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Study Protocol

OFFICIAL TITLE: Developing a Dyadic (Partner-Based) Intervention for Sexually Transmitted Infections (STI)/HIV Prevention in Youth

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1. Abstract

Adolescents and young adults less than 25 years of age continue to have the highest rates of sexually transmitted infections [STIs] in the United States. While public health control programs have shown some success the disparities for this population remain. For this reason additional supports to increase engagement in care and reduction in acquisition of STIs as a part of establishing a healthy sexuality are needed. STI prevention work with adolescents has primarily targeted individual level factors and fails to address higher level factors such as peer, media, and relationship influences that may influence sexual decision-making and behavior. Partner notification and treatment is a key strategy for disease control within the population to improve the health and well-being of the individuals affected by the disease process and has previously been explored among adults for STI/HIV prevention work but has yet to be explored in adolescents and young adults. In our prior research, we demonstrated that adolescent girls with complicated sexually transmitted infections are highly likely to notify their partners for treatment (88-92%), but that only those who experience brief behavioral interventions are 3 times more likely to be successful in arranging for partner treatment than girls receiving standard of care. There has been a failure to use our knowledge about the structure and function of romantic relationships occurring during critical developmental learning periods, to engage youth for individual and dyadic behavior change. Partner interventions for STI prevention have significant promise for harnessing the power of relationship dynamics to enhance sexual decision-making, communication, and subsequent health behaviors. In the EXPERIENCE study, we propose to pilot an intervention designed to change STI outcomes by understanding partners and the learning environment related to sex. If successful, this pilot will support adoption of an alternative cost conscious, but effective strategy for engaging young men involved in sexual relationships affected by an STI diagnosis for both individual and relationship behavior change. Proving that heterosexual adolescents and young adults can consistently and safely engage their partners in a supportive outpatient setting that integrates treatment with evidence-based STI/HIV prevention interventions delivered by gender matched professional dyads.

During this COVID-19 pandemic, urban centers have been hard hit, but there has been little discussion regarding the impacts of sexual behavior and relationship interactions on the spread of COVID-19 within the community. The Women's BioHealth cohort presents a vulnerable group of adolescent and young adults (AYA) who may be able to provide insights on how COVID-19 stay at home orders have impacted sexual behaviors and overall risk for STIs. COVID-19 stay at home orders may complicate the social situations for some AYA in the greater Baltimore Metropolitan Area given the known disparities in health, poverty, housing, and violence. We would like to conduct follow-up outreach calls to the Tech2Check participants to include questions about impacts of COVID-19 stay at home orders on sexual risk-taking behaviors, access and unmet need for sexual and reproductive health (SRH) services. We include assessments of social support, perceived safety, and resources to evaluate the impact of those factors on SRH risks. We also determine need for re-engagement in care and willingness/ability to use telemedicine services to fulfill unmet health needs.

2. Objectives

1. To demonstrate the feasibility of the dyadic intervention for young urban dyads with a recent STI diagnosis as evidenced by recruitment and short-term retention [6 weeks].
2. To demonstrate acceptability of a dyadic intervention for STI/HIV prevention for urban young dyads with a recent STI diagnosis as evidenced by appointment attendance, visit completion, and satisfaction by those who complete the intervention.
3. To demonstrate the preliminary effectiveness of the intervention for increasing mutual sexual negotiation self-efficacy and self-reported communal coping at the end of the intervention visit and condom consistency at 6 weeks compared with dyads who receive *individual interventions* in a primary care setting to better operationalize the notion of transformational motivation in AYA dyads in the context of sexual relationships.
4. To improve our understanding of urban adolescent and young adult relationships in which a STI diagnosis has occurred and the extent to which partner dynamics and social context influence sexual health among urban partner-dyads affected by a STI diagnosis using in-depth interviews.

The focus of this pilot will be on completion of EXPERIENCE study visits, delivery of the intervention, patient satisfaction with the experience, and learning more about relationships and sexual health among young dyads that will inform any future iterations of the dyadic intervention.

To evaluate the impact of the COVID-19 stay-at home orders on TECH-N participants' SRH behaviors and risk for STI.

