

Reducing sexually transmitted infections (STIs)

[F] Evidence reviews for increasing uptake of hepatitis A, hepatitis B and human papillomavirus (HPV) vaccinations in gay, bisexual and other men who have sex with men

NICE guideline <number>

Evidence reviews underpinning recommendations 1.4.1 to 1.4.4 and research recommendations in the NICE guideline

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Draft for Consultation

These evidence reviews were developed by Public Health Internal Guideline team

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1 Effective and cost-effective interventions to increase uptake of vaccinations in men who have sex with men

1.1 Review question

What interventions are effective and cost effective at increasing uptake of hepatitis A, hepatitis B or human papillomavirus (HPV) vaccination in gay, bisexual and other men who have sex with men (MSM)?^a

1.1.1 Introduction

Sexually transmitted infections (STIs) include a range of clinical syndromes that can be acquired and transmitted through sexual activity and may be caused by various types of pathogens, including bacteria, fungi, viruses, and parasites. It can affect personal wellbeing, mental health and relationships and can also lead to serious health problems including pelvic inflammatory disease, ectopic pregnancy or infertility. Preventive interventions can reduce the spread of infection and avoid complications and consequences.

From 1st April 2018 there has been a national HPV vaccination programme for men who have sex with men. This offers the vaccine to those aged up to and including 45-years-old through Specialist Sexual Health Services (SSHS) and/or HIV clinics. A pilot conducted in 2016/17 and using data from the GUMCAD and HARS reporting systems found first dose uptake was 45.5% (3.4% were offered and declined the vaccine, and 50.9% had no vaccination code), though this was expected to be an underestimate of true uptake due to variations in data recording. Uptake rates following the full introduction of the programme are not yet available for England, but a similar programme in Scotland had an uptake of 63.7% among eligible MSM attending sexual health clinics in 2017/18.

Since June 2017, it has been recommended that all men who have sex with men attending HIV, GUM or sexual health clinics should be opportunistically offered vaccination against hepatitis A. There are currently no published national data on uptake rates for this vaccination.

1.1.2 Summary of the protocol

Table 1: PICO inclusion criteria

Eligibility criteria	Content
Population	Gay, bisexual and other men who have sex with men (MSM) from age 16
Interventions	Interventions with the primary aim of increasing uptake of hepatitis A and B and HPV vaccinations in MSM such as: <ul style="list-style-type: none">targeted mass media campaignseducation for example peer led educationrecommendations from for example health care practitionerinternet based interventions for example social mediainterventions designed to increase recall / adherence / vaccination schedule completioninterventions that aim to reduce any difficulties with access or expand access

^a Throughout this review, the term men who have sex with men (MSM) is used to refer to gay, bisexual and other men who have sex with men

Eligibility criteria	Content
Comparator	No intervention Usual care Comparator as defined by the paper
Outcomes	<p>Primary outcomes:</p> <ul style="list-style-type: none"> Changes in uptake of hepatitis A and B vaccination in MSM Changes in uptake of HPV vaccination in MSM Uptake of initial and subsequent vaccinations <p>Secondary outcomes:</p> <ul style="list-style-type: none"> Safety or adverse effects Health related quality of life

1.1.3 Methods and process

This evidence review was developed using the methods and process described in [Developing NICE guidelines: the manual](#). Methods specific to this review question are described in the review protocol in [Appendix A](#) and the [methods document](#).

Declarations of interest were recorded according to [NICE's conflicts of interest policy](#).

1.1.4 Identification of public health evidence

The effectiveness and qualitative reviews were carried out using a single literature search ([Appendix B](#)). 858 references were identified for title and abstract screening and 81 quantitative papers were ordered for full-text review. Of these, 3 RCTs met the inclusion criteria for the effectiveness review, as outlined in the review protocol. 78 studies were excluded. See [Appendix C](#) for a PRISMA flow diagram of the study selection process.

1.1.4.1 Included studies

Of the 3 RCTs included for the effectiveness review, 1 study was conducted in the Netherlands and two in the USA. 1 study reported on hepatitis B vaccination uptake and the other two studies reported on HPV vaccination uptake. See [Table 2](#) for included study details for the effectiveness review.

1.1.4.2 Excluded studies

The full list of excluded studies and reasons for exclusion are in [Appendix J](#).

Table 2: Summary of studies included in the effectiveness evidence review

Study	Setting	Population	Intervention	Comparator	Outcome(s)
Bass (2021)	USA	Gay, bisexual and other men who have sex with men (GBMSM) aged 18-25 years n = 150	Txt2protect: a text-messaging based HPV vaccination intervention. Information Motivation Behaviour (IMB) informed messages focused primarily on HPV vaccination, with brief mention of other sexual health practices (e.g. condom use, HIV testing). Daily text messages for first 3 weeks then	Attention control: text messages focusing on a variety of sexual health practices; only brief mention of HPV vaccination.	HPV vaccine initiation HPV vaccine completion

Study	Setting	Population	Intervention	Comparator	Outcome(s)
			monthly text messages for the remaining 8 months		
Reiter (2018)	USA	Young gay and bisexual men (YGBM) aged 18-25 years n = 150	The Outsmart HPV intervention consisting of two components: (a) population-targeted individually tailored content about HPV, HPV-related disease, and the HPV vaccine; (b) monthly HPV vaccination reminders sent via email and/or text message	Standard information about HPV and the HPV vaccine	HPV vaccine initiation HPV vaccine completion
Vet (2014)	The Netherlands	Men who have sex with men aged 13 to 88 years (mean = 32.6 years; SD = 12.4) n = 616	The intervention was based on implementation intention formation: participants were prompted to consider and respond to questions about when, where and how they would make an appointment to obtain vaccination against HBV. Also received information about local sites offering HBV vaccination.	General information providing contact details of Public Health Services offering hepatitis B vaccination	Hepatitis B vaccination uptake

1 See [Appendix D](#) for full evidence tables.

1 **1.1.5 Summary of the effectiveness evidence**

2 **Table 3: Summary of findings table**

Interventions to increase vaccine uptake vs. control						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Control	Corresponding risk Intervention				
HPV vaccine initiation Follow-up: up to 9 months	160 per 1000	307 per 1000 (203 to 466)	RR 1.92 (1.27 to 2.91)	298 (2 studies ^{1,2})	⊕⊕⊖⊖ low ^{3,4}	
HPV vaccine completion Follow-up: up to 9 months	20 per 1000	65 per 1000 (18 to 234)	RR 3.26 (0.91 to 11.72)	298 (2 studies ^{1,2})	⊕⊖⊖⊖ very low ^{3,4,5}	
Hepatitis B vaccine uptake	90 per 1000	212 per 1000 (118 to 380)	RR 2.37 (1.32 to 4.24)	300 (1 study ⁶)	⊕⊕⊖⊖ moderate ⁷	

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹ Bass 2021

² Reiter 2018

³ Downgraded once for some concerns of bias due to no information about allocation concealment for Bass 2021, and no information on randomisation and allocation concealment for Reiter 2018

⁴ US studies

⁵ Downgraded once as 95%CI crosses line of no effect and 1 MID

⁶ Vet 2012

⁷ Downgraded once for some concerns of bias due to no information on randomisation or allocation concealment

3 See [appendix F](#) for full GRADE Tables.

1 **1.1.6 Economic evidence**

2 A search for relevant economic studies was undertaken, using the strategy in [appendix B](#)
3 and applying a cost-effectiveness filter. 146 references were identified from this literature
4 search; all of which were excluded during title and abstract screening. As such, no economic
5 studies were included to inform this review question.

6 **1.1.7 Economic model**

7 No economic modelling was undertaken for this review question.

1 **2 Barriers and facilitators for increasing**
2 **uptake of vaccines in men who have sex**
3 **with men**

4 **2.1 Review question**

5 What are the barriers to, and facilitators for, increasing uptake of hepatitis A, hepatitis B or
6 human papillomavirus (HPV) vaccinations in men who have sex with men?

7 **2.1.1 Introduction**

8 Current practice recommends that men who have sex with men attending HIV, GUM or
9 sexual health clinics should be opportunistically offered vaccination against hepatitis A and
10 there is a national HPV vaccination programme for men who have sex with men aged up-to
11 and including 45 years attending Specialist Sexual Health Services (SSHS) and/or HIV
12 clinics. Data on vaccine uptake rates are not available but strategies for improving uptake are
13 important as vaccinations against hepatitis A, hepatitis B and HPV are important STI
14 prevention strategies. The purpose of this review is to establish the barriers to, and
15 facilitators for, vaccine uptake in MSM.

16 **2.1.2 Summary of the protocol**

17 **Table 4: PICO inclusion criteria**

Eligibility criteria	Content
Population	Men who have sex with men (MSM) from age 16
Interventions	Barriers to, and facilitators for, increasing uptake of Hepatitis A, Hepatitis B and HPV vaccinations This will include interventions or strategies identified in the effectiveness review, but is not restricted to these
Comparator	Not applicable
Outcomes	Barriers to and facilitators for increasing vaccine uptake at individual and system level. These may include: <ul style="list-style-type: none">• Affective attitude• Acceptability• Preferences• Burden• Value system

18 For the full review protocol see [appendix A](#).

19 **2.1.3 Methods and process**

20 This evidence review was developed using the methods and process described in
21 [Developing NICE guidelines: the manual](#). Methods specific to this review question are
22 described in the review protocol in [appendix A](#) and the methods document.

23 Declarations of interest were recorded according to [NICE's conflicts of interest policy](#).

24 **2.1.4 Identification of qualitative evidence**

25 The effectiveness and qualitative reviews were carried out using a single literature search
26 ([Appendix B](#)). 858 references were identified for title and abstract screening and 18

1 qualitative papers were ordered for full-text review. Of these, 9 qualitative studies reported in
2 10 papers met the inclusion criteria for the qualitative review, as outlined in the review
3 protocol. 8 studies were excluded.

4 **2.1.4.1 Included studies**

5 Of the 9 qualitative studies included in the qualitative review, 1 study was conducted in
6 Canada, 2 in the United Kingdom, and 6 in the USA. All studies reported on the barriers to,
7 facilitators for, or acceptability of HPV vaccine. Studies reported individual, provider and
8 system level barriers, facilitators or acceptability. See [Table 5](#) for included study details.

9 **2.1.4.2 Excluded studies**

10 The full list of excluded studies and reasons for exclusion are in [Appendix J](#).

1 **Table 5: Summary of studies included in the qualitative evidence review**

Study	Design and analysis	Country	Setting	Population and number included in study	Objective	CASP Risk of Bias
Apaydin (2018)	Focus groups Thematic content analysis	USA	Urban community health centre specialising in care for sexual and gender minority patients	Vaccine eligible sexual and gender minority youth, including trans and cisgender men and women. 53% were gay cisgender men. 80% reported HPV vaccine initiation and 73% reported HPV vaccine completion. n = 15	To identify and understand patient-, provider- and system-level barriers to and facilitators for HPV vaccination among sexual and gender minority patients	Moderate risk of bias (limited information about recruitment strategy and data analysis)
Fontenot (2016)	Focus groups and individual interviews Content analysis	USA	Private conference rooms at health and community centres	Young MSM 18-26 years. 58.8% reported HPV vaccine initiation and 35.3% reported HPV vaccine completion. n = 34	To elicit YMSM's beliefs about HPV and the HPV vaccine and to describe perceived barriers and facilitators of vaccine initiation and completion.	Moderate risk of bias (Insufficient detail on how codes were developed; interrater reliability or agreement between coders not reported)
Gerend (2019)	Semi-structured interviews Analysis method unclear	USA	Unclear; assumed community settings	Young MSM 18-26 years. Participants were vaccinated (n=9) and unvaccinated (n=20) n = 29	To identify young sexual minority men's perspectives on HPV vaccination, using the Information, Motivation and Behavioural Skills model as a framework	Moderate risk of bias (researcher and participant relationship not adequately considered and limited discussion of ethical considerations)

Study	Design and analysis	Country	Setting	Population and number included in study	Objective	CASP Risk of Bias
Grace (2018)	Semi-structured interviews Grounded theory	Canada	Private meeting rooms at the University of Toronto	HIV positive gay men. 24% had received the HPV vaccine. n = 25	To explore HPV vaccination barriers and hesitancy among HIV-positive gay men by examining participants' narrative accounts of their knowledge, experiences and perceptions related to HPV and HPV vaccination.	Moderate risk of bias (researcher and participant relationship not adequately considered; process of researcher agreement not described and inter-rater reliability not reported)
Jaiswal (2020)	Semi-structured interviews Multi-step approach to identify salient themes	USA	Unclear	Young sexual minority men aged 24-27 years. n = 38	To elucidate the nature and depth of (a) HPV and HPV vaccine knowledge and (b) provider communication about HPV vaccine, in a diverse sample of young urban sexual minority men; and to understand barriers and facilitators to vaccination, the degree of vaccine literacy, and sources of vaccine knowledge in SMM.	Moderate risk of bias (researcher and participant relationship not adequately addressed; no critical examination of researcher's own role or the potential for bias, and no discussion of the credibility of findings or inter-rater reliability).
Kesten (2019)	Focus groups Thematic analysis	UK	LGBTQ organisational settings and a University student's union	Young men who have sex with men aged 16-24 years. 22% had received the HPV vaccine n = 17	To understand young MSM's knowledge and attitudes towards HPV vaccination	Low risk of bias

Study	Design and analysis	Country	Setting	Population and number included in study	Objective	CASP Risk of Bias
Koskan (2018)	Semi-structured interviews Content analysis	USA	Settings of the participants' choice (usually fast food restaurants)	HIV positive gay and bisexual men aged 18-30 years. 13% had received the first dose of the vaccine n = 15	To explore HIV-positive gay and bisexual men's understanding of HPV and the HPV vaccine as well as preferences for future health promotion.	Low risk of bias
Nadarzynski (2017)	Focus groups and individual interviews Framework analysis	UK	Community-based LGBT venues and organisations	MSM aged 16-40 years. n = 33	To explore men who have sex with men's' perceptions of HPV and HPV vaccination prior to the introduction of the vaccination programme in the UK	Moderate risk of bias (researcher and participant relationship not adequately considered and some lack of rigour in data analysis)
Wheldon (2017)	Semi-structured interviews 5-step analysis process	USA	Participants recruited from Student Pride groups and sexual networking apps. Interviews conducted in person or via telephone.	HIV positive young MSM aged 18-26 years. 23% reported receiving at least one dose of the HPV vaccine. n = 22	To (1) describe salient beliefs related to HPV vaccination among young MSM (2) determine factors that underlie these beliefs; and (3) describe a model for HPV vaccine decision-making.	Moderate risk of bias (authors report the results are exploratory as they are based on a small and socio-demographically limited sample)

1 See [Appendix D](#) for full evidence tables

1 **2.1.5 Summary of the qualitative evidence**

2 **2.1.5.1 Summary of themes and sub-themes**

3 Iterative aggregation of codes generated two main themes and 10 sub-themes. These are
4 outlined in Table 6.

5 **Table 6: Summary of themes and sub-themes**

Major theme	Sub-themes
Barriers to HPV vaccination	Lack of knowledge about HPV, HPV-related diseases, and the HPV vaccine
	Questions over vaccine effectiveness and potential side effects
	Vaccination series, including the timing of doses
	Possible stigma
	Clinical settings
Facilitators for HPV vaccination	Awareness of vaccines and the health benefits of getting vaccinated
	Interactions with health care practitioners (HCPs)
	Support from friends and family
	Making vaccination part of other clinical interactions
	Mobile applications

6

7 **2.5.1.2 Summary of qualitative findings**

8 The qualitative findings for the barriers to and facilitators for HPV vaccination in MSM are
9 presented in [Table 7](#). Full CERQual tables are presented in [Appendix G](#).

1 **Table 7: Summary of qualitative findings**

Summary of review finding	Studies contributing to the review finding	Illustrative quotes	CERQual assessment	Explanation of GRADE-CERQual assessment
Barriers to HPV vaccination uptake				
<p>Lack of knowledge about HPV, HPV-related disease, and the HPV vaccine</p> <p>Participants lacked knowledge about HPV in general, transmission in MSM, and the connection between HPV and male associated cancers. Participants often confused HPV and other STIs. There was a pervasive lack of knowledge of HPV vaccination and misunderstandings about efficacy. There was a widespread perception that only cisgender women are vulnerable to HPV and that the vaccine was predominantly or exclusively for women.</p>	<p>Apaydin 2018 Fontenot 2016 Gerend 2019 Grace 2018 Jaiswal 2020 Kesten 2019 Koskan 2018 Nadarzynki 2017</p>	<p><i>"I've heard it doesn't affect men, but they can transmit it. I don't know if that's true"</i></p> <p><i>"I didn't know like it affected guys at all"</i></p> <p><i>"My own ignorance was that HPV was something that really only affected women and cervical cancer. I didn't hear it as much as something that was affecting men"</i></p>	<p>Moderate confidence</p>	<p>Downgraded because of moderate concerns regarding methodological limitations</p>
<p>Questions over vaccine effectiveness and potential side effects</p> <p>Participants wanted clear information about the vaccine and any possible side effects. They questioned vaccine effectiveness.</p>	<p>Fontenot 2016 Gerend 2019 Koskan 2018 Nadarzynki 2017 Wheldon 2017</p>	<p><i>"I think like with all vaccines there are probably side effects"</i></p> <p><i>"I mean I don't know, I mean I'm not too fond of the guinea pig thing, so I don't know, it depends on the side effects, I actually [inaudible] that. So I would have to see—weigh my options and see what my side effects are"</i></p>	<p>Moderate confidence</p>	<p>Downgraded because of moderate concerns regarding methodological limitations</p>
<p>Vaccination series, including timing of doses</p> <p>Participants discussed barriers to vaccine completion due to long time intervals between doses, multiple doses, and the inconvenience of work conflicting with clinic hours.</p>	<p>Apaydin 2018 Fontenot 2016 Kesten 2019</p>	<p><i>"... you know, going back and coming back, and going back [for 3 doses], it's too much work"</i></p> <p><i>"It is hard to remember, keep track of all the shots"</i></p>	<p>Low confidence</p>	<p>Downgraded because of moderate concerns regarding methodological limitations and adequacy of data</p>
<p>Possible stigma</p> <p>Participants described stigmas related to being gay, gay health, acceptance by HCPs, and STIs. They were</p>	<p>Fontenot 2016 Gerend 2019 Koskan 2018</p>	<p><i>"If there's another virus, like HPV, it's going to be strongly linked to gay men community again. I don't think it's a</i></p>	<p>Moderate confidence</p>	<p>Downgraded because of moderate concerns</p>

Summary of review finding	Studies contributing to the review finding	Illustrative quotes	CERQual assessment	Explanation of GRADE-CERQual assessment
<p>concerned that they would be labelled as promiscuous upon receiving vaccination.</p> <p>Participants described the importance of being able to discuss sexual activity with healthcare professionals.</p> <p>There was some concern about people being singled out by their sexuality when offering the vaccine</p>	Nadarzynki 2017 Wheldon 2017	<p><i>good thing for people because it will strengthen the gay label to this specific disease. I don't think people will like it. Since they just got rid of HIV labels and they don't want another stigma again"</i></p> <p><i>"...some people will consider somebody very promiscuous. 'Oh, you're getting a vaccine because you're sleeping with multiple people,' and there's just a stigma associated with that"</i></p>		regarding methodological limitations
<p>Clinical settings</p> <p>Most participants suggested sexual health clinics were the most suitable setting to reach MSM as the openness and non-judgemental attitudes of staff in these settings may be reassuring. Others suggested GP practices may be more suitable as some young men do not access specialist sexual health services. Some noted the difficulty of discussing their sexual health with their GPs. Participants also noted that MSM who do not identify as gay may not benefit from the vaccine if it was only targeted to gay or bisexual men.</p>	Gerend 2019 Nadarzynki 2017 Wheldon 2017	<p><i>"Well, it was offered right there while I was getting the physical done. So I didn't even have to make a special trip or anything"</i></p> <p><i>"I feel like he judges me. I feel like if I had a provider or somebody who is a little more open-minded ... my doctor is a staunch Republican, white dude who is like 65 and I'm sitting there like a gay little Puerto Rican kid, and you know, it is just always awkward when I go to my doctor. We come from opposite ends of the earth"</i></p>	Low confidence	Downgraded because of moderate concerns regarding methodological limitations and minor concerns regarding adequacy of data
Facilitators for increasing HPV vaccination uptake				
<p>Awareness of vaccines and the health benefits of getting vaccinated</p> <p>Participants acknowledged the physical and psychological health benefits of HPV vaccination, including reducing their anxieties around the risk of anal cancer. Participants were also enthusiastic about the ability to protect both themselves and their partner(s). They discussed the need to raise public awareness and suggested that HPV education should be widespread</p>	Apaydin 2018 Fontenot 2016 Gerend 2019 Grace 2018 Kesten 2019 Koskan 2018 Nadarzynki 2017 Wheldon 2017	<p><i>"Yeah like I care about my health, but I also care about other people's health too and I don't want anyone else to get infected or have to go through with something like that"</i></p> <p><i>"I would be less susceptible to anal cancer at least from HPV"</i></p>	Moderate confidence	Downgraded because of moderate concerns regarding methodological limitations

Summary of review finding	Studies contributing to the review finding	Illustrative quotes	CERQual assessment	Explanation of GRADE-CERQual assessment
and more inclusive of all sexes, particularly in the sexual health education curriculum in schools. Participants believed that better understanding of the benefits and side effects of the vaccine would encourage uptake.		<i>"If there was more education about it [HPV vaccine], if the vaccine gets known, then it won't be as taboo"</i>		
Interactions with health care practitioners (HCPs) Participants perceived healthcare providers and doctors to be the most trusted source of information, and their opinions as well as recommendations would substantially influence their decision to obtain the vaccine	Fontenot 2016 Gerend 2019 Grace 2018 Kesten 2019 Koskan 2018 Nadarzynki 2017 Wheldon 2017	<i>"I think I'd be more likely to accept it if it were offered than I would actively request it. I think because if it was, if it was recommended to you it would be coming from a trusted source"</i> <i>"It was the doctor's recommendation. I honestly wouldn't have thought about it had he not recommended it"</i>	Moderate confidence	Downgraded because of moderate concerns regarding methodological limitations
Support from friends and family Participants highlighted that most people in their lives would be supportive of their decision to get vaccinated. Participants with unsupportive referents typically mentioned their parents (notably their father). Awareness and knowledge about the HPV vaccine was primarily limited to female friends and siblings.	Apaydin 2018 Fontenot 2016	<i>"Maybe my dad. Because he's just ignorant with regard to sexuality and vaccines and stuff like that. He's kind of a anti-government conspiracies person, so I don't really have a good relationship with him"</i> <i>"I know [about HPV vaccine] because my sister got it"</i>	Very low confidence	Downgraded because of moderate concerns regarding methodological limitations and serious concerns about adequacy
Making HPV vaccination part of other clinical interactions Participants described wanting to combine HPV vaccination with other types of visits like annual physical examinations, general sexual health screening or other STI tests.	Fontenot 2016 Gerend 2019 Nadarzynki 2017	<i>"Well, it was offered right there while I was getting the physical done. So I didn't even have to make a special trip or anything"</i> <i>"If they start routinely testing for this at GUM clinics, and you're negative and not carrying it, then it should be suggested to you at the same point [like] they would suggest a hepatitis A and C vaccine"</i>	Low confidence	Downgraded because of moderate concerns regarding methodological limitations and adequacy of data

Summary of review finding	Studies contributing to the review finding	Illustrative quotes	CERQual assessment	Explanation of GRADE-CERQual assessment
<p>Mobile applications</p> <p>Participants suggested the use of mobile applications for booking appointments and creating a reminder system. They felt that flexibility in scheduling and app-based reminder systems would facilitate 3-dose completion</p>	Fontenot, 2016	<i>“People are uncomfortable having to make phone calls. . . it’s a lot easier to just do something on your phone, like an appointment confirmation, so that you can go in without having to talk [to someone] or feel uncomfortable disclosing things [on the phone]”</i>	Very low confidence	Downgraded because of moderate concerns regarding methodological limitations and very serious concerns regarding adequacy

1 **3 Integration and discussion of the** 2 **evidence**

3 **3.1 Mixed methods integration**

4 **Are the results/findings from individual syntheses supportive or contradictory?**

5 The effectiveness evidence showed that text-messaging based interventions designed to
6 increase vaccine uptake were effective at increasing HPV vaccine initiation MSM. Similarly,
7 an intervention focusing on implementation intention formation (prompting participants to
8 consider ways to implement their intentions to get vaccinated by thinking about when, where
9 and how they would obtain hepatitis B vaccine) was effective at increasing hepatitis B
10 vaccine initiation in MSM. The text-messaging based interventions were not effective in
11 supporting HPV vaccine completion and there were no studies that examined hepatitis B
12 vaccine completion.

13 The qualitative evidence generated themes that showed a lack of information about HPV,
14 HPV-related disease, and the HPV vaccine was a barrier to vaccination in MSM. This
15 supports findings from the effectiveness review because the interventions that were effective
16 at increasing vaccination initiation included information-based components that educated
17 people about HPV and HPV-related disease.

18 **Does the qualitative evidence explain why the intervention is/is not effective?**

19 The qualitative evidence highlighted lack of knowledge about HPV as a barrier to
20 vaccination, particularly relating to the widespread perception that HPV is something that
21 only affects cisgender women. It also showed vaccine hesitancy, uncertainty about vaccine
22 effectiveness and concerns about side effects were barriers to vaccination. Interventions that
23 provided information about HPV, the vaccine, how it works, and potential side effects were
24 effective in improving vaccine initiation, which suggests that the interventions were effective
25 because they filled knowledge gaps or allayed fears about the vaccine that were acting as
26 barriers to initial vaccine uptake.

27 The qualitative evidence suggested that some of the barriers to vaccination completion were
28 related to the need for multiple doses, the long time intervals between doses, and the
29 potential inconvenience of having to schedule appointments around other commitments. The
30 effectiveness evidence showed that vaccine completion rates were generally very low in both
31 the intervention and control arms (range 1.3% to 11%) and the text messaging based
32 interventions were not effective in improving HPV vaccine course completion. The
33 interventions may not have been effective because they focused more on information,
34 motivation and behaviour needs rather than addressing issues relating to scheduling and
35 appointment flexibility. Nevertheless, the interventions did include regular text or email
36 reminders which still did not appear to be effective at facilitating vaccine course completion.

37 **Does the qualitative evidence explain differences in the direction and size of effect** 38 **across the included quantitative studies?**

39 Quantitative findings for interventions to increase both HPV vaccine initiation and completion
40 had relatively wide confidence intervals, indicating some uncertainty in the estimate of effect.
41 This uncertainty may be partly explained by the qualitative findings because they identified a
42 range of different barriers to, and facilitators for, vaccination. Different people may require
43 different support from interventions to overcome personal barriers and encourage them to
44 obtain vaccination, so digital interventions that focused primarily on information, motivation
45 and behavioural needs may be effective for some, but not all people, contributing to the wide
46 confidence intervals seen in the quantitative evidence.

