

Dear Colleagues

PRENATAL PERTUSSIS (WHOOPING COUGH) – VACCINE CHANGE FROM 1 JULY 2024

1. We are writing to inform you of a vaccine change from 1 July 2024 when ADACEL[®] (Tdap) a vaccine without Inactivated Polio Virus (IPV), will replace Boostrix-IPV[®] (dTaP/IPV) for the pertussis vaccination in pregnancy programme.

Background

2. A safe and highly effective maternal pertussis vaccination programme was first introduced in October 2012, with the aim of providing passive immunity from pregnant woman to unborn baby to afford protection in the first few weeks of life before the infant becomes eligible to begin their immunisation course. UK Studies demonstrated maternal pertussis vaccination offers around 90% vaccine effectiveness against confirmed disease and 97% protection against death from pertussis in infants under 3 months of age.
3. In October 2022, the Joint Committee on Vaccination and Immunisation (JCVI) reviewed the latest evidence. Studies observing antibody levels of infants of mothers who had received pertussis-containing vaccines in pregnancy, exhibited lower antibody responses (described as ‘blunting’) to polio compared to infants born to unvaccinated mothers. It is important to note however that all antibody levels remained above the protective threshold.

**From Chief Medical Officer for
Scotland**
Interim Chief Nursing Officer
Chief Pharmaceutical Officer
Professor Sir Gregor Smith
Anne Armstrong
Professor Alison Strath

29 May 2024

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Addresses

For action

Chief Executives, NHS Boards
Midwifery Leads, Obstetricians
Medical Directors, NHS Boards
Nurse Directors, NHS Boards
Primary Care Leads, NHS Boards
Chief Officers of Integration
Authorities

Directors of Pharmacy
Directors of Public Health
Immunisation Co-ordinators
CPHMs

For information

Chairs, NHS Boards
Chief Midwifery Officer, Scottish
Government
Infectious Disease Consultants
Consultant Paediatricians
Public Health Scotland
Chief Executive, Public Health
Scotland
NHS 24
General Practitioners
Practice Nurses

Further Enquiries to:

Policy Issues

Vaccination Policy Team
immunisationpolicy@gov.scot

Medical Issues

Dr Lorna Willocks
Senior Medical Officer
St Andrew's House
Lorna.Willocks@gov.scot

PGD/Pharmaceutical and Vaccine

Supply Issues

William Malcolm
Public Health Scotland
William.Malcolm@nhs.scot

4. The JCVI has [advised](#) a preference for a non-IPV containing pertussis vaccine ([Tdap](#)) in the maternal programme, to address this potential immunity gap caused by the blunting of the polio immune response in infants born to dTaP/IPV vaccinated women, when they receive their own primary vaccines.
5. Tdap vaccine has safely and effectively been used in maternal pertussis vaccination programmes in many countries, including other European countries, USA and Australia, and millions of doses have been administered.

Current pertussis epidemiology

6. Pertussis continues to circulate in Scotland therefore the immunisation of pregnant women continues to be extremely important.
7. Increased numbers of pertussis cases generally occur in 3 to 4-year cycles. Since early 2024, an increasing number of laboratory-confirmed cases of pertussis have been reported in Scotland. This follows very few cases since the beginning of the COVID-19 pandemic with an increase in cases also reported in other UK countries and in Europe.
8. We have observed a small decline in immunisation uptake rates for pregnant women and routine childhood immunisations following the COVID-19 pandemic, and with a likely increase in circulating pertussis cases; further notifications of cases and outbreaks are expected. The highest incidence of laboratory confirmed pertussis is seen in children including teenagers and those aged under one year. Those aged under one are vulnerable to severe infection and hospitalisation and therefore it is important to protect young infants through maternal vaccination and early uptake of primary immunisation.
9. Every effort should be made by medical practitioners, midwives and other health professionals to signpost and encourage pregnant women to take up the offer of pertussis vaccination.

Changes to the Programme

10. From 1 July 2024, the vaccine used in the programme will change to ADACEL®.
11. The ADACEL® vaccine, manufactured by Sanofi, contains tetanus, diphtheria, and pertussis (acellular) antigens and was licensed for UK use in 2016. The Summary of Product Characteristics (SmPC) is available [here](#).
12. The JCVI recognised the importance of vaccinating pregnant women to protect their babies from pertussis and they have advised that a dTaP/IPV vaccine should be administered if Tdap (ADACEL®) is not available or is clinically contraindicated.

