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Protocol Paper

Using Partner Referral to Increase Human Papillomavirus Vaccine Uptake: Protocol for a Pilot Randomized Controlled Trial

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Abstract

Background: Human papillomavirus (HPV) infection causes several types of cancers. People with HIV (PWH), men who have sex with men (MSM), and their partners are at higher risk of HPV infection. HPV vaccine uptake in these high-risk adult groups remains low, creating a pressing need to promote HPV vaccination in these populations. **Objective:** This pilot 2-group randomized controlled trial aims to determine the feasibility and preliminary efficacy of our novel chain partner referral strategy designed to increase HPV vaccination rates in these high-risk adult groups. **Methods:** Participants (n=50) were recruited online and from sexual health clinics and were randomized into either Standard Referral (SR) or Enhanced Referral (ER) (n=25/group). Participants completed a baseline assessment and received the according intervention. Participants were advised to encourage all eligible sexual partners to contact the research team for HPV vaccine information and receipt during a 3-month post-enrollment period. Participants completed a final assessment at 3 months post enrollment. **Results:** This study was funded by the Stephenson Cancer Center's Pilot Grant Program. The intervention materials were pilot tested with 15 PWH and MSM aged 25–53 years to gain their feedback. Data collection was completed. Preliminary data indicate that the proposed approach is highly feasible. Data analysis is ongoing. **Conclusions:** Findings from this pilot project will be critical for future clinical trials to examine the efficacy of chain partner referral approach in promoting vaccination. If our approach is effective, current patient-care guidelines related to partner services for high-risk adults may be changed to include HPV vaccination to reduce HPV-related cancers.

Keywords: Human Papillomavirus; Human Immunodeficiency Virus; Partner Referral; Chain Referral; Vaccination

Introduction

Human papillomavirus (HPV) infection, mainly genotypes 16 and 18, causes several types of cancers, including cancers of the cervix, vagina, vulva, penis, oropharynx, and anus [1]. Patients with sexually transmitted infections (STI), particularly with HIV, and their partners are at significantly higher risk of HPV infection with multiple oncogenic types, intraepithelial neoplasia, and invasive cervical or anal cancers [2]. HPV vaccines offer substantial protection against HPV infection and intraepithelial neoplasia in men and women [3], and even in women with previous HPV exposure to 1 or more HPV genotypes. Trials show that in women who have had previous serologic exposure to vaccine-targeted HPV types but are not infected with HPV, HPV vaccines are as effective as they are in HPV-naïve women [3, 4]. Even when women have been infected with an HPV genotype, vaccines can still protect them from other HPV types [5], particularly with the availability of the nonavalent HPV vaccine (Gardasil 9). In people with HIV (PWH), clinical trials have shown that HPV vaccines are safe, immunogenic, and efficacious [6]. The United States (US) Centers for Disease Control and Prevention (CDC) recommends HPV vaccination for all women, men who have sex with men (MSM), bisexual individuals, transgender individuals, and people with HIV (PWH) [1, 2]. In sum, it is still beneficial to vaccinate age-eligible high-risk adults and their partners.

For PWH, the effectiveness of antiretroviral therapy increases life expectancy, yet these patients now face several cancer risks related to their immunocompromised status. Thus, the US National Cancer Institute (NCI) has emphasized the critical need for cancer-prevention strategies for this population [7], including immunization against oncogenic viruses. The availability of the nonavalent HPV vaccine has made HPV-related cancer one of the most preventable malignancies for these high-risk populations. Despite a significant increase in HPV vaccination among female adolescents in the US and in Oklahoma specifically [8, 9], general coverage in eligible adults remains low [10, 11]. Only 5-17% of the national MSM population aged 18-26 years has received HPV vaccination [12, 13]. In Oklahoma, there are about 38,000 MSM (21,000 MSM in Oklahoma City) [14]; of these, about 35% are eligible for HPV vaccination [15]. Thus, there is a pressing need to promote HPV vaccination in these high-risk adult groups to prevent HPV-related cancers.

Systematic reviews have shown that partner referral is effective in treatments for sexually transmitted infection (STI) [16-18]. Most index STI patients (55%-97%) expressed their willingness to engage in partner referral for STI treatment or partner notification of HIV-positive status, and this willingness did not vary by gender or sexual orientation [16, 19]. Unlike partner referral for STI treatment, in which the index patients need to disclose their STI/HIV exposure or status to their partners, referring partners for HPV vaccination will not involve such a disclosure and thus will be easier. Therefore, this approach is very likely to increase HPV vaccination uptake. The partner referral approach is also feasible and has a potentially wide reach because of the high number of sexual partners per individual in the targeted populations.

