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## Recommending HPV Vaccine to PrEP Patients in Primary Care: Patient Perspectives

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## Recommending HPV Vaccine to PrEP Patients in Primary Care: Patient Perspectives

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## Abstract

**Objectives:** Men who have sex with men (MSM) who use pre-exposure prophylaxis (PrEP) have not traditionally been targets for HPV vaccine programs, despite their high risk for HPV-related cancers and HPV vaccine being FDA approved for people up to age 45. The objective of this study was to assess attitudes and barriers towards HPV vaccine for adult PrEP users in the primary care context.

**Methods:** Semi-structured phone interviews of 16 primary care patients taking PrEP in the Kansas City metropolitan area were conducted, with interviews assessing HPV vaccination status, and attitudes, beliefs, and perceived barriers surrounding HPV vaccine. Interview notes were open-coded by student authors, and themes were generated through code review and consensus.

**Results:** The results showed that most patients believed that preventative health was important and felt the HPV vaccine was important. Most patients were open to vaccination if recommended by their primary care physician and covered by insurance. Most participants believed HPV infection to be far worse in women, and there were gaps in knowledge surrounding HPV and its effects in men.

**Conclusions:** While more research is needed to better understand facilitators of a linkage between PrEP and HPV vaccine in clinical settings for groups at high risk of HPV-related cancers, getting primary care providers involved in educating high risk patients about the importance of HPV vaccine and actively recommending vaccine to those patients has the potential to prevent HPV-related cancers.

**Keywords:** HPV, Papillomavirus Infections, Papillomavirus Vaccines, Pre-exposure Prophylaxis, Sexual and Gender Minorities, Vaccination

### STRENGTHS AND LIMITATIONS

- Major strengths: interviewers were blinded to participant health information; interview questions were modeled from previous studies; interview was scripted and semi-structured; and thematic saturation achieved.
- Major limitations: small sample size, mostly from one PCP; no formal recordings or transcripts; six separate interviewers, which may affect participant responses and recorded notes; low external validity.
- Important limitation to note: lack of outreach to underserved and marginalized populations, which resulted in a lack of diversity in the sample.

## INTRODUCTION

Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States.<sup>1</sup> Almost every American who is sexually active will get HPV at some point in their life if they do not receive HPV vaccine.<sup>1</sup> Men who have sex with men (MSM) are at especially high risk for developing cancers from HPV. Studies have found that this population has up to 40 times the risk of developing anal cancer when compared with the general population.<sup>2,3</sup> An underlying human immunodeficiency virus (HIV) infection compounds the already heightened risk for HPV-related cancer, and the increased risk of HIV in this population increases the risk for HPV and related cancers.<sup>4</sup> Furthermore, out of any population, HIV-positive MSM have the highest risk of anal cancer, as well as significantly higher risk of HPV-related oropharyngeal cancers.<sup>5</sup> Despite these findings, little research exists on cancer prevention in the form of HPV vaccine for this specific population.

In 2009, three years after HPV vaccine was recommended for the prevention of cervical cancer in adolescent females, the Advisory Committee on Immunization Practices (ACIP) issued a recommendation that HPV vaccine also be administered to adolescent males.<sup>6</sup> Further research found the vaccine to be effective for adults, even those already exposed to HPV.<sup>7</sup> In 2018, the FDA approved HPV vaccine for adults up to age 45.<sup>8</sup> Although HPV vaccine is efficacious for prevention of anal and oropharyngeal cancer,<sup>9</sup> males (particularly adults) have problematically low vaccination rates. As of 2016, less than three percent of males 30 years and older had received at least one dose of HPV vaccine.<sup>10</sup> Barriers to HPV vaccination for MSM include: minimal awareness of health consequences to men from HPV, little to no awareness of HPV vaccination availability for adults, and lack of insurance or access to healthcare.<sup>11</sup> Particularly

troubling is the fact that young MSM have low perceived risk from HPV.<sup>12</sup> This underscores the need to further educate both providers and patients about HPV vaccination and how to access it.

Widespread use of HIV pre-exposure prophylaxis (PrEP) among MSM in certain demographic groups suggests an existing culture of prevention in that MSM are motivated to accept and use pharmaceutical technologies to prevent disease.<sup>13,14</sup> However, the high prevalence of preventable HPV-related cancers reflects the failure of healthcare thus far to leverage this culture of prevention and expand immunization. In fact, only 2.7% of MSM respondents to the National HIV Behavioral Surveillance System reported receiving one or more doses of HPV vaccine.<sup>15</sup> Given the risks for HPV-related cancers among MSM, coupled with elevated risks for contracting HIV, linking preventative strategies represents an important avenue of study.

Primary care clinics have an incredible opportunity to increase HPV vaccination rates and affect HPV-related complications in their communities. Previous studies have shown that clinic initiatives to improve HPV vaccination rates by strongly recommending the vaccine to eligible patients have been successful.<sup>16</sup> This is likely to be especially true when HPV vaccine recommendation is paired with PrEP prescribing.

There are many parallels between access issues to PrEP and HPV vaccination among MSM, including lack of provider awareness about current guidelines and lack of insurance coverage.<sup>17,18</sup> Addressing these barriers, as well as the gap in the literature surrounding co-administration of HPV vaccination with PrEP treatment, is vital. This study aims to add to the literature by assessing the perceptions of PrEP patients of HPV vaccine and determining any potential barriers to linkage and, ultimately, reducing the incidence of HPV-related cancers in high-risk populations.



## METHODS

This study aimed to determine the attitudes, beliefs, and barriers of primary care patients on PrEP towards HPV vaccine. The study was approved by the IRB at the [BLINDED, AUTHORS' INSTITUTION] (IRB #: STUDY00145228). Sixteen interviews were completed (n=16). Inclusion criteria was status as a PrEP patient in the two family medicine clinics where recruitment occurred. Primary care clinics were chosen for recruitment, given the potential of future intervention in that setting. There were no exclusion criteria. Participants were selected through convenience sampling due to the physicians' roles as co-investigators in the study and because of the relationship and trust they had already built with their patients. Medical and graduate public health students collected data and were able to refer to their relationship with the academic medical center, as well as with the primary care physicians.