Hypothesis 1: AYA with a greater number of psychosocial risk factors across housing, food insecurity, income, and social support will have greater engagement in sexual risk-taking behaviors (e.g. non-condom use, non-use of contraception) during the COVID-19 stay at home order.
Hypothesis 2: AYA with reduced SRH risk-taking behaviors during the COVID-19 stay at home orders are more likely to engage in increased SRH risk-taking behaviors once the order has been lifted.

3. Background

Our team has conducted prior research that serves as a backdrop for dyadic research with adolescent and young adults and a strategy to reach males for treatment and preventive services. Our Gender-Based Differences Study utilized secondary data analysis from the Adolescent Health Study, a population-based telephone survey study in which urban adolescents from a high STI-prevalent community were queried about their sexual experience, fertility-related knowledge, beliefs related to timing of childbearing, and risk assessment of future fertility problems. Regression analyses indicated that female adolescents were more likely than male adolescents to identify chlamydia and pelvic inflammatory disease as causes of fertility problems. The most disturbing finding was that 72% of adolescent girls perceived significant risk for future fertility problems and almost 60% thought they had little or no control over it. We surmised that additional health education and motivation would be needed to increase adolescent participation in asymptomatic STI screening programs and the greatest challenge would be how to involve male adolescents given that fewer male adolescents understand the link between female fertility and common STI-related conditions despite their high value for partner fertility.

The Young Women's Health study (was a randomized controlled trial (RCT) funded by the Robert Wood Johnson Foundation that tested the effectiveness of a brief video intervention grounded in the health belief model to improve self-care behaviors associated with PID. The study was conducted at

two institutions with clinic and emergency department sites in Baltimore, Maryland covering census tracts most affected by STIs. The major finding from this work was that it demonstrated that the group viewing the video intervention prior to discharge [which included the treatment tag line "…. if he loves you, he'll do it right?" was significantly more likely to engage in secondary prevention through partner notification for treatment compared to the standard of care control group. Although there were no differences in the rates of partner notification, girls in the intervention arm were 3 times more likely to facilitate partner treatment. This work suggests that one of the most powerful elements of intervention after an STI is partner engagement.

Male Sexual and Reproductive Health Needs

Dr. Gaydos has conducted extensive research with young men demonstrating the impact of STIs on young men and has been intrinsically involved in 1) guiding diagnostic testing, screening, and prevention approaches for STIs 2) pushing the field by using internet ordered-self-testing and 3) evaluating new diagnostic tests for STIs to further improve public health outcomes for men. Dr. Trent conducted secondary analyses of data from the Adolescent Health study, a household study of urban adolescents 15-19 years in high STI prevalent communities in California, which demonstrated the high value of future fertility to youth across gender, but significant gender-based differences in STI knowledge as it related to infertility prevention. We identified the need at that time to involve male adolescents in STI prevention efforts given the high value they place on fertility preservation.

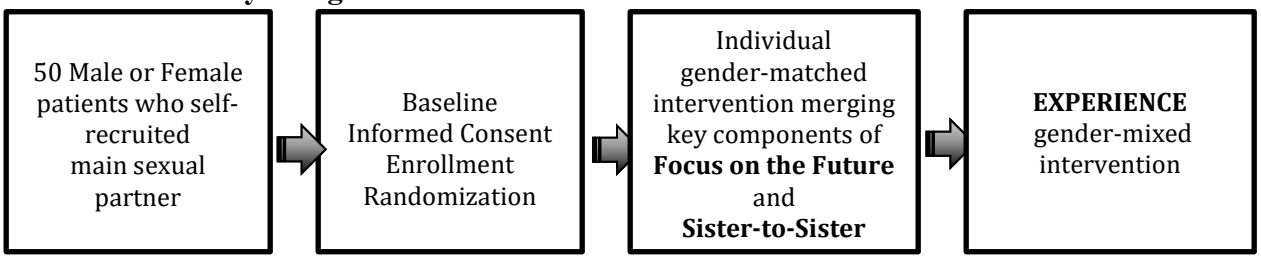
In a series of projects lead by our team, the evidence for investment in and guidance for male sexual and reproductive health (SRH) services has been established. As an example, an analysis of data from the National Survey on Family Growth demonstrated that adolescent males were significantly less likely than female youth to receive SRH counseling from their health providers In a more recent cross-sectional study of 16-35 year old males, 346 participants' willingness to talk about 11 SRH topics with their healthcare provider and their preferred approach (provider- or self-initiated) was examined. Almost all participants (84%–98%) were willing to talk about all SRH topics and the top three were STI risk (98%); testicular cancer (98%); and HPV vaccine (97%). The majority preferred that the health provider initiated discussions, demonstrating the potential openness to clinic-based conversations by health providers as a proactive strategy for prevention with males experiencing STI exposure and/or diagnosis. An earlier analysis demonstrated that this work could be performed in clinical settings primarily geared towards women. This suggests that seeking care in a non-gendered adolescent-centered practice as employed in our design may be equally or more conducive male engagement. Finally, a sexual health curriculum for SRH was developed for use in a Baltimore youth employment and training program in 2008–2010 involving 197, mostly African American males aged 16–24 years. Ninety-eight participants received three one-hour curriculum sessions on consecutive days; 99 served as controls. In analyses adjusting for baseline characteristics, intervention participants 3 months later were more likely than control males to report increases in knowledge of STIs and health care use (odds ratio, 1.6 for each), frequency of condom use (1.8), use of lubricant with condoms (23.6), communication with a provider about STIs (12.3) and STD testing (16.6). We will use the specific experiences in implementation of a male SRH intervention to incorporate and effectively engage the male partner as a part of the STI treatment visit.

