PROTOCOL TITLE:

Using Text Messaging to Increase HPV Vaccination among Young Sexual Minority Men

SHORT TITLE:

txt2protect

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Table of Contents

1.0 Objectives

Objectives and Aims

The objective of this project is to develop and pilot test a text messaging intervention to increase human papillomavirus (HPV) vaccination in young adult men who self-identify as gay, bisexual, or queer (which for the sake of brevity, will be referred to as MSM throughout this application, although some men will be sexually inexperienced).

Specific Aim 1: Develop, iteratively refine, and pre-test messages using a 5-step formative research procedure. To achieve this aim we will use a well-established formative approach for designing targeted health interventions. The procedure consists of 5 steps: 1) conduct online focus groups, an online survey, and in-depth interviews to inform message content, 2) draft initial messages based on focus group findings and pilot data, 3) refine message content and assess acceptability using content advisory teams, 4) conduct internal alpha testing to ensure software functionality, and 5) beta test the protocol. Intended users of the program (i.e., MSM aged 18-26 years old from the Chicago metro area) will be recruited to assist with this process.

Specific Aim 2: Test the feasibility, acceptability, and preliminary efficacy of the txt2protect (t2p) text messaging intervention in a pilot randomized controlled trial (RCT). To achieve this aim, 460 unvaccinated MSM (ages 18-26) who live in the Chicago metro area will be randomly assigned to the treatment (t2p) or control condition. The treatment condition will receive a culturally appropriate text messaging-based HPV vaccination intervention based on the IMB model, whereas the control condition will receive a text messaging-based sexual health intervention that includes basic facts about HPV vaccination readily accessible online. Primary outcome measures include intervention feasibility (recruitment and retention in the trial), acceptability (satisfaction with the intervention), and preliminary efficacy as determined by initiation (receipt of the first dose) and completion of the 3-dose HPV vaccine series at the end of the 9-month trial. Vaccination status will be verified by participants' medical records and the Illinois Immunization Registry.

Hypotheses

Specific Aim 2: Participants in the t2p condition (vs. control) will report greater acceptability of the intervention and will be significantly more likely to initiate and complete the 3-dose HPV vaccine series by the end of the trial.

2.0 Background

Significance and Innovation

HPV is a common STI that can cause cancer (anal, penile, oropharyngeal cancer) and genital warts in men.[1] Due to their sexual practices (e.g., receptive anal intercourse), **MSM are at particularly high risk for HPV infection and are disproportionately affected by HPV-related cancers**. Over a 1-year study, for example, oncogenic HPV types 16 and/or 18 were detected in 37% of MSM aged 16-30 years.[2] Rates of anal cancer are over 17 times higher among MSM relative to heterosexual men,[3] and the burden of anal cancer is exceptionally high among HIV-positive MSM.[4] In addition to cancer, HPV causes genital warts, which are costly to treat and negatively impact quality of life.[5] **A safe and effective vaccine is available to prevent HPV infection, yet HPV vaccination rates in the U.S. have been disappointingly low, particularly among males.** The quadrivalent HPV vaccine (for types 6, 11, 16, 18) and more recently, the 9-valent HPV vaccine (plus types 31, 33, 45, 52, 58) are extremely effective in preventing

HPV infection.[1, 6] The HPV vaccine is given as a 3-dose series, with the 2nd and 3rd doses administered 1-2 and 6 months after the 1st dose, respectively. The Advisory Committee on Immunization Practices (ACIP) recommends *routine* HPV vaccination in 11- and 12-year-old girls and boys, and catch-up vaccination among 13-26 year-old females and 13-21 year-old males not previously vaccinated, although males aged 22-26 may also be vaccinated.[1] Although HPV vaccine is most effective in sexually naïve youth, given their high-risk status, ACIP recommends HPV vaccine for all MSM up to age 26 regardless of whether they have been sexually active, as it is unlikely they have been exposed to all HPV types covered by the vaccine.[1, 6] Nationally, HPV vaccine uptake in males lags far behind females: About 60% of adolescent females have received at least one dose of the vaccine compared to only 41.7% of males.[7] A similar disparity holds for completion of the 3-dose series (39.7% of females vs. 21.6% of males).[7] **Although HPV vaccine is recommended for all MSM though age 26 years, relatively few have been vaccinated.** Recent studies with national samples of gay and bisexual men aged 18-26 found that only 13-21% had initiated the series.[8, 9] Our pilot work suggests that many MSM are simply unaware of the vaccine or perceive other important barriers to getting vaccinated. **To remedy this gap, the goal of the proposed research is to develop and pilot test a text messaging intervention to increase HPV vaccination in young MSM.** This contribution is significant because it will identify new strategies for promoting HPV vaccination among a high-risk population. Beyond these more immediate outcomes, the ultimate goal of this research is to reduce morbidity, mortality, and disparities associated with HPV-related cancers among MSM. This work will also shed light on factors that affect use of other health services for young MSM that, like vaccination, typically involve interaction with the health care system (e.g., HIV testing, mental health screening and treatment).

Although MSM are disproportionately affected by HPV-related cancers, **this group has been neglected in previous HPV vaccination research**. Research has centered largely on parents and young adult women.[10-18] While such work has identified important factors that promote and/or discourage HPV vaccination, it falls short of recognizing factors that may be unique to young MSM. **Existing research suggests relatively high acceptance of HPV vaccine among MSM;[19-28] nevertheless many of these studies have significant limitations:** 1) they were conducted prior to ACIP's 2011 recommendation for *routine* HPV vaccination among boys and men and thus were hypothetical in nature, 2) involved MSM older than age 26 years, and 3) lacked a strong theoretical framework.[29] To our knowledge, only two studies (one by our team) have been conducted with young adult gay and bisexual men since HPV vaccination became routine for males in 2011.[8, 9] **As the HPV vaccination intervention field is still in its relative infancy, no known HPV vaccination interventions have been designed specifically for MSM.** In addition to its focus on young MSM, the proposed research is innovative in several ways: 1) Our intervention will *target young adults directly* rather than indirectly through their parents. 2) We will build on and further strengthen an existing evidence-based intervention for vaccination ("reminder-recall") by including messages that *address barriers to HPV vaccine uptake with special emphasis on barriers unique to MSM*. 3) Because our pilot data identified provider recommendation as the strongest predictor of HPV vaccination,[8] several *messages will come directly from a physician specializing in sexual minority health*. To facilitate this objective we have partnered with one of the largest LGBT health care centers in Chicago, Howard Brown Health Center (HBHC). 4) We will encourage participants to receive HPV vaccine in primary care clinics as well as at pharmacies. Pharmacies have been identified as a *promising alternative setting for increasing HPV vaccination rates*, particularly for