1 **Which aspects of the quantitative evidence were/were not explored in the qualitative**
2 **studies?**

3 The quantitative evidence included interventions that focused on intention formation
4 implementation and how to move people from considering vaccination to making a specific
5 plan to obtain it. The qualitative evidence looked more broadly at person- and system-level
6 factors that may act as barriers or facilitators to vaccination, rather than individual
7 approaches to supporting people in making behavioural changes that encouraged
8 vaccination. The quantitative evidence also assessed the effectiveness of text- and email-
9 based interventions while the qualitative evidence only considered app-based approaches for
10 booking appointments and creating a reminder system and did not explore the potential
11 barriers and facilitators for text messaging-based interventions.

12 **Which aspects of the qualitative evidence were/were not tested in the quantitative**
13 **studies?**

14 The qualitative evidence highlighted themes relating to health care professionals and their
15 role in supporting people to obtain vaccination. Specific themes included the importance of
16 HCPs being open, accepting, and non-judgemental; that HCPs were considered to be the
17 most trusted source of information about vaccination; and that recommendations from HCPs
18 were seen as something that would substantially influence people's decision to obtain the
19 vaccine. Findings from the qualitative evidence also showed that people wanted vaccinations
20 to be offered during other routine interactions with HCPs such as general sexual health
21 checks or STI testing. The quantitative evidence did not examine the role of health care
22 practitioners and did not evaluate the efficacy of offering vaccinations during other clinical
23 interactions.

24

25 **3.2 The committee's discussion and interpretation of the**
26 **evidence**

27 The qualitative and quantitative reviews are presented as a combined discussion.

28 **3.2.1. The outcomes that matter most**

29 The committee discussed the evidence and agreed that vaccine uptake is the most important
30 outcome, but also emphasised the importance of vaccine course completion. They agreed
31 that both vaccine initiation and vaccine course completion should be considered together.

32 The committee discussed and agreed on the importance of considering the barriers to or
33 facilitators for vaccine uptake and completion, described by those who are likely to benefit
34 from having vaccines, that may have substantial impact on the effectiveness of any
35 intervention that aims to increase vaccine uptake.

36 The committee considered it important that gay, bisexual and other men who have sex with
37 men are aware of, and able to easily access, HPV, Hepatitis A and Hepatitis B vaccinations.
38 Particularly in relation to HPV they noted that many people in this group will not have been
39 included in the school's vaccination programme that has now been expanded to include
40 boys. In future this group will have been offered vaccination at school, but currently this
41 group have not been included as the vaccination programme did not initially include boys.

1 **3.2.2 The quality of the evidence**

2 ***Quantitative evidence***

3 The committee discussed the lack of evidence on vaccine uptake in gay, bisexual and other
4 men who have sex with men, with only 3 studies identified: two for HPV and one for Hepatitis
5 B vaccination. They noted that there were some methodological concerns about these
6 included papers because of the lack of detail provided about the randomisation methods
7 used and on allocation concealment methods. They further noted that the studies had not
8 specified the number of vaccine doses offered.

9 The committee discussed the evidence and noted that the interventions had a positive
10 impact on HPV vaccine initiation but not on HPV vaccine completion. It was also noted that
11 the finding for HPV vaccine completion had a very wide confidence interval, suggesting a
12 high degree of imprecision for this outcome. The committee agreed that the evidence was
13 useful in drafting recommendations on vaccine initiation and agreed that while there was a
14 lack of evidence for interventions to encourage vaccine completion, it was important to also
15 make recommendations about this because people need to have both doses of the vaccine
16 to be fully protected. This absence of evidence prompted the committee to make a qualitative
17 research recommendation on the barriers to HPV vaccine course completion and how people
18 think they might be encouraged to complete it.

19 The committee highlighted that while the 7- and 9-month follow ups described in the two
20 trials fit with the recommended HPV vaccine course of doses at 0, 1 and 4 months, in
21 practice doses are often more widely spaced and, in some clinics, at least a year is allowed
22 to complete the full course. The committee therefore considered that 7- and 9-month follow-
23 up periods were a relatively short timeframe for people to complete the vaccine doses and
24 this may have contributed to the lack of effect for this outcome.

25 The committee discussed the evidence showing an effect of motivational information and
26 implementation intention formation activities on improving Hepatitis B vaccine uptake, though
27 it was not clear from the study what the vaccination schedule was or whether participants
28 completed their course. As noted previously, the committee considered vaccine completion
29 to be important so this was acknowledged as a limitation of the applicability of this evidence.
30 The committee also noted that drop out was 25% higher in the intervention group than the
31 control group, although attrition analyses found no significant differences between
32 participants in the experimental and control groups, or between completers and those lost to
33 follow-up, indicating that attrition was not selective. The committee discussed the limited
34 evidence for specific interventions that aim to improve vaccine uptake. They considered that
35 there was not sufficient evidence to specifically recommend any of the included interventions,
36 but they recognised the importance of including vaccination information within healthcare and
37 specifically sexual health services that gay, bisexual and other men who have sex with men
38 use. They noted that even though the evidence alone was insufficient, with the broader
39 experience and expertise of the committee members, they were able to make
40 recommendations about the importance of opportunistically providing information on and
41 discussing vaccination with gay, bisexual and other men who have sex with men during
42 routine or other healthcare appointments.

43 The committee noted the NICE guidance on [behaviour change: individual approaches](#) and
44 noted that the recommendations about behaviour change techniques that could be effective
45 may be useful when thinking about approaches to improving vaccine uptake.

46 ***Qualitative evidence***

47 Evidence addressing barriers to and facilitators for increasing uptake of vaccination in gay,
48 bisexual and other men who have sex with men was only identified for HPV vaccination.
49 Nonetheless, the committee discussed and agreed that many of the identified themes for
50 both barriers and facilitators identified for HPV vaccination for gay, bisexual and other men

1 who have sex with men are also applicable to the other vaccines. These include barriers
2 such as those around the approachability of healthcare staff for gay, bisexual and other men
3 who have sex with men, the need for clear information about vaccines and the possible
4 provision of vaccines as part of other healthcare visits. The committee discussed the
5 identified barriers including a general lack of knowledge about HPV and HPV related
6 diseases and vaccines; and concerns about vaccine effectiveness and potential side effects.
7 Additional barriers included possible stigma or concerns about having discussions with
8 healthcare professionals and the impact of previous negative experiences of this; and some
9 potential difficulties with the scheduling of vaccines. The committee also discussed the
10 identified facilitators including increasing knowledge and awareness of the benefits of getting
11 vaccines, the influence of the views of healthcare providers on vaccination decisions, the
12 possibility of vaccinations being offered during routine sexual health or other healthcare
13 visits.. The Committee agreed that the themes identified were similar to those that they had
14 expected and reflected their expertise and clinical experience.

15 The committee discussed the qualitative evidence in combination with the findings from the
16 quantitative review and noted that the qualitative evidence supported the importance of
17 discussing vaccination opportunistically. They also discussed the evidence that noted that
18 there can be a misconception that HPV only has relevance for cisgender females and that
19 the link with male cancers may not be widely known. The committee considered that this
20 misconception also supports the recommendation for opportunistic discussion as it may be
21 that gay, bisexual and other men who have sex with men do not know that the vaccination is
22 relevant for them.

23 The evidence identified that there are ongoing concerns for gay, bisexual and other men who
24 have sex with men around the perceived approachability of healthcare staff and this affects
25 whether or not they are comfortable discussing their sexual history. The committee further
26 discussed and agreed that gay, bisexual and other men who have sex with men need to feel
27 confident discussing their healthcare needs, concerns, and sexual history with healthcare
28 professionals without any apprehension about a negative reaction or stigma. The committee
29 agreed that healthcare settings need to adopt approaches that will signal to gay, bisexual
30 and other men who have sex with men that healthcare providers will support and facilitate
31 these important discussions. They discussed programmes such as the 'You're Welcome'
32 quality criteria, which lays out key principles that help health services to be young people
33 friendly, and considered how similar approaches could be used for gay, bisexual and other
34 men who have sex with men to provide assurance to those using the services that it is
35 designed with their needs in mind.

36 The committee discussed accessibility of vaccination appointments and the possibility of
37 combining this with other healthcare visits. The qualitative evidence suggested that ensuring
38 flexibility about when vaccines are given and reducing the number of visits by combining
39 vaccines or combining vaccination with other healthcare visits may improve uptake. The
40 committee agreed to recommend that services consider ways they can do this. The
41 committee noted that one study identified the possible use of mobile apps for booking
42 appointments and reminding people about them. They agreed that this is already current
43 practice and approaches like this are already in use.

44 **3.2.3 Benefits and harms**

45 The committee agreed that improving vaccine uptake and completion in gay, bisexual and
46 other men who have sex with men is beneficial. They noted that there is a widespread
47 misconception that the HPV vaccine is only important for cisgender women and that the link
48 with male cancers is not known, so correcting this misconception is important. The
49 committee also recognised that there are people who consider vaccines harmful, and that
50 many gay, bisexual and other men who have sex with men do not consider vaccination
51 important, so providing clear information about the benefits and harms of HPV, Hepatitis A

1 and Hepatitis B vaccines is important. The quantitative and qualitative evidence did not
2 identify any harms of HPV and hepatitis B vaccinations.

3 **3.2.4 Cost effectiveness and resource use**

4 No economic evidence was identified for this review question. Nevertheless, the committee
5 discussed the potential cost-effectiveness and resource impact of the recommendations
6 made. They agreed that the recommendations on providing information and opportunistically
7 assessing eligibility for vaccination should reflect current practice, and therefore did not
8 consider that there would be a substantial resource impact associated with implementing
9 them.

10 Combining vaccinations alongside other routine healthcare (either care around sexual health
11 or more general healthcare) would be expected to increase rates of vaccination and be a
12 more efficient and therefore less costly method of providing vaccination, as the person does
13 not need an additional separate appointment solely for the purpose of delivering the
14 vaccination. The committee noted such an approach would not be suitable for all vaccine
15 eligible men but would be a cost-effective approach for those it can be delivered to.

16 It was also noted that because these vaccines had already been assessed as being cost-
17 effective by the Joint Committee on Vaccination and Immunisation, an increase in the
18 number of people being vaccinated should also be cost-effective.

19 **3.3 Recommendations supported by this evidence review**

20 This evidence review supports recommendations 1.4.1 to 1.4.4 and the research
21 recommendation on barriers to vaccination course completion.

22 **3.4 References – included studies**

23 **3.4.1 Effectiveness**

24 Bass, Michael, Gerend, Mary A., Madkins, Krystal et al. (2021) Evaluation of a Text
25 Messaging-Based Human Papillomavirus Vaccination Intervention for Young Sexual Minority
26 Men: Results from a Pilot Randomized Controlled Trial. *Annals of behavioral medicine* : a
27 publication of the Society of Behavioral Medicine 55(4): 321-332

28 Reiter, Paul L, Katz, Mira L, Bauermeister, Jose A et al. (2018) Increasing Human
29 Papillomavirus Vaccination Among Young Gay and Bisexual Men: A Randomized Pilot Trial
30 of the Outsmart HPV Intervention. *LGBT health* 5(5): 325-329

31 Vet, Raymond; de Wit, John B F; Das, Enny (2014) The role of implementation intention
32 formation in promoting hepatitis B vaccination uptake among men who have sex with men.
33 *International journal of STD & AIDS* 25(2): 122-9

34 **3.4.1 Qualitative**

35 Apaydin, Kaan Z, Fontenot, Holly B, Shtasel, Derri et al. (2018) Facilitators of and barriers to
36 HPV vaccination among sexual and gender minority patients at a Boston community health
37 center. *Vaccine* 36(26): 3868-3875

38 Fontenot, Holly B, Fantasia, Heidi C, Veters, Ralph et al. (2016) Increasing HPV vaccination
39 and eliminating barriers: Recommendations from young men who have sex with men.
40 *Vaccine* 34(50): 6209-6216

41 Gerend, M.A., Madkins, K., Crosby, S. et al. (2019) A Qualitative Analysis of Young Sexual
42 Minority Men's Perspectives on Human Papillomavirus Vaccination. *LGBT health* 6(7): 350-
43 356

- 1 Grace, Daniel, Gaspar, Mark, Paquette, Rachelle et al. (2018) HIV-positive gay men's
2 knowledge and perceptions of Human Papillomavirus (HPV) and HPV vaccination: A
3 qualitative study. PloS one 13(11): e0207953
- 4 Jaiswal, Jessica, LoSchiavo, Caleb, Maiolatesi, Anthony et al. (2020) Misinformation,
5 Gendered Perceptions, and Low Healthcare Provider Communication Around HPV and the
6 HPV Vaccine Among Young Sexual Minority Men in New York City: The P18 Cohort Study.
7 Journal of community health 45(4): 702-711
- 8 Kesten, J.M., Flannagan, C., Ruane-Mcateer, E. et al. (2019) Mixed-methods study in
9 England and Northern Ireland to understand young men who have sex with men's knowledge
10 and attitudes towards human papillomavirus vaccination. BMJ Open 9(5): e025070
- 11 Koskan, Alexis M and Fernandez-Pineda, Madeline (2018) Human Papillomavirus Vaccine
12 Awareness Among HIV-Positive Gay and Bisexual Men: A Qualitative Study. LGBT health
13 5(2): 145-149
- 14 Koskan, Alexis M and Fernandez-Pineda, Madeline (2018) Anal Cancer Prevention
15 Perspectives Among Foreign-Born Latino HIV-Infected Gay and Bisexual Men. Cancer
16 control : journal of the Moffitt Cancer Center 25(1): 1073274818780368
- 17 Nadarzynski, Tom, Smith, Helen, Richardson, Daniel et al. (2017) Perceptions of HPV and
18 attitudes towards HPV vaccination amongst men who have sex with men: A qualitative
19 analysis. British journal of health psychology 22(2): 345-361
- 20 Wheldon, C.W., Daley, E.M., Buhi, E.R. et al. (2017) HPV vaccine decision-making among
21 young men who have sex with men. Health Education Journal 76(1): 52-65

1 Appendices

2 Appendix A – Review protocols

3 Review protocol for interventions for increasing uptake of hepatitis A, hepatitis B or HPV vaccinations in MSM

ID	Field	Content
0.	PROSPERO registration number	Not registered
1.	Review title	Effective and cost-effective interventions to increase uptake of hepatitis A, hepatitis B and human papillomavirus (HPV) vaccination in gay, bisexual and other men who have sex with men (MSM)
2.	Review question	1.3a What interventions are effective and cost effective at increasing uptake of hepatitis A and hepatitis B vaccination in MSM? 1.3b What interventions are effective and cost effective at increasing uptake of HPV vaccination in MSM?
3.	Objective	Gay, bisexual and other men who have sex with men (MSM) are at a higher risk of hepatitis A, hepatitis B and HPV. Vaccinations have been shown to be effective in preventing these infections. The aim of this review is to establish which interventions are effective and cost effective at increasing the uptake of these vaccinations among men who have sex with men.
4.	Searches	The following databases will be searched: Cochrane Central Register of Controlled Trials (CENTRAL) Cochrane Database of Systematic Reviews (CDSR) Embase (OVID) Medline (OVID) Medline in Process (OVID) PsycINFO (Ovid) EmCare (OVID) Web of Science (for citation searching* only, if judged to be required) *Citation searching Depending on initial database results, forward citation searching on key papers may be conducted, if judged necessary, using Web of Science (WOS). Only those references which NICE can access through its WOS subscription would be added to the search results. Duplicates would be removed in WOS before downloading. Reference searching may also be done depending on initial database results. Websites

ID	Field	Content
		<p>5 key websites will be searched for relevant reports or publications Database functionality will be used, where available, to exclude: Non-English language papers Animal studies Editorials, letters or commentaries Conference abstracts or posters Dissertations or theses Duplicates Sources will be searched from 2009 to current. The searches will be re-run 6 weeks before final submission of the review and further studies retrieved for inclusion. The guidance Information Services team at NICE will quality assure the principal search strategy and peer review the strategies for the other databases. Any revisions or additional steps will be agreed by the review team before being implemented. Any deviations and a rationale for them will be recorded alongside the search strategies. A record will be kept of number of records found from each database and of the strategy used in each database. A record will be kept of total number of duplicates found and of total results provided to the Public Health team. The full search strategies for MEDLINE database will be published in the final review.</p>
5.	Condition or domain being studied	Hepatitis A, Hepatitis B and HPV
6.	Population	<p>Gay, bisexual and other men who have sex with men (MSM) from age 16. This may also include younger people who contact or use sexual health services and are considered to be Gillick competent and satisfies the Frasier guidelines</p>
7.	Intervention/Exposure/Test	<p>Interventions with the primary aim of increasing uptake of hepatitis A and B and HPV vaccinations in MSM such as: targeted mass media campaigns for example newspapers and other printed material, radio, television, billboards education for example peer to peer programs (peer led education) – teaching or sharing of information, values, and behaviours recommendations from for example health care practitioner, sexual health adviser, community health worker</p>

ID	Field	Content
		internet-based interventions for example social media, websites and banners on dating apps where the primary purpose is to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM interventions designed to increase recall / adherence / vaccination schedule completion, including letters, telephone calls, text message or email reminders, case management programs, accelerated schedules Interventions that aim to reduce any difficulties with access or expand access, such as out of hours services, delivery in clinical and non-clinical settings Single or multi component interventions.
8.	Comparator/Reference standard/Confounding factors	No intervention Other intervention aiming to increase uptake Comparator as defined by the paper
9.	Types of study to be included	Inclusion: RCTs Cluster RCTs Controlled before-and-after studies Prospective cohort Studies Systematic reviews of included study designs Interrupted time series Exclusion: Case control studies Cross-sectional studies Correlational studies
10.	Other exclusion criteria	Only papers published in the English language will be included Only full published studies (not protocols or summaries) will be included. Non-OECD countries
11.	Context	The Department of Health and Social Care in England has asked NICE to update the guideline on sexually transmitted infections and under-18 conceptions: prevention (PH3), published in 2007. Changes in policy and commissioning, service provision, financial pressures and new evidence identified through the surveillance process led to the decision to update this guideline. The updated guideline will focus solely on the reduction of sexually transmitted infections (STIs), as prevention of under-18 conceptions is covered in other guidelines.

ID	Field	Content
		Data from Public Health England show the overall number of STI diagnoses increased by 5% between 2017 and 2018. STIs can affect personal wellbeing, mental health and relationships and can also lead to serious health problems including pelvic inflammatory disease, ectopic pregnancy or infertility. It is therefore important to address interventions to help prevent or reduce STIs.
12.	Primary outcomes (critical outcomes)	Changes in uptake of hepatitis A and B vaccination in MSM Changes in uptake of HPV vaccination in MSM Uptake of initial and subsequent vaccinations
13.	Secondary outcomes (important outcomes)	Secondary outcomes: Safety or adverse effects Health related quality of life
14.	Data extraction (selection and coding)	All references identified by the searches and from other sources will be uploaded into EPPI reviewer and de-duplicated. This review may use the EPPI reviewer priority screening functionality where at least 50% of the identified abstracts will be screened. After this point, screening will only be terminated if a pre-specified threshold is met for a number of abstracts being screened without a single new include being identified. This threshold is set according to the expected proportion of includes in the review (with reviews with a lower proportion of includes needing a higher number of papers without an identified study to justify termination) and is always a minimum of 250. A random 10% sample of the studies remaining in the database when the threshold is met will be additionally screened, to check if a substantial number of relevant studies are not being correctly classified by the algorithm, with the full database being screened if concerns are identified. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. A standardised template will be used to extract data from studies (this is consistent with the Developing NICE guidelines: the manual section 6.4).
15.	Risk of bias (quality) assessment	Risk of bias for individual studies will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual
16.	Strategy for data synthesis	Studies will be grouped by intervention type as appropriate.

ID	Field	Content
		<p>Data from eligible studies will be meta-analysed (combined) if studies are judged to be similar enough in terms of population, interventions, outcomes, study design or risk of bias.</p> <p>It is anticipated that meta-analysed studies will be heterogeneous. Where appropriate, heterogeneity will be explored by conducting subgroup analyses and incorporated by performing random-effect analyses.</p> <p>If studies are found to be too heterogeneous to be pooled statistically, a narrative approach with sufficient information to make judgements about study effectiveness will be conducted.</p> <p>Tables and other forms of visual presentation may be used to summarise data where appropriate.</p> <p>Dichotomous data will be pooled where appropriate and the effect size will be reported using risk ratios in a standard pair-wise meta-analysis.</p> <p>Continuous outcomes reported on the same scale will be pooled in a standard pair-wise meta-analysis using mean difference where possible.</p> <p>Continuous outcomes not reported on the same scale will be pooled using a standardised mean difference in a standard pair-wise meta-analysis.</p> <p>Where appropriate, the quality or certainty across all available evidence will be evaluated for each outcome using an the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/</p> <p>Network meta-analysis maybe conducted where appropriate</p>
17.	Analysis of sub-groups	<p>Where evidence allows, sub-group analysis will be conducted to include:</p> <ul style="list-style-type: none"> People from a Black African or Caribbean family background People with low socio-economic status Older age groups People with learning disabilities Trans and non-binary people Migrant communities <p>Where evidence allows, sub-group analyses will also be used to answer questions about the effectiveness of intervention types, including:</p> <ul style="list-style-type: none"> Mode of delivery
25.	Review team members	<p>A multidisciplinary committee including the Public Health England Topic Advisor (PHETA) will be involved in developing the evidence review.</p> <p>NICE Public Health guideline development technical guideline team:</p> <p>Technical lead: Robby Richey</p>

ID	Field	Content
		Technical analyst: Jonathan Nyong Information specialist: Daniel Tuvey Project Manager: Adam O’Keefe
26.	Funding sources/sponsor	This systematic review is being completed by Public Health guideline development, NICE
27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
28.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual . Members of the guideline committee are available on the NICE website: [NICE guideline webpage].
32.	Keywords	Hepatitis A, Hepatitis B, HPV, vaccine, vaccination, intervention, promoting uptake, sexually transmitted infections, STIs.

1

2 **Review protocol for barriers to, and facilitators for, increasing uptake of hepatitis A, hepatitis B or HPV vaccinations in MSM**

ID	Field	Content
0.	PROSPERO registration number	Not registered
1.	Review title	Barriers to, and facilitators for, uptake of hepatitis A, hepatitis B and HPV vaccination in gay, bisexual and other men who have sex with men (MSM)
2.	Review question	1.4a What are the barriers to, and facilitators for, uptake of hepatitis A, and hepatitis B vaccination in MSM? 1.4b What are the barriers to, and facilitators for, uptake of HPV vaccination in MSM?
3.	Objective	Gay, bisexual and other men who have sex with men (MSM) have a higher risk of hepatitis A, hepatitis B and HPV. Vaccinations have been shown to be effective in preventing these infections. The aim of this review is to establish the barriers to and facilitators for vaccine uptake in MSM.

ID	Field	Content
4.	Searches	<p>The following databases will be searched:</p> <ul style="list-style-type: none"> Cochrane Central Register of Controlled Trials (CENTRAL) Cochrane Database of Systematic Reviews (CDSR) Embase (OVID) Medline (OVID) Medline in Process (OVID) PsycINFO (Ovid) EmCare (OVID) Web of Science (for citation searching* only, if judged to be required) <p>*Citation searching</p> <p>Depending on initial database results, forward citation searching on key papers may be conducted, if judged necessary, using Web of Science (WOS). Only those references which NICE can access through its WOS subscription would be added to the search results. Duplicates would be removed in WOS before downloading.</p> <p>Reference searching may also be done depending on initial database results.</p> <p>Websites</p> <p>5 key websites will be searched for relevant reports or publications</p> <p>Database functionality will be used, where available, to exclude:</p> <ul style="list-style-type: none"> Non-English language papers Animal studies Editorials, letters or commentaries Conference abstracts or posters Dissertations or theses Duplicates <p>Sources will be searched from 2009 to current.</p> <p>The searches will be re-run 6 weeks before final submission of the review and further studies retrieved for inclusion.</p> <p>The guidance Information Services team at NICE will quality assure the principal search strategy and peer review the strategies for the other databases. Any revisions or additional steps will be agreed by the review team before being implemented. Any deviations and a rationale for them will be recorded alongside the search strategies.</p>

ID	Field	Content
		<p>A record will be kept of number of records found from each database and of the strategy used in each database. A record will be kept of total number of duplicates found and of total results provided to the Public Health team.</p> <p>The full search strategies for MEDLINE database will be published in the final review.</p>
5.	Condition or domain being studied	Hepatitis A, Hepatitis B and HPV
6.	Population	<p>Gay, bisexual and other men who have sex with men (MSM) from age 16.</p> <p>This may also include younger people who contact or use sexual health services and are considered to be Gillick competent and satisfies the Frasier guidelines</p>
7.	Intervention/Exposure/Test	<p>Any barrier or facilitator that may impact on vaccine uptake?</p> <p>To consider both person-specific and system level barriers and facilitators (Ideally this will include interventions or strategies identified in RQ1.3, but is not restricted to these)</p>
8.	Comparator/Reference standard/Confounding factors	Not applicable
9.	Types of study to be included	<p>Qualitative studies</p> <p>Mixed methods studies with relevant qualitative data.</p>
10.	Other exclusion criteria	<p>Only papers published in the English language will be included.</p> <p>Only studies from the Organisation for Economic Cooperation and Development (OECD) countries will be included.</p> <p>Only full published peer-reviewed qualitative studies will be included. Non-OECD countries and the USA.</p>
11.	Context	<p>The Department of Health and Social Care in England has asked NICE to update the guideline on sexually transmitted infections and under-18 conceptions: prevention (PH3), published in 2007. Changes in policy and commissioning, financial pressures and new evidence identified through the surveillance process led to the decision to update this guideline. The updated guideline will focus solely on the reduction of sexually transmitted infections (STIs), as prevention of under-18 conceptions is covered in other guidelines</p> <p>Data from Public Health England show the overall number of STI diagnoses increased by 5% between 2017 and 2018. STIs can affect personal wellbeing, mental health and relationships and can also lead to serious health problems including pelvic inflammatory disease, ectopic pregnancy or infertility.</p> <p>It is therefore important to address interventions to help prevent or reduce STIs. Such interventions will be delivered in settings where sexual health services are provided, including:</p>

ID	Field	Content
12.	Primary outcomes (critical outcomes)	<p>Outcomes will include attitudes, experiences and views of people receiving the interventions people delivering the interventions</p> <p>The attitudes, experiences and views relating to barriers and facilitators to increasing uptake of hepatitis A, hepatitis B and HPV vaccinations in MSM may include:</p> <p>Affective attitude How an individual feels about the intervention Burden The perceived amount of effort that is required to participate in the intervention Ethicality The extent to which the intervention has good fit with an individual's value system Coherence The extent to which the participant understands the intervention and how it works Perceived effectiveness The extent to which the intervention is perceived as likely to achieve its purpose</p>
13.	Secondary outcomes (important outcomes)	<p>Changes in vaccination uptake related;</p> <p>Knowledge Beliefs Attitudes Acceptance</p>
14.	Data extraction (selection and coding)	<p>All references identified by the searches and from other sources will be uploaded into EPPI reviewer and de-duplicated.</p> <p>This review may use the EPPI reviewer priority screening functionality. At least 50% of the identified abstracts will be screened. After this point, screening will only be terminated if a pre-specified threshold is met for a number of abstracts being screened without a single new include being identified. This threshold is set according to the expected proportion of includes in the review (with reviews with a lower proportion of includes needing a higher number of papers without an identified study to justify termination) and is always a minimum of 250.</p> <p>A random 10% sample of the studies remaining in the database when the threshold is met will be additionally screened, to check if a substantial number of relevant studies are not being correctly classified by the algorithm, with the full database being screened if concerns are identified.</p>

ID	Field	Content
		<p>10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer.</p> <p>The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above.</p> <p>A standardised template will be used to extract data from studies (this is consistent with the Developing NICE guidelines: the manual section 6.4).</p>
15.	Risk of bias (quality) assessment	<p>Risk of bias will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual</p>
16.	Strategy for data synthesis	<p>The key findings from the studies will be categorised into themes relevant to the review across all studies using a thematic analysis. Supporting quotations and summaries of data may be included.</p> <p>Where appropriate, the quality or certainty across all available evidence will be evaluated for each outcome using the GRADE CERQual approach.</p> <p>A mixed methods synthesis including studies from question 1.3.</p> <p>Where evidence allows, a synthesis matrix will be produced to combine results from the two different analytical approaches. Findings from one analytical approach will be compared to findings from the second approach, and outcomes paired up if they provide relevant information on the same underlying topic (for example, barriers to, and facilitators for may be paired up with interventions from 1.3). The agreement between the findings of the two approaches will be qualitatively assessed, with each paired set of findings put into categories relating to the strength of the identified correlation.</p> <p>The results may be presented as a narrative summary or diagram with quantitative findings mapped onto the qualitative ones.</p>
17.	Analysis of sub-groups	<p>Where evidence allows, sub-group thematic analysis will be conducted to include:</p> <ul style="list-style-type: none"> People from a Black African or Caribbean family background People with low socioeconomic status People with learning disabilities Older age groups Trans and non-binary people Migrant communities
25.	Review team members	<p>[Give the title, first name, last name and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong.]</p> <p>From the [Insert Development centre]:</p>

ID	Field	Content
		[Tech lead] [Tech analyst] [Health economist] [Information specialist] [Others]
26.	Funding sources/sponsor	This systematic review is being completed by Public Health guideline development, NICE.
27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
28.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual . Members of the guideline committee are available on the NICE website: [NICE guideline webpage].
32.	Keywords	Hepatitis A, Hepatitis B, HPV, vaccine, vaccination, intervention, promoting uptake, sexually transmitted infections, STIs.