Furthermore, several organizations, such as the US CDC and the World Health Organization, have endorsed or applied the Respondent-Driven Sampling (RDS) approach, a specific form of chain referral, to reach hidden populations for surveillance or program impact evaluation [20, 21]. In RDS, recruited individuals continue to refer their known peers in their hidden networks for study recruitment [22, 23]; these participants otherwise would be very difficult to reach by outsiders. This referral process continues for several waves. Peer-or partner-driven intervention dissemination has also been demonstrated to be effective because members in social/sexual networks are more likely than outsiders to influence health behaviors of other members owing to their shared social norms, pressure, and support [24, 25]. Thus, partner-driven chain referral is very likely to substantially increase HPV vaccination.

Combining the partner referral and chain referral approaches, we propose a novel strategy to promote HPV vaccination in the high-risk adult groups–chain partner referral. We propose a pilot Randomized Controlled Trial (RCT) to determine the feasibility and preliminary efficacy of this innovative, theory-based chain partner referral approach to increase HPV vaccination rates in the high-risk populations. Our study will engage STI/HIV/sexual minority patients (i.e., index patients) in referring their sexual partners for HPV vaccination, and the referred partners in turn will refer other partners; this referral process continues for several waves throughout their hard-to-reach sexual networks. We will investigate 2 specific referral strategies: simple referral (SR; healthcare providers give patients standardized letters to encourage their sexual partners to receive HPV vaccination) and enhanced referral (ER; counselors equip patients with verbal communication skills to motivate sexual partners to obtain HPV vaccination). This protocol paper aims to describe our proposed pilot RCT with the chain partner referral approach.

If our proposed aims are achieved in this pilot and subsequent fully powered trials, current national concepts and patient-care guidelines related to partner services for STI/HIV patients may be changed to include HPV vaccination to help end vaccine-preventable cancers. Furthermore, our findings will help various stakeholders adopt appropriate strategies to engage social/sexual networks to deliver similar preventive services to these hard-to-reach populations (e.g., anal cancer screening for MSM).

Materials and Methods

Study Overview and Design

We propose a 2-group intervention RCT to compare the feasibility and preliminary efficacy of the 2 partner referral approaches: SR and ER. We hypothesize that the ER arm will show a greater change from baseline to the 3-month follow-up in the mean proportion of partners referred than the SR arm. We used various methods to recruit the first wave of high-risk index participants (i.e., seed participants; n= 20). Seed participants were randomized into either SR or ER (n= 10/group). All participants completed baseline assessments and received the according intervention/instruction. After receiving the interventions, seed participants encouraged all eligible sexual partners to contact the research team for HPV vaccination information within the next 3 months. We tracked the referral process by using cards with unique referral identification numbers (RIN) that linked referred partners to the index participants. When a referred partner contacted the research team for HPV vaccination and presented the RIN, s/he was screened for eligibility; if eligible, s/he was enrolled in the study as an index participant and was assigned to the same study group as the seed. The referral process continued for several waves until we reached our target sample size of n=25 index participants in each group (including 10 seeds and 15 subsequently recruited partners), and thus the total sample size for analysis is n=50. We contacted all index participants every 2 weeks by telephone to briefly assess whether they had discussed HPV vaccination with their partners and reminded them to do so. All participants completed a final assessment at 3 months post-enrollment (Figure 1).