promoting completion of the 3-dose series due to their convenient locations and longer hours of operation.[30, 31] 5) We will be recruiting participants directly from the community and thus will be able to *extend the reach of the intervention to those individuals who might not normally see a physician*.[32, 33] Together, these elements reflect a novel approach to promoting HPV vaccination among young MSM.

Preliminary Data

HPV vaccination among young MSM. To inform the proposed project, Drs. Gerend, Phillips, and Mustanski conducted a pilot study to identify barriers and facilitators to HPV vaccine uptake among young MSM.[8] We recruited a national sample of 336 MSM aged 18-26 to complete an online survey. 21% had received ≥1 dose of HPV vaccine. Provider recommendation was the strongest predictor of uptake such that MSM with a recommendation were over 40 times more likely to have been vaccinated. We also observed disparities in uptake, with lower rates among 21-26 year-olds (vs. 18-20), Latinos (vs. Whites), and HIV-negative (vs. HIV-positive) men. Primary barriers to uptake included lack of information about HPV and the vaccine, lack of provider recommendation, and not having disclosed their sexual identify to their provider.

Reducing barriers to HPV vaccination. In previous work (R03CA138069), Dr. Gerend identified primary barriers to HPV vaccine uptake among young adult women aged 18-26[34] and demonstrated that tailoring intervention materials to women's perceived barriers increased their intentions to receive HPV vaccine.[35] Intervention materials addressed common barriers to uptake including lack of information about HPV and the vaccine, concerns about side effects and vaccine safety, low perceived need due to not being sexually active or in a committed relationship, disliking shots, and vaccine cost. In the proposed RCT, we will use a *targeted approach*[36, 37] such that treatment messages will be specifically designed for MSM (e.g., provide tips to address common and unique barriers to HPV vaccine uptake among young MSM).

Guy2Guy (G2G): A text messaging intervention for young MSM. To design our messages we will follow the 5-step procedure used to develop Guy2Guy[38] (G2G; R01MH096660, Mustanski & Ybarra, Multiple PIs), a text messaging-based HIV prevention intervention for adolescent gay, bisexual and queer men. MSM were randomly assigned to the treatment (a culturally appropriate HIV prevention and healthy sexuality intervention that was informed by the target population and guided by the IMB model[39]) or control arm (that provided basic HIV prevention facts plus healthy lifestyle information). Participants received 5-10 text messages daily for 5 weeks. In addition to being highly feasible and acceptable,[38, 40] short-term outcome analyses found that the rate of condomless sex acts over the course of the intervention was 61% lower in treatment vs. control (although long term effects were more modest). Of particular relevance to the proposed study, participants in the treatment group were over twice as likely to get tested for HIV relative to control.

Rationale

Reminder-recall and text messaging interventions. Reminder-recall interventions are a well-established evidence-based approach to increasing vaccination that are endorsed by the US Task Force on Community Preventive Services.[41, 42] The goal of these interventions is to both educate and notify individuals that they are due (or overdue) for a vaccine. Historically, reminder-recall interventions used letters, postcards, or telephone calls, but have recently transitioned to electronic formats such as text messages and email. Text messages (or short-message service, SMS) serve as particularly effective reminders in that, relative to a letter or postcard, they are more likely to grab attention, reach the intended recipient, and because they can be stored on

a cellular phone, can be easily accessed almost any time.[42] Beyond providing basic education and a cue to action, text messages can be tailored to address barriers to vaccine uptake. Although research is still accumulating, text messaging-based interventions appear to be a promising, cost-effective strategy for promoting health behaviors.[43-45] Such interventions may be particularly effective for young adults, as nearly all young adults in the U.S. own a cell phone (mainly a smartphone) and 97% use text messaging.[46] We chose to create a text messaging intervention rather than a smartphone application because text messages can be sent proactively and are routinely used by the target age group.

Theoretical framework. The theoretical framework guiding the proposed project is the Information, Motivation, and Behavioral Skills (IMB) model.[39] This model, originally developed for HIV prevention, proposes that individuals will engage in a given health behavior when they are adequately informed, motivated to act, and have the appropriate behavioral skills and self-efficacy do to so. Text messages can provide basic information (e.g., about HPV and the vaccine; convenient locations to get vaccinated such as a pharmacy) and serve as a reminder (e.g., to schedule an appointment, to receive the 2nd or 3rd dose). They can also boost motivation (e.g., by promoting favorable attitudes and norms; by addressing barriers like safety concerns) and improve necessary skills (e.g., talking with one's doctor about the vaccine, verifying health insurance coverage).

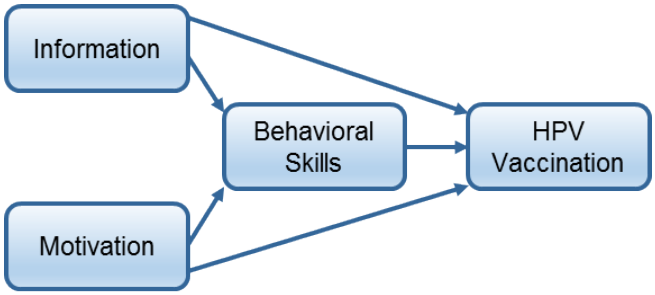

Figure 1. Guiding Theoretical Framework

3.0 Inclusion and Exclusion Criteria

Specific Aim 1

Participants for this project will be self-identified gay, bisexual, and queer males between the ages of 18-26 years who provide informed consent to participate. (Please note that the upper age limit will be reduced to age 25 for the beta test and RCT so participants will continue to remain eligible for HPV vaccination throughout the length of the study.) Participants will be recruited online through ads placed on websites and dating apps such as Facebook, Twitter, Grindr, Craigslist, and Jack'd, a strategy that has been extremely successful by the current team across multiple NIH-funded projects and in a number of metropolitan areas across the U.S. including Chicago.[40, 47-49]

ResearchMatch.org will also be utilized as a recruitment tool. ResearchMatch.org is a national electronic, web-based recruitment tool that was created through the Clinical & Translational Science Awards Consortium in 2009 and is maintained at Vanderbilt University as an IRB-approved data repository (see IRB #090207). Participants may also be recruited from existing participant registries (e.g., Institute for Sexual and Gender Minority Health and Wellbeing [ISGMH]; Third Coast Center for AIDS Research [CFAR]).

