THE OPENS TRIAL: OFFERING WOMEN PREP WITH EDUCATION, SHARED DECISION-MAKING, AND TRAUMA-INFORMED CARE

NCT05619497

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Study Protocol

The OPENS Trial: Aim 2
Offering women PrEP with education, shared decision-making and trauma-informed care

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This document reflects the final IRB-approved protocol for Aim 1 (NCT04621760) and Aim 2 (NCT05619497). Minor editorial changes were made to improve readability for reporting purposes; no substantive study procedures were changed.

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OVERVIEW

This manual provides procedures for the study entitled "Offering women PrEP with education, shared decision-making and trauma-informed care: The OPENS Trial." The protocol will be updated as necessary and as indicated by our Institutional Review Board (IRB) approval. This study is funded by the National Institute of Minority Health and Health Disparities (R01MD013565).

This manual describes procedures for research that will take place between 2020 and 2024, across Aim 1 and Aim 2.

Study staff members are encouraged to contact the Principal Investigator (PI), Christine Dehlendorf, with all questions related to interpretation and proper implementation of the protocol.

Intentional protocol deviations may not be carried out without prior approval from the PI. However, if a protocol deviation is required to protect the rights, safety or welfare of a participant in an emergency, it may be carried out without prior approval. In the case of inadvertent protocol deviations study staff should note the error and notify the research coordinator or PI to address it accordingly.

1. STUDY INFORMATION

1.1 Background

Although 13% of the U.S. female population is Black, 60% of new HIV diagnoses in U.S. women are in Black women. The South is the epicenter of the U.S. HIV epidemic, including in women, and Black Southern women are disproportionately affected: Black women account for 69% of new HIV diagnoses in women in the South. As the first highly effective, discrete, woman-controlled HIV prevention method, oral pre-exposure prophylaxis (PrEP) with tenofovir disoproxil fumarate/emtricitabine radically expands HIV prevention options for women. However, uptake of PrEP in U.S. women has lagged, particularly among groups most affected by HIV. The Centers for Disease Control and Prevention (CDC) estimates 180,000 women in the U.S. are eligible for PrEP, but only approximately 19,000 have ever been prescribed PrEP. Moreover, despite disparities in incident HIV in U.S. women, White women are 4 times more likely to have received PrEP than Black women.

PrEP cascades outline the necessary steps for accessing PrEP, including screening and identifying eligible individuals, linkage to care, prescription and initiation of PrEP. Data suggest there are multilevel barriers related to the process of screening for HIV risk in women and identifying potential PrEP candidates that may drive a significant drop off early in the PrEP cascade for women. Women report feeling judged by risk assessment questions and experience stigma around disclosing sexual practices. As a result, if screening is required to educate patients about PrEP - as is true in most clinical settings - many women for whom PrEP is appropriate may never learn about PrEP. Further, women have low levels of

knowledge about HIV risk and HIV prevention options, and therefore will not seek out PrEP services themselves. By offering education to all women about vulnerabilities to HIV as well as information about HIV prevention methods including PrEP, at-risk women can circumvent these multifactorial barriers and request PrEP. Digital decision support tools (DST), which have been used with success in a range of healthcare contexts including contraception, provide an efficient and private mechanism for this information-sharing step.

The study team developed a tablet-based tool that is designed to provide universal PrEP education and facilitate women's agency to identify their own risks and interest in PrEP. It was refined with iterative feedback from patient and community stakeholders, and finalized based on cognitive testing.

The DST provides information about vulnerabilities to HIV and core characteristics of different HIV prevention methods, and then the opportunity to explore these characteristics in depth, including efficacy, safety and side effects. The user chooses the level of information that they wish to receive through the interactive interface, allowing for an individualized experience. Upon coming to the end of the tool, information on the tablet suggests that women ask their provider about HIV prevention methods they are interested in using, based on their preferences for method characteristics, and their questions in order to facilitate deliberation with the provider. The DST takes approximately 10 minutes to complete. A decision support tool was chosen as a key component of the study following its proven effectiveness in offering contraceptive options to patients.

Aim 1 of this study will examine the effect of the HIV prevention DST on PrEP prescriptions. In this Aim, participants were randomized to viewing the DST or not, prior to receiving usual care.

Additionally, the study team recognizes the importance of receiving health information from a trusted source, such as health care providers or health educators, when making important health decisions. Therefore, Aim 2 of the study offers and assesses the effects of a combined intervention of the DST following a clinic-wide training on shared decision making and trauma-informed care. Shared decision making is an effective strategy to offer information and services to patients as it allows the health care provider to share their clinical knowledge and expertise while partnering with the patient to elicit their experiential knowledge, needs and preferences. Through partnership between a patient and provider, the patient can make an informed decision about HIV prevention and other health needs that align with their values and desires and can result in greater adherence to the prevention or treatment options and satisfaction with care. The training will also include information about trauma-informed approaches to deliver health care in a person-centered and affirming manner. This training will highlight how many people, particularly those vulnerable to HIV due to intersecting oppressions, carry traumas that impact their exposure to health issues and the resources needed to mitigate these harms. It is critical that health care providers and health professionals are aware of intersecting forms of oppression that create trauma, including those that the medical profession create and perpetuate. A combined approach of shared decision making at the interpersonal level and trauma-informed care at the clinic-level is an equity-oriented strategy to offering HIV prevention information to women in the Southeastern U.S. who are disproportionately impacted by HIV.