Appendix B – Literature search strategies

Database name: MEDLINE

Database: Ovid MEDLINE(R) <1946 to December 17, 2019>

Search Strategy:

-
- 1 Papillomavirus Infections/ (24693)
 - 2 (papillomavirus adj (human* or infect*)).ti,ab. (3726)
 - 3 hpv*.ti,ab. (36531)
 - 4 exp Hepatitis A/ (20348)
 - 5 exp Hepatitis B/ (56963)
 - 6 ((hepatitis or hep) adj (B or A)).ti,ab. (77275)
 - 7 (HBV or HAV).ti,ab. (39563)
 - 8 or/1-7 (148914)
 - 9 exp Vaccination/ (82370)
 - 10 Immunization/ or Immunization Programs/ or vaccines/ (78346)
 - 11 (vaccin* or immuni*).ti,ab. (457972)
 - 12 booster*.ti,ab. (10253)
 - 13 or/9-12 (492518)
 - 14 Papillomavirus Vaccines/ (7347)
 - 15 Human Papillomavirus Recombinant Vaccine Quadrivalent, Types 6, 11, 16, 18/ (718)
 - 16 Hepatitis B Vaccines/ (9124)
 - 17 Hepatitis A Vaccines/ (1670)
 - 18 (Cervarix or Gardasil).ti,ab. (464)
 - 19 (Ambirix or Twinrix).ti,ab. (68)
 - 20 8 and 13 (31118)
 - 21 14 or 15 or 16 or 17 or 18 or 19 or 20 (33313)
 - 22 (gay adj3 (male* or men)).ti,ab. (3861)
 - 23 Homosexuality, Male/ (14972)
 - 24 "Sexual and Gender Minorities"/ (2698)

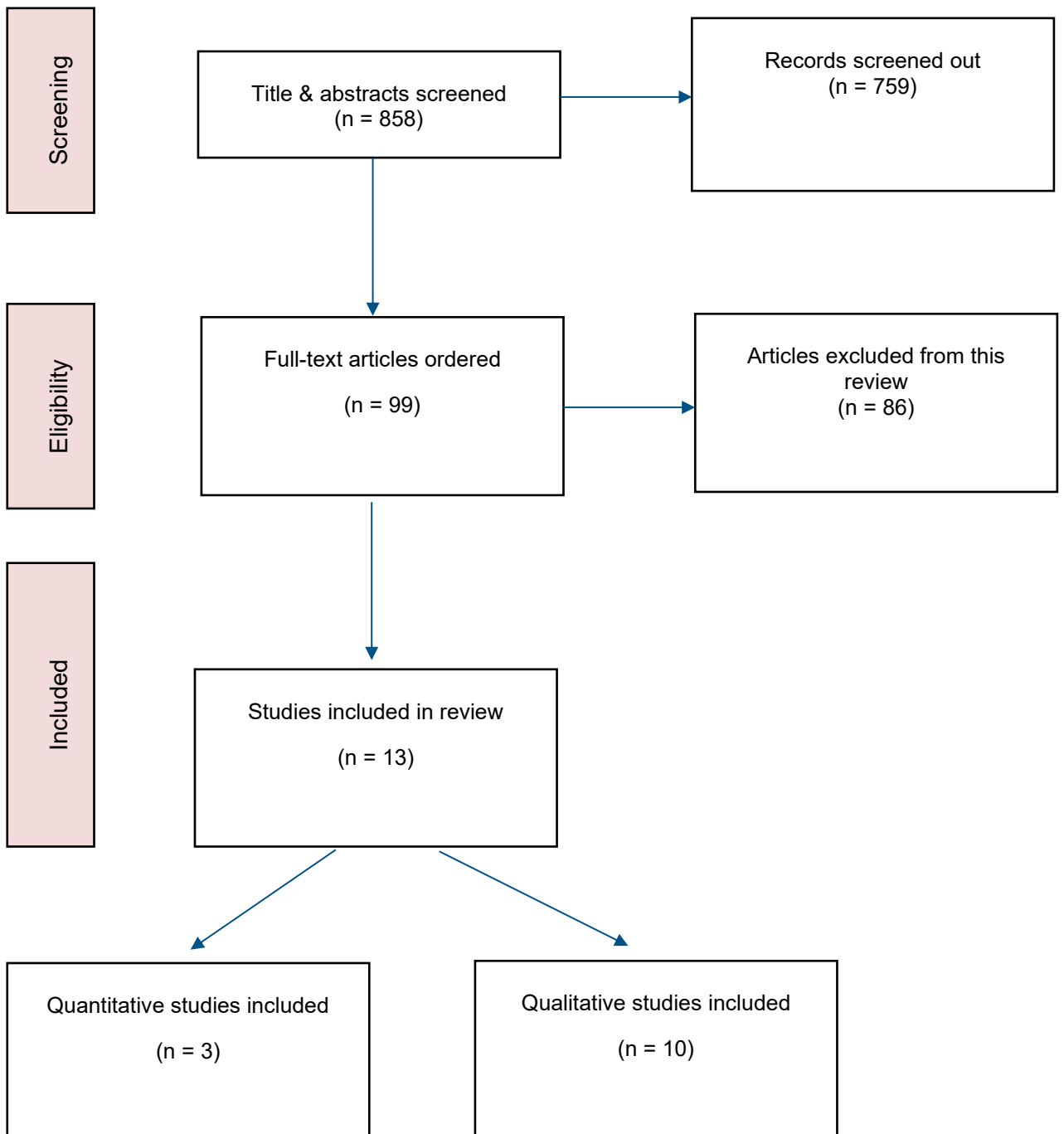
- 25 Bisexuality/ (3979)
- 26 Transgender Persons/ (2682)
- 27 Homosexuality/ (12257)
- 28 men who have sex with men.ti,ab. (8850)
- 29 (same sex or non heterosexual* or non-heterosexual*).ti,ab. (5637)
- 30 MSM.ti,ab. (7797)
- 31 (transgender* or transexual* or trans man or trans men or trans masculine or (gender adj (queer* or fluid* or variant*)) or nonbinary or non binary or non-binary or genderless or agender or bi-gender or bi gender or neutrois).ti,ab. (3965)
- 32 (bisexual* or homosexual* or lgbt).ti,ab. (18306)
- 33 (male adj3 (sex work* or prostitut* or transactional sex or escort*).ti,ab. (503)
- 34 or/22-33 (46060)
- 35 21 and 34 (738)
- 36 limit 35 to english language (686)
- 37 limit 36 to (letter or historical article or comment or editorial or news or case reports) (60)
- 38 36 not 37 (626)
- 39 Animals/ not (Humans/ and Animals/) (4622703)
- 40 38 not 39 (626)
- 41 limit 40 to yr="2009 -Current" (372)

Database name: MEDLINE - UPDATE (17 December 2019 – 14 June 2021)

1	Papillomavirus Infections/	26869
2	(papillomavirus adj (human* or infect*)).ti,ab.	3107
3	hpv*.ti,ab.	35638
4	exp Hepatitis A/	4047
5	exp Hepatitis B/	40003
6	((hepatitis or hep) adj (B or A)).ti,ab.	59662
7	(HBV or HAV).ti,ab.	35664
8	or/1-7	109809
9	exp Vaccination/	56971
10	Immunization/ or Immunization Programs/ or vaccines/	46020
11	(vaccin* or immuni*).ti,ab.	365262
12	booster*.ti,ab.	8532
13	or/9-12	380401
14	Papillomavirus Vaccines/	8371
15	Human Papillomavirus Recombinant Vaccine Quadrivalent, Types 6, 11, 16, 18/	759
16	Hepatitis B Vaccines/	7358
17	Hepatitis A Vaccines/	1543
18	(Cervarix or Gardasil).ti,ab.	522
19	(Ambirix or Twinrix).ti,ab.	76
20	8 and 13	27624
21	14 or 15 or 16 or 17 or 18 or 19 or 20	29609
22	gay*.ti,ab.	9140
23	Homosexuality, Male/	16311
24	"Sexual and Gender Minorities"/	5223
25	Bisexuality/	3759
26	Transgender Persons/ or Transsexualism/ or Transgender/ or Health Services for Transgender Persons/	6071
27	Homosexuality/	3331
28	men who have sex with men.ti,ab.	10510
29	(same sex or non heterosexual* or non-heterosexual*).ti,ab.	5214

30	MSM.ti,ab.	9181
31	(transgend* or transex* or transsex* or transma* or transmen* or trans man or trans men or trans masculine or transfem* or transwom* or trans woman or trans women or transperson* or transpeopl* or trans person* or trans people* or (gender adj (queer* or fluid* or variant*)) or nonbinary or non binary or non-binary or genderless or genderqueer* or agender or bi-gender or bi gender or neutrois or crossgender* or cross-gender* or crossex* or cross-sex*).ti,ab.	12967
32	(bisexual* or homosexual* or lgbt).ti,ab.	11740
33	((male or man or men or boy*) adj3 (sex work* or prostitut* or transactional sex or escort*).ti,ab.	803
34	or/22-33	46337
35	21 and 34	730
36	limit 35 to english language	689
37	limit 36 to (letter or historical article or comment or editorial or news or case reports)	46
38	36 not 37	643
39	Animals/ not (Humans/ and Animals/)	2621905
40	38 not 39	643
41	limit 40 to ed=20191217-20210614	121

Appendix C – Public health evidence study selection



Appendix D – Effectiveness evidence

D.1 Quantitative evidence

Bass, 2021

Bibliographic Reference Bass, Michael; Gerend, Mary A.; Madkins, Krystal; Crosby, Shariell; Korpak, Aaron K.; Phillips, Gregory L.; Mustanski, Brian; Houlberg, Magda; Evaluation of a Text Messaging-Based Human Papillomavirus Vaccination Intervention for Young Sexual Minority Men: Results from a Pilot Randomized Controlled Trial; *Annals of behavioral medicine* : a publication of the Society of Behavioral Medicine; 2021; vol. 55 (no. 4); 321-332

Study details

Study design	Randomised controlled trial (RCT)
Trial registration number	Clinical Trial Registration NCT02994108.
Study start date	Jan-2018
Study end date	Sep-2018
Aim	To test the acceptability, feasibility and preliminary efficacy of a text messaging-based HPV vaccination intervention for young sexual minority men.
Country/geographical location	Chicago, USA
Setting	Participants were recruited online and the intervention was delivered via text messaging
Inclusion criteria	<ul style="list-style-type: none"> - 18–25 years old - assigned male sex at birth and have a male gender identity - self-identify as gay, bisexual, or queer, be physically attracted to men, or ever have had sex with a man - able to read and understand English - live in the Chicago area and plan to live there for the next 9 months - exclusive owner of a cell phone - have used text messaging for at least 6 months

	<ul style="list-style-type: none"> - plan to have the same phone number for the next 9 months - have an unlimited text messaging plan - have not received any HPV vaccine doses
Exclusion criteria	None reported
Method of randomisation	1:1 allocation ratio but specific randomisation method not reported
Method of allocation concealment	Not reported
Unit of allocation	Participant
Unit of analysis	Participant
Statistical method(s) used to analyse the data	<p>- A power analysis was conducted to estimate the required sample size based on two-sided $\alpha = .05$, 20% attrition, and the hypothesis that 18%–21% of intervention arm versus 6%–8% of control arm participants would receive their first dose of HPV vaccine. The analysis indicated >80% power to detect hypothesized effects by enrolling 230 participants per arm.</p> <p>- Descriptive statistics were calculated for sample characteristics among participants in the intervention and control conditions. To assess whether randomisation was successful, t-tests and chi-square analyses were used to compare participants across conditions.</p> <p>- Intervention efficacy, as indicated by the receipt of ≥ 1 dose of HPV vaccine, was assessed with logistic regression for all participants who were randomised and did not withdraw from the study.</p> <p>- Analyses were conducted using SPSS (version 26; IBM Corp., Armonk, NY).</p>
Attrition	<p>1359 potential participants were screened for eligibility; 175 people were eligible (primary reasons for ineligibility included having already received 1 or more doses of HPV vaccination, being outside of the age range, or not living in the Chicago area).</p> <p>N = 150 were randomised to intervention (n=74) or control (n=76) groups. Trial retention was high and did not vary by condition at both the 3 week follow up (intervention = 93% 67/72; control = 96% 73/76) or the 9 month follow up (intervention = 88% 63/72; control = 91% 69/76).</p>
Study limitations	<ul style="list-style-type: none"> - Null effects may have reflected the lack of statistical power as the study sample size was relatively small. - A relatively low number of participants completed the three-dose series during the relatively short follow-up period. Although the recommended dosing schedule specifies the receipt of three doses over a 6 month period, research indicates that a significant

percentage of patients take longer to complete the series. Thus, because the series takes time to complete, the current study design did not allow for a sufficient evaluation of series completion
- HPV vaccination was self-reported and it was not possible to verify all reported doses in the immunisation registry, although previous research suggests a relatively high accuracy of self-reported HPV vaccination among young adults.
- Only one HIV-positive participant enrolled in the trial; thus, the extent to which the current findings generalise to HIV positive sexual minority men is unknown.
- Participant recruitment was limited to the Chicago area so the sample may not be representative of young sexual minority men across the USA

Study arms

Intervention (N = 72)

Txt2protect: a text-messaging based HPV vaccination intervention based on the IMB model

Control (N = 76)

Attention control text messages

Characteristics

Arm-level characteristics

Characteristic	Intervention (N = 72)	Control (N = 76)
Age Mean (SD)	22.78 (2.03)	23.06 (2.39)
Sexual orientation		
Gay	n = 53 ; % = 74	n = 57 ; % = 75

Characteristic	Intervention (N = 72)	Control (N = 76)
Bisexual	n = 17 ; % = 24	n = 15 ; % = 20
Other (e.g. queer, pansexual)	n = 2 ; % = 3	n = 4 ; % = 5
Race / Ethnicity		
American Indian	n = 1	n = 1 ; % = 1
Asian	n = 4 ; % = 6	n = 7 ; % = 9
Black or African American	n = 13 ; % = 18	n = 18 ; % = 24
White	n = 42 ; % = 58	n = 38 ; % = 50
Multiracial	n = 3 ; % = 4	n = 5 ; % = 7
Unknown	n = 9 ; % = 13	n = 7 ; % = 9
Education		
Some high school / high school degree / GED	n = 23 ; % = 32	n = 19 ; % = 26
Some college or trade school certificate	n = 27 ; % = 37	n = 29 ; % = 39
College degree	n = 15 ; % = 21	n = 16 ; % = 21
Some graduate school / graduate degree	n = 7 ; % = 10	n = 11 ; % = 15
Latino		
Yes	n = 27 ; % = 38	n = 20 ; % = 26

Characteristic	Intervention (N = 72)	Control (N = 76)
No	n = 45 ; % = 62	n = 56 ; % = 74
Health insurance		
None	n = 11 ; % = 16	n = 10
Parents' insurance	n = 27 ; % = 38	n = 35 ; % = 47
Personal insurance	n = 33	n = 30 ; % = 40

Outcomes

Study timepoints

- 9 month

HPV vaccine uptake

Outcome	Intervention, 9 month, N = 72	Control, 9 month, N = 76
HPV vaccine initiation	n = 14 ; % = 19.4	n = 5 ; % = 6.6
No of events		
HPV vaccine completion	n = 2 ; % = 2.8	n = 1 ; % = 1.3
No of events		

HPV vaccine initiation - Polarity - Higher values are better

HPV vaccine completion - Polarity - Higher values are better

Study details

Rationale/theory/Goal	Current estimates indicate that although the HPV vaccine is specifically recommended for all MSM up to age 26, less than 40% have received one or more doses of the HPV vaccine. These low uptake rates coupled with the high disease burden of HPV-related disease point to the critical need for effective interventions to increase HPV vaccination uptake among young sexual minority men. Research demonstrating the keen interest of young MSM in the use of mobile technology for facilitating sexual health suggests mHealth interventions may be a particularly effective strategy for engaging young sexual minority populations in preventive health behaviour (p. 321-322).
Procedures used	<ul style="list-style-type: none"> - Participants were recruited via advertisements on social media sites (e.g. Facebook, Instagram and Twitter), online dating apps for MSM, and a local participant registry for sexual minority individuals interested in research. - Eligible participants received a text message with link to online consent form and baseline survey. - All participants received daily text messages for the first 3 weeks of the study (phase 1) then received monthly text messages for the remaining 8 months of the trial (phase 2) - In phase 1, participants received 10-12 messages per day, grouped into batches of 3-4 messages sent at 10am, 2pm and 6pm. In phase 2, participants received 5-8 messages on a given day once per month. - Participants completed follow-up surveys at 3 weeks and 9 months <p>(p. 323)</p>
Other details	Participants could earn up to \$75 in gift cards for completing surveys (p. 323).

Study arms

Intervention (N = 72): Txt2protect: a text-messaging based HPV vaccination intervention based on the IMB model

Brief name	Txt2protect (p. 322)
Rationale/theory/Goal	The Information, Motivation, Behavioural Skills (IMB) model was used to guide intervention development, alongside extensive formative research with the target population and input from young sexual minority men on message content and delivery (p. 323)
Materials used	Text message software and a supporting website tailored to condition (p. 323)

Procedures used	<ul style="list-style-type: none"> - Intervention text messages followed the IMB model format; each week of phase 1 reflected a different IMB model component. - Week 1 messages covered information (e.g. information about the HPV vaccination, safety, efficacy and dosing; how and where to get first dose) - Week 2 messages covered motivation (e.g. overcoming perceived barriers such as HPV misinformation; norms for HPV vaccination; reasons other young MSM decided to get vaccinated) - Week 3 messages covered behavioural skills (e.g. vaccine cost and health insurance, list of clinics offering vaccination, search tool for local pharmacies, action plan for getting vaccinated) - Messages in phase 2 reinforced phase 1 content and encouraged continued program engagement - Intervention messages focused primarily on HPV-based content, but did also address other sexual health practices such as condom use, PrEP, and HIV testing - Text messages were supported with a website tailored to condition and included essential information about HPV and contact information for local clinics providing HPV vaccine <p>(p. 323)</p>
Intensity/duration of the intervention	<p>During phase 1 (first 3 weeks), participants were sent 10-12 messages per day, grouped into 3 batches (3-4 messages, delivered at ~10am, 2pm and 6pm).</p> <p>During phase 2 (remaining 8 months), participants received between 5 and 8 messages on a given day, once per month</p> <p>(p. 322-323)</p>
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Intervention exposure was assessed as number of texts read during phase 1: 1 = <i>almost none</i> to 6 = <i>all of them</i> (p. 323)

Actual treatment fidelity	Mean intervention exposure scores indicated that most participants had read 'almost all of the messages' (p. 327).
Control (N = 76): Attention control text messages	
Materials used	Text message software and a supporting website tailored to condition (p. 323)
Procedures used	<ul style="list-style-type: none"> - Control participants received attention matched text messages addressing a variety of sexual health practices while providing only basic information on HPV vaccination. - In week 1, control participants received information about HIV/STI facts, prevalence, symptoms, transmission and treatments - In week 2, text messages contained information about prevention and testing, including condom use, PrEP, and STI and HIV testing - In week 3, text messages contained information about healthy relationships, communication, and meeting each others health, emotional and sexual needs <p>(p. 323)</p>
Intensity/duration of the intervention	<p>During phase 1 (first 3 weeks), participants were sent 10-12 messages per day, grouped into 3 batches (3-4 messages, delivered at ~10am, 2pm and 6pm).</p> <p>During phase 2 (remaining 8 months), participants received between 5 and 8 messages on a given day, once per month</p> <p>(p. 322-323)</p>
Tailoring/adaptation	None reported
Unforeseen modifications	None reported
Planned treatment fidelity	Not reported for control group
Actual treatment fidelity	Not reported for control group

Risk of Bias

Domain 1: Bias arising from the randomisation process

Risk of bias judgement for the randomisation process

Some concerns:

No information on allocation concealment but no baseline differences between groups

Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Risk of bias for deviations from the intended interventions (effect of assignment to intervention)

Low:

Participants were blinded and received automated text messages so deviations from intended intervention unlikely

Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)

Risk of bias judgement for deviations from the intended interventions (effect of adhering to intervention)

Low

Participants reported reading 'almost all of the messages' they received (although this was a self-reported outcome)

Domain 3. Bias due to missing outcome data

Risk-of-bias judgement for missing outcome data

Low:

Trial retention was high and did not vary by condition

Domain 4. Bias in measurement of the outcome

Risk-of-bias judgement for measurement of the outcome

Low:

Outcome assessment the same across groups and where possible, self-reported vaccine uptake was verified with clinic data

Domain 5. Bias in selection of the reported result

Risk-of-bias judgement for selection of the reported result

Low:

Analyses completed in line with those outlined in trial registry analysis plan

Overall bias

Risk of bias judgement

Some concerns: No information on allocation concealment

Reiter, 2018

Bibliographic Reference

Reiter, Paul L; Katz, Mira L; Bauermeister, Jose A; Shoben, Abigail B; Paskett, Electra D; McRee, Annie-Laurie; Increasing Human Papillomavirus Vaccination Among Young Gay and Bisexual Men: A Randomized Pilot Trial of the Outsmart HPV Intervention.; LGBT health; 2018; vol. 5 (no. 5); 325-329

Study details

Trial registration number	Trial is registered at Clinical Trials.gov: identifier NCT02835755
Study start date	July and September 2016
Aim	To pilot test a web-based human papillomavirus (HPV) vaccination intervention among young gay and bisexual men (YGBM)

Country/geographical location	Ohio, USA
Setting	Digitally (online) delivered survey
Inclusion criteria	Male, be aged 18–25 years, reside in the United States, self-identify as gay or bisexual, and not have received any HPV vaccine doses. Age 25, instead of age 26 was used as the study's upper age limit so that men did not "age out" of the recommended HPV vaccination age range during the study
Exclusion criteria	Not reported
Method of randomisation	Participants were randomised using a 1:1 allocation ratio to receive either intervention or control group materials
Method of allocation concealment	Not reported
Unit of allocation	Individual
Unit of analysis	Individual
Statistical method(s) used to analyse the data	Descriptive statistics to examine demographic and health-related characteristics. Logistic regression models were used to compare study groups on all outcomes and produce odds ratios (ORs) and 95% confidence intervals (CIs). All analyses were intent-to-treat and used two-tailed statistical tests with a critical alpha of 0.05.
Attrition	Authors categorised participants who did not complete follow up surveys as 'no' for all outcomes 26% loss to follow up after 7 months
Study limitations	Small sample size and self-reported HPV vaccination data. However, authors claim that self-reported HPV vaccination data among young adults result in only a 2% net bias compared to medical records. Authors did not collect data on the type of healthcare provider or clinic where participants received the HPV vaccine, or whether participants were trans people. Participants were recruited through Facebook, which could limit generalizability of results, although participants in our study were demographically similar to YGBM from other national studies.

Study arms**Outsmart HPV intervention (N = 76)**

The Outsmart HPV intervention was based on the protection-motivation theory and consisted of two components: (a) population-targeted, individually tailored content about HPV and HPV vaccine; and (b) monthly HPV vaccination reminders sent via email and/or text message.

The first component (a) had 4 sequential sections:

1. “Learn about HPV” provided targeted information about the prevalence and transmission of HPV and HPV-related disease among gay and bisexual men
2. “Learn about the Vaccine” provided information about HPV vaccine recommendations for YGBM and vaccine effectiveness, as well as individually tailored testimonials that illustrated reasons why men may decide to get vaccinated.
3. “Get Answers” provided information to address potential barriers and concerns about HPV and HPV vaccine using a question and answer format.
4. “Get Vaccinated” provided resources for accessing HPV vaccine (e.g., finding a healthcare provider and potential transportation options), information about vaccine cost and health insurance, and skills-building strategies for talking with a provider about the vaccine.