The same script was used by all six interviewers. Interviews were not audio-recorded; interviewers took notes instead in order to maintain confidentiality and rapport. Data were entered in REDCap, a secure research platform. Data were then downloaded into Microsoft Excel for analysis. Questions covered three domains: 1) demographics (age, education level, ethnicity/race, gender, sexual orientation, and health insurance); 2) HPV vaccine status; and 3) patients' attitudes, beliefs, and perceived barriers towards HPV vaccination. The questions were modeled after previous studies about HIV-positive MSM's knowledge and perceptions of HPV,<sup>19</sup> as well as incarcerated women's engagement with cervical cancer prevention.<sup>20</sup> The interviews also included an intervention component in the form of contacting either of the primary care physicians on the team if a patient was interested in receiving HPV vaccine after the interview.

Participants were recruited through 1) cold calls made by the research team using a secure phone app, 2) flyers distributed at in-person visits, or 3) messages sent by clinic nurses

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through patient charts. These recruitment strategies were selected because of the COVID-19 pandemic, which meant the team could not recruit in person. If participants were called directly, a scripted voicemail was left on the first call if it was not answered. If a potential participant was given a flyer or sent a chart message, they emailed the research team, who then called the participant to conduct the interview. Of the potential participants who were contacted (n=23), 69.6% participated (n=16).

The data underwent qualitative analysis in the form of inductive coding and subsequent development of themes. The primary exposure was PrEP user status. The primary outcome was attitudes, beliefs, and perceived barriers toward HPV vaccination. The research team reviewed the first 11 interviews individually and determined potential codes, subsequently collectively deciding on 16 codes. Next, the team collectively reviewed code occurrence in the data and determined three overarching themes. The five subsequent interviews were analyzed in relation to the 16 codes to look for thematic saturation. The themes were determined to be the same across all 16 interviews. The research team then pulled quotes to support the themes. The goal was to complete as many interviews as possible in order to perform an exploratory study, rather than to reach thematic saturation. However, thematic saturation was reached.

### Patient and Public Involvement

No patient involved. Patients and the public were not involved in the design, conduct, or dissemination of this research, as this was a preliminary, exploratory study to determine early attitudes and perceptions.

## RESULTS

All participants were between ages 23 and 55 years old, with a mean age of 36 years old. All participants were male, with one participant identifying as transgender male. Fifteen

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participants (93.75%) identified as gay, and one participant identified as bisexual (6.25%). All participants had at least some college education, with the majority (n=14, 87.5%) completing at least a four-year college degree. All participants were insured, with the majority (n=11, 68.75%) covered by Blue Cross Blue Shield (BCBS). The majority of the participants identified as White/Caucasian (n=14, 87.5%), with 12.5% (n=2) identifying as Black/African American. The same number of participants were vaccinated as were unvaccinated (n=7, 43.75%), with 12.5% (n=2) participants unsure of their vaccination status. Further demographic information for the participants is listed in Table 1.

**Table 1: Demographics and HPV vaccination status of 16 primary care patients taking PrEP**

<i>Variables</i>	<i>n (%)</i>
Age group	
<30	7 (43.75%)
30-45	5 (31.25%)
>45	4 (25%)
Highest level of education completed	
Some college	2 (12.5%)
Undergraduate college degree	7 (43.75%)
Post graduate degree	7 (43.75%)
Ethnicity / Race	
White/Caucasian	14 (87.5%)
Black/African American	2 (12.5%)
Gender identity	
Male	15 (93.75%)
Transgender male	1 (6.25%)
Sexual Orientation	
Gay/homosexual	15 (93.75%)
Bisexual	1 (6.25%)
Insurance Status	
Insured	16 (100%)
Insurance Provider	
BCBS	11 (68.75%)
Cigna	1 (6.25%)
GEHA	1 (6.25%)
United	1 (6.25%)

<b>Ambetter</b>	1 (6.25%)
<b>Not answered</b>	1 (6.25%)
Vaccination Status	
<b>Vaccinated</b>	7 (43.75%)
<b>Unvaccinated</b>	7 (43.75%)
<b>Unsure</b>	2 (12.5%)

Of those patients who were vaccinated (n=7), 86% (n=6) were vaccinated 5 or more years ago. As no vaccinated participant was over age 30 at the time of their interview, (M=27 years old), no participants were vaccinated under the new guidelines extending vaccination to age 45. Rather, vaccinated participants received HPV vaccine when they were younger than the initial guideline age of 26. Of the seven participants who were vaccinated, 71% (n=5) stated that they did so because of a doctor's recommendation. One did so because he felt he should as a gay man at higher risk for HPV. Another did so at as a teenager because his parents wanted him to.

Sixteen codes were determined and used: female/women; why not/no reason not to; cancer; warts; recommended; sexual activity; STD/STI; preventative; vaccine; HPV is dangerous; I don't know/not sure; insurance; research; doctor; important; age. These codes led to creation of three major themes in the three domains of attitudes, beliefs, and barriers. The themes were: 1) there is a commitment to preventative health, 2) there are gaps in knowledge about HPV risks and immunization options, and 3) other barriers include age, lack of doctor recommendation, and lack of insurance coverage. Supporting quotes for each theme are listed in Table 2.