Interested participants will be directed to a screening survey where eligibility will be assessed. The **inclusion criteria** will closely match that of the intended users of the eventually designed program and be consistent with the latest CDC guidelines for HPV vaccination. Participants must:

1) be male (sex at birth and gender identity)

2) be 18-26 (*Upper age limit will be age 25 for the beta and RCT) years old
3) self-identify as gay, bisexual, or queer; ever had sex with a man; or be physically attracted to men
4) be English speaking
5) live in the Chicago metro area
6) be the exclusive owner of a cell phone
7) have used text messaging for at least 6 months
8) plan to have the same cell phone number for the next 9 months
9) be enrolled in an unlimited text messaging plan

The screener will also assess HPV vaccination status, which will be confirmed by consulting the Illinois Immunization Registry before enrollment. Vaccinated and unvaccinated participants will take part in Step 1, but Steps 3 and 5 will be limited to unvaccinated participants. Participants will be selected using a purposive sampling strategy to ensure a sample that is diverse in age, race, ethnicity, and sexual identity. Individuals meeting inclusion criteria will be contacted by telephone to complete the enrollment process (e.g., confirm eligibility, describe the study).

Specific Aim 2
Inclusion criteria will be identical to Aim 1 except that enrollment will be limited to individuals who have not been previously vaccinated for HPV. HPV vaccination status will be assessed twice – once in the screener and again in the baseline survey – before participants are randomized and enrolled into the study. Participants' self-reported vaccination status in the screener and baseline survey will be confirmed by consulting the Illinois Immunization Registry before enrollment.

Special Populations
We will not be recruiting any special populations (e.g., adults unable to consent, individuals who are not yet adults, pregnant women, or prisoners) for this project.

4.0 Study-Wide Number of Subjects
N/A

5.0 Study-Wide Recruitment Methods
N/A

6.0 Multi-Site Research
N/A

7.0 Study Timelines
Participants who take part in Aim 1 will be involved with the study for the length of the focus group (2 days). We anticipate using the first 10 months of the 24-month project to complete Aim 1. Participants who take part in Aim 2 will be involved with the study for the length of pilot RCT (9 months). We plan to begin recruiting for the pilot RCT in month 11 and expect recruitment to take approximately 3 months.

We anticipate that the duration required to enroll all study subjects will be approximately one year and a half.

We anticipate completing the study approximately 4-6 months after the pilot RCT. The funding period for this project is 2 years; however, we suspect that we may need to request a no-cost extension to wrap up the study.

8.0 Study Endpoints

Primary Outcomes – Aim 2

Feasibility. Intervention feasibility will be evaluated by recruitment and retention in the RCT. We will record recruitment and enrollment statistics at every step (e.g., number of clicks on online ads, number who complete the screener, number of eligible participants, number randomized). Retention rates will be computed for each assessment period. An 80% 9-month retention rate will be used to indicate a feasible intervention.

Acceptability. Intervention acceptability will be assessed at the end of Phases 1 and 2 with an adapted version of a scale used in G2G[38] and KIU! (an online HIV prevention intervention; R34MH079714, Mustanski PI).[49] The scale includes both open- ("What did you like about the program? What could be improved?") and closed-ended questions (e.g., "I would recommend a program like this to my friends" 1=*strongly disagree* to 5=*strongly agree*). Average scores ≥4 will be used to indicate an acceptable intervention.

Vaccination Status. A final confirmatory assessment of HPV vaccination status will be conducted at the 9-month follow-up. Participants will be asked whether they received any doses of HPV vaccine (yes/no) since baseline and if yes, the number of doses and where they were received. Vaccination status will be confirmed by consulting the Illinois Comprehensive Automated Immunization Registry (I-CARE). Pharmacies in Illinois are required to report all vaccinations to the registry,[50] thus any HPV vaccines administered at a local pharmacy over the trial will be documented in I-CARE. Medical chart data will be sought from those participants who report receiving any doses from their primary care physician over the 9-month trial and those doses are not found in I-CARE. Medical chart data will only be sought for those participants who sign the medical release form (see supporting documents).

Vaccination status will be checked in I-CARE at the beginning and end of the trial. Please see supporting documents and below for additional detail.

9.0 Procedures Involved

Note: Version 2 of this IRB application was associated with a Just-in-Time request from NIH for this project. Since that time, this project was funded and officially began on July 1, 2016. Some of the attachments associated with the approved (Version 2) IRB application are in draft form. We will be sure to submit updated versions of all study-related documents and report any changes regarding study procedures or personnel as appropriate.

Research Design for Aim 1

Overview. The primary goal of Aim 1 is to develop content for the text messaging intervention and conduct initial pre-testing using a 5-step formative approach developed by Mustanski and Ybarra:[38] (1) Conduct 4 online focus groups to inform message content, (2) Draft initial messages based on focus group findings and our pilot data, (3) Further refine message content and assess acceptability using 3 content advisory teams, (4) Conduct internal alpha testing to ensure software functionality, and (5) beta test the protocol.