ADACEL®

13. ADACEL® is an inactivated vaccine. **A single dose of ADACEL®** is recommended for pregnant women from week 16 of pregnancy (ideally between weeks 16 and 32) to provide passive protection to infants against pertussis, unless contraindicated.
14. Vaccine administered between 16 to 32 weeks of pregnancy is likely to maximise the levels of pertussis antibodies transferred across the placenta, thereby providing passive immunity to the unborn child. However for women who present late Pertussis vaccine can be offered to pregnant women up until they go into labour, and up to two months after birth.
15. ADACEL® contains a natural rubber latex derivative in the tip caps of the prefilled syringes. **Therefore this vaccine is unsuitable for any individual with a severe latex allergy.**
16. It is essential to ensure that pregnant women are offered a suitable and available pertussis-containing antigen vaccine, rather than risk not being immunised against pertussis. ADACEL® is preferred for the maternal programme, however if ADACEL® is not available or otherwise unsuitable, such as in individuals with a severe allergy to latex, either Boostrix-IPV® or Repevax® should be offered.

Action

17. Health Boards are requested to action this change in policy and ensure that their midwifery, vaccination teams and primary and secondary care colleagues are aware of it. Further information is included in the Annex set out below.
18. Vaccination events should continue to be recorded on the Vaccination Management Tool and/ or Badgernet/TRAK care.
19. We would like to recognise and express our gratitude for your professionalism and continuing support in planning and delivering this important maternity vaccination service within the Scottish Vaccination and Immunisation Programme.

Yours sincerely,

Gregor Smith

Professor Sir Gregor Smith
**Chief Medical Officer
for Scotland**

Anne Armstrong

Anne Armstrong
**Interim Chief Nursing
Officer**

Alison Strath

Professor Alison Strath
**Chief Pharmaceutical
Officer**

PRENATAL PERTUSSIS (WHOOPING COUGH) VACCINATION PROGRAMME

Immunisation against Infectious Disease (The Green Book)

1. Full details on use, dosage, administration, concomitant administration with other vaccines, contraindications, consent and reporting of adverse reactions with ADACEL® is set out in [chapter 24 of the Green Book](#). This will be updated before 1 July 2024.

Patient Group Direction (PGD)

2. A national specimen Patient Group Direction (PGD) for administration of ADACEL® in pregnancy will be produced by PHS.

Supply and Storage

3. ADACEL® will be available to order through vaccine holding centres from June 2024
4. Vaccines should be stored in the original packaging at +2°C to +8°C and protected from light. All vaccines may be sensitive to some extent to heat and cold. Heat speeds up the decline in potency of most vaccines, thus reducing their shelf life. Do not freeze as freezing may cause increased reactogenicity and loss of potency for some vaccines. It can also cause hairline cracks in the container, leading to contamination of the contents.

Adverse Events

5. Adverse events should continue to be escalated to PHS as appropriate.

Reporting of Adverse Reactions

6. Suspected adverse drug reactions (ADR) to vaccines should be reported via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard). Chapter 9 of the Green Book gives detailed guidance about which ADRs to report and how to do so. Additionally, Chapter 8 of the Green Book provides detailed advice on managing adverse events following vaccination. Information on the side effects of Adacel® is available in Chapter 24 of the Green Book. These chapters are available at: [Immunisation against infectious disease - GOV.UK \(www.gov.uk\)](http://www.gov.uk/government/publications/immunisation-against-infectious-disease).

Communication Materials for Patients

7. Public Health Scotland provides an overview of pertussis immunisations [here](#). They are also developing a [toolkit](#) to encourage the promotion of the prenatal vaccine that will support NHS and midwifery colleagues. There is also information for pregnant women available on the [NHS inform website](#).

Workforce Education Resources for Healthcare Practitioners

8. NHS Education for Scotland (NES), in partnership with Public Health Scotland and stakeholders, are developing educational resources for healthcare practitioners in relation to the introduction of ADACEL® vaccine for the whole programme. These will be available on [Turas Learn](#).