**Table 2: Themes and supporting quotes from interviews about HPV vaccine with 16 primary care patients taking PrEP**

<i>Domain</i>	<i>Theme</i>	<i>Supporting Quotes</i>
<b>Attitudes</b>	There is a commitment to preventative health	"Anything that prevents cancer is a good thing." -56 years old, unvaccinated

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		<p>“All vaccines are extremely important.” -27 years old, vaccinated</p> <p>“[There is] peace of mind that you are protecting yourself to the extent you can.” -43 years old, unsure of vaccination status</p> <p>“Sex is universal, everyone is having sex. To be safe everyone should get it.” -23 years old, vaccinated</p> <p>“I like knowing it is another safeguard/layer of protection, similar to PrEP as a level of protection... It is another way to protect myself.” – 29 years old, unvaccinated (with appointment scheduled to get vaccinated)</p>
<b>Beliefs</b>	There are gaps in knowledge about HPV risks and immunization options	<p>“I don't really know anything. I think the effects are worse in females than males.” -30 years old, vaccinated</p> <p>“You can get genital warts. It can be very deadly for women if they get it.” - 26 years old, unvaccinated</p> <p>“It causes warts also known as crabs.” -23 years old, vaccinated</p> <p>“Males are generally asymptomatic, though if they have it, they can spread to women who can have cervical cancer. I don't really know.” – 30 years old, vaccinated</p> <p>“It is something that is mainly an issue for girls, but I don't know much about the virus specifically or what it does.” – 29 years old, vaccinated</p>
<b>Barriers</b>	The largest potential barriers are age/lack of knowledge around new age guidelines, lack of doctor recommendation, and lack of insurance coverage	<p>“[The only barrier would be] my doctor not recommending it.” 51 years old, unsure of vaccinated status</p> <p>“[The only barrier would be] age. I did not know you could get it now, last I heard vaccine cut off was 26.” - 29 years old, vaccinated</p>

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		<p>“[The only barrier would be] if I didn't have any insurance or ability to pay for it.” – 23 years old, vaccinated</p> <p>“I happen to be outside the age bracket, so it wouldn't apply specifically to me.” - 55 years old, unvaccinated</p> <p>“I didn't even know I could get it. I thought I was too old now.” – 29 years old, unvaccinated, (with appointment scheduled to get vaccinated)</p>
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The first theme revealed a commitment to preventative health. Participants viewed HPV vaccine very favorably. They saw HPV vaccine as part of a preventative health package, and consistently rated it as highly important to overall health. Participants found peace of mind in the knowledge that they could further protect themselves from disease, especially disease from such a common act as sex.

The second theme revealed gaps in knowledge about HPV risks and immunization options. Participants held a variety of beliefs about HPV and its consequences. The majority of participants had inaccurate ideas about infection with HPV, particularly for males. Participants generally believed that males had little to no consequences from HPV infection. The main concern regarded transmitting HPV to females. This belief about HPV is especially concerning for MSM. If they are not engaging in sexual relations with females, they may see no harm in infection with HPV due to the lack of risk of passing it to females.

The third theme was that the largest potential barriers are age/lack of knowledge around new age guidelines, lack of doctor recommendation, and lack of insurance coverage. Participants were unaware that age guidelines were extended to age 45. Some participants aged out without receiving HPV vaccine. This is concerning for other high-risk patients who may be nearing age

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3 45 but are unaware they are still eligible for vaccination. Participants stated receiving HPV  
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5 vaccine was contingent on insurance coverage. They also stated that they may not get vaccinated  
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7 if a doctor did not recommend it. This shows the weight of provider recommendation, as well as  
8  
9 the importance of knowledge about insurance coverage options.

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12 Six patients received the intervention component and were contacted to schedule  
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14 appointments for HPV vaccination. This was 37.5% of the study population and 85.7% of the  
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16 unvaccinated study population. The only participant who declined to be contacted for HPV  
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18 vaccination was over age 45 and ineligible for vaccination. Therefore, 100% of eligible  
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20 unvaccinated participants elected to be contacted to schedule HPV vaccination.  
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**DISCUSSION**

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26 The results of this study augment the sparse, albeit promising, literature about  
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28 combination of HPV vaccine and PrEP therapy for at-risk populations. A cross-sectional survey  
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30 was administered to MSM seen for PrEP consultations throughout Orléans, France.<sup>21</sup> The mean  
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32 age in this study was 36 years old, identical to that of our study. The study prevalence of HPV  
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34 was 93.4%, with prevalence of high cancer risk HPV subtypes being 81.9%.<sup>21</sup> Authors  
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36 recommended including HPV vaccination as primary prevention among HIV-negative MSM  
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38 utilizing PrEP.<sup>21</sup> In another study, a global systematic review examined HPV type distribution in  
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40 anal cancer and anal intraepithelial lesions.<sup>22</sup> The results suggest that prophylactic HPV vaccine  
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42 administration could prevent up to two-thirds of anal cancer and lesions in both women and  
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44 men.<sup>22</sup>  
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49  
50 The results from our study further support the feasibility of HPV vaccine administration  
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52 to high-risk populations. Although participants lacked knowledge about the severity of HPV  
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54 infection in males, they still felt that HPV vaccine was highly important. Once participants  
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learned that the guidelines had been extended for HPV vaccination, they overwhelmingly wanted to receive the vaccine if they had not already. This is a promising sign for generalizing to other populations who may have gaps in knowledge about HPV and its long-term adverse effects.

Even with limited knowledge about HPV, participants still saw HPV vaccine as an important part of a healthy lifestyle.

It is important to educate MSM about the risk of HPV infection in males. The study population was more highly educated than the general population and they still had large gaps in HPV knowledge. Increasing knowledge of HPV infection, its effects in men, and extended eligibility of the vaccine are all tantamount to increasing vaccination rates. It is also important that providers stay up to date on insurance eligibility so that patients get the vaccine covered, whether through a commercial insurance company, Medicaid, or a patient assistance program.

Although lack of knowledge about severity of HPV in males and the extended age guidelines for the vaccine were barriers, overall, these barriers did not keep many participants from vaccination once offered. Indeed, there were relatively few barriers to HPV vaccination in PrEP users younger than 45. For those not already vaccinated, the results from the intervention component of the study are extremely promising. All eligible unvaccinated participants elected to be contacted for HPV vaccination scheduling. This is hugely important for direct action that can help prevent cancer. It is also strong evidence that knowledge of eligibility leads to vaccination, at least in patients who are already invested in preventative sexual health in the form of PrEP use. Finally, it demonstrates the power of healthcare providers in encouraging patients to receive HPV vaccine.