Step 1: Develop message content. We will conduct online focus groups (FGs) using a password-protected message board to inform message content and delivery preferences. This approach has been used by Mustanski and colleagues and proven to be a rich source for intervention development by allowing participants to identify barriers and potential solutions and make suggestions on how to frame intervention content.[38, 47, 48] Relative to traditional in-person FGs, online FGs can accommodate a larger number of participants who can participate throughout the day from any location at their convenience. FG participants will be required to visit the message board 2-3 times per day for 2 days to respond to the moderators' questions and comments from other participants. We will conduct 4 FGs total, 2 with vaccinated and 2 with unvaccinated participants. See Appendix 1 for a sample moderator script.

To complement the online FGs, we will also conduct an online survey and in-depth interviews. Our pilot data for this project focused on a national sample of YMSM. As the current project specifically targets YMSM in the Chicago area, we would like to gain a better understanding of facilitators and barriers to HPV vaccination for our local population. Although these factors will be assessed in the online focus groups, we believe that these additional data collection formats will allow for a richer understanding of men's knowledge, attitudes, and beliefs regarding HPV vaccination than could be supplied in a focus group alone. See Appendix 8 and 9 for the online survey and interview guide.

Step 2: Draft initial messages. Transcripts from the FGs will be imported into Dedoose,[51] a mixed-methods analysis program. Two rounds of constant comparison analysis will be conducted to create and refine the codebook, which will be followed by a thematic content analysis.[52, 53] Using these themes in conjunction with results from our pilot work,[8] Dr. Gerend will draft an initial pool of messages. Treatment condition messages will be written to directly address IMB components, with special emphasis on barriers relevant to each component. Messages will take into account unique socio-cultural and developmental factors relevant to gay, bisexual, and queer men to ensure that content is appealing and culturally appropriate. Control condition messages will include basic facts about HPV vaccination currently available online plus general sexual health content adapted from G2G. Control messages will be largely informational yet, to ensure a blinded control group, will be aligned with what young MSM might expect in a sexual health program. Messages will be reviewed by Drs. Phillips, Mustanski, and Houlberg and subjected to further edits and review, as necessary.

Step 3: Refine messages and assess acceptability. We will use content advisory teams (CATs) to further refine the messages. CAT1 and CAT2 will focus on treatment condition messages and CAT3 will focus on control condition messages. CAT members will receive an email link to the list of initial messages hosted on a secure web-based application called REDCap and will be asked to provide feedback on their overall tone, clarity, and appeal, and to identity their favorite and least favorite messages (See Appendix 2 for draft survey). Several days later, CAT members will take part in a 2-day online FG (similar to Step 1) to discuss the messages as a group and provide suggestions for improvement. Feedback from CAT1 will be used to further refine the messages. This process will then be repeated with another team (CAT2). CAT3 will complete this process for control condition messages. See Appendix 3 for a sample FG guide.

Step 4: Test software functionality. We will conduct alpha testing with the study team to ensure that the text messaging software is functioning correctly. In addition, we will verify the enrollment process and randomization procedure, assess message delivery and display, and correct any programming bugs.

Step 5: Beta-test the protocol. To identify opportunities for improving program usability and to ensure functionality we will beta test the protocol. Twenty participants will be recruited for the beta test. Participants will complete a baseline survey and then receive 5-10 messages daily (similar to the number sent in G2G) for 3 weeks (similar to Phase 1 of the pilot RCT described below). At the end of week 1 and 2, participants will receive a brief check-in survey to provide open-ended feedback on the program. After the final week of messages (week 3), participants will complete a final check-in survey plus additional items to assess intervention acceptability and immediate outcomes of interest (e.g., HPV/HPV vaccine knowledge, IMB constructs, intentions to get vaccinated). See Appendix 4 for draft surveys associated with the Beta-test.

Research Design for Aim 2

Overview. The primary goal of Aim 2 is to pilot test the intervention to establish feasibility, acceptability, and preliminary efficacy. Young MSM in the Chicago metro area will be recruited primarily online as well as from Howard Brown Health Center, and randomly assigned to the treatment or control condition. The intervention will be divided into two phases: During Phase 1 (weeks 1 through 3) participants will receive about 10 messages per day (similar to G2G). During Phase 2 (weeks 4 through 36) message frequency will decrease to monthly messages. The precise number of messages sent per day and delivery schedule may be altered based on feedback from participants in Aim 1. To give participants sufficient time to get vaccinated and because HPV vaccination is currently achieved with 3 doses administered over a 6-month period, participants will be followed for 9 months. Participants will complete assessments at baseline, immediately after Phase 1, and at the end of the 9-month trial (in order to observe all doses). Upon study completion, vaccination status will be verified by participants' medical records and the Illinois Immunization Registry, which tracks pharmacy-delivered vaccines.

Pilot RCT. Participants will be randomized 1:1 to the treatment or control condition using the REDCap (Research Electronic Data Capture) randomization module. Intervention content will be delivered in two phases over a 36-week period. During Phase 1 (weeks 1 through 3), participants will receive about 10 messages daily. During Phase 2 (weeks 4 through 36), message frequency will decrease to monthly messages. To match for attention, message frequency will be equal across the treatment and control conditions. During Phase 2, participants will receive up to three "pop-up" surveys where they will be able to inform us if/when they receive a/each dose of HPV vaccine so messages can be appropriately tailored (e.g., switch from promoting initiation to completion of the 3-dose series). Participants with a primary care provider will be instructed to contact their provider about receiving the vaccine. If their provider does not carry the vaccine, participants will be directed to seek the vaccine at a local pharmacy (e.g., Walgreens, CVS). Uninsured and underinsured participants will be directed to HBHC, a FQHC that provides care on a sliding fee scale.

***Treatment condition*.** Phase 1 content will be presented in 3 modules (1 per week), each reflecting a component of the IMB: Module 1 will address **information** about HPV infection and the HPV vaccine. It will also include a "doctor's blog" to capture the important influence providers have in promoting HPV vaccination and to further legitimize the information. Module 2 will address **motivations** to receive HPV vaccine. Content will address attitudes and social norms about HPV vaccination, vulnerability to HPV infection, and vaccination intentions. Module 3 will focus on **behavioral skills** and self-efficacy for initiating and completing the 3-dose series such as scheduling an appointment, talking with their doctor about the vaccine (and possibly their sexual identity), verifying whether their health insurance covers the vaccine, and finding

alternative locations to receive the vaccine (such as a pharmacy) if it is not carried by their physician. Each module will include tips that address potential barriers relevant to each IMB component. Phase 2 "booster" messages will largely reinforce Phase 1 content to foster continued engagement with the program, although some new content will also be introduced. For example, messages will shift to encourage vaccine completion when a participant initiates the series.