1.2 Study Aim

The first aim of this study is to determine the effects of an HIV prevention DST coupled with standard counseling on women's PrEP initiation at a reproductive health clinic in Duval County, Florida. The second aim of this study is to determine how provider training on shared decisions making and clinic-wide training on trauma-informed care, on their own and paired with the DST, affect counseling and women's PrEP initiation at a reproductive health clinic, and an STI clinic. Due to staffing changes at the reproductive health clinic during Aim 2, patients who present to the clinic for STI testing and treatment are referred to an STI clinic in the same building for these services. Consequently, this STI clinic is also included in Aim 2.

We will recruit up to 784 participants to Aims 1 and 2 in this study. In Aim 1, approximately 384 women presenting to a reproductive health clinic in Duval County, Florida, will be randomized to standard counseling plus use of an HIV prevention DST, providing education about PrEP and encouraging self-assessment of HIV risk, or standard counseling alone. Then in Aim 2, after provider and clinic trainings are conducted, approximately 366 women (and up to 400) presenting to two health clinics will be enrolled in two Phases; in Phase 1, the first 183 will not use the DST, and in Phase 2, the second 183 will use the DST. The primary outcome of interest is PrEP initiation, with additional quantitative and qualitative evaluation of women's experiences of care and quality of decision making.

1.3 Principal Investigator Responsibilities

It is the responsibility of the Principal Investigator to ensure that the study is conducted according to the following guidelines:

- Conduct the study in accordance with the current protocol.
- Personally conduct or supervise the described investigation.
- Maintain adequate and accurate records.
- Ensure that all staff assisting in the conduct of the study are informed about their obligations to meet the above commitments.
- Ensure that the staff is properly trained in the goals and purpose of the study and the proper conduct of study procedures in accordance with this protocol (recruitment, interviewing, data collection and analysis, etc.).
- Report any protocol deviations to the FDOH IRB and departmental personnel.

1.4 Study Contacts

Principal Investigator: Dr. Christine Dehlendorf
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Study Coordinator: Whitney Wilson
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2. STUDY DESIGN

Aim 1 is a randomized controlled trial to investigate the effect of an HIV prevention decision support tool coupled with standard counseling offered to women attending a reproductive health clinic, compared to standard counseling alone, on PrEP initiation.

Aim 2 is a study to evaluate how clinic-wide trainings on shared decision making and trauma-informed care, on their own and paired with the DST, affect patient counseling and decision making about PrEP among women attending a reproductive health clinic, and an STI clinic where patients from the reproductive health clinic are referred.

A subset of participants, individuals who self-identify as Black or Latina, will also complete a post-clinic visit interview.

We will collect quantitative and qualitative data to determine the impact of the implementation of this tool and trainings on the experience of patients and providers. Data collection will occur in clinic and via phone or email for follow-up with patients three months after their visit.

3. STUDY PROCEDURES

3.1 Study staff

All study procedures will be conducted by UCSF and FDOH research staff. FDOH staff will be responsible for recruiting participants at a reproductive health clinic and an STI clinic in Duval County, Florida. The research coordinator or assistants will assess eligibility and consent participants, as well as conduct intervention-related activities. FDOH will collect and share data with UCSF. UCSF team members will be responsible for data analysis.

3.2 Intervention phase procedures

3.2.1 Randomization

For this trial, the unit of randomization will be the individual participant. In Aim 1, participants will be randomized to a study arm. In Aim 1 and Aim 2, participants will be randomized to a qualitative interview and/or audio-recording of their visit. All randomization will occur by research staff with the use of a REDCap randomization instrument, based on an allocation table. Results of randomization will be documented in REDCap.

Individuals will not be considered participants until they are randomized in Aim 1 (in Aim 2, consent is the point of enrollment). Prior to being randomized in Aim 1, if an eligible patient participant does not wish to continue with study procedures, they will be considered as a "decline to participate." If they do not wish to continue with study procedures after the point of randomization, they will be considered "dis-enrolled" (see dis-enrollment procedures).

Intervention arm randomization

In Aim 1, randomization (#1) to the study's intervention (HIV prevention DST) or control (standard counseling) arms will occur immediately before receipt of the intervention.

In-depth interview and audio-recording randomization

After enrollment in the study, participants will then be randomized to determine if they will be invited to conduct a qualitative interview or audio recording of their counseling visit. This randomization will be based on the participant's response during the eligibility screening regarding racial/ethnic identity.

For participants who self-identify as Black or Latina, or multiracial including Black or Latina, a REDcap randomization instrument will be used within each study arm in Aim 1 (those randomized to the DST or control), and across all participants in Aim 2, to determine if the participant will be invited to complete an in-depth qualitative interview after their visit or have their counseling session audio-recorded. If yes, the participant will be offered the opportunity to complete an interview or audio recording, and consented if they agree.