This study had several major strengths: the interviewers were blinded to participant health information; the interview questions were modeled from previous studies; the interview



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was scripted and semi-structured; and thematic saturation achieved. However, the study also had several major limitations: the study had a small sample size; the majority of the sample size came from one PCP; there were no formal recordings or transcripts (due to privacy concerns); there were six interviewers, which may affect participant responses and recorded notes; and there was low external validity (all participants were PrEP users, had insurance, were well-educated, and therefore may not be representative of the broader population). An additional and important limitation was the lack of outreach to underserved and marginalized populations, which resulted in a lack of diversity in the sample.

**CONCLUSION**

It is important to recognize that PrEP users are interested in HPV vaccination. Based on this, as well as perceived barriers to vaccination, we have developed these specific recommendations: 1) Providers should capitalize on the interest in preventative medicine and should offer HPV vaccine to patients with initiation of PrEP; 2) Providers should include a patient's background on HPV and HPV vaccine status in the "After Visit Summary" for PrEP users; and 3) When PrEP is prescribed in the electronic medical record (EMR), the prescriber should be prompted to assess the patient's HPV vaccination status automatically. Patients listen to and trust their providers when it comes to preventative care recommendations. If providers take a moment to initiate a conversation about HPV vaccination and its benefits with patients, we may be able to increase HPV vaccination rates before patients age out of eligibility. By increasing understanding of HPV and HPV vaccine, we have the potential to significantly decrease the incidence of HPV-related cancers in high-risk populations.

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### Ethical Approval Statement

This study was approved by the IRB at the University of Kansas Medical Center (IRB #: STUDY00145228). Informed consent was obtained for experimentation with human subjects.

### Author Contribution Statement

Author ZSB was responsible for all drafts of this manuscript and conducting interviews. Senior author MR was responsible for conception of the study, securing funding, and editing the drafts. Student authors MB, RD, RN, HS, and SW were responsible, with ZSB, for writing sections of the manuscript and conducting interviews. Authors KS, CD, and PR worked with MR and ZSB on study design, conceptualization of the manuscript, and editing drafts prior to submission.

### Conflict of Interest/Disclosure Statement

No conflict of interest.

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## Standards for Reporting Qualitative Research (SRQR)\*

<http://www.equator-network.org/reporting-guidelines/srqr/>

Page no(s).

### Title and abstract

<p><b>Title</b> - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended</p>	1
<p><b>Abstract</b> - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</p>	2

### Introduction

<p><b>Problem formulation</b> - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement</p>	4-5
<p><b>Purpose or research question</b> - Purpose of the study and specific objectives or questions</p>	5

### Methods

<p><b>Qualitative approach and research paradigm</b> - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**</p>	6
<p><b>Researcher characteristics and reflexivity</b> - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability</p>	6
<p><b>Context</b> - Setting/site and salient contextual factors; rationale**</p>	6
<p><b>Sampling strategy</b> - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</p>	6-7
<p><b>Ethical issues pertaining to human subjects</b> - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues</p>	6; 15
<p><b>Data collection methods</b> - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**</p>	6

<b>Data collection instruments and technologies</b> - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	6
<b>Units of study</b> - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	7-8
<b>Data processing</b> - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	7
<b>Data analysis</b> - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	7
<b>Techniques to enhance trustworthiness</b> - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	7

### Results/findings

<b>Synthesis and interpretation</b> - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	7-9
<b>Links to empirical data</b> - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	9-11

### Discussion

<b>Integration with prior work, implications, transferability, and contribution(s) to the field</b> - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	11-12
<b>Limitations</b> - Trustworthiness and limitations of findings	13-14

### Other

<b>Conflicts of interest</b> - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	15
<b>Funding</b> - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	15

\*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.



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\*\*The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

**Reference:**

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014  
DOI: 10.1097/ACM.0000000000000388

For peer review only

# BMJ Open

## Original research: PrEP patient attitudes, beliefs, and perceived barriers surrounding HPV vaccination: a qualitative study of semi-structured interviews with PrEP patients in primary care clinics in Kansas and Missouri

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Keywords:	HIV & AIDS < INFECTIOUS DISEASES, SEXUAL MEDICINE, PUBLIC HEALTH, QUALITATIVE RESEARCH, PREVENTIVE MEDICINE

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## HPV Vaccine PrEP Patient Perspectives

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Original research: PrEP patient attitudes, beliefs, and perceived barriers surrounding HPV vaccination: a qualitative study of semi-structured interviews with PrEP patients in primary care clinics in Kansas and Missouri

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**Word Count:** 2,938

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## Abstract

**Objectives:** Men who have sex with men (MSM) who use pre-exposure prophylaxis (PrEP) have not traditionally been targets for HPV vaccine programs, despite their high risk for HPV-related cancers and HPV vaccine being FDA approved for people up to age 45. The objective of this study was to assess attitudes and barriers towards HPV vaccine for adult PrEP users in the primary care context.

**Methods:** Semi-structured phone interviews of 16 primary care patients taking PrEP in the Kansas City metropolitan area were conducted, with interviews assessing HPV vaccination status, and attitudes, beliefs, and perceived barriers surrounding HPV vaccine. Interview notes were open-coded by student authors, and themes were generated through code review and consensus. Data were then analyzed using thematic analysis.

**Results:** The results showed that most patients believed that preventative health was important and felt the HPV vaccine was important. Most patients were open to vaccination if recommended by their primary care physician and covered by insurance. Most participants believed HPV infection to be far worse in women, and there were gaps in knowledge surrounding HPV and its effects in men.

**Conclusions:** While more research is needed to better understand facilitators of a linkage between PrEP and HPV vaccine in clinical settings for groups at high risk for HPV-related cancers, getting primary care providers involved in educating high risk patients about the importance of HPV vaccination and actively recommending the vaccine to those patients has the potential to prevent HPV-related cancers.

**Keywords:** HPV, Papillomavirus Infections, Papillomavirus Vaccines, Pre-exposure Prophylaxis, Sexual and Gender Minorities, Vaccination

### STRENGTHS AND LIMITATIONS

- Major strengths: interviewers were blinded to participant health information; interview questions were modeled from previous studies; interview was scripted and semi-structured; and thematic saturation was achieved.
- Major limitations: small sample size, mostly from one PCP; no formal recordings or transcripts, which limits verbatim quotations; and six separate interviewers, which may have affected participant responses, recorded notes, and strength of interviewers in this topic.
- Important limitation to note: there was a lack of outreach to underserved and marginalized populations, which resulted in a lack of diversity in the sample, as well as low external validity.