***Control condition*.** Phase 1 content will be presented in 3 modules; however, unlike the treatment group, content will be topic-based rather than theory-based and will focus on general sexual health. Module 1 will address basic facts about HIV and STIs, including HPV. Module 2 will address HIV/STI prevention (e.g., condom use) and will include basic facts about HPV vaccination that are currently available online. Module 3 will address healthy relationships. Phase 2 messages will reinforce Phase 1 content to maintain engagement.

Text Messaging and Data Collection Platform. With the exception of screening survey data (which will be collected using Limesurvey for the Beta test and RCT), study data will be collected and managed using REDCap (Research Electronic Data Capture) an electronic data capture system hosted at Northwestern University. REDCap is a secure, web-based application designed to support data capture for research studies. REDCap added the functionality to send SMS and phone surveys in the 6.6.0 release. This functionality is enabled through the cloud-based telephony service provider Twilio (www.twilio.com). In accordance with the defined text-messaging schedule of the pilot RCT, we will use REDCap to send text messages to participants. We will also use REDCap to inform participants about online assessments. Participants will receive the link to the survey via text message. This will provide consistency for participants in that all messages will be coming from one source. We chose REDCap as our platform because it is cost-effective, user friendly, open source, and scalable, features that will be particularly important in future implementation of the t2p intervention.

Assessments. Participants will complete the screener plus three assessments at baseline, end of Phase 1 (end of week 3), and end of Phase 2 (end of the 9-month trial), with participants initially receiving $10, $10, and $30 for each respective survey. Beginning in June 2018, the incentives were increased so that participants received $15 each at baseline and the end of Phase 1, and $45 at the end of Phase 2. The study team hopes that the increase in incentives will help with meeting recruitment and enrollment scopes. The changes to the incentive dollar amounts will be updated on all study materials (e.g. online screener, recruitment materials, intervention/control text messages, surveys, etc.).

For participants enrolled with the original payment structure and still active in June 2018, we will make up the difference at their next scheduled payment. For example, if a participant is in Week 2 when the change in payment is instituted, they would receive the new Phase 1 payment ($15) plus an extra $5 for baseline (total $20) after completing the Phase 1 survey. If a participant is in Month 6 when the change is instituted, they would receive the new Phase 2 payment ($45) plus an extra $10 ($5 each) for baseline and Phase 1 (total $55) after completing the Phase 2 survey.

Participants who are difficult to reach and are out of window for completing their Phase 2 survey will be offered the option to complete a shorter version of the survey. This survey will take approximately 5 minutes to complete and have an emphasis on the primary outcomes of the study. This will be a last resort option, as we want most participants to complete the full Phase 2 survey. Participants will also have the option to complete this shorter survey online on their own or over the phone with the Project Coordinator. Participants who complete the shorter version of the Phase 2 survey will be

paid $20 instead of the standard $45 received by participants who complete the full Phase 2 survey.

During Phase 2, participants may also receive up to three "pop-up" surveys, depending on their vaccination status at the end of Phase 1. Participants who complete a pop-up survey within the designated time frame will be eligible for a monthly $50 e-raffle. Surveys will be brief and configured for easy completion on multiple platforms (cell phone, tablet). Participants will receive special data collection text messages with the link to each survey. Participants who do not respond will receive up to 3 reminders by text and email. See Appendix 5 for draft surveys for the pilot RCT.

Sources of Materials

Participants enrolled in Steps 1 and 3 will take part in an online focus group. Some participants enrolled in Step 1 will take part in an online survey or an in-depth interview. Participants enrolled in Step 3 (CATs) will also complete a survey to provide feedback on the initial messages. Participants enrolled in Step 5 (beta test) will complete assessments at baseline and immediate post-test (3 week follow-up). Participants enrolled in the pilot RCT will complete assessments at baseline, immediately after Phase 1, and at the end of the 9-month trial. RCT participants may also receive up to three "pop-up" surveys during Phase 2.

Data for the focus groups will be collected using a secure online message board that members of our team have used successfully in previous research. All survey data will be collected online through REDCap, a secure, web-based application designed to support data capture for research studies.

Data for the in-depth interviews will be collected in person or by phone. Interviews will take place in the privacy of the PI's (Dr. Gerend's) office and will last approximately 45-60 minutes. Participants will be able to skip any questions they are not comfortable answering.

Surveys will include sensitive questions such as questions about sexual behavior. The benefits to collecting data online include increased self-disclosure compared to interviewer-based data collection; convenience for the participant, as he can decide when to complete it; and increased safety, as he can decide when and where it is best to answer these questions. Participants will also be able to skip any questions that make them uncomfortable.

We are sensitive to how the survey experience can affect the validity of the data. All online surveys will be as brief as possible and configured for easy completion on multiple platforms (e.g., cell phone, tablet, laptop). Based on previous research, we estimate that the Step 1 online survey will take approximately 10-15 minutes, the baseline survey will take approximately 15-20 minutes, the immediate post-test survey (end of Phase 1) will take approximately 25-30 minutes, and the end of trial survey will take about 15-20 minutes. The shorter version of the end of trial survey offered to participants who are difficult to reach and out of window will take about 5 minutes. Pop-up surveys (during Phase 2) will take less than one minute to complete.

HPV vaccination status will be verified via the Illinois Comprehensive Automated Immunization Registry (I-CARE) and participants' medical chart. Vaccination status will be confirmed in I-CARE for all RCT participants both before participants begin receiving messages and at the end of the 9-month trial. Pharmacies in the state of Illinois are required to report all vaccinations to the registry,[57] thus any HPV vaccines administered to participants at a local pharmacy over the course of the 9-month trial will be documented in I-CARE.

