Adaptation of an HPV education resource to promote HPV vaccination among Latino Young Men who Have Sex with Men in Puerto Rico and Florida (Proyecto Hombres Previniendo el VPH (Proyecto HPV)

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Proyecto Hombres Previniendo el VPH (Proyecto HPV)

Coordinating Center: H. Lee Moffitt Cancer Center and Research Institute

Principal Investigator: Shannon M. Christy, PhD
[redacted]
Email: shannon.christy@moffitt.org

Co-Principal Investigator: Melissa Marzán-Rodriguez, DrPH
Ponce Health Sciences University
[redacted]
Email: mmarzan@psm.edu

Research Team: Cathy D. Meade, PhD (Co-Investigator at H. Lee Moffitt Cancer Center and Research Institute)
Susan T. Vadaparampil, PhD (Co-Investigator at H. Lee Moffitt Cancer Center and Research Institute)
Julian Sanchez, MD (Co-Investigator at H. Lee Moffitt Cancer Center and Research Institute)
Julio Jimenez, MD (Co-Investigator at Ponce Health Sciences University

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TABLE OF CONTENTS

1. Specific Aims

Persistent infections from oncogenic human papillomavirus (HPV) strains can develop into several types of cancers in both men and women (i.e., oropharyngeal, cervical, anal, penile, vaginal, and vulvar cancers).[1] Rates of oropharyngeal and anal cancers have been increasing in recent years,[2] and HPV disproportionately affects men who have sex with men (MSM).[2] Indeed, compared to heterosexual men, MSM are 17 times more likely to develop anal cancer.[3] MSM infected with human immunodeficiency virus (HIV) are at even higher risk.[3] Geographic disparities in HPV-related cancer incidence and mortality also exist. For example, Florida (FL) has among the highest incidence of HPV-related cancers in the United States (U.S.)[4] and men in Puerto Rico (PR) experience higher incidence and mortality from oropharyngeal and penile cancers than those in the continental U.S.[5,6] Given the risk for HPV infection and HPV-related cancers among young MSM (YMSM) and the HPV-related geographic disparities in FL and PR, HPV prevention efforts for this underserved population are vitally needed in both FL and PR. To date, no Spanish language HPV educational interventions have been targeted for young adult MSM.

The HPV vaccine can protect 9 HPV strains, including 7 oncogenic strains, and has the potential to prevent against 92% of HPV-related cancers.[4] Young adults experience the highest prevalence of HPV infection.[7] Yet, nationwide, HPV vaccine rates among young adult males ages 19-26 are suboptimal (21.2% in 2017).[8] In FL, HPV vaccine rates among adult males is even lower (only 2% in 2015).[9] For the same age groups, HPV vaccine rates in PR among males is 23.7%.[10] Despite their increased risk for HPV infection, HPV vaccination rates are most suboptimal among YMSM, with only 13.7% reported receiving any doses of HPV vaccine.[11] Prior research has demonstrated low knowledge about HPV and HPV vaccine among Latinos and MSM.[12] However, little is known about HPV knowledge, HPV vaccine attitudes, health beliefs, and intentions among Latino MSM (YLMSM). Educational interventions that promote HPV vaccination are critical to prevent HPV-related cancer incidence and mortality among this high-risk and underserved group. However, no prior HPV vaccine educational interventions have been targeted to YLMSM. Previously, an educational resource was developed as part of the Ponce Health Sciences University-Moffitt Cancer Center Partnership (U54) Outreach Core. The module is titled “Cancer 101 HPV” and was developed in Spanish language for a wide community audience including information for individuals born male and female, of adult age, and presented in a Microsoft PowerPoint presentation format.[13, 14]

Prior studies adapting educational materials for Latino communities incorporate culture, language, context, and other characteristics that enhance meaning and value for the target audience.[13, 14]Researchers have found that language preference influences intervention adoption.[15] About two thirds of young adult Latinos in the U.S. and about 45% of young adult Latinos born in Puerto Rico or abroad speak English proficiently.[16] Furthermore, our Community Advisory Board (CAB) has voiced that Latino young adults in Florida may prefer English language materials (and may or may not be fluent in Spanish). Recognizing that young Latinos in Florida and Puerto Rico may have different language preferences, we seek to simultaneously adapt and refine the Cancer 101 modules considering culture, Spanish or English language preferences, and relevancy to our specific audience (YLMSM ages 18-26 years old).[18,19] Intervention material content will be identical aside from language. That is, the color scheme, photos, infographics,

graphics, intervention modality, and intervention delivery methods, etc. will be the same. In the current study, a transcreation process[20] will be utilized to adapt the Cancer 101 module to a Latino MSM population. Transcreation aims to culturally and linguistically adapt a resource for a different population while allowing for flexibility to create something new that is meaningful for the new audience.[20] We expect that transcreating the Cancer 101 module will yield a culturally-responsive educational resource that incorporates content that is targeted to Latino MSM in preferred format(s) (delivery modality/modalities) and including content and aesthetics that are salient, appealing, meaningful, and actionable for young adult Latino MSM. This study, informed by the Theory of Planned Behavior (TPB)[21] and Health Belief Model (HBM),[22] will be carried out in both PR and FL. The specific aims are:

Specific Aim #1. To assess HPV and HPV vaccination knowledge, awareness, attitudes, health beliefs, and behaviors as well as educational preferences among 260 Spanish-speaking YLMSM ages 18-26 in Florida and Puerto Rico. We will identify knowledge gaps, health beliefs, attitudes, and educational learning preferences through a cross-sectional survey.

Specific Aim #2. To conduct 20 in-depth interviews with key stakeholders (10 in PR and 10 in FL) eliciting feedback to inform intervention content and delivery methods and identify potential facilitators and barriers to intervention implementation. Informed by the Consolidated Framework for Implementation Research model (CFIR),[23] we will conduct individual interviews with key stakeholders (i.e., healthcare clinic leadership, providers and staff, community-based organization staff, and individuals who serve and/or have provided services to YLMSM within the past 12 months).

