend the temporary programme of pertussis vaccination of pregnant and post-natal women in response to ongoing increased levels of pertussis activity.

Pertussis Immunisation for Pregnant and Post-natal Women Scheme

- **4.**—(1) As part of its Pertussis Immunisation for Pregnant and Post-natal Women Scheme, each Local Health Board may enter into arrangements with each primary medical services contractor ("the contractor") in its area (unless it already has such arrangements with the contractor in respect of that financial year), thereby affording the contractor a reasonable opportunity to participate in the Scheme during that financial year.
- (2) The plan setting out the arrangements that a Local Health Board enters into, or has entered into, with the contractor must, in respect of each financial year to which the plan relates include—
 - (a) a requirement that the contractor develop and maintains a register ("the Pertussis Immunisation for Pregnant and Post-natal Women Scheme Register"), of all the at-risk patients to whom the contractor is to offer pertussis immunisations. The Pertussis Immunisation for Pregnant and Post-natal Women Scheme Register may comprise electronically tagged entries in a wider computer database. For these purposes a patient is at-risk of pertussis infection if she is—
 - (i) a pregnant woman from 16 weeks onwards, with the optimal time in the period of weeks 16 to 32 inclusive, and with a gap of at least one month between any previous immunisation against pertussis, diphtheria, tetanus and/or polio, and this dose;
 - (ii) a pregnant woman from 32 weeks until the onset of labour, if immunisation was not given during the optimal time period set out in paragraph (i); or
 - (iii) a new mother who was not vaccinated against pertussis during her pregnancy and whose child has not received their first vaccinations;
 - (b) a requirement that the contractor undertakes, when they are aware that their patient is pregnant—
 - (i) to offer immunisation to those patients;
 - (ii) to record the information it has in its the Pertussis Immunisation for Pregnant and Postnatal Women Scheme Register using the applicable National Read codes; and
 - (iii) to develop a proactive and preventative approach to offering the pertussis immunisation by adopting robust call and reminder systems with the aims of—
 - (aa) maximising uptake in the interest of at risk patients; and
 - (bb) meeting any public health targets in respect of such immunisations;
 - (c) a requirement that the contractor takes all reasonable steps to ensure that the lifelong medical records held by an at-risk patient's general practitioner are kept up to date with regard to her immunisation status, and in particular include—
 - (i) any refusal of an offer of vaccination; or
 - (ii) where an offer of vaccination was accepted—
 - (aa) details of the consent to the vaccination (where a person has consented on an at-risk patient's behalf, that person's relationship to the at-risk patient must also be recorded);
 - (bb) the batch number, expiry date and title of the vaccine;

- (cc) the date of administration of the vaccine:
- (dd) where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;
- (ee) any contraindications to the vaccination; and
- (ff) any adverse reactions to the vaccination;
- (d) a requirement that the contractor ensures that any healthcare professional who is involved in administering a vaccine has—
 - (i) any necessary experience, skills and training with regards to the administration of the vaccine with reference to national minimum standards; and
 - (ii) training with regard to the recognition and initial treatment of anaphylaxis;
- (e) a requirement that the contractor ensures that—
 - (i) all vaccines are stored in accordance with the manufacturer's instructions;
 - (ii) all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that readings are taken from that thermometer on all working days; and
 - (iii) all vaccines are ordered, stored and monitored to reduce wastage;
- (f) a requirement that the contractor supply its Local Health Board with such information and at such frequencies as the Local Health Board may reasonably request for the purposes of monitoring the contractor's performance of its obligations under the plan; and
- (g) the payment arrangements for the contractor.
- (3) The payment arrangements must provide that—
 - (a) where the contractor and Local Health Board have agreed arrangements as outlined in subparagraphs (a) to (g) and the contractor meets its obligations under the plan, the contractor will be able to claim (after verification by the Local Health Board) a payment of £7.80 per registered patient; and
 - (b) such payment will be payable quarterly in arrears and will be payable on the first date after the payment is authorised on which one of the contractor's Global Sum monthly payments falls due in accordance with the Statement of Financial Entitlement.
- (4) Any disputes arising will be dealt with in the prescribed way. Local Health Boards and contractors should make every effort to resolve the dispute locally before formally submitting it through the NHS dispute resolution procedure.
- (5) The Local Health Board must, where necessary, vary the contractor's general medical services contract so that the plan comprises part of the contractor's contract and the requirements of the plan are conditions of the contract.

Dr Grant L. Duncan

Signed by Dr Grant L. Duncan, Deputy Director, Primary Care Division under the authority of the Cabinet Secretary for Health, Well-being and Sport, one of the Welsh Ministers

Date 16 June 2016