The Perceived Risks for Sexually Transmitted Diseases (PRSTD) Study showed the importance of measuring risk perception in a partner specific manner, a second cohort was recruited and followed prospectively for three years to determine 1) age-related patterns of sexual behavior and STD acquisition among adolescents and young adults, 2) how an adolescents' relative power in a sexual relationship affects condom behavior, 3) the accuracy of adolescents' partner-specific PRSTD, and the concordance of childbearing plans among adolescent heterosexual dyads. Data was collected from 392 sexually experienced 14 - 19 year old males and females who were seeking care at either the Baltimore City Health Department STD clinic or the Johns Hopkins Adolescent Medicine Clinic.

Most recent main sex partners of a random selection of participants at baseline were recruited into the study resulting in data on 132 adolescent heterosexual dyads. This dyadic data has led to significant contributions to the literature, leading to a greater understanding of the poor agreement between adolescents' perception of their partner having other sex partners and partner-reported behavior, such that adolescents who presume that they are in a mutually monogamous relationship often underestimate their own sexually transmitted disease risk. Findings from the second cohort motivated recruitment of a third prospective cohort, which collected daily electronic diaries to examine how changes in intimacy and perceived partner concurrency impact STD risk perception, sexual behaviors, and STD acquisition over time within adolescent dating relationships. Data from this cohort has shown significant variability in adolescents' STI-associated feelings, perceptions, and behaviors within their sexual relationships and that this variability predicts behavior. Further findings demonstrate that adolescent relationships last for a long duration despite concurrency within the relationship. It is on this premise that we further build our case for intervention designed to reduce and improve the quality of the relationship with this vulnerable population of youth.

4. Study Procedures

Overview of Study Design



Setting: This research study will be conducted in Baltimore, Maryland. Maryland currently ranks 12th in the nation for incident infections with Neisseria gonorrhea (GC) and Chlamydia (CT) among its citizens and there are disproportionate rates of infection among individuals residing in Baltimore. The Maryland Department of Health and Mental Hygiene has determined that every county is a Chlamydia hotspot and county maps demonstrate that among hotspots, the city of Baltimore is the most densely affected. Although there are extremely low rates of youth non-insurance, the utilization of primary care providers for routine health maintenance drops off considerably. The Adolescent and Young Adult Clinic at Johns Hopkins established a Title X reproductive health clinic to serve the youth of Baltimore to aid in resolving the reproductive health access issues facing urban youth. The clinic sees over 200 unduplicated positive STI cases and partner referrals annually. Patients may also be referred for treatment through the Johns Hopkins Wellness Center, the Johns Hopkins Pediatrics Emergency Department, and/or the Baltimore City Health Department clinical sites.

Participants and Recruitment:
Fifty dyads will be recruited from Johns Hopkins primary and affiliated institutions in the greater Baltimore metropolitan area. Index participants engaged in heterosexual relationships will be asked to recruit their main partner for enrollment in the dyadic intervention pilot. The index participant and their partner will contact study staff to be scheduled for a research visit together. Our target is to have complete data on 40 dyads so we set sample size at 50 in order to account for attrition. However, we will stop recruiting when we reach 40 participants.