Additionally, medical chart data will be sought from those participants who report receiving any doses of HPV vaccine from their primary care physician over the 9-month

trial and those doses are not found in I-CARE. The project coordinator will contact these participants at the end of the trial and ask them to complete the medical release form (see supporting documents). Upon receipt of the signed form, the project coordinator will contact the participant's primary care doctor to verify the number and timing of any HPV vaccine doses that were received during the trial. Medical chart data will only be sought for those participants who sign the medical release form.

10.0 Data and Specimen Banking

Specimen Banking

No specimens will be banked for future use.

Data Banking

The research team agrees to develop a transportable de-identified database, codebook, and mechanism by which data could be shared with other investigators upon approval of the CO-PIs. Data will be stored in the secure Feinberg School of Medicine managed storage system.

Interested investigators will be asked to complete a standardized request form stating the specific aims of the analysis, the analytic plans, resources the requestors have to carry out the project, the proposed timeline, and distribution goals (manuscripts and/or grant application). The CO-PIs will review these requests to determine whether the proposed analyses constitute an innovative and significant exploration of the data, whether the proposed team has sufficient resources to undertake the request, how data will be protected/managed, and whether there are sufficient resources to honor the request. If any of these issues are problematic, the CO-PIs will attempt to negotiate a fair resolution with the interested parties and/or with NIH program staff. The CO-PIs will keep a record of all individuals/research teams who receive a copy of the data.

11.0 Data and Specimen Management

Analysis Strategy

Intervention feasibility will be computed as outlined above and summarized in a CONSORT map. Acceptability of the intervention will be assessed with descriptive statistics for the closed-ended items and with the same qualitative approach used for the online FG data for the open-ended items. Intervention efficacy will be assessed using an intent-to-treat approach. T-tests and chi-square analyses will be used to compare baseline characteristics of participants in the treatment vs. control condition. Separate chi-square analyses will be conducted for HPV vaccine initiation (receipt of ≥1 dose) and completion (receipt of 3 doses) to assess effects of treatment. Secondary analyses will examine potential differences in IMB constructs at the end of Phase 1 by treatment arm and assess whether they mediate effects of t2p on vaccine uptake. Following Gerend,[34] we will also conduct a detailed analysis of barriers to vaccine uptake among participants who did not get vaccinated over the course of the study to inform additional modifications for the large-scale trial.

Power Analysis

Based on previous studies,[14, 41, 43, 54] we hypothesize that 18-21% of treatment arm participants will receive their 1st dose of HPV vaccine, compared to 6-8% of control arm participants. The comparison of outcomes between arms, with two-sided alpha = 0.05, will have > 80% power for all scenarios with N=192 per condition. Based on previous

studies with similar samples (G2G, Keep It Up! [KIU!])[38, 49] and retention rates as high as 85-95% with follow-ups as long as one year, we anticipate an attrition rate of 5-20%. Using the most conservative estimate (20%) we will enroll 230 participants per arm to account for attrition.

Steps to Maintain Data Security and Confidentiality

Participant privacy and data will be carefully protected. Online surveys will be conducted online using a secure web-based application (REDCap).

To maintain privacy in the online focus groups, all participants will be asked to use pseudonyms rather than their real names, and to refrain from mentioning others by name. This will help to ensure openness. If any personal information is inadvertently disclosed, names or other identifying information will be redacted from the focus group transcripts.

Each participant will be given a unique identifier in the data set which will be stripped of all personal information to protect confidentiality. Data sets used for analysis will contain participant identification numbers but neither names nor other identifying information such as home address. Identification information will be retained by the PI for the duration of the study and stored separately from the responses provided by subjects.

Collaborators will receive data stripped of personal identifiers (de-identified data). To ensure complete confidentiality, access to the "key" linking personal identifiers to usernames and passwords will be restricted to the CO-PIs. Reports will not identify individual participants. Drs. Gerend and Mustanski will oversee the data storage and reporting procedures. De-identified data will be stored into perpetuity. The "key" linking personally identifiable information to the participant's ID in the data set will be destroyed at the end of the study. Reports will only use aggregated data. All study staff will be trained in security and confidentiality procedures before receiving access to any participant data.

Data will be stored on a dedicated secure server at the Feinberg School of Medicine. All data will be transmitted securely by connecting to the SFTP server using the encrypted SSH protocol. Users initiate that connection using a client application like Filezilla. The connection uses a non-standard port to further obscure the connection. A username and strong password will be assigned to each user and each username is unique to an individual. User accounts on the server can only access data folders that have been assigned to them. The CO-PIs are responsible for telling the system administer if there are new users or users that should be deleted. The CO-PIs are responsible for all additions, edits, or deletion of data during the study.

12.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

N/A

13.0 Withdrawal of Subjects*

The CO-PIs do not anticipate having to a) withdraw subjects from this research without their consent or b) terminate the study early.

Participants may decide to withdraw from the study at any time. No additional data will be collected after a participant withdraws. When a participant shares his intent to withdraw, the investigator will ask if the information already collected can be used or whether it should be destroyed.

14.0 Risks to Subjects*

There are minimal risks to participants in this study. The greatest risk is the potential loss of confidentiality if someone were to see a participant's survey responses or other online material that would disclose their sexual orientation. Some of the sensitive topics covered in the text messaging intervention could cause discomfort for some participants. Further, a participant could feel uncomfortable answering some of the survey questions about their sexual behaviors.

15.0 Potential Benefits to Subjects

Participants will learn about steps they can take to reduce their risk of HPV infection, genital warts, and HPV-related cancers (e.g., anal cancer, oral cancer, and penile cancer) through HPV vaccination.

16.0 Vulnerable Populations

N/A

17.0 Community-Based Participatory Research

N/Aa

18.0 Sharing of Results with Subjects

N/A

19.0 Setting

The primary location where this research will take place is the Feinberg School of Medicine, within the Department of Medical Social Sciences.

