



Public Health
England



NHS public health functions agreement 2019-20

Service specification No.11
Human papillomavirus (HPV) programme

NHS England and NHS Improvement



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Promoting equality and addressing health inequalities are at the heart of NHS England and NHS Improvement 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 and those who do not share it (as required under the Equality Act 2010); and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities (in accordance with the duties under sections 13G and 13N of the NHS Act 2006, as amended).

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Service specification No.11

This is a service specification to accompany the 'NHS public health functions agreement 2019-20 (the '2019-20 agreement').

This service specification is to be applied by NHS England and NHS Improvement in accordance with the 2019-20 agreement. Where a specification refers to any other published document or standard, it refers to the document or standard as it existed at the date when the 2019-20 agreement was made between the Secretary of State and NHS England and NHS Improvement Board, unless otherwise specified. Any changes in other published documents or standards may have effect for the purposes of the 2019-20 agreement in accordance with the procedures described in Chapter 3 of the 2019-20 agreement.

Service specifications should be downloaded in order to ensure that commissioners and providers refer to the latest document that is in effect.

The 2019-20 agreement is available at www.gov.uk (search for 'commissioning public health').

All current service specifications are available at www.england.nhs.uk (search for 'commissioning public health').

This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply. It must always be read in conjunction with the [core service specification](#) and the online version of the [Green Book](#).

1 Purpose of the HPV immunisation programme

- 1.1 This document relates to the human papillomavirus (HPV) immunisation programme, a national programme delivered with the aim of reducing the incidence of cervical cancer and other HPV related cancers. This vaccine forms part of the national childhood immunisation programme, which aims to prevent children from developing vaccine preventable diseases that are associated with significant mortality and morbidity. The purpose of the service specification is to enable NHS England to commission HPV immunisation services to a standard which will prevent women and men from HPV related cancers. This means maintaining high vaccine coverage rates in England within the context of populations with protected characteristics as defined by the Equality Act 2010
- 1.2 This specification provides a brief overview of the HPV vaccine, including the diseases it protects against, the context, evidence base, and wider health outcomes, and should be read alongside the core service specification which underpins national and local commissioning practices and service delivery
- 1.3 The existing, highly successful programme provides a firm platform on which local services can meet the needs of their local population and work towards improving health outcomes. This specification will promote a consistent and equitable approach to the provision of the commissioning and delivery of the HPV immunisation programme across England. It is important to note that this programme can change and evolve in light of emerging best practice and scientific evidence. NHS England and NHS Improvement and providers are required to implement these changes in a timely way as directed by the national schedule.
- 1.4 [*Immunisation against infectious disease*](#) (known as ‘the Green Book’), issued by Public Health England (PHE) provides guidance and is the main evidence base for all immunisation programmes. This service specification must be read in conjunction with the core service specification, the online version of the Green Book and all relevant official public health letters, and with additional evidence, advice and recommendations issued by the [Joint Committee on Vaccination and Immunisation \(JCVI\)](#).
- 1.5 This service specification is not designed to replicate, duplicate or supersede any relevant legislative provisions that may apply, e.g. the Health and Social Care Act 2012. The specification will be reviewed and amended in line with any new recommendations or guidance, and in line with reviews of the Section 7A agreement.

