Study Protocol

Title: Advancing Pre-exposure Prophylaxis (PrEP) Access in Pharmacies to Improve PrEP Uptake in Disadvantaged Areas

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Full title:
Advancing pre-exposure prophylaxis (PrEP) access in pharmacies to improve PrEP uptake in disadvantaged areas" (1R34 MH119007-01)

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1. Background

1.1 Specific aims of the study

Black men who have sex with men (BMSM) suffer from alarmingly high rates of HIV in the United States[1,2]. The most recent statistics indicate that BMSM are 550% more likely to be diagnosed with HIV than white MSM (WMSM)[1,2]. Pre-exposure prophylaxis (PrEP) reduces risk of HIV infection by 92%[3], yet profound racial disparities in the uptake of PrEP persist. In 2015, among those offered PrEP, only 10% of blacks compared to 75% of whites used PrEP[4]. Low PrEP uptake in BMSM is driven by: *poor access* to PrEP including inconvenient locations of PrEP-prescribing physicians[5-10] and *distrust of physicians and stigma,* which limit communication about PrEP and its side effects[6,11]. According to Cohen's structural theory improving access to PrEP will improve PrEP uptake[12]. Since HIV among BMSM is largely clustered in high poverty, racial minority neighborhoods[13,14], we can improve access by directing PrEP delivery to these areas. Pharmacists in these neighborhoods have strong rapport with the residents[15] and as a trusted source for health information, could effectively inform BMSM about PrEP. Our work indicates that offering HIV prevention services in pharmacies located in high poverty, racial minority neighborhoods is feasible[16] and can reduce stigma because pharmacies offer a host of less stigmatized health services (e.g. vaccinations)[18]. Moreover, preliminary data among BMSM show strong support for obtaining PrEP in pharmacies.

The purpose of this study is to develop a culturally appropriate pharmacy PrEP delivery model for BMSM who live in high poverty, racial minority neighborhoods. Pharmacies have proven to be a feasible source for offering PrEP for WMSM[17,18], but have failed to reach the most at-risk, vulnerable population – BMSM[19]. State regulations limit pharmacists' ability to screen and prescribe PrEP in 21 states, so many pharmacies use nurse practitioners (NPs) instead[18]. But, pharmacies in high poverty, racial minority neighborhoods often lack NPs. Thus, we have designed a multi-level intervention that does not rely on pharmacists or NPs to screen BMSM for PrEP. Increasing PrEP access and uptake will reduce HIV incidence and racial inequities in HIV, two NIH HIV/AIDS high priority areas. This protocol describes the aims of this study, which are to:

Aim 1. Develop a pharmacy PrEP delivery model by evaluating the barriers to and facilitators of integrating PrEP into existing pharmacy practice among key stakeholders (pharmacists, technicians, PrEP-prescribing physicians and BMSM).

Aim 2. Evaluate eligibility and willingness to receive PrEP in pharmacies among BMSM and collect data on customer engagement with PrEP delivery information from pharmacy staff during COVID-19.

Aim 3. Pilot test the pharmacy PrEP delivery model and examine its feasibility, acceptability and safety, and gather early evidence of its impact and cost with respect to PrEP uptake at baseline and at 3-months (the clinically suggested follow-up period) among pharmacy client participants.

1.2 Background and preliminary studies that support this stage of research

BMSM bear the highest burden of HIV in the US. Between 2005 and 2014, HIV diagnoses increased 22% for BMSM but declined 19% for WMSM[1,2]. In Georgia, blacks make up less than 40% of the population

but represent 74% of new AIDS diagnoses. And almost two-thirds of incident HIV infections were among blacks via male-male sex[20].

PrEP is the single most effective HIV prevention strategy yet under-utilized among BMSM. When taken every day PrEP can prevent up to 92% of HIV infections[3,19]. Studies estimate that 48-70% of BMSM are willing to use PrEP[5,21]. Yet, uptake among blacks remains low (~10%)[4]. Lower insurance rates among blacks compared to whites[22] may be a barrier to PrEP. But, evidence of comparable insurance rates among BMSM and WMSM[23], as well as prescription payment programs that cover most or all of the costs of PrEP do not completely explain significant disparities in PrEP uptake[24]. Indeed, limited access to PrEP, distrust of physicians and stigma are noted as critical barriers to PrEP that must be improved to reduce HIV[5,21].

Neighborhood residence shapes BMSM HIV exposure and access to HIV prevention resources[13]. A recent study showed that 60% of prevalent HIV cases were located in one central Atlanta cluster[14]. Census tracts with high HIV had 20% higher poverty and 200% larger MSM populations. High poverty neighborhoods also have the fewest HIV physicians[10,25,26]. While most census tracts are within 15 minutes of an HIV physician by car, residents in HIV prevalent areas have low rates of car ownership and commute time more than doubles when traveling by public transportation[10], which is unavailable in some areas.

There is a strong scientific premise for increasing PrEP delivery in pharmacies for BMSM. About 95% of Americans live within 5 miles of a pharmacy; pharmacies have flexible hours and pharmacists have high credibility with community members[15]. Studies have shown pharmacies can engage with high risk populations including people who inject drugs (PWID) to reduce HIV risk behaviors[27-30] and provide primary prevention services including immunizations[31], blood pressure screenings[32] and HIV testing[16,33-35]. PrEP has also been sustainably offered in a Seattle pharmacy, but mostly to white MSM (85%). Nevertheless, almost 100% initiated PrEP and 75% followed up for continued PrEP[17]. Following this, 188 Walgreens across the US have offered PrEP through their existing clinics[18,36].

Existing pharmacy PrEP models have limited potential for reaching BMSM. In Seattle, state regulations give pharmacists authority to administer biological screenings (HIV, STI and creatinine) and prescribe PrEP[19]. Many states do not have legislation that expand pharmacists' purview in service delivery[37,38]. Walgreens has overcome this regulatory limitation by using nurse practitioners to screen and prescribe PrEP in their existing clinics[18]. While Collaborative Practice Agreements between pharmacists and physicians are another route to deliver services through pharmacies[39,40], they are time-consuming and thus infeasible for community pharmacists in high morbidity neighborhoods who already have a hectic workflow; and for chain pharmacies these partnerships are determined on a corporate rather than individual pharmacy level[40-43].

