Public Health England

Protecting and improving the nation's health

Human papillomavirus (HPV) vaccination for Men who have sex with Men (MSM)

2016/17 pilot evaluation

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health, and are a distinct delivery organisation with operational autonomy to advise and support government, local authorities and the NHS in a professionally independent manner.

Public Health England
Wellington House
133-155 Waterloo Road
London SE1 8UG
Tel: 020 7654 8000
www.gov.uk/phe
Twitter: @PHE_uk
Facebook: www.facebook.com/PublicHealthEngland

Prepared by: Nalini Iyanger, David Mesher, Marta Checchi, Mark McCall, Kate Soldan, Karen Powell, Julie Nugent, Jonathan Crofts, Joanne Yarwood, Michael Edelstein

The authors would also like to acknowledge the support and contribution of the GUMCAD and HARS teams at PHE's HIV/STI department.

For queries relating to this document, please contact: immunisation@phe.gov.uk

Published February 2018
PHE publications gateway number: 2017373

PHE supports the UN Sustainable Development Goals

Contents

Executive summary

In November 2015, the Joint Committee on Vaccination and Immunisation (JCVI) advised that a targeted Human papillomavirus (HPV) vaccination programme should be introduced in England for men who have sex with men (MSM) aged up to 45 years, attending sexual health clinics. The JCVI acknowledged the potential complexity of delivering an opportunistic national vaccination programme in such a setting. As a result a pilot was set up to evaluate the feasibility, acceptability, uptake, impact and equity of a potential national HPV vaccination programme for MSM. This report presents an evaluation of the first year (2016/2017) of the pilot.

To evaluate the pilot, data from clinical recording systems and a survey administered to individuals receiving the vaccine were used, together with feedback from clinics and sexual health commissioners.

Overall, recorded first dose uptake was 45.5%. Only 3.4% of eligible individuals were recorded as being offered and declining the vaccine. Anecdotal reports from clinics plus prior experience with introduction of new codes into the recording systems suggest that data recording has been incomplete and these percentages are likely to be underestimated. Recorded first dose uptake decreased slightly with increasing age and was higher in rural areas. Analysis of attendance data suggested a limited impact of HPV vaccination on clinic attendance, although longer follow up is needed.

Survey results suggested that 8.1% of those receiving the first dose of HPV vaccine were new attendees and that among those, under 11% attended just to receive the vaccine. Vaccination delivery was successfully integrated into usual sexual health clinic attendances and sexual health clinics were the setting preferred by patients for completing these vaccinations. Of those having their first HPV vaccination, 94.6% indicated they would like to receive the next vaccine doses at the same clinic and 85.4% of patients reported accessing other health services at the same time as attending for the first dose of vaccine.
Feedback from sexual health providers suggested that the model used, where vaccine was centrally provided free of charge and clinics claimed an administration fee of £10 per dose, was acceptable.

The first review of the pilot demonstrated that such a programme can be delivered opportunistically in an acceptable and, as far as can be evaluated, equitable manner, without major disruption to GUM and HIV clinics.

Background

This report presents an evaluation of the first year (2016/2017) of the Human papillomavirus (HPV) vaccination pilot programme for men who have sex with men (MSM), delivered by genito-urinary medicine (GUM[1]) and HIV clinics in England. The pilot was intended to inform the implementation of a national HPV vaccination programme for MSM. The pilot continues until March 2018.

The disease

HPV is a virus transmitted through sexual contact. There are over 100 different types of HPV, 13 of which are known to be associated with 99% of cervical cancers, with 2 types (HPV16 and HPV18) responsible for about 80% of all cervical cancers in the UK. HPV strain types 6 and 11 are also associated with about 90% of genital warts, whilst HPV strain types 16 and 18 are associated with cancers of the anus, penis, mouth and throat, vagina and vulva in addition to cervical cancers. Further information about the disease can be found in the 'Human papillomavirus (HPV): Immunisation Against Infectious Disease, the Greenbook chapter 18a[2].'

The vaccine

In 2008, on the advice of the Joint Committee on Vaccination and Immunisation (JCVI), a HPV vaccination programme was introduced across the UK to routinely offer a course of vaccine to all girls aged 12-13. The girls' HPV vaccine programme is expected to provide substantial indirect protection to boys as long as there is high vaccine coverage in girls. Further information about the girls vaccination programme, including vaccine coverage is available on the Public Health England (PHE) website[3]. The JCVI recognised that MSM where expected to receive far less indirect protection from the HPV vaccination programme in adolescent girls[4].

In November 2015, the JCVI advised that a targeted HPV vaccination programme should be introduced for MSM aged up to 45 years who attend GUM and HIV clinics, subject to procurement of the vaccine and delivery of the programme at a cost-effective price[4]. JCVI recognised that the mechanisms and arrangements by which a targeted programme of vaccinating MSM in GUM and HIV clinics could be undertaken were complex[5]**.** A pilot approach was therefore adopted.

---

[1] GUM services include GUM and integrated GUM/sexual and reproductive health services, and are also known as specialist sexual health services
[2]https://www.gov.uk/government/publications/human-papillomavirus-hpv-the-green-book-chapter-18a
[3]https://www.gov.uk/government/collections/vaccine-uptake#hpv-vaccine-uptake
[4]https://www.gov.uk/government/publications/jcvi-statement-on-hpv-vaccination-of-men-who-have-sex-with-men
[5] https://www.gov.uk/government/publications/jcvi-statement-on-hpv-vaccination-of-men-who-have-sex-with-men

The vaccine schedule for the girls' programme and other individuals under the age of 15 is two doses at 0 and 6-24 months. For individuals over the age of 15 years old and for HIV positive individuals, a three dose schedule at 0, 1, and 4-6 months is recommended[6]. All three doses should ideally be given within a 12-month period. For opportunistic delivery, in order to accommodate the attendance patterns of MSM at GUM clinics, it was deemed clinically acceptable to extend the timeframe of three-dose delivery to MSM to 24 months.