2 Population needs

Background

- 2.1 The HPV vaccination is highly effective at preventing the infection of susceptible women and men with the HPV types covered by the vaccine.
- 2.2 HPV is one of the most common sexually transmitted infections. Persistent infection with high-risk HPV types can lead to the development of cervical and other rarer anogenital cancers and some cancers of the head and neck, while low-risk HPV types cause the majority of genital warts.
- 2.3 The UK implemented an HPV immunisation programme for girls in September 2008. This followed advice from the JCVI recommending that the HPV vaccine should be offered routinely to females aged 12 to 13 years. The committee also recommended a time-limited catch-up vaccination of females aged from 14 to less than 18 years. Originally the primary aim was to reduce the incidence of cervical cancer in women by protecting females before they become sexually active and the risk of acquiring HPV infection increases.
- 2.4 The HPV vaccine used routinely in the national programme when it started in 2008 was Cervarix, which protects against HPV types 16 and 18. This was changed to Gardasil in September 2012, which protects against a further two strains of HPV – types 6 and 11 – that cause the vast majority of genital warts.
- 2.5 In 2014 the JCVI recommended that the schedule change from three to two doses for girls starting their vaccination under 15 years of age. Recent research shows that antibody response to two doses in adolescent girls is as good as a three-dose course. This change was implemented from September 2014.
- 2.6 In the first 10 years of the HPV programme the coverage achieved was amongst the highest in the world. There is already evidence that the vaccine is making a difference. For example there has been a large drop in the rates of infection with the two main cancer-causing HPV types. The number of diagnoses of genital warts in England has also fallen sharply in both girls and boys since the vaccination programme started, suggesting that boys are already benefiting indirectly from the girls' programme through herd protection. It has been estimated that this programme will prevent hundreds of women each year from developing cervical cancer and hundreds of men and women from developing other HPV related cancers.
- 2.7 In July 2018, it was announced that the HPV vaccine will be extended to boys in England, based on advice from the JCVI. It is anticipated that from the 2019/2020 academic school year, 12 to 13 year old boys will become eligible. This extension will help prevent more cases of HPV-related cancers such as head and neck cancers and ano-genital cancers which can also affect boys. There will be no catch-up programme for older boys as the evidence suggests that they are already benefiting significantly from the herd protection which has built up from ten years of the girls' programme.

The HPV immunisation programme – key details

2.8 The key details are that:

- The routine national HPV immunisation programme started in September 2008 as a three-dose course for all 12 to 13 year-old (i.e. school year 8) girls. School-based delivery of the programme was recommended.
- In March 2014, the Joint Committee on Vaccination and Immunisation (JCVI) revised its existing recommendation on the HPV immunisation programme for adolescent girls, changing the schedule from three to two doses. The key changes to the programme, implemented from September 2014, were as follows:
 - the first dose can be given at any time during school year 8;
 - the minimum time between the first and second dose should be six months, where the priming dose is received at less than 15 years of age;
 - the maximum time between the first and second dose is 24 months;
 - for operational purposes, PHE recommended around a 12-month gap between the two doses which would reduce the number of HPV vaccination sessions. However, local needs should be considered when planning the programme.
- In July 2018 it was announced that the HPV vaccine will be extended to boys in England, based on advice from the JCVI. It is anticipated that from the 2019/2020 academic school year, 12 to 13 year old boys will become eligible. There will be no catch-up programme for older boys. Further details are awaited.

3 Scope

Aims

- 3.1 The aim of the HPV immunisation programme is to reduce morbidity and mortality from cervical cancer and other HPV related cancers such as anogenital cancers and some cancers of the head and neck, by routinely offering the vaccination to 12 to 13 year-old (i.e. school year 8) girls and boys.

Objectives

- 3.2 The aim will be achieved by delivering a population-wide, evidence-based immunisation programme that:
- identifies the eligible population and ensures effective, timely delivery with high coverage (see eligible population set out in paragraph 4.6);
 - is safe, effective, of a high quality and is externally and independently monitored;
 - is delivered and supported by suitably trained, competent and qualified clinical and non-clinical staff who participate in recognised ongoing training and development;
 - delivers, manages and stores vaccine in accordance with national guidance;
 - is supported by regular and accurate data collection using the appropriate returns.

Direct health outcomes

- 3.3 In the context of health outcomes, the HPV immunisation programme aims to:
- reduce the number of preventable infections and their onward transmission;
 - reduce HPV-related disease;
 - achieve high coverage in the target cohort;
 - minimise adverse physical/psychological/clinical aspects of immunisation (e.g. anxiety, adverse reactions).

Baseline vaccine coverage

- 3.4 Local services must ensure they maintain and improve current immunisation coverage (with reference to vaccine coverage public health outcomes framework indicators) with the aim of 100% of relevant individuals being offered immunisation in accordance with *Immunisations against infectious disease* (the Green Book) and other official DH/PHE guidance. This includes performance indicators and key deliverables that are set out in Annex B of the NHS Public Health Functions Agreement (Section 7A) for 2017-2018.