1.3 Significance/ justification for the current study

The contribution of the proposed research is expected to be a sustainable, pharmacy PrEP delivery model that can be implemented without regulatory barriers to increase PrEP access in high poverty, racial minority neighborhoods for BMSM who have the highest need. *This contribution will be significant because it will lay the foundation for making PrEP available in pharmacies specifically for populations that are disconnected from HIV prevention resources.*

2. Design

To accomplish these aims, we will conduct a four-phase study:
(1) **formative phase** of in-depth interviews and workflow assessments among 40 key stakeholders to inform phase two.
(2) **intervention development phase** to integrate formative data with input from an existing advisory board to develop a culturally relevant pharmacy PrEP delivery model.
(3) **transitional pilot phase** to assess customer eligibility and willingness to receive PrEP in pharmacies during COVID-19.
(4) **pilot test phase** to test the model in two pharmacies in high poverty, racial minority neighborhoods, where we have existing relationships.

For the remainder of the protocol, we will describe the methods according to each phase of the study.

2.1 Sample

This study will include various participant groups across each phase of the study. For clarification in terminology of each type of participant, here we provide definitions of each group:

Pharmacist – Pharmacist participant
Technician – Pharmacy technician participant
Pharmacy staff – Pharmacist, pharmacy technician and pharmacy clerk participant
Client – Pharmacy client participant who patronizes pharmacy enrolled in the study

In the formative phase, we will collect data from key stakeholders: 10 pharmacists, 10 technicians, 10 PrEP-prescribing physicians and 10 black men who have sex with men (BMSM) via in-depth interviews. Interviews will assess support for PREP screening, referral and monitoring in pharmacies, pharmacy-level policies influencing PrEP provision, potential barriers to the delivery of an intervention in a pharmacy, existing interactions between pharmacists and physicians, advocacy resources, knowledge of epidemiologic data on HIV, sexual behavior, drug use and PREP, and sustainability through pharmacy-physician-community collaboration. We will also perform workflow assessments among pharmacists, technicians and PrEP prescribing physicians to examine the facilitators and barriers to PrEP implementation.

In the intervention development phase, *there are no pharmacy staff or client participants, thus no data protections are needed*. In this phase of the study the investigative team and advisory board will use the data analyzed from the formative phase to develop the pharmacy PrEP delivery model to be implemented in the pilot study. We will also iteratively revise the protocol over the course of the study to ensure its feasibility, acceptability, and safety. We will debrief about the study activities ***every month*** of the pilot study to refine the protocol for immediate implementation in the study activities. Each proposed change will be assigned a subject matter expert from the co-I's on the grant. The subject matter expert and at least two other co-I's will be asked to vote on whether the change will be made immediately, revoked or followed through the next monthly meeting. Any change that requires the recruitment, protocol or survey instruments to be revised will be submitted to the IRB for approval. Meticulous records of the development and revision process of the pharmacy PrEP delivery model will be kept throughout the study.

In the transitional pilot phase, two pharmacies will be chosen to estimate how many pharmacy client participants would be eligible for the pilot phase. Among those who would be eligible, we will assess their willingness to receive PrEP in pharmacies. In order to recruit a sample of pharmacy client participants, pharmacy staff participants will place flyers in pharmacy client participants' medication delivery packages and hang posters in their pharmacies. Given the COVID19 pandemic, many client participants are opting for medication delivery versus in-person pick up. The flyers and posters will contain information about the pharmacy-based PrEP delivery study. A QR code will allow client participants to be directly linked to the eligibility screener. After taking the eligibility screener, client participants will be eligible for the social and behavioral survey if they are: 1) male or trans male, 2) had any types of sex in the past 6 months, 3) engaged in unprotective sex in the past 6 months, 4) had protected and/or unprotected sex with HIV positive partners in the past 6 months, and 4) injected any drugs in the past 6 months. We will ask pharmacy staff to insert flyers into patient medication deliveries over a 3-month period and during this time we will assess pharmacy staff barriers and facilitators of engaging with client participants regarding the study.

In the pilot test phase, two pharmacies will be chosen to pilot test the pharmacy PrEP delivery model. We will recruit pharmacy staff participants who work in each pharmacy and pharmacy client participants that patronize these pharmacies. Pharmacy staff participants will complete a pharmacy-based HIV prevention training to equip them with the tools needed for optimal PrEP delivery. Since the pharmacies selected to be a part of the study are located in racial minority neighborhoods, we anticipate that most client participants will be racial minorities. We will be collecting both qualitative and quantitative data to assess the impact of the pharmacy PrEP intervention on the pharmacy environment, personnel, and business flow. Among the pharmacy client participants, we will assess feasibility, acceptability and safety of the intervention activities, satisfaction with the activities and participation in activities without stigmatization, discomfort, or harm.

Pharmacy client participants will be considered eligible for the social behavioral survey if they:

- Consent to participate in the online screener
- Are 18 years or older
- Can speak and read English without any help

In accordance with current CDC guidelines, Pharmacy client participants will be considered eligible for HIV testing if answers from the social behavioral survey indicate that:

- They consent to participate in the social behavioral survey
- They are willing to be tested for HIV today

Respond "yes," "don't know," or "prefer not to say" to one or more of the following conditions:

- Identify as male, trans female, gender-non-conforming," or "other" and reports having sex with men within the past 3 months
- Having vaginal or anal sex without a condom within the past 3 months
- Having ever used injectable drugs

Pharmacy client participants will be considered ineligible for HIV testing if they do not consent to partake in the social behavioral survey, do not consent to be tested for HIV, or answer **"yes"** to both of the following conditions:

- Reports no vaginal or anal sex without a condom within the past 3 months **and** identifies as a woman or trans male who has not had sex without a condom within the past 3 months
- Has never used injectable drugs

Pharmacy client participants will be eligible for a 30-day supply of PrEP from the pharmacy if they:

- Test negative for HIV
- Agree to receive medication from the pharmacy

2.2 Setting

Formative phase

All interviews will be conducted in a *private* setting identified either by the researcher or the key stakeholder (i.e., personal office). The researcher will arrange a private office in a convenient location for the interview to be conducted.

Intervention Development Phase

The investigative team and the advisory board will work together to develop the pharmacy PrEP delivery model.

Transitional Pilot Phase

The transitional pilot phase will take place in two pharmacies that are located in high poverty and racial minority neighborhoods. We will provide pharmacy staff participants with flyers to disseminate to their pharmacy clients to take an eligibility screener and social and behavioral survey. Posters advertising the survey will also be placed throughout the pharmacy in case any client participants who visit the pharmacy in-person are interested.