Pilot characteristics

- The pilot began in summer 2016.
- Forty-two sites across England, covering ~20% of clinics in England and around a third of the MSM population attending GUM and HIV clinics were recruited (appendix 1).
- The pilot sites offered opportunistic HPV vaccination for MSM (up to the age of 45) who attended GUM and HIV clinics.
- A full course consisted of three doses given, ideally, within twelve months, but up to 24 months. Given the timing of the doses, it was considered possible to align the vaccination with the usual recommended re-attendance interval for the target group[7]. Alternatively, clinics could use existing call/recall systems for 2nd and 3rd doses to maximise the proportion of eligible individuals completing their courses.
- Vaccine was provided free of charge to clinics by PHE. Clinics could claim a vaccine administration fee of £10 per dose.
- Vaccines for the pilot could be ordered through ImmForm; an established online ordering platform used by healthcare providers to order all vaccines which are centrally procured by PHE, and used for the national immunisation programme.
- Vaccine coverage was monitored using new codes introducted to existing surveillance and reporting systems, namely the The GUMCAD STI surveillance system[8] (GUMCAD) and the HIV and AIDS reporting system (HARS).
- The pilot was not advertised, in order to evaluate the impact of the programme when delivered opportunistically and to discourage health seeking behaviour from disrupting clinic attendance patterns.

[6]https://www.gov.uk/government/publications/human-papillomavirus-hpv-the-green-book-chapter-18a
[7]https://www.bashh.org/documents/BASHH%20Recommendations%20for%20testing%20for%20STIs%20in%20MSM%20-%20FINAL.pdf
[8] Savage EJ, Mohammed H, Leong G, et al. Improving surveillance of sexually transmitted infections using mandatory electronic clinical reporting: the genitourinary medicine clinic activity dataset, England, 2009 to 2013. Euro Surveill 2014;19:20981.

Aims of the evaluation

The evaluation was intended to review the programme's delivery, including feasibility, acceptability, uptake, impact on services and equity. The evaluation aimed to answer the following questions:

Feasibility

1. Is the current vaccine ordering and distribution system suitable for this service?
2. What is the level of vaccine usage and overage?
3. Can the programme be monitored adequately using existing surveillance systems?
4. Does an opportunistic vaccination strategy allow PHE to deliver the vaccine programme to the target population?

Uptake

5. What is the uptake of vaccination in the target group?

Impact on services

6. Has the pilot increased attendance to GUM/HIV services?

Acceptability

7. Are GUM/HIV clinics the preferred vaccination setting for the target population?
8. Is the administration fee acceptable to the providers?

Equity

9. Are there differences in uptake in terms of type of area (rural, town, major urban centres) and age?

Evaluation methods

The evaluation brings together a number of data sources, both routine and specifically collected for this purpose. These are:

- vaccine supply data
- GUMCAD and HARS data
- patient survey data
- provider and stakeholder feedback

The time period covered by the evaluation was April 2016 to March 2017.

Vaccine supply

Gardasil 4 is the trade name of the vaccine used for both the pilot and the national girls' programme. It is currently centrally procured for the national girls HPV immunisation programme. Sufficient HPV vaccine is held by PHE to support the delivery of the pilot, to continue to meet the requirement of the girls' programme and to support the delivery of the pilot without adversely impacting on the level of buffer stock, which is maintained to mitigate against supplier manufacturing and delivery failures.
Data on ordering and vaccine usage were collected in order to determine the requirements of both the second year of the pilot, and also to build the requirements of a potential national programme into future procurement planning for HPV vaccines.

GUMCAD and HARS data

Vaccine uptake

Vaccination uptake in GUM and HIV clinics is being monitored on an ongoing basis via two existing surveillance and reporting systems: GUMCAD and HARSv1.2, respectively. GUMCAD is a mandatory reporting system, providing disaggregate records of all attendances, testing and diagnoses at GUM clinics (among other sexual health services) in England. Data have been reported to PHE since 2008, with full coverage from 2009. This surveillance data are collected by local areas via specialist sexual health clinics (GUM and integrated GUM/Sexual and Reproductive Health (SRH) services) and submitted to PHE on a quarterly basis. HARSv1.2, also mandatory, collects data on patients diagnosed with HIV infection attending all NHS HIV outpatient services in England. It replaced the Survey of Prevalent HIV Infections Diagnosed

(SOPHID) and the HIV & AIDS New Diagnoses Database (HANDD). It is a consultation based, disaggregate dataset, submitted to PHE on a quarterly basis.

New HPV-specific reporting codes were developed and incorporated into both reporting systems before the start of the HPV MSM pilot. The codes capture the vaccine dose given (1st, 2nd, or 3rd dose), as well as whether vaccination was offered and refused, not offered, or whether it was previously received in full[9]. HARSv1.2 is currently undergoing a phased roll-out and is not yet available at all HIV clinics. A bespoke data collection system for HIV pilot clinics was used to collect uptake data in the interim.

Data were extracted from GUMCAD and HARS for participating pilot clinics from site-specific vaccination implementation start dates up to the end of March 2017. Eligible individuals were defined as those who have ever reported being MSM aged up to and including 45 years attending pilot site clinics on or after the date of first implementation at the clinic in question, and who did not initiate vaccination prior to the start of the pilot. Two participating pilot clinics had already started vaccinating MSM for HPV before the June 2016 start of the pilot. MSM attending these clinics will comprise the majority of those excluded for initiating vaccination prior to pilot start. Data from eight clinics were excluded on the basis of known data issues, to avoid inaccuracies in both the numerator and denominator.

