

Enhanced Service Specification

**Pertussis (pregnant women) vaccination
programme 2020/21**

NHS England and NHS Improvement



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Pertussis (pregnant women) vaccination programme

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Equalities and health inequalities statement

"Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it;
- given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way where this might reduce health inequalities."

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Please be aware that all aspects of this service specification outline the requirements for this programme. As such, commissioners and practices should ensure they have read and understood all sections of this document as part of the implementation of this programme.

Practices are advised that to ensure they receive payment, particular attention should be paid to the payment and validation terms. Practices will need to ensure they understand and use the designated clinical codes as required to ensure payment.

Other formats of this document are available on request. Please send your request to: england.gpcontracts@nhs.net

1 Introduction

- 1.1 All GP practices must to provide essential services and those additional services they are contracted to provide to all their patients. This enhanced service (ES) specification outlines more specialised services to be provided. The specification of this service is designed to cover the enhanced aspects of clinical care, all of which are beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.
- 1.2 This ES¹ is directed at GP practices² delivering vaccination and immunisation services in England.
- 1.3 This ES is agreed between NHS England and NHS Improvement, the British Medical Association's (BMA) and the General Practitioners Committee (GPC) England.

2 Background

- 2.1 The pertussis vaccination programme was introduced in October 2012 following a recommendation from the Joint Committee on Vaccination and Immunisation (JCVI), that a temporary programme of pertussis (pregnant women) vaccination be implemented - to respond to an ongoing outbreak resulting in a number of infant deaths across the country³.
- 2.2 Pertussis immunisation should take place from ideally from 20 to 32 weeks of each pregnancy (but can be offered from 16 weeks and after 32 weeks⁴).
- 2.3 Vaccination of pregnant women from 16 weeks will provide greater opportunity for pregnant women to access the vaccine, will provide additional benefit to infants, where delivery is premature and will potentially improve neonatal antibody levels offering protection to newborns during the first two months of life when the risk of complications from pertussis are greatest and before

¹ Section 7a functions are described as 'reserved functions' which are not covered by the 'enhanced services delegated to CCG' category in the delegation agreement. NHS England remains responsible and accountable for the discharge of all the Section 7a functions. As this vaccination is defined as a Section 7a function, this agreement cannot be changed or varied locally.

² Reference to 'GP practice' in this specification refers to a provider of essential primary medical services to a registered list of patients under a GMS, PMS or APMS contract.

³ DH. Letter to the Service re introduction of temporary vaccination programme. September 2012. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/212947/CMO-Pertussis-27-09-2012-FINAL.pdf

⁴ Vaccination is best offered on or after the foetal anomaly scan at around 20 weeks. Women may still be immunised after 32 weeks pregnancy but this may not offer as high a levels of passive protection to the baby.

infants can be directly protected through routine vaccination. See section 5.

- 2.4 The recommended vaccine(s) for this programme is Boostrix®-IPV (containing diphtheria, tetanus, acellular pertussis and inactivated polio antigens – dTaP/IPV. If Boostrix®-IPV is not available, Repevax® (dTaP/IPV) may be used as an alternative. Vaccines for this programme can be ordered via ImmForm.
- 2.5 Further information about the immunisation programme can be found in “Vaccination against pertussis (whooping cough) for pregnant women - information for healthcare professionals”⁵. Details on background to the programme can be found in the tripartite letter dated 10 May 2013⁶.
- 2.6 Further details on the background, dosage, timings and administration of the vaccination can be found in the Green Book⁷.

3 Aims

- 3.1 The aim of this ES is to support commissioners in commissioning pertussis vaccination from GP practices, in order to prevent cases of the disease and deaths in infants. Pertussis vaccination will boost immunity in women so that pertussis antibodies are passed from mother to baby to passively protect infants in the first months of life (before they receive their routine childhood immunisations from aged two months). It is important for all women to be offered the pertussis vaccine during **each** pregnancy.
- 3.2 The vaccine has been shown to be both safe in pregnancy⁸ and 91-92 per cent^{9,10} effective in preventing pertussis infection in babies whose mothers were immunised at least one week prior to delivery. It is therefore important that all pregnant women are offered the vaccine at the appropriate stage of

⁵ Vaccination against pertussis (whooping cough) for pregnant women.