Pharmacy staff participants will complete a short orientation to learn the study activities. The study activities are as follows: place study flyers in client participants' medication delivery packages; hang posters in their pharmacies about the study; and direct any questions that client participants may have about the study to our research team. Given that the study will ask sensitive questions about HIV and PrEP, pharmacy staff participants will receive two Continuing Education (CE) credit by participating in a training on understanding HIV in the community and mobilizing community pharmacies to improve access to PrEP. The orientation and training will take place online on Zoom.

Pharmacy staff participants will participate in a one-hour phone interview at baseline and 3-month of the intervention.

Pharmacy client participants who are made aware of the study by the pharmacy staff participants, and are interested will take a 3-minute eligibility screener. Eligible participants will then be prompted to complete a 20-minute social and behavioral survey. The screener and survey will be administered online using links for Survey Gizmo. The screener and survey, similar to self-administered online surveys, will not require the presence of the research or pharmacy staff. During the survey, we will inquire about sensitive subjects (mental, sexual and behavioral health). If needed, pharmacy client participants may be offered linkages to community services to meet their healthcare needs. Pharmacy client participants may refuse to participate in the study or to receive additional referrals at any time.

Pilot Phase

The pilot phase will take place in two pharmacies that are located in high poverty and racial minority neighborhoods. All pharmacies will have a large, private space where client participants/patients who agree to be screened and linked to PrEP can have privacy. If necessary, we will provide additional wall partitions/ screens, noise machines and noise-cancelling curtains to enhance privacy.

Pharmacy staff participants will complete a thorough training via the Canvas platform to learn the study activities. Our Canvas site will link trainees to privately posted YouTube videos that contain training material. Additionally, pharmacy staff participants will complete a module in HIV Prevention and Counseling. During training, pharmacy members will complete a pre-post survey about HIV Care and Prevention using Alchemer software. These trainings will take place virtually.

Pharmacy staff participants will participate in a one-hour interview at baseline, 3-month and 6-month of the intervention. These interviews will take place in a private office in the pharmacy.

Pharmacy client participants who are recruited into the pilot study will complete a 20-minute social and behavioral screener using Alchemer on an easy to use, touch screen tablet in a private room in the pharmacy. *Trained pharmacy staff will set up these interviews in the private area of the pharmacy but will not administer the survey*. In the event that a participant has a physical or intellectual disability that renders the m unable to use the tablet, a study team member will orally administer the survey. The screening survey, similar to the self-administered online surveys, will not require the presence of the research or pharmacy staff participants outside of them showing them to the tablet in a private room. Potential pharmacy client participants may complete the screener using the QR code found on recruitment flyers, complete it on study iPads if recruited by staff, or (if needed) be screened orally by a team member. If eligible, pharmacy client participants may be offered a free HIV test. If pharmacy client participants accept, then the HIV test will be completed in the same private area of the pharmacy. Pharmacy client participants may refuse to participate at any time or if they have time constraints, they can schedule the test at a later date. If they are uncomfortable completing the screening in the pharmacy, we will also provide them with a referral for a PrEP prescribing physician.

2.3 Recruitment and enrollment

Formative Phase

To enroll *pharmacists* (n=10) and *technicians* (n=10), we will identify all pharmacies in the highest HIV zip code in Atlanta as shown by AIDSVu. AIDSVu is an online, interactive display of HIV prevalence across the US. Using an existing list of all pharmacies in the state of Georgia obtained from the Georgia Board of Pharmacy, we will generate a list of pharmacies from high HIV zip codes and then randomly contact each pharmacy to determine whether pharmacists or technicians are interested in participating in the study. Preliminary studies have indicated a sampling frame of about 43 pharmacies.

To enroll *PrEP prescribing physicians* (n=10) we will randomly select, and call physicians located in (or near) high HIV zip codes in Atlanta who have registered with PrEP locator (PrEPlocator.com). PrEP locator is an online, Emory maintained database of physicians who offer PrEP across the US, which was developed by co-investigator (co-I) Siegler.

To enroll *BMSM* we will rely on referral of the population by NAESM, our community partners. NAESM hosts large HIV testing drives at sites frequented by BMSM (i.e., bars, clubs' college events). They will inform men of our study and will schedule interviews with interested men at pre-specified dates on our

behalf.

Intervention Development Phase
The investigative team and advisory board are identified on this IRB protocol. These are experts in HIV prevention, rather than study participants. Thus, no recruitment will occur during this phase.

Transitional Pilot Phase
To enroll pharmacies, we will choose two pharmacies located in high poverty, racial minority neighborhoods will be selected from a sampling frame of about 43 pharmacies. In order for the pharmacy to participate, consent will have to be obtained from at least 1 pharmacist participant and 2-3 technician participants (n=4 per pharmacy).

To enroll pharmacy client participants, trained pharmacy staff will discreetly place flyers in clients' medication delivery packages to inform men about the eligibility screener and the social and behavioral survey. Pharmacy client participants will be directed online where they can privately consent to the study and complete the screener and survey. Pharmacy client participants who complete the eligibility screener will receive a $1 pharmacy coupon regardless of their eligibility or willingness to participate in our study. Eligible pharmacy client participants who are willing to complete the social and behavioral survey will be compensated $25 for their time. Pharmacy client participants will be informed during the informed consent process that the information they provide will be used to determine their HIV risk, and they may be offered referrals for STIs/HIV testing and PrEP.

Pilot Phase
To enroll pharmacies, we will choose two pharmacies to pilot test the pharmacy PrEP delivery model. Pharmacies that are located in high poverty, racial minority neighborhoods will be selected from a sampling frame of about 43 pharmacies. In order for the pharmacy to participate, consent will have to be obtained from at least 1 pharmacist participant and 2-3 technician participants (n=4 per pharmacy).

Pharmacy staff participants will discreetly inform their pharmacy clients about the study. If the pharmacy client is interested and willing to learn more about the study, the pharmacy staff participant will direct them to an area where they can privately provide electronic informed consent and complete the electronic screener. If they are unwilling or do not have time, they will be encouraged to return to the pharmacy when they have time. Pharmacy client participants who agree to complete the social and behavioral screener will be compensated $25 for their time regardless of their eligibility or interest in being clinically screened for PrEP. Participants will be informed during the informed consent process that the information they provide will be used to determine their HIV risk and they may be offered a free HIV test.

