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18th September 2015

H.M Senior Coroner for South Yorkshire (East District) Ms N J Mundy Coroner's Court & Office Crown Court College Road Doncaster DN1 3HS

Your Ref: NJM/lb/tji/46385-2014

Dear Ms Mundy,

RE: Isabella Rosa Drew (Deceased), DOB: 11.08.2014 - DOD: 09.09.2014

Thank you for your letter dated 16 July regarding Isabella Rosa Drew. Firstly may I say that I was sorry to hear of Isabella's death, as a result of whooping cough on 9th September 2014 and wish to express my deepest sympathy to the Drew family.

Whooping cough (pertussis) is a disease that the Department of Health, Public Health England (PHE) and NHS England take very seriously as it continues to be a life-threatening illness in babies, particularly those who are too young to be protected by our routine infant immunisation programme which begins at 2 months of age. As immunisation programmes are the responsibility of this tripartite, I am writing on behalf of the three organisations, each of which have contributed to this response.

As you are aware, we introduced pertussis vaccination for pregnant women in October 2012, in order to protect babies from birth through transplacental transfer of maternal antibodies. This programme was introduced by the Department of Health as an outbreak response measure following a rise in cases of infants too young to be vaccinated. The programme introduction was based on expert, independent, scientific advice from the Joint Committee on Vaccination and Immunisation (JCVI).

Acceptance of the programme has been high when compared with other countries offering a similar programme, with the most recent recorded vaccine uptake at 63% for women giving birth in December 2014 compared, for example, to 57% reported coverage in Argentina in 2014 and state-based estimates of pertussis-containing vaccine receipt during pregnancy in the US typically not exceeding 20%. Equity of access is important for this programme and assessment of this is being undertaken. For example, PHE has recently introduced collection of pertussis vaccination in pregnancy uptake figures by ethnicity. In addition, the enhanced surveillance for pertussis that has been in place nationally since 1994 (where every laboratory-confirmed case of pertussis is followed up with the patient's GP for additional information including; vaccination history, hospitalisation and complications) has been extended to cover information on maternal immunisation history, maternal ethnicity and gestational age at delivery for

babies born since the immunisation in pregnancy programme was introduced.

There were 14 deaths in infant cases in 2012. These infants were all born before the introduction of the maternal pertussis immunisation programme and were too young to be protected by their first infant dose of pertussis vaccine. Up to 14 August 2015, 12 deaths have been reported in infants with confirmed whooping cough who were born after the introduction of the maternal programme. Eleven of these 12 babies were born to unvaccinated mothers and only one infant had received their first dose of pertussis-containing vaccine.

Whilst cases and deaths in young infants have fallen since the introduction of the immunisation in pregnancy programme, PHE has been concerned that babies have continued to die from pertussis. Most of these babies, as the figures above show, appear to have been born to women who were not offered immunisation during their pregnancy, despite the demonstrated protection against severe disease and death. As a result, PHE has contacted all the Child Death Overview Panels (CDOP) in the areas where these babies were resident to request a copy of the relevant CDOP report(s) to develop further understanding and learn from the deaths that have arisen in infants diagnosed with whooping cough with a view to collating findings and sharing learning at a national level.

PHE has also put in place a number of other actions to support the improvement of access, communication and health professional understanding. These include:

· Engagement with pregnant women.

In addition to the materials prepared specifically for pregnant women, PHE has shared information through social media and used pregnancy apps to raise awareness of pertussis vaccine in pregnancy and when and how pregnant women can get the vaccine.

• Improved communication with healthcare professionals. PHE has:

- Engaged with the Royal College of Midwives (RCM) and the Royal College of Obstetricians and Gynaecologists to ensure they have clear statements and links to clinical advice on immunisation in pregnancy on their websites.
- Published articles in professional journals highlighting to midwives the importance of immunisation in pregnancy against both pertussis and influenza.
- Attended four regional infectious diseases in pregnancy screening events to highlight to midwives immunisation in pregnancy and will be presenting a paper at the national maternity conference in Manchester in September.
- Had a research paper on maternal attitudes to immunisation in pregnancy accepted for publication in British Journal of Midwifery.
- Met with the RCM Heads of Midwifery and the NHS Heads of Midwifery at national and local level.
- Undertaken attitudinal research amongst midwives, practice nurses and health visitors on immunisation in pregnancy in collaboration with the RCM, the Royal College of Nursing and the Institute of Health Visiting.
- Worked with NICE to have flu and pertussis immunisations in antenatal clinical guidance.