<https://www.gov.uk/government/publications/vaccination-against-pertussis-whooping-cough-for-pregnant-women>

⁶ DHSC. Letter to the Service re extension of temporary vaccination programme. May 2013.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/197839/130510_Pertusis_continuation_letter_FINAL.pdf

⁷ Green Book Chapter 24. <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

⁸ Donegan K, King B, Bryan P. 2014. Safety of pertussis vaccination in pregnant women in UK: observational study, *BMJ* 2014;349:g4219

⁹ Amirthalingam G, Andrews N, Campbell H, Ribeiro S, Kara E, Donegan K, et al. Effectiveness of maternal pertussis vaccination in England: an observational study. *The Lancet*, Volume 384, Issue 9953. Pages 1521-1528. 25 October 2014.

¹⁰ Dabrera G, Amirthalingam G, Andrews N, Campbell H, Ribeiro S, Kara E, Fry N, Ramsay M. A case-control study to estimate the effectiveness of maternal pertussis vaccination in protecting newborn infants in England and Wales. 2012/13. *Clinical Infectious Diseases*. 19 October 2014.

each pregnancy i.e. 16 to 32 weeks.

4 Process

- 4.1 This ES begins on 1 April 2020 until 31 March 2021
- 4.2 Commissioners will invite GP practices to participate in this ES before 30 April 2020. All practices who participate in this ES must respond to the commissioners' offer no later than 30 June 2020. The agreement should be recorded in writing with their commissioner.
- 4.3 Payment and activity recording will be managed by the Calculating Quality Reporting Service (CQRS)¹¹ and all practices must sign-up to CQRS – no later than 30 June 2020¹² whether or not they intend to deliver the ES in order to ensure that they can claim payment once this becomes an essential service.

5 Service specification¹³

- 5.1 The requirements for GP practices participating in the ES are outlined within this section.
- 5.2 **Offer and (where accepted) provide pertussis vaccination** to all eligible patients registered at the GP practice; unless contra-indicated.

- a. Eligible patients are those who:
 - i. are registered patients,
 - ii. pregnant women who reach, or were already at the 16th week of their pregnancy at the time of vaccination.

The contractor is required to offer vaccination between 16 to 32 weeks of pregnancy, ideally between 20 and 32 weeks. The optimal time is from 16 weeks pregnancy, or soon after, to maximise transplacental transfer of antibodies to the unborn child. Pregnant women who miss vaccination and are beyond week 32 of pregnancy should be offered immunisation¹⁴.

- b. Immunisation is contra-indicated where the patient has previously had a confirmed anaphylactic reaction to a previous dose of the vaccine, or

¹¹ Guidance relating to CQRS and GPES will be provided by NHS Digital when services are updated.

¹² Practices will be required to sign-up to CQRS in order for payment to be calculated and processed.

¹³ Commissioners and practices should ensure they have read and understood all sections of this document as part of the implementation of this programme and to ensure accurate payment.

¹⁴ Vaccination is best offered on or after the foetal anomaly scan at around 20 weeks. Women may still be immunised after week 32 but this may not offer as high a level of passive protection to the infant. Vaccination late in pregnancy may, directly protect the mother against disease and thereby reduce the risk of exposure to her infant. GP practices should aim to immunise eligible patients in weeks 16 to 32.

to any component of the vaccine.

- c. Vaccination must be delivered during the period of this ES, namely between 1 April 2020 and 31 March 2021

5.3 Vaccination must be with the appropriate vaccine and dosage.

Contractors may also offer vaccination to new mothers (up to two months after the birth of the baby) who missed the opportunity to be vaccinated during pregnancy to reduce the risk of the mother contracting pertussis in the post-partum period and therefore prevent her from infecting her infant.