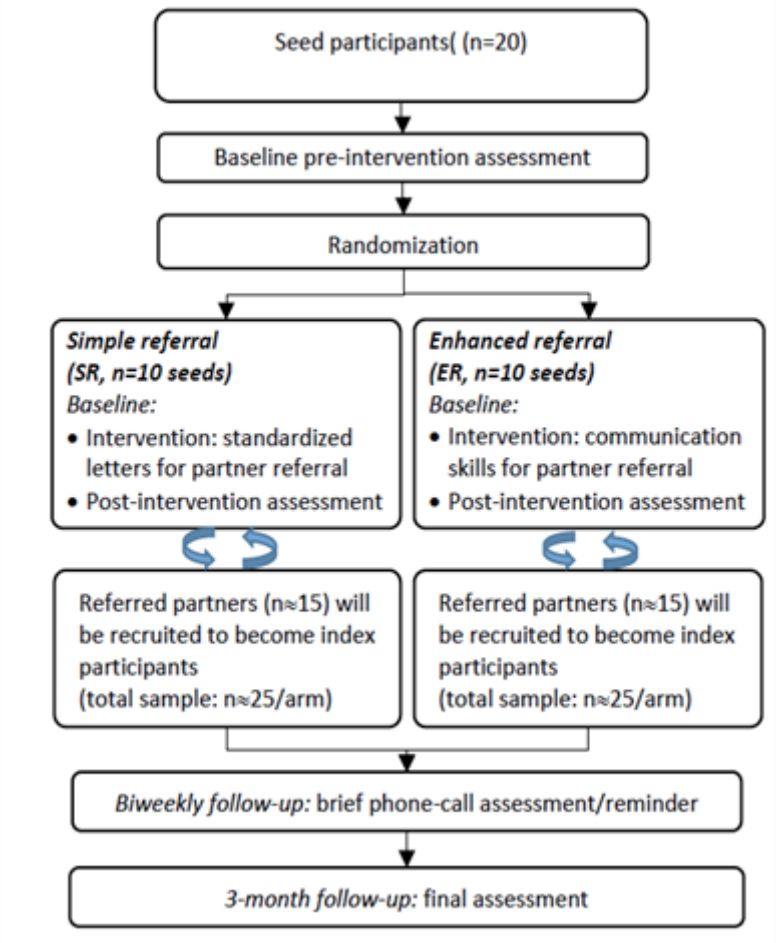

Figure 1. Trial Schema.

Participant Recruitment and Enrollment

We leveraged multiple strategies to recruit a diverse group of seed participants from the historically hard-to-reach populations across Oklahoma. We partnered with the Oklahoma City-County Health Department (OCCHD) to screen adults visiting OCCHD sexual health clinics for study eligibility and invited eligible patients to participate. We also placed recruitment ads on various social media sites (Facebook, Instagram, Craigslist, etc.). Finally, we partnered with TrialFacts (a research participant recruitment company) to target and recruit underrepresented individuals.

Eligibility Criteria

Inclusion Criteria

Seeds and all subsequent index participants were required to be aged 18–49 years and have at least 1 sexual partner who was ≤26 years old, who had never received any dose of any HPV vaccine, and who was likely to see the index participants in the following 6 months. If potential seeds were eligible for HPV vaccination but had not yet received it, they were encouraged to obtain the first dose and then enroll in the study. This helped ensure that the seeds supported HPV vaccination and could serve as role models in the referral process.

Exclusion Criteria

Participants were excluded from the study if they had experienced a medical adverse event due to HPV vaccination, had experienced domestic violence from a partner in the past year, or were unable to speak or read English.

Enrollment took place remotely or in person at the sexual health clinics and at the University of Oklahoma Health Sciences campus (OUHSC, where the research team is located). Remote enrollment, which was particularly necessary after the COVID-19 pandemic, took place via video calls (Zoom). During the remote appointment, study staff 1) sent the participant a link to a Research Electronic Data Capture (REDCap) webpage that contained informed consent and Health Insurance Portability and Accountability Act (HIPAA) forms, 2) reviewed both forms with the participant and gave the participant a chance to ask questions, and 3) asked the participant to sign both forms electronically. Remote participants received copies of the forms via email/mail. After the informed consent process, enrolled participants were asked to complete a baseline assessment via REDCap (see the Assessments section below) and were stratified and randomized to the SR or ER group.

Intervention Conditions

Standard Referral Arm

Participants assigned to the SR group watched a 7-minute video about the importance and necessity of partner referral for HPV vaccination. The video included 2 modules. The first module, produced by NCI covered facts about HPV and HPV-related diseases and information about the HPV vaccine. The second module highlighted reasons participants should tell partners to obtain vaccination, including the 2 most salient reasons in STI-management literature: for the participants' own health benefits and because it is normatively considered "the right thing to do." [26, 27] After watching the video, participants talked with a research staff member for 15 minutes about partner elicitation. Then, participants were provided with standardized letters (electronic and/or mailed copies) to give to their partners. The letter briefly conveyed the partners' high risk for HPV-related cancers and the importance of cancer prevention through HPV vaccination. The letter also contained web links to the videos, other sources of information [5, 27] and contact information for the research project. A referral card that contained a RIN was attached to the letter.