Participants who do not identify as Black or Latina, or multiracial, will only be randomized to have their counseling session audio-recorded or not. If yes, participants will be invited to participate and consented if they agree.

3.2.2 **Blinding**

Given the nature of the intervention, blinding of participants to whether they receive the intervention (DST or not) will not be feasible. Clinicians and counselors in the clinic will not be alerted to whether participants used the DST or not; however, participants may discuss information in the DST, unmasking the study arm in Aim 1 or the second phase in Aim 2. Consequently, clinicians and counselors are unlikely to be blinded to study interventions. However, at follow-up, study personnel conducting surveys by phone will not be aware of participants' study arm; assignment will be concealed in a different page of the participant's record. Consent forms intentionally do not disclose the specific outcome of interest (i.e. PrEP initiation), so as not to influence participant behavior. Additionally, participants will not be aware of their arm assignment until after they have been consented in Aim 1, or what phase the study is in in Aim 2 until after they have been consented. Study staff will be blinded during quantitative data analysis of participants' use of the DST or not. Qualitative data will not be blinded as study participants will be asked about use of the DST.

3.2.3 **Baseline procedures**

Patients

The baseline procedures for patient participants are as follows:

On the day of enrollment:

- Individuals will be handed a paper or laminated information card about the study and eligibility criteria when they present to the front desk for check in. Eligibility criteria on this sheet will include:
    - Identify as a woman
    - Age 18 years old to 45
    - Not known to be living with HIV
    - Not known to be taking PrEP

    - English speaking
    - Interested in participating in the study
- If patients self-identify as eligible and interested in learning more about the study, they will be instructed to hold onto the information card (indicating to the research assistant that they would like to be approached). If they are not interested in participating, patients will hand this card back to front desk staff.
- Research staff will approach patients who have held onto the card in the clinic waiting room before their appointment and invite them to be screened for study eligibility in a semi-private space. Research staff will share a brief description of the study and assess eligibility using a verbal eligibility checklist.
    - Researchers will also ask patients if they self-identify as Black or Latina, or multiracial including Black or Latina, to determine eligibility for randomization to interviews or audio-recordings after randomization to the study.
- If participants are eligible, they will be consented to enroll in the study.
    - If individuals decline to enroll or are ineligible, the reason for ineligibility will be recorded or reason for declining if shared.
- All participants will be asked to complete a contact information form in REDCap on a tablet computer and complete a pre-visit survey collecting information on experience with and knowledge of HIV prevention.
- In Aim 1, participants will then be randomized to the intervention arm (DST) or control (standard care) at this point.
- Based on response during eligibility screening regarding racial identity, participants will then be randomized to determine if they will be invited to conduct a qualitative interview or audio-recording of their counseling visit. Specifically:
    - Participants who identify as Black or Latina will be randomized to participate in a qualitative interview or audio-recording
    - Participants who do not identify as Black or Latina will be randomized only to audio-recording or not.
- Participants who are randomized to participate in an interview will be invited to have an interview the same day if the qualitative interviewer is available. Interviews will be conducted either in-person in a private space, or over Zoom over (using a hotspot), both HIPAA-compliant video conferencing programs. Interviews will be conducted within 1 week of the clinic visit.
- Participation in each study activity (participation to be randomized (in Aim 1) or assigned (based on Phase in Aim 2) to standard care or the DST, participation in a qualitative interview, and/or participation in an audio-recorded clinic visit) will require a unique consent. Participants randomized to the audio recordings will be consented for the audio recording at this time. Participants who are randomized to participate in an in-depth interview and interested in being interviewed, will be consented by Dr. Rachel Logan, a member of the study team, or another study staff member, on the day of the interview before the interview begins.
    - If participants decline to enroll in additional study components, their reason for declining will be recorded and they will be allowed to continue with primary study activities.

- In Aim 1 and the second phase of Aim 2, research staff will give the tablet-based DST to participants randomized to the intervention arm to complete prior to their visit.
- All participants will then have a clinical visit with their healthcare provider, per standard clinic protocol.
    - During the visit, participants who are randomized and consented to audio-recordings will have their visits audio-recorded on a HIPAA-compliant recorder.
- After the clinical visit, each study participant will complete a post-visit survey about their demographics, HIV prevention method choice and experience of the counseling they received. If a participant must leave the clinic without completing their post-visit survey due to time constraints (and not because they want to withdraw from the study), study staff will attempt to contact the participant using the contact information provided and request that they complete the post-visit survey by phone or email.
- Participants will receive a $20 gift certificate after completion of post-visit survey on the day of enrollment. If a participant does not complete the post-survey on the day of their appointment a $20 gift certificate will be sent by mail or email after completing the survey by the RA.
- After completing the post-visit survey, participants who completed an audio-recorded session will receive an additional $20 gift certificate.
- After the post-visit survey, participants who consented to participate in an in-depth interview will complete the interview in a private room in the clinic immediately following their appointment (in person or via video conference), or schedule the interview with research staff to take place within one week of the visit. After completion of the interview, participants will be compensated with a $40 gift certificate in Aim 1 and $60 in Aim 2. Compensation is being increased in Aim 2 to encourage completion of the interview and address high rates of no-shows seen in Aim 1. Details regarding interview procedures can be found in Section 7.4.
- Study staff will provide each patient with a flyer summarizing the timing of follow-up at three months and providing contact information for study staff in case a participant changes their contact information or wishes to dis-enroll.
- Participants will be offered the opportunity to take or receive FDOH informational materials about HIV prevention or have them sent over email, text, or mailed at the end of the study. Patients who decide not to participate in the study but want information about HIV prevention, will be offered the same materials by the research staff. Research staff will have these informational materials with them in clinic.