4 Service description / care pathway

Local service delivery

- 4.1 The delivery of immunisation services at a local level is based on evolving best practice. This section of the document specifies the high-level operational elements of the HPV vaccination programme, based on the best practice that NHS England and NHS Improvement must use to inform local commissioning, contracts and service delivery.
- 4.2 It is recommended that the HPV immunisation programme is delivered in schools as the evidence suggests that this will ensure highest vaccine coverage among the target population.
- 4.3 There is also scope to enable NHS England and NHS Improvement and providers to enhance and build on specifications to incorporate national or local service aspirations that may include increasing local innovation in service delivery. However, it is essential, in order to promote a nationally aligned, high-quality programme focusing on improved outcomes, that all the core elements set out in the core service specification are included in contracts and specifications.

Target population

- 4.4 Providers are required to make the HPV vaccine available to:
 - all 12 to 13 year old boys and girls from the 2019/20 academic year (school year 8) and those 13 to 14 year old girls (school year 9) who require their second dose of vaccine, where the programme is offered across two academic years;
 - Eligible girls (ie have been previously eligible for HPV immunisation who attained eligibility on or after 1 September 2008) and who have not completed a full course of HPV immunisation up to their 25th birthday This may include girls (and in due course boys from eligible cohorts) who are resident in neighbouring CCGs but are attending school in a different CCG. This will include girls in eligible age groups (and in due course boys from eligible cohorts) who move into the area, school or who newly register with a general practice after the invitations for the school aged programme have been issued.
 - as noted earlier there are no plans for a catch up programme for older boys, however all boys in eligible cohorts will remain eligible for the HPV vaccine until their 25th birthday and should be caught up in the same way as girls are.
- 4.5 Additionally NHS England and NHS Improvement will wish to ensure that providers:
 - offer immunisation to eligible girls and boys who are in special schools, pupil referral units and independent schools. Immunisation should also be offered to eligible children who are educated at home;
 - ensure that any child who misses a routine visit is automatically invited to the next planned sessions, or given a suitable, locally agreed alternative;
 - ensure efforts are made to include as part of the programme, eligible children from communities with objections to immunisation on family or religious beliefs and hard to reach groups, which may include looked after children and children from traveller

communities. Health professionals must take all opportunities, particularly those contacts during the early years, to remind parents and carers of the importance of immunisations and the need to have them at the appropriate times;

- GPs should offer a course of HPV vaccine to any girl, and in due course (subject to GP negotiations) cohorts of eligible boys under the age of 25 who have not received or completed it at school.

Vaccine schedule

4.6 For planning purposes, PHE has recommended a 0 and 12 month schedule but local needs should be considered when planning the programme; some local areas may choose to schedule the second dose from six months after the first. Any gap between 6 and 24 months is acceptable. Children from eligible cohorts who miss appointments should be caught up as soon as possible and remain eligible to start the course until their 18th birthday. A locally commissioned HPV service should immunise the eligible population using one of the following proposed options:

	Dose 1 - Year 8	Dose 2 - Year 8	Dose 2 - Year 9 girls only (this does not include boys in year 9 during the academic year 2019/20)
Option 1	Autumn Term	n/a	Autumn Term
Option 2	Spring Term	n/a	Spring Term
Option 3	Summer Term	n/a	Summer Term
Option 4	Autumn Term	Summer Term	n/a

4.7 Further information on scheduling is available in the HPV chapter of the Green Book: <https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>

4.8 For children who are immunised in a non-school setting the schedule is the same.

4.9 In addition:

- local 'catch-up' arrangements must be considered;
- health professionals must take all opportunities to remind the eligible population of the importance of HPV immunisation. In addition girls should be reminded of the need to attend cervical screening when eligible/invited;
- the HPV immunisation status of a young person must actively be considered at the time of the teenage booster, and if incomplete or missed, the vaccine should be offered.

Vaccine ordering

4.10 All centrally procured vaccines must be ordered via the ImmForm online ordering system, details of which are given in the core immunisation service specification.