## INTRODUCTION

Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States.<sup>1</sup> Almost every American who is sexually active will get HPV at some point in their life if they do not receive the HPV vaccine.<sup>1</sup> Men who have sex with men (MSM) are at especially high risk for developing cancers from HPV; incidence of anal cancer in particular in this population is significantly higher than in the general population.<sup>2,3</sup> An underlying human immunodeficiency virus (HIV) infection compounds the already heightened risk for HPV-related cancer, and the increased risk of HIV in this population increases the risk for HPV and related cancers.<sup>4</sup> Furthermore, out of any population, HIV-positive MSM have the highest risk of anal cancer, as well as significantly higher risk of HPV-related oropharyngeal cancers.<sup>5</sup> Despite these findings, little research exists on cancer prevention in the form of HPV vaccination for this specific population.

In 2009, three years after the HPV vaccine was recommended for the prevention of cervical cancer in adolescent females, the Advisory Committee on Immunization Practices (ACIP) issued a recommendation that the HPV vaccine also be administered to adolescent males.<sup>6</sup> Further research found the vaccine to be effective in some instances at preventing precancerous lesions and new HPV infection in adults, even those already exposed to HPV.<sup>7</sup> In 2018, the FDA approved the HPV vaccine for adults up to age 45.<sup>8</sup> This does not equate to universal recommendation for everyone age 27 and older, but it does support vaccination efforts for certain populations who had previously “aged out” of the vaccine. Although a large number of people have already been infected with HPV by age 27, the HPV vaccine is still beneficial to many people aged 27 and older as it can protect against new HPV infections.<sup>7</sup> The HPV vaccine



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3 is immunogenic in both women and men aged 27-45,<sup>8</sup> and numerous benefits outweigh the costs  
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5 of vaccination, especially in high-risk populations.  
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8 Although HPV vaccination is efficacious for prevention of anal and oropharyngeal  
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10 cancer,<sup>9</sup> males (particularly adults) have problematically low vaccination rates. As of 2016, less  
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12 than three percent of males 30 years and older had received at least one dose of the HPV  
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14 vaccine.<sup>10</sup> Barriers to HPV vaccination for MSM include: minimal awareness of health  
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16 consequences to men from HPV, little to no awareness of HPV vaccination availability for  
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18 adults, and lack of insurance or access to healthcare.<sup>11</sup> Particularly troubling is the fact that  
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20 young MSM have low perceived risk from HPV.<sup>12</sup> This underscores the need to further educate  
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22 both providers and patients about HPV vaccination and how to access it.  
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26 Widespread use of HIV pre-exposure prophylaxis (PrEP) among MSM in certain  
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28 demographic groups suggests an existing culture of prevention in that MSM are motivated to  
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30 accept and use pharmaceutical technologies to prevent disease.<sup>13,14</sup> However, the high prevalence  
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32 of preventable HPV-related cancers reflects the failure of healthcare thus far to leverage this  
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34 culture of prevention and expand immunization. As of 2017, 32.8% of MSM respondents to the  
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36 National HIV Behavioral Surveillance System reported receiving one or more doses of the HPV  
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38 vaccine.<sup>15</sup> Given the risks for HPV-related cancers among MSM, coupled with elevated risks for  
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40 contracting HIV, linking preventative strategies represents an important avenue of study.  
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45 Primary care clinics have an incredible opportunity to increase HPV vaccination rates and  
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47 affect HPV-related complications in their communities. Previous studies have shown that clinic  
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49 initiatives to improve HPV vaccination rates by strongly recommending the vaccine to eligible  
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51 patients have been successful.<sup>16</sup> This is likely to be especially true when HPV vaccination  
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53 recommendation is paired with PrEP prescribing.  
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There are many parallels between access issues to PrEP and HPV vaccination among MSM, including lack of provider awareness about current guidelines and lack of insurance coverage.<sup>17,18</sup> Addressing these barriers, as well as the gap in the literature surrounding co-administration of HPV vaccination with PrEP treatment, is vital. This study aims to add to the literature by assessing PrEP patients' HPV vaccine perceptions and determining any potential barriers to linkage and, ultimately, reducing the incidence of HPV-related cancers in high-risk populations.

## METHODS

This study aimed to determine the attitudes, beliefs, and barriers of primary care patients on PrEP towards the HPV vaccine. The study was approved by the IRB at the University of Kansas Medical Center (IRB #: STUDY00145228). Sixteen interviews were completed (n=16). Inclusion criteria was status as a PrEP patient in the two family medicine clinics where recruitment occurred. Primary care clinics were chosen for recruitment, given the potential of future intervention in that setting. There were no exclusion criteria. Participants were selected through convenience sampling due to the physicians' roles as co-investigators in the study and because of the relationship and trust they had already built with their patients. Medical and graduate public health students collected data and were able to refer to their relationship with the academic medical center, as well as with the primary care physicians.

Six students were trained in qualitative research, including how to perform a semi-structured interview. The interviewers read a script, but were also trained in interview techniques: rapport building, probing, note-taking, etc. The same script was used by all six interviewers. The interview guide may be found in Table 1. Interviews were not audio-recorded; interviewers took notes instead in order to maintain confidentiality and rapport. Data were

## HPV Vaccine PrEP Patient Perspectives

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entered in REDCap, a secure research platform. Data were then downloaded into Microsoft Excel for thematic analysis. Questions covered three domains: 1) demographics (age, education level, ethnicity/race, gender, sexual orientation, and health insurance); 2) HPV vaccination status; and 3) patients' attitudes, beliefs, and perceived barriers towards HPV vaccination. The questions were modeled after previous studies about HIV-positive MSM's knowledge and perceptions of HPV,<sup>19</sup> as well as incarcerated women's engagement with cervical cancer prevention.<sup>20</sup> The interviews also included a cue to action in the form of contacting either of the primary care physicians on the team if a patient was interested in receiving the HPV vaccine after the interview.

