



Public Health  
England



# NHS public health functions agreement 2019-20

**Service specification No.32**  
**Human papillomavirus immunisation programme**  
**for men who have sex with men (HPV-MSM)**

NHS England and NHS Improvement



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Version number: FINAL

First published: July 2019

Publication number: 000019

Prepared by: Public Health England with NHS England and NHS Improvement Public Health Commissioning

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 and those who do not share it (as required under the Equality Act 2010); and
- Given due 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.32

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](http://www.gov.uk) (search for 'commissioning public health').

All current service specifications are available at [www.england.nhs.uk](http://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-MSM immunisation programme

- 1.1 This document relates to the human papillomavirus (HPV) immunisation programme for men who have sex with men (MSM) up to and including the age of 45 years, who attend Specialist Sexual Health services (SSHS) and/or HIV clinics. It follows the advice of the Joint Committee for Vaccination and Immunisation (JCVI) that the HPV vaccine should be offered to MSM in this age group who attend these services.
- 1.2 This programme will be delivered with the aim of reducing the incidence of anal, penile and oropharyngeal cancers and anogenital warts. The purpose of the service specification is to enable NHS England and NHS Improvement to commission specific local HPV-MSM immunisation services to a standard that will help to protect men from developing anal, penile and oropharyngeal cancer and anogenital warts. NHS England and NHS Improvement may choose to collaborate with the relevant SSHS/HIV commissioner where appropriate. 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 [clinical and operational guidance](#), the [core service specification](#) which underpins national and local commissioning practices and service delivery, the online version of the [Green Book](#), all current relevant official public health letters and with additional evidence, advice and recommendations by the Joint Committee on Vaccination and Immunisation (JCVI).
- 1.3 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.

## 2 Population needs

### Background

- 2.1 The HPV vaccination is highly effective at preventing the infection of susceptible women with the HPV types covered by the vaccine. The UK successfully implemented a HPV immunisation programme for adolescent girls 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 2016/17 annual report on HPV immunisation coverage reports 83.1% of the target population of 12-13 year-old females completed the recommended two-dose course.
- 2.2 Following advice from JCVI in July 2018, DHSC announced the same month that the programme will be extended to boys. From academic year 2019/20, both boys and girls in school year 8 (aged 12 and 13 years), will be offered HPV vaccine. No catch up programme is planned for boys. Although the gender neutral programme will eventually protect all males, including MSM, this will not happen for a number of years.
- 2.3 Evidence has emerged that HPV immunisation is likely to provide protection against a wider range of HPV-related diseases, including anal, penile and oropharyngeal cancers and anogenital warts. Men who have sex with men (MSM) are a group at high risk of HPV infection and associated disease, who receive very little indirect health benefit from the adolescent girls programme.
- 2.4 HPV infection is associated with a range of cancers, including around 80-85% of anal cancers, 36% of oropharyngeal cancer, and 50% of penile cancers.
- 2.5 The current vaccine Gardasil® protects against HPV types 6, 11, 16 and 18.
- 2.6 JCVI advised that a targeted HPV vaccination programme for MSM aged up to 45 who attend GUM and HIV clinics should be undertaken, subject to procurement of the vaccine and delivery of the programme at a cost-effective price. MSM aged between 15 and up to and including the age of 45 years will receive a three dose course while those under 15 years will receive a two dose course of the vaccine.
- 2.7 It is expected that a high proportion of eligible MSM would be vaccinated in the first few years of the programme. The number of individuals eligible for vaccination (i.e. those not yet vaccinated) will reduce and stabilise after a few years, although this is offset to some extent by new MSM attenders to SSHS.

### Other clinical groups and delivery in prison settings

- 2.8 An opt-out approach is intended to be piloted in up to six prisons during 2019/20.

## 3 Scope

### Aims

- 3.1 The aim of the HPV-MSM immunisation programme is to reduce morbidity and mortality from anal, penile and oropharyngeal cancers and anogenital warts.

### Objectives

- 3.2 The aim will be achieved by delivering a targeted, evidence-based immunisation programme that:
- identifies the eligible population and ensures effective, timely delivery with high coverage (see eligible population set out in paragraph 4.5);
  - 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;
  - provides relevant information and advice to the identified cohort;
  - is supported by regular and accurate data collection, audit and using the appropriate returns to support formal evaluation of the program.

### 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 timely vaccination and high coverage in the target population;
  - minimise adverse physical/psychological/clinical aspects of immunisation (e.g. anxiety, adverse reactions).