Specific Aim #3. To culturally adapt an existing Cancer 101 educational resource in English and Spanish for YLMSM ages 18-26 and to conduct focus groups or individual interviews with 24 YLMSM in PR (n=12) and FL (n=12) to gain feedback on the acceptability, accessibility, content, delivery preferences, and aesthetics of the theoretically informed, HPV educational intervention targeted for English and/or Spanish-speaking YLMSM. We will leverage a previously-developed educational resource and transcreate the educational intervention based upon Aim 2 and Aim 3 feedback.

The goal of this research program is to promote HPV vaccination to reduce HPV-related cancer incidence and mortality among Hispanic/Latino sexual minority men. Our team is ideally suited to complete the proposed study and will submit an R34 or R01-equivalent grant application in 2022 or 2023 aimed at testing the efficacy of the targeted educational intervention through a multi-site randomized controlled trial in PR and FL. The current protocol outlines the activities to be conducted by the Moffitt Cancer Center-based team (led by Dr. Shannon Christy) and the complementary activities that will be conducted by the team at Ponce Health Sciences University (led by Dr. Melissa Marzán-Rodriguez).

2. Background and Significance

2.1 HPV Infection Risk among YMSM

MSM are at increased risk for acquiring an HPV infection[24] and subsequently developing

an HPV-related cancer.[24] In 2014, the prevalence of an anal HPV infection was 57.8% among high-risk men (of whom 84.% were MSM) in PR.[24] Prevalence of genital HPV infection was approximately 50.1% among MSM in the Tampa area, with 29.7% experiencing a high-risk infection.[25] Among MSM in the Tampa area, 44.7% had an anal HPV infection and 34.1% had a high-risk HPV anal infection.[26] In addition, HIV+ MSM are at higher risk of anal HPV infection, anal cancer precursors, and anal cancer compared with persons who do not have HIV.[27,28] There are currently no Food and Drug Administration (FDA)-approved HPV tests or HPV-related cancer screening tests for men.[29] Correct and consistent condom use can lower HPV transmission risk, but does not offer complete protection.[29] Thus, HPV vaccination is the best method for protecting males from developing HPV-related cancers.[30]

2.2 HPV Vaccine Recommendations

The nine-valent HPV vaccine has been shown to be safe and provide effective and long-lasting protection from 9 HPV strains, including 7 oncogenic strains.[31,32] In 2018, the Food and Drug Administration (FDA) approved administration of the vaccine in individuals ages 9-45, extending the previous licensure from those aged 9-26 years.[33] A two doses series is recommended for those aged 9-14 and a three doses series is recommended for those ages 15 and older.[34] In 2019, the Advisory Committee on Immunization Practices (ACIP) continued to recommend routine vaccination in individuals aged 11-12 and updated their recommendations to include catch-up vaccination for all individuals ages 15-26 who did not previously complete the HPV vaccine series.[35] Also, in 2019, ACIP updated their recommendations for individuals ages 27-45, suggesting that patients in this age group and their providers engage in a discussion and shared decision-making about HPV vaccination.[36] Thus, we focus upon young adults ages 18-26, as all males in this age cohort are recommended to receive the HPV vaccine series.

2.3 Barriers and Facilitators to Vaccination among YMSM

Prior studies have identified multiple barriers to YMSM receiving HPV vaccination, including lack of knowledge that men can have HPV-related health concerns, that men can receive the vaccine, low perceived HPV risk, beliefs related to sexual promiscuity, lack of awareness that the vaccine cost is covered by health insurers, lack of provider recommendation, among others.[37,38,39,40,41,42] HPV vaccine knowledge, disclosure of sexual orientation to one's provider, and completion of a STI test in the prior year have been predictive of vaccine uptake among MSM.[43]

2.4 Theoretical Framework

The Theory of Planned Behavior (TPB) and Health Belief Model (HBM) have been used to effectively guide prior HPV research. Relevant TPB constructs include attitudes, subjective norms, and behavioral intentions.[44] HBM constructs to be utilized include perceived barriers, perceived efficacy, cues to action, self-efficacy, and perceived risk.[44] In addition, the role of precipitating factors, awareness, and affect will be considered (see Figure 1).

2.5 Consolidated Framework for Implementation Research (CFIR)

Implementation research seeks to understand the processes and factors that are associated with successful integration of evidence-based interventions within a setting (e.g., a clinic).[45] The CFIR framework focuses on organization-level measures about the settings in which an intervention could be implemented by exploring five domains: intervention characteristics; outer setting; inner setting; individuals/organization characteristics and process effects intervention implementation. CFIR will guide the key stakeholder interviews, whereby we will explore possible facilitators and barriers in the intervention implementation, reach, and engagement processes to inform a multi-level intervention to promote HPV vaccination among English- and/or -speaking YLMSM.

2.6 Innovation

The proposed study is innovative for multiple reasons. First, no prior interventions have been developed to improve HPV knowledge and promote HPV vaccination and targeted to young Latino MSM, an understudied population significantly and disproportionately impacted by sexual transmitted infections including HPV. Second, using mixed-methods approaches, we will enroll participants in both PR and FL. Finally, although the current Cancer 101 HPV module covers topics such as HPV natural history, descriptive epidemiology, modes of transmission and prevention measures, it is not culturally adapted to YLMSM, a population who are at increased risk for HPV infection.[47,47] Our proposed study will result in an intervention that is responsive to culture, language and context, it will be targeted to English- or Spanish-speaking YLMSM, and designed with input from the target audience and key stakeholders and with implementation and dissemination in mind. Although the current Cancer 101 HPV module was designed to be delivered in a group setting via PowerPoint, YLMSM may prefer HPV education to be delivered in

another format or modality. Thus, we seek to also adapt the intervention to a preferred modality based upon feedback from YLMSM and key stakeholders.

3. Research Design and Methods

3.1 Study Design Overview

We are proposing a mixed-method study with three research aims that uses rigorous, systematic steps (see Figure 2). For Aim 1, we will recruit 260 YLMSM to assess HPV knowledge, awareness, health beliefs, attitudes toward the HPV vaccine, healthcare experiences, behaviors, and among those unvaccinated, intentions to receive the HPV vaccination, HPV vaccine education learning preferences, social media use, health literacy, sociodemographic characteristics, among others. For Aim 2, we will interview 20 key stakeholders to inform intervention content and delivery methods as well as to identify potential implementation facilitators and barriers and receive feedback on the intervention. In Aim 3, informed by PHM and HBM and the data collected in Aim 2, we will adapt and update the Cancer 101 HPV module to develop an educational intervention in Spanish targeted for YLMSM. Finally, we will receive feedback on the educational intervention (e.g., content, aesthetics, appeal, modality, format) from 24 YLMSM in PR (up to n=12) and FL (up to n=12) via focus groups or individual interviews.