Providers & counselors

The pre-study procedures for providers and counselors are as follows:

- The study will be discussed at staff meetings or individually with providers and counselors, as determined by each clinic. Procedures will be explained, and questions will be answered.
- Following these sessions, study staff will meet individually with providers, counselors and clinic staff to answer questions and provide information necessary for

informed consent. Study staff will obtain consent from any providers or counselors who may be audio-recorded during a study visit.
- For providers who consent to be enrolled, they will then be invited to complete a short survey about their demographics and work experience.

The study procedures for providers and counselors are as follows:

- Each provider and counselor will conduct visits in the usual fashion in the clinic with patients participating in the study.
- Up to 60 visits in Aim 1 and up to 80 in Aim 2 will be audio-recorded (as described above) over the course of the year. The specific protocol for audio-recording will be determined by clinic leadership.

The post-study procedures for providers and counselors are as follows, upon the completion of patient participant recruitment:

- Each provider and counselor will be invited to complete a short survey about PrEP and HIV prevention counseling.

3.2.4 **Patient participant follow-up surveys**

Each study participant will be contacted by whatever method they prefer (phone, mail, SMS, email, in person at a follow-up medical visit) three months after their study visit to complete a follow-up survey.

The survey will be completed either over the phone with an RA or in the patient's own time, online, using REDCap.

- Patient contact information and enrollment dates will be entered into REDCap at baseline, where follow-up contact due dates will be calculated. RAs will conduct follow-up attempts via the patient's preferred method, logging each attempt and its outcome in REDCap.
- Participants' study arm assignment will be concealed in a different page of the participant's record, and study personnel will not look up assignment.
- Google Voice will be used for text and phone follow-up contact attempts. By using Google Voice as the platform from which to make calls and send text messages, no personal cell phones will have saved participant information on them. Record of contact with participants will be deleted from the Google Voice account monthly by RAs (i.e. call logs). In the case that we are unable to use Google Voice, we will use study staff landlines to call study participants where no participant information will be saved.
- Contact attempts for the 3 month survey will be declared unsuccessful after 4 weeks.
- $10 gift certificates for completed surveys will be mailed, or picked up at the FDOH office or clinic if the patient prefers, or digital codes will be texted or emailed based on participant's preference. For more detail on participant payments, see Section 6.

3.2.5 **Medical record data**

In addition to the above procedures, after participants consent to the study, research staff will obtain participants' medical record numbers (MRN) on the day of their visit. At the conclusion of each day, research assistants will request medical record numbers based on patient names and date of birth on the schedule from clinic staff. Participants who consented to the study will have their medical record number entered into a secure REDCap form that is separate from study survey responses, and links study identification numbers to medical record numbers. Access to this REDCap form will be restricted to FDOH employees, and is password protected on secure servers. RAs will shred the paper copy in the clinic after the MRN entered electronically.

Three months after the last participant has been enrolled, a study RA will submit study participants' medical record numbers to FDOH IT, to extract the following information:

- Zip code at the time of the study visit
- Insurance status at the time of the study visit
- PrEP prescription (ever) and date of prescription
- PEP prescription (ever) and date of prescription
- Dates of HIV testing and results
- Hepatitis B and C diagnoses (ever)
- Dates of STI testing and results including chlamydia, gonorrhea, syphilis and trichomonas (within 6 months and ever)

The Duval County DoH Information Technology (IT) Department will be supplied with a list of study ID numbers and medical record numbers. IT will extract relevant outcome variables and create a dataset ONLY with study ID and outcome variables; no PHI will be included in the main dataset. Only this de-identified dataset will be shared among the study team for analysis. These data will be securely transferred to UCSF for analysis, using MoveIt, an encrypted and secure file transfer program that is used by the Florida Department of Health.

The DoH IT department will also extract aggregate data by clinic during the study period of clinic patient demographics (age, race, insurance status), STI diagnoses, HIV diagnoses, and PrEP & PEP prescriptions. In addition, DoH will provide the number of clinic visits per week for the duration of the study, as well as the number of providers at each site and scope of services of each clinic.

This de-identified information will then be stored on secure servers to ensure the privacy of research participants. Information about the above processes is included in the participant's consent form for the main study.

3.2.6 **Participant disenrollment procedures**

Participants who express the desire to discontinue their participation in the study will be withdrawn from the study.