2.4 Procedures

Formative Phase
Procedures for qualitative in-depth interviews

1. Initial contact and invitation to participate in an in-depth interview about PrEP screening and referral in pharmacies for MSM will be performed over the phone.
2. An appointment will be made with individuals who are willing to participate in the interview.
3. We will conduct individual in-depth qualitative interviews with two different kinds of key informants: **1) interactor participants** (pharmacists, technicians and PrEP prescribing

physicians) who interact with BMSM on a day to day basis and will be able to provide information about how the pharmacy and medical systems works at a practical level; and **2) BMSM participants** who will describe their interactions with and perceptions of pharmacists and PrEP prescribing physicians, their receptiveness to pharmacy-based interventions, as well as their interactions with and attitudes towards the legal, public health and HIV prevention and care systems.

4. The interview process will be semi-structured and the interview guide will be targeted to the type of key informant. Topic guides will be used to guide the interview.
5. Qualitative data collection will assess barriers and facilitators of pharmacy PrEP delivery and discuss ways to support a sustainable pharmacy PrEP delivery model. Moreover, with each participant, we will describe the preliminary PrEP model for specific feedback on each step with respect to advertising, recruitment of BMSM, costs and other concerns. The interviews will also cover a range of topics within four domains: general public health and HIV/AIDS policy, pharmacy utilization of health services, pharmacy-based HIV prevention services including PREP, and pharmacy-physician partnerships. Specific questions will address: support for PREP screening, policies influencing PrEP delivery, referral and monitoring in pharmacies, potential barriers to the delivery of an intervention in a pharmacy, knowledge of epidemiologic data on HIV, sexual behavior, drug use and PREP, and sustainability through pharmacy-physician collaboration.
6. All interviews will be recorded for transcription and data analysis.
7. Interview recordings and paper notes will be stored in a locked cabinet in a lock office.
8. All of the data (transcripts) and analysis related to this study will be stored on network drives only available to the investigator and research assistant. The data will be anonymized, and the identity of the participants will be kept in a separate network drive, only available to the study investigator.

Procedures for workflow assessments

1. Direct observation of the pharmacy (for pharmacists and technicians) or physician office (for PrEP prescribing physicians) will be performed to understand routine and non-routine activities[44].

   For *pharmacists and technicians*, the research assistant will focus on the door-to-door patient experience of obtaining a prescription as well as the process implemented behind the counter for filling a prescription. We will also pay particular attention to the pharmacist and technician procedures for patients obtaining a primary prevention service such as an immunization in the pharmacy. We will take note of the procedures performed to prepare for the immunization (i.e., authorization calls, collection of all materials, privacy partition set up) and following the administration of the immunization (i.e., logging of service performed, department of health reporting) including the time taken to perform each of these procedures.

   For *PrEP-prescribing physicians*, researchers will focus the workflow assessment on the administrative process performed before and after seeing patients. In consideration of patient privacy, research assistants **will not sit in on patient visits.** Rather they will shadow the physicians once a patient visit is complete to understand how patient prescriptions are filled and how interaction occurs between the pharmacist and physician.
2. Research assistants will monitor the day-to-day procedures in each environment during a morning or afternoon work shift; whichever is most convenient for the participant. Observations will be made from a non-intrusive area. As time allows, open-ended questions will be asked to clarify observations.
3. Workflow diagrams for the pharmacy and physician offices will be created and patterns will be

examined across each environment to create an overall description that best represents a typical prescribing encounter[44].

Intervention Development Phase

1. The investigative team will review and analyze the data from the qualitative interviews and work-flow assessment.
2. All of the data will be reviewed, summarized and shared with the advisory board to assist with the development of the pharmacy PrEP delivery model.
3. The investigative team will develop 2-3 simulations of the potential pharmacy PrEP delivery model and present those step-by-step to the advisory board.
4. The advisory board will provide feedback on the study protocol, pharmacy trainings, pharmacy recruitment brochure, survey instruments and other materials as needed.
5. Using the adaptive protocol method, we will iteratively revise the protocol over the course of the study to ensure its feasibility, acceptability, and safety[45,46].
6. We will debrief about the study activities ***every month*** of the pilot study to refine the protocol for immediate implementation in the study activities.
7. Proposed changes will be assigned to subject matter experts from the co-I's on the grant.
8. Subject matter expert and other co-Investigators will vote on whether the change will be made immediately, revoked or followed through the next monthly meeting.
9. Agreed upon changes will be submitted to the IRB for approval.
10. Meticulous records of the development and revision process of the pharmacy PrEP delivery model will be kept throughout the study.

Transitional Pilot Phase

Pharmacy eligibility, enrollment and data collection

1. Two pharmacies that are located in high poverty, racial minority neighborhoods will be chosen to evaluate eligibility and willingness of BMSM to receive PrEP in pharmacies.
2. We will obtain consent from at least 1 pharmacist and 2-3 technicians at each pharmacy to participate in the study.
3. Pharmacy staff participants will earn 2 CE credit at an online Pharmacy Training Seminar to teach them how to mobilize community pharmacies to improve PrEP access.
4. Pharmacy staff participants will also participate in a short orientation to learn the study activities. The study activities are as follows: place study flyers in pharmacy client participants' medication delivery packages; hang posters in their pharmacies about the study; and answer any questions that client participants may have about the study.
5. Research staff will provide each pharmacy with flyers, posters, and information in case client participants need to be referred to third-party organizations for health services.
6. One-hour in-depth interviews will be administered to pharmacy staff participants at baseline and 3-month of the transitional pilot study.
7. Pharmacy client participants will receive information about the study from flyers or pharmacy posters.
    a. Pharmacy client participants will use the QR code on the flyers or posters to access the eligibility screener.
    b. After taking the screener, eligible pharmacy client participants will be prompted to take the social and behavioral survey.
    c. Pharmacy client participants will receive electronic compensation at the end of the eligibility screener and/or social and behavioral screener.

Pilot Phase

Pharmacy eligibility, enrollment and data collection

8. Two pharmacies that are located in high poverty, racial minority neighborhood will be chosen to pilot test the pharmacy PrEP delivery model.
    a. All pharmacies will have a large, private space where pharmacy clients who agree to be screened and linked to PrEP can have privacy. If necessary, we will provide additional wall partitions/ screens, noise machines and noise-cancelling curtains to enhance privacy.
9. We will obtain informed consent from at least 1 pharmacist and 2-3 technicians at each pharmacy to participate in the study.
10. Pharmacy staff participants will participate in a virtual Pharmacy Training Seminar that will take approximately 1.5 hours to complete. The training will follow the guidelines of the Pharmacy Staff Training Manual for all participating pharmacies.
11. During the virtual Pharmacy Training Course, pharmacy staff participants will participate in a HIV Prevention and Counseling module to learn post-test HIV counseling.
12. One-hour in-depth interviews will be administered to pharmacy staff participants at baseline, 3-month and 6-month of the pilot study.