In addition, to better facilitate the vaccination of pregnant women by midwives, PHE has ensured that its Patient Group Directions (PGDs) template for influenza and pertussis immunisation (in pregnancy) includes midwives as nominated health

professionals. PGDs are written instructions for the supply or administration of medicines (including vaccines) to groups of patients who may not be individually identified before presentation for treatment.

PHE has also identified that a barrier to more effective implementation of the vaccination programme is that GPs do not always know in a timely way when a woman is pregnant and their expected date of delivery in order to schedule the vaccination, ideally between 28 and 32 weeks. As part of the GP enhanced service specification (contract), GPs have to compile a register of pregnant women and contact them to offer vaccination. However, this is dependent on whether or not they have been informed of pregnancies, and requires good communication between primary care and maternity services.

Your area of particular concern relates to guidance available. As you rightly point out, guidance from the Department places a responsibility on medical health practitioners to discuss with and offer pertussis immunisation to all pregnant women. At the start of the programme in 2012, the Department issued an alert about the announcement to the NHS using the Central Alert System and pager messaging just before 7pm on 27 September 2012:

https://www.cas.dh.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=101844

Primary Care Trusts (at the time) were asked to cascade the information to healthcare professionals including general practitioners (GPs) urgently and within 24 hours. The announcement stated that "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 these letters."

Since April 2013 the pertussis immunisation programme has been commissioned as part of the Public Health Section 7a Agreement:

(<u>https://www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2015-to-2016</u>) (s7a) – an agreement between the Secretary State for Health and NHS England – delivered in partnership with PHE and DH.

PHE has published a range of information materials aimed at both expectant mothers and healthcare professionals about the maternal immunisation programme. This is available at:

https://www.gov.uk/government/publications/resources-to-support-whooping-cough-vaccination

These include:

- A leaflet aimed at expectant mothers that goes into detail about the vaccination programme in a question and answer format;
- A flyer aimed at expectant mothers, explaining what they will need to know before having the vaccination;
- A factsheet for healthcare professionals that gives the scientific background to the need for, and development of, the vaccination programme:
- A training slide set for healthcare professionals:
- A poster to raise awareness in pregnant women.

You suggested that consideration should be given to:

- The need for further and more explicit guidance as to how local healthcare providers ensure systems put in place effectively capture their responsibility to advise all pregnant women of the importance of whooping cough vaccination with provision for auditing and follow up procedures
- The need for further national guidance regarding the importance of effective communication links between the various limbs of antenatal healthcare providers

Since the pertussis outbreak was declared in April 2012 this situation has been managed as a level 3 (national level) incident by PHE. For such an incident there is a nationally co-ordinated response that includes regular incident team meetings, regular written situation reports and review and updating of all public health guidance for the management of suspected cases and local outbreaks.

In addition, an independent review of maternity services in England was initiated in April 2015 chaired by Baroness Julia Cumberlege with Professor Sir Cyril Chantler as vice chair. It will assess current maternity care provision and consider how services should be developed to meet the changing needs of women and babies, and is expected to report by the end of the calendar year. There are 5 working groups covering models of care, choice, professional culture and accountability, levers and incentives, and quality assessment. Your concerns about the need to better integrate the pertussis and other immunisation services into routine maternity care and the need for additional guidance will be taken into consideration as the review progresses.

I hope that this letter reassures you that we are taking appropriate action to ensure that access, communication and health professional understanding of this programmes is improved and that the need for additional guidance along the lines that you have suggested will be given active consideration.

Yours sincerely,

Bruce Keogh KBE, MD, DSc, FRCS, FRCP

National Medical Director

NHS England