Enrollment, Consent, Randomization, and Treatment: Recruiters will be available via phone during office and some evening hours for the Title X clinical setting. Providers for study contact will refer patients. Patients who agree to be contacted will be approached by a recruiter in person-or via phone and if eligible, the dyad will be scheduled for written informed consent and intervention procedures. At enrollment, the research staff will perform a detailed review of the EXPERIENCE

study with informed consent. While the index patient and their partner are required to present together for study enrollment, they will each be consented separately. Participants will have the option to separately consent for 1) completing both the ACASI and dyadic intervention and 2) additionally completing an in-depth interview. All study protocol study forms will be faxed to the project director at the time of enrollment and online questionnaire/ interview will be automatically uploaded to a secure server for warehousing in a central database. After enrollment, participants will be assigned to the control (1) versus intervention (2) using a computer generated randomization assignment. Envelopes based on dyadic study group number will be available to the research staff at the time of enrollment to adhere to the randomization sequence.

Participants, Recruitment, Enrollment, and Consent for an In-Depth Interview Only:
Index participants that are screened and eligible for the EXPERIENCE study intervention, but cannot recruit a partner or are not interested in the dyadic intervention will be asked to participate in a one-time in depth interview about AYA sexual health. Consent for the in depth interview only will be a separate form. We expect to enroll up to 40 participants for the in depth interview.

STI Testing/Notification of Positive cases
All participants will be offered bacterial STI Testing through the Johns Hopkins Title X program and will be notified and treated for positive results by a team clinician who will assist with arranging treatment. Three attempts will be made to reach the patient using their preferred contact number. Patients who fail to respond after three attempts via phone and/or MyChart will be sent the standard certified letter indicating that they have laboratory results that require their attention. No detailed results will be sent via mail. Documentation of attempts to reach patient will be placed in the electronic medical record to facilitate follow-up by medical providers during future visits. Patients who contact the team at any later date while the study is active will be referred for care. By law, the Johns Hopkins Hospital laboratory and the research team have an obligation to report positive cases of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* to the Baltimore City Health Department (BCHD). Faxed reports will be sent to the health department.

Remuneration
Index patients and partners who complete treatment and the intervention will receive $50 remuneration for the EXPERIENCE pilot visit, $50 for the 6-8 week telephone or in-person follow-up interview, and $50 for participation in optional the in-depth interview. Bus tokens will be provided participants with transportation issues.

Participants who agree to participate for the 2 COVID-19 calls will receive a total of $50. After each completed call, a $25 gift card will be sent via mail.

Figure 1: The EXPERIENCE Study Recruitment Algorithm

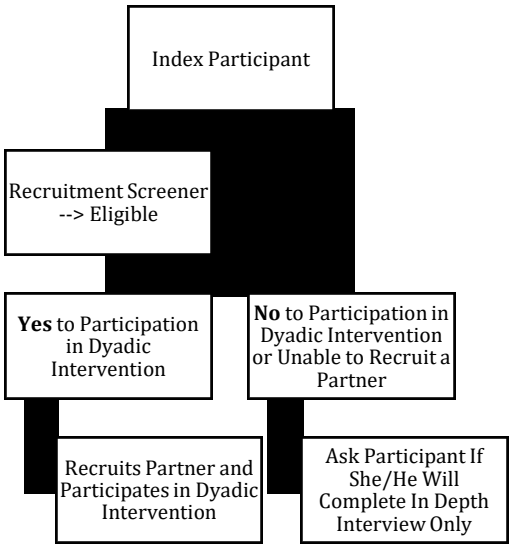
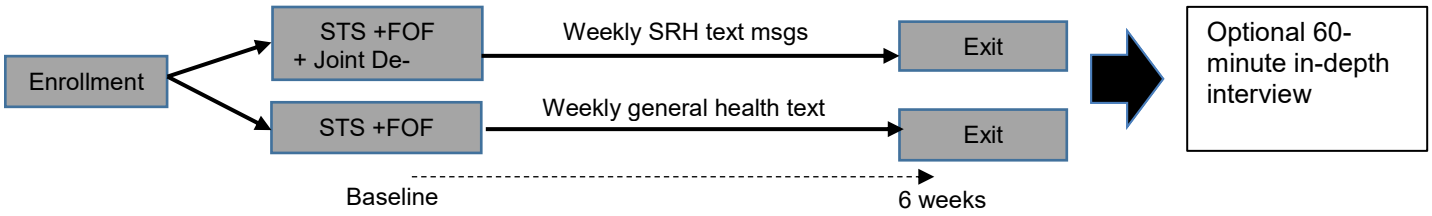