Pharmacy training seminars

1. The objective of the pharmacy training seminar is to equip participating pharmacy staff with the tools needed for optimal PrEP delivery. *While pharmacy staff participants will not be required to provide care to pharmacy client participants, our goal is to assess pharmacy staff participants increase in HIV knowledge over time.*
2. The investigators will provide pharmacy staff participants with a training manual to help pharmacy staff participants understand the specific challenges of the BMSM population with respect to HIV prevention and PrEP. The sections of the training manual will be as follows: pharmacy staff as public health providers, the scope of the problem with HIV in the community, understanding cultural challenges and barriers of BMSM, research ethics, patient eligibility for PrEP, PrEP payment options, training services that will be offered in the pharmacy (i.e. PrEP delivery, HIV testing), the importance of PrEP in HIV prevention, PrEP safety, the availability of PrEP locally in the community and relevant contact information, and other PrEP and HIV services available in the community that may be important to know about (e.g., medical/healthcare services, prevention, mental health services, support groups for HIV positives, etc.).
3. Research assistants will undergo extensive training to ensure standardization of the pharmacy training protocol in both pharmacies.
    a. Research staff will practice role-playing strategies to suggest various techniques for engaging client participants.
4. Pharmacy staff participants will receive virtual training via Canvas and walk-through the intervention activities including engaging client participants, providing the social and behavioral survey, offering the biological screening kit, interpreting the results and linking to PrEP.
5. Pharmacy staff participants will be required to complete a HIV Prevention and Counseling module through the virtual Canvas training course to equip them with HIV counseling concepts, basic counseling skills, HIV prevention counseling and how to conduct the six-step HIV prevention counseling protocol.

Pharmacy-based PrEP delivery

1. Pharmacist participants will be asked to stock generic PrEP medication to ensure that eligible

participants are provided with 30-days of PrEP medication. Pharmacies will be compensated by the research team for the cost of the medication and receive a $50 dispensing fee for each prescription dispensed.

2. Pharmacy staff participants will provide a pharmacy brochure highlighting that they offer pharmacy PrEP delivery tailored to the Atlanta area and for those who patronize the pharmacy. Pharmacy posters normalizing PrEP and HIV will be carefully tailored to the community of the pharmacy. These posters will be designed to appeal to the general customer base and be placed inside and outside of the pharmacy. These posters will be placed with other health literature to avoid singling out HIV-related services that may inadvertently add stigma.

3. Pharmacy staff participants will discreetly inform pharmacy clients (n=60) about the study. Pharmacy clients who are interest and willing will complete an electronic eligibility screener.
    a. *In cases of long lines in the pharmacy and privacy is not possible, we will discourage pharmacy staff from delivering detailed information (at this particular visit) to protect anonymity of their customer; this will be done consistently across each pharmacy.*

4. Pharmacy client participants who agree to participate will be directed to an area where they can privately provide electronic informed consent and complete the eligibility screener. They will be informed at the end of the survey if they are eligible for the 20-minute social and behavioral survey via an electronic prompt. Eligible pharmacy client participants can immediately complete the social and behavioral survey or return to the pharmacy at a later time to do so. and their customer visit will be logged.
5. The consent form and survey will be self-administered via an electronic tablet so it will NOT require the presence of the pharmacy staff participants outside of them directing them to the private room where the tablet is set up. To circumvent potential literacy issues, the participant will listen to questions via headphones and mark their answers using the touch screen computer. If the participant has a physical or mental condition that renders them unable to use the tablet, the survey will be administered orally by a study team member. Audio recordings of the questions will be utilized throughout Alchamer wherever possible in case of literacy barriers.
    a. The electronic survey platform, Alchemer, will allow us to automatically identify individuals who are behaviorally appropriate for PrEP. A password-protected document will be automatically generated to inform the pharmacy staff participants if the individual is eligible for the clinical PrEP screening. The pharmacy staff participants will not know what behaviors were reported by the pharmacy client participant to deem eligibility. They will just have an affirmative or non-affirmative response that indicates the pharmacy client participants eligibility.
    b. Pharmacy client participants who complete the eligibility screener will receive $1 and $25 for the social and behavioral survey regardless of their eligibility or interest in being clinically screened for PrEP.
6. The pharmacy client participants will inform the pharmacy client participant if they are eligible to participate in the clinical screener.
7. Pharmacy client participants who are eligible and agree to the HIV test will be provided with a pre-packaged kit of a self-administered test for HIV and directed back to the private area of the pharmacy to perform their screenings. A recent “PrEP-at-home” pilot study conducted by co-I Siegler showed high levels of comfort and efficacy of MSM self-administering HIV tests at home without supervision[47].

    a. Video and visual instructions will be provided on the tablet and paper to guide pharmacy client participants through the process of each test. Pharmacy client participants will also be able to reach an Emory staff member via phone or videoconference for questions about specimen collection.
    b. We expect that 90% of pharmacy client participants will be able to complete these tests in a private area[47]. Our community partners at NAESM also conduct self-testing at their community center and have high levels of participation.
4. We will ask pharmacy client participants who decline to be screened for PrEP to complete a 1-2-minute survey to explain their reasoning for declining the HIV test.
8. Pharmacy client participants will be asked to return the screening tests to the pharmacy staff participants. While their tests are being processed, we will ask them to complete an electronic post clinical screener survey that collects their follow-up information (phone number, email, address and contact for someone who can reach them) and ascertains their experience performing the self-screening tests in the private area.
    a. They will be assured that we will only use this information to follow-up with them about the study and their information nor personal data will be shared with anyone other than themselves.
9. The pharmacy staff participants will process/ interpret the results of the rapid HIV test first in case a treatment referral needs to be set up.
10. Pharmacy client participants who test HIV negative will be provided with their results and be given a 30-day prescription for PrEP, culturally appropriate PrEP counseling and a follow-up appointment with co-I Holland or another PrEP prescribing physician identified through PrEPlocator.org, whichever is closest.
    a. A PrEP prescribing physician will be available via phone during the testing process to provide participants with a prescription of 30-day PrEP.
    b. We will inform the individual that a 30-day PrEP prescription will be required to achieve protection from HIV but in order to sustain protection, they need to continue PrEP beyond the 30-day period.
11. Pharmacy client participants may refuse to participate at any time or if they have time constraints, they can schedule the clinical screening at a later date. If they are uncomfortable completing the screening in the pharmacy, we will also provide them with a referral for a PrEP prescribing physician.
12. Pharmacy client participants who test HIV positive will receive post-test counseling from the pharmacy staff, who underwent intensive post-test counseling. Pharmacy client participants will be immediately sent for confirmatory testing and linkage to treatment at our community partner (NAESM) or co-I Holland.
    a. If needed, we will provide transportation for those who test positive to the clinic (if physically open pending COVID-19) and a research assistant from Emory or NAESM will be available to accompany the participant.
13. Pharmacy client participants who have an inconclusive HIV test will be told that their test is inconclusive and will be referred to our community partner, NAESM, for a confirmatory HIV test.
14. Once the pharmacy client participant completes the study activities they will be thanked for their time. In case of inclement weather, a research team member will offer to order an Uber or Lyft for the participants.