Enhanced Referral Arm

For the ER group, we used the information-motivation-behavioral skills model to encourage participants to refer partners; this model has frequently been applied to HIV preventive behaviors [28] and is potentially applicable to HPV vaccination [29]. The ER group first watched the 7-minute informational video and went through the partner elicitation process, as in the SR arm. Then, a research staff member conducted a 20-minute counselling session to discuss when, where, and how to talk to partners about HPV vaccination; common barriers to HPV vaccination; and how to overcome these barriers [28]. If participants were unsure about how to talk to their partners, the RC presented some examples of communication strategies, including what to do if the first attempt fails. For example, using an emotional coercion strategy, a participant may tell a partner that s/he will feel anxious or frigid instead of sexually aroused during sex if the partner is not vaccinated. After counselling, the RC gave participants standardized letters with referral cards (as in the SR arm) to give to their partners when verbally persuading them to obtain HPV vaccination.

For both the ER and SR arms, after receiving the interventions, seed participants encouraged all eligible sexual partners to obtain HPV vaccination within the next 3 months. Given the scope of this pilot RCT, each index participant could refer up to 5 regular partners, 8 casual partners, and 10 one-time partners. When a referred partner contacted the research team for HPV vaccination and presented the referral card with his/her unique RIN, s/he was enrolled in the study as an index participant and assigned to the same study arm as the seed participant. This referral process continued for several waves until we reached a total sample size of 50 index participants (approximately 25 in each study arm).

Assessments and Measures

Table 1 displays the assessments and measures used in our pilot RCT. At baseline, enrolled participants (seeds or subsequently recruited index participants) self-administered a 25-minute assessment prior to being randomized (i.e., pre-intervention assessment) and another brief assessment after receiving the intervention (i.e., post-intervention assessment). These assessments consisted of structured questions and were delivered by the REDCap platform. The post-intervention assessment aimed to evaluate their psychological changes related to partner referral.

Measures	References (Notes)	Pre-intervention	Post-intervention	3-month follow-up
Demographics: sex, sexual orientation, ethnicity, age, education level, income	[30, 31]	X		
Health behaviors: number of partners, cigarette use, alcohol use	[30, 32]	X		
Information (knowledge) about HPV vaccination, HPV vaccination history	[29, 31, 33-35]	X		
RDS variables: RIN, residential areas, number of partners elicited (network size)	[22, 23]	X	X	
Motivation to refer partners (Likert scale, from *1=not likely at all* to *5=very likely*)	[29, 35, 36]	X	X	
Self-efficacy in referring (Likert scale, from *1=not confident at all* to *5=very confident*)	[29, 37]	X	X	
Number of partners identified, types of partners (e.g., regular or casual)	[17, 38]	X		X
Self-reported number of partners notified/motivated	[17]	X		X
Numbers of partners who contact the research team to receive HPV vaccine information or HPV vaccine (documented by RIN)	(actual count)			X
Barriers to partner referral (open-ended questions)	[16]			X
Harmful events: emotional abuse, verbal abuse, or physical violence	[16, 19]			X

Table 1: Trial assessments and measures.

At 3 months post-enrollment, all participants were asked to complete a final follow-up assessment. The 3-month follow-up assessment lasted approximately 20 minutes and took place remotely or in person as described for the baseline. This final assessment aimed to determine participants' partner referral activities in the past 3 months. The ER group also answered some semi-structured questions about barriers to and perceived effective strategies in referring partners.

Data Analysis

To assess feasibility, we will generate descriptive statistics to summarize the feasibility outcomes in the overall sample and within each arm. Feasibility outcomes include the proportion of individuals who met eligibility criteria, the proportion of eligible participants who agreed to participate, groups of index participants (e.g., PWH, MSM), average numbers of partners identified/eligible for each index participant, types of partners (e.g., regular or casual), and attrition rate at 3-month follow-up.

To evaluate the preliminary efficacy of the interventions, the primary variable for analysis will be the change in the proportion of the identified partners referred for HPV vaccination information from baseline to the 3-month follow-up (i.e., partners who contact the research team, as evidenced by RIN). We will use the Respondent Driven Sampling Analysis Tool (RDSAT) to generate individual network size, homophily, sample population proportions, and sample weights for each variable, as well as bootstrap estimates of the standard errors and confidence intervals of partner referral in each arm. The weights generated in RDSAT can be used in weighted generalized estimating equation models [39]. Multiple variable linear mixed models, or Generalized Linear Mixed Models (GLMM), can be used to account for the network structure created by RDSAT by incorporating social network as a random effect [40]. We will consider the use of Poisson or negative binomial GLMM, depending on the dispersion of the data, and explore models both unadjusted and adjusted for a limited number of covariates (e.g., participants' sexual orientations or types of partners). Given this study's preliminary nature, we do not expect

enough power to test the hypothesis. However, assuming an overly conservative mean change in the proportion of partner referrals in the SR group of 0.4 and an attrition rate of roughly 10%, we will have about 70% power to identify a difference in the mean change in referral proportions as small as 0.4 (SD 0.6) between the ER and SR groups (α=0.05, one-tailed).