Figure .2: Overview of Study Procedures



Intervention

EXPERIENCE Intervention

The EXPERIENCE intervention is designed to utilize the STI partner treatment visit to engage young males and their female partners in treatment and risk reduction interventions. Integral to the EXPERIENCE intervention is use of two effective behavioral interventions designed to reduce STI/HIV risk behaviors. We will use the Focus on the Future [FOF] for male and Sister-to-Sister [STS] for female participants. Both have 20-minute one-on-one sessions with a gender-matched health educator to guide the patient through skills-based risk reduction counseling. These interventions have been evaluated with African American males and females residing in communities with high STI rates and were found to increase condom use, reduce unprotected intercourse, and reduce new STIs among participants and are considered effective interventions for clinical implementation by the Centers for Disease Control and Prevention. The novel part of this intervention is that sexual partners will come together at the end of the individual sessions for a joint debriefing session that includes viewing of the condom negotiation videos and role-playing communication for condom use. At the end of the session with the EXPERIENCE health educators, the patient will be able to state/demonstrate: 1) understanding of the definition of STIs 2) how to prevent future STI episodes; 3) proper use of male and female condoms, 4) use of effective communication and condom negotiation strategies with their partner. Low-resource patients in our practice have been receptive to health educator support and our preliminary studies indicate that improved communication between an adolescent and her partner occurs with the support of a professional who can educate and motivate adolescents with an STI, and provide expertise on STI management. We will record a subsample (N=20) of intervention sessions for quality assurance purposes. We will use video/audio recording of dyadic intervention sessions to ensure intervention delivery is consistent with the protocol and to identify content themes to bolster our understanding of relationship dynamics and the potential of communal coping.

We will provide text message boosters related to care-seeking behavior, condom use, and condom access, over the six weeks of the study. Messages will be standardized and delivered via an automated one-way system. These messages have well tested in the field with urban adolescents and young adults. No protected health information is disclosed as a part of this communication, but youth will be encouraged to provide an extra layer of protection on existing cell phone security to allow for an additional degree of privacy related to message content. We will send a welcome message right after enrollment "welcome to the EXPERIENCE study", followed by one text every week, including: "don't' forget to try out your new communication skills", "Did you practice the *Experience* role play? Text the # of times you practiced together", "Condoms prevent STDs. Stop by the clinic if you need some", "Condoms can improve pleasure, if you need some stop by the clinic", and "Want to up your game, practice your condom technique". In week six, we will send "Thanks for trying EXPERIENCE, we'll call you soon for feedback".

We will use SMS services through TextNow for communicating with participants in both arms of the study. TextNow is one of the fastest growing technology companies in North America and has created an all IP, cloud-based mobile phone carrier and mobile messaging and application service that has more than 8 million monthly active users. It is the hybridization of Wi-Fi with cellular for texting and calling and can be enabled for use on a phone, tablet, or computer that makes this platform optimal for our pilot study. Further, TextNow has strict policies to protect the user to prevent unauthorized disclosure of information and physical, electronic, and procedural safeguards are in place according to industry standard procedures and security procedures. Research staff will be responsible for monitoring and using the online account to send standardized text-message boosters to participants in the study. Since a telephone number is created with each account, the telephone number will be recognizable to participants as EXPERIENCE communication. Finally**,** all participants will be encouraged to use standard safety mechanisms such as a pin or password to lock access to their cell phones by others.