Electronic data for participants who dis-enroll at any point

1. Mark participant as "dis-enrolled" in backend survey of REDCap.
2. Remove from follow-up calendar in REDCap.
3. Delete all contact information from REDCap.
4. Mark participant as "dis-enrolled" in tracking docs.

Paperwork

If a participant disenrolls at baseline and a paper consent form had been used, research assistants will move any study participant paper consents and/or HIPAA forms to the folder labeled "withdrawn patients," stratified by clinic. Research assistants will mark on any remaining paperwork the step at which the participant was when they disenrolled, e.g. mark on consent that the participant disenrolled before completing the HIPAA form.

If a participant disenrolls at any point after baseline (e.g. at 3 month follow-up) *and had filled out a paper consent form at baseline,* their consent and HIPAA forms will remain in the folder with the rest of the remaining enrolled participants. The procedure for electronic records will then be followed.

4. ELIGIBILITY

4.1 Patient eligibility

We are seeking to recruit female participants presenting to a reproductive health clinic, and an STI clinic where reproductive health patients are referred, in Duval County, Florida.

Inclusion Criteria:

- Self-identify as a woman (regardless of pregnancy status)
- Age 18 to 45 years old
- Not known to be living with HIV (based on self-report)
- English speaking
- Interested in participating in the study

Exclusion criteria:

- Unable to consent
- Currently using PrEP
- Cisgender men
- Unwilling to be contacted in 3 months
- Already participated in the study

4.2 Provider / counselor eligibility for audio-taped counseling visits

We are seeking to recruit providers who provide sexual and reproductive health counseling from a reproductive health clinic, and an STI clinic where reproductive health patients are referred, in Duval County, Florida.

Inclusion Criteria:

- Providing health care services, including reproductive health counseling, in one of the participating clinics (includes MDs, DOs, nurse practitioners, physician assistants, nurses, and health educators)

5. PARTICIPANT RECRUITMENT

Patient

Recruitment of study participants will be conducted by FDOH study coordinator and research assistants based on coordination with clinic directors and staff at the study site. Procedures will be tailored to meet the needs of clinic flow.

The clinic will identify a point person, likely at the front desk, who will hand a laminated information card about the study and eligibility criteria to patients when they present to the front desk for check-in. If patients self-identify as eligible and are interested in participating, they will hold onto the information card (indicating to the research assistant that they would like to be approached). If they are not interested in participating, patients hand this sheet back to front desk staff (or throw it away if it is a paper, in the context of COVID).

Study staff will approach potential participants in the waiting room and invite them to a semi-private room where they will share a brief description of the study and assess eligibility using a verbal eligibility checklist. All recruitment, consent, and baseline activities may occur before, during or after appointments in accordance with clinic flow.

If the patient is eligible and wishes to participate, the research assistant will complete the consent process and enroll her in the study.

Providers

At the invitation of the clinic, research staff will attend provider and staff meetings. The intervention will be discussed, study procedures will be explained, and questions will be answered. Providers and counselors will also be invited to meet individually with study staff to answer questions about the study, and audio recording of clinic visits of participants who consent.

5.1 Obtaining Informed Consent

5.1.1 Patient consent

Study staff will ensure that potential participants are aware that the study is separate from clinical care, and that declining to participant will have no effect on medical services.

Eligible individuals will be asked if they would like to participate in the study after research staff have read each section of the consent form to them, or allowed them to review the entire consent form, and answered any questions potential participants may have about the study. If the patient is willing to participate, they will provide written informed consent (i.e. an e-signature) on an iPad. Participants will have the opportunity to keep a copy of the consent sheet.

Following randomization to an audio-recording of their visit, patient participants will be consented to these activities in the same fashion detailed above.

If a participant is randomized to an in-depth interview, they will be consented on the day of their interview before the interview begins. Dr. Rachel Logan, a member of the study team, or another study staff member will conduct the interview consents. Dr. Logan has been approved by leadership in the Duval County Health Department to consent participants for the interviews she will be conducting. Since these interviews will primarily be conducted remotely, we will be conducting verbal consents for the in-depth interviews.

Details on participant payment can be found in Section 6.

5.1.2 **Provider / counselor consent**

Informed consent will be obtained from providers and counselors to audio record their counseling sessions. Study staff will emphasize that enrollment is entirely voluntary and will not affect professional standing. If the provider/counselor is willing to participate, they will provide written informed consent (i.e. an e-signature) on an iPad.

5.1.3 **Avoiding Coercion and Undue Influence**

It is extremely important that participants do not feel coerced or subjected to undue influence to participate in this study. Research staff will strive to find a balance between being inviting towards participants, and respecting individual autonomy and each individual's right to decline.

5.1.4 **Confidentiality**

The confidentiality of research participants is critical to this study and will be respected at all times. Due to the sensitive nature of the topic of research, and because a breach of information could potentially harm study participants, study staff will make it clear from the start that patients' names will not be connected to any surveys, interviews, or audio-recordings, and that private information will be accessible only by study staff. Information pertaining to their clinical records will only be accessible to DOH staff, and will be stored in a separate secure dataset. We will collect first names, phone numbers, email addresses, and addresses only, in order to be able to communicate via text and mail gift certificates to participants. We will give participants the option of using a pseudonym.