First dose uptake was calculated as the proportion of eligible MSM who had a recorded first HPV vaccine dose. Second and third dose completion were calculated as the proportion of eligible MSM with a first dose who have a second dose recorded and with a second dose who have a third dose recorded, respectively. HPV vaccination data for HIV patients not included in HARS 1.1 or SOPHID were excluded.

Uptake figures were further stratified by clinic type (GUM and HIV clinics), age group, and clinic urban/rural classifications. Age groups were constructed by taking the age at first attendance following date of implementation of vaccination at the pilot site, and defined as up to and including age 25, 26-30, 31-35, 36-40, and 41-45 years of age. Urban and rural classifications were defined as ‘Urban major conurbation’, ‘Urban city and town’, and ‘Rural village and dispersed’, based on clinic Lower Super Output Area[10] (LSOA).

[9]h+ttps://www.gov.uk/government/uploads/system/uploads/attachment_data/file/547397/Clinical_and_operational_guidance_for_HPV_MSM_pilot.pdf

[10]http://www.datadictionary.nhs.uk/data_dictionary/nhs_business_definitions/l/lower_layer_super_output_area_de.asp?shownav=1

Attendance patterns

Attendance patterns were analysed for GUM clinics using GUMCAD data on attendances. HARS data were excluded due to inability to de-duplicate patients attending GUM and HIV clinics on same date. It is unlikely that changes in attendances will be seen in HIV positive MSM due to HPV vaccination, as the proportion of HIV positive MSM attending for care is already high. Data were extracted from the GUMCAD dataset for participating clinics from site-specific pilot implementation start dates to end of March 2017. Similarly to uptake, the analysis was restricted to MSM aged up to and including 45 years.

Trends in attendance patterns pre- and post-introduction of HPV vaccination were compared between participating pilot clinics and non-pilot clinics in order to detect whether attendances have increased since the HPV MSM pilot was implemented in June 2016.

Patient survey

Patients attending for the first dose of the HPV vaccination were asked to complete a survey aimed to address the questions the pilot purported to answer (appendix 2), with regards to feasibility, acceptability, impact on attendance and equity. In order to calculate sample size, the 42 participating clinics were aggregated by provider into 29 geographical clusters. For each cluster a minimum number of responses required to have a 95% confidence interval (95%CI) of a maximum of +/- 5% around the point estimate for each question was calculated, using the number of estimated courses that would be delivered at each clinic as population size. Each clinic was asked to consecutively administer the questionnaire in the clinic to every person receiving the vaccine until the sample size for that clinic was reached.

Survey responses were discarded where the information provided did not allow linkage with one of the pilot clinics. Responses were weighted by clinic population size (calculated using GUMCAD, as for uptake) in each clinic, in order to account for the fact that the response rate varied between clinics.

Free text answers were not analysed for the purpose of this evaluation and ‘other’ responses are reported as such.

The proportion of answers to each question contributing to answering the evaluation’s questions was presented along with 95% confidence intervals.

Survey responses were stratified where necessary to answer pilot questions, specifically:

-Reason for attendance (Q4) was stratified by new/existing sexual health service attendees (Q1) in order to evaluate the pilot’s impact on services.

-Awareness of the availability of the vaccine (Q3), setting preference for subsequent doses (Q9) and access to other services (Q6) were stratified by urban/rural setting classifications, as described above, in order to evaluate the pilot's equity.
Survey responses were aggregated where necessary, specifically answers to the choices 'I wanted vaccine and my local clinic does not have it' and 'I wanted vaccine and knew this clinic provided it' in Q7 were aggregated in order to evaluate the pilot's impact on services.

Provider feedback

A meeting was held with providers in March 2017, attended by sixteen leads from the pilot clinics. This was a one-off event intended to give information to providers on the pilot and learn from their experience.

Results

Feasibility

Evaluation of the feasibility of an opportunistic vaccination programme in these settings includes a review of:

- vaccine ordering and distribution arrangements
- vaccine overage
- uptake monitoring arrangements
- patient survey
- provider and stakeholder feedback

Vaccine ordering and distribution arrangements

Delivery points for the pilot were, in general, to hospital pharmacies that were already using ImmForm (an established online ordering platform used by the NHS to order all centrally procured vaccines) and receiving deliveries of centrally procured vaccines, with further distribution managed locally where necessary. There were a small number of new accounts at new locations (where pilot clinics required direct deliveries) but the overall impact on the existing ordering and distribution arrangements for centrally procured vaccines was small.

The pilot included forty-two clinics, approximately 20% of the total number of GUM and HIV clinics in England. A national programme would require supplying the remaining 80% of the GUM and HIV clinics. This will require liaising with these clinics and establishing their requirements (ie to existing delivery points or new accounts) in order to determine the impact on current ordering and distribution arrangements.
Efforts were made to keep ordering for the pilot separate from ordering for the girls' HPV programme so that vaccine used for the pilot could be monitored both pilot-wide and for each clinic individually. Some errors, for example, where HPV vaccine being held for the girls'

programme was used for the pilot (or vice-versa), were picked up and rectified throughout the pilot. It is likely that there remains a level of cross use between the two programmes despite best efforts to keep them separate. This is an important factor to consider in the procurement planning for a potential national programme where the vaccine used for two separate programmes are currently the same, and in many cases the ordering and storage functions for both are carried out by the same personnel. In such instances, the administrative and logistical implications of ordering and storing separately may not have been perceived as worthwhile where the volumes ordered for MSM are comparatively small.

For the second year of the pilot new ordering arrangements have been put in place which should reduce the administrative burden of the ordering process (making it more likely that clinics order separately for the pilot and girls' programme). It will not resolve the issues around vaccine for both programmes being stored together for sites that order for both programmes.