5.4 Produce and maintain a satisfactory register of all eligible pregnant women on the contractor's registered list during each financial year of the programme. Simple registers of pregnant women are all that is required, although these will need to be updated regularly to capture the target population and record the estimated due date (EDD) so it is known when they are eligible for vaccination.

5.5 GP practices will need to decide on the best mechanisms to contact all eligible pregnant women on the contractor's register to maximise uptake. They will particularly need to consider how to contact women who are solely in the care of a midwife or hospital consultant.

5.6 Liaise with and inform all eligible pregnant women of the benefits of being immunised, making full use of all publicity and information materials available for national/local campaigns. 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 be given reasonable opportunity to discuss any concerns before being immunised.

5.7 Take all reasonable steps to adhere to defined standards of record keeping ensuring that the medical records of patients receiving the pertussis immunisation are kept up-to-date with regard to the immunisation status and in particular, include:

- a. any refusal of an offer of immunisation.
- b. where an offer of immunisation was accepted and:
 - i. details of the consent to the immunisation (including persons that have consented on the patient's behalf and that person's relationship to the patient must also be recorded),

- ii. the batch number, expiry date and title of the vaccine,
- iii. the date of administration,
- iv. where two vaccines are administered in close succession the route of administration and the injection site of each vaccine,
- v. any contra-indication to the vaccination or immunisation,
- vi. any adverse reactions to the vaccination or immunisation¹⁵.

5.8 Ensure that all healthcare professionals who are involved in administering the vaccine have:

- a. referred to the clinical guidance available.
- b. the necessary experience, skills and training, including training with regard to the recognition and initial treatment of anaphylaxis.

5.9 Ensure that all vaccine ordering is conducted in line with national guidance, including adherence to any limits on stocks to be held at any one time.

5.10 Ensure that all vaccines are stored in accordance with the manufacturer's and Public Health England's¹⁶ instructions and that all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that the readings are taken and recorded from that thermometer on all working days and that appropriate action is taken when readings are outside the recommended temperature.

5.11 Services will be accessible, appropriate and sensitive to the needs of all service users. No eligible patient shall be excluded or experience particular difficulty in accessing and effectively using this ES due to protected characteristics as outlined in the Equality Act (2010) – this includes Age, Gender Reassignment, Marriage and Civil Partnership, Pregnancy and Maternity, Race, Religion or Belief, sex or sexual orientation,

5.12 Providers will monitor and report all activity information via ImmForm¹⁷ on a monthly basis. The activity information shall include a monthly count of all eligible patients who received a vaccination in the relevant month. This information will be used by NHS England and NHS Improvement and Public

¹⁵ This should be reported via the yellow card scheme. <https://yellowcard.mhra.gov.uk/>

¹⁶ PHE's ordering, storing and handling protocol <https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines>

¹⁷ PHE. Pre-natal pertussis vaccine uptake surveys. 2014. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/347085/2902749_PHE_PertussisVaccination_acc.pdf

Health England for monitoring, coverage, payment provision, population coverage, uptake achievement and national reporting.

- 5.13 GP practices should take reasonable steps to ensure that the patient records of all pregnant women in their practice have the following fields completed to ensure that the relevant records are included in the collection:
- a. The expected date of delivery;
 - b. date of receipt of a pertussis-containing vaccine at or after week 16 of pregnancy, regardless of the setting where the vaccine was administered; and
- 5.14 **Practices who agree to participate in this ES must indicate acceptance on CQRS** to enable CQRS to calculate the monthly payment achievement data via manually entered data. Practices must input data manually into CQRS until GPES is available.
- 5.15 **Practices who do not intend to deliver the ES must still indicate acceptance on CQRS 30 June 2020 in order to ensure payment once this becomes an essential service.**
- 5.16 **Where the patient has indicated they wish to receive the vaccination but is physically unable to attend the practice** (for example is housebound) the practice must make all reasonable effort to ensure the patient is vaccinated.