**Table 1: Interview guide for perceptions about the HPV vaccine from 16 primary care patients taking PrEP**

<i>Topic</i>	<i>Question</i>
HPV vaccination status	Have you ever gotten the HPV or human papillomavirus vaccine (also known as Gardasil)?
HPV vaccination status	[If vaccinated] When did you get the vaccine? How many vaccines did you get? What were the reasons you got the vaccine?
HPV knowledge	What do you know about HPV or human papillomavirus?
HPV knowledge	What do you know about the long-term effects of infection with HPV?
HPV vaccine perceptions	The FDA recently approved the 3-vaccine series for people up to age 45. The HPV vaccine prevents cervical cancer in women, but also penile cancer in men and anal, head, neck, and throat cancers. It also prevents genital warts. How important do you think it is to get the vaccine?
HPV vaccine perceptions	[If not vaccinated] What would prevent you from getting the vaccine?
HPV vaccine perceptions	Where does the HPV vaccine fit into your general health?

Cue to action	[If patient has not already been vaccinated and <45 years old] The vaccine is covered by almost all insurance companies up to age 45. And if you're not insured, the clinic nurse may be able to help you fill out a form for a patient assistance program to get the cost of the vaccine covered by the company that makes it. Would you be interested in completing the HPV vaccine at your next appointment with [doctor's name]?
Demographics	How old are you?
Demographics	What is the highest level of education you have completed?
Demographics	In terms of ethnicity or race, how do you identify?
Demographics	In terms of gender, how do you identify? [If clarification needed] Female, male, non-binary, transgender, etc.
Demographics	In terms of sexual orientation, how do you identify? [If clarification needed] Gay or lesbian, bisexual, straight or heterosexual, etc.
Demographics	Are you insured? [If yes] What health insurance company covers your healthcare policy?

Participants were recruited through 1) cold calls made by the research team using a secure phone app, 2) flyers distributed at in-person visits, or 3) messages sent by clinic nurses through patient charts. These recruitment strategies were selected because of the COVID-19 pandemic, which meant the team could not recruit in person. If participants were called directly, a scripted voicemail was left on the first call if it was not answered. If a potential participant was given a flyer or sent a chart message, they emailed the research team, who then called the participant to conduct the interview. Of the potential participants who were contacted (n=23), 69.6% participated (n=16).

The data underwent thematic analysis in the form of inductive coding and subsequent development of themes<sup>21, 22</sup>. Inductive coding was used and theme development aligned with established thematic analysis protocols.<sup>21, 22, 23</sup> The primary exposure was PrEP user status. The

primary outcome was attitudes, beliefs, and perceived barriers toward HPV vaccination. The research team reviewed and coded the first 11 interviews individually and determined potential codes, subsequently collectively deciding on 16 codes. Codes were reviewed by the team prior to extracting overall themes. Agreement and disagreement over codes were resolved through discussion by the team. Next, the team collectively reviewed code occurrence in the data and determined three overarching themes. The five subsequent interviews were analyzed in relation to the 16 codes to look for thematic saturation. The themes were determined to be the same across all 16 interviews. The research team then pulled quotes to support the themes. The goal was to complete as many interviews as possible in order to perform an exploratory study, rather than to reach thematic saturation. However, thematic saturation was reached.

### **Patient and Public Involvement**

No patients or public were involved in the design, conduct, or dissemination of this research, as this was a preliminary, exploratory study to determine early attitudes and perceptions.

### **RESULTS**

All participants were between ages 23 and 55 years old, with a mean age of 36 years old. All participants were male, with one participant identifying as transgender male. Fifteen participants (93.75%) identified as gay, and one participant identified as bisexual (6.25%). All participants had at least some college education, with the majority (n=14, 87.5%) completing at least a four-year college degree. All participants were insured, with the majority (n=11, 68.75%) covered by Blue Cross Blue Shield (BCBS). The majority of the participants identified as White/Caucasian (n=14, 87.5%), with 12.5% (n=2) identifying as Black/African American. The same number of participants were vaccinated as were unvaccinated (n=7, 43.75%), with 12.5%

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(n=2) participants unsure of their vaccination status. Further demographic information for the participants is listed in Table 2.

**Table 2: Demographics and HPV vaccination status of 16 primary care patients taking PrEP**

<i>Variables</i>	<i>n (%)</i>
Age group	
<30	7 (43.75%)
30-45	5 (31.25%)
>45	4 (25%)
Highest level of education completed	
Some college	2 (12.5%)
Undergraduate college degree	7 (43.75%)
Post graduate degree	7 (43.75%)
Ethnicity / Race	
White/Caucasian	14 (87.5%)
Black/African American	2 (12.5%)
Gender identity	
Male	15 (93.75%)
Transgender male	1 (6.25%)
Sexual Orientation	
Gay/homosexual	15 (93.75%)
Bisexual	1 (6.25%)
Insurance Status	
Insured	16 (100%)
Insurance Provider	
BCBS	11 (68.75%)
Cigna	1 (6.25%)
GEHA	1 (6.25%)
United	1 (6.25%)
Ambetter	1 (6.25%)
Not answered	1 (6.25%)
Vaccination Status	
Vaccinated	7 (43.75%)
Unvaccinated	7 (43.75%)
Unsure	2 (12.5%)

Of those patients who were vaccinated (n=7), 86% (n=6) were vaccinated 5 or more years ago. As no vaccinated participant was over age 30 at the time of their interview, (M=27 years

## HPV Vaccine PrEP Patient Perspectives

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old), no participants were vaccinated under the new guidelines extending vaccination to age 45. Rather, vaccinated participants received the HPV vaccine when they were younger than the initial guideline age of 26. Of the seven participants who were vaccinated, 71% (n=5) stated that they did so because of a doctor's recommendation. One did so because he felt he should as a gay man at higher risk for HPV. Another did so at as a teenager because his parents wanted him to.