Results

This study was funded by the OUHSC Stephenson Cancer Center's (SCC) Pilot Grant Program, which is partially funded by the US National Cancer Institute's P30 Cancer Center Support Grant awarded to the SCC (P30CA225520). After developing the intervention materials and prior to the pilot RCT, we tested the interventions with 15 PWH and MSM aged 25–53 years to gain their feedback and modified the interventions. We also took this opportunity to gain their opinions about the feasibility of partner referral for HPV vaccination. Responding to a brief survey, most of these PWH/MSM (87%) revealed that they had at least 1 sexual partner over the past 1-year period; of these, 54% had a spouse or a main partner, 77% had 1–10 casual partners, and 8% had >10 casual partners; the average number of partners was 2.7. Among those who had a main partner, 62% reported that their main partners had never received any dose of the HPV vaccine and another 31% were not sure. About 71% indicated that they would be willing to refer their main partners to the study, and 57% believed that their partners would participate. These data indicate the appropriateness and high feasibility of the proposed approach. The pilot RCT data collection has been completed and data analysis is in progress.

Discussion

The goal of our research in this and subsequent projects is to increase HPV vaccination coverage in eligible adults (aged 18-45 years) in Oklahoma and subsequently in the US. The target populations for HPV vaccination, per the US CDC recommendations, include women, MSM, bisexual individuals, transgender individuals, and PWH [12, 41]. Presumably, sexual partners of these individuals are also at increased risk of HPV infection. However, HPV vaccination interventions have not targeted partners of these high-risk people. Although Oklahoma has devoted considerable resources to promoting HPV vaccination among adolescents, almost nothing has been done for eligible adults. Therefore, to prevent HPV-related cancers, there is a critical need to vaccinate at-risk adults and their partners before they reach the age limit. Our proposed project will address this need.

To promote HPV vaccination in general, researchers have used behavioral methods and interventions to target adolescents, parents, teachers, and healthcare providers [29, 42]. However, no study has engaged sexual partners in promoting HPV vaccination. Systematic reviews have shown that patient-engaged partner referral is highly effective in managing STIs [16-18]. Furthermore, the hidden nature of these target high-risk populations has made it difficult for vaccination campaigns to reach them and meet their specific needs. Chain referral is effective in reaching these hidden populations. Using a novel approach of chain partner referral, which combines partner referral and chain referral, our study will contribute to filling the gap in knowledge regarding to what extent STI/HIV participants or other high-risk adults could be engaged in promoting vaccination and other preventive services.

This project is significant for not only cancer prevention but also HIV prevention. A systematic review of 12 longitudinal studies suggested that HPV infection doubles the risk of HIV acquisition [43], and an ongoing clinical trial is examining the protection of HPV vaccination against HIV acquisition [44]. The CDC has regarded PWH co-infected with a STI (both ulcerative and non-ulcerative) as high-priority index patients for partner services because evidence shows that STIs increase the HIV transmission risk between partners [45]. Therefore, expanding HPV vaccination to patients or partners at risk of STIs and to HIV-negative partners in HIV-serodiscordant partnerships would reduce the risk of HIV infection in these high-risk individuals.

Conclusion

Findings from this pilot project will be critical for future robust, fully powered clinical trials to examine the efficacy of chain partner referral in promoting vaccination. If our proposed approach is demonstrated to be effective, current national concepts and patient-care guidelines related to partner services for STI/HIV patients and for other high-risk adults may be changed to include HPV vaccination to help end vaccine-preventable cancers. Furthermore, our findings may help various stakeholders adopt appropriate strategies to engage social/sexual networks to deliver future similar preventive services to these hard-to-reach populations (e.g., anal cancer screening for MSM).

Author Contribution Statement

Conceptualization, TCB; methodology, TCB, DEK, and SF; formal analysis, TNL and CJ; investigation, TCB, TNL, KTD, JK, DAD, PM, and CM; resources, TCB, DAD, and PM; writing—original draft preparation, CJ and TCB; writing—review and editing, all; visualization, TCB and CJ; supervision, TCB, DAD, and PM; project administration, CM and TNL; funding acquisition, TCB. All authors have read and agreed to the published version of the manuscript.

Ethics Approval Statement

The study was approved by the Institutional Review Board of The University of Oklahoma Health Sciences Center (#9992/2019).

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Conflict of Interest Statement: The authors declare no conflict of interest.

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