Control Group

Participant dyads in the control group will also receive the 20-minute Focus on the Future [FOF] for male and Sister-to-Sister [STS] for female participants one-on-one sessions with a gender-matched health educator to guide the patient through skills-based risk reduction counseling. As noted above, these interventions have been evaluated with African American males and females residing in communities with high STI rates and were found to increase condom use, reduce unprotected intercourse, and reduce new STIs among participants and are considered effective interventions for clinical implementation by the Centers for Disease Control and Prevention. **While they will check out of the intervention together and be given information to set up next steps, they will NOT engage in the facilitated dyadic group process that includes viewing the condom negotiation video, role-playing, and group debrief with the health educators.** Participants in the control arm will also receive positive health-related attention-control text messages focused on general health (healthy eating, exercise, spending time with family and friends, healthy sleep). No text messages related to relationships or condom use will be sent. As with the intervention group, we will send "Thanks for trying EXPERIENCE, we'll call you soon for feedback" in 6 weeks. None of texts will request a response.

<u>COVID-19 Procedures</u>

<u>Due to the COVID-19 pandemic, the remainder of participants will be recruited and enrolled virtually. We will be utilizing social media for recruitment and zoom to complete the enrollment visit. Recruiters will screen potential recruits over the phone and if eligible, set up a zoom meeting for enrollment. Participants will be consented with the oral consent script. The recruiters will read the baseline ACASI to the participants and record their answers. There will be separate zoom meeting for the individual gender-matched intervention and if the participants are randomized to the</u>

intervention group, they will join after for the joint-debrief session. The exit survey through Qualtrics will be read to the participants afterwards by the recruiters and record their answers.

Gift cards will be mailed to the participants after the enrollment visit has been completed.

The 6-8 follow-up survey will remain the same and be completed over the phone with the participant.

In-depth Interviews

For a subset of participants, we will conduct separate in-depth, semi-structured, face-to-face and/or via telephone interviews. Participants for the interview will either be 1) enrolled in the EXPERIENCE study intervention and agree to the additional and optional in depth interview or 2) agree to participate in an in depth interview only and not enrolled in the intervention. The interview will explore the social context, specifically social support; relationship qualities, modeling, and communication; and communal coping, that informs AYA partner-dyad's sexual health individually and at the partner level. For those participants that are enrolled in the intervention: the interview will occur 6-8 weeks after the dyad has completed the intervention. For those participants agreeing to an in depth interview only: the interview will be scheduled after written consent is completed. Participants will also be asked to complete a brief demographic questionnaire. We anticipate 40 individual interviews, but will continue sampling until we reach data saturation. The interviews for female and male partners will be conducted separately as to avoid any bias or influence of partner presence in given responses. An in-depth interview guide has been developed for the individual interviews. The semi-structured interview guide focuses on obtaining AYA perceptions of how social context informs sexual health. The concepts of sexual health that will be explored will include sexual experiences, partnering decisions, sexual communication, and prevention of STIs. The development of the interview guide will be an iterative process, which will allow additional questions to be added to the interview guide as necessary. Using the interview guide, the interviewer will ask open-ended questions and seek clarification or elaborations as necessary. All sessions will be audio-recorded and the interviewer will take written notes during and after each interview. During the interview, the interviewee will be asked to refer to themselves, partner(s), and/or other individuals only by an initial to protect confidentiality on recorded audio. Participants who complete the in-depth interview will receive $50 in remuneration.

COVID-19 Survey

We will conduct outreach regarding COVID-19 via phone. Questions will include basic information about living conditions, sexual behavior, relationship status, and SRH behaviors and healthcare needs since the stay-at-home order [March 16, 2019 (school closings)] through the present. We will interview individuals at baseline and three months from their designated call to determine if there is any change in behavior or circumstance [attached].

Quality Control

1. Treatment Fidelity: Drs. Trent and Dr. Marcell [with technical assistance [TA] for specific interventions] will train and supervise research staff to ensure protocol execution with dyads.

2. Recruitment Screener: Includes collection of basic demographic data and the outcome of recruitment effort so that we can keep an accurate account of referral patients who are ineligible and/or refuse to participate in the intervention. We include a standard question about (intimate partner violence) IPV in the screener to determine if this is a reason for refusal and/or influence the communication/behavior in the relationship over time. Participants who screen positively, will be provided with information and resources about IPV in the individual visit and referrals placed to the primary health provider for additional services.