Whilst the issue of cross-use of vaccine ordered for the pilot and girls programme needs to be considered, currently there are no concerns around the impact of ordering for the national buffer stock.

Vaccine overage

There were no restriction on volumes ordered per week; however an individually agreed overall allocation was applied to each account as the pilot was working within a finite amount of vaccine that was divided into individual allocations for each clinic with a small buffer. Clinics were requested to hold no more than two weeks' vaccine supply and re-order as required to limit stockpiling and potential vaccine overage. The amount of vaccine being ordered was monitored by PHE. The central team were not alerted to any issues where clinics were not able to access vaccine as needed. All pilot clinics worked within their allocations and there were no requests for additional vaccine by the end of March 2017. Ordering of vaccine for the pilot was monitored weekly and any unusual activity was investigated.

Clinics were asked to report any vaccine wasted either through accident, cold chain failure or expiry before use, through the stock incident facility provided through the ImmForm website. Only 2 stock incidents (cold chain failures) were reported which resulted in a total of 90 doses of vaccine being wasted.

Patient survey

The questions on the survey sought to identify if the HPV vaccines had been integrated into general access to GUM clinics as intended. Patients were asked if they accessed services other than just the HPV vaccine when attending the GUM clinic. Of the 7,169 patients who answered the question, 85.4% (95%CI 84.5-86.1) accessed other health services as part of their attendance for the HPV vaccine (table 1).

Table 1. Responses to patient survey

No.	Question	Number of individuals answering the questions	Response	Number of responses (n)	Percent* (%)	95% Confidence Intervals (%)
1	Have you ever attended a GUM/HIV clinic before?	8511	Yes	7734	91.8	91.3-92.4
			No	777	8.1	7.6-9.2
2	Is this your usual/local clinic?	8499	Yes	7293	86.8	86-87.5
			No	1206	13.0	12.5-14.0
3	Did you know prior to attending the clinic that the HPV vaccination is recommended for MSM?	8503	Yes	2709	31.1	30 -32.2
			No	5794	68.9	67.8-70
4	Was getting the HPV vaccine the main reason that you attended the clinic today?	4137	Yes	512	12.40	11.3-13.6
			Yes but also had another reason	521	11.1	10.1-12.2
			No	3104	76.5	75-77.9
6	Did you access any other health services?	8469	Yes	7169	85.4	84.5-86.1
			No	1300	14.6	13.9-15.5
7	Why did you choose to attend this particular clinic?	8486	Clinic I usually attend	5313	66.1	65.1-67.1
			My local clinic	2018	19.8	19.1-20.6
			Most convenient for me	2226	25.1	24.1-26.1
			I wanted vaccine and my local clinic does not have it	115	1.6	0.9-1.4
			I wanted vaccine and knew this clinic provided it	205	2.2	1.9-2.6
			Other reason	744	9.0	8.3-9.7
9	Where would you like to have your next vaccine dose?	8368	At this clinic	7821	94.6	94.2-95.2
			Clinic closer to where I live	500	5.0	4.6-5.5
			Clinic closer to where I work	241	2.2	1.9-2.6
			High street pharmacy	339	4.1	3.6-4.6
			My GP practice	677	7.2	6.6-7.7
			Other	6	0.05	0.002-0.16

*Proportions are weighted so may differ from dividing the number of responses to specific questions by the number of responders
Questions 5 and 8 were not used as part of the pilot evaluation

Provider and stakeholder feedback

Feedback from the provider meeting was largely positive. The pilot was considered successful in:

- engaging staff in thinking about interventions for MSM across the board
- achieving low rates of refusals
- achieving good uptake

The £10 per vaccine administration fee was considered to be acceptable and the leaflets provided for the programme were considered to be helpful.

Providers raised the following operational issues:

- busy clinics, therefore challenging to fit in vaccination
- time consuming and difficult to set up internally – specifically, training for staff and setting up patient group directions (PGDs) for nurses to administer vaccines
- fragmented commissioning arrangements
- coding difficulties in some clinics
- hard to catch the target population in some clinics as, under new provision models, asymptomatic patients are increasingly encouraged onto an on-line system and away from clinics

Uptake

Overall recorded first dose uptake was 45.5% (8,580/18,875, table 2) among all clinics included in the analysis. This is likely to be an underestimate due to variations in data recording as described below.

Among all attending MSM, 3.4% (636/18,875) were recorded as unvaccinated due to being offered the vaccine and declining it, while 51.2% (9,659/18,875) had no HPV-MSM vaccination code. The proportion of MSM offered and declining the vaccine decreased slightly with increasing age. Conversely, the proportion of attending MSM with no HPV-MSM vaccination code increased with increasing age. Proportions of MSM not recorded as vaccinated did not differ substantially between GUM and HIV only clinics. Among MSM attending GUM clinics, 3.4% (597/17,666) were offered and declined the vaccine, while 50.9% (8,995/17,666) had no HPV-MSM vaccination code. At HIV only clinics, 3.2% (39/1,209) of attending MSM were offered and declined the vaccine, while 54.9% (664/1,209) had no HPV-MSM vaccination code.