15. We will complete a 3-month follow-up phone call with pharmacy client participants who have test for HIV to assess linkages to PrEP/HIV care.

2.5 Quality Assurance

Due to COVID-19, research assistants will work remotely with pharmacies to complete the transitional pilot phase. Research staff will conduct a short online orientation with pharmacy staff participants to review the study activities. There are only two study activities for the transitional pilot phase: 1) place flyers in client participants' medication delivery packages about the study; 2) place posters about the study in their pharmacies and be willing to refer client participants with questions about the study to our research staff.

Research staff will proceed with the pilot phase of this study when in-person human interaction is favorable. Prior to the pilot phase, research assistants will undergo extensive training to ensure standardization of the pharmacy training protocol. Research staff will practice role-playing strategies to suggest various techniques for engaging client participants, which will be used during the pharmacy staff trainings.

To check the consistency of pharmacy PrEP delivery by pharmacy staff participants, the research staff will conduct at least one "test-buy" without knowledge to the pharmacy staff at each pharmacy. At enrollment and during informed consent, pharmacy staff participants will be made aware that we will be evaluating their services at various times throughout the data collection period and that our staff will not identify themselves as Emory research staff. If inconsistencies are observed, additional one-on-one trainings will be performed. Pharmacy activities will also be assessed through bi-weekly check-in visits/phone calls and through semi-structured interviews. This will help inform potential changes and/or booster trainings that may need to take place. While pharmacy staff participants will have gone through extensive training on how to engage their client participants, our research staff will closely monitor the first couple of months to encourage the highest quality of service delivery.

2.6 Risks to participation

In terms of the key stakeholder surveys and workflow assessments completed for Aim 1, there are no psychological, social or biological risks involved.

In the transitional pilot phase, research assistants will engage with pharmacy staff participants online through Zoom. Pharmacy staff participants will complete a short orientation of the study activities. Pharmacy staff participants will also earn 2 CE credit through an online training seminar to learn how to mobilize pharmacies to improve PrEP access. There are only two study activities for this phase. Firstly, pharmacy staff participants will place flyers within their client participants' medication delivery packages. Secondly, pharmacy staff participants will hang posters about the study and the assessments in their pharmacies.

With COVID-19 unabated, pharmacies primarily deliver medication to their client participants, which provide the opportunity to place study flyers in client participants' medication delivery packages. Additionally, few pharmacy client participants still visit pharmacies. Pharmacy staff participants will place posters in their pharmacies to increase costumer engagements with the study information. The aforementioned study activities do not require pharmacy staff participants to perform duties outside of their current scope of practices. Therefore, there are no additional psychological, social or biological risks involved. However, there are minimal risks for pharmacy client participants who complete the eligibility and social and behavioral screeners to determine behavioral eligibility for PrEP. Pharmacy client participants may feel mild discomfort in answering personal and lifestyles questions.

In the pilot study phase, pharmacy staff participants will inform pharmacy clients about the study and will be trained on the importance of confidentiality and discretion with respect to the pharmacy client participants. Pharmacists have extensive experience working with patients for a host of health outcomes and are bounded by the Code of Ethics that are adopted by the American Pharmacists Association. The Code of Ethics promote covenantal relationship, respect, and confidentiality for every patient. Therefore, we do not foresee any problems with pharmacists' ability to uphold fundamental principles of ethics when interacting with study participants[48].

We will, however, provide additional training to pharmacy staff participants on research ethics during the pharmacy training. There is a small possibility of other patrons in the pharmacy over-hearing pharmacy staff discuss the study with potentially eligible pharmacy client participants. To circumvent this, we will train pharmacy staff participants to engage pharmacy client participants during a discreet time when customer flow is low. Discussions of sensitive topics (i.e., drug and sex behaviors, PrEP, HIV, etc…) will be conducted in a private room or an area that we have created with partitions, noise cancelling curtains and a sound machine to muffle noise.

There are minimal risks for pharmacy client participants who complete the social and behavioral screener to determine behavioral eligibility for PrEP. For those who are behaviorally appropriate for PrEP and agree to be clinically screened for PrEP (HIV testing), they may learn that they have a positive HIV diagnosis, which may result in emotional or psychological distress. The pharmacy staff participant, who will undergo intensive post-test counseling training, will counsel the patient. The pharmacy staff participant will immediately link the patient to confirmatory testing and HIV care through our community partners at NAESM (who have significant experience counseling and treating newly diagnosed patients) or co-I Holland who directs Atlanta's Fulton County HIV clinic. We will provide transportation for those who test HIV positive to the clinic and research assistants from Emory and

NAESM will be available to accompany the patient if needed. NAESM and Dr. Holland have extensive experience working directly with patients who have HIV. They will be available to study participants who need referrals, are not linked to a regular health care provider and need health care treatment. We will also provide mental health referrals tailored to their needs and community.

2.7 Adequacy of Protection Against Risks

Recruitment and Informed Consent

For the key stakeholder interviews and workflow assessments (Aim 1), written informed consent will be obtained at recruitment into the study. The data will be summarized within each key stakeholder subgroup without the inclusion of personal identifying information.

For the transitional pilot phase, pharmacy staff participants will provide written informed consent once the pharmacy is recruited into the study. We will complete pre/post pharmacy training surveys as well as baseline and 3-month surveys throughout the period of the transitional study. These data will include personal identifying information as this will be used for tracking quality control and identifying areas where the pharmacy PrEP delivery model needs adjustment for the pilot phase.