Sixteen codes were determined and used: female/women; why not/no reason not to; cancer; warts; recommended; sexual activity; STD/STI; preventative; vaccine; HPV is dangerous; I don't know/not sure; insurance; research; doctor; important; age. These codes led to creation of three major themes in the three domains of attitudes, beliefs, and barriers. The themes were: 1) there is a commitment to preventative health, 2) there are gaps in knowledge about HPV risks and immunization options, and 3) other barriers include age, lack of doctor recommendation, and lack of insurance coverage. Supporting quotes for each theme are listed in Table 3. Quotes were notated during each interview and are presented as directly as possible. However, these quotes are not fully verbatim and may be slightly paraphrased.

**Table 3: Themes and supporting paraphrased quotes from interviews about HPV vaccination with 16 primary care patients taking PrEP**

<i>Domain</i>	<i>Theme</i>	<i>Supporting Quotes</i>
<b>Attitudes</b>	There is a commitment to preventative health	<p>“Anything that prevents cancer is a good thing.” -56 years old, unvaccinated</p> <p>“All vaccines are extremely important.” -27 years old, vaccinated</p> <p>“[There is] peace of mind that you are protecting yourself to the extent you can.” -43 years old, unsure of vaccination status</p> <p>“Sex is universal, everyone is having sex. To be safe everyone should get it.” -23 years old, vaccinated</p>

## HPV Vaccine PrEP Patient Perspectives

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		<p>“I like knowing it is another safeguard/layer of protection, similar to PrEP as a level of protection... It is another way to protect myself.” – 29 years old, unvaccinated (with appointment scheduled to get vaccinated)</p>
<b>Beliefs</b>	<p>There are gaps in knowledge about HPV risks and immunization options</p>	<p>“I don't really know anything. I think the effects are worse in females than males.” -30 years old, vaccinated</p> <p>“You can get genital warts. It can be very deadly for women if they get it.”- 26 years old, unvaccinated</p> <p>“It causes warts also known as crabs.” -23 years old, vaccinated</p> <p>“Males are generally asymptomatic, though if they have it, they can spread to women who can have cervical cancer. I don't really know.” – 30 years old, vaccinated</p> <p>“It is something that is mainly an issue for girls, but I don't know much about the virus specifically or what it does.” – 29 years old, vaccinated</p>
<b>Barriers</b>	<p>The largest potential barriers are age/lack of knowledge around new age guidelines, lack of doctor recommendation, and lack of insurance coverage</p>	<p>“[The only barrier would be] my doctor not recommending it.” 51 years old, unsure of vaccinated status</p> <p>“[The only barrier would be] age. I did not know you could get it now, last I heard vaccine cut off was 26.”- 29 years old, vaccinated</p> <p>“[The only barrier would be] if I didn't have any insurance or ability to pay for it.” – 23 years old, vaccinated</p> <p>“I happen to be outside the age bracket, so it wouldn't apply specifically to me.” - 55 years old, unvaccinated</p> <p>“I didn't even know I could get it. I thought I was too old now.” – 29 years old, unvaccinated, (with appointment scheduled to get vaccinated)</p>



## HPV Vaccine PrEP Patient Perspectives

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The first theme revealed a commitment to preventative health. Participants viewed the HPV vaccine very favorably. They saw HPV vaccination as part of a preventative health package, and consistently rated it as highly important to overall health. Participants found peace of mind in the knowledge that they could further protect themselves from disease, especially disease from such a common act as sex.

The second theme revealed gaps in knowledge about HPV risks and immunization options. Participants held a variety of beliefs about HPV and its consequences. The majority of participants had inaccurate ideas about infection with HPV, particularly for males. Participants generally believed that males had little to no consequences from HPV infection. The main concern regarded transmitting HPV to females.

The third theme was that the largest potential barriers are age/lack of knowledge around new age guidelines, lack of doctor recommendation, and lack of insurance coverage. Participants were unaware that age guidelines had been adjusted to recommend HPV vaccination up to age 45 for certain individuals. Some participants aged out without receiving the HPV vaccine. This is concerning for other high-risk patients who may be nearing age 45 but are unaware they may still be eligible for vaccination. Participants stated receiving the HPV vaccine was contingent on insurance coverage. They also stated that they may not get vaccinated if a doctor did not recommend it. This shows the weight of provider recommendation, as well as the importance of knowledge about insurance coverage options.

Six patients were contacted to schedule appointments for HPV vaccination. This was 37.5% of the study population and 85.7% of the unvaccinated study population. The only participant who declined to be contacted for HPV vaccination was over age 45 and ineligible for

vaccination. Therefore, 100% of eligible unvaccinated participants elected to be contacted to schedule HPV vaccination.

## DISCUSSION

The results from our study further support the acceptability of HPV vaccination administration to high-risk populations. Although participants lacked knowledge about the severity of HPV infection in males, they still felt that the HPV vaccine was highly important. Once participants learned that the guidelines had been extended for HPV vaccination, they overwhelmingly wanted to receive the vaccine if they had not already. This is a promising sign for generalizing to other populations who may have gaps in knowledge about HPV and its long-term adverse effects. Even with limited knowledge about HPV, participants still saw the HPV vaccine as an important part of a healthy lifestyle. Our results were consistent with other qualitative studies that have misconceptions about HPV: belief that HPV primarily affects women, belief that HPV is not a concern for men, and belief that the HPV vaccine is not available to anyone over 26.<sup>4, 19</sup>

The results of this study augment the sparse, albeit promising, literature about combination of HPV vaccination and PrEP therapy for at-risk populations. A cross-sectional survey was administered to MSM seen for PrEP consultations throughout Orléans, France.<sup>24</sup> The mean age in this study was 36 years old, identical to that of our study. The study prevalence of HPV was 93.4%, with prevalence of high cancer risk HPV subtypes being 81.9%.<sup>24</sup> Authors recommended including HPV vaccination as primary prevention among HIV-negative MSM utilizing PrEP.<sup>24</sup> In another study, a global systematic review examined HPV type distribution in anal cancer and anal intraepithelial lesions.<sup>25</sup> The results suggest that prophylactic administration

## HPV Vaccine PrEP Patient Perspectives

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of the HPV vaccine could prevent up to two-thirds of anal cancer and lesions in both women and men.<sup>23</sup>

It is important to educate MSM about the risk of HPV infection in males. Participants overwhelmingly saw HPV as a primarily “female” problem. This belief about HPV is especially concerning for MSM. If they are not engaging in sexual relations with females, they may see no harm in infection with HPV due to the lack of risk of passing it to females. The study population was more highly educated than the general population and they still had large gaps in HPV knowledge. Increasing knowledge of HPV infection, its effects in men, and extended eligibility of the vaccine are all tantamount to increasing vaccination rates. It is also important that providers stay up to date on insurance eligibility so that patients get the vaccine covered, whether through a commercial insurance company, Medicaid, or a patient assistance program.