We have also partnered with one of the largest LGBT health care centers in Chicago, Howard Brown Health Center (HBHC), which will serve as a consortium site contributing to the project. Magda Houlberg, M.D., Chief Clinical Officer at HBHC, will serve as site Principal Investigator and will be responsible for supervising all aspects of the proposed research associated with HBHC. Dr. Houlberg will review intervention messages for medical accuracy, tone and clarity. Lastly, HBHC has agreed to serve as a referral clinic for the pilot randomized controlled trial associated with this project. Participants who are uninsured or underinsured will be directed to HBHC—a Federally Qualified Health Center (FQHC) specializing in LGBTQ care—to receive HPV vaccine. Dr. Houlberg will oversee the patient referral process.

Participants for this project will be recruited online, from HBHC clinics, and from participant registries (explained in further detail below), and most research procedures will largely take place online as well. For example, the focus groups for Aim 1 will take place online and the intervention associated with the pilot RCT (Aim 2) will be delivered via text messages. Participant assessments will also take place online. The in-depth interviews will be conducted in person or by phone in the PI's (Dr. Gerend's) office (FSM Department of Medical Social Sciences).

20.0 Resources Available

Investigative Team

The investigative team has the skills, experience, and resources to successfully carry out the proposed project. Dr. Gerend is one of the leading experts on HPV vaccination

and has been PI of two NCI-funded projects on HPV vaccination. Dr. Phillips brings expertise in conducting HIV/STI epidemiological research with MSM. Mr. Bass is a software architect with years of experience in programming, systems integration, and information technology. Dr. Mustanski directs a program focused on the health of LGBT youth and has been PI of multiple NIH-funded studies. Dr. Houlberg, Chief Medical Officer at our partner clinic (HBHC), brings expertise in infectious diseases and patient-centered care for sexual minorities.

The CO-PIs will provide close monitoring of the study to ensure steady progress of the pilot trial and the safety of its participants. The CO-PIs will also train all study personnel about the protocol, the research procedures, and their duties and functions. The CO-PIs will be in daily contact with study personnel and will actively oversee participant recruitment and enrollment, intervention administration, and all data collection activities. The research team will hold regular meetings to monitor and discuss study progress.

21.0 Prior Approvals

Howard Brown Health Center will be relying on the NU IRB for this study and thus has completed the required IRB Authorization Agreement form.

22.0 Recruitment Methods

Participants will be recruited online through ads placed on websites and dating apps such as Facebook, Twitter, Grindr, Craigslist, and Jack'd. ResearchMatch.org will also be utilized as a recruitment tool. ResearchMatch.org is a national electronic, web-based recruitment tool that was created through the Clinical & Translational Science Awards Consortium in 2009 and is maintained at Vanderbilt University as an IRB-approved data repository (see IRB #090207). Participants may also be recruited from existing participant registries (e.g., Institute for Sexual and Gender Minority Health and Wellbeing [ISGMH]; Third Coast Center for AIDS Research [CFAR]). Participants may also be recruited from Howard Brown Health clinics through passive recruitment. Howard Brown staff will post flyers with txt2protect study information, including a link to the online eligibility screener, in clinic waiting areas and other spaces deemed appropriate.

Interested candidates will be directed to complete the screening survey, which will assess eligibility criteria. All eligible candidates will then be directed to complete an online informed consent form. Eligible candidates will be informed that they will be contacted by the Study Manager with information about next steps for taking part in the study.

Interested candidates recruited from paid dating app ad campaigns (e.g. Grindr and Jack'd) who screen as ineligible will be directed to an optional, online survey on smoking and e-cigarettes. The study team has added this supplemental survey because of the high cost of dating app ad campaigns and the anticipated large number of participants who will screen as ineligible. This will allow us to make the most of the large reach of the dating app ad campaigns and collect data that can help inform future research studies on smoking and e-cigarettes, and cancer risk.

Please see supporting documents for sample recruitment ads and the smoking and e-cigarette survey.

Participant Payments

Aim 1

Focus group members taking part in Step 1 will receive $25 for their participation. Participants who complete the Step 1 online survey will receive $10 for their participation. Participants who complete the Step 1 in-depth interview will receive $40. Individuals who serve on the content advisory teams in Step 3 will receive $50 for providing initial feedback and their focus group participation. Participants who take part in the beta test (Step 5) will receive $75 for their participation. Given the nature of the study (online), payments will be in the form of an electronic gift card.

Aim 2

Participants will be asked to complete the screener plus three assessments at baseline, end of Phase 1 (end of week 3), and end of Phase 2 (end of the 9-month trial), with participants initially receiving $10, $10, and $30 for each respective survey. Beginning in June 2018, the incentives were increased so that participants received $15 each at baseline and the end of Phase 1, and $45 at the end of Phase 2. The study team hopes that the increase in incentives will help with meeting recruitment and enrollment scopes. The changes to the incentive dollar amounts will be updated on all study materials (e.g. online screener, recruitment materials, intervention/control text messages, etc.).

For participants enrolled with the original payment structure and still active in June 2018, we will make up the difference at their next scheduled payment. For example, if a participant is in Week 2 when the change in payment is instituted, they would receive the new Phase 1 payment ($15) plus an extra $5 for baseline (total $20) after completing the Phase 1 survey. If a participant is in Month 6 when the change is instituted, they would receive the new Phase 2 payment ($45) plus an extra $10 ($5 each) for baseline and Phase 1 (total $55) after completing the Phase 2 survey.

Participants who are difficult to reach and are out of window for completing their Phase 2 survey will be offered the option to complete a shorter version of the survey. This survey will take approximately 5 minutes to complete and have an emphasis on the primary outcomes of the study. This will be a last resort option, as we want most participants to complete the full Phase 2 survey. Participants will also have the option to complete this shorter survey online on their own or over the phone with the Project Coordinator. Participants who complete the shorter version of the Phase 2 survey will be paid $20 instead of the standard $45 received by participants who complete the full Phase 2 survey.

During Phase 2, participants who complete a pop-up survey within the designated time frame will be eligible for a monthly $50 e-raffle. Given the nature of the study (online), payments will be in the form of an electronic gift card.

23.0 Local Number of Subjects

We plan to enroll **950 participants total**.