6 Monitoring

- 6.1 Commissioners will monitor services and calculate payments under this ES using CQRS, wherever possible. GPES will provide information, using the defined clinical codes, on the number of patients on the practices registered list, who are pregnant women who reach, or were already at the 16th week of their pregnancy at the time of vaccination and who are recorded as being vaccinated against pertussis during the period 1 April 2020 to 31 March 2021.
- 6.2 If automated collection via GPES is not available for any reason, Practices must manually input data into CQRS, until such time as GPES¹⁸ is available again. For information on how to manually enter data into CQRS, see the NHS Digital website¹⁹. Alternatively, Practices may choose to wait until the automated collection is available again and claim payment later.
- 6.3 When GPES is available, each GPES data collection will capture data for all

¹⁸ When GPES becomes available it will be communicated via the NHS Digital.

¹⁹ NHS Digital. <https://digital.nhs.uk/article/279/General-Practice-GP-collections>

counts and report on activities from the start of the reporting period e.g. 1 April to the end of the relevant reporting month. The reporting month will be the month prior to the month in which the collection is run e.g. if the collection month is May, the reporting month will be April.

- 6.4 When collections begins, GPES will provide to CQRS the monthly counts.
- 6.5 Practices should ensure that they only use the relevant clinical codes included in the supporting Business Rules (<http://content.digital.nhs.uk/gofesextractspecs>) and should also re-code patients where necessary. This will allow CQRS to calculate achievement and payment and for commissioners to audit payment and service delivery. Commissioners and practices should refer to the supporting Business Rules to ensure that they have the most up-to-date information on management counts and clinical codes.

7 Payment and validation

- 7.1 Payment is available to participating GP practices under this ES as an item of service payment of £10.06 per dose to eligible patients.
- 7.2 GP practices will only be eligible for payment for this ES in circumstances where all of the following requirements have been met:
- a. The GP practice is contracted to provide vaccine and immunisations as part of additional services.
 - b. All patients in respect of whom payments are being claimed were on the GP practice's registered list at the time the vaccine was administered and all of the following apply:
 - i. The GP practice administered the vaccine to all patients in respect of whom the payment is being claimed.
 - ii. All patients in respect of whom payment is being claimed were within the cohort (as per the service specification section) at the time the vaccine was administered.
 - iii. The GP practice did not receive any payment from any other source or under any other programme in respect of the vaccine (should this be the case, then the commissioner may reclaim any payments as set out in the annex).
 - iv. The GP practice submits the claim within six months²⁰ of administering the vaccine (commissioners may set aside this

²⁰ Consistent with payment claims for other vaccination programmes which are covered by the SFE

requirement if it considers it reasonable to do so²¹).

- 7.3 Claims for payments for this programme should be made monthly, after the final completing dose has been administered. Where claims are entered manually, this should be within 12 days of the end of the month when the completing dose was administered. Where there is an automated data collection, there is a five day period following the month end to allow practices to record the previous month's activity before the collection occurs. Activity recorded after the collection period is closed (five days), will not be collected and recorded on CQRS. Practices must ensure all activity is recorded by the cut-off date to ensure payment.
- 7.4 Payment will be made by the last day of the month following the month in which the practice validates and commissioners approve the payment.
- 7.5 Payments will begin provided that the GP practice has manually entered and declared achievement, or GPES²² has collected the data and the practice has declared such data²³. The first payment processed will include payment for the same period.
- 7.6 As the vaccine is centrally supplied, no claim for reimbursement of vaccine costs or personal administration fee apply.
- 7.7 Commissioners are responsible for post payment verification. This may include auditing claims of practices to ensure that they meet the requirements of this ES.
- 7.8 Administrative provisions relating to payments under this ES are set out in the Annex.
1. Payment under this ES, or any part thereof, will be made only if the GP practice satisfies the following conditions:
 - a. the GP practice must make available to commissioners any information under this ES, which the commissioner needs and the GP practice either has or could be reasonably expected to obtain,
 - b. the GP practice must make any returns reasonably required of it (whether computerised or otherwise) to the payment system or CQRS, and do so promptly and fully; and,

²¹ By exception only, for example where payment processes are made manually without CQRS and take longer to complete

²² See 'Process' section for information relating to sign-up and automated collection.