Although lack of knowledge about severity of HPV in males and the extended age guidelines for the vaccine were barriers, overall, these barriers did not keep many participants from vaccination once offered. Indeed, there were relatively few barriers to HPV vaccination in PrEP users younger than 45. For those not already vaccinated, the results from the intervention component of the study are extremely promising. All eligible unvaccinated participants elected to be contacted for HPV vaccination scheduling. This is hugely important for direct action that can help prevent cancer. It is also strong evidence that knowledge of eligibility leads to vaccination, at least in patients who are already invested in preventative sexual health in the form of PrEP use. Finally, it demonstrates the power of healthcare providers in encouraging patients to receive the HPV vaccine.

This study had several major strengths: the interviewers were blinded to participant health information; the interview questions were modeled from previous studies; the interview

## HPV Vaccine PrEP Patient Perspectives

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was scripted and semi-structured; and thematic saturation achieved. However, the study also had several major limitations: the study had a small sample size; the majority of the sample size came from one PCP; there were no formal recordings or transcripts (due to privacy concerns); there were six interviewers, which may affect participant responses and recorded notes; and there was low external validity (all participants were PrEP users, had insurance, were well-educated, and therefore may not be representative of the broader population). An additional and important limitation was the lack of outreach to underserved and marginalized populations, which resulted in a lack of diversity in the sample.

It is important to recognize that PrEP users are interested in HPV vaccination. Based on this, as well as perceived barriers to vaccination, we have developed these specific recommendations: 1) Providers should capitalize on the interest in preventative medicine and should offer the HPV vaccine to patients with initiation of PrEP; 2) Providers should include a patient's background on HPV and HPV vaccination status in the "After Visit Summary" for PrEP users; and 3) When PrEP is prescribed in the electronic medical record (EMR), the prescriber should be prompted to assess the patient's HPV vaccination status automatically. Patients listen to and trust their providers when it comes to preventative care recommendations. If providers take a moment to initiate a conversation about HPV vaccination and its benefits with patients, we may be able to increase HPV vaccination rates before patients age out of eligibility. By increasing understanding of HPV and the HPV vaccine, we have the potential to significantly decrease the incidence of HPV-related cancers in high-risk populations.

**CONCLUSION**

The results of this study support the idea that providers should offer the HPV vaccine to all eligible PrEP patients, even those over the age of 26. PrEP users are already invested in

## HPV Vaccine PrEP Patient Perspectives

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3 preventative health via their PrEP use and are excited by the opportunity for further prevention  
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5 via the HPV vaccine. The PrEP patients in this study have a high acceptability of the HPV  
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7 vaccine, appreciation for disease prevention, and low vaccine hesitancy. However, we also found  
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9 that many PrEP patients are unaware that the HPV vaccine is available up to age 45. It is  
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11 important that providers actively educate their patients, especially those who are at high-risk,  
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13 about the risks of HPV vaccine and offer the vaccine if a patient is eligible and a good candidate.  
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## DECLARATIONS AND ACKNOWLEDGEMENTS

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### Ethical Approval Statement

This study was approved by the IRB at the University of Kansas Medical Center (IRB #: STUDY00145228). Verbal informed consent was obtained for experimentation with human subjects.

### Author Contribution Statement

Author ZSB was responsible for all drafts of this manuscript, conducting interviews, and data analysis. Senior author MR was responsible for conception of the study, securing funding, overseeing data collection and analysis, and editing the drafts. Authors MB, RD, RN, HS, and SW were responsible, with ZSB, for writing sections of the manuscript, conducting interviews, and data analysis. Authors KJS, CD, MA, and PR worked with MR and ZSB on study design, conceptualization of the manuscript, and editing drafts prior to submission.

### Conflict of Interest/Disclosure Statement

No conflict of interest.

### Funding Statement

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### Data Sharing Statement

No additional data available.

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## Standards for Reporting Qualitative Research (SRQR)\*

<http://www.equator-network.org/reporting-guidelines/srqr/>

Page no(s).

### Title and abstract

<p><b>Title</b> - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended</p>	1
<p><b>Abstract</b> - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</p>	2

### Introduction

<p><b>Problem formulation</b> - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement</p>	4-5
<p><b>Purpose or research question</b> - Purpose of the study and specific objectives or questions</p>	6

### Methods

<p><b>Qualitative approach and research paradigm</b> - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**</p>	7-8
<p><b>Researcher characteristics and reflexivity</b> - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability</p>	6
<p><b>Context</b> - Setting/site and salient contextual factors; rationale**</p>	6
<p><b>Sampling strategy</b> - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</p>	6
<p><b>Ethical issues pertaining to human subjects</b> - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues</p>	6; 18
<p><b>Data collection methods</b> - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**</p>	7-9

<b>Data collection instruments and technologies</b> - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	6-8
<b>Units of study</b> - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	9-11
<b>Data processing</b> - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	7
<b>Data analysis</b> - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	8-9
<b>Techniques to enhance trustworthiness</b> - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	9

### Results/findings

<b>Synthesis and interpretation</b> - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	9-11
<b>Links to empirical data</b> - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	11-12

### Discussion

<b>Integration with prior work, implications, transferability, and contribution(s) to the field</b> - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	14-15
<b>Limitations</b> - Trustworthiness and limitations of findings	16

### Other

<b>Conflicts of interest</b> - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	18
<b>Funding</b> - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	18

\*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

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\*\*The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

**Reference:**

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014  
DOI: 10.1097/ACM.0000000000000388

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