The study as a whole will be enhanced by input from a community advisory board (CAB) comprised of 4-10 community members. At least two members will be in FL and at least two will be in PR. We anticipate that CAB members will be individuals who work for an organization or government agency that provides healthcare or social services to YLMSM or that they themselves identify as a YLMSM. The CAB will meet with the team on a quarterly basis to provide guidance on recruitment, procedures, and interpretation of results. Additional meetings may be scheduled if further guidance is needed during the progression of the project. Additionally, CAB members will work with the study team to adapt existing Cancer 101 education materials to produce a draft intervention to be utilized in initial Aim 3 focus groups or individual interviews. CAB members may also assist with recruitment efforts by sharing recruitment materials in various means (e.g., social media platforms, websites, etc.). CAB members in both FL and PR will be compensated $400 per year for their participation on the CAB. In-person meetings with CAB members may also include refreshments. Review and approval of study by the MCC Scientific Review Committee and MCC and PHSU Institutional Review Board (IRB) of Records and the IRBs of the community partners, as applicable, will be sought prior to initiation of study activities.

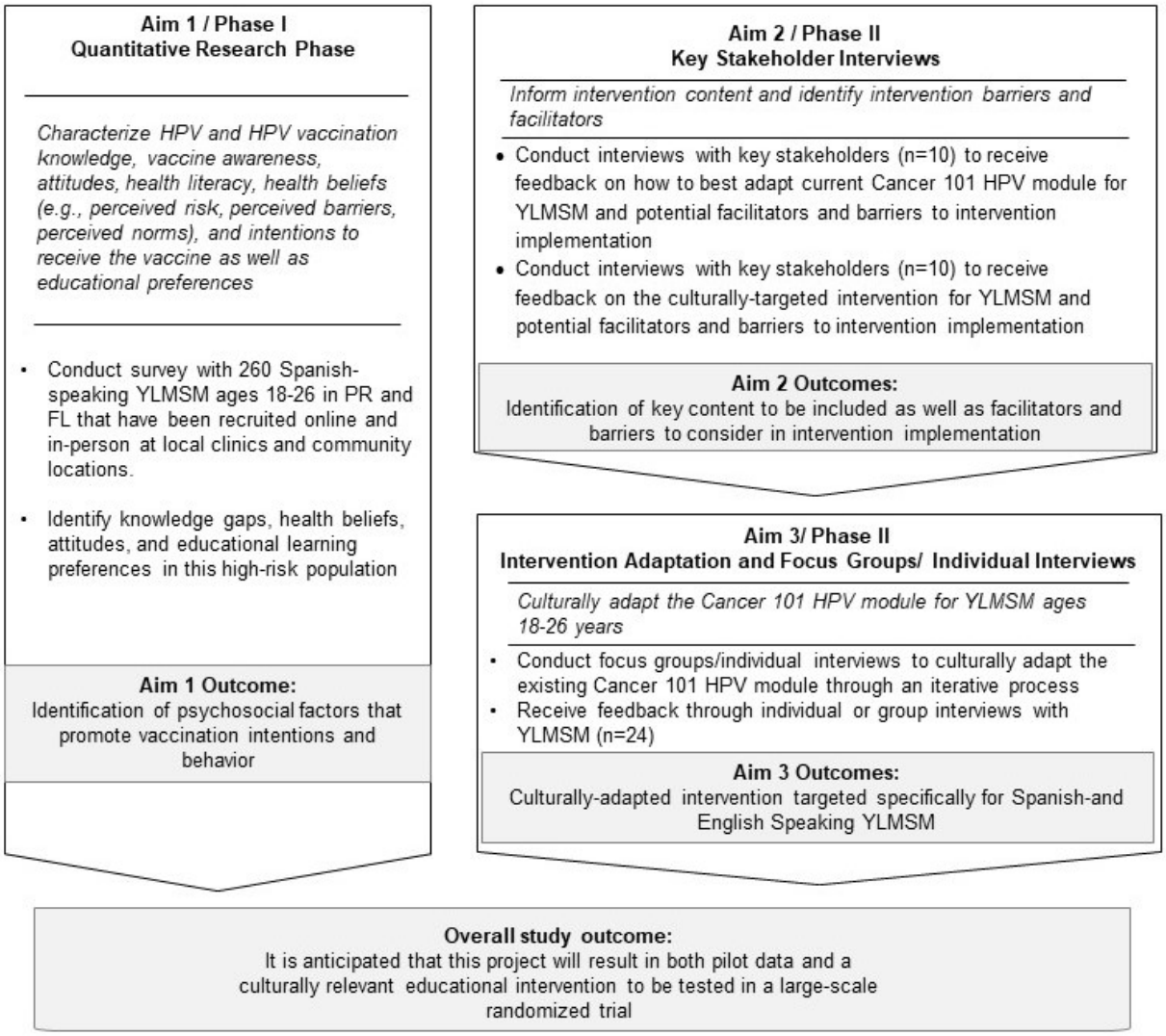

Figure 2. Study Design

3.2 Study Methods

3.2.a. Aim 1 Participant Recruitment

We will recruit a total of 260 YLMSM in PR and FL between 18 to 26 years of age using multiples recruitment strategies: 1) advertisements on social media platforms and dating applications such as Instagram®, Snapchat®, and/or Grindr®;2) broadcasting media such as television, radio, magazine, newspaper, or newletter; 3) in-person recruitment through organizations or healthcare clinics that serve YLMSM; 4) printed materials (e.g., flyers in community sites); 5) study flyers in physical spaces, via social media, via presentations, and via email, and among other dissemination methods shared by our team, other Moffitt and PHSU teams/departments/cores, and groups, organizations, and networks in the

community, and 6) a study invitation to online survey using organizations or clinics who serve YLMSM or participants from prior studies who have indicated interest in taking part in future studies. CAB members may also assist with recruitment efforts by sharing recruitment materials in various means (e.g., emails, websites, etc.). For those aged 18-20 living in PR, a parental waiver is requested in order to promote participation and protect sexual rights. Studies in the United States, regulated by Federal Law, who included Hispanic/Latino samples also emphasizing the need for policy changes to allow parental consent waivers for research targeting Sexual Minorities Youth. Also, public health practices in PR allow individuals under 21 years old request Sexual Transmitted Infections (STIs) testing and treatment without parental permission (PR Law #36, 2008).