Recruitment staff will not ask any personally identifiable information from participants except for first name, phone number, email address, address for mailing gift certificates and contact information for up to two personal contacts, in case study staff can't reach the participant. During the recruitment process this means that study staff will not ask for a participant's date of birth, or ask potential participants to sign any forms prior to completing the informed consent process.

This study has been issued a Certificate of Confidentiality from the NIH to protect identifiable information from disclosure. This will allow the investigator and others who have access to research records to refuse to disclose identifying information on research

participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state or local level. There is a clause in each consent form describing the Certificate to patient participants.

**If there is any breach of PHI either by the loss of documents or the audio recorders, the research coordinator and PI will be notified immediately so they can immediately contact the FDOH IRB.

6. PARTICIPANT PAYMENTS

6.1 Patient participant payments

Patient participants will receive a $20 gift certificate when they enroll and complete the baseline survey post-visit. They will also receive a $10 gift certificate upon completion of a follow-up survey at 3 months post enrollment by phone, email or SMS. The research staff will distribute and track all gift certificate disbursements in the database along with the date.

Additional compensation will be given to eligible patient participants who complete an in-depth qualitative interview ($40 in Aim 1 and $60 in Aim 2) and/or have their visit audio-recorded ($20).

Compensation will be given after clinic visits or interviews to improve retention throughout the visit when the majority of data collection occurs. Compensation has been increased for Aim 2 interviews to encourage completion of this study activity, and address no-show rates observed in Aim 1.

6.2 Provider / counselor participant appreciation

Due to Florida DOH policy, DOH staff are not able to accept gift cards or certificates. However, at staff meetings throughout the year, the study team will bring food to show appreciation to clinic providers and counselors.

7. DATA COLLECTION AND ANALYSIS

7.1 Outcomes of Interest

The primary outcome will be PrEP initiation within 3 months of the initial visit, as measured by PrEP prescriptions ascertained from chart review. Secondary outcomes include self-report of PrEP use at 3 months, as well as perceived HIV risk, knowledge of and interest in PrEP, decisional conflict, and interpersonal quality of HIV prevention care.

7.1.1 *Primary outcome*

- **PrEP prescriptions:** The number of participants who received a PrEP prescription and date of prescription, obtained by chart extraction from the medical record.

7.1.2 *Secondary outcomes*

- **Number of Patients Reporting PrEP use:** Participants will be contacted at follow-up and asked if took PrEP in the past 3 months regardless of where it was obtained.
- **Patient-Perceived HIV risk:** Participants will be asked about how worried they are about getting HIV in the next 6 months.
- **Knowledge of PrEP:** Participants will be asked a series of questions about PrEP to assess PrEP knowledge.
- **Decisional Conflict:** Participants will be asked questions derived from the Decisional Conflict Scale to provide a measure of decision quality about their HIV prevention decision immediately following their visit.
- **Interpersonal Quality of HIV Prevention Care:** A scale for patient-centered HIV prevention counseling focusing on patient preferences and reflecting satisfaction and confidence in the counseling session, derived from the Interpersonal Quality of Family Planning Care Scale developed by the PI.
- **Interpersonal Quality of Health Services (<u>Aim 2 only</u>):** A scale for patient-centered health services focusing on patient preferences and reflecting satisfaction and confidence in services offered, derived from the Interpersonal Quality of Family Planning Care Scale developed by the PI.
- **Intention to Use Any HIV Prevention Method:** Participants will be asked if they plan to use any HIV prevention method after the initial visit.
- **Satisfaction with Information Received about HIV Prevention:** Participants will be asked about their satisfaction with HIV prevention counseling.
- **Perceived Quality of Information Received about HIV Prevention:** Participants will also be asked questions about the perceived quality of the HIV prevention information they received during their health care visit.
- **Perceived Quality of Health Information Received (<u>Aim 2 only</u>):** Participants will be asked questions about the perceived quality of health information they received during their health care visit.
- **Acceptability of HIV Prevention Methods:** Participants will be asked to rate their preference for a method (even if they never used it). Participants can select from condoms, PrEP, PEP, treatment as prevention, regular partner testing, or other method.
- **Acceptability of the Decision Support Tool:** Participants in the experimental arm are asked four questions about their experiences using the DST.
- **HIV Prevention Method Continuation:** A self-reported measure of HIV prevention method continuation.
- **HIV Prevention Method Use:** A self-reported measure of HIV prevention method use, including those who reported discontinuing the initial HIV prevention method(s) that were reported post-clinic visit.