Control (N = 74)

The control group received standard information about HPV and the HPV vaccine, which was modelled after the Centres for Disease Control and Prevention: Vaccine information statements (VIS) for HPV vaccine

Characteristics**Study-level characteristics**

	Study (N = 150)
Gender	
Male	150

Arm-level characteristics

	Outsmart HPV intervention (N = 76)	Control (N = 74)
Age		
18-21 years	n = 31; % = 41	n = 31; % = 42

	Outsmart HPV intervention (N = 76)	Control (N = 74)
22-25 years	n = 45; % = 59	n = 43; % = 58
Sexual orientation		
Bisexual	n = 14; % = 18	n = 12; % = 16
Gay	n = 62; % = 82	n = 62; % = 84
Ethnicity		
White	n = 44; % = 58	n = 41; % = 55
African American	n = 8; % = 11	n = 12; % = 16
Other race	n = 5; % = 7	n = 5; % = 7
Hispanic	n = 19; % = 25	n = 16; % = 22
Education level		
Some college or less	n = 49; % = 64	n = 45; % = 61
College degree or more	n = 27; % = 36	n = 29; % = 39
History of sexually transmitted infection (STI)		
No	n = 60; % = 79	n = 59; % = 80
Yes	n = 16; % = 21	n = 15; % = 20

Outcomes

Study timepoints	7 (month)
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HPV vaccination uptake

	Outsmart HPV intervention	Control
	7 (month)	7 (month)
	N = 76	N = 74
HPV vaccine initiation	n = 34; % = 45	n = 19; % = 26
Odds ratio	OR 2.34 (1.18 to 4.67)	
Relative risk (calculated)	RR 1.74 (1.10 to 2.76)	

	Outsmart HPV intervention	Control
	7 (month)	7 (month)
	N = 76	N = 74
HPV vaccine completion	n = 8; % = 11	n = 2; % = 3
Odds ratio	OR 4.24 (0.87 to 20.66)	
Relative risk (calculated)	RR 3.89 (0.86 to 17.74)	

Study details

Brief name	Increasing Human Papillomavirus (HPV) vaccination among young gay and bisexual men (YGBM)
Rationale/theory/Goal	To pilot test a web-based human papillomavirus (HPV) vaccination intervention among YGBM
Materials used	Paid Facebook advertisements to recruit participants. Advert was then linked to project website. Potential participants completed an eligibility screener. Online consent forms.
Procedures used	Intervention was mobile friendly and accessible by desktop, laptop, tablet computer or smartphone. After participants gave consent, they completed a survey. Additional follow-up surveys occurred 3 and 7 months later.
Provider	Not reported
Method of delivery	Digitally (online) delivered.
Setting/location of intervention	Ohio, USA
Intensity/duration of the intervention	Not reported
Tailoring/adaptation	Intervention tailored to YGBM
Unforeseen modifications	Not applicable
Planned treatment fidelity	Not applicable
Actual treatment fidelity	Not applicable

Other details	<p>Authors used self-reported HPV vaccination data to examine vaccination outcomes (yes or no for each): HPV vaccine initiation (receipt of one or more doses) and completion (receipt of all three doses recommended for our study's age range).</p> <p>McRee, Annie-Laurie, Shoben, Abigail, Bauermeister, Jose A et al. (2018) Outsmart HPV: Acceptability and short-term effects of a web-based HPV vaccination intervention for young adult gay and bisexual men. <i>Vaccine</i> 36(52): 8158-8164</p> <p>Authors received research grants from Merck Sharp & Dohme Corp. and Cervical Cancer-Free America, through an unrestricted educational grant from GlaxoSmithKline. Grants were not used to support the research study.</p>
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Risk of Bias

Domain 1: Bias arising from the randomisation process
<i>Risk of bias judgement for the randomisation process</i>
Some concerns: no details on randomisation and allocation concealment
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)
<i>Risk of bias for deviations from the intended interventions (effect of assignment to intervention)</i>
Low
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)
<i>Risk of bias judgement for deviations from the intended interventions (effect of adhering to intervention)</i>
Low
Domain 3. Bias due to missing outcome data
<i>Risk-of-bias judgement for missing outcome data</i>
Some concerns:

Though intention-to-treat analysis was conducted, a 27% loss to follow up was reported.

Domain 4. Bias in measurement of the outcome

Risk-of-bias judgement for measurement of the outcome

Low

Domain 5. Bias in selection of the reported result

Risk-of-bias judgement for selection of the reported result

Low

Overall bias

Risk of bias judgement

Some concerns

Vet, 2014

Bibliographic Reference

Vet, Raymond; de Wit, John B F; Das, Enny; The role of implementation intention formation in promoting hepatitis B vaccination uptake among men who have sex with men.; International journal of STD & AIDS; 2014; vol. 25 (no. 2); 122-9

Study details

Study design

Randomised controlled trial (RCT)

Trial registration number

Not reported

Aim	To assess the effects of, and associations between, intention strength, implementation intention formation and completeness of implementation intentions with respect to obtaining HBV vaccination among MSM. Authors hypothesized that MSM who form implementation intentions to obtain HBV vaccination will be more likely to attain this goal than MSM who do not form an implementation intention.
Country/geographical location	The Netherlands
Setting	Not reported
Inclusion criteria	(a) being male; (b) having had sex with a man in the previous year; (c) not being infected with HBV and (d) not having been vaccinated against HBV before
Exclusion criteria	(a) women; (b) men who only had sex with women; (c) men who were previously infected with HBV; (d) and men who were vaccinated against HBV
Method of randomisation	Not reported
Method of allocation concealment	Not reported
Unit of allocation	Individual
Unit of analysis	Individual
Statistical method(s) used to analyse the data	<p>A randomization check was undertaken by conducting a multivariate logistic regression analysis with study condition as dependent variable and age, education and ethnicity as independent variables. To test for differences in attrition according to study condition, a multivariate logistic regression analysis was performed with respondents' provision of a valid code to identify HBV vaccination uptake from the vaccination registry as a dependent variable and age, education and ethnicity as independent variables.</p> <p>A logistic regression analysis was performed to examine the effect of the interaction between intention strength and implementation intention formation on vaccine uptake.</p>
Attrition	<p>51% attrition. Analysis conducted based participants with valid data linkage code. Authors claim attrition was not significantly affected by participants' characteristics.</p> <p>Attrition analysis found no significant differences between participants in the experimental and control groups or between men who did and did not provide a valid code for data linkage. This indicates the participants in the conditions were similar and that attrition was not selective.</p>

Study limitations	A potential limitation of this study is the substantial drop out that occurred at different points in the data collection process. However, randomization check and attrition analysis found no significant differences between participants in the experimental and control groups or between men who did and did not provide a valid code for data linkage.
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Study arms

Intervention (N = 161)

Intervention group received instructions to promote the formation of implementation intentions on the uptake of hepatitis B vaccination (HBV). Instructions were: *“You are about to make an appointment to obtain vaccination against HBV. A good intention! But often people do not act upon their good intentions. It can help if you record your intention now by making an agreement with yourself. Now, think about when, where and how to make an appointment for hepatitis B vaccination.”*

Upon completion of the implementation intention formation, participants received information about their site of choice offering HBV vaccination.

Control (N = 455)

Participants in the control group were routed to a general information page providing contact details of Public Health Services offering HBV vaccination

Characteristics

Study-level characteristics

	Study (N = 616)
Age	Not reported
Gender	Male
Sexual orientation	Men who have sex with men
Ethnicity	Not reported
Education level	Not reported
History of sexually transmitted infection (STI)	Not reported

Outcomes

Vaccine uptake

	Intervention	Control
	Analysis data available for N = 99	Analysis data available for N = 201
MSM who obtained HBV vaccination by motivational information	n = 21; % = 21.2	n = 18; % = 9
Odds ratio	OR 2.74 (1.38 to 5.42)	
Relative risk (calculated)	RR 2.37 (1.32 to 4.24)	

Study details

Brief name	The role of implementation intention formation in promoting hepatitis B vaccination uptake among men who have sex with men
Rationale/theory/Goal	To assess the effects of, and associations between, intention strength, implementation intention formation and completeness of implementation intentions with respect to obtaining HBV vaccination among MSM.
Materials used	Survey asking if participants wanted to make an appointment for HBV vaccination. HBV vaccination uptake was determined from the HBV vaccination registry of the joint Public Health Services in the Netherlands
Procedures used	Participants were recruited online, via banners and other links placed on a variety of Dutch websites for MSM and routed to the newly developed website of the HBV vaccination project for MSM in the Netherlands, where they were asked to provide online informed consent. Of the men who completed this assessment, those who immediately wanted to make an appointment online were excluded from the full study and were instead directly routed to an online agenda to make an appointment for HBV vaccination to ensure that during the study period standard of care services would be provided through the website as much as possible
Provider	Not reported
Method of delivery	Online survey. Completeness of implementation intentions was rated and hepatitis B virus uptake was assessed through data linkage with the joint vaccination registry of the collaborating Public Health Services
Setting/location of intervention	The Netherlands
Intensity/duration of the intervention	Not reported
Tailoring/adaptation	Not reported
Unforeseen modifications	Not reported
Planned treatment fidelity	Not applicable

Actual treatment fidelity	Not applicable
Other details	Study was supported by a grant from the Netherlands Organization for Health Research and Development (ZonMw; grant number 23000032). Authors claim funder was not involved in the study design; the collection, analysis and interpretation of data; the writing of the report and the decision to submit this article for publication

Risk of Bias

Domain 1: Bias arising from the randomisation process

Risk of bias judgement for the randomisation process

Some concerns: no details on randomisation and allocation concealment

Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Risk of bias for deviations from the intended interventions (effect of assignment to intervention)

Low

Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)

Risk of bias judgement for deviations from the intended interventions (effect of adhering to intervention)

Low

Domain 3. Bias due to missing outcome data

Risk-of-bias judgement for missing outcome data

Low

Domain 4. Bias in measurement of the outcome

Risk-of-bias judgement for measurement of the outcome

Some concerns: outcome measurement was subjective scale. Not based on a validated measurement scale.

Domain 5. Bias in selection of the reported result

Risk-of-bias judgement for selection of the reported result

Low

Overall bias

Risk of bias judgement

Some concerns

D.2 Qualitative evidence

Apaydin, 2018

Bibliographic Reference Apaydin, Kaan Z; Fontenot, Holly B; Shtasel, Derri; Dale, Sannisha K; Borba, Christina P C; Lathan, Christopher S; Panther, Lori; Mayer, Kenneth H; Keuroghlian, Alex S; Facilitators of and barriers to HPV vaccination among sexual and gender minority patients at a Boston community health center.; Vaccine; 2018; vol. 36 (no. 26); 3868-3875

Study details

Study design	Qualitative study
Trial registration number	Not reported
Study start date	Jun-2016
Study end date	Sep-2016
Aim	To identify patient-, provider- and systems-level barriers to and facilitators for HPV vaccination among eligible sexual and gender minority (SGM) patients.
Country/geographical location	Boston, Massachusetts, North America

Setting	Focus groups were conducted at an urban community health centre specialised in care for SGM patients.
Inclusion criteria	Vaccine-eligible SGM youth ages 18-26 years, could read/understand English, recruitment into study had to be authorised by the participant's primary care provider. 4 focus groups, HIV negative and 3 dose HPV vaccine complete; HIV negative and vaccine not complete; HIV positive and vaccine complete; HIV positive and vaccine not complete.
Exclusion criteria	Not reported
Statistical method(s) used to analyse the data	<p>Transcripts were imported into Dedoose Version 7.0.23 (SocioCultural Research Consultants, LLC, Los Angeles, CA) for data management and thematic content analysis.</p> <p>Thematic content analysis of all transcripts was undertaken. One researcher read all transcripts and created the initial codebook using both deductive and inductive analysis. This researcher and another then independently coded all transcripts using the initial codebook. These two researchers then met to discuss and resolve discrepancies in coding before reaching final agreement in codes and higher level themes.</p>
Study limitations	<p>Authors reported a small and predominantly white sample size that specifically focuses on sexual and gender minority health. This may impact on generalisability.</p> <p>Data on how many participants initiated or completed HPV vaccination prior to initiating care at the SGM specialized health centre was not collected.</p>
Study theme 1	<p>Patient-level barriers and facilitators</p> <p><u>HPV-related knowledge and beliefs:</u></p> <p>Most participants identified a lack of knowledge about how HPV affects both male and females as a vaccination barrier. Regardless of vaccination status, participants had low knowledge of HPV and HPV-related cancers. Many did not know what HPV was, how HPV-related diseases progress, or ways to prevent HPV-related disease.</p> <p>Some gay men reported believing that most men do not know HPV can affect men, and so do not receive the vaccine.</p> <p>One transgender man reported believing that being “born in a female body” made him susceptible to HPV-related disease. Another transgender man reported believing that many SGM people do not understand appropriate timing of HPV vaccination, such as whether to receive the vaccine before or after engaging in sexual activity. One gay man reported:</p>

	<p><i>"I had no idea that it associated itself with cancer. As far as I did know, it [HPV] just caused warts."</i></p> <p><i>"If I didn't have the knowledge [about HPV vaccination]. Because I think that that's what stops people in general. (cisgender man, HIV-infected, vaccinated)."</i></p> <p><u>Behaviours related to engagement in care:</u></p> <p>Some participants stated that they had started the vaccine series with a previous provider but had not complete all doses. Participants who reported not completing the vaccine series described barriers with: long time intervals between doses; multiple doses; and the inconvenience of work conflicting with clinic hours. Fully vaccinated participants described monitoring their own timeline for dose completion and following up with their PCP to confirm appointments as behaviours that facilitated 3-dose completion.</p> <p><i>"... you know, going back and coming back, and going back [for 3 doses], it's too much work. (transman, HIV-uninfected, vaccinated)"</i></p> <p><i>"I kind of had the whole timeline laid out before I started even with the first dose, and then just before I would leave the office that same day schedule a follow-up appointment. So it was already in my calendar"</i></p> <p><u>Fear of HPV-related disease:</u></p> <p>Fear of HPV-related disease was a vaccine facilitator among HIV-infected gay men. Three HIV-infected gay men reported that HIV seroconversion made them more cautious about their health.</p> <p><i>"... fear and wanting that assurance of I will not get these things [warts and cancer] if I do this [getting the vaccine] kind of outweighed that ethical value set that I had"</i></p> <p><i>"there's definitely this like fear for me I feel like, and probably a lot of people, of getting genital warts or anal warts or more so than even cancer. I feel like people are just like – the physical disgust around that kind of thing and that stigma in our culture I think really propels – propelled me and a lot of people to get the vaccine to prevent that kind of thing from happening"</i></p>
Study theme 2	Provider-level barriers and facilitators

	<p><u>The primary care provider's (PCP's) knowledge/expertise related to HPV:</u></p> <p>Some also stated that their PCP's expert care was the only facilitator for vaccination. Fully vaccinated gay men described how their PCPs took the time to explain the benefits of HPV vaccination for males, and how the vaccine prevents genital warts and anal cancers. As a result of this education, fully vaccinated HIV-infected gay men reported awareness of being at lower risk for HPV-related diseases. Fully vaccinated transgender men stated that their SGM affirming PCPs' HPV recommendation sparked their series completion, which had been previously initiated but never completed.</p> <p><i>"it helped ... when my doctor asked about that, and I said, "Oh yeah, I think I've heard about that. If the vaccination is something I should look into." And then she recommended it"</i></p> <p>Identity-affirming care;</p> <p>Participants described uncomfortable interactions relating to discussing their sexual activity and this as a possible barrier to vaccination. Several participants reported affirming care by their PCP as a facilitator.</p> <p><i>"I think it's about being comfortable with your doctor, and having those [sexual health and HPV-related] conversations with them."</i></p>
<p>Study theme 3</p>	<p>System level barriers and facilitators</p> <p>Identity-affirming healthcare system;</p> <p>Participants described experiences that did not affirm their identities. A gay man stated that he had previously encountered accessing health services relevant to him as MSM.</p> <p><u>Public awareness of HPV-related disease:</u></p> <p>Participants identified the overall lack of public awareness about HPV-related disease as a barrier to vaccination. One transgender woman stated that she had heard of HIV and AIDS as something to worry about, but not HPV. Others described lower levels of public awareness about HPV as compared to other sexually transmitted infections:</p> <p><i>"I still don't think that it's necessarily included in the top STDs people think of. When I think of it, it's like HIV is this big scary thing and then like syphilis, gonorrhoea, chlamydia is like this conglomerated thing."</i></p>

Characteristics

Study-level characteristics

	Study (N = 15)
Age Mean (SD)	25 (0.7)
Cisgender man	n = 9 ; % = 60
Cisgender woman	n = 1 ; % = 7
Transman	n = 3 ; % = 20
Transwoman	n = 2 ; % = 13
Ethnicity	
White	n = 10 ; % = 66.7
Hispanic / Latino	n = 1 ; % = 7
Black / African American	n = 2 ; % = 13
Asian	n = 1 ; % = 7
More than one race	n = 1 ; % = 7
Sexual orientation	
Gay/lesbian	n = 9 ; % = 60
Straight/heterosexual	n = 1 ; % = 7
Bisexual	n = 2 ; % = 13
Queer	n = 1 ; % = 7
Asexual	n = 1 ; % = 7
Pansexual	n = 1 ; % = 7
Education level	
Less than high school	n = 1 ; % = 7
High school graduate	n = 5 ; % = 33
College graduate	n = 6 ; % = 40

	Study (N = 15)
Post graduate	n = 3 ; % = 20
History of sexually transmitted infections (STIs)	
HIV infected	n = 4 ; % = 27
HIV uninfected	n = 11 ; % = 73
Ever diagnosed with HPV (yes)	n = 2 ; % = 13
Ever diagnosed with HPV (no)	n = 13 ; % = 86
HPV vaccination status, yes	N=12, 80%
HPV vaccination status, no	N=2, 20%

Critical appraisal - CASP Qualitative checklist

Aims of the research

Was there a clear statement of the aims of the research?

Yes

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Can't tell

Data collection

Was the data collected in a way that addressed the research issue?

Yes

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Yes

Ethical Issues

Have ethical issues been taken into consideration?

Yes

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

Findings

Is there a clear statement of findings?

Yes

Research value

How valuable is the research?

The research is valuable

Overall risk of bias and directness

Overall risk of bias

Moderate

Fontenot, 2016

Bibliographic Reference Fontenot, Holly B; Fantasia, Heidi C; Veters, Ralph; Zimet, Gregory D; Increasing HPV vaccination and eliminating barriers: Recommendations from young men who have sex with men.; Vaccine; 2016; vol. 34 (no. 50); 6209-6216

Study details

Study design	Qualitative study
Study start date	May-2014
Study end date	May-2015
Aim	To elicit young men who have sex with men's (YMSM) beliefs about HPV and the HPV vaccine and to describe perceived barriers and facilitators of vaccine initiation and completion.
Country/geographical location	Boston, USA
Setting	Flyers describing the study were posted at an urban lesbian, gay, bisexual, transgender, queer (LGBTQ) youth-led and adult supervised safe space and at an urban community health center focused on the unique health needs of homeless and LGBTQ youth ages 12–29 years. Focus groups were conducted in private conference rooms at health and community centres in Boston.
Inclusion criteria	YMSM ages 18–26 years who were able to read and understand English, irrespective of HPV vaccination status
Exclusion criteria	None reported

Statistical method(s) used to analyse the data	<p>Descriptive analyses of means, standard deviations and percentages were calculated for questionnaire data.</p> <p>All focus groups and interviews were audio-tape recorded and transcribed verbatim. Data were analysed using conventional content analysis. The steps of analysis included: preparing and organizing data, re-reading each transcript along with field notes for orientation and data immersion, reducing data into initial codes, combining codes into broader categories based on content and thematic saturation, then final definitions for each category were developed, relationships were examined and exemplar quotes were highlighted. The coding process was performed by two investigators with expertise in qualitative data analysis. The overall process was reviewed continuously to verify data and coding, and the final themes were independently verified by 2 investigators and a research fellow.</p>
Study limitations	<p>The authors note that data saturation was reached. The study was conducted in one geographical location and the participants were only interviewed once, therefore the results may not be transferable to other populations.</p>
Study theme 1	<p><u>Low HPV Knowledge and Awareness</u></p> <p>Unrelated to vaccination status, the overwhelming majority of participants demonstrated low levels of HPV knowledge; low knowledge related to male associated cancers; and evidence of a disconnect between MSM and HPV risk, with most believing that HPV infection was more prevalent and serious for females.</p> <p><i>So I know very little about it [HPV]</i></p> <p><i>I've never thought about gay men being especially at risk for HPV</i></p> <p>The men had all heard of the HPV vaccine, understood that the vaccine required multiple shots in a particular time frame, and it was best to get it before you were sexually active. However, the majority believed it was primarily a vaccine for females, though many were aware the vaccine was available for men</p> <p><i>There is a misconception that if you're a gay man, you don't need to get it [HPV vaccine]</i></p> <p>They did not realise the HPV is the most common STI. The participants talked about how the focus of providers and those within the MSM community was on STIs that are less prevalent than HPV among YMSM:</p> <p><i>We hear about AIDS; we hear about HIV but we don't hear about HPV</i></p>
Study theme 2	<p><u>Positive Vaccine Beliefs</u></p>

	<p>Largely, the YMSM viewed vaccines in general positively and believed they were useful tools to prevent disease and maintain health.</p> <p><i>I'm definitely pro vaccine</i></p> <p>Participants were aware of controversies relating to vaccines.</p> <p>In terms of the HPV vaccine specifically, the men strongly supported access to and education about HPV vaccination for all persons regardless of gender or sexual orientation. Overwhelmingly, the men believed that if they or other YMSM were educated about HPV and the HPV vaccine and if health care providers offered the HPV vaccine, they would get it.</p> <p><i>Now knowing all the cancers it causes, which I wasn't aware of before it seems like more of a reason to get it</i></p> <p>Concerns related to the HPV vaccine did not differ from their concerns related to any other vaccine (e.g. fear of needles, side effects, adverse reactions).</p> <p><i>I think like with all vaccines there are probably side effects</i></p> <p><i>It is hard to remember, keep track of all the shots</i></p>
Study theme 3	<p><u>Perceived Stigmas</u></p> <p>The men described stigmas related to being gay, gay health, acceptance by HCPs, and STI care. Many described feeling more comfortable seeking care at “gay friendly” health centres. A need for more education of HCP to reduce the perceived stigmas of seeking health care.</p> <p>Stigma relating to the HPV vaccine was noted and if asking for it would single them out as promiscuous or sexually active with other men.</p> <p>Men described being embarrassed asking for the vaccine and wished providers just recommended it first, so they would not have to ask for it.</p> <p><i>[HPV] that's like a girl thing and they don't market it towards men so we are embarrassed sometimes because we're like that a girl's thing, why are we over here getting treated for this</i></p>

	<p>The men suggested that HPV education should be widespread and more inclusive of all sexes:</p> <p><i>If there was more education about it [HPV vaccine], if the vaccine gets known, then it won't be as taboo</i></p>
<p>Study theme 4</p>	<p><u>Facilitators of HPV Vaccination</u></p> <p>The men described barriers to vaccination such as: lack of knowledge, misconception that the vaccine was not for men or gay men in particular, inconvenience of scheduling 3 shots, pain or fear of shots, cost/ insurance coverage, stigmas, parents/family because the vaccine is related to sex, and their own internal motivations or "laziness"</p> <p>The men described 3 main facilitators:</p> <p><u>Use of technology:</u> such as a mobile app that could provide health and HPV information. An app for booking appointments, creating a reminder system, keep track of health history. The men also believed that flexibility in scheduling and app-based reminder systems would facilitate 3-dose completion</p> <p><i>People are uncomfortable having to make phone calls. . . it's a lot easier to just do something on your phone, like an appointment confirmation, so that you can go in without having to talk [to someone] or feel uncomfortable disclosing things [on the phone]</i></p> <p><u>Making vaccines part of a package deal:</u> Participants also described wanting to combine HPV vaccination with other types of visits like annual exams and other STI tests. They described routinely being tested for HIV and how they could also have been vaccinated against HPV at those visits</p> <p><u>Increasing HPV and HPV vaccine awareness:</u> Participants described a need for overall increased awareness regarding HPV and HPV vaccination. Overwhelmingly they described that having factual information about HPV and the vaccine would increase vaccination. They wished HPV was discussed in schools, thought commercials were good ideas and they felt HCPs should recommend this vaccine to everyone.</p> <p><i>If it were advertised like the flu vaccine. Everybody come get the HPV vaccine. All of the students would just do it.</i></p>

Characteristics

Study-level characteristics

	Study (N = 34)
Age Mean (SD)	20.8 (2)
Gender	Male
Ethnicity	
Black	n = 12 ; % = 35
White	n = 8 ; % = 24
Multiracial	n = 8 ; % = 24
Asian	n = 3 ; % = 9
Other	n = 2 ; % = 6
Education	
< High school	n = 6 ; % = 18
High school graduate	n = 3 ; % = 9
Some college	n = 22 ; % = 65
College graduate	n = 3 ; % = 9
HPV Vaccination	
Yes	n = 20 ; % = 59
No	n = 10 ; % = 30
I don't know	n = 4 ; % = 12

Critical appraisal - CASP Qualitative checklist

Aims of the research
<i>Was there a clear statement of the aims of the research?</i>
Yes
Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Can't tell

Data collection

Was the data collected in a way that addressed the research issue?

Yes

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

Data analysis

Was the data analysis sufficiently rigorous?

No

*(Insufficient detail regarding how codes were developed. Inter rater reliability or agreement between coders not reported)***Findings***Is there a clear statement of findings?*

Yes

Research value*How valuable is the research?*

The research is valuable

Overall risk of bias and directness*Overall risk of bias*

Moderate

Gerend, 2019**Bibliographic Reference**

Gerend, M.A.; Madkins, K.; Crosby, S.; Korpak, A.K.; Phillips, G.L.; Bass, M.; Houlberg, M.; Mustanski, B.; A Qualitative Analysis of Young Sexual Minority Men's Perspectives on Human Papillomavirus Vaccination; LGBT health; 2019; vol. 6 (no. 7); 350-356

Study details**Study design**

Qualitative study

Study start date

Aug-2016

Study end date	Aug-2016
Aim	To identify young sexual minority men’s perspectives on HPV vaccination
Country/geographical location	United States of America
Setting	Participants were recruited through advertisements posted on Facebook and a local participant registry associated with the IMPACT LGBT Health and Development Program, which conducts translational research for improving the health of individuals in LGBT communities
Inclusion criteria	Assigned male sex at birth; male gender identity; ages 18–26 years; self-identify as gay, bisexual, or queer; and currently live in the Chicago metro area. Participants were also required to own a cell phone and have used text messaging in the past 6 months
Exclusion criteria	Not reported
Statistical method(s) used to analyse the data	Interviews were transcribed verbatim. Descriptive statistics were computed for sociodemographic and background characteristics that had been assessed on the screening survey and during the interview. Transcripts were imported into Dedoose (Socio- Cultural Research Consultants, LLC, Los Angeles, CA) and coded by two study team members. Any coding inconsistencies were discussed and resolved.
Attrition	Not applicable
Study limitations	Relatively small sample size, and convenience sample, may have limited generalizability. Authors noted that findings may not extend to rural populations, HIV +ve men or men who have sex with men and do not identify as gay, bisexual or queer. Participants were recruited primarily from neighborhoods with higher socioeconomic status. Findings may not extend to rural sexual minority populations, HIV-positive men, or MSM who do not identify as gay, bisexual, or queer.
Study theme 1	<p><u>Information</u></p> <p>Knowledge of HPV infection</p> <p>The most common misconception was that HPV affects women, but not men. Common misunderstanding that men primarily carry but do not experience symptoms.</p> <p>Most participants lacked specific details about how HPV is transmitted and were unaware of the connection between HPV and anal cancer. Although many men knew about the link between HPV infection and cancer in women, they were often shocked to learn that HPV could cause anal and oropharyngeal cancers in men. Several men expressed surprise and frustration about the lack of HPV testing for men</p> <p><i>I’ve heard it doesn’t affect men, but they can transmit it. I don’t know if that’s true.</i></p>

	<p><i>I didn't know like it affected guys at all.</i></p>
<p>Study theme 2</p>	<p>Knowledge of HPV vaccine</p> <p>Approximately 20% had never heard of HPV vaccination, vaccine knowledge varied across participants.</p> <p>The most common misconception regarding HPV vaccination was that only women could receive the vaccine. At the same time, several participants were aware that men could be vaccinated for HPV.</p> <p><i>"Not getting HPV and not developing any of the cancers or anything related to it. Don't have to worry as much. One of the few STIs have vaccine for—click that one off the list"</i></p> <p><i>"I've always assumed it was geared toward women more than men"</i></p> <p>Vaccine effectiveness</p> <p>Participants were unsure about whether the HPV vaccine is effective for men who have already been sexually active. They also had questions about the recommended number and timing of doses, typical age for receiving the HPV vaccine, and common side effects</p> <p><i>"So, if someone were to get a vaccine, but say they already have it (HPV), how does that work?"</i></p>
<p>Study theme 3</p>	<p><u>Motivation</u></p> <p>Behavioural beliefs</p> <p>Primary advantages included preventing HPV and reducing risk of HPV-related diseases, peace of mind, and protecting sexual partners. Participants acknowledged the physical and psychological health benefits of HPV vaccination and were enthusiastic about the ability to protect both themselves and their partner(s).</p> <p><i>Not getting HPV and not developing any of the cancers or anything related to it.</i></p> <p><i>Don't have to worry as much. One of the few STIs have vaccine for—click that one off the list.</i></p>

Yeah like I care about my health, but I also care about other people's health too and I don't want anyone else to get infected or have to go through with something like that.