3.2.b. Eligibility Criteria for Aims 1 and 3

Inclusion criteria for Aims 1 and 3 will include self-identification as: (1) having had sex with a man and/or being attracted to men; (2) Hispanic/Latino ethnicity; (3) able to read, write, and understand Spanish (for Aim 1) and Spanish or English (for Aim 3); (4) aged 18-26 years; (5) primary residence in either FL or PR. An additional eligibility criterion for Aim 1 is having access to the internet (to complete the online survey). Additional eligibility criteria for Aim 3 are having either regular access to a working telephone or being able to attend an in-person focus group (modifications related to COVID-19 situation will allow virtual modality to complete the focus groups or individual interviews). Exclusion criteria for Aims 1 and 3 will include self-identification as: (1) transman or transwoman or (2) aged $<$18 years or $\geq$27 years. Individuals who contact the research team about interest in participating on Aims 1 or 3 can be directed to Aims 1 or 3 for possible recruitment. Individuals can participate in more than 1 aim, but not more than one time in a single aim.

3.2.c. Aim 1 Procedures

For the quantitative Aim 1 survey, we will recruit participants via Spanish-language social media, broadcasting media, online dating applications advertisements, Spanish-language flyers in community locations (e.g., community clinics, community events, other community locations), in-person (e.g., community clinics or community events), and at virtual events (e.g., cancer education events). In addition, Aim 1 study flyers may be disseminated in physical spaces, via social media, via presentations, and via email, among other dissemination methods by our team, other Moffitt and PHSU teams/departments/cores, and groups, organizations, and networks in the community. Flyers will contain a QR code that will re-direct individuals to the study email address (or an institutional website) to learn more about the study and receive an online survey link. Interested individuals will be asked to contact the study team to learn more about the study and eligibility, and may be emailed an online survey link. CAB members may also assist with recruitment efforts by sharing recruitment materials in various means (e.g., social media platforms, websites, etc.). For in-person recruitment, participants will be provided with an information sheet and a QR code that will be clipped to the information sheet. During in-person recruitment, participants will be able to complete the survey by scanning the QR code on their own device, or with assistance of a research team member who can scan the QR code on an iPad; the QR code will re-direct participants to the survey. After completing eligibility screening in Spanish via a web-based platform (i.e., Qualtrics, a HIPAA-compliant system), eligible participants will be presented with study information in Spanish, asked to provide informed consent electronically, and complete a Re-CAPTCHA task prior to start of the survey. Consenting participants will complete a survey in Spanish

requiring approximately 30 minutes. The survey will be programmed and maintained by the Moffitt Participant Research, Interventions, and Measurement (PRISM) Core. PRISM will program the survey such that only 260 participants will be able to complete the survey. PRISM will collect IP addresses, web browser, device ID, as well as, GeoLocation coordinates and may enable additional available settings to identify and prevent multiple null survey submissions that may affect data integrity. For in-person recruitment, surveys will be administered either via the participants' personal device or via password-protected tablets containing a link to the survey. At the end of survey, the following information is requested: 1) incentive delivery preference and 2) contact information to send the incentive (e.g., name, email or mailing address). Eligible participants who complete a valid survey will receive the incentive in the chosen modality. Participants will be removed from the study without compensation if the research team finds evidence of fraudulent responses.

After completing the online survey, participants will be automatically directed to a separate online survey that will ask them to provide their contact information in order to receive their incentive (a $25 gift card). IP addresses, web browser, device ID, as well as, GeoLocation coordinates will be recorded, and additional settings may be enabled by PRISM to identify and prevent multiple gift card entries by the same participant. Gift card survey entries will be forwarded by PRISM to the research team through a project-specific, institutional e-mail developed by PHSU. The e-mail will only be managed by designated research staff members. At the end of the survey, participants will indicate whether they are interested in potentially participating in other parts of the study (e.g., Aim 3).

Recruitment of Seeds: Instances where the recruitment needs a booster to achieve the sample goal of 260 participants for Aim 1, we will conduct a respondent driven sampling approach. When each eligible participant is able to identify up to three peers with the study characteristics. HPV project team will recruit an initial group of approximately 10-15 seeds. The number of initial seeds will depend on the capacity of the project team as well as the locations and community partners population scope. The eligibility criteria for the seeds will be the same for aim 1. When a potential seed is identified or contacted thru the HPV team or Community-Based or Clinic Partner, HPV project team will briefly describe the current HPV Survey and ask the potential seed if he would be willing to share with peers a study coupon to invite them to the study. If the potential seed do so at that time, he will be given a referral card to provide to their peers who has the eligibility criteria (a recruitment coupon may also serve as a referral card for seeds, see Appendix A). The referral card (coupon) will have: 1) QR code to access the survey, 2) ID Number, 3) general information about the study.

Eligibility Criteria for Valid Seeds: Once eligible seeds agreed they would be willing to recruit other participants for a small incentive. After a brief training on the recruitment process, those who agree to recruit will be given up to 3 coded, non-replicable coupons (Appendix A). The participant will be told to give one coupon to each of up to 3 individuals he knows and has seen in the past 30 days who live in the project area and meet certain specific criteria. Each coupon will have the current HPV logo, location(s) of field site locations, phone number(s) where staff can be reached in case of any question or concern, and a Survey ID number printed on it. The Survey ID on the coupon will be linked

to (but not identical to) the Survey ID of the participant the coupon is issued to (i.e., the recruiter), which will be documented in the coupon manager log (Appendix B).

Coupon Redemption: All persons who bring a valid coupon will scan QR code for eligibility. Those found to be eligible and who give consent to participate in the survey. After completion of the survey, the HPV team will identify the valid seed entries to provide the small incentive ($5.00 per valid seed recruited) and send through electronic gift card to the recruiter.