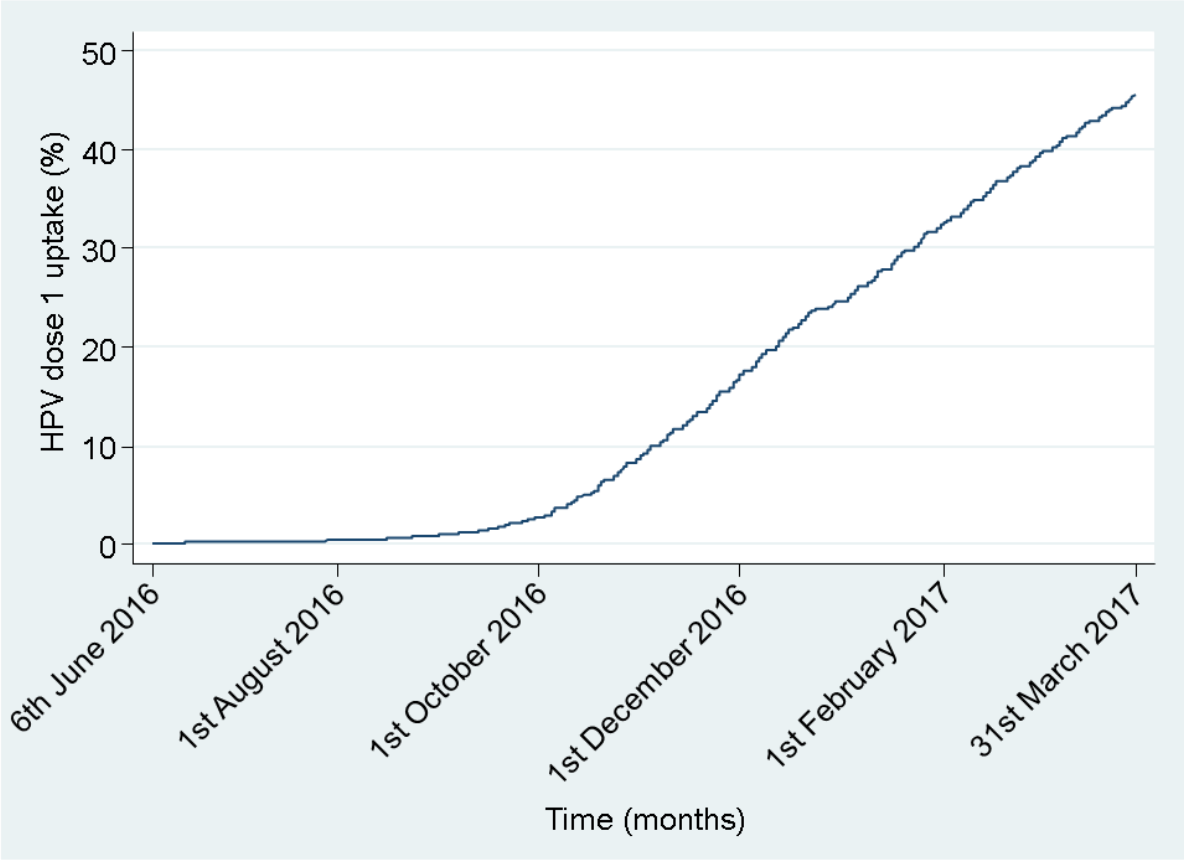
Table 2: Uptake of MSM HPV vaccination stratified by age and clinic type

Clinic type		All ages	≤25 years	26-30 years	31-35 years	36-40 years	41-45 years
All attending MSM	Attending MSM	***18,875***	***4,535***	***4,086***	***3,817***	***3,332***	***3,105***
	Vaccinated with 1st dose	**8,580 (45.5%)**	**2,323 (51.2%)**	**1,965 (48.1%)**	**1,748 (45.8%)**	**1,399 (42%)**	**1,145 (36.9%)**
	Unvaccinated						
	Offered vaccine and declined	**636 (3.4%)**	**201 (4.4%)**	**168 (4.1%)**	**120 (3.1%)**	**93 (2.8%)**	**54 (1.7%)**
	No HPV-MSM vaccination code	**9,659 (51.2%)**	**2,011 (44.3%)**	**1,953 (47.8%)**	**1,949 (51.1%)**	**1,840 (55.2%)**	**1,906 (61.4%)**
GUM clinics	Attending MSM	***17,666***	***4,436***	***3,909***	***3,537***	***3,029***	***2,755***
	Vaccinated with 1st dose	**8,074 (45.7%)**	**2,269 (51.1%)**	**1,876 (48%)**	**1,627 (46%)**	**1,279 (42.2%)**	**1,023 (37.1%)**
	Unvaccinated						
	Offered vaccine and declined	**597 (3.4%)**	**198 (4.5%)**	**163 (4.2%)**	**108 (3.1%)**	**83 (2.7%)**	**45 (1.6%)**
	No HPV-MSM vaccination code	**8,995 (50.9%)**	**1,969 (44.4%)**	**1,870 (47.8%)**	**1,802 (50.9%)**	**1,667 (55%)**	**1,687 (61.2%)**
HIV only clinics	Attending MSM	***1,209***	***99***	***177***	***280***	***303***	***350***
	Vaccinated with 1st dose	**506 (41.9%)**	**54 (54.5%)**	**89 (50.3%)**	**121 (43.2%)**	**120 (39.6%)**	**122 (34.9%)**
	Unvaccinated						
	Offered vaccine and declined	**39 (3.2%)**	**3 (3%)**	**5 (2.8%)**	**12 (4.3%)**	**10 (3.3%)**	**9 (2.6%)**
	No HPV-MSM vaccination code	**664 (54.9%)**	**42 (42.4%)**	**83 (46.9%)**	**147 (52.5%)**	**173 (57.1%)**	**219 (62.6%)**

Among all MSM recorded as receiving a first dose, 42.8% (3,669/8,580) and 6% (519/8,580) completed a second and third dose, respectively during this first pilot year. Vaccine uptake for second and third doses is incomplete at this time as the interval between 1st and 3rd dose could be up to two years.