Also, in the transitional pilot study, pharmacy client participants will provide electronic informed consent before initiating the eligibility screener and social and behavioral survey. Participants will receive links and given instructions to take surveys. The screener and survey will provide a brief statement regarding the purpose of the study. Pharmacy client participants who take the eligibility screener will be compensated a $1 pharmacy coupon. Pharmacy client participants who are eligible and take the social and behavioral survey will be compensated $25 for their time. Before survey questions appear, pharmacy client participants will provide electronic consent, similar to online surveys. On the consent, pharmacy client participants are told that they may refuse to answer any question or to drop out of the study at any time they feel uncomfortable with the process. This wording will be bolded. Surveys will be administered privately through the use of Alchemer; we will have the participant select their answers using their mobile or other electronic devices. Alchemer can be used on mini-computers, tablets, and phones (which increases privacy). They will be told that the information obtained will be summarized with information from others and only aggregate data will be reported; that in no case will individual information be released (except to the pharmacy who is liable under Health Insurance Portability and Accountability Act of 1996) without their written consent. Records of the consent, which include personal identifying information will be stored in locked files separate from data collection forms that have no personal identifying information but are noted with a unique study number.

For the pilot study, pharmacy staff participants will provide written informed consent once the pharmacy is recruited into the study. We will complete pre/post pharmacy training surveys as well as baseline, 3-month and 6-month surveys throughout the period of the pilot study. Pharmacy staff participants will also complete electronic logs of their recruitment efforts of the study population. These data will include personal identifying information as this will be used for tracking quality control and identifying areas where the pharmacy PrEP delivery model needs adjustment.

Also, in the pilot study, pharmacy client participants will provide electronic informed consent before initiating the social and behavioral screening survey. For pharmacy client participants who are interested in being in the study, pharmacy staff participants will escort the pharmacy client participant to a private

area where they can begin the electronic informed consent process. On the consent, pharmacy client participants are told that they may refuse to answer any question or to drop out of the study at any time they feel uncomfortable with the process. This wording will be bolded. Surveys will be administered privately through the use of Alchemer we will have the participant listen to questions via headphones and mark their answers using the touch screen tablet computer. Alchemer can be used on mini-computers and tablets (which increases privacy). They will be told that the information obtained will be summarized with information from others and only aggregate data will be reported; that in no case will individual information be released (except to the pharmacy who is liable under Health Insurance Portability and Accountability Act of 1996) without their written consent. Under Georgia State law, the researcher(s) will not maintain as confidential, information about known or reasonably suspected incidents of abuse or neglect of a child, elder, or vulnerable adult, including but not limited to physical, sexual, emotional, and financial abuse or neglect. If any researcher has or is given such information, he or she may be required to report it to the authorities. Records of the consent, which include personal identifying information will be stored in locked files separate from data collection forms that have no personal identifying information but are noted with a unique study number. Those records will be stored in a physically secure environment. All data files will have encryption and strong password protection. Any identifiable data will be stored on Emory University's secure servers.

Protections Against Risk

In terms of the key stakeholder surveys and the pharmacist/ technician surveys during the transitional pilot phase and pilot phase of the study, there are no psychological, social or biological risks involved.

Since in this proposed research plan, pharmacy client participants will be informed about the study by the pharmacy staff participants, the importance of confidentiality will be conveyed to all study pharmacy staff participants. To minimize the risk of pharmacy client participants feeling uncomfortable about answering personal questions, we will use an electronic survey platform, Alchemer, for the study's surveys. In Alchemer, participants will select answers to the survey questions. In the Alchemer survey, participants listen to questions via headphones and mark their answers using the touch screen tablet computer. During the transitional pilot phase, pharmacy client participants will self-interview using Alchemer. However, for the pilot phase, pharmacy staff will be available to assist participants with questions regarding technical difficulties on Alchemer. But, for questions specific to the pharmacy client participants data or survey instrument, the participant will be told that they can call or videoconference an Emory research assistant. Pharmacy client participants may refuse to answer any question that makes them uncomfortable.

To minimize risks to confidentiality, we will secure study data with all appropriate physical, electronic and operational protections. Data will be stored in a physically secure environment. All data files will have encryption and strong password protection. Any identifiable data will either be stored on Emory University's secure servers or will be on fully encrypted laptops. Alchemer surveys will take place on an encrypted commercial survey website, SurveyGizmo (http://www.surveygizmo.com/survey-software-features/secure-link/). This site has been used by one of our Co-I for thousands of online surveys with MSM with no data security breaches. Access to data will be on a role-based standard; only those study staff who require access to each type of data to complete their study- related roles will be allowed access. All study staff will be trained in security and confidentiality procedures and will sign a confidentiality agreement before receiving access to any participant data. While we do not expect any problems, all adverse events and unanticipated problems will be promptly reported to the Emory IRB.

The investigators will provide a Certificate of Confidentiality for this study to further protect the individually identifiable protected health information from compelled disclosure during legal proceedings. Though we will not be collecting information on the identities of sexual partners, our study will be collecting detailed sexual behavior information from participants who may be HIV-positive. This protection will be important in Georgia because of past prosecutions of HIV- positive persons for lack of zero-status disclosure or hypothetical transmission of HIV to sex partners.

Additional protections for children (aged 18-21): According to 46 CFR subpart D, children are defined for the purpose of that section as **"**persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." In Georgia, persons aged 18-21 have attained the legal age of consent for HIV/STI services, including HIV testing, care and treatment. However, we are aware that the consequences of disclosure of positive HIV status or of having male sex partners may be particularly difficult for men in this age group. For all participants, we will specifically ask when contact information is requested if there are any special instructions or considerations for contact, for example, if the participants live with parents or other family who should not be made aware of the participant's enrollment in the health study.

2.8 Reportable events

All adverse events and unanticipated problems will be promptly reported to the Emory IRB and/or NIH program official in accordance with the NIMH reportable events policy for definitions and timeframes.

2.9 Benefits to subject or future benefits

Although there are no direct personal benefits to the participants included in the study, the results of the study will lay the critical groundwork for understanding whether pharmacy PrEP delivery can be achieved for BMSM in high poverty, racial minority neighborhoods. This study will inform a future efficacy trial that is implemented to test the uptake of PrEP through pharmacies for BMSM. In addition, this model could be adopted for pharmacies across the country, in communities at high risk for HIV, and other underserved populations in the US without another point of access to PrEP in their communities.

2.10 Compensation

<u>Formative Phase</u>

Pharmacists, technicians, PrEP-prescribing physicians, and BMSM will be compensated $50 for 1.5 hours for their time completing the interview. Pharmacists and/or PrEP-prescribing physicians will receive an additional $50 for their time if we perform a guided walk around of their office to assess their workflow.