3.2.d. Aim 2 Participant Recruitment

Participants will be recruited via flyers in English and Spanish distributed by email or in person (depending on COVID restrictions) at community partner locations, community health clinics, health departments, colleges/universities, and interest groups that have served or provided services to YLMSM within the last twelve months. In addition, Aim 2 study flyers may be disseminated in physical spaces, via social media, via presentations, and via email, among other dissemination methods by our team, other Moffitt and PHSU teams/departments/cores, and groups, organizations, and networks in the community.
Additionally, English and Spanish-language emails will be sent to community organizations. In FL, examples of these community partner and clinic locations might include Metro Inclusive Health and Ybor Youth Clinic, clinics associated with the University of South Florida and Florida Department of Health (e.g., HIV/HCV Ryan White Specialty Care Center), LGBTQ student organizations, among others. In PR, examples of community partners include COAI, Inc., a non-profit organization dedicated to promoting health and preventing diseases from a perspective of social justice and human rights for lesbian, gay, bisexual, transgender, transgender, questioning, queer and intersex people [LHBTTQQI]). Interested individuals will be asked to contact the study team who will assess eligibility. Community partners in FL will be compensated $200 per year to allow us to post study recruitment flyers for Aims 1, 2, and 3 and to send the Aim 2 emails to their organization staff or group members. Community partners in PR will receive a stipend for recruitment support for Aims 1, 2 and 3 during the study period.

3.2.e. Eligibility Criteria for Aim 2

Eligibility criteria includes: (1) Individuals with a current or prior role (within last twelve months) in a community-based organization, private or public healthcare clinic, health department, college/university organization, or interest group that provides services to sexual minorities in FL or PR as a healthcare provider, staff member, group member, or in a leadership role; (2) aged 21 or older; (3) able to understand, read, and speak either Spanish or English; and (4) have access to a working telephone or computer.

3.2.f. Aim 2 Procedures

Using a CFIR-informed semi-structured guide (see Aim 2 Semi-structured Interview Guide), initially 10 key stakeholders (5 in PR and 5 in FL) will be engaged to review the current Cancer 101 HPV module content and will be interviewed to provide suggestions for intervention content updates and delivery modalities as well as to explore potential structural facilitators and barriers to implementing a multi-level intervention that includes the culturally-adapted intervention to promote HPV vaccination among YLMSM. Following the Aim 3 focus groups and/or individual interviews, we will ask 10 additional key stakeholders (5 in PR and 5 in FL) to provide feedback on the culturally-adapted intervention. Participants will be interviewed in-person or remotely (e.g., Zoom, phone) by

trained study staff. Interviews are anticipated to last between 30 to 90 minutes and will be audio digitally recorded. Interviews will be transcribed verbatim. Participants will receive a $30 gift card. If recruitment has completed for first half of Aim 2, remaining potential participants who were identified for this aim will be recontacted for the second half of Aim 2 recruitment.

3.2.g. Aim 3 Participant Recruitment

Participants will be recruited through a variety of approaches including 1) Spanish and English Language flyers at community partner locations, community events (e.g., PRIDE events), and community locations, 2) broadcasting media including television, newspaper, magazine, radio, or newsletter; 3) Spanish and English-language online ads (e.g., social media platforms), 4) Aim 3 study flyers may be disseminated in physical spaces, via social media, via presentations, and via email, among other dissemination methods by our team, other Moffitt and PHSU teams/departments/cores, and groups, organizations, and networks in the community, 5) email invitation to participants from prior studies who have indicated interest in taking part in future studies, and 6) from ResearchMatch.org. ResearchMatch is a national health volunteer registry that was created by several academic institutions and supported by the U.S. National Institutes of Health as part of the Clinical Translational Science Award (CTSA) program. ResearchMatch has a large population of volunteers who have consented to be contacted by researchers about health studies for which they may be eligible. Upon IRB approval and when ready to start data collection, the research team will register the study on ResearchMatch.org. Utilizing the study eligibility criteria for men ages 18-26 who identify as Latino and reside in FL or PR, a list of potentially eligible volunteers will be generated. The research team will then send our IRB-approved initial recruitment message to potential matches who will have the option of replying “yes,” “no”, or providing no response. The study’s home page in ResearchMatch will provide information about volunteers who have responded “yes.” After the volunteer has authorized ResearchMatch to provide their contact information to the study team, the study team will contact the participant about potential participation, assess eligibility, explain the study, and informed consent through email, phone call, or a mailed letter.

3.2.h. Aim 3 Procedures

Cultural adaptation of the Cancer 101 HPV module will be informed by data results from Aims 2 and CAB members, and it will be guided by TPB and HBM theories. Individuals interested in participating in Aim 3 will be asked to contact the study team who will assess eligibility. Following development of an initial draft of the educational materials in English and Spanish, using a semi-structured interview guide (see Aim 3 Semi-structured Interview Guide) and established procedures, we will conduct Spanish and/or English-language focus groups and/or individual interviews with 24 YLMSM (12 in each site) to obtain feedback on the intervention. Focus groups or individual interviews will be conducted in-person or remotely (e.g., Zoom, phone) by trained study staff. Focus groups or individual interviews will be conducted in-person or remotely (e.g., Zoom, phone) by trained study staff. Focus groups or individual interviews may be conducted in Spanish or English, depending upon participant preference. Participants will be asked to complete a brief sociodemograhics survey (examples include: age, race, employment status) either online (for those participating remotely) or with a pen-and-paper version (for those

participating in person). During the interview and guided by a semi-structured interview guide, participants will be shown examples of platforms and prototypes of materials to solicit their feedback and preferences. Examples include PowerPoint Presentation, Brochure, YouTube and TikTok videos of HPV-related content. We expect that Aim 3 findings will: (1) provide feedback on the acceptability, accessibility, content, and aesthetics of the intervention to be iteratively adapted based upon participant feedback; and (2) identify the preferred dissemination/learning platform(s) and format(s) to deliver the adapted intervention to YLMSM. Focus groups or individual interviews will be audio digitally recorded. Focus groups or individual interviews are anticipated to last between 90-120 minutes. Interviews will be transcribed verbatim. Participants will receive a $50 gift card. At the end of the interviews, participants will indicate whether they are interested in participating in other parts of the study (e.g., Aim 1).