3. Surveys: We have developed a survey to collect sexual and reproductive health history, perceived barriers to treatment, and self-efficacy data to be administered online during the study visit. This interview will be modified for this study, but will include: demographics, reproductive and sexual history (# partners, partner status (main versus casual), relationship status, coital frequency, prior STIs, condom use consistency, contraceptive use preferences for partner notification (e.g. female partner notification, case worker notification, email, text message), emotional response to diagnosis, access to medical care, access to technology (phone, internet, text), social provisions scale, and the short-form survey instrument (SF-12) as a measure of health-related quality of life, Fertility Knowledge and Awareness Scale, clinical symptoms, sensation seeking scale, relationship qualities scale and intimate disclosure scales to measure relationship quality and dyad communication, childbearing motivation, and communal coping. We will also query patients at the end of the intervention to determine their level of confidence for negotiating with their partner and their satisfaction with the experience. It is important to test these measures with participants and the timing of completion.

Participants will be contacted in 6-8 weeks for a brief (~30 min) telephone (or in-person) follow-up interview to assess sexual risk-taking behaviors, relationship status, social support, and satisfaction with the intervention experience.

5. Inclusion/Exclusion Criteria

Inclusion Criteria: The index patient must be 16-25 years, engage in male-female [heterosexual] intercourse, permanently reside in the Greater Baltimore Metropolitan Area (includes surrounding counties, i.e. Baltimore County, Anne Arundel, Howard County), willing to recruit their main sexual partner for the study, are willing to participate in a single individual session with a health educator followed by a joint debriefing session together with both health educators. The partner must be 16-30 years, engage in male-female [heterosexual] intercourse, , permanently reside in the Greater Baltimore Metropolitan Area (includes surrounding counties, i.e. Baltimore County, Anne Arundel, Howard County), willing to recruit their main sexual partner for the study, are willing to participate in a single individual session with a health educator followed by a joint debriefing session together with both health educators.

Exclusion Criteria: Index participants and partners who are unable to communicate with staff or participate in study procedures due to cognitive, mental, or language difficulties, will not be eligible for recruitment into the study. Dyads will also be excluded if in same-sex main partnership or a member of the dyad is currently enrolled in another sexual behavior study, the patient/partner is currently pregnant, one or both partners has a known concurrent HIV infection, one or more partners has a pending incarceration, there is more than five years age difference between the two partners, or there is evidence of intimate partner violence [IPV] in the relationship. Couples who are married, engaged or in a committed relationship greater than two years will be excluded. Individuals who screen positive for IPV will be referred to local resources for assistance. The Title X Clinic has adopted the RADAR screening approach with identified social work services in place for registered clinic patients who need further assessment and assistance.

6. Drugs/ Substances/ Devices

a. The rationale for choosing the drug and dose or for choosing the device to be used. **N/A**
b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed. **N/A**
c. Justification and safety information if non-FDA approved drugs without an IND will be administered. **N/A**

7. Study Statistics

a. Primary outcome variable. The primary outcome variable for this pilot study is feasibility of recruitment. Recruitment feasibility will be defined as the number of dyads completing the intervention out of number of eligible dyads. The feasibility of short-term retention will be calculated as the proportion of enrolled participants, who complete a follow-up interview at 6 weeks.
b. Secondary outcome variables. The secondary outcome variable for this pilot study is acceptability, measured as participant satisfaction with their intervention experience. Participant satisfaction will be measured using a brief survey asking participants to rate their experience and qualitative feedback documented.
c. Statistical plan including sample size justification and interim data analysis.
We will enroll a total of 50 adolescent dyads. While the choice of 50 dyads is inherently arbitrary, it is the number we feel we can realistically enroll within our limited time of this pilot study. While we won't have power to detect statistically significant differences, we will be able to examine correlations, which will be informative for future research proposals. To address each aim, we will evaluate our outcomes, feasibility and acceptability, against benchmarks from previous studies. To address aim 1, we will compare observed recruitment rates from the proposed pilot study to expected recruitment rates. Expected recruitment rates will be determined from previous studies that recruited adolescents with an STI diagnosis. Prior studies recruiting from the Adolescent Medicine Clinic have achieved recruitment rates ranging from 48to 91%. To address aim 2, we will use a similar approach, comparing satisfaction scores to an a priori benchmark of patient satisfaction. Based on previous work, average patient satisfaction greater than 80% would be necessary to conclude that the intervention is acceptable.