As per Figure 1 below, overall uptake of dose 1 HPV vaccination among all attending MSM did not begin to increase substantially until October 2016, reflecting the start of HPV-MSM pilot implementation at the majority of participating clinics. Only two of the total 42 clinics had implemented HPV vaccination for MSM in June 2016, and further clinics did not implement the HPV-MSM pilot until September 2016.

Figure 1: Uptake of HPV vaccination doses since June 2016 (dose-1 only)



June 6th represents the date the first clinic started delivering vaccine- 31st March represents the end of the first year of the pilot.

Impact on services

Patient survey

The survey sought to quantify the impact on GUM services by asking if patients who received the HPV vaccine were new attendees to the GUM clinic and if they attended specifically to receive the vaccine or for other reasons. Of the 8,511 patients who responded, 8.1% (95%CI 7.6-9.2) reported never having attended a GUM/HIV clinic before. Among the 366 new attendees who answered, 10.8% (95%CI 7.7-14.8) attended only to receive the vaccine.

Of 4,137 responders, 12.4% (95%CI 11.3-13.6) attended just to receive the HPV vaccination. A further 11.1% (95%CI 10.1-12.2) attended for HPV as well as other services. The remaining 76.5% (95%CI 75-77.9) did not mention HPV as a reason for attendance.

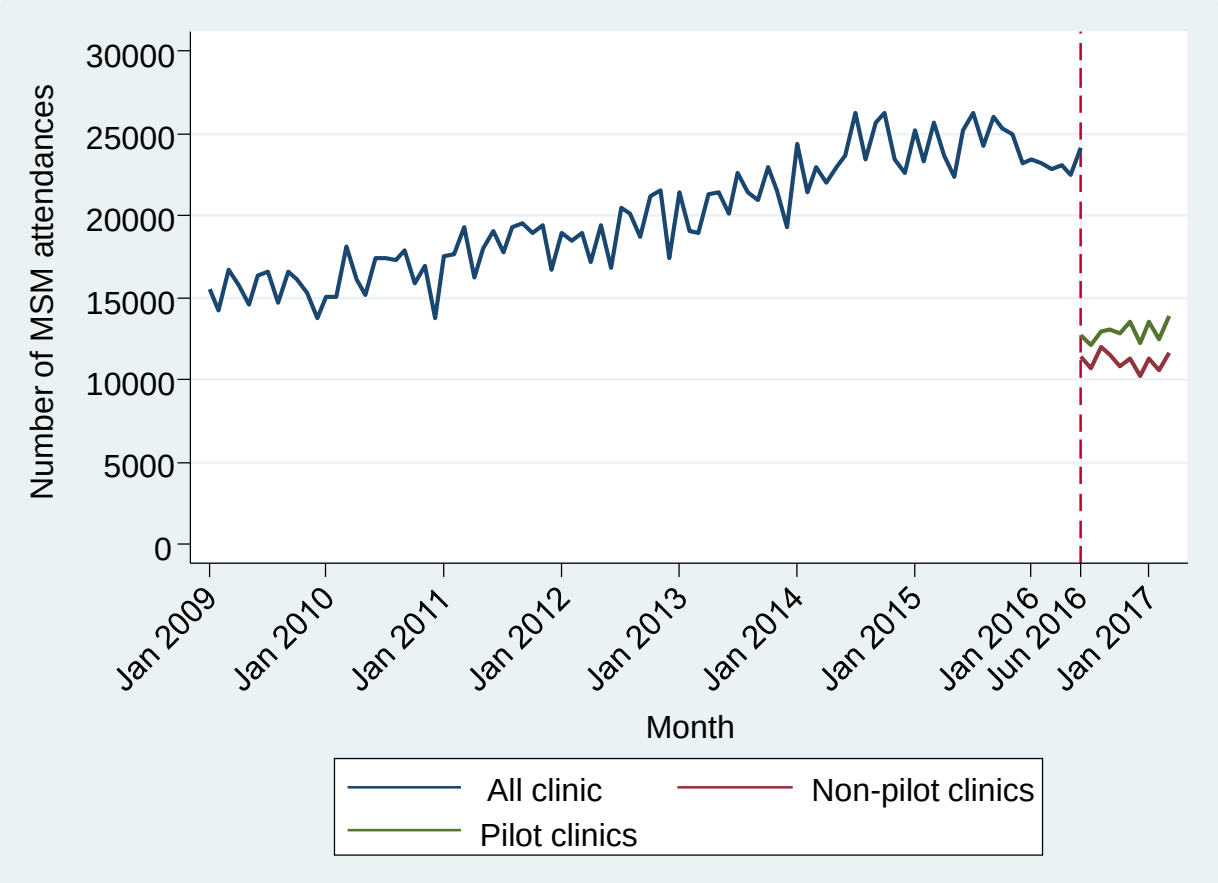
Patients were asked for their reason for choosing to attend a particular clinic and only 3.2% (95%CI 2.8-3.6) attended specifically because that clinic offered the HPV vaccine.

GUMCAD data

The number of MSM attendances at GUM clinics has been increasing steadily over time since GUMCAD data became fully available from 2009 to the start of the HPV-MSM pilot in June 2016 (Figure 2). MSM attendances in all GUM clinics increased from 15,585 in January 2009 to 24,206 in June 2016.

Between the start of HPV-MSM vaccination in June 2016 and end of March 2017, only relatively small increases were identified in the number of MSM attendances at pilot GUM clinics, specifically from 12,762 in June 2016 to 13,382 in March 2017. Attendances in non-pilot clinics in this same time period remained mostly stable, from 11,444 in June 2016 to 11,705 in March 2017. GUMCAD data on attendance were only available for 9 months after the introduction of the pilot. It is therefore too early to make definitive conclusions on the precise impact of the pilot on attendance from GUMCAD data.

