

# NHS public health functions agreement 2016-17

Service specification No.11 Human papillomavirus (HPV) programme

Classification: official

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- 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; 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

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**Prepared by Public Health England** 

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# Service specification No.11

This is a service specification to accompany the 'NHS public health functions agreement 2016-17 (the '2016-17 agreement') published in December 2015.

This service specification is to be applied by NHS England in accordance with the 2016-17 agreement. This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

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 2016-17 agreement was made between the Secretary of State and NHS England Board, unless otherwise specified. Any changes in other published documents or standards may have effect for the purposes of the 2016-17 agreement in accordance with the procedures described in Chapter 3 of the 2016-17 agreement

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

The 2016-17 agreement is available at www.gov.uk (search for 'commissioning public health').

All current service specifications are available at <a href="www.england.nhs.uk">www.england.nhs.uk</a> (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 <a href="Green Book">Green Book</a>.

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# 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. 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 from developing cervical cancer. 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 disease 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 providers are required to implement these changes in a timely way as directed by the national schedule.
- 1.4 <u>Immunisation against infectious disease</u> (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 vaccines are highly effective at preventing the infection of susceptible women with the HPV types covered by the vaccine.
- 2.2 The UK successfully implemented an HPV immunisation programme in September 2008. This programme has achieved coverage that is amongst the highest in the world. It has been estimated that this programme will prevent 400 women each year from developing cervical cancer. The 2013/14 annual report on HPV immunisation coverage reports 86.7% of the target population of 12-13 year-old females completed the three-dose course.
- 2.3 The UK has a population of 25.51 million women aged 15 years and older who are at risk of developing cervical cancer. Cancer registration data show that around 2500 women are diagnosed with invasive cervical cancer and about 1000 die from the disease every year. Cervical cancer ranks as the eleventh most frequent cancer among women in the UK, and the second most frequent cancer among women between 15 and 44 years of age worldwide.
- 2.4 Persistent infection by high-risk HPV types is detectable in more than 99% of cervical cancers. Of these high-risk types, HPV16 is responsible for more than 50% and HPV18 for more than 15% of all cervical cancers in Europe. A further 11 high-risk types have been described. Two vaccines against HPV16 and HPV18 have been found to be highly efficacious in preventing disease due to these HPV types, and to have a limited effect on disease associated with other, non-vaccine, high-risk types.
- 2.5 The introduction of a national cervical screening programme in the UK in the late 1980s made a major contribution to the fall in the incidence of and the mortality associated with cervical cancer. It is estimated that the cervical cancer screening programme saves around 5000 lives a year. The HPV immunisation programme builds on this and will help to further protect women by preventing HPV infection and the development of cervical cancer.
- 2.6 In March 2014, the Joint Committee on Vaccination and Immunisation (JCVI) revised its existing recommendation on the HPV vaccination programme for adolescent girls to change from a three-dose to a two-dose schedule. Emerging evidence from evaluations of the programme around the world has shown that the number of young women with pre-cancerous lesions is falling and all the current indications are that this protection will last for many years. More recent research shows that the antibody levels provided by two doses of the vaccine in young adolescent girls is very good and therefore protection from this schedule is also likely to be long lasting.

#### The HPV immunisation programme – key details

#### 2.7 The key details are that:

- in October 2007, the Department of Health (DH) announced the introduction of the HPV vaccine into the routine national immunisation schedule, and a catch-up programme for girls above the age of routine immunisation (up to age 18). The routine national programme started in September 2008 as a three-dose course for all 12 to 13 year-old (i.e. school year 8) girls given over a six-month period. Schoolbased delivery of the programme was recommended.
- the catch-up programme, originally planned to run over two years (2009/10 and 2010/11) targeted girls up to age 18 in September 2008. In December 2008, DH announced the acceleration of the HPV catch-up programme for these older girls. This acceleration enabled all girls identified for the catch-up programme (girls born between 1 September 1991 and 31 August 1995) to be offered the vaccine in the 2009/10 academic year.
- 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, are 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.

### 3 Scope

#### **Aims**

3.1 The aim of the HPV immunisation programme is to reduce morbidity and mortality from cervical cancer by routinely offering the vaccination to 12 to 13 year-old (i.e. school year 8) girls.

#### **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 2016-2017.

# 4 Service description / care pathway

#### Local service delivery

- 4.1 The delivery of immunisation services at the 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 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 is will ensure highest vaccine coverage among the target population.
- 4.3 There is also scope to enable NHS England 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 girls (school year 8) and those 13 to 14 year old girls (school year 9) where the programme is offered across two academic years;
  - any girl in school years 8, 9, 10 and 11 regardless of date of birth who has not had
    the full course of HPV vaccines. This may include girls who are resident in
    neighbouring CCGs but are attending school in a different CCG. This will include
    girls in eligible age groups who move into the area, school or who newly register
    with a general practice after the invitations have been issued.
- 4.5 Additionally NHS England will wish to ensure that providers:
  - offer immunisation to girls who are in special schools, pupil referral units and independent schools. Immunisation should also be offered to girls who are educated at home;
  - ensure that any girl 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 girls from communities
    with objections to immunisation on family or religious beliefs and hard to reach
    groups, which may include looked after children and girls 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, under the age of 18 who has not received or completed it, as a matter of good practice.

#### 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. Girls who miss appointments should be caught up as soon as possible and remain eligible to start the course until their 18<sup>th</sup> birthday. A locally commissioned HPV service should immunise the eligible population using one of the following proposed options:

	Dose 1 - Year 8 girls	Dose 2 - Year 8 girls	Dose 2 - Year 9 girls
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: <a href="https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book">https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book</a>
- 4.8 For girls 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, and of 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**

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 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 documented 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 girls who are not up to date can be caught up before their 18<sup>th</sup> birthday.
- The provider must ensure that HPV vaccine status of girls and young women is recorded on the <a href="NHAIS">NHAIS</a> (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

- 4.11 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). This has been recently updated to reflect the change to the two-course schedule. More information about SCCI can be found on the HSCIC SCCI web pages <a href="http://www.hscic.gov.uk/isce">http://www.hscic.gov.uk/isce</a>
- 4.12 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.
- 4.13 The HPV collection consists of one annual survey with data collected at the local authority level. The data are collected via ImmForm, which provides a manual online data submission function for NHS England 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 <a href="HPV collection user guide">HPV collection user guide</a> for detail this is updated on an annual basis.