Aim 1 participants will be recruited to assist with the development of the intervention messages:

Step 1: Four online focus groups with 20 participants per group = **80**
Online survey with 250-300 participants = **300**
In-depth interviews with 25-30 participants = **30**
Step 3: Three content advisory teams with 20 participants per team = **60**
Step 5: Beta test will include 20 participants total = **20**

Aim 2, participants will be recruited to pilot test the text messaging-based intervention:

Pilot RCT: We will recruit 230 participants per arm (treatment vs. control) = **460**

24.0 Confidentiality

N/A

25.0 Provisions to Protect the Privacy Interests of Subjects

Participant Privacy and Study Experience

Participant privacy and data will be carefully protected. Online surveys will be conducted online using a secure web-based application (REDCap). Surveys will include sensitive questions such as questions about sexual behavior. The benefits to collecting data online include increased self-disclosure compared to interviewer-based data collection; convenience for the participant, as he can decide when to complete it; and increased safety, as he can decide when and where it is best to answer these questions. Participants will also be able to skip any questions that make them uncomfortable.

We are sensitive to how the survey experience can affect the validity of the data. All online surveys will be as brief as possible and configured for easy completion on multiple platforms (e.g., cell phone, tablet, laptop). Based on previous research, we estimate that the Step 1 online survey will take approximately 10-15 minutes, the baseline survey will take approximately 15-20 minutes, the immediate post-test survey (end of Phase 1) will take approximately 25-30 minutes, and the end of trial survey will take about 15-20 minutes. The shorter version of the end of trial survey offered to participants who are difficult to reach and out of window will take about 5 minutes. Pop-up surveys (during Phase 2) will take less than one minute to complete.

To maintain privacy in the online focus groups, all participants will be asked to use pseudonyms rather than their real names, and to refrain from mentioning others by name. This will help to ensure openness. If any personal information is inadvertently disclosed, names or other identifying information will be redacted from the focus group transcripts.

Accessing Participant Information (e.g., Medical Records)

On the eligibility screener, participants will be asked whether they have been vaccinated against HPV. It is possible that some participants will not know their status. Although Step 1 will involve participants who have and have not been vaccinated against HPV, enrollment for Steps 3 and 5 as well as the pilot RCT will be limited to unvaccinated participants, thus it will be important to confirm vaccination status before participants are enrolled in the study. Before enrollment begins, we will consult the Illinois Immunization Registry (I-CARE) to assess HPV vaccination status for all participants who have provided consent and meet eligibility criteria for the study.

Vaccination status will be confirmed in I-CARE for all RCT participants both before participants begin receiving messages and at the end of the 9-month trial.

Additionally, medical chart data will be sought from those participants who report receiving any doses of HPV vaccine from their primary care physician over the 9-month trial and those doses are not found in I-CARE. The project coordinator will contact these participants at the end of the trial and ask them to complete the medical release form (see supporting documents). Upon receipt of the signed form, the project coordinator will contact the participant's primary care doctor to verify number and timing of any HPV vaccine doses that were received during the trial. Medical chart data will only be sought for those participants who sign the medical release form.

26.0 Compensation for Research-Related Injury

N/A

27.0 Economic Burden to Subjects

N/A

28.0 Consent Process

Participants will be recruited online through ads placed on websites and dating apps such as Facebook, Twitter, Grindr, Craigslist, and Jack'd. ResearchMatch.org will also be utilized as a recruitment tool. ResearchMatch.org is a national electronic, web-based recruitment tool that was created through the Clinical & Translational Science Awards Consortium in 2009 and is maintained at Vanderbilt University as an IRB-approved data repository (see IRB #090207). Participants may also be recruited from existing participant registries (e.g., Institute for Sexual and Gender Minority Health and Wellbeing [ISGMH]; Third Coast Center for AIDS Research [CFAR]). Participants may also be recruited from Howard Brown Health clinics through passive recruitment. Howard Brown staff will post flyers with txt2protect study information, including a link to the online eligibility screener, in clinic waiting areas and other spaces deemed appropriate.

Interested candidates will be directed to complete the screening survey, which will assess eligibility criteria. All eligible candidates will then be directed to complete an **online informed consent form**. Please see attached consent forms for further details. Please note that we will be using different consent forms for each separate step of the study (Aim 1: Steps 1, 3 and 5; Aim 2).

Eligible candidates who have provided informed consent will be informed that they will be contacted by the Study Manager with information about next steps for taking part in the study.

Ineligible candidates or individuals who do not provide informed consent will be thanked for their interest in the study and directed to relevant resources (e.g., the IMPACT Program's website).

To enroll in the study, all participants (with the exception of those participants who take part in the online survey for Step 1) will talk by telephone with the Study Manager. The Study Manager will re-confirm the candidate's eligibility and then describe the study. The next step in the enrollment process will depend on the activity for which we are currently recruiting. For the in-depth interviews, online FGs, and content advisory teams, participants will be given information about next steps (e.g., scheduling the interview, scheduling the online focus group, reviewing the initial pool of messages, etc).

For the beta test and pilot RCT, participants deemed to be eligible (based on their screening survey responses) will be sent a text message welcoming them into the study. The text message will also contain a link to the consent form, which will be followed by the baseline survey. The project coordinator will direct and oversee the consent and enrollment process. Before participants are randomized, the project coordinator will confirm that participants have received no doses of HPV vaccine since screening by checking their self-reported vaccination status in the baseline survey as well as the I-CARE registry.

29.0 Process to Document Consent in Writing

As the research activities for this project will largely take place online, we will not be obtaining written documentation of consent for most participants. Instead, participants who take part in this project will be required to provide online consent (by selecting "I agree" to participate in this study). The one exception will be those participants who take part in the in person interview (Step 1) in Dr. Gerend's office. For those participants, we will obtain written consent prior to conducting the interview (see attached consent form: Aim 1 Step 1 Interview hard copy version). Participants who complete the interview by phone will be asked to complete an online version of the consent form prior to beginning the interview (see attached consent form: Aim 1 Step 1 Interview online version). This research presents no more than minimal risk of harm to participants and does not involve procedures for which written documentation of consent is normally required outside the research context.

30.0 Drugs or Devices

N/A

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