Documentation

4.11 Accurate recording of all vaccines given and good management of all associated documentation is essential. Commissioners must ensure that all the core elements set out in the core service specification are included in contracts and specifications. In addition there are specific recording requirements for the HPV programme as follows:

- The provider must ensure that information on vaccines administered is submitted directly to any relevant population immunisation registers, in most areas this is the Child Health Information System (CHIS).
- Following an immunisation session/clinic or individual immunisation, local arrangements should be made for the transfer of data onto the relevant CHIS. Where possible this should aim to be within two working days.
- Arrangements will also be required to inform neighbouring areas when children resident in their area are immunised outside their local area.
- The provider must ensure that information on vaccines administered is forwarded to in the general practice record (if not given in general practice). In most areas, the CHIS will inform GPs that a patient on their list has been immunised via the current vaccination history printout. This is important in order to ensure eligible children who are not up to date can be caught up before their 25th birthday.
- The provider must ensure that HPV vaccine status of girls and young women is recorded on the [NHAIS \(Open Exeter System\)](#), in addition to the local recording on CHIS and GP clinical records. This is essential so that as these young women become eligible for the NHS Cervical Screening programme (currently at the age of 25) their immunisation history is known. It is expected that in due course different screening protocols may be introduced for women who were vaccinated as girls but this will be dependent on the vaccination status being recorded in the correct systems. It is imperative that this information is added to the NHAIS system as soon as possible after vaccination in order that it can be as accurate as possible and, as changes to name and location occur through life, the record will then follow the woman as part of her NHS history. Data can be uploaded manually or by electronic transfer from CHIS to NHAIS: current instructions should be consulted and complied with.

Vaccine coverage data collection

4.12 The HPV vaccine coverage collection is mandated through an Information Standard Notice Human Papilloma Virus (HPV) Vaccine Uptake (SCCI0133 Amd 60/2015) issued by the Standardisation Committee for Care Information (SCCI) which has the remit for the national governance of information standards and collections (including extractions). More information about SCCI can be found on the NHS Digital SCCI web pages - <http://www.hscic.gov.uk/isce>

4.13 The annual HPV coverage statistics are classified as 'official statistics' and are published as a sub-indicator in the Public Health Outcomes Framework (PHOF). The Statistics and Registration Service Act 2007 defines 'official statistics' as all those statistical outputs produced by the UK Statistics Authority's executive office (the

Office for National Statistics), by central Government departments and agencies, by the devolved administrations in Northern Ireland, Scotland and Wales, and by other Crown bodies (over 200 bodies in total). Official statistics are fundamental to good government, to the delivery of public services and to decision-making in all sectors of society. They provide Parliament and the public with a window on society and the economy, and on the work and performance of government.

- 4.14 The HPV collection consists of one annual survey with data collected at the local authority level. From the 2019/20 academic year, when, as anticipated, the HPV vaccine is rolled out to eligible boys aged 12 -13 years vaccine coverage will need to be collected separately for boys and girls. This will enable close monitoring of the offer of vaccination to boys and inform programme planning in future. Further details will be provided in the PHE adolescent vaccine coverage user guide. The data is collected via ImmForm, which provides a manual online data submission function for NHS England and NHS Improvement local teams and other data providers, together with relevant survey information and guidance for the HPV vaccine coverage collection. PHE is responsible for managing ImmForm, as well as the data collection, validation, reporting and analysis of the data. See [HPV collection user guide](#) for detail – this is updated on an annual basis.
- 4.15 In the 2019/20 academic year there will be a need to closely monitor the roll-out of the HPV vaccine to boys and ensure that the girls' programme is not negatively impacted. For this purpose, there will be additional reporting requirements during the year for NHS England and NHS Improvement assurance purposes. This is in addition to the annual HPV vaccine coverage collection managed by PHE. The PHE HPV data collection tool can and should be used by areas to monitor coverage in real-time:
- i) areas that offer the first HPV dose in the Autumn Term will be asked to report provisional vaccine coverage figures at school level and / or LA level by gender by the end of financial year Q3 2019/20, i.e. December 2019.
 - ii) areas that offer the first HPV dose in the Spring Term will be asked to report provisional vaccine coverage at school level and / or LA level by gender by the end of financial year Q4 2019/20 i.e. March 2020.
 - iii) NHS England and NHS Improvement will provide details of how this assurance reporting will work in due course. These data will not be published as they will be partial and unvalidated – they will be used solely for internal programme monitoring and planning purposes.