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Dear colleagues,

Change of vaccine for the pertussis (whooping cough) vaccination in pregnancy programme from 1 July 2024

This letter provides information about a vaccine change from 1 July 2024 when ADACEL® (Tdap), a non-IPV-containing vaccine, will replace Boostrix-IPV® (dTaP/IPV) for the pertussis vaccination in pregnancy programme.

The letter provides information for both commissioners and health professionals who are responsible for the safe delivery of this important NHS vaccination programme to pregnant women. We encourage you to share this guidance with those in your area.

Background

A safe and highly effective maternal pertussis vaccination programme was first introduced in October 2012, using dTaP/IPV (a combined tetanus, diphtheria, pertussis and polio containing vaccine) to protect young infants from birth at highest risk of severe disease.

Evaluation of the programme in England has demonstrated that maternal pertussis vaccination offers very high level of protection against confirmed disease and death from pertussis in infants under 3 months of age.

In October 2022, following a review of the latest evidence, the Joint Committee on Vaccination and Immunisation (JCVI) advised a preference for a non-IPV-containing pertussis vaccine in the maternal programme.

This followed studies measuring antibody levels in the infants of mothers who had received pertussis-containing vaccines (dTaP/IPV) in pregnancy. These studies showed lower antibody responses to polio (after completion of their primary infant schedule) compared to infants born to unvaccinated mothers, although all remained above the protective threshold.

To address this potential immunity gap caused by the blunting of the infant's polio response to primary vaccines, a non-IPV-containing (Tdap) vaccine has now been procured.

Tdap vaccine has been shown to be both safe and effective in the maternal pertussis vaccine programmes in many other European countries, the USA and Australia, with millions of doses administered worldwide.

Summary of key changes to the programme

- From 1 July 2024, the vaccine used in the programme will change to ADACEL[®]
 (Tdap). Vaccine ordering will open in June (exact date will be confirmed via an
 ImmForm news item).
- The ADACEL® (Tdap) vaccine, manufactured by Sanofi, contains tetanus, diphtheria, and pertussis (acellular) antigens and was licensed for UK use in 2016. The SPC is available here: <u>ADACEL suspension for injection in pre-filled syringe - Summary of</u> <u>Product Characteristics (SmPC) - (emc) (medicines.org.uk)</u>.
- The JCVI recognised the importance of vaccinating pregnant women to protect their babies from pertussis and the advice is clear that dTaP/IPV vaccine should still be given if ADACEL® (Tdap) is not available to avoid delays in administration.
- See Annex A for details of resources to support the programme.

For any operational and vaccine programme enquiries, please contact your NHS England Regional Public Health Commissioning team.

This is a good opportunity to highlight the continued importance of ensuring all pregnant women are offered vaccination against pertussis in every pregnancy. Women should normally receive their whooping cough vaccine around the time of their mid-pregnancy scan (usually 20 weeks) but can receive it from 16 weeks.

To help provide optimal protection, the vaccine should be given before 32 weeks; but women who miss out can still have the vaccine later. Sadly, 5 babies died from pertussis in the first quarter of 2024. Since the programme began, the vast majority (21/26) of deaths have been in infants of unvaccinated mothers under the age of 3 months.

Vaccine uptake levels in pregnant women, babies and young children have fallen in recent years across England. Maternal vaccine uptake fell from over 72.3% in December 2019 to around 59.5% in December 2023.² Vaccination in pregnancy is key to protecting young babies and the fall in coverage is of concern given current high levels of pertussis activity in England.³

Practices are reminded that in line with their contractual requirements, pertussis vaccination should be offered and provided to eligible patients either opportunistically or on request. Pertussis vaccination should also be correctly coded in the patient's medical record, regardless of where it was administered.