Figure 2: Attendances at GUM clinics



Acceptability

Patient survey

Of 8,554 patients who answered the question, 94.6% (95%CI 94.1.6-95.1%) indicated they would like to receive the next HPV vaccine doses at the same clinic as the first dose. General practice was mentioned by 7.2% (95%CI 6.6-7.7) as the preferred setting for the next HPV vaccine dose.

Feedback from providers

The providers did not raise any issues suggesting that the setting for the vaccinations or the process was not acceptable to the target group. The £10 administration fee was considered to be acceptable.

Equity

GUMCAD/HARS data

Recorded first dose uptake decreased slightly with increasing age. Uptake ranged from 51.2% (2,323/4,535) in the youngest age group (≤25 years of age) to 36.9% (1,145/3,105) in the oldest age group (41-45 years of age). First dose uptake was 45.7% (8,074/17,666) and 41.9% (506/1,209) in GUM and HIV clinics, respectively.

Compared with urban conurbation, cities and towns, recorded uptake in rural areas was higher (table 3).

Patient survey

There was less awareness about the HPV recommendation for MSM among those attending rural clinics. A higher proportion of those attending clinics in rural areas indicated a preference for receiving subsequent doses in general practice (table 3), however, sexual health services were the preferred option in all settings.

Table 3: Uptake of first dose and survey responses by urban/rural setting of clinic

	First dose uptake (%)	Aware of recommendation for MSM to received vaccine (%, 95%CI)	Would like next dose at same clinic (%, 95%CI)	Would like next dose at GP (%, 95%CI)	Accessed other services as part of attendance (%, 95%CI)
Major Urban Conurbation	45.3 (6,243/13,773)	31.3 (30.0-32.5)	92.7 (92.1-93.3)	6.3 (5.7-6.9)	85.4 (84.4-86.3)
Urban city and town	44.3 (1,919/4,330)	31.5 (29.4-33.7)	92.7 (91.3-93.9)	10.5 (9.1-12.1)	85.7 (84.1-87.2)
Rural village and dispersed	54.1 (418/772)	23.3 (0.2-26.9)	89. 2 (86.3-91.5)	12.2 (9.7-15.3)	82.7 (79.3-85.6)

Data completeness and quality

GUMCAD data

Feedback from providers suggested that the introduction of new GUMCAD codes for HPV vaccination and subsequent recording of vaccination status has been a challenge for clinics. Over 50% of eligible individuals had no recorded HPV-MSM vaccination code at all. Anecdotal reports from clinics plus prior experience with introduction of new codes into the recording systems suggests that data recording has been incomplete. Therefore, vaccine uptake for the pilot is likely to be underestimated in these initial data reports and estimates presented are likely to be minimum. Based on experience from other new codes in GUMCAD, the use of these new codes is likely to increase with time.

GUMCAD and HARS collect data on gender and sexual orientation only. For our analyses, we have identified men as eligible if they have had their sexual orientation recorded as homosexual or bisexual at any visit in their clinic attendance history. Whilst for most clinics, these data are likely to reflect a patient's sexual behaviour (rather than their sexual identity), the assessment of sexual risk at a clinic level may be different. Therefore, it is possible that there is error in the estmation of the denominator of eligible that could result in some underestimation or overestimation of uptake.

GUMCAD patient identifiers are unique within each clinic and it is not possible to track patients between clinics. Therefore, it is not possible to monitor completion of course (ie second and third doses) at another clinic. However, most individuals attend the same clinic rather than move between clinics. We have made the assumption that the majority of individuals will attend the same clinic rather than move between clinics. This is supported by the results from the patient survey that suggest the vast majority of individuals would prefer to have their next doses at the same clinic.
In addition, the '2nd dose' and '3rd dose' codes mitigate this issue, although it relies on patients accurately reporting how many doses were received when previous doses were delivered at a different clinic.

Patient survey

A minimum of 7,109 responses were required to attain the required width of the confidence intervals at cluster level. Overall, 9,009 responses were received from 25/29 clusters. Of these, 16 clusters (64%) returned 80% or more of the number of questionnaires required, 6(24%) provided between 50-80% and 3 (12%) less than 50%.

Of 9,009 received questionnaires, 8,554 responses were retained for analysis. Responses were discarded if they were returned blank, returned with comments instead of selecting one of the response options or the clinic could not be identified. Questionnaires were anonymised and undated, so it was not possible to estimate an exact response rate. However, informal feedback from the clinics suggested very few individuals refused to fill the questionnaire. Patient eligibility to answer specific questions depended on responses to previous questions. The number of responses to individual questions therefore ranged quite widely, from 8,554 to 4,137.

Conclusions

The 2016/17 pilot of HPV vaccination for MSM demonstrated that such a programme can be delivered in an acceptable and, as far as can be evaluated, equitable manner, without major disruption to GUM and HIV clinics. Recorded first dose uptake for the first year was 45% and this figure is likely to be an underestimate, mainly due to variable coding practice in clinics. Recorded uptake was lower among older individuals and higher in rural areas although these differences remained small, and may be partly due to measurement errors. Complete second and third dose uptake for individuals who started the vaccine course in 16/17 will not be available until 2018/19 as completing a course can take up to 24 months.

Sexual health services were the preferred setting for delivery in both rural and urban settings. The vast majority of individuals who received the vaccine did so alongside other services, suggesting delivering the vaccine opportunistically is feasible. Evidence from both patient questionnaire and GUMCAD data suggested a very modest increase in clinic attendance. Feedback from sexual health services providers suggested providing the vaccine in this setting, with an administration fee of £10 per dose, was acceptable. In terms of vaccine ordering, delivering vaccine to sexual health services creates an initial burden for pharmacies in particular to ensure stock can be managed independently from the girl's programme. However, no major issues have been identified once vaccination is ongoing.