Primary disadvantages included side effects (e.g., pain), sexual disinhibition (i.e., concern that someone would become less inhibited in their sexual behaviour after vaccination), and stigma (e.g., being labeled as promiscuous).

I imagine that there are some people who are more concerned about side effects. Some people may be more prone to them than others

Just one I can think of is that, maybe now that the vaccine—you have the vaccine, a mindset might think, like, "Unprotected sex might be okay." Or, "You don't need to be as careful," or whatnot

...some people will consider somebody very promiscuous. 'Oh, you're getting a vaccine because you're sleeping with multiple people,' and there's just a stigma associated with that

Perceived threat of HPV

Many spontaneously shared threat-related comments after the fact sheet. There was surprise about the high level of exposure to HPV, there was a lack of awareness of the link between HPV and cancer.

Motivation

Personal experience with genital warts was often cited as a reason for getting HPV vaccine, with acknowledgement that vaccination could protect them from other HPV types.

Normative beliefs

Participants thought that most people in their lives would be supportive of them receiving the HPV vaccine. Participants had more difficulty identifying unsupportive referents. Those who did typically mentioned their parents (especially their father) or extended family members.

Several participants had had female friends or relatives who had received the HPV vaccine, very few knew another gay man who had been vaccinated.

	<p><i>I have a very good relationship with my entire family. They all know I'm gay. No one cares one bit. I'm very fortunate. So if I were to say I was getting the Gardasil vaccine, they would be (very supportive)</i></p> <p><i>Maybe my dad. Because he's just ignorant with regard to sexuality and vaccines and stuff like that. He's kind of an anti-government conspiracies person, so I don't really have a good relationship with him</i></p> <p>Social support from significant others</p> <p>Among vaccinated participants, the primary social factor that motivated them to get vaccinated was a recommendation from a health care provider. Nearly all vaccinated participants mentioned the central role of the provider in their decision to receive the HPV vaccine.</p> <p><i>"It was the doctor's recommendation. I honestly wouldn't have thought about it had he not recommended it</i></p>
<p>Study theme 5</p>	<p><u>Behavioural skills</u></p> <p>Disclosure of sexual orientation</p> <p>Two thirds had discussed sexuality with healthcare provider. Willingness to disclose was connected to the type of clinic and expectations of how the provider might respond. Some described providers uncomfortable or awkward in asking questions, or described feeling stigma or judgment – several shared positive experiences of disclosure.</p> <p>Comfort discussing HPV vaccine</p> <p>Majority would be comfortable asking provider for the HPV vaccine. Some expressed hesitation, especially if they had to discuss their sexuality.</p> <p>Control/efficacy beliefs</p> <p>Although a few participants said that they would ask their primary care provider for the vaccine, most did not know where they could receive the vaccine.</p> <p>When asked to identify what made it easier for them to receive the HPV vaccine, nearly all vaccinated participants cited the convenience of being offered the vaccine while at the clinic. Participants suggested that coupling HPV vaccination</p>

with another reason for going to the clinic (e.g., HIV testing and PrEP follow-up) could increase accessibility. Participants were especially keen on getting vaccinated at a walk-in clinic or pharmacy, or if they were students, on campus.

Participants acknowledged the inconvenience of having to receive three doses to complete the series.

I think ease of access. I don't know how many hospitals or locations would have this vaccine or if it's accessible in that capacity.

Well, it was offered right there while I was getting the physical done. So I didn't even have to make a special trip or anything.

Characteristics

Study-level characteristics

	Study (N = 29)
Age	22.66 (2.3)
Ethnicity	
Asian	n = 2 ; % = 7
Black or African American	n = 4 ; % = 14
White	n = 17 ; % = 59
Multiracial	n = 4 ; % = 14
Latino or Hispanic (yes)	n = 7 ; % = 24
Latino or Hispanic (no)	n = 22 ; % = 76
Other or unknown	n = 2 ; % = 7
Sexual Orientation	
Gay	n = 22 ; % = 76
Bisexual	n = 4 ; % = 14
Queer	n = 3 ; % = 10
HIV serostatus	
HIV negative	n = 24 ; % = 83

	Study (N = 29)
HIV positive	n = 1 ; % = 3
Never tested	n = 4 ; % = 14
HPV Vaccination status	
Don't know	n = 1 ; % = 3
HPV vaccine - No	n = 19 ; % = 66
HPV vaccine - Yes	n = 9 ; % = 31

Critical appraisal - CASP Qualitative checklist

Aims of the research

Was there a clear statement of the aims of the research?

Yes

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

Data collection

Was the data collected in a way that addressed the research issue?

Yes

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

(Ethics approval not mentioned but study reported that procedures were approved by the Institutional Review Board at Northwestern University)

Data analysis

Was the data analysis sufficiently rigorous?

Yes

Findings

Is there a clear statement of findings?

Yes

Research value

How valuable is the research?

The research is valuable

Overall risk of bias and directness

Overall risk of bias

Moderate

Grace, 2018

Bibliographic Reference

Grace, Daniel; Gaspar, Mark; Paquette, Rachele; Rosenes, Ron; Burchell, Ann N; Grennan, Troy; Salit, Irving E; HIV-positive gay men's knowledge and perceptions of Human Papillomavirus (HPV) and HPV vaccination: A qualitative study.; PloS one; 2018; vol. 13 (no. 11); e0207953

Study details

Study design	Qualitative study
Study start date	Nov-2016
Study end date	Jul-2017
Aim	To explore HPV vaccination barriers and hesitancy among HIV-positive gay men in Canada by examining participants' narrative accounts of their knowledge, experiences and perceptions related to HPV and HPV vaccination.
Country/geographical location	Toronto, Canada
Setting	With the exception of one interview conducted by phone for accommodation reasons, all interviews were conducted in-person at the University of Toronto in a private meeting room.
Inclusion criteria	Participants were purposively recruited from a subsample of men who took part in the larger HPV Screening and Vaccine Evaluation (HPV-SAVE) study and who indicated a willingness to be contacted for additional research activities. Participants were HIV positive, self-identified as gay and were at various stages of the anal cancer screening process
Exclusion criteria	None reported
Statistical method(s) used to analyse the data	Interviews were audio recorded, transcribed verbatim, and reviewed for accuracy. QSR NVivo 11 qualitative software was used to code transcripts following Grounded Theory. Using an iterative, constant comparative method, transcripts were

	<p>systematically reviewed and coded as interviews were completed. Codes were written for sections or units of texts, and memos were created that expanded upon sections of coded text and described relationships across the codes. Qualitative coding was conducted concurrently with data collection, allowing the interview guide to be iteratively refined and enabling the exploration of emergent themes in subsequent interviews.</p>
Study limitations	<p>Authors highlight that they exclusively focused on HIV-positive GBM, noting that these men may have different understandings of the necessity of the HPV vaccine than HIV negative GBM, because they are at higher risk for HPV associated cancers. They also noted that participants tended to be older (mean age of 50.4 years old), white, and identified as gay males. The authors did not interview any transgender males. Participants were recruited from a clinical trial on anal Pap testing and thus the participants may be more active in their health care than the general GBM population. Nonetheless, the authors point out that their finding of vaccine hesitancy and low awareness of the HPV vaccine among a group of highly active health seekers may indicate just how significant the problem may be across a more generalized population of GBM.</p>
Study theme 1	<p><u>Vaccination History</u></p> <p>Some decided to be vaccinated after their first anal Pap. Others still felt their risk level for HPV related cancers to be low or minimal – were not currently considering vaccination.</p> <p>Men described no negative or unusual experiences, such as adverse events or pain, associated with receiving the vaccine. Some men expressed the positive benefits to vaccination, including that their anxieties around anal cancer risks had been substantially reduced.</p> <p>Vaccination decision making and risk perception;</p> <p>Almost all were aware of HPV vaccine before entering the HPV-SAVE study. Some men said that they first became familiar with the vaccine after they were diagnosed with anogenital warts. A history of anogenital warts increased concern over HPV-associated disease and was discussed by some participants as a facilitator to receive vaccination and anal Pap testing.</p> <p>The majority had not considered HPV vaccine until their involvement in HPV-SAVE.</p> <p>Most reported beliefs that vaccines were safe, effective and necessary.</p>

	<p>Nonetheless, despite an emerging sense among many participants that HPV and anal cancer are serious health risks to HIV-positive men, and a reported interest by many to be vaccinated, most men in our sample had not received the vaccine and many remained ambivalent about HPV vaccination.</p> <p>Overall factors affecting vaccine hesitancy in the themes below.</p>
<p>Study theme 2</p>	<p><u>HPV, gendered risk perceptions and vaccination knowledge</u></p> <p>Almost all participants reported initially believing HPV vaccination was predominately or exclusively an intervention designed for cisgender girls or women and it was for the prevention of cervical cancer.</p> <p>The earliest recollections of HPV tended to involve education and campaigns addressing women about the risk of cervical cancer.</p> <p>The perceived association between HPV and women appeared to be a significant factor affecting the vaccine hesitancy of the participants we interviewed.</p> <p><i>I've always associated it to cervical cancer and to women. I didn't realize at the time, until recently, that it affected men as well</i></p> <p><i>My own ignorance was that HPV was something that really only affected women and cervical cancer. I didn't hear it as much as something that was affecting men</i></p> <p>Some participants described that the association between HPV and women made it hard for them to locate health promotion material that was directly relevant for them once they realized that they could be at risk.</p> <p><i>[I] tried to look up HPV and there wasn't a whole lot for men.</i></p> <p>Many participants reported low levels of health literacy regarding HPV risks among GBM. Once informed about the risks posed by HPV to gay men in the form of anal cancer, most men were interested in learning more and becoming vaccinated. In other words, the gendered associations held about HPV appear to have impacted HPV risk perception and vaccine health literacy levels.</p> <p>Gendered associations and the role of physicians in decision making</p>

	<p>The gendered associations about HPV, seem to have impacted risk perception going into the study. this didn't appear to impact on attitudes towards accepting HPV as a health concern once risks were clearly presented.</p> <p>Some of our participants reported that their physicians had never brought up either HPV or the HPV vaccine to them. None of our participants reported that the vaccine was strongly recommended by a physician: the vaccine may have been recommended but it was still presented as optional from the perspective of participants.</p> <p>Some were uncertain about whether or not it was useful to receive the vaccine, given they had most likely already been infected with HPV.</p> <p>Many patients described requiring a very clear recommendation about the vaccine from their physician before they would get the vaccine. In the absence of this recommendation, they said that they would not actively pursue HPV vaccination.</p>
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Characteristics

Study-level characteristics

	Study (N = 25)
Age Mean (SD)	50.44 (9.99)
Ethnicity	
White	n = 20 ; % = 80
First nations	n = 1 ; % = 4
Asian	n = 2 ; % = 8
Other	n = 2 ; % = 8
Sexual Orientation	
Gay	n = 24 ; % = 96
Two-Spirit	n = 1 ; % = 4
Education	
Some secondary	n = 1 ; % = 4
Completed secondary	n = 3 ; % = 12
Some college	n = 6 ; % = 24

	Study (N = 25)
Completed college	n = 10 ; % = 40
Graduate education	n = 5 ; % = 20
HPV Vaccination status	
HPV vaccinated	n = 6 ; % = 24
Not HPV vaccinated	n = 19 ; % = 76

Critical appraisal - CASP Qualitative checklist

Aims of the research

Was there a clear statement of the aims of the research?

Yes

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

Data collection

Was the data collected in a way that addressed the research issue?

Yes

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

Data analysis

Was the data analysis sufficiently rigorous?

No

(Process of researcher agreement not described; inter-rater reliability not reported)

Findings

Is there a clear statement of findings?

Yes

Research value

How valuable is the research?

The research is valuable

Overall risk of bias and directness*Overall risk of bias*

Moderate

Jaiswal 2020

Bibliographic Reference Jaiswal, Jessica; LoSchiavo, Caleb; Maiolatesi, Anthony; Kapadia, Farzana; Halkitis, Perry N; Misinformation, Gendered Perceptions, and Low Healthcare Provider Communication Around HPV and the HPV Vaccine Among Young Sexual Minority Men in New York City: The P18 Cohort Study.; Journal of community health; 2020; vol. 45 (no. 4); 702-711

Study details

Study design	Qualitative study
Trial registration number	Not reported
Study start date	Apr-2018
Study end date	Jun-2018
Aim	To elucidate the nature and depth of (a) HPV and HPV vaccine knowledge and (b) provider communication about HPV vaccine, in a diverse sample of young urban sexual minority men (SMM). It also sought to illuminate barriers and facilitators to vaccination, the degree of vaccine literacy, and sources of vaccine knowledge in SMM.
Country/geographical location	New York City, USA
Setting	Not reported

Inclusion criteria	<p>Interview participants were recruited from a larger cohort study of emerging adult sexual minority men and transgender women. The inclusion criteria of the parent study were:</p> <ul style="list-style-type: none"> - aged 22-23 years at the time of recruitment - were assigned male at birth - had sex with a man in the previous 6 months - reported negative or unknown HIV serostatus - lived in the New York City metropolitan region
Exclusion criteria	None reported
Method of randomisation	
Statistical method(s) used to analyse the data	<ul style="list-style-type: none"> - Interviews were audio-recorded by trained research assistants, transcribed by research interns, and checked for accuracy by two additional interns. - Participant names and other potentially identifying information were redacted while transcribing, so that participants were anonymous during analysis; pseudonyms are used to identify participants in the manuscript. - A multi-step approach to analysis was used to identify and analyse salient themes. This included open coding, application of codes to transcripts, and rigorous review of transcripts and codes to identify themes and patterns. - Once coding was complete, quotations were extracted and organised by codes and sub-codes into larger themes, based on patterns revealed throughout analysis. - Occasional differences in interpretation were resolved by discussion between the first two authors - Qualitative data were coded and organised using Dedoose v8.0.35

<p>Study limitations</p>	<ul style="list-style-type: none"> - The interview guide was designed to take about 30 minutes and to complement the larger quantitative component of the study. The brief nature of the interview did not permit an in-depth exploration of the guide topics. - It is not possible to establish causality between low knowledge, gendered perceptions of HPV and the HPV vaccine, and low vaccine initiation and completion rates. - This study took place in New York City, where participants likely have more access to sexual health resources than in other parts of the United States. Thus, findings are not necessarily generalisable to the experiences of sexual minority men in other areas.
<p>Study theme 1</p>	<p><u>Knowledge about HPV and the vaccine is generally low</u></p> <p>Participant knowledge about HPV and the vaccine widely varied, but was most often incorrect. In many cases, participants shared incorrect information with elements of correct information. Participants frequently confused HPV with other STIs, and often conflated transmission routes with those of HIV.</p> <p><i>"Interviewer: Anything you know about ways that HPV is transmitted? Or ways that you can give or get HPV? Participant: Well I'm sure it's vaginal, anal, oral. I'm sure there's, yeah, like open wounds. Pretty sure it's similar to like HIV... I know with HIV it's through blood, vaginal, anally, breast milk, and there's one more but I'm missing that."</i></p> <p><i>"I mean I think the most common thing is that we would think of as a preventing, as a presenting symptom would be warts, I think as with any kind of virus, I'm sure when you have uptake, depending on the severity, you could have general symptoms of virus from being a temperature, or cramps, or aches, or things like that, maybe chills, I don't know."</i></p> <p>The pervasive lack of knowledge around HPV also extended to issues related to vaccination. For example, this participant explains his understanding of HPV vaccine efficacy, framing it in terms of the age guidelines: <i>"The vaccine, it works best when you're between, I guess fourteen and twenty-six. Or twenty-four. Yeah. But when you're past that, it doesn't really work anymore, and it could cause some adverse reactions."</i></p>
<p>Study theme 2</p>	<p><u>Sexual minority men think only cisgender women are vulnerable to HPV</u></p> <p>Many participants were under the impression that HPV was only experienced by women, suggesting a widespread perception that boys and men are not affected by it. This also led to many participants perceiving that the HPV vaccine was only for cisgender women. Very few participants discussed HPV with their family. For those that did, HPV most often</p>

	<p>came up in the context of a female relative's vaccination. Participants also reported that Gardasil commercials contributed to the perception that only cisgender women are affected by HPV.</p> <p><i>"I think the vaccine is for woman... I heard it's only, the vaccine...no no, the virus only target woman, even if the man got it, it wouldn't affect them. But he would be the carrier of that [virus], he might transmit that [virus] to his partner who is a female."</i></p> <p><i>"I just vaguely remember [women] being like the target audience like earlier on. I would, yeah there was like a, a commercial, I don't know for, for, it might've been for the vaccine but that's just the impression I had."</i></p>
<p>Study theme 3</p>	<p><u>Healthcare providers under-communicate about HPV and vaccination</u></p> <p>Participants overwhelmingly reported inadequate HPV-related communication with their healthcare providers, with most reporting minimal, if any, communication about HPV. Although some were offered the vaccine, their clinicians rarely explained the importance of the vaccine or facilitated discussion. For participants that initiated the series, HCPs did not adequately follow-up their patients to facilitate vaccine completion. The data strongly suggest that sexual minority men are not receiving adequate messaging around HPV or the vaccine.</p> <p><i>"When I was 17 or something, my doctor was like "Oh it's on your shot list!" And I was like "Okay." Beyond that, not really... it was just like a annual checkup thing. It's like "Oh okay you also need your flu shot as well," so I probably got that."</i></p> <p><i>"No doctor has ever brought [HPV] up to me. And I've always had to advocate for this. I remember when it came out, and it was just women getting it, I read somewhere like gay men need to get this because you can get anal cancer, so I went to my doctor, and she was like "Oh I guess that's technically correct," and I was like "Okay so vaccinate me," and she was like "Well, your insurance isn't gonna cover it." So I ended up getting it, but I had to pay for it out of pocket."</i></p> <p><i>"I remember getting one shot...And I know that it's supposed to be more I just don't know if I ever got the other ones."</i></p>

Characteristics

Study-level characteristics

Characteristic	Study (N = 38)
Age Range	24 to 27
Age Mean (SD)	25.82 (0.95)
Ethnicity	
Hispanic/Latino	n = 10 ; % = 26.3
Black	n = 10 ; % = 26.3
Asian	n = 9 ; % = 23.7
White	n = 9 ; % = 23.7
Sexual orientation	
Exclusively homosexual	n = 21 ; % = 55.3
Not exclusively homosexual	n = 17 ; % = 44.7
Education	
High school degree or less	n = 8 ; % = 21
Some college education, including associate's degree and current undergraduate students	n = 13 ; % = 34.2
Bachelor's or graduate degree	n = 17 ; % = 44.7
HIV Serostatus	
HIV negative	n = 35 ; % = 92.1
HIV positive	n = 2 ; % = 5.3
Not tested	n = 1 ; % = 2.6

Critical appraisal - CASP qualitative checklist

Aims of the research

Was there a clear statement of the aims of the research?

Yes

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

Data collection

Was the data collected in a way that addressed the research issue?

Yes

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

No

Ethical Issues

Have ethical issues been taken into consideration?

Yes

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Analyses appear rigorous but no critical examination of researcher's own role or potential for bias)

Findings

Is there a clear statement of findings?

Yes

(Findings are stated clearly and good use of quotes to evidence themes, but no discussion of credibility of findings or inter-rater reliability)

Research value

How valuable is the research?

The research is valuable

Overall risk of bias and directness

Overall risk of bias

Moderate

(No critical examination of researcher-participant relationship, the researcher's own role or the potential for bias. Findings are stated clearly and well supported with quotes to evidence themes, but no discussion of credibility or inter-rater reliability.)

Kesten, 2019

Bibliographic Reference Kesten, J.M.; Flannagan, C.; Ruane-Mcateer, E.; Merriel, S.W.D.; Nadarzynski, T.; Shapiro, G.; Rosberger, Z.; Prue, G.; Mixed-methods study in England and Northern Ireland to understand young men who have sex with men's knowledge and attitudes towards human papillomavirus vaccination; BMJ Open; 2019; vol. 9 (no. 5); e025070

Study details

Study design	Qualitative study
Study start date	Sep-2016
Study end date	Dec-2016
Aim	To understand young MSM's (YMSM) knowledge and attitudes towards HPV vaccination
Country/geographical location	United Kingdom
Setting	Questionnaires were completed online or on paper. Focus groups were conducted within Lesbian Gay Bisexual Transgender Queer organisational settings and a university student's union in England and Northern Ireland
Inclusion criteria	YMSM were defined through self-identification as male (including transgender male), at or over the age of sexual consent, sexually attracted to men or had sex with a man. Aged 16-24years
Exclusion criteria	Not reported
Statistical method(s) used to analyse the data	Focus groups were audio recorded, transcribed verbatim, anonymised and analysed thematically ²³ using QSR NVivo (V.10.0). At each stage findings were verified and discussed by the research team to assess the interpretation, promote inter-rater reliability and ensure rigour.
Attrition	Not applicable
Study limitations	Due to recruitment difficulties, data collection was not saturated. Authors linked lack of data saturation to the sensitivity of the topic, the hard to reach population and the lack of monetary compensation for participant's time. Recruitment through LGBTQ organisations narrowed the participants to those engaged with services who had disclosed their sexual orientation.

Study theme 1	<p>Willingness to be vaccinated</p> <p>Despite a perceived lack of knowledge about HPV and the vaccine and the threat posed to men, most participants were willing to receive the vaccine and wanted more information.</p> <p><i>"I only knew about it because of the cervical cancer (...)"</i></p> <p><i>"I didn't know even if like that would apply to us, so I don't even know what the dangers are"</i></p> <p>A small number of participants suggested that the cost and number of doses of the vaccine were not barriers to vaccination</p> <p><i>I'm not going to say like get rid of worry because you still have to...it's your sexual health, but it would be safer in a sense (...) I'm better protected – I think would be a better way of putting it. So, I think my own health would encourage me more [to ask or accept the HPV vaccine]. I'd rather be protected than not protected</i></p>
Study theme 2	<p>Promoting and raising awareness of the vaccine</p> <p>Participants noted that better understanding of the benefits and side effects of the vaccine would be expected to encourage uptake. Awareness campaigns and adverts including conventional channels and social media and apps.</p> <p>Participants suggested including information about the vaccine for YMSM in primary care and the sexual health education curriculum in schools. Indeed, it was noted that there is a lack of MSM-specific sexual health and relationship information provided in the latter.</p> <p><i>When you're receiving that [heterosexual relationship education] in school, (...) it just reinforces the fact that you're (...) not relating to it means that you're not normal like everyone else, so you don't want to speak about it. So it would just be better if it [HPV vaccine education for MSM] was just part of that education anyway</i></p>

	<p>Better understanding of the benefits and side effects of the vaccine were expected to encourage uptake. To promote the vaccine and inform YMSM, awareness campaigns and advertisements on the internet, radio, television, social media, in University society's, LGBTQ youth groups and dating apps were suggested</p> <p><i>For this generation particularly, social media and TV ads and newspapers – well, probably not newspapers, but radio ads as well. You know, a campaign around getting people vaccinated, I think that would be very beneficial for young people these days</i></p>
<p>Study theme 3</p>	<p>Identifying and offering YMSM the HPV vaccination</p> <p>The ideal pre-exposure timing for vaccination and the fluid, undefined nature of sexual preferences at a young age were perceived as barriers to identifying eligible recipients. There were mixed feelings about whether it would be acceptable for HCPs to ask boys (<16 years) to disclose their sexuality for this purpose due to concern about parents being informed and a lack of a trusting relationship. It was, however, also noted that questions about sexuality need to be normalised, particularly in primary care.</p> <p>Interviewer: If everybody was getting the HPV vaccine...</p> <p><i>That's probably what they should do, because, I mean, (...) someone might think now, oh, I'll never have sex with a man, but then, later down the line, they might do</i></p> <p>Participants wanted the benefits of vaccination to be explained and for the vaccine to be offered in a natural, relaxed manner, opportunistically, rather than having to request it. Participants felt that they would be unlikely to request the vaccine because they would need more knowledge and they felt too uncomfortable.</p> <p><i>As long as there was someone professional telling me what's it about, what's it going to do, and what it could do if it goes wrong</i></p> <p>Participants reckoned it was not feasible to expect young boys to identify themselves for the HPV vaccine when they potentially had not disclosed or decided their sexual orientation. There was also a preference for not singling boys out by their sexuality when offering the vaccine. Similarly, receiving the vaccine confidentially was important because the potential for bullying and embarrassment would act as barriers. It was noted by participants that universal vaccination of all boys would avoid these problems.</p> <p><i>I would want them to approach me. I wouldn't go out of my way to go and get it.</i></p>

	<p><i>When you get your vaccinations in school, you all, (...) used to go in to get your vaccinations [as a class]. If it were like that, I wouldn't do it, because I wouldn't like anyone seeing.</i></p> <p><i>Why wouldn't it be offered to like young males in school, (...) so it was like before like presumably anybody had had sex (...). A lot more people would get it that way.</i></p>
Study theme 4	<p>General practitioners (GPs) or specialist sexual HCPs offering the vaccine</p> <p>There were mixed feelings about general practitioners (GPs) or specialist sexual HCPs offering the vaccine. The relationship with the HCP was important; if YMSM have a good relationship with their GP then being offered the HPV vaccine by them is preferable. In contrast, a small number would feel more comfortable being offered the vaccine by someone they trust from a community LGBTQ group or local sexual health centre.</p> <p>A comment was also made about the nature of the vaccine being related to sexual health. Meaning it made more sense/was easier to offer it via specialist services. However, prior to disclosure or sexual activity, the participants commented that boys may not engage with or know about sexual health or LGBTQ organisations, so offering the vaccine in these settings may represent a barrier.</p> <p><i>Telling your family GP you're gay before you've told your family would be a big no I think because the GP might go back and tell your parents and then out you</i></p> <p><i>If you have to go and ask about it and ask for it, who would you ask because you wouldn't be able to come here [Community LGBTQ group] because you wouldn't know here existed</i></p>

Characteristics

Study-level characteristics

	Study (N =17)
Age Mean/SD	20.5 (2.73)
Ethnicity	
White	n = 15 ; % = 83.3
Education	

	Study (N =17)
Full-time education	n = 11 ; % = 61

Critical Appraisal – CASP Qualitative Checklist

Aims of the research

Was there a clear statement of the aims of the research?