### Baseline Vaccine Coverage

- 3.4 Local areas must ensure they deliver good immunisation coverage (with reference to vaccine coverage public health outcomes framework indicators) with the aim of 100% of eligible 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 SSHS and HIV clinics are by far the most accessed sexual healthcare service by self-declaring MSM, who might not otherwise self-declare to a GP. The majority of MSM accessing SSHS services are within a high-risk group within the MSM population in terms of risky behaviour and STI transmission.
- 4.2 Delivery of the immunisation programme at the local level will be ideally via Level 3 SSHS clinics commissioned by Local Authorities and outpatient HIV clinics commissioned as part of prescribed specialised services by NHS England and NHS Improvement.
- 4.3 Vaccine delivery will be opportunistic, with the first dose offered when the eligible individual attends SSHS or HIV services for other reasons. Where accepted the service will arrange for the full course of vaccination to be given according to the schedule, and where possible, alongside existing appointments for other sexual health care/treatment, recommended GUM re-attendance, or other SSHS or HIV care. Individuals accessing sexual health services online will be assessed for vaccine eligibility and signposted to a clinic for vaccination where appropriate. The delivery of immunisation services at the local level will be based on evolving best practice. There will not be a specific call system; rather, eligible individuals will be offered the initial dose when they turn up at the clinic or access online services.

### Target population

- 4.4 Level 3 SSHS clinics (specialist services, led by a consultant on the specialist register for genitourinary medicine services, and offering a comprehensive range of STI services) and HIV clinics should make the HPV vaccine available to all MSM up to and including the age of 45 years who attend the clinic.

### Vaccine schedule

- 4.5 The recommended schedule for individuals 15 years of age and older is three doses, and two doses at least 6 months apart for individuals under 15 years of age.
- 4.6 Whenever possible, immunisations for all individuals eligible for a three-dose schedule should follow the recommended 0, 1, 4-6 month schedule. However, due to the flexibility in the Gardasil® Summary of Product Characteristics (SPC), variable spacing options for the three doses are possible. This should enable the administration of subsequent doses to be aligned with recommended SSHS re-attendance in order to avoid the need for additional visits for vaccination only. In a 3 dose schedule, the second dose should be administered at least 1 month after

the first dose and the third dose should be administered at least 3 months after the second dose. All three doses should ideally be given within one year; however a 24 month period is clinically acceptable.

- 4.7 If the course is interrupted, it should be resumed but not repeated, ideally allowing the appropriate interval between the remaining doses.
- 4.8 Clinics may use existing recall systems to maximise the proportion of eligible individuals completing their courses (such as SMS and/or email recall system) where it is understood that delivery of vaccine is covered by S7a.
- 4.9 Further information on scheduling is available in the clinical and operational guidance and the HPV chapter of the Green Book:  
<https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>

### Vaccine ordering

- 4.10 All centrally procured vaccines must be ordered via the ImmForm online ordering system. Providers should register to order vaccine via ImmForm:
  - Online: <http://www.immform.dh.gov.uk/SignIn.aspx?ReturnUrl=%2f>
  - Via email: Send your request to [helpdesk@immform.org.uk](mailto:helpdesk@immform.org.uk)
- 4.11 Further help is available at:
  - <http://www.gov.uk/government/organisations/public-health-england/series/immform>
  - ImmForm Helpdesk: 0844 376 0040.
- 4.12 Vaccines will be distributed by Movianto UK (Tel: 01234 248631) as part of the national immunisation programme.

### Vaccine storage and wastage

- 4.13 Effective management of vaccines is essential to ensure patient safety and reduce vaccine wastage. Providers will have effective cold chain and administrative protocols that reduce vaccine wastage to a minimum and reflect national protocols (e.g. Chapter 3 of the Green Book and the PHE (2014) [Protocol for ordering, storing and handling vaccines](#)) including:
  - how to maintain accurate records of vaccine stock;
  - how to record vaccine fridge temperatures;
  - how to reset fridge thermometers;
  - what to do if the temperature falls outside the recommended range.
- 4.14 For help using ImmForm, providers need to log-in to the site and access the help pages: [https:// portal.immform.dh.gov.uk/Logon.aspx?returnurl=%2f](https://portal.immform.dh.gov.uk/Logon.aspx?returnurl=%2f)
- 4.15 The Provider will:
  - ensure all vaccines are delivered to an appointed place;
  - ensure that at least one named individual is responsible for the receipt and safe storage of vaccines in each premise;

- ensure that approved pharmaceutical grade cold boxes are used for transporting vaccines;
- ensure that only minimum stock levels (two to four weeks maximum) of vaccine will be held in pharmaceutical grade vaccine fridges, to reduce the risk of wastage caused by power cuts or inadvertent disconnection of fridges from power supplies;
- Any cold chain failures or other stock incidents must be documented and reported as part of the evaluation and recorded through the ImmForm website on the Stock Incident page found in the Vaccine Supply section, and to the Public Health Commissioning Team: [england.phs7apmo@nhs.net](mailto:england.phs7apmo@nhs.net)
- monitor usage and any wastage of vaccine.