Reconfiguration of sexual health services, with a move towards reduced clinic attendance and more services online, could be a challenge to delivering the programme in the future. It is anticipated that individuals who use online sexual health services will be signposted to clinics for vaccination when eligible, similarly to hepatitis B vaccination. The recommended delivery schedule was designed to align with recommended GUM re-attendance for the target group. However, not all MSM will attend enough times within a 24 month period to receive the full course without active recall. This issue would need to be considered as part of a national programme.

Appendices

Appendix 1. List of clinics taking part in the pilot

Brighton & Hove
- SHAC East (Claude Nicol Centre):
- SHAC Central (Morley St)

Bournemouth & Dorset:
- Over the Rainbow
- Department for Sexual Health, Royal Bournemouth Hospital
- Park Centre for Sexual Health, Weymouth Community Hospital

London:
- Mortimer Market Clinic
- Patrick Clements GUM Clinic, Central Middlesex Hospital
- Northwick Park Hospital GUM
- John Hunter Clinic, Chelsea and Westminster Hospital
- 56 Dean Street (not Dean Street Express)
- 10 Hammersmith Broadway (formerly West London Centre Sexual Health)
- Burrell Street Sexual Health Clinic
- Lloyd Clinic, Guy's Hospital
- Walworth Road Clinic
- Streatham Hill Sexual Health Clinic
- Vauxhall Riverside Sexual Health Clinic
- Harrison Wing, St Thomas' Hospital
- Jefferiss Wing Centre for Sexual Health, St Mary's Hospital

Milton Keynes:
- Sexual Health & HIV Clinic, Milton Keynes Hospital

Norfolk
- iCASH Great Yarmouth (Breydon Clinic), Northgate Hospital
- iCASH Norwich (Oak Street)

Bristol:
- North Bristol NHS Trust HIV Service (Brecon Unit), Southmead Hospital
- Bristol Sexual Health Centre

Swindon and Wiltshire:

- Department of Sexual Health, Salisbury District Hospital
- Sexual Health Department, The Great Western Hospital, Swindon
- Sexual Health, Chippenham Community Hospital

Manchester:

- Infectious Diseases Department, North Manchester General Hospital
- Sexual Health Clinic, North Manchester General Hospital
- The Hathersage Centre, Manchester Royal Infirmary
- UHSM Sexual Health Service, Withington Community Hospital

Birmingham and Solihull:

- Queen Elizabeth Hospital HIV Clinic
- Heartlands Hospital HIV Service
- Whittall Street Clinic
- Birmingham Boots High Street Clinic
- Birmingham Hawthorn House Clinic
- Erdington Clinic
- Northfield Community Partnership
- Chelmsley Wood Primary Care Centre
- Soho Health Clinic
- Birmingham LGBT Centre
- Umbrella at Boots, Mell Square, Solihull

Newcastle:

- New Croft Centre

Appendix 2. Patient questionnaire

Human papillomavirus (HPV) vaccination pilot for men who have sex with men
Patient questionnaire

Public Health England (PHE) is piloting this new HPV vaccination programme in selected clinics across England. This clinic is one of the first to offer the vaccine as part of the pilot.

Your feedback is important to us. We would be really grateful if you could take the time to answer this short questionnaire to help us determine how we can roll out this programme successfully across the country. Your participation in this questionnaire is completely voluntary, and your decision to participate or not will have no impact on your future care.

This information is being collected by PHE exclusively for the evaluation of the pilot programme. The answers provided will be stored and used securely, and will not be shared with other organisations. No attempt will be made to identify or contact individuals in the future.

Q1 - Have you ever attended a GUM/HIV clinic before?

- Yes I have attended a clinic before
- No I have never attended a clinic before

Q2 – Is this your local/usual clinic?

- Yes
- No

Q3 - Did you know that HPV vaccination is recommended for men who have sex with men before your appointment today?

- Yes
- No – if no, please go to Question 6

Q4 - Was getting the HPV vaccine the main reason that you attended the clinic today?

- Yes
- Yes, but wanted a check-up or had other reasons to attend as well
- No – if no, please go to Question 6

Q5 – How did you know the HPV vaccine was available at this particular clinic? (please select all that apply)

- Someone told me
- I read a leaflet about it
- A charity
- A newspaper / magazine
- Another clinic told me
- The internet (please specify website)

  [ ]
- I did not know that I could get the vaccine at this particular clinic, but knew that it was available at GUM/sexual health clinics
- Other (please specify)

  [ ]

Q6 - Did you access any other health services as part of attendance today (eg HIV and/or STI testing, health advice, condoms, HIV care and treatment monitoring, etc)?

- Yes
- No

Q7 - Why did you choose to attend <u>this</u> particular clinic?
(please select all that apply)

- This is the clinic I usually attend
- This is my local clinic
- This is the most convenient clinic for me
- I wanted the HPV vaccine but my local/usual clinic does not have it.
- I wanted the HPV vaccine and knew this clinic provided it
- Other reason (please specify)

  [ ]

The next two questions will help us to plan for possible wider availability of the vaccine

Q8 – To ensure maximum protection from HPV infection you will need two more doses of vaccine over the next 12 months to complete this course. If we were to send reminders about your next dose, how would you like us to do this? (please select all that apply)

- Text message/SMS

- Email
- Phone call
- Other (please specify)

- All of the above
- I would not want a reminder

Note: some clinics may offer a reminder service already – clinic staff will advise you about this.

Q9 – If you had the choice, where would you like to have your next HPV vaccine doses? (please select all that apply)

- At this clinic
- A clinic closer to where I live
- A clinic closer to where I work
- A high street pharmacy
- My GP practice
- Other (please specify)