Yes

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

Data collection

Was the data collected in a way that addressed the research issue?

Yes

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

Data analysis

Was the data analysis sufficiently rigorous?

Yes

Findings

Is there a clear statement of findings?

Yes

Research value

How valuable is the research?

The research is valuable

Overall risk of bias and directness

Overall risk of bias

Low

Koskan, 2018

Bibliographic Reference Koskan, Alexis M; Fernandez-Pineda, Madeline; Human Papillomavirus Vaccine Awareness Among HIV-Positive Gay and Bisexual Men: A Qualitative Study.; LGBT health; 2018; vol. 5 (no. 2); 145-149

Study details

Study design	Qualitative study
Aim	To explore this HIV-positive gay and bisexual men's (GBM)' understanding of HPV and the HPV vaccine as well as preferences for future health promotion.
Country/geographical location	United States of America
Setting	Health-related organizations that offer outreach services to HIV-positive populations (e.g. health department, nonprofit organizations which focus on the health of racial/ethnic minority HIV-positive men, and LGBT community health center). Participants also recruited via snowball sampling. This study was part of a larger study of 91 gay and bisexual men were interviewed about anal cancer prevention.
Inclusion criteria	HIV-positive, self-identify as gay or bisexual men, age 18-30, English or Spanish fluency, reside in Miami-Dade County), and a Google number that rang directly to the PI's cell phone (for English speakers) or the bilingual Graduate Research Assistant's (GRA's) cell phone (for Spanish speakers) to screen potential participants
Exclusion criteria	Transgender populations were excluded from this study
Statistical method(s) used to analyse the data	All interviews were audio recorded. All audio files were translated, back translated, and transcribed removing any identifying information. All transcribed files were read to ensure that such information had been removed. Coding guide were created for the interview using the interview guide for a priori themes
Attrition	Not applicable
Study limitations	All participants were engaged in HIV primary care. Therefore, the study findings may not be generalizable to HIV-positive GBM who are currently not sustained in HIV care. Authors suggest that a potential limitation may include interviewer variability. However, the PI tried to eliminate potential variability in how questions and probes were asked by training and conducting mock interviews with the Graduate Research Assistant's (GRA's)
Study theme 1	<u>HPV related knowledge</u>

	<p>Knowledge about HPV:</p> <p>Majority could describe HPV as a health condition that can be spread via sex.</p> <p>None knew that the HPV vaccine is used to prevent genital warts and cancer.</p> <p>Some participants lacked knowledge about HPV, HPV related diseases and the vaccine. Most participant perceived it as a vaccine for women only</p> <p><i>I haven't heard about that disease. Personally, I have never—my doctors have never told me about it</i></p> <p><i>I heard that it's really contagious. I heard that some people catch it through [having] sex</i></p> <p><i>I mean I've heard it mentioned on the news here and there, but my understanding, which is minimal, is that it's not just affecting gay men</i></p> <p><i>Well, I heard it when it first came out, and it was only for females, right? For girls at a certain age? I didn't pay that much attention because it didn't pertain to me</i></p>
<p>Study theme 2</p>	<p><u>Facilitators to HPV vaccine</u></p> <p>Participants reported willingness to receive HPV vaccine if their provider recommended it for disease prevention. Lack of provider recommendation was the most cited barrier to HPV vaccination.</p> <p>All expressed positive attitudes towards vaccination in general.</p> <p>Desire to prevent diseases:</p> <p><i>I'm looking at HPV vaccine I'm thinking that it will prevent me from getting this [virus]. I don't think I've ever had a doctor speak of it either. But I would be willing to take it if it's going to prevent me from getting sick</i></p> <p>Provider recommendation:</p> <p><i>If my doctor brings it to my attention that I need to get a vaccine for something, I will take it. I know it's in my best interest</i></p>

Study theme 3	<u>Barriers to HPV vaccine uptake</u>
	Lack of awareness, some described needing needing more information to make an informed decision.
	<i>There's a lack of information. And ignorance about it.</i>
	Potential side effects:
	<i>I mean I don't know, I mean I'm not too fond of the guinea pig thing, so I don't know, it depends on the side effects, I actually [inaudible] that. So I would have to see—weigh my options and see what my side effects are</i>
	Belief that HPV affects women and children only:
<i>Well, I heard it when it first came out, and it was only for females, right? For girls at a certain age? I didn't pay that much attention because it didn't pertain to me</i>	
Stigma:	
<i>The embarrassment, being embarrassed about getting a vaccine shot or whatever type of vaccine they may need. I know when I first had to get a vaccine shot for a STD, I was kind of nervous about that and embarrassed about that</i>	

Characteristics

Study-level characteristics

	Study (N = 15)
Age Mean	25.5

Critical Appraisal – CASP Qualitative Checklist

Aims of the research

Was there a clear statement of the aims of the research?

Yes

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Can't tell

Data collection

Was the data collected in a way that addressed the research issue?

Yes

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Yes

Ethical Issues

Have ethical issues been taken into consideration?

Yes

Data analysis

Was the data analysis sufficiently rigorous?

Yes

Findings

Is there a clear statement of findings?

Yes

Research value

How valuable is the research?

The research is valuable

Overall risk of bias and directness

Overall risk of bias

Low

Nadarzynski, 2017

Bibliographic Reference

Nadarzynski, Tom; Smith, Helen; Richardson, Daniel; Pollard, Alex; Llewellyn, Carrie; Perceptions of HPV and attitudes towards HPV vaccination amongst men who have sex with men: A qualitative analysis.; British journal of health psychology; 2017; vol. 22 (no. 2); 345-361

Study details

Study design	Qualitative study
Study start date	Nov-2014
Study end date	Mar-2015
Aim	To explore men who have sex with men's perceptions of HPV and HPV vaccination prior to the introduction of the vaccination programme in the UK
Country/geographical location	Brighton, United Kingdom
Setting	Community-based lesbian, gay, bisexual, transgender (LGBT) venues and organizations
Inclusion criteria	English-speaking men who have sex with men between 16 and 40 years old. All self-identified men, who were sexually attracted to or had already had sex with other men, were eligible for inclusion in the study
Statistical method(s) used to analyse the data	Study applied 'methodological pluralism' utilizing both focus groups and individual interviews to facilitate the capture not only the depth of views but also the range of perspectives on the HPV vaccination
Attrition	Not applicable
Study limitations	<p>Authors report that it is possible that men who have sex with men, who live in other parts of the United Kingdom, where LGBT matters are not so visible, might report other/different potential barriers to HPV vaccination.</p> <p>Also, the level of education and sexual health literacy of the sample was not assessed, risking the possibility of self-selection bias if men who were willing to take part in the study had existing high levels of knowledge about STIs and sexual health services.</p> <p>Authors suggest that the information on the relative risk of anal cancer in MSM could evoke unrealistic expectations about the prevalence of anal cancers in MSM. The attitudes towards HPV vaccine might have been different if men were made aware of the prevalence of anal cancers in the population</p>
Study theme 1	<p><u>Awareness about HPV</u></p> <p>Generally poor awareness of HPV and the HPV vaccine amongst participants. Older MSM were unaware of HPV and were unable to recall any information related to the HPV vaccine. Younger men were more familiar with the term 'HPV' and were able to recall that the HPV vaccine was offered to girls at school. They knew that it could cause cervical cancer and believed that HPV only affected women:</p> <p><i>I know that it's more dangerous for girls. It can cause genital warts and it can also increase their chances of cervical cancer?</i></p>

<p>Study theme 2</p>	<p><u>Beliefs about HPV</u></p> <p>MSM were often surprised that HPV could affect men. They reported that the lack of media coverage about HPV in men led them to believe that HPV was not relevant or deserving of their attention:</p> <p><i>I didn't realise this was an issue for men. I've heard of HPV because when I was at school all the girls had to have vaccinations</i></p> <p>The lack of visible symptoms in most cases of HPV was related to their perceptions of HPV being relatively innocuous and trivial. Some thought HPV was easily curable and the majority of participants did not express any worry or concerns. They thought that there were 'bigger ones' to worry about, referring mainly in this context to HIV infection:</p> <p><i>It's not something that, you know, being concerned about getting, because HIV they're the ones that are kind of worried about</i></p> <p>Participants varied in their individual perceived susceptibility to HPV. They were unable to assess their personal risk of exposure. Some participants believed that having two sexual partners would be sufficient to acquire the virus, others thought that only more promiscuous men are at risk of HPV and other STIs:</p> <p><i>I'm sexually active with other people who have sex with other people so I would say probably quite a big risk of HPV, and I would just get on with it and say that's probably gonna be part of my life at some point. So, not scared of that one</i></p> <p>Several participants believed that being in a monogamous sexual relationship and using condoms would protect them from acquiring HPV. Most men did not perceive HPV to be a serious concern and assumed that men could only 'carry' the virus without symptoms or affect. Some participants had received consistent negative STI test results, which led them to believe they were free from any STI.</p> <p>Others were uncertain whether HPV was included in standard STI screening and most expressed a willingness to test for the virus in the future.</p> <p><i>Not at risk [of HPV] on the basis that I was sort of tested for everything that was available and so was my sexual partner and neither of us had anything</i></p>
	<p><u>Perceptions of genital warts</u></p>

	<p>Over half thought HPV and genital warts to be two discrete conditions. After reading the information provided, several struggled to understand that HPV is the virus that causes genital warts. The causal role of HPV in the development of genital warts increased their level of concern about genital warts.</p> <p><u>Perceptions of HPV related cancers</u></p> <p><u>The majority were surprised to read information on how they could develop genital cancers related to an STI. This increased anxiety and worry about HPV.</u></p>
<p>Study theme 3</p>	<p><u>Attitudes towards targeted HPV vaccination for MSM</u></p> <p>Most men expressed willingness to be vaccinated against HPV. Three participants would only be willing to be vaccinated if it was free of charge. Some reported that they would prefer to wait until an HCP offered the vaccine to them rather than actively seeking it. Doctors were perceived as the most trusted source of medical information, and their opinions as well as recommendations would substantially influence their decision to obtain the vaccine:</p> <p><i>I think I'd be more likely to accept it if it were offered than I would actively request it. I think because if it was, if it was recommended to you it would be coming from a trusted source</i></p> <p>One man stated that offering the vaccine solely to women and gay men would undermine men's masculinity because the vaccine has been initially introduced to combat female genital diseases:</p> <p><i>It may be that masculinity aspect of it if it's been given to women only previously. Services that are exclusively given to women I suppose seem feminine. I can imagine that there are some people who would resist against something if they thought it had feminine associations to it</i></p> <p>More information was not necessarily seen as helpful. A few participants believed that highlighting the additional risk of anal cancer amongst MSM only would increase stigma and prejudice, comparable to the AIDS epidemic. Some men believed that a targeted HPV vaccination programme for MSM would not be received well by the gay community that have already been marginalized because of high HIV incidence:</p> <p><i>If there's another virus, like HPV, it's going to be strongly linked to gay men community again. I don't think it's a good thing for people because it will strengthen the gay label to this specific disease. I don't think people will like it. Since they just got rid of HIV labels and they don't want another stigma again</i></p>

	<p>A few participants emphasized the need to educate MSM about the vaccine in order to encourage them to visit their doctor and ask to be vaccinated. Some men were afraid that the vaccine could have serious side effects or even lead to autism. Participants also questioned the effectiveness of the vaccine in sexually active men who might already have been exposed to HPV and/or had genital warts in the past. Some thought that the vaccine would probably be ineffective, and they did not need to be vaccinated:</p> <p><i>I suppose the only reason why you would not is because it says it does not cure existing HPV infections so if you already have it, that would be the only reason</i></p> <p>Most participants were in favour of HPV vaccination at school for both sexes. They expressed regret and a sense of injustice that HPV vaccination was not routinely offered to boys, as HPV affects all men:</p> <p><i>If it's been proven to protect you against problem in men then yeah I'm a man so. . . I would be more concerned about why health authorities are considering whether to vaccinate gay or bisexual men in the future. What are they gonna do? Cos it seems to me like it's all men, not just gay and bisexual men. So they should just offer it with the girls at school</i></p>
<p>Study theme 4</p>	<p><u>Eligibility based on sexuality perceived as barriers to HPV vaccination</u></p> <p>Participants perceived sexuality as a barrier to HPV vaccination. Men believed that same sex sexual contacts were becoming more acceptable and it was difficult to set boundaries between men that identify as gay or straight. Some men argued that MSM, who do not identify as gay or bisexual, would be unable to benefit from the vaccine if it was only offered to self-declared gay or bisexual men.</p> <p><i>Sexuality is more fluid and flexible than we like to think. I know many people who identify as heterosexual or straight but at some point in their lives experimented with the same sex partner</i></p> <p>One participant, who had never been to a sexual health clinic, stressed the importance of the vaccine needing to be available in other accessible settings. As he did not want to be associated with the gay culture he might consider refusing the HPV vaccine.</p>

	<p>One participant was not willing to disclose his sexuality to a doctor and would not like to be labelled as ‘gay man’ and therefore also perceived himself to be unlikely to uptake the HPV vaccine.</p> <p><i>I don't want to reveal my sexual orientation and if the leaflets keep telling me that if you're gay then it's more serious and if you're not then it's not, that it's fine, then probably I still don't want to take it because I don't want to be labelled that I'm a gay man</i></p> <p>Though several participants believed that young men do not feel comfortable discussing their sexuality with HCPs, nearly all agreed that it would not stop themselves being vaccinated. Another participant indicated that he searches for signs of friendliness towards gay and bisexual men in HCPs before he is ready to discuss any issues related to sexuality.</p> <p><i>Just body language. I guess a reluctance to make conversation or just being almost cold in that they're just getting information without taking into account that this could be some sort of sensitive issue. Especially if sexuality is involved</i></p>
<p>Study theme 5</p>	<p><u>Perceived motivational barriers</u></p> <p>Dislike or distrust of vaccinations were perceived as barriers.</p> <p>Some MSM associated the vaccine with promiscuity and expressed concerns about being stigmatized if they were to accept the HPV vaccination. Several men stated that despite seeing vaccinations as important for their health, they never felt an urge to be vaccinated against any disease. They expressed a ‘fatigue’ about health advice, where they might be aware of the value of vaccination, but still not make any effort to obtain it.</p> <p><i>You can push and push and push with posters and campaigns and stuff but the people that ain't gonna do it, ain't gonna do it</i></p> <p>Two men who disclosed being diagnosed with HIV were concerned about the interaction between the HPV vaccine and their HIV treatment. Several participants had difficulties understanding why MSM are at an increased risk for HPV-related diseases and requested more statistics on the prevalence of these diseases in gay and bisexual men. They wished to know more about HPV symptoms, routes of transmission, and whether they could be tested for it before making their decision whether to accept the HPV vaccine. A few participants suggested that having a picture of genital warts and HPV-related cancers would help them to better understand these diseases.</p> <p>The majority of men thought targeted HPV vaccination of MSM at school was not acceptable, and preferred sexual health clinics as the most suitable setting to reach MSM. These health care settings were perceived as relevant to sexual health and the openness and non-judgemental attitudes of staff in sexual health clinics were thought to be reassuring. HPV vaccination was most acceptable when given alongside sexual health screening, together with Hepatitis B vaccination.</p>

Although some men had experienced difficulties discussing sexual health with their general practitioners, some suggested that the vaccine should be offered at GP surgeries as some young men do not access sexual health services:

If they start routinely testing for this at GUM clinics, and you're negative and not carrying it, then it should be suggested to you at the same point [like] they would suggest a hepatitis A and C vaccine

I think the best thing is to do it at your GP everywhere, offer it so don't make it like you have to go to a place to get it cos then there is potentially like, oh I have to make an appointment at a sexual health clinic, two, there's a stigma oh I need to go to a sexual health clinic so remove all that offer it at GP, if you want it, you'll get it

Study arms

Focus group (N = 20)

Interview (N = 13)

Characteristics

Study-level characteristics

	Study (N = 33)
Age Median IQR	35 (21 to 27)
Sexual orientation	Most had disclosed sexual orientation to a HCP
Transgender	n = 3 ; % = 9

Critical Appraisal – CASP Qualitative Checklist

Aims of the research

Was there a clear statement of the aims of the research?

Yes

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

Data collection

Was the data collected in a way that addressed the research issue?

Yes

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

Findings

Is there a clear statement of findings?

Yes

Research value

How valuable is the research?

The research is valuable

Overall risk of bias and directness

Overall risk of bias

Moderate

Wheldon, 2017

Bibliographic Reference

Wheldon, C.W.; Daley, E.M.; Buhi, E.R.; Baldwin, J.A.; Nyitray, A.G.; Giuliano, A.R.; HPV vaccine decision-making among young men who have sex with men; Health Education Journal; 2017; vol. 76 (no. 1); 52-65

Study details

Study design	Qualitative study
Study start date	2014
Study end date	2014
Aim	The purpose of this study was to (1) describe salient beliefs related to HPV vaccination among young MSM (2) determine factors that underlie these beliefs; and (3) describe a model for HPV vaccine decision-making.

Country/geographical location	Florida, USA
Setting	Participants were recruited from organisations (n = 9; e.g. Student Pride Groups) and virtual sites (n = 13; e.g. sexual networking applications commonly used by MSM) in a mid-sized city in Florida USA. Interviews were conducted in person (n = 14) or on the telephone (n = 8).
Inclusion criteria	MSM between the ages of 18 and 26 years who may or may not identify as gay or bisexual (referred to here as YMSM), and who self-reported HIV-infection in their profile on sexual networking applications.
Exclusion criteria	None reported
Statistical method(s) used to analyse the data	Interviews were digitally recorded and transcribed verbatim. A five-step process was used to analyse the data. This approach included (1) coding transcripts using the main categories from the Integrative Model (IM); (2) in vivo coding to identify text within the main categories that exemplify that category; (3) classifying in vivo codes into generic categories; (4) refining generic categories into specific and conceptually meaningful sub-categories; and (5) assessing the trustworthiness of the findings using independent coders. Inter-coder agreement was assessed by examining the number of times a code was used in a given transcript, the frequency with which each code was used to describe the text and how well the representative quotes represented the categories. Inconsistencies between coders were discussed and the codebook was revised to resolve these inconsistencies. In the revised codebook, codes with overlapping conceptual definitions were combined and further refined. In total, four researchers trained in qualitative data analysis worked independently to assess the trustworthiness of the findings.
Attrition	Not applicable
Study limitations	<p>The authors highlight that the study results are exploratory as they are based on a small sample that was relatively constrained within a specific geographic region and across a narrow spectrum of sociodemographic characteristics. Considered to have reached data saturation.</p> <p>Most participants had health insurance and were well educated. All but one participant self-identified as gay. There are likely important factors that may be unique to YMSM without health insurance, who have limited socioeconomic resources or who claim other sexual identities.</p>
Study theme 1	<p><u>Behavioural Beliefs</u></p> <p>Physical Advantages</p> <p>Participants perceived direct physical benefits from HPV vaccination, including better health and a lower risk of infection. General sense of as a preventive measure, few gave specific details.</p> <p><i>I would be less susceptible to anal cancer at least from HPV</i></p>

	<p>Psychological Advantages</p> <p>Participants mentioned feeling 'safer', having 'one less thing to worry about' and feeling better by not 'spreading' a sexually transmitted infection (STI). Most of these discussions focused on the infection itself and not HPV-related disease.</p> <p><i>It would be one less thing to worry about</i></p> <p>Concerns of Getting Vaccinated</p> <p>Concerns over side effects were nominal. There were more concerns about vaccine efficacy and whether HPV could be contracted from the vaccine itself.</p> <p><i>There is always the risk that you could contract it from getting the vaccine...</i></p>
<p>Study theme 2</p>	<p><u>Normative Beliefs</u></p> <p>Descriptive Norms</p> <p>Overall, there was a general expectation among the men in this study that the people in their lives would be supportive of their decision to get vaccinated; however, awareness and knowledge about the vaccine through their social networks were primarily limited to female friends and siblings. Only one knew of a gay man having had the vaccine.</p> <p><i>I know [about HPV vaccine] because my sister got it</i></p> <p>Supportive Referents</p> <p>Provider recommendation was the most salient interpersonal influence. Some mentioned older gay friends as a potential source of trusted health information. In general, similarly aged peers were not considered valuable sources of informational or emotional support regarding HPV vaccination. Some respondents felt that their family would be supportive (although overall perceived family support was mixed).</p> <p>Unsupportive Referents</p>

	<p>Some participants talked about anticipated negative responses from family or friends. In particular, they expressed a concern that – because HPV is an STI – some may assume they wanted to get vaccinated because they were being promiscuous.</p>
<p>Study theme 3</p>	<p><u>Control Beliefs</u></p> <p>Control beliefs characterise an individual’s assessment of factors that will inhibit or facilitate their ability to get the HPV vaccine, the most salient of which were cost (not relevant to current review), availability and convenience of getting vaccinated.</p> <p>External Facilitators - Convenience</p> <p>Convenience influenced vaccination. Participants mentioned clinics close to their homes or places of employment where they would prefer to be vaccinated. For students, getting vaccinated on campus was mostly preferred. Walk-in availability was also a noted facilitator. Overall, participants seemed open about where to get the vaccine as long as it fit into their schedule.</p> <p>Self-Efficacy Beliefs</p> <p>Participants were probed regarding their perceived self-efficacy for getting the HPV vaccine if they had to discuss aspects of their sexuality with their provider (i.e. sexual behaviours and/or identity). Some participants described themselves as having high self-efficacy to ask for the HPV vaccine, even if they had to discuss their sexuality. However, others expressed feeling uncomfortable disclosing their sexuality to healthcare providers, suggesting that they would be ‘very selective’ about answering questions regarding their sexual behaviour.</p> <p><i>I just feel weird talking to someone like that [healthcare provider] about those kind of things</i></p>
<p>Study theme 4</p>	<p><u>Background Factors</u></p> <p>HPV Knowledge and Information</p> <p>Nearly all of the participants had heard of HPV and typically described it as a STI that has multiple ‘strains’ that mostly affected women. Most men mentioned a vaccine but were not aware that men could be vaccinated. Genital warts and cancer were named as distinctive characteristics of HPV infection; however, when cancer was mentioned, it was usually limited to a generic explanation (e.g. ‘life threatening diseases like cancer’) or an explicit mention of cervical cancer. No participant mentioned anal, oral or penile cancers. Participants expressed minimal information needs related</p>

to related to (1) vaccine effectiveness in older, sexually active men; (2) the vaccine side effects; and (3) the types of sexual behaviours that spread HPV.

Perceived Threat of HPV Infection and Disease

Perceptions regarding susceptibility to HPV infection were mixed. Some men described their risk as high because it 'only takes one sexual partner'. It was common for respondents to discuss their own risk in general terms like 'I always use protection to keep myself healthy' or 'I don't sleep around a lot'. There was a tendency to focus on anal sex as the only risk behaviour. Participants were surprised when informed that HPV can cause anal cancer.

Anogenital warts

Personal experience of these was tied to attitudes and beliefs on HPV and vaccination, this was a primary reason for vaccination.

Sexuality and patient-provider relationship

Majority of participants had talked about their sexual behaviour in a healthcare setting, often receiving STI testing. Sometimes the interactions were negative, affecting expectations around disclosure and confidence in healthcare providers.

Negative Emotions Surrounding Disclosure

Feeling ashamed, awkward and judged were some of the emotions associated with discussing sexual behaviours with a healthcare provider which can act as a barrier to HPV vaccination. Negative experiences or the anticipation of a negative reaction were salient concerns expressed by YMSM when seeking treatment or information on sexual health-related issues from their healthcare providers.

I feel like he judges me. I feel like if I had a provider or somebody who is a little more open-minded ... my doctor is a staunch Republican, white dude who is like 65 and I'm sitting there like a gay little Puerto Rican kid, and you know, it is just always awkward when I go to my doctor. We come from opposite ends of the earth.

Management of Disclosure

When seeking sexual health services, some participants were most comfortable going to clinics focused on STI testing (e.g. public health departments, planned parenthood, university medical services), even if they had established

relationships with primary care providers. Because of the perceived stigma and fear of judgement, they valued the privacy and anonymity provided by these venues when seeking sexual health services (including HPV vaccination). Seeking alternative venues for sexual health services was especially important for participants who received primary care services from a family physician or who depended on parents for health insurance. There was some concern that providers might – deliberately or non-deliberately – disclose sexual health information to parents. In addition, participants were concerned about the confidentiality of billing practices. In some cases, participants would not want their parents to know that they had received HPV vaccination.

LGBT Competence

Previous negative interactions with a healthcare provider influenced some men's future expectations and perceptions regarding the overall competence of healthcare providers in caring for lesbian, gay, bisexual and transgender (LGBT) patients and their specific health needs. These men discussed a need to know where their providers stand on issues related to sexuality for fear that he or she may be biased or incompetent in providing care.

A gay provider would be more into or up-to-date with newer things that are coming out. Especially like with the threats that are more for the gay lifestyle. Because I really don't think that my health provider would know about HPV

Overall, there were conflicts with seeking sexual health services in some participants, due to previous experiences.

Characteristics

Study-level characteristics

	Study (N = 22)
Age Mean (range)	22 (18 to 26)
Ethnicity	
African American	n = 5
Hispanic / Latino	n = 6
White	n = 9
Other race/ethnicity	n = 2
Sexual Orientation	

	Study (N = 22)
Gay	% = 95
Bisexual	% = 5

Critical Appraisal – CASP Qualitative Checklist

Aims of the research

Was there a clear statement of the aims of the research?

Yes

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Can't tell

Data collection

Was the data collected in a way that addressed the research issue?

Yes

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Yes

Ethical Issues

Have ethical issues been taken into consideration?

Yes

Data analysis

Was the data analysis sufficiently rigorous?

Yes

Findings

Is there a clear statement of findings?

Can't tell

(Authors report that results are exploratory as they are based on a small sample size)

Research value

How valuable is the research?