## Documentation

- 4.16 Accurate recording of all vaccines given and good management of all associated documentation is essential.
- 4.17 Suspected adverse reactions (ADR) to vaccines will be reported via the Yellow Card Scheme (<https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/>). Chapter Nine of the Green Book gives detailed guidance on which ADRs to report and how to do so. Additionally, Chapter Eight of the Green Book provides detailed advice on managing ADRs following immunisation.
- 4.18 Any reported adverse incidents, errors or events during or post vaccination must follow determined procedures. In addition, teams will keep a local log of reports and discuss such events with the Screening and Immunisation Team staff.
- 4.19 A Patient group Direction (PGD) may be used where required to facilitate service delivery. A PHE PGD template for the service is available for local authorisation: <https://www.gov.uk/government/publications/human-papillomavirus-hpv-vaccine-for-msm-pgd-template>

## Vaccine coverage data collection

- 4.20 Vaccine uptake will be monitored primarily via two existing surveillance and reporting systems, namely the GUMCAD STI Surveillance System and the HIV and AIDS reporting system (HARS). These systems record sexual preference of clinic attendees. Providers should ensure that GUMCAD data are in line with the latest technical specification and that they are using the latest version of HARS (HARSv1.2).
- 4.21 GUMCAD collection will use three existing SHHAPT codes:
- W1: HPV vaccination: 1st dose
  - W2: HPV vaccination: 2nd dose
  - W3: HPV vaccination: 3rd dose,
- 4.22 and two new SHHAPT codes:
- W4: HPV vaccine offered and declined (pending approval from NHS Digital in 2018/19)

- W5: HPV vaccine not offered: previously received in full.

4.23 HARS collection will include two new items:

- AN2: Human papillomavirus (HPV) vaccine activity offer status code:
  - 01: Offered and Undecided
  - 02: Offered and Declined
  - 03: Offered and Accepted
  - 05 Not Offered: HPV vaccination previously received in full
  - 06: Not offered: Other reason
  - 09: Not known (Not recorded),
- AN1: HPV Vaccination Dose Number Given:
  - 1: 1st dose given
  - 2: 2nd dose given
  - 3: 3rd dose given.

4.24 Vaccination records for each eligible MSM attending a SSHS clinic should be coded on GUMCAD. Vaccination records for each eligible MSM attending for HIV related care should be coded on HARS (in addition, if your clinic would usually also enter an attendance for HIV related care on GUMCAD (i.e. SHHAPT code H2) then the HPV vaccination records should be entered on both GUMCAD and HARS).

4.25 The number of HPV vaccination doses given at SHSS is anticipated to be published annually as part of official statistics.

## 5 Clinical and Corporate Governance

### Documentation

- 5.1 Accurate recording of all vaccines given and good management of all associated documentation is essential.
- 5.2 The Provider will ensure that:
- the following information is recorded:
    - any contraindications to the vaccine;
    - any refusal of an offer of vaccination;
    - details of consent and the relationship of the person who gave the consent (if not the patient);
    - the batch number, expiry date and the product name of the vaccination;
    - the date of administration of the vaccine;
    - the site and route of administration;
    - any adverse reactions to the vaccine;
    - the name of the immuniser.

### Governance

- 5.3 The provider will ensure that there are clear lines of accountability for clinical governance and reporting to assure the on-going quality and success of the service.
- 5.4 Providers are required to ensure:
- there is a clear line of accountability from local Providers to the Commissioner;
  - clear incident reporting mechanisms are in place so that any learning can be shared;
  - that there is appropriate internal clinical oversight of the service's management and a nominated lead for immunisation is in place;
  - evidence of governance should be available, if requested, to the commissioner, a clinical lead and immunisation system leader;
  - there is regular monitoring and audit of the service, including the establishment and review of a risk register by the Provider as a routine part of clinical governance arrangements, in order to assure the Commissioner of the quality and integrity of the service;
  - the supply of evidence of clinical governance and effectiveness arrangements to the Commissioner, if requested. Public Health England will alert the Commissioner to any issues that need further investigation;

- the provision of high quality, accurate and timely data to relevant parties including the Commissioner. This is a requirement for payment. Data will be analysed and interpreted by Public Health England and any issues that arise will be shared quickly with the Commissioner and others;
- the documentation, management and reporting on programmatic or vaccine administration errors, including serious incidents, and escalate as needed. This will include involving the Commissioner and relevant partners and where appropriate for the Commissioner to inform Department of Health. The NHS England and NHS Improvement press office will liaise closely with Department of Health and Social Care, Public Health England and the Medicines and Healthcare Products Regulatory Agency press offices on the management of press enquiries as necessary.