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¹ Confirmed cases of pertussis in England by month - GOV.UK (www.gov.uk)

² Pertussis immunisation in pregnancy: vaccine coverage (England) - GOV.UK (www.gov.uk)

³ Pertussis epidemiology in England 2024 - GOV.UK (www.gov.uk)

The completeness of patient data recording in GP records has an impact on our ability to monitor and evaluate vaccination programmes. Wherever possible, the following information should be recorded in GP records for all pregnant women:

- the date of delivery
- the date of receipt of a pertussis-containing vaccine at or after week 16 of pregnancy, regardless of the setting where the vaccine was administered
- where relevant, fields indicating stillbirth or miscarriage.

We would like to take this opportunity to thank everyone involved in commissioning and operationally delivering the pertussis vaccination programme for pregnant women.

Yours sincerely,

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Annex A: Supporting programme information

Vaccine supply

ADACEL® (Tdap) will be available to order online via the ImmForm website from June (exact date will be confirmed via an ImmForm news item), so that providers can ensure local stocks are held from 1 July. See the ImmForm help sheet for information on registering an ImmForm account. It is recommended that practices hold no more than 2 weeks' worth of stock.

After the introduction of ADACEL® on 1 July, local stocks of Boostrix-IPV® can be used in the preschool programme. Providers who do not provide pre-school boosters should plan to use up local stocks of Boostrix-IPV® ahead of 1 July, and any remaining stocks of Boostrix-IPV® may continue to be offered to pregnant women if this will prevent vaccine wastage.

The Green Book

Detailed clinical guidance on administering prenatal pertussis vaccination is contained in Pertussis: the green book, chapter 24.

Patient group directions (PGDs)

An updated <u>Pertussis vaccination PGD template</u> will be produced by UKHSA for NHS England areas to authorise for their commissioned services. Trusts must have plans in place to update their PGDs prior to the commencement of the programme change.

It is imperative to ensure individuals are offered a suitable and available vaccine containing a pertussis-containing antigen, rather than risk not being immunised against pertussis. This PGD permits the use of ADACEL®, Boostrix-IPV® or Repevax®; while noting the JCVI's preference for a non-IPV-containing pertussis vaccine over the other vaccines.

Though a non-IPV vaccine is preferred for the maternal programme, if ADACEL® is not available or is otherwise unsuitable (such as in individuals with a severe allergy to latex), offer either Boostrix-IPV® or Repevax®.

Commissioners will need to ensure that all providers have processes in place to deliver the new Tdap vaccine (ADACEL®) using the appropriate legal framework which needs to be in place prior to 1 July 2024.

Information for healthcare practitioners and slide set

Further clinical guidance and information about the programme and a slide set for trainers is available at <u>Vaccination against pertussis</u> (whooping cough) for pregnant women - GOV.UK (www.gov.uk).

Data reporting

For accurate denominators to be extracted from GP IT systems by the automated survey, and precise coverage estimates to be calculated, it is important that the medical records of all women who have given birth have the following fields completed:

- the date of delivery
- the date of receipt of a pertussis-containing vaccine at or after week 16 of pregnancy, regardless of the setting where the vaccine was administered
- · where relevant, fields indicating stillbirth or miscarriage

Further information can be found at: <u>Pertussis immunisation in pregnancy: vaccine coverage (England) - GOV.UK (www.gov.uk)</u>.

Consent

Guidance on informed consent can be found in chapter 2 of the Green Book.

Reporting suspected adverse reactions

Health professionals and those vaccinated are asked to report suspected adverse reactions through the online Yellow Card scheme (www.mhra.gov.uk/yellowcard), by downloading the Yellow Card app or by calling the Yellow Card scheme on 0800 731 6789, 9am – 5pm, Monday to Friday.

Patient information

Printed copies of patient information materials can be ordered free of charge from the <u>Health</u> <u>Publications website</u>:

- Pertussis vaccine in pregnancy leaflet and poster: Whooping cough: vaccination in pregnancy programme resources – GOV.UK (www.gov.uk)
- General vaccination in pregnancy leaflet: <u>Pregnant? Immunisation helps to protect</u> you and your baby from infectious diseases (publishing.service.gov.uk).

Communications resources

Communications resources to support pertussis vaccination uptake are available on the DHSC campaign resource centre website.