7.1.3 *Additional data to be obtained by chart extraction from the medical record at the end of the study*

Data extracted from the medical record will include participants':

- Zip code at the time of the study visit

- Insurance status at the time of the study visit
- PrEP prescription (ever) and date of prescription
- PEP prescription (ever) and date of prescription
- Dates of HIV testing and results*
- Hepatitis B and C diagnoses
- Dates of STI testing and results including chlamydia, gonorrhea, syphilis and trichomonas

**NOTE post study: In Aim 2, dates of HIV testing and results were not able to be collected from the EHR due to administrative changes at the Florida DOH that changed permissions to access HIV testing data in Aim 2.*

7.2 Sample Size

Aim 1

We plan to recruit up to 384 patient participants total and up to 35 provider participants. Of the 384 patient participants, up to 60 will participate in audio recordings and 40 will participate in an in-depth interview.

Aim 2

We plan to recruit 366 patient participants total and up to 35 provider participants. Of the 366 participants, approximately 80 will participate in audio recordings and 80 will participate in an in-depth interview.

7.3 Quantitative Data Collection

Data from surveys will be entered into REDCap by participants with the use of a tablet computer, and by research staff in real-time over the phone during follow-up.

After obtaining informed consent, research staff will explain and administer the pre-visit survey, which collects information on HIV prevention knowledge and interest, before the intervention participants use the decision support tool.

After the participant's visit with the provider, they will be asked to complete a post-visit survey about their clinic visit and counseling, risk perception, decision making, sexual history, and their experience with the decision support tool if they are in the intervention arm.

Three months post-visit, research staff will follow-up with participants by phone, email, or SMS to administer a short survey and ask participants about their chosen HIV prevention method, and if they initiated PrEP.

Upon completion of the study, research staff will extract data from the medical record pertaining to participants' PrEP prescriptions, history of sexually transmitted infections, zip code, and insurance status.

7.4 Qualitative Data Collection

Participants who are randomized and consented to participate in an in-depth interview will complete the interview directly after their clinic visit or within one week of the visit. Study staff will conduct all interviews. These individuals are all trained in qualitative research techniques, patient-centered counseling, and contraceptive counseling. All discussions will be conducted in a welcoming, culturally-sensitive manner.

Audio recording of all interviews will be transcribed for qualitative data analysis, and then the recordings will be destroyed.

Semi-structured interview

After the participant has completed their appointment and post-visit survey, the interviewer (a research staff member) will explain the process of the semi-structured interview. The interviewer will reiterate the confidentiality aspect and the right of the participant to ask questions or decline to answer specific questions, and ask for permission to begin recording.

Interviews will be conducted either in-person in a private space at the clinic, or over Zoom, a HIPAA-compliant video conferencing program. Zoom interviews can take place either at the clinic, or remotely at the participant's home or another private space outside of the clinic.

The interview consists of a series of open-ended questions about their experience using the decision support tool, HIV risk perception, screening and counseling about HIV prevention and PrEP, as well as perceived effects on the subsequent decision-making process about PrEP use and thoughts and perceptions about patient-provider communication about the social determinants of health and structural trauma/vulnerability. The interviewer will maintain a neutral and patient-centered tone and will ask probe questions to prompt more exploration of relevant topics.

Once the participant agrees to be audio-recorded, the interviewer will switch on the HIPAA-compliant digital recorder and begin the interview. Interviews over Zoom will be automatically recorded using a HIPAA-compliant system. The interviewer will remind the participant that the interview is being recorded at the beginning of the conversation. The audio recording will automatically be saved to the interviewer's desktop and the interviewer will immediately save the audio recording to a secure server and delete the audio recording from their desktop after it has been saved to the server.

Below are procedures for each type of interview:

- In-person interview:
  - Directly after appointment - If the qualitative researcher conducting the interviews is available and at the clinic that day, the participant will be offered an in-person interview to take place directly after their appointment.
  - Within one week of appointment- If the qualitative researcher conducting the interviews is available to meet in person at the clinic within one week of the appointment, the participant will be offered an opportunity to come back to the clinic to participate in an in-person interview. The RA will schedule a time for the participant to come

back to the clinic and will follow up over with the participant by phone to confirm the appointment.

- Video interview using Zoom at the clinic
  - Directly after appointment – If the qualitative interviewer is available, the participant will be offered an opportunity to have a video interview directly after their appointment. The RA will accompany the participant to a private room in the clinic where the interview will take place. The RA will help with setting up the interview and will be there to give the participant a gift certificate once the interview is finished.
  - Within one week of appointment – The participant will also be offered the opportunity to return to the clinic within one week of their appointment to participate in a video interview. The RA will schedule a time for the participant to come back to clinic and will follow up over with the participant by phone to confirm the appointment.
- Video interview using Zoom at home
  - Participants with internet at home, private servers, and computers or tablets with video cameras, can choose to participate in a video interview at home within one week of their appointment. Participants will be asked to have the interview in a private, quiet, and confidential space where they feel comfortable. The RA will schedule a time for the interview to take place. The RA will mail the participant a gift certificate after the interview has taken place.

8. DATA ENTRY

8.1 Entering Data

Survey data for each participant will be entered into REDCap in real-time, either in-person or over the phone.

Qualitative data attained from audio transcriptions will be imported into NVivo 10 software, or an alternative qualitative data analysis software package, for analysis.