The research is valuable

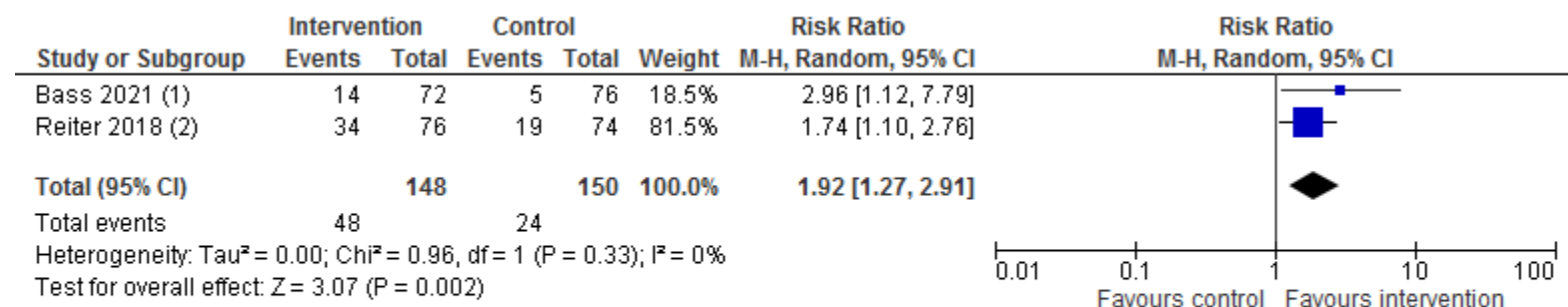
Overall risk of bias and directness

Overall risk of bias

Moderate

Appendix E – Forest plots

Figure 1: Digital interventions compared to control for HPV vaccination initiation

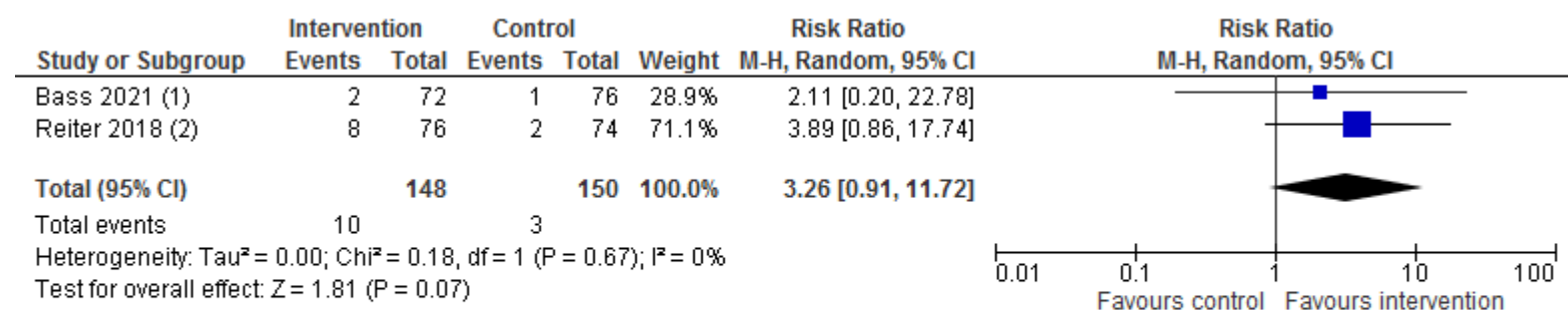


Footnotes

(1) 9 month follow up

(2) 7 month follow up

Figure 2: Digital interventions compared to control for HPV vaccination completion



Footnotes

(1) 9 month follow up

(2) 7 month follow up

Appendix F – GRADE tables

F.1 Human papillomavirus vaccination initiation

Quality assessment							No of patients		Effect		Quality Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
HPV vaccine initiation (follow-up up to 9 months)											
2 ^a	randomised trials	serious ¹	no serious inconsistency	serious ²	no serious imprecision	none	48/148 (32.4%)	24/150 (16%)	RR 1.92 (1.27 to 2.91)	147 more per 1000 (from 43 more to 306 more)	LOW

^a Bass 2021, Reiter 2018

¹ Downgraded for some concerns of bias due to no information on allocation concealment for Bass 2021, and no information on randomisation or allocation concealment for Reiter 2012

² US studies

F.2 Human papillomavirus vaccination completion

Quality assessment							No of patients		Effect		Quality Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
HPV vaccine initiation (follow-up up to 9 months)											
2 ^a	randomised trials	serious ¹	no serious inconsistency	serious ²	serious ³	none	10/148 (6.8%)	3/150 (2%)	RR 3.26 (0.91 to 11.72)	45 more per 1000 (from 2 fewer to 214 more)	VERY LOW

^a Bass 2021, Reiter 2018

¹ Downgraded for some concerns of bias due to no information on allocation concealment for Bass 2021, and no information on randomisation or allocation concealment for Reiter 2012

² US studies

³ Downgraded once as 95%CI crosses line of no effect and 1 MID

F.3 Hepatitis B vaccination uptake

Quality assessment							No of patients		Effect		Quality Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute	
HPV vaccine initiation (follow-up up to 9 months)											
1 ^a	randomised trial	serious ¹	NA	no serious indirectness	no serious imprecision	none	21/99 (21.2%)	18/201 (9%)	RR 2.37 (1.32 to 4.24)	123 more per 1000 (from 29 more to 290 more)	MODERATE

^a Vet 2014

¹ Downgraded for some concerns of bias due to no information on randomisation or allocation concealment

Appendix G – GRADE CERQual Tables

G.1 CERQual: Barriers to increasing uptake of HPV vaccinations in gay, bisexual and other men who have sex with men (MSM)

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Relevance	Coherence	Adequacy	CERQual assessment of confidence in the evidence
<p><u>Lack of knowledge about HPV, HPV related diseases and vaccine</u></p> <p>Almost all participants reported initially believing HPV vaccination was predominately or exclusively an intervention designed for girls or women and that it was for the prevention of cervical cancer. Participants lacked knowledge about HPV in general, transmission in MSM and were unaware of the connection between HPV and male associated cancers. There were some who believed that men carried the virus without symptoms or any effect on them.</p>	<p>Apaydin 2018, Fontenot 2016, Gerend 2019, Grace 2018, Jaiswal 2020, Kesten 2019, Koskan 2018, Nadarzynki 2017</p>	<p>Moderate concerns</p> <p>(small sample size reported in 7 of the studies which might be due to sampling method. One study also reported a lack of data saturation)</p>	<p>No or very minor concerns</p> <p>(data is of direct relevance and is applicable to the context specified in the review question).</p>	<p>No or very minor concerns</p> <p>(there is a good fit between the studies and the review finding)</p>	<p>No or very minor concerns</p> <p>(data is sufficiently rich and comes from 8 out of 9 studies)</p>	<p>Moderate confidence</p> <p>This finding was graded as moderate confidence because of moderate concerns regarding methodological limitations</p>
<p>Supporting statements: "I've heard it doesn't affect men, but they can transmit it. I don't know if that's true"</p>						

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Relevance	Coherence	Adequacy	CERQual assessment of confidence in the evidence
<p>"I didn't know like it affected guys at all"</p> <p>"I've always associated it to cervical cancer and to women. I didn't realize at the time, until recently, that it affected men as well"</p> <p>"My own ignorance was that HPV was something that really only affected women and cervical cancer. I didn't hear it as much as something that was affecting men"</p> <p>"I had no idea that it associated itself with cancer. As far as I did know, it [HPV] just caused warts."</p> <p>"If I didn't have the knowledge [about HPV vaccination]. Because I think that that's what stops people in general. (cisgender man, HIV-infected, vaccinated)."</p> <p>"I haven't heard about that disease. Personally, I have never—my doctors have never told me about it"</p> <p>"I heard that it's really contagious. I heard that some people catch it through [having] sex"</p> <p>"I mean I've heard it mentioned on the news here and there, but my understanding, which is minimal, is that it's not just affecting gay men"</p> <p>"Well, I heard it when it first came out, and it was only for females, right? For girls at a certain age? I didn't pay that much attention because it didn't pertain to me"</p>						
<p><u>Vaccine effectiveness and potential side effects</u></p> <p>Participants noted the importance of having clear information about the vaccine and any possible side effects.</p> <p>They questioned the effectiveness of the vaccine in sexually active men who might already have been exposed to HPV and/or had genital warts in the past.</p>	<p>Fontenot 2016, Gerend 2019, Koskan 2018, Nadarzynki 2017, Wheldon 2017</p>	<p>Moderate concerns</p> <p>(small sample size reported in 4 of the included studies which might be due to sampling method.)</p>	<p>No or very minor concerns</p> <p>(data is of direct relevance and is applicable to the context specified in the review question).</p>	<p>No or very minor concerns</p> <p>(there is a good fit between the studies and the review finding)</p>	<p>No or very minor concerns</p> <p>(data is sufficiently rich and comes from 5 studies)</p>	<p>Moderate confidence</p> <p>This finding was graded as moderate confidence because of moderate concerns regarding methodological limitations</p>
<p>Supporting statements:</p> <p>"I mean I don't know, I mean I'm not too fond of the guinea pig thing, so I don't know, it depends on the side effects, I actually [inaudible] that. So I would have to see—weigh my options and see what my side effects are"</p>						

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Relevance	Coherence	Adequacy	CERQual assessment of confidence in the evidence
<p>"I imagine that there are some people who are more concerned about side effects. Some people may be more prone to them than others"</p> <p>"I suppose the only reason why you would not is because it says it does not cure existing HPV infections so if you already have it, that would be the only reason"</p> <p>"I think like with all vaccines there are probably side effects"</p>						
Summary of review finding	Studies contributing to the review finding	Methodological limitations	Relevance	Coherence	Adequacy	CERQual assessment of confidence in the evidence
<p><u>Vaccination series including timing of doses</u></p> <p>Participants who reported not completing the vaccine series described barriers such as the long time intervals between doses; multiple doses; and the inconvenience of work conflicting with clinic hours.</p> <p>Fully vaccinated participants described monitoring their own timeline for dose completion and following up to confirm appointments as behaviours that facilitated 3-dose completion.</p>	<p>Apaydin 2018, Fontenot 2016, Kesten 2019</p>	<p>Moderate concerns</p> <p>(small sample size reported in included studies which might be due to sampling method.)</p>	<p>No or very minor concerns</p> <p>(data is of direct relevance and is applicable to the context specified in the review question).</p>	<p>No or very minor concerns</p> <p>(there is a good fit between the studies and the review finding)</p>	<p>Moderate concerns</p> <p>(data is moderately rich and comes 3 studies)</p>	<p>Low confidence</p> <p>This finding was graded as low confidence because of moderate concerns regarding methodological limitations and adequacy of data</p>
<p>Supporting statements:</p> <p>"... you know, going back and coming back, and going back [for 3 doses], it's too much work"</p> <p>"I kind of had the whole timeline laid out before I started even with the first dose, and then just before I would leave the office that same day schedule a follow-up appointment. So it was already in my calendar"</p> <p>"It is hard to remember, keep track of all the shots"</p>						

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Relevance	Coherence	Adequacy	CERQual assessment of confidence in the evidence
<p>“People are uncomfortable having to make phone calls. . . it’s a lot easier to just do something on your phone, like an appointment confirmation, so that you can go in without having to talk [to someone] or feel uncomfortable disclosing things [on the phone]”</p>						
<p><u>Possible stigma</u></p> <p>Participants described stigmas related to being gay, gay health, acceptance by HCPs, and STIs.</p> <p>Participants described the importance of being able to discuss sexual activity with healthcare professionals and the importance of being in health care situations where they feel comfortable doing that. Some described previous negative experiences of this.</p> <p>Participants were also concerned that they would be labelled as promiscuous upon receiving vaccination.</p> <p>There was concern from participants about possibly singling out people, especially boys, by their sexuality when offering the vaccine.</p>	<p>Fontenot 2016, Gerend 2019, Koskan 2018, Nadarzycki 2017, Wheldon 2017</p>	<p>Moderate concerns</p> <p>(small sample size reported in 4 out the 5 studies included, which might be due to sampling method.)</p>	<p>No or very minor concerns</p> <p>(data is of direct relevance and is applicable to the context specified in the review question).</p>	<p>No or very minor concerns</p> <p>(there is a good fit between the studies and the review finding)</p>	<p>No or very minor concerns</p> <p>(data is sufficiently rich and comes from 5 studies)</p>	<p>Moderate concerns</p> <p>This finding was graded as moderate confidence because of moderate concerns regarding methodological limitations</p>
<p>Supporting statements:</p> <p>“The embarrassment, being embarrassed about getting a vaccine shot or whatever type of vaccine they may need. I know when I first had to get a vaccine shot for a STD, I was kind of nervous about that and embarrassed about that”</p> <p>“I just feel weird talking to someone like that [healthcare provider] about those kind of things”</p>						

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Relevance	Coherence	Adequacy	CERQual assessment of confidence in the evidence
<p>“If there’s another virus, like HPV, it’s going to be strongly linked to gay men community again. I don’t think it’s a good thing for people because it will strengthen the gay label to this specific disease. I don’t think people will like it. Since they just got rid of HIV labels and they don’t want another stigma again”</p> <p>“...some people will consider somebody very promiscuous. ‘Oh, you’re getting a vaccine because you’re sleeping with multiple people,’ and there’s just a stigma associated with that”</p> <p>“[HPV] that’s like a girl thing and they don’t market it towards men so we are embarrassed sometimes because we’re like that a girl’s thing, why are we over here getting treated for this”</p> <p>“You can push and push and push with posters and campaigns and stuff but the people that ain’t gonna do it, ain’t gonna do it.</p>						
<p>Clinical settings</p> <p>Most of the participants suggested sexual health clinics to be the most suitable setting to reach MSM as the openness and non-judgemental attitudes of staff in sexual health clinics were thought to be reassuring.</p> <p>Though some suggested that the vaccine should be offered at GP surgeries as some young men do not access sexual health services, others highlighted difficulties discussing sexual health with their general practitioners.</p> <p>Some men mentioned that MSM who do not identify as gay or bisexual, will not benefit from the vaccine if it was only targeted to gay or bisexual men.</p>	<p>Gerend 2019, Nadarzynki 2017, Wheldon 2017</p>	<p>Moderate concerns</p> <p>(small sample size reported in 2 out the 3 studies included which might be due to sampling method)</p>	<p>No or very minor concerns</p> <p>(data is of direct relevance and is applicable to the context specified in the review question).</p>	<p>No or very minor concerns</p> <p>(there is a good fit between the studies and the review finding)</p>	<p>Minor concerns</p> <p>(data is moderately rich with supporting statements from 2 out of 3 studies)</p>	<p>Low confidence</p> <p>This finding was graded as low confidence because of moderate concerns regarding methodological limitations and minor concerns regarding adequacy of data</p>

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Relevance	Coherence	Adequacy	CERQual assessment of confidence in the evidence
Supporting statements:						
<p>"I think the best thing is to do it at your GP everywhere, offer it so don't make it like you have to go to a place to get it cos then there is potentially like, oh I have to make an appointment at a sexual health clinic, two, there's a stigma oh I need to go to a sexual health clinic so remove all that offer it at GP, if you want it, you'll get it"</p> <p>"Well, it was offered right there while I was getting the physical done. So I didn't even have to make a special trip or anything"</p> <p>"I feel like he judges me. I feel like if I had a provider or somebody who is a little more open-minded ... my doctor is a staunch Republican, white dude who is like 65 and I'm sitting there like a gay little Puerto Rican kid, and you know, it is just always awkward when I go to my doctor. We come from opposite ends of the earth"</p> <p>"I think ease of access. I don't know how many hospitals or locations would have this vaccine or if it's accessible in that capacity"</p> <p>"Sexuality is more fluid and flexible than we like to think. I know many people who identify as heterosexual or straight but at some point in their lives experimented with the same sex partner"</p>						

G.2 CERQual: Facilitators for increasing uptake of HPV vaccinations in gay, bisexual and other men who have sex with men (MSM)

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Relevance	Coherence	Adequacy	CERQual assessment of confidence in the evidence
<p><u>Awareness of vaccines and the health benefits of getting vaccinated</u></p> <p>Participants acknowledged the physical and psychological health</p>	<p>Apaydin 2018, Fontenot 2016, Gerend 2019, Grace 2018, Kesten 2019, Koskan 2018,</p>	<p>Moderate concerns</p> <p>(small sample size reported in 6 of the studies which</p>	<p>No or very minor concerns</p> <p>(data is of direct relevance and is applicable to the</p>	<p>No or very minor concerns</p> <p>(there is a good fit between the</p>	<p>No or very minor concerns</p> <p>(data is sufficiently rich</p>	<p>Moderate confidence</p> <p>This finding was graded as moderate</p>

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Relevance	Coherence	Adequacy	CERQual assessment of confidence in the evidence
<p>benefits of vaccination in general and HPV vaccination and were enthusiastic about the ability to protect both themselves and their partner(s).</p> <p>Some men expressed the positive benefits to vaccination, including reducing their anxieties around the risk of anal cancer. They also mentioned feeling 'safer', having 'one less thing to worry about' and feeling better by not 'spreading' a sexually transmitted infection (STI)"</p> <p>Participants noted the lack of MSM-specific sexual health and relationship information provided in the sexual health education curriculum in schools and suggested including information about the vaccine for YMSM in primary care. The suggested that HPV education should be more widespread and more inclusive of all sexes, and believed that better understanding of the benefits and side effects of the vaccine would encourage uptake.</p>	Nadarzynki 2017, Wheldon 2017	might be due to sampling method.)	context specified in the review question).	studies and the review finding)	and comes from all 8 studies)	confidence because of moderate concerns regarding methodological limitations
<p>Supporting statements:</p> <p>"Yeah like I care about my health, but I also care about other people's health too and I don't want anyone else to get infected or have to go through with something like that"</p>						

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Relevance	Coherence	Adequacy	CERQual assessment of confidence in the evidence
<p>"I'm not going to say like get rid of worry because you still have to...it's your sexual health, but it would be safer in a sense (...) I'm better protected – I think would be a better way of putting it. So, I think my own health would encourage me more [to ask or accept the HPV vaccine]. I'd rather be protected than not protected"</p> <p>"Not getting HPV and not developing any of the cancers or anything related to it"</p> <p>"Don't have to worry as much. One of the few STIs have vaccine for—click that one off the list"</p> <p>"I'm looking at HPV vaccine I'm thinking that it will prevent me from getting this [virus]. I don't think I've ever had a doctor speak of it either. But I would be willing to take it if it's going to prevent me from getting sick"</p> <p>"I would be less susceptible to anal cancer at least from HPV"</p> <p>"It would be one less thing to worry about"</p> <p>"I'm definitely pro vaccine"</p>						
<p><u>Interactions with health care practitioners (HCPs)</u></p> <p>Participants perceived healthcare providers and doctors to be the most trusted source of information, and their opinions as well as recommendations would substantially influence their decision to obtain the vaccine</p> <p>Overall, participants reported that provider recommendation was the most significant interpersonal influence. This was linked with the importance of being able to discuss sexual activity with healthcare professionals and the approachability of healthcare professionals in this.</p> <p>Conversely, participants reported lack of communication from</p>	<p>Fontenot 2016, Gerend 2019, Grace 2018, Jaiswal 2020, Kesten 2019, Koskan 2018, Nadarzynki 2017, Wheldon 2017</p>	<p>Moderate concerns</p> <p>(small sample size reported in 6 of the studies which might be due to sampling method.)</p>	<p>No or very minor concerns</p> <p>(data is of direct relevance and is applicable to the context specified in the review question).</p>	<p>No or very minor concerns</p> <p>(there is a good fit between the studies and the review finding)</p>	<p>No or very minor concerns</p> <p>(data is sufficiently rich and comes from 7 of the 8 included studies)</p>	<p>Moderate confidence</p> <p>This finding was graded as moderate confidence because of moderate concerns regarding methodological limitations</p>

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Relevance	Coherence	Adequacy	CERQual assessment of confidence in the evidence
healthcare providers as a barrier to HPV vaccination. Many reported minimal, if any, communication, and those that were offered the vaccine reported scant communication about it and inadequate support or follow-up to ensure vaccine completion.						

Supporting statements:

"I think I'd be more likely to accept it if it were offered than I would actively request it. I think because if it was, if it was recommended to you it would be coming from a trusted source"

"It was the doctor's recommendation. I honestly wouldn't have thought about it had he not recommended it"

"As long as there was someone professional telling me what's it about, what's it going to do, and what it could do if it goes wrong"

"Telling your family GP you're gay before you've told your family would be a big no I think because the GP might go back and tell your parents and then out you"

"If my doctor brings it to my attention that I need to get a vaccine for something, I will take it. I know it's in my best interest"

"Now knowing all the cancers, it causes, which I wasn't aware of before it seems like more of a reason to get it"

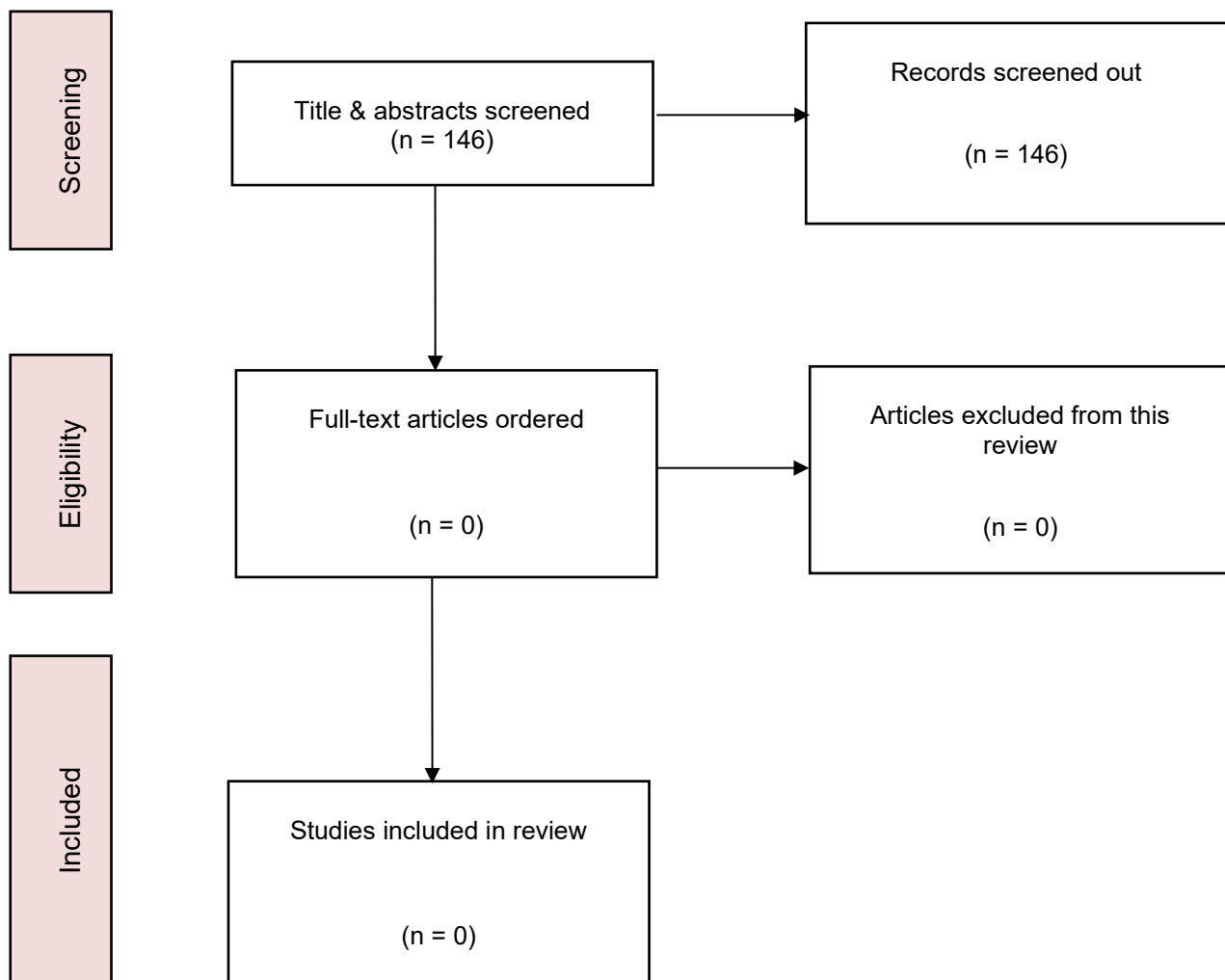
"No doctor has ever brought [HPV] up to me. And I've always had to advocate for this. I remember when it came out, and it was just women getting it, I read somewhere like gay men need to get this because you can get anal cancer, so I went to my doctor, and she was like "Oh I guess that's technically correct," and I was like "Okay so vaccinate me," and she was like "Well, your insurance isn't gonna cover it." So I ended up getting it, but I had to pay for it out of pocket."