3.2.i. Assessment of Study Related Variables in Aim 1

Validated scales used in prior studies (e.g., BRFSS, HINTS) will be included for assessment: sociodemographics (location [PR or FL], age, sexual orientation, gender identification, relationship status, race/ethnicity, household income, health insurance status, employment status, education; Hispanic/Latino-specific cultural items; health literacy; numeracy; prior health behaviors and health care experiences; HPV and HPV vaccine awareness/knowledge; HBM constructs; TPB constructs, information sources/trust in information sources; educational preferences; vaccine receipt preferences; vaccine behaviors; vaccine intentions (among those unvaccinated); comfort with sexual health; sexual experiences & social media use, among others (see Aim 1 Quantitative Survey).

3.2.j. Statistical Considerations

3.2.j.i. Data Analysis

For Aim 1, standard descriptive statistics (e.g., frequencies, proportions, means, standard deviations) will summarize all variables and provide excellent estimates of population parameters. The dependent variables are HPV vaccination status and HPV vaccine intentions. The factors to be evaluated for potential associations will be: sociodemographic characteristics, sexual practices, sexual orientation disclosure, social media preferences, vaccination history, among others. Covariation among variables, including predictors of intentions, will also be estimated, using measures appropriate for the paired variables (e.g., r, beta, odds ratio). For Aims 2 and 3, thematic-content analysis techniques using the principles of Grounded Theory will be performed[47,48] whereby themes from the focus group transcripts and key stakeholder interviews are identified.

3.2.j.ii. Sample Size/Power Calculations

The overarching goal of Aim 1 is to generate excellent parameter estimates for the design of subsequent research proposals. With a precision of 0.05 and an 80% of statistical power, we estimate a total of n=260 participants, both estimates of single variable means or proportions and the relationships among predictors and outcome variables will have relatively small 95% confidence intervals. If data collection yields complete and high-quality data, a sample size of n=227 is required to achieve 80% power with a 0.05 precision.

3.2.j.iii. Data Management

MCC and PHSU will complete a data sharing agreement to safely share the database for secondary analysis. The data sharing agreement will include all the HIPAA requirements. A data entry system, designed by the PRISM Core, will store and manage study flow information and questionnaire data. Data will be stored on password-protected computers on the secure MCC and PHSU network servers. Study documents will be secured in locked filing cabinets. Following data cleaning, de-identified data will be sent electronically to Dr. Sutton who will convert the Excel file into SAS (SAS Institute, Inc., Cary, NC) to conduct data analyses. Drs. Marzan, Christy (MPIs), and Sutton (Co-I; biostatistician) the staff statistician will meet regularly to discuss Aim 1 data processing and analyses. NVivo® transcription will be used to transcribe all audio files according to HIPAA requirements. For Aims 2 and 3, all transcriptions will be submitted to review process for accuracy.[49] All qualitative data will be gathered, organized, and managed using NVivo®.

To ensure integrity of responses in the survey in Aim 1, a multi-step approach informed by recommendations in the literature will be conducted. This includes the addition of re-CAPTCHA tasks[50]and/or attention checks throughout the survey.[51] To verify the validity of the data post-survey, staff members (including PRISM and study staff) will check IP addresses to identify duplicates, assess response times to identify fast respondents, identify consecutive responses using a straight lining method, and check the quality of open-ended survey responses. Participants will be removed from the study without compensation if the research team finds evidence of fraudulent responses. Respondents who fail these checks will be removed from the final analytic sample.

3.3 Future Plans

3.3.a. Future Directions/Summary

Guided by health behavior theories and applying systematic and rigorous methods, the proposed innovative study seeks to address multiple cancer disparities through the development of a salient HPV vaccine educational intervention targeted to YLMSM. The culturally-adapted intervention will be tested in a future multi-site randomized controlled trial among YLMSM in FL and PR. Ultimately, this line of research has a significant potential to reduce cancer morbidity and mortality and improve public health.

4. Human Subjects Considerations

4.1.a. Human Subjects Involvement and Characteristics

Procedures for Aim 1:

We will recruit a total of 260 YLMSM in PR and FL using multiple strategies, including in-person recruitment in community settings and at community clinic or community organization locations, social media and dating applications advertisements in Spanish, on platforms such as Instagram®, Snapchat®, and Grindr®, broadcasting media, recruitment flyers in the community, and email invitation to participants from prior studies who have indicated interest in taking part in future studies. CAB members may also assist with recruitment efforts by sharing recruitment materials in various means (e.g., social media platforms, websites, etc.). Individuals who contact the research team about interest in participating on Aims 1 or 3 can be directed to Aims 1 or 3 for possible recruitment when

they indicate that they are interested in participating in other parts of the study. Individuals can participate in more than 1 aim, but not more than one time in a single aim.

For Aim 1 Participants:

For Aim 1, 260 participants will be enrolled. To be eligible participants must self-identify as: (1) having had sex with a man and/or being attracted to men; (2) Hispanic/Latino ethnicity; (3) able to read, write, and understand Spanish; (4) aged 18-26 years; (5) primary residence in either FL or PR; and (6) having internet access (either via personal device or research team tablet). Exclusion criteria for the online survey will include self-identification as: (1) transman or transwoman, and (2) aged >26 years, 364 days. For the online survey, we will recruit participants with the help of CAB members through the dissemination of recruitment materials (e.g., flyers, social media posts, emails, messages), in-person recruitment in community clinics and/or community organization locations, virtual events (e.g. virtual cancer education events), and by using social media, broadcasting media, and online dating applications advertisements in Spanish. In addition, Aim 1 study flyers may be disseminated in physical spaces, via social media, via presentations, and via email, among other dissemination methods by our team, other Moffitt and PHSU teams/departments/cores, and groups, organizations, and networks in the community. Participants may contact the study team from the contact information or QR code linked to the study lab email address for more information, eligibility inquiry, and for the online survey link. For in-person recruitment, participants will be provided with an information sheet and a QR code that will be clipped to the information sheet. They will be able to complete the survey by scanning the QR code on their own device, or with assistance of a research team member who can scan the QR code on an iPad. The QR code will re-direct participants to the survey. After completing eligibility screening in Spanish via a web-based platform (i.e., Qualtrics, a HIPAA-compliant system), eligible participants will be presented with study information in Spanish, asked to provide informed consent electronically, and complete a Re-CAPTCHA task prior to start of the survey. Consenting participants will complete a survey in Spanish requiring approximately 30 minutes. The survey will be able to be completed on various devices with internet capabilities, including desktop computers, laptops, tablets, and mobile phones. The survey will be programmed and maintained by the Moffitt Participant Research, Interventions, and Measurement (PRISM) Core. PRISM will collect IP addresses as well as GeoLocation Coordinates and may enable additional available settings to identify and prevent multiple null survey submissions that may affect data integrity.

