NHS England

Enhanced Service Specification

Pertussis (pregnant women) vaccination programme 2015/16

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Description	All GMS practices are expected to provide essential 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. This Enhanced Service is directed at GP practices delivering vaccination and immunisation services in England.
Cross Reference	
Superseded Docs (if applicable)	Pertussis (pregnant women) enhanced service specification published 9 March 2015 - amendement to cost per dose.
Action Required	Regions, clinical commissioning groups (CCGs) and contractors taking part should ensure they have read and understood the document.
Timing / Deadlines (if applicable)	
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Document Status

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Enhanced Service Specification

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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1 Introduction

1.1 All GMS practices are expected to provide essential 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 ES is directed at GP practices[1] delivering vaccination and immunisation services in England.

1.3 This ES is agreed between NHS Employers (on behalf of NHS England[2]) and the General Practitioners Committee (GPC) of the British Medical Association (BMA).

2 Background

2.1 The pertussis vaccination programme was introduced in October 2012 following a recommendations 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 of infection that led to a number of infant deaths across the country[3].

2.2 Vaccination of pregnant women in the third trimester (ideally between 28 and 32 weeks of pregnancy but can be given up to 38 weeks) offers protection to newborns during the early weeks after birth when the risk of complications from pertussis are greatest.

2.3 The recommended vaccine for this programme is Boostrix-IPV® (containing diphtheria, tetanus, acellular pertussis and inactivated polio antigens – dTaP/IPV). Boostrix-IPV® is licensed as a booster from aged four and

[1] Reference to 'GP practice' in this specification refers to a provider of essential primary medical services to a registered list of patients under a General Medical Services, Personal Medical Services or Alternative Provider Medical Services contract.
[2] From 1 April 2013 the NHS Commissioning Board (NHS CB) is the body legally responsible for the commissioning of primary care in England. However, the NHS CB operates under the name NHS England, therefore the name NHS England is used throughout this Specification.
[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

contains low dose diphtheria suitable for adults. Vaccine for this programme can be ordered via Immform.

2.4 Further information about the immunisation programme can be found in "Vaccination against pertussis (Whooping cough) for pregnant women - Information for healthcare professionals"[4]. Details on background to the programme can be found in the tripartite letter dated 10 May 2013[5].

2.5 Further details on the background, dosage, timings and administration of the vaccination can be found in the Green Book[6] and supporting guidance[7].

3 Aims

3.1 The aim of this ES is to support commissioners in delivering pertussis vaccination within GP practices, in order to prevent cases of the disease and deaths in infants. Pertussis vaccination will boost immunity in women in late pregnancy 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 Since this temporary ES was introduced in 2012 uptake levels have been similar to that of influenza vaccination in pregnant women. The vaccine has been shown to be both safe in pregnancy[8] and 91-92 per cent[9,10] effective in preventing pertussis infection in babies whose mothers were immunised during pregnancy. It is therefore important that all pregnant women are offered

[4] Vaccination against pertussis (whooping cough) for pregnant women. https://www.gov.uk/government/publications/vaccination-against-pertussis-whooping-cough-for-pregnant-women

[5] DH. 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_Pertussis_continuation_letter_FINAL.pdf

[6] DH. Green Book. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

[7] NHS Employers. Vaccination and immunisation programmes 2015/16 guidance and audit requirements. www.nhsemployers.org/vandi

[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, Sonia 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.

the vaccine at the appropriate stage of each pregnancy.

4 Process

4.1 This ES commences on 1 April 2015 until 31 March 2016.

4.2 Commissioners will seek to invite GP practices to participate in this ES before 30 June 2015. Practices who participate in this ES should respond to the commissioners offer within 42 days. The agreement should be recorded in writing with their commissioner no later than 31 July 2015.

4.3 Participating practices are also required to sign up to CQRS and GPES[11]. Commissioners will record GP practices' participation on the Calculating Quality Reporting Service (CQRS) by 31 July 2015.

5 Service specification

5.1 The requirements for GP practices participating in the ES are as follows in 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 28th week of their pregnancy at the time of vaccination.

The contractor is expected to offer vaccination before week 38 of pregnancy. The optimal time is in the period weeks 28 to 32 inclusive to maximise transplacental transfer of antibodies to the unborn child. Pregnant women who miss vaccination and are beyond week 38 of pregnancy should be offered immunisation up to the onset of labour so that some direct protection may still be provided to the infant.

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

[11] Further guidance relating to CQRS and GPES will be provided by HSCIC when services are updated.

a. Vaccination must be delivered during the period of this ES, namely between 1 April 2015 and 31 March 2016.

b. Vaccination must be with the appropriate vaccine and dosage: practices should ensure that the correct dosage is administered as clinically appropriate.

5.3 **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 and 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 ensure 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 immunisation.

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. The vaccine recommended for this programme is Boostrix-IPV®.

5.10 **Ensure that all vaccines are stored in accordance with the manufacturer's 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.

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 their race, gender, disability, sexual orientation, religion and/or age.

5.12 **Monitoring of vaccine uptake is via a fully automated bulk data transfer to the Immform website**[12]. 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:

[12] 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

a. the date of delivery;

b. date of receipt of a pertussis-containing vaccine at or after week 28 of pregnancy, regardless of the setting where the vaccine was administered; and

c. where relevant, any record of a premature delivery occurring at less than 28 weeks gestational age.