8.2 Checking Data

Downloaded de-identified survey data will be exported to Excel and then to STATA for analysis. Tabs will be run in Stata to identify any errors in survey data. This will include the examination of descriptive statistics for plausibility (i.e. participant ages), distribution, and missing values.

8.3 Data Cleaning

<u>Quantitative data</u>

Quantitative data required for primary analyses will be cleaned and locked before primary analysis begins. The raw data will be saved in a separate directory to ensure that it will not be manipulated, saved over, or deleted (i.e. c:\data\raw_data). Any manipulated datasets, including cleaned data, will be saved with a new name in a separate directory (i.e. c:\data\cleaned).

Research staff will document any changes performed during the data cleaning process through comments or notes in the do-file. The goal is that a future team member who opens the do-file will be able to understand exactly what was done to the data and the purpose of each change. Comments will be inserted using an asterisk before text.

A codebook for quantitative data will be created, maintained, and updated throughout the data cleaning process. Any new variables, including dummy variables, will be documented with its type (string or numeric) and a description in plain language.

Missing values in the raw data set will be indicated by a variation of "888" or "999." These missing values will be recoded with either a period (".") for missing numeric variables or a blank space (" ") for character values. If a correction is verifiable through review of an individual's record, it will replaced with the correct value in the dataset and documented within the do-file. Any inconsistencies in data entry (i.e. Male, male, M, mael) will be cleaned using the *replace* or *generate* command.

Qualitative data

Qualitative data, captured through transcribed interview audio recordings, will be closely monitored for quality. A research staff member will examine transcriptions for sections the transcription service had identified as "unintelligible" (due to background noise, low audio quality). The staff member will listen to these audio recordings again to ensure all accessible data was captured. Any changes will be reviewed by another staff member.

9. DATA MANAGEMENT

Only personnel approved through the IRB will have access to study data. As much data as possible will be collected and stored electronically in order to minimize the number of pieces of paper containing PHI and the possibility for participant data to be lost or breached. Collecting data electronically also eliminates the possibility for study staff to make errors in data entry when transferring data from paper to electronic storage.

All paper files are kept in a locked file cabinets that are accessible only to the PI, Co-PI and study staff. Additionally, electronic files such as the interview recordings are kept on a secure server or encrypted laptop belonging to the PI or study staff and accessible only with passwords.

9.1 Data storage

9.1.1 Consent forms

Consent forms will be administered electronically via REDCap using iPads. REDCap Paper consent forms will be used as back-up in the event of technological difficulties. Paper consent forms will be stored in locked file cabinets in a locked office for three years after study completion.

9.1.2 Surveys

All patient surveys will be administered via REDCap using secure iPads. Paper surveys will only be used as back-up in the event of technological difficulties, and will be locked in HIPAA-compliant bags and entered into REDCap as soon as possible. Paper surveys will then be destroyed (i.e. shredded and disposed of at FDOH).

Survey data will then live in the secure UCSF REDCap database, to which UCSF and FDOH staff will have access. All user actions in REDCap are tracked by user and time (for example, editing or downloading data). Participant names and contact information will be marked as PHI and will not be downloadable. Only de-identified survey data will be able to be downloaded.

9.1.3 Contact information

Contact information will be entered directly into REDCap. Paper contact information will only be used as a back-up if technological issues occur in clinic. Paper contact information will be locked in HIPAA-compliant bags and entered into REDCap as soon as possible. Paper contact information will then be destroyed.

All contact information will be deleted 1 year after the last participant is contacted at her 3 month follow-up.

9.1.4 Audio recordings

All audio recordings of intervention sessions will be managed in accordance with Dr. Dehlendorf's standard operating procedures. This includes promptly transferring recordings off of the recording device and onto a secure server. All audio recording transfers to UCSF will occur by secure, encrypted file transfer using MoveIt (approved by FDOH).

9.2 Data transfer

All hard copies of PHI will be transferred directly in the care of a research staff member from their sites in a HIPAA approved bag to the main research office at FDOH, where they will be stored in a secure location.

Electronic data, namely audio files, will be transferred from audio recorders to a secure server as soon as possible and before more than 3 files are on any one recorder. Once transferred, audio files are immediately deleted from recorders. While being transported, recorders should be brought directly to the main research office and not be left in cars or any other possibly

vulnerable location. All audio recorders will require a passcode to unlock. (These protocols were formed based on security consultations from past studies with this PI involving audio recordings).

We will use MoveIt encryption software for all internet file transfers from FDOH to UCSF. For all file transfers, we will ensure that all passwords follow UCSF guidelines, including being a minimum of 7 characters and containing three of the four categories of characters (lower-case letters, upper-case letters, numbers, and symbols). We will ensure that all files are encrypted and securely transferred. We will communicate all passwords related to file transfers over the phone.

9.3 Security of files in use

All work will be done either directly on secure server or on an encrypted, institution-approved laptop in a private and secure setting.

10. DATA ANALYSIS

10.1 Methods of Quantitative Data Analysis

See Statistical Analysis Plan.