²³ Practices are reminded that they are responsible for checking their 'achievement' is accurate before they 'declare' it on CQRS.

- c. all information supplied pursuant to or in accordance with this paragraph must be accurate.
2. If the GP practice does not satisfy any of the above conditions, commissioners may, in appropriate circumstances, withhold payment of any, or any part of, an amount due under this ES that is otherwise payable.
3. If a commissioner makes a payment to a GP practice under this ES and:
 - a. the contractor was not entitled to receive all or part thereof, whether because it did not meet the entitlement conditions for the payment or because the payment was calculated incorrectly (including where a payment on account overestimates the amount that is to fall due);
 - b. the commissioner was entitled to withhold all or part of the payment because of a breach of a condition attached to the payment, but is unable to do so because the money has already been paid; or
 - c. the commissioner is entitled to repayment of all or part of the money paid,

commissioners may recover the money paid by deducting an equivalent amount from any payment payable to the GP practice, and where no such deduction can be made, it is a condition of the payments made under this ES that the contractor must pay to the commissioner that equivalent amount.

4. Where the commissioner is entitled under this ES to withhold all or part of a payment because of a breach of a payment condition, and the commissioner does so or recovers the money by deducting an equivalent amount from another payment in accordance with paragraphs 5 and 6 of this annex, it may, where it sees fit to do so, reimburse the contractor the amount withheld or recovered, if the breach is cured.

Provisions relating to GP practices that terminate or withdraw from this ES prior to 31 March 2021 (subject to the provisions below for termination attributable to a GP practice split or merger)

5. Where a GP practice has entered into this ES but its primary medical care contract subsequently terminates or the GP practice withdraws from the ES prior to 31 March 2021, the GP practice is entitled to a payment in respect of its participation if such a payment has not already been made, calculated in accordance with the provisions set out below. Any payment calculated will fall due on the last day of the month following the month during which the GP practice provides the information required.
6. In order to qualify for payment in respect of participation under this ES, the GP practice must provide the commissioner with the information in this ES specification or as agreed with commissioners before payment will be made. This information should be provided in writing, within 28 days following the termination of the contract or the withdrawal from the ES agreement.
7. The payment due to GP practices that terminate or withdraw from the ES agreement prior to 31 March 2021 will be based on the number of vaccinations given to eligible patients prior to the termination or withdrawal.

Provisions relating to GP practices who merge or split

8. Where two or more GP practices merge or are formed following a contractual split of a single GP practice and as a result the registered population is combined or divided between new GP practice(s), the new GP practice(s) may enter into a new or varied agreement to provide this ES.
9. The ES agreements of the GP practices that formed following a contractual merger, or the GP practice prior to contractual split, will be treated as having terminated and the entitlement of those GP practice(s) to any payment will be assessed on the basis of the provisions of paragraph 8 of this annex.
10. The entitlement to any payment(s) of the GP practice(s), formed following a contractual merger or split, entering into the new or varied agreement for this ES, will be assessed and any new arrangements that may be agreed in writing with the commissioner, will begin at the time the GP practice(s) starts to

provide such arrangements.

11. Where that new or varied agreement is entered into and the arrangements begin within 28 days of the new GP practice(s) being formed, the new arrangements are deemed to have begun on the date of the new GP practice(s) being formed. Payment will be assessed in line with this ES specification as of this date.

Provisions relating to non-standard splits and mergers

12. Where the GP practice participating in the ES is subject to a split or a merger and:
 - a. the application of the provisions set out above in respect of splits or mergers would, in the reasonable opinion of the commissioner, lead to an inequitable result; or,
 - b. the circumstances of the split or merger are such that the provisions set out in this section cannot be applied,commissioners may, in consultation with the GP practice or GP practices concerned, agree to such payments as in the commissioner's opinion are reasonable in all circumstances.