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Relevance	Coherence	Adequacy	CERQual assessment of confidence in the evidence
<u>Support from friends and family</u>	Apaydin 2018, Fontenot 2016,	Moderate concerns	No or very minor concerns	No or very minor concerns	Serious concerns	Very low confidence
Participants highlighted that most people in their lives would be supportive of their decision to get		(small sample size reported in	(data is of direct relevance and is	(there is a good fit between the		

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Relevance	Coherence	Adequacy	CERQual assessment of confidence in the evidence
vaccinated; however, awareness and knowledge about the vaccine through their social networks were primarily limited to female friends and siblings. Participants with unsupportive referents typically mentioned their parents (notably their father) or extended family members.		included studies which might be due to sampling method.)	applicable to the context specified in the review question).	studies and the review finding)	(data is limited and comes from 2 studies)	This finding was graded as low confidence because of moderate concerns regarding methodological limitations and adequacy of data
<p>Supporting statements:</p> <p>"I have a very good relationship with my entire family. They all know I'm gay. No one cares one bit. I'm very fortunate. So if I were to say I was getting the Gardasil vaccine, they would be (very supportive)"</p> <p>"Maybe my dad. Because he's just ignorant with regard to sexuality and vaccines and stuff like that. He's kind of a anti-government conspiracies person, so I don't really have a good relationship with him"</p> <p>"I know [about HPV vaccine] because my sister got it"</p>						
<p><u>Making vaccine part of other clinical interactions</u></p> <p>Participants described wanting to combine HPV vaccination with other types of visits like annual physical examinations and other STI tests. They gave examples of their routine HIV tests or sexual health screening and how HPV vaccination could have been incorporated into those visits.</p>	Fontenot 2016, Gerend 2019, Nadarzycki 2017	Moderate concerns (small sample size reported in 2 out of the 3 studies included, which might be due to sampling method)	No or very minor concerns (data is of direct relevance and is applicable to the context specified in the review question).	No or very minor concerns (there is a good fit between the studies and the review finding)	Moderate concerns (data is moderately rich and comes from 3 studies)	Low confidence This finding was graded as low confidence because of moderate concerns regarding methodological limitations and adequacy of data
<p>Supporting statements:</p> <p>"Well, it was offered right there while I was getting the physical done. So I didn't even have to make a special trip or anything"</p>						

Summary of review finding	Studies contributing to the review finding	Methodological limitations	Relevance	Coherence	Adequacy	CERQual assessment of confidence in the evidence
<p>“If they start routinely testing for this at GUM clinics, and you’re negative and not carrying it, then it should be suggested to you at the same point [like] they would suggest a hepatitis A and C vaccine”</p>						
<p><u>Mobile applications</u></p> <p>Participants suggested the use of mobile applications for booking appointments, creating a reminder system, keep track of health history. They were of the opinion that flexibility in scheduling and app-based reminder systems would facilitate 3-dose completion.</p>	<p>Fontenot, 2016</p>	<p>Moderate concerns</p> <p>(limited small sample size reported, which might be due to sampling method)</p>	<p>No or very minor concerns</p> <p>(data is of direct relevance and is applicable to the context specified in the review question).</p>	<p>No or very minor concerns</p> <p>(there is a good fit between the studies and the review finding)</p>	<p>Very serious concerns</p> <p>(data is limited and comes from one study)</p>	<p>Very low confidence</p> <p>This finding was graded as very low confidence because of moderate concerns regarding methodological limitations and very serious concerns regarding adequacy of data</p>
<p>Supporting statements:</p> <p>“People are uncomfortable having to make phone calls. . . it’s a lot easier to just do something on your phone, like an appointment confirmation, so that you can go in without having to talk [to someone] or feel uncomfortable disclosing things [on the phone]”</p>						

Appendix H – Economic evidence study selection



Appendix I – Economic evidence tables

No economic evidence was identified for this review question

Appendix J Health economic model

No economic modelling was undertaken for this review question

Appendix K – Excluded studies

Study	Reason
<p>Abara, Winston E, Qaseem, Amir, Schillie, Sarah et al. (2017) Hepatitis B Vaccination, Screening, and Linkage to Care: Best Practice Advice From the American College of Physicians and the Centers for Disease Control and Prevention. <i>Annals of internal medicine</i> 167(11): 794-804</p>	<p>- Literature review. References checked for eligible studies</p>
<p>Agenor, M., Murchison, G.R., Chen, J.T. et al. (2019) Impact of the Affordable Care Act on human papillomavirus vaccination initiation among lesbian, bisexual, and heterosexual U.S. women. <i>Health services research</i></p>	<p>- Surveillance data. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM</p>
<p>Alberts, C.J., Boyd, A., Bruisten, S.M. et al. (2019) Hepatitis A incidence, seroprevalence, and vaccination decision among MSM in Amsterdam, the Netherlands. <i>Vaccine</i> 37(21): 2849-2856</p>	<p>- Surveillance data. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM</p>
<p>Allen-Leigh, B., Rivera-Rivera, L., Yunes-Diaz, E. et al. (2019) Uptake of the HPV vaccine among people with and without HIV, cisgender and transgender women and men who have sex with men and with women at two sexual health clinics in Mexico City. <i>Human Vaccines and Immunotherapeutics</i></p>	<p>- Cross-sectional study. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM</p>
<p>Anderson, Jonathan S, Hoy, Jennifer, Hillman, Richard et al. (2009) A randomized, placebo-controlled, dose-escalation study to determine the safety, tolerability, and immunogenicity of an HPV-16 therapeutic vaccine in HIV-positive participants with oncogenic HPV infection of the anus. <i>Journal of acquired immune deficiency syndromes (1999)</i> 52(3): 371-81</p>	<p>- RCT. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM</p>
<p>Apaydin, Kaan Z, Fontenot, Holly B, Shtasel, Derri L et al. (2018) Primary care provider practices and perceptions regarding HPV vaccination and anal cancer screening at a Boston community health center. <i>Journal of Community Health: The Publication for Health Promotion and Disease Prevention</i> 43(4): 792-801</p>	<p>- Survey to evaluate primary care providers' HPV vaccination and anal cancer screening practices and perceptions. Data not usable</p>
<p>Bhagey, A, Foster, K, Ralph, S et al. (2018) High prevalence of anti-hepatitis A IgG in a cohort of UK HIV-negative men who have sex with men: implications for local hepatitis A vaccine policy. <i>International journal of STD & AIDS</i> 29(10): 1007-1010</p>	<p>- Cohort. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM</p>
<p>Bonafide, K.E. and Venable, P.A. (2015) Male human papillomavirus vaccine acceptance is enhanced by a brief intervention that emphasizes both male-specific vaccine benefits and altruistic motives. <i>Sexually Transmitted Diseases</i> 42(2): 76-80</p>	<p>- Cross-sectional study on perceptions of HPV and acceptability of vaccine</p>
<p>Budenz, A., Klassen, A., Leader, A. et al. (2019) HPV vaccine, Twitter, and gay, bisexual and other men who have sex with men. <i>Health promotion international</i></p>	<p>- Cross-sectional study. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM</p>

Study	Reason
Burrell, S., Vodstrcil, L.A., Fairley, C.K. et al. (2019) Hepatitis A vaccine uptake among men who have sex with men from a time-limited vaccination programme in Melbourne in 2018. <i>Sexually Transmitted Infections</i>	- Retrospective cohort study. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Calin, Ruxandra, Massari, Veronique, Pialoux, Gilles et al. (2020) Acceptability of on-site rapid HIV/HBV/HCV testing and HBV vaccination among three at-risk populations in distinct community-healthcare outreach centres: the ANRS-SHS 154 CUBE study. <i>BMC infectious diseases</i> 20(1): 851	- Cohort. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Charlton, Brittany M, Reisner, Sari L, Agenor, Madina et al. (2017) Sexual Orientation Disparities in Human Papillomavirus Vaccination in a Longitudinal Cohort of U.S. Males and Females. <i>LGBT health</i> 4(3): 202-209	- Prospective cohort. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM. Mixed population
Checchi, M., Mesher, D., McCall, M. et al. (2019) HPV vaccination of gay, bisexual and other men who have sex with men in sexual health and HIV clinics in England: Vaccination uptake and attendances during the pilot phase. <i>Sexually Transmitted Infections</i> 95(8): 608-613	- Surveillance data. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Cummings, Teresa, Kasting, Monica L, Rosenberger, Joshua G et al. (2015) Catching Up or Missing Out? Human Papillomavirus Vaccine Acceptability Among 18- to 26-Year-old Men Who Have Sex With Men in a US National Sample. <i>Sexually transmitted diseases</i> 42(11): 601-6	- Cross-sectional study on HPV vaccine acceptability
Edmiston, E.K., Donald, C.A., Sattler, A.R. et al. (2016) Opportunities and Gaps in Primary Care Preventative Health Services for Transgender Patients: A Systematic Review. <i>Transgender Health</i> 1(1): 216-230	- Systematic review. References checked for eligible studies
Farfour, Eric, Lesprit, Philippe, Chan Hew Wai, Aurelie et al. (2018) Acute hepatitis A breakthrough in MSM in Paris area: implementation of targeted hepatitis A virus vaccine in a context of vaccine shortage. <i>AIDS (London, England)</i> 32(4): 531-532	- Editorial. References checked for eligible studies
FitzGerald, S.M.; Savage, E.B.; Hegarty, J.M. (2014) The Human Papillomavirus: Men's Attitudes and Beliefs Toward the HPV Vaccination and Condom Use in Cancer Prevention. <i>Journal of Men's Health</i> 11(3): 121-129	- Qualitative. Not on MSM
Fontenot, H.B., Rosenberger, J.G., McNair, K.T. et al. (2019) Perspectives and preferences for a mobile health tool designed to facilitate HPV vaccination among young men who have sex with men. <i>Human Vaccines and Immunotherapeutics</i> 15(78): 1815-1823	- Qualitative. Not on barriers and facilitators
Fontenot, Holly B, White, Bradley Patrick, Rosenberger, Joshua G et al. (2020) Mobile App Strategy to Facilitate Human	- Cohort. Not on interventions to increase uptake of Hepatitis A,

Study	Reason
Papillomavirus Vaccination Among Young Men Who Have Sex With Men: Pilot Intervention Study. <i>Journal of medical Internet research</i> 22(11): e22878	Hepatitis B and HPV vaccinations in MSM
Forster, A.S. and Gilson, R. (2019) Challenges to optimising uptake and delivery of a HPV vaccination programme for men who have sex with men. <i>Human Vaccines and Immunotherapeutics</i> 15(78): 1541-1543	- Editorial. References checked for eligible studies
Galea, Jerome T, Monsour, Emmi, Nurena, Cesar R et al. (2017) HPV vaccine knowledge and acceptability among Peruvian men who have sex with men and transgender women: A pilot, qualitative study. <i>PloS one</i> 12(2): e0172964	- Non-OECD country
Gerend, Mary A, Madkins, Krystal, Phillips, Gregory 2nd et al. (2016) Predictors of Human Papillomavirus Vaccination Among Young Men Who Have Sex With Men. <i>Sexually transmitted diseases</i> 43(3): 185-91	- Cross-sectional study on predictors of HPV vaccine
Gilbert, L K, Levandowski, B A, Scanlon, K E et al. (2010) A comparison of hepatitis A and hepatitis B measures among vaccinated and susceptible online men who have sex with men. <i>International journal of STD & AIDS</i> 21(6): 400-5	- Surveillance data. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Gilbert, Paul A; Brewer, Noel T; Reiter, Paul L (2011) Association of human papillomavirus-related knowledge, attitudes, and beliefs with HIV status: a national study of gay men. <i>Journal of lower genital tract disease</i> 15(2): 83-8	- Cross-sectional study on knowledge, attitudes and beliefs
Gilbert, Paul, Brewer, Noel T, Reiter, Paul L et al. (2011) HPV vaccine acceptability in heterosexual, gay, and bisexual men. <i>American journal of men's health</i> 5(4): 297-305	- Cross-sectional study on HPV vaccine acceptability
Giuliani, Massimo, Vescio, Maria Fenicia, Dona, Maria Gabriella et al. (2016) Perceptions of Human Papillomavirus (HPV) infection and acceptability of HPV vaccine among men attending a sexual health clinic differ according to sexual orientation. <i>Human vaccines & immunotherapeutics</i> 12(6): 1542-50	- Cross-sectional study on perceptions of HPV and acceptability of vaccine
Gorbach, Pamina M, Cook, Ryan, Gratzner, Beau et al. (2017) Human Papillomavirus Vaccination Among Young Men Who Have Sex With Men and Transgender Women in 2 US Cities, 2012-2014. <i>Sexually transmitted diseases</i> 44(7): 436-441	- Cross-sectional study. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Grace, D., Gaspar, M., Rosenes, R. et al. (2019) Economic barriers, evidentiary gaps, and ethical conundrums: A qualitative study of physicians' challenges recommending HPV vaccination to older gay, bisexual, and other men who have sex with men. <i>International Journal for Equity in Health</i> 18(1): 159	- Study on cost implications of recommending HPV vaccination. Not addressing UK context

Study	Reason
Groene, E.A., Mohammed, I., Horvath, K. et al. (2019) Online media scans: Applying systematic review techniques to assess statewide human papillomavirus vaccination activities. <i>Journal of Public Health Research</i> 8(2): 1623	- Literature review. References checked for eligible studies
Gutierrez, Baudelio Jr, Leung, Anthony, Jones, Kevin Trimell et al. (2013) Acceptability of the human papillomavirus vaccine among urban adolescent males. <i>American journal of men's health</i> 7(1): 27-36	- Mixed sample of MSM and heterosexual men. Themes were not reported separately by group (although quotes for each theme were provided separately)
Halkitis, Perry N, Valera, Pamela, LoSchiavo, Caleb E et al. (2019) Human Papillomavirus Vaccination and Infection in Young Sexual Minority Men: The P18 Cohort Study. <i>AIDS patient care and STDs</i> 33(4): 149-156	- Cohort. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Hernandez, Brenda Y, Wilkens, Lynne R, Thompson, Pamela J et al. (2010) Acceptability of prophylactic human papillomavirus vaccination among adult men. <i>Human vaccines</i> 6(6): 467-75	- Prospective cohort. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM. Mixed population
Hidalgo-Tenorio, Carmen, Ramirez-Taboada, Jessica, Gil-Anguita, Concepcion et al. (2017) Safety and immunogenicity of the quadrivalent human papillomavirus (qHPV) vaccine in HIV-positive Spanish men who have sex with men (MSM). <i>AIDS research and therapy</i> 14: 34	- RCT. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Hoefler, Lea, Tsikis, Savas, Bethimoutis, George et al. (2018) HPV vaccine acceptability in high-risk Greek men. <i>Human vaccines & immunotherapeutics</i> 14(1): 134-139	- Cross-sectional study on perceptions of HPV and acceptability of vaccine
Hoover, Karen W, Butler, Mary, Workowski, Kimberly A et al. (2012) Low rates of hepatitis screening and vaccination of HIV-infected MSM in HIV clinics. <i>Sexually transmitted diseases</i> 39(5): 349-53	- Surveillance data. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Houlihan, Catherine F, Larke, Natasha L, Watson-Jones, Deborah et al. (2012) Human papillomavirus infection and increased risk of HIV acquisition. A systematic review and meta-analysis. <i>AIDS (London, England)</i> 26(17): 2211-22	- Systematic review. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM. References checked for eligible studies
Jones, Jeff, Parrish, Adam, Collins, Tom et al. (2016) HPV vaccine acceptance among a sample of Southern men who have sex with men: A comparison of younger and older men. <i>Journal of Gay & Lesbian Social Services: The Quarterly Journal of Community & Clinical Practice</i> 28(3): 245-254	- Survey on vaccine acceptability. Not qualitative

Study	Reason
Juvet, Lene K., Saeterdal, Ingvil, Couto, Elisabeth et al. (2015) No title provided.	- Editorial. References checked for eligible studies
King, Eleanor M, Oomeer, Soonita, Gilson, Richard et al. (2016) Oral Human Papillomavirus Infection in Men Who Have Sex with Men: A Systematic Review and Meta-Analysis. PloS one 11(7): e0157976	- Systematic review. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM. References checked for eligible studies
Kourkounti, Sofia, Papparizos, Vassilios, Leuow, Kirsten et al. (2015) Adherence to hepatitis A virus vaccination in HIV-infected men who have sex with men. International journal of STD & AIDS 26(12): 852-6	- Retrospective cohort study. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Lau, Joseph T F, Wang, Zixin, Kim, Jean H et al. (2013) Acceptability of HPV vaccines and associations with perceptions related to HPV and HPV vaccines among men who have sex with men in Hong Kong. PloS one 8(2): e57204	- Non-OECD country
Lee Mortensen, Gitte and Larsen, Helle K (2010) Quality of life of homosexual males with genital warts: a qualitative study. BMC research notes 3: 280	- Qualitative. Not on barriers and facilitators
Lee, S.-J., Newman, P.A., Duan, N. et al. (2014) Development of an HIV vaccine attitudes scale to predict HIV vaccine acceptability among vulnerable populations: L.A. VOICES. Vaccine 32(39): 5013-5018	- Surveillance data. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Looker, Katharine J, Ronn, Minttu M, Brock, Patrick M et al. (2018) Evidence of synergistic relationships between HIV and Human Papillomavirus (HPV): systematic reviews and meta-analyses of longitudinal studies of HPV acquisition and clearance by HIV status, and of HIV acquisition by HPV status. Journal of the International AIDS Society 21(6): e25110	- Systematic review. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM. References checked for eligible studies
Lott, Breanne E., Okusanya, Babasola O., Anderson, Elizabeth J. et al. (2020) Interventions to increase uptake of Human Papillomavirus (HPV) vaccination in minority populations: A systematic review. Preventive Medicine Reports 19: 101163	- Literature review. References checked for eligible studies
Mangen, M-J J, Stibbe, H, Urbanus, A et al. (2017) Targeted outreach hepatitis B vaccination program in high-risk adults: The fundamental challenge of the last mile. Vaccine 35(24): 3215-3221	- Study on cost analysis
Marra, E, Alberts, C J, Zimet, G D et al. (2016) HPV vaccination intention among male clients of a large STI outpatient clinic in Amsterdam, the Netherlands. Papillomavirus research (Amsterdam, Netherlands) 2: 178-184	- Cross-sectional study. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM

Study	Reason
McGrath, Launcelot, Fairley, Christopher K, Cleere, Eoin F et al. (2019) Human papillomavirus vaccine uptake among young gay and bisexual men who have sex with men with a time-limited targeted vaccination programme through sexual health clinics in Melbourne in 2017. <i>Sexually transmitted infections</i> 95(3): 181-186	- Retrospective cohort study. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Mclver, R., Dyda, A., Knight, V. et al. (2015) Hepatitis B screening and vaccination: How does a Sexual Health service measure up?. <i>Sexual Health</i> 12(5): 458-459	- Editorial. References checked for eligible studies
Mclver, Ruthy, Dyda, Amalie, McNulty, Anna M et al. (2016) Text message reminders do not improve hepatitis B vaccination rates in an Australian sexual health setting. <i>Journal of the American Medical Informatics Association : JAMIA</i> 23(e1): e88-92	- Before and after study design on text message reminders to improve Hep B vaccination. Not a controlled trial
McRee, Annie-Laurie, Reiter, Paul L, Chantala, Kim et al. (2010) Does framing human papillomavirus vaccine as preventing cancer in men increase vaccine acceptability?. <i>Cancer epidemiology, biomarkers & prevention : a publication of the American Association for Cancer Research, cosponsored by the American Society of Preventive Oncology</i> 19(8): 1937-44	- Survey on vaccine acceptability. Not qualitative
McRee, Annie-Laurie, Shoben, Abigail, Bauermeister, Jose A et al. (2018) Outsmart HPV: Acceptability and short-term effects of a web-based HPV vaccination intervention for young adult gay and bisexual men. <i>Vaccine</i> 36(52): 8158-8164	- RCT. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Meites, Elissa, Markowitz, Lauri E, Paz-Bailey, Gabriela et al. (2014) HPV vaccine coverage among men who have sex with men - National HIV Behavioral Surveillance System, United States, 2011. <i>Vaccine</i> 32(48): 6356-9	- Cross-sectional study. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Metheny, Nicholas and Stephenson, Rob (2016) Disclosure of Sexual Orientation and Uptake of HIV Testing and Hepatitis Vaccination for Rural Men Who Have Sex With Men. <i>Annals of family medicine</i> 14(2): 155-8	- Surveillance data. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Nadarzynski, Tom, Miller, Danny, Frost, Miles et al. (2021) Vaccine acceptability, uptake and completion amongst men who have sex with men: A systematic review, meta-analysis and theoretical framework. <i>Vaccine</i>	- Literature review. References checked for eligible studies
Nadarzynski, Tom, Smith, Helen E, Richardson, Daniel et al. (2015) Sexual healthcare professionals' views on HPV vaccination for men in the UK. <i>British journal of cancer</i> 113(11): 1599-601	- Survey on health professionals' views. Not qualitative
Nadarzynski, Tom, Smith, Helen, Richardson, Daniel et al. (2018) Men who have sex with men who do not access sexual health clinics nor disclose sexual orientation are unlikely to receive the HPV vaccine in the UK. <i>Vaccine</i> 36(33): 5065-5070	- Cross-sectional study. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM

Study	Reason
Nadarzynski, Tom, Smith, Helen, Richardson, Daniel et al. (2014) Human papillomavirus and vaccine-related perceptions among men who have sex with men: a systematic review. <i>Sexually transmitted infections</i> 90(7): 515-23	- Systematic review. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM. References checked for eligible studies
Oliver, Sara E, Hoots, Brooke E, Paz-Bailey, Gabriela et al. (2017) Increasing Human Papillomavirus Vaccine Coverage Among Men Who Have Sex With Men-National HIV Behavioral Surveillance, United States, 2014. <i>Journal of acquired immune deficiency syndromes (1999)</i> 75suppl3: 370-s374	- Surveillance data. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Onyeabor, Onyekachi S, Martin, Nicolle, Orish, Verner N et al. (2015) Awareness of Human Papillomavirus Vaccine Among Adolescent African American Males Who Have Sex with Males: a Pilot Study. <i>Journal of racial and ethnic health disparities</i> 2(3): 290-4	- Qualitative themes not reported
Ou, Lihong and Youngstedt, Shawn D. (2020) The Role of Vaccination Interventions to Promote HPV Vaccine Uptake Rates in a College-Aged Population: a Systematic Review. <i>Journal of cancer education : the official journal of the American Association for Cancer Education</i>	- Literature review. References checked for eligible studies
Palefsky, Joel M, Giuliano, Anna R, Goldstone, Stephen et al. (2011) HPV vaccine against anal HPV infection and anal intraepithelial neoplasia. <i>The New England journal of medicine</i> 365(17): 1576-85	- RCT. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Pollock, K.G., Wallace, L.A., Wigglesworth, S. et al. (2019) HPV vaccine uptake in men who have sex with men in Scotland. <i>Vaccine</i> 37(37): 5513-5514	- Editorial. References checked for eligible studies
Rank, Claudia, Gilbert, Mark, Ogilvie, Gina et al. (2012) Acceptability of human papillomavirus vaccination and sexual experience prior to disclosure to health care providers among men who have sex with men in Vancouver, Canada: implications for targeted vaccination programs. <i>Vaccine</i> 30(39): 5755-60	- Survey on vaccine acceptability. Not qualitative
Reiter, P.L., McRee, A.-L., Katz, M.L. et al. (2015) Human papillomavirus vaccination among young adult gay and bisexual men in the United States. <i>American Journal of Public Health</i> 105(1): 96-102	- Survey on vaccine acceptability. Not qualitative
Reiter, Paul L, Brewer, Noel T, McRee, Annie-Laurie et al. (2010) Acceptability of HPV vaccine among a national sample of gay and bisexual men. <i>Sexually transmitted diseases</i> 37(3): 197-203	- Survey on vaccine acceptability. Not qualitative
Reiter, Paul L, Katz, Mira L, Bauermeister, Jose A et al. (2017) Recruiting Young Gay and Bisexual Men for a Human	- Editorial. Main study included

Study	Reason
Papillomavirus Vaccination Intervention Through Social Media: The Effects of Advertisement Content. JMIR public health and surveillance 3(2): e33	
Sadler, C, Lynam, A, O'Dea, S et al. (2016) HPV vaccine acceptability in HIV-infected and HIV negative men who have sex with men (MSM) in Ireland. Human vaccines & immunotherapeutics 12(6): 1536-41	- Survey on vaccine acceptability. Not qualitative
Said, A. and Jou, J.H. (2014) Hepatitis B vaccination and screening awareness in primary care practitioners. Hepatitis Research and Treatment 2014: 373212	- Survey on health professionals' views. Not qualitative
Sauvageau, Chantal and Dufour-Turbis, Christine (2016) HPV vaccination for MSM: Synthesis of the evidence and recommendations from the Quebec Immunization Committee. Human vaccines & immunotherapeutics 12(6): 1560-5	- Literature review. References checked for eligible studies
Segura, Marcela, Bautista, Christian T, Marone, Ruben et al. (2010) HIV/STI co-infections, syphilis incidence, and hepatitis B vaccination: the Buenos Aires cohort of men who have sex with men. AIDS care 22(12): 1459-65	- Non-OECD country
Seto, Katherine, Marra, Fawziah, Raymakers, Adam et al. (2012) The cost effectiveness of human papillomavirus vaccines: a systematic review. Drugs 72(5): 715-43	- Systematic review. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM. References checked for eligible studies
Siconolfi, Daniel E; Halkitis, Perry N; Rogers, Meighan E (2009) Hepatitis vaccination and infection among gay, bisexual, and other men who have sex with men who attend gyms in New York City. American journal of men's health 3(2): 141-9	- Cross-sectional study. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Solomon, Marc M, Schechter, Mauro, Liu, Albert Y et al. (2016) The Safety of Tenofovir-Emtricitabine for HIV Pre-Exposure Prophylaxis (PrEP) in Individuals With Active Hepatitis B. Journal of acquired immune deficiency syndromes (1999) 71(3): 281-6	- RCT. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Storholm, Erik David, Fisher, Dennis G, Reynolds, Grace L et al. (2010) Hepatitis vaccination of men who have sex with men at gay pride events. Prevention Science 11(2): 219-227	- Prospective cohort. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM. Mixed population
Tsachouridou, O., Georgiou, A., Naoum, S. et al. (2019) Factors associated with poor adherence to vaccination against hepatitis viruses, streptococcus pneumoniae and seasonal influenza in HIV-infected adults. Human Vaccines and Immunotherapeutics 15(2): 295-304	- Before and after study design on adherence. Not controlled trial

Study	Reason
Vet, R; de Wit, J B F; Das, E (2011) The efficacy of social role models to increase motivation to obtain vaccination against hepatitis B among men who have sex with men. Health education research 26(2): 192-200	- RCT. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Vet, Raymond; de Wit, John Bf; Das, Enny (2017) Factors associated with hepatitis B vaccination among men who have sex with men: a systematic review of published research. International journal of STD & AIDS 28(6): 534-542	- Systematic review. References checked for eligible studies
Wheldon, Christopher W (2016) HPV vaccine decision-making among male sexual minorities: An integrative theoretical framework for vaccine promotion. Dissertation Abstracts International: Section B: The Sciences and Engineering 76(9be): no-specified	- Dissertation. References checked for eligible studies
Wheldon, Christopher W, Daley, Ellen M, Buhi, Eric R et al. (2011) Health beliefs and attitudes associated with HPV vaccine intention among young gay and bisexual men in the Southeastern United States. Vaccine 29(45): 8060-5	- Cross-sectional study. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Wheldon, Christopher W, Sutton, Steven K, Fontenot, Holly B et al. (2018) Physician Communication Practices as a Barrier to Risk-Based HPV Vaccine Uptake Among Men Who Have Sex with Men. Journal of cancer education : the official journal of the American Association for Cancer Education 33(5): 1126-1131	- Cross-sectional study. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Wielding, Sally; Ma, Andy Hy; Clutterbuck, Daniel J (2016) An audit of hepatitis B vaccination for men who have sex with men before and after sexual health service integration. International journal of STD & AIDS 27(10): 898-900	- Audit. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Xavier, Martinez-Gomez, Curran, A., Campins, M. et al. (2019) Multidisciplinary, evidence-based consensus guidelines for human papillomavirus (HPV) vaccination in highrisk populations, Spain, 2016. Eurosurveillance 24(7): 1700857	- Guideline on the effects of HPV vaccination on high risk groups
Zhang, S X, Shoptaw, S, Reback, C J et al. (2018) Cost-effective way to reduce stimulant-abuse among gay/bisexual men and transgender women: a randomized clinical trial with a cost comparison. Public health 154: 151-160	- RCT. Not on interventions to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM
Zou, Huachun, Grulich, Andrew E, Cornall, Alyssa M et al. (2014) How very young men who have sex with men view vaccination against human papillomavirus. Vaccine 32(31): 3936-41	- Survey on vaccine acceptability. Not qualitative

Appendix L – Research recommendations – full details

L.1.1 Research recommendation

What are the barriers to completing the full course of hepatitis A and B or HPV vaccinations and how do people think they might be encouraged to complete it?

L.1.2 Why this is important

The committee discussed the lack of evidence for interventions to facilitate vaccine completion for gay, bisexual and other men who have sex with men and emphasised the importance of people having all doses of the vaccine to be fully protected. They agreed that both the quantitative and qualitative evidence focused largely on vaccine initiation so there was an evidence gap relating to vaccine completion. They considered that understanding the barriers to vaccine course completion would help to support eligible gay, bisexual and other men who have sex with men to have all vaccine doses to obtain full protection.

L.1.3 Rationale for research recommendation

Importance to 'patients' or the population	The overall effectiveness of HPV vaccination in reducing HPV-related diseases is affected by delayed or incomplete vaccination. Similarly, for hepatitis A and B vaccinations, evidence shows optimal seroprotection requires receipt of all recommended doses. It is therefore important that people who are eligible for these vaccinations complete the full course.
Relevance to NICE guidance	The committee was unable to recommend specific interventions to facilitate vaccination completion and agreed this was a gap in the guideline they would like to address in future versions.
Relevance to the NHS	The outcome would affect interventions to increase vaccine completion rates in MSM which would reduce the overall burden on the health system.
National priorities	DHSC will publish a new sexual health strategy in winter 2021
Current evidence base	Two studies (Bass 2021, Reiter 2018) provided low quality evidence from the US on vaccine completion but both had short follow-up periods that may have been insufficient for participants to obtain the full vaccine course
Equality considerations	Supporting gay, bisexual and other men who have sex with men to obtain vaccinations may reduce inequalities

SPIDER table

Setting	Non-clinical setting
Phenomenon of interest	Barriers to hepatitis A, hepatitis B, and HPV vaccine completion in MSM and how to overcome them
Design	Interviews or focus groups

Evaluation	Target groups experiences and beliefs about vaccine completion, barriers they have encountered, and how to overcome them
Research design	Qualitative