After completing the online survey, participants will be auto directed to a separate online survey that will ask them to provide their contact information in order to receive their incentive (a $25 gift card). IP addresses as well as GeoLocation coordinates will be recorded, and additional settings may be enabled by PRISM to identify and prevent multiple gift card entries done by the same participant. Gift card survey entries will be forwarded by PRISM to the research team through a project-specific, institutional e-mail developed by PHSU. The e-mail will only be managed by designated research staff members.

Procedures for Aim 2:

We will conduct 20 in-depth interviews with key stakeholders (i.e., healthcare clinic leadership, providers and staff, community-based organization staff, staff and leadership

from health departments, colleges/universities, and interest groups who have served or provided services to YLMSM within the last 12 months in PR and FL (10 in PR, 10 in FL). This will elicit their feedback and inform intervention content and delivery methods and identify potential facilitators and barriers to intervention implementation. Participants will be interviewed in-person or remotely (e.g., Zoom, phone) by trained study staff. If recruitment has completed for first half of Aim 2, remaining potential participants who were identified for this aim will be recontacted for the second half of recruitment in the Spring.

For Aim 2 Participants:

For Aim 2, initially 10 key stakeholders will be interviewed (5 in PR and 5 in FL) in English or Spanish. Following Aim 3 focus groups or individual interviews and adaptation of the materials, an additional 10 key stakeholders will be interviewed (5 in PR and 5 in FL) in English or Spanish. Participants will be recruited via flyers in English and Spanish distributed by email or in person (depending on COVID restrictions) at community partner locations, community health clinics, health departments, colleges/universities, and interest groups who have served or provided services to YLMSM within the last 12 months. In addition, Aim 2 study flyers may be disseminated in physical spaces, via social media, via presentations, and via email, among other dissemination methods by our team, other Moffitt and PHSU teams/departments/cores, and groups, organizations, and networks in the community. Additionally, English and Spanish-language emails will be sent to community organizations. Interested individuals will be asked to contact the study team who will assess eligibility. To be eligible participants must be (1) individuals with a current or prior role (within last 12 months) in a community-based organization, private or public healthcare clinic, health department, college/university organization, or interest group that provides services to sexual minorities in FL or PR as a healthcare provider, staff member, or in a leadership role; (2) aged 21 or older; (3) able to understand, read, and speak either Spanish or English; and (4) access to a working telephone. Interviews are anticipated to last between 30-90 minutes and will be audio digitally recorded. Participants will receive a $30 gift card.

Procedures for Aim 3:

We will conduct focus groups or individual interviews (i.e., approximately 2-3 in FL and 2-3 in PR) with 24 YLMSM in Spanish and English. Participants will be recruited via Spanish and English flyers at community partner locations, community locations, and community events in PR and FL (e.g., PRIDE events), broadcasting media, online ads (e.g., on social media platforms commonly-used by YLMSM), disseminated in physical spaces, via social media, via presentations, and via email, among other dissemination methods by our team, other Moffitt and PHSU teams/departments/cores, and groups, organizations, and networks in the community, and/or ResearchMatch. For ResearchMatch recruitment, our study will be registered on ResearchMatch.org. The research team will then send our IRB-approved initial recruitment message to potential matches who will have the option of replying “yes,” “no”, or providing no response. The study’s home page in ResearchMatch will provide information about volunteers who have responded “yes.” After the volunteer has authorized ResearchMatch to provide their contact information to the study team, the study team will contact the participant about potential participation, assess eligibility, explain the study, and informed consent through encrypted email, phone call, or a mailed letter. Focus groups or individual interviews will be conducted in-person or remotely (e.g., Zoom, phone) by trained study staff in either English or Spanish, depending upon

participant preference. A brief sociodemographic online or in-person survey will be completed by Aim 3 participants prior to the focus group or individual interview. Individuals who contact the research team about interest in participating on Aims 1 or 3 (when recruitment cap has been completed for that aim) can be directed to Aims 1 or 3 for possible recruitment. Individuals can participate in more than one aim, but not more than one time in a single aim.

For Aim 3 Participants:

Eligibility criteria for Aim 3 participants have been described previously. Inclusion criteria for Aims 3 will include self-identification as: (1) having had sex with a man and/or being attracted to men; (2) Hispanic/Latino ethnicity; (3) able to read, write, and understand Spanish or English; (4) aged 18-26 years; (5) primary residence in either FL or PR. Additional eligibility criteria for Aim 3 is having either regular access to a working telephone or being able to attend an in-person focus group (modifications related to COVID-19 situation will allow virtual modality to complete the focus groups or individual interviews). Exclusion criteria for Aim 3 will include self-identification as: (1) transman or transwoman; (2) aged $<$18 years or $\geq$27 years. Cultural adaptation of the Cancer 101 HPV modules will be informed by data results from Aim 2 and guided by TPB and HBM. A brief sociodemographic survey will be completed by Aim 3 participants either online or in-person prior to completing an individual interview or focus group. Following development of an initial draft, using a semi-structured interview guide and established procedures, we will conduct focus groups or individual interviews with approximately 24 YLMSM to obtain feedback on the intervention. During the interview and guided by a semi-structured interview guide, participants will be shown examples of platforms and prototypes of materials to solicit their feedback and preferences. Examples include YouTube and TikTok videos of HPV-related content. We expect that Aim 3 findings will: (1) provide feedback on the acceptability, accessibility, content, and aesthetics of the intervention to be iteratively adapted based upon participant feedback; and (2) identify the preferred dissemination/learning platform(s) and format(s) to deliver the adapted intervention to YLMSM. Focus groups or individual interviews will be audio digitally recorded. Focus groups and individual interviews are anticipated to last between 90-120 minutes. Participants will receive a $50 gift card. Refreshments may also be served at in-person focus groups or individual interviews.