5.13 **Practices who agree to participate in this ES will be required to indicate acceptance on CQRS** to enable CQRS to calculate the monthly payment achievement data via manually entered data.

5.14 **Practices will be required to input data manually into CQRS until GPES is available.** The Read codes which must be used to record activity are available in the document "Technical requirements for 2015/16 GMS contract changes"[13].

5.15 **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 Read2 and CTV3 codes, on the number of patients on the practices registered list, who are pregnant women who reach, or were already at the 28th week of their pregnancy at the time of vaccination and who are recorded as being vaccinated against influenza during the period 1 April 2015 to 31 March 2016.

6.2 Practices will be required to manually input data into CQRS, until such time as GPES[14] is available to conduct electronic data collections. The data input will be in relation to the payment count only, with zeros being entered in the interim for the management information counts. For information on how to manually enter data into CQRS, see the HSCIC website[15].

[13] NHS Employers. Technical requirements for 2014/15 GMS contract changes. www.nhsemployers.org/gms2014/15

[14] Details as to when GPES becomes available to support this service will be communicated via the HSCIC.

[15] HSCIC. http://systems.hscic.gov.uk/cqrs/participation

6.3 When GPES is available, each GPES data collection will capture data for all counts and report on activities from the start of the reporting period e.g. 1 April 2015 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 October, the reporting month will be September.

6.4 When collections commence, GPES will provide to CQRS the monthly counts.

6.5 The 'Technical Requirements document' contains the payment counts, management information counts and Read2 and CTV3 codes[16] which are required for this service. The Read2 and CTV3 codes will be used as the basis for the GPES data collection, which will allow CQRS to calculate payment and support the management information collections, when available. Practices should use the relevant Read2 or CTV3 codes or re-code if necessary, only those included in this document and the supporting Business Rules will be acceptable to allow CQRS to calculate achievement and payment and for commissioners to audit payment and service delivery. Practices will therefore need to ensure that they use the relevant codes from the commencement of this service and re-code patients where necessary.

6.6 Supporting Business Rules will be published on the HSCIC website. Commissioners and practices should refer to these for the most up to date information on management information counts, Read2 and CTV3 codes.

7 Payment and validation

7.1 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.

[16] Please note that the code descriptions in clinical systems may not exactly match the guidance text.

7.2 Payment will be made by the last day of the month following the month in which the practice validates and commissioners approve the payment.

7.3 Payments will commence provided that the GP practice has manually entered achievement, or GPES[17] has collected the data, the first payment processed will include payment for the same period.

7.4 Practices who wish to participate in this ES will be required to sign up to CQRS no later than 31 July 2015.

7.5 Payment is available to participating GP practices under this ES as an item of service payment of £7.67 per dose to eligible patients in accordance with the 'Service specification section' and provisions within this ES specification.

7.6 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 practices 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)[18].

iv. The GP practice submits the claim within six months[19] of administering the vaccine (commissioners may set aside this requirement if it considers it reasonable to do so).

7.7 As the vaccine is centrally supplied, no claim for reimbursement of vaccine costs or personal administration fee apply.

[17] See 'Process' section for information relating to sign-up and automated collection.
[18] Patients vaccinated as part of the MenC booster programme in the current or previous years should not be claimed for under the freshers programme if they have been claimed as part of the adolescents programme.
[19] In line with the SFE and only applicable if CQRS is not being used.
http://www.nhsemployers.org/vandi

7.8 Commissioners will be responsible for post payment verification. This may include auditing claims of practices to ensure that they meet the requirements of this ES.

7.9 Administrative provisions relating to payments under this ES are set out in the Annex.

Annex. Administrative provisions relating to payments under the ES for pertussis (pregnant women) vaccination programme

1. Payments under this ES are to be treated for accounting and superannuation purposes as gross income of the GP practice in the financial year.
2. 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.
3. Payment will be made by the last day of the month following the month in which the practice validates and commissioners approve the payment.
4. 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 required of it (whether computerised or otherwise) to the Exeter Registration System or CQRS, and do so promptly and fully; and,

    c. all information supplied pursuant to or in accordance with this paragraph must be accurate.
5. 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.
6. 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.

7. 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 paragraph 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 2016 (subject to the provisions below for termination attributable to a GP practice split or merger)

8. 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 2016, 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.

9. 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.

10. The payment due to GP practices that terminate or withdraw from the ES agreement prior to 31 March 2016 will be based on the number of vaccinations given, prior to the termination or withdrawal.

Provisions relating to GP practices who merge or split

11. 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 agreement to provide this ES.
12. 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.
13. The entitlement to any payment(s) of the GP practice(s), formed following a contractual merger or split, entering into the agreement for this ES, will be assessed and any new arrangements that may be agreed in writing withthe commissioner, will commence at the time the GP practice(s) starts to provide such arrangements.
14. Where that agreement is entered into and the arrangements commence within 28 days of the new GP practice(s) being formed, the new arrangements are deemed to have commenced on the date of the new GP practice(s) being formed. Payment will be assessed in line with this ES specification as of this commencement date.

Provisions relating to non-standard splits and mergers

15. 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 commissioners opinion are reasonable in all circumstances.