<u>Transitional Pilot Phase</u>

During the transitional pilot phase, each pharmacist participant will receive $250 for 3 months of participation in study activities as outlined in the pharmacist participant consent forms. Each pharmacy staff participant (we estimate 1 pharmacist and 3 technicians per pharmacy) will receive $25 for the orientation session plus $25 for each semi- structured interview. We have noted that this amount of compensation for pharmacy staff has been sufficient in earlier work with pharmacies. Pharmacy client participants who agree to complete the eligibility screener and social and behavioral survey will be compensated $1 and $25, respectively, for their time regardless of their eligibility or

interest in being clinically screened for PrEP.

Pilot Phase

In this proposed study, each pharmacist participant will receive $2,500 ($1,250 for each pharmacist participant in the pharmacy) for 6-months of participation in study activities as outlined in the pharmacist participant consent forms. Each pharmacy technician participant (we estimate 3 technicians per pharmacy) will receive $50 for the training session plus $25 for each semi- structured interview. We have noted that this amount of compensation for pharmacy technician participants has been sufficient in earlier work with pharmacies. Additionally, pharmacies will be compensated for the price of PrEP medication and be provided with a dispensing fee of $50 per bottle.

Pharmacy client participants who agree to complete the social and behavioral screener will be compensated $25 for their time regardless of their eligibility or interest in taking an HIV test.

2.11 Data analysis

Formative Phase

Qualitative interviews will be taped and transcribed. Field notes from the workflow assessment will be transferred to electronic files. Two separate interviewers will double code the transcripts and workflow assessments for content and themes in order to identify emergent patterns[49]. As the domains are defined, we will construct a preliminary codebook, and coding scheme. Transcripts will be coded into Atlas.ti with open codes first in order to identify broad themes or patterns. Following open coding and broad thematic analysis, transcripts will be coded with axial codes, or more interpretive codes that will be used in order to identify core concepts. With coherent axial coding we will construct detailed narratives of the interviewees understanding of the pharmacy PrEP delivery model and how it can be implemented in the context of their current day-to-day activities.

Intervention Development Phase

The advisory board will provide feedback on the study protocol, pharmacy trainings, pharmacy recruitment brochure, survey instruments and other materials as needed. We will also iteratively revise the protocol over the course of the study to ensure its feasibility, acceptability, and safety. Adaptive protocol development is recommended in early phase clinical trials since it allows for continued process improvement and time-savings from data as it is being collected[45,46]. We will debrief about the study activities ***every month*** of the pilot study to refine the protocol for immediate implementation in the study activities. Each proposed change will be assigned a subject matter expert from the co-I's on the grant. The subject matter expert and at least two other co-I's will be asked to vote on whether the change will be made immediately, revoked or followed through the next monthly meeting. Meticulous records of the development and revision process of the pharmacy PrEP delivery model will be kept throughout the study.

Transitional Pilot Phase

Quantitative data will be transferred to analyses using analysis software (i.e., SAS) to derive descriptive statistics and quantitative profiles of customer data. Exploratory data analysis (EDA) will be conducted through data editing using SAS. EDA will include calculation of means, medians, percentages,

proportions, standard deviations, and skewness/kurtosis as appropriate. If outliers or nonstandard distributions exist, variable transformations or standardized cut-points in the data will guide recoding of continuous variables. Externally validated standards will be used to recode the data if possible. The influence of outliers will be assessed and medians (or rank tests) used if required. Differences between two means (or medians) will be tested using t- tests or rank tests and categorical variables will be compared between groups using Chi-square tests, exact tests and/or with 95% confidence intervals to guide interpretation. Correlates of interest include health insurance, sexual behavior, substance use and HIV testing behavior. Other relevant mediators and/ or confounders will include variables such as previous and/ or consistent access to health care. We plan to separately examine the relationship between each confounder and outcome of interest using t-tests or rank tests on continuous measures and exact tests on categorized values if categorizations are used. Initial unadjusted comparisons will be made using exact tests. If significant bivariate associations are found, we will incorporate these exposures as covariates using linear regression for continuous variables and logistic regression for binary variables where sample size allows.

Pilot Phase

Pharmacist and technician participant data

Transcripts from the audio-recorded pharmacists and technician interviews will be loaded into Atlas.ti, a qualitative data analysis software package. Research assistants will enter the data immediately so that intervention activities and protocols can be altered during the study, if needed. Patterns of knowledge, beliefs, behaviors, and practices that point to practical barriers or facilitators of effective training of pharmacists, feasibility of intervention delivery and effective risk reduction will be identified. These data will include pharmacy-identifying information so that each pharmacy can be monitored for consistency of study activities. In terms of quality control, these data will also be used to inform the necessity of additional training for pharmacy staff.

For the data analysis, all interviews will be double coded by two different research assistants. Topic guides for the interviews will be used to establish preliminary codes for interpretation. Coding will begin with the first interview by creating open codes of broad themes found in the four SEIPS components of inquiry: person, organization, environment and tasks. More interpretive codes within those open codes will then be used to identify patterns of knowledge, beliefs, behaviors, and practices that point to practical barriers or facilitators of effective training of pharmacists, feasibility of intervention delivery and effective pharmacy PrEP delivery.

Pharmacy client participant data

Formation of new variables and collapsing variables will be done when exploring the proportion and correlates of feasibility, acceptance, safety and PrEP use at baseline and at 3-months among BMSM. Exploratory data analysis (EDA) will be conducted through data editing using SAS. EDA will include calculation of means, medians, percentages, proportions, standard deviations, and skewness/kurtosis as appropriate. If outliers or nonstandard distributions exist, variable transformations or standardized cut-points in the data will guide recoding of continuous variables. Externally validated standards will be used to recode the data if possible. The influence of outliers will be assessed, and medians (or rank tests) used if required. Differences between two means (or medians) will be tested using t- tests or rank tests and categorical variables will be compared between groups using Chi-

square tests, exact tests and/or with 95% confidence intervals to guide interpretation. Correlates of interest include health insurance, sexual behavior, substance use and HIV testing behavior. Other relevant mediators and/ or confounders will include variables such as previous and/ or consistent access to health care. We plan to separately examine the relationship between each confounder and outcome of interest using t-tests or rank tests on continuous measures and exact tests on categorized values if categorizations are used. Initial unadjusted comparisons will be made using exact tests. If significant bivariate associations are found, we will incorporate these exposures as covariates using linear regression for continuous variables and logistic regression for binary variables where sample size allows.

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