4.1.b. Sources of Materials

4.1.c Potential Risks

We do not expect that participants will have "more than the minimal risk" associated with this type of research. Participants can feel uncomfortable sharing their sexual practices or sexual orientation experiences. First, the interviewers will be trained to create a safe space and group rules to increase participants comfort and minimize distress. Furthermore, all participants will be informed that participation is voluntary, and that any information provided will be kept strictly confidential. Finally, staff will be trained to recognize symptoms of distress and to provide assistance when they see evidence of distress or any emergency situation. Loss of confidentiality is a potential risk. To minimize risk of loss of confidentiality, participants will be reminded that their information will not be shared with other entities not involved in research. The network is password protected with daily back up for increased security. Furthermore, identifying information will not be reported to the

funding agency or in publications. Data exchanged electronically among the researchers will contain no name or medical record numbers or will be in aggregate form with no direct identifiers. The study database will be password protected and only our research team members will have access to it. The PI will monitor the welfare of each participant and report any adverse events to the IRB as they occur. Participants may withdraw participation at any time for any reason by notifying the study PI or staff.

4.2. Adequacy of Protection Against Risks

4.2.a. Recruitment and Informed Consent

Review and approval of study by the MCC Scientific Review Committee and MCC and PHSU Institutional Review Board of Records will be sought prior to initiation of study activities. For Aim 1 recruitment, we will recruit a total of 260 YLMSM in PR and FL using social media and dating applications advertisements on platforms such as Instagram®, Snapchat®, and Grindr®, in-person recruitment at community events and locations, and flyers posted in the community. Individuals that agree to participate will be directed to a web-based platform to complete eligibility screening electronically (e.g., Qualtrics). Eligible individuals will be asked to provide informed consent electronically. Consenting participants will complete a survey requiring approximately 30 minutes via an approved HIPAA-compliant system (i.e., Qualtrics). The survey will be able to be completed on various devices with internet capabilities, including desktop computers, laptops, tablets, and mobile phones. The survey will be programmed and maintained by the Moffitt Participant Research, Interventions, and Measurement (PRISM) Core. Participants will receive an incentive for participation in the form of a $25 gift card that will be sent electronically or by mail depending on the participant's preference. For Aim 2 recruitment, Participants will be recruited via flyers in English and Spanish distributed by email or in person (depending on COVID restrictions) at community partner locations, community health clinics, health departments, colleges/universities, and interest groups who have served or provided services to YLMSM within the last 12 months. Additionally, English and Spanish-language emails will be sent to community organizations. Interested individuals will be asked to contact the study team who will assess eligibility. For Aim 3 recruitment, participants will be recruited via English and Spanish- language flyers at community partner locations, community locations, and community events in PR and in FL (e.g., PRIDE events) as well as via social media platforms. In addition, ResearchMatch will be utilized to recruit for Aim 3. After study information is presented, individuals will be asked if they would like to participate in the study.

4.2.b. Protections Against Risk

There are no potential physical risks to participants posed by this study. This study involves minimal risk for emotional or psychological distress. However, these risks are not expected to be any greater than risks posed in everyday life. Participant documents, including participant tracking documents, will be kept in a locked cabinet in a locked location. Computers will be password-protected and data will be backed-up daily on a secure server. Only authorized research staff will have access to data. Research staff will be trained to interact with participants in a sensitive manner during all study components. For Aim 1, consenting participants will complete a survey via an approved HIPAA-compliant system (i.e., Qualtrics). The survey will be able to be completed on various devices with internet capabilities, including desktop computers, laptops, tablets, and

mobile phones. The survey will be programmed and maintained by the Moffitt Participant Research, Interventions, and Measurement (PRISM) Core. PRISM will collect IP addresses as well as GeoLocation Coordinates and may enable additional available settings to identify and prevent multiple null survey submissions that may affect data integrity. Once the participant completes the survey, it will automatically be returned to the study staff in a confidential manner. For Aim 2, key stakeholders will be asked to refrain from using identifying information. For Aim 3, focus group participants will be told not to share their full names (use first name only), and are encouraged to use a pseudonym if they prefer to maintain confidentiality. Focus group participants will be told to keep private anything discussed in the focus group. In addition, any data transmitted within the research team will be stripped of identifying information and labeled with a unique identification number.

4.3. Potential Benefits of the Proposed Research to Human Subjects and Others

There are no definitive or guaranteed benefits to participants. The overall goal is to promote HPV vaccination in order to reduce HPV-related cancer incidence and mortality in Latino Sexual and Gender Minorities. Also, the completion of the proposed study will lay the groundwork for a multi-site randomized controlled trial (e.g., NIH R01 or R34) in PR and FL.

4.4. Importance of the Knowledge to be Gained

We will identify knowledge gaps, health beliefs, attitudes, and educational learning preferences in this high-risk population which will inform content for the educational intervention to promote HPV vaccination. The goal of this research program is to promote HPV vaccination in order to reduce HPV-related cancer incidence and mortality.

4.5. Gender and Minority Inclusion for Research Involving Human Subjects

The overall goal is to promote HPV vaccination in order to reduce HPV-related cancer incidence and mortality in Latino Sexual and Gender Minorities, including Hispanic/Latino individuals that self-identify as gay, bisexual and, queer cis-male and are able to read, speak, and understand Spanish.

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Appendix A. Referral Card (SPA)

Appendix A. Referral Card (ENG)

Appendix B. Coupon Manager Log (SPA)

Fecha Mm/dd/aaaa	Localización	ID Reclutador Semilla (Ej. A-001)	ID Válido Y/N	Initials Staff or CBO member

Appendix B. Coupon Manager Log (ENG)

Date Mm/dd/yyyy	Location	Seed Recruiter ID (Ej. A-001)	Valid ID Y/N	Initials Staff or CBO member