For the in-depth interviews, audiotapes and notes from the sessions will be transcribed verbatim and uploaded to NVivo 11, a qualitative data analysis software package. We will use constant comparative method of grounded theory to analyze the qualitative data. Using a 3-stage analytic coding strategy, the transcripts will be examined for salient categories (codes) through constant comparison between text within a single interview, within dyads, and between interviews. Axial coding will be completed to identify relationships between the codes. Finally, through selective coding the core category will be identified and a theory will be developed that integrates and explains relationships between axial codes. To ensure validity and qualitative rigor, we will use the following three strategies: audit trail with external review, deviant case analysis, and peer debriefing. Additionally, to ensure reliability in coding, two coders will independently code each transcript and through regular meetings will compare and discuss application of the codebook to each transcript until they reach consensus.

<u>COVID-19 Outreach Study</u>
<u>Descriptive and bivariate analyses will be performed to determine the general impact of COVID-19 risk on AYA in the sample and to evaluate the covariates such as change in living situation, cohabitation, stress, access to SRH services and COVID-fears on SRH behaviors.</u>
<u>Bivariate analyses generating p ≤0.1will be evaluated using logistic regression models, accounting for potential confounders or effect modifiers.</u>

8. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

There are no significant medical risks involved in this study. Sexual history interviews and collection of vaginal and urine specimens are a part of routine care. While the study will attempt to preserve patient confidentiality, there is potential for breaches of confidentiality, but miniscule

given the limited number of personnel with access to participant information. Disclosures by the partner to others are an ongoing risk dictated by public health practice given the CDC recommendations for partner notification and treatment. Non-enrolled patients will be given the option to notify partners anonymously for treatment and study participation using standard issue notification cards commonly employed through the health department. Finally, while the EXPERIENCE intervention focuses on positive communication and condom negotiation; dyad strife may develop during the context of the joint session. While health educator will be trained in basic conflict resolution; there are staff onsite to provide both mental health [social work; mental health counselors, psychologists] and seasoned security staff available to intervene as needed. We have previously followed AYA and their partners as a part of clinical practice and in research trials [clinic and community-based] without complaints of undue exposure, confidentiality breach, or adverse event such as physical or emotional harm to a patient, family member, and/or sexual partners who have presented for STI treatment. There have also been no complaints by patient, parents/guardians about AYA participation in the sexual health research studies. Further, this project was presented to the community advisory board (CAB) for the Harriet Lane Clinical Program (Home of the Adolescent Young Adult Practice) [Meeting December 18, 2014] and community youth and parents found the project highly relevant and were overwhelmingly support or this research strategy. Input on youth engagement and retention from CAB members has been incorporated alongside preliminary data and research expertise to optimize our approach and to minimize risk.

There are no additional risks associated with these telephone calls as this is in line with the work that we are currently doing in this study.

b. Steps taken to minimize the risks.

Human subject approval has been granted for beta testing of this research protocol by the Johns Hopkins institutional review (IRB00083609). As previously noted, all participants will provide informed consent and will be informed that their participation in the study will have no effect on subsequent medical care. All patient data will be kept confidential and secure. Individual patient data shared during health education sessions and clinical visits [sexual history data, lab results, clinical findings] will not be disclosed to the partner in accordance with HIPAA regulations, however, the patient will be encouraged to notify partners regarding behavioral risks that impact their partner per standard of care and public health practice. The research team on this project has training and experience in the protection of human research participants and the treatment of protected health information as evidence by completion of their institutional compliance courses that are reviewed every 3 years per Johns Hopkins Medicine faculty and staff requirements. New staff without prior training must complete human subjects training through the Johns Hopkins Committee on Clinical Investigation courses as a part of orientation training and as a condition of their employment.

Maryland state law permits an adolescent under 18 years old to consent to research when receiving reproductive care and most adolescents being seen in ambulatory sites at Johns Hopkins seek care unaccompanied by a parent, we will not require parental consent for participation in this study. The Johns Hopkins Institutional Review Board has approved this approach for the TECH-N, YWHS, PRSTD and other research studies described in the preliminary data section without experiencing adverse outcomes. Due to the longitudinal approach involved in this study and our data showing that they discuss sexual and reproductive health issues with mothers we encourage adolescents to keep parents informed about their general participation in the study. For the

purposes of this research, we are only recruiting patients 16 years or older given the range of patients seeking care and the primary age of consent in the state of Maryland.

While minors can consent to confidential counseling and treatment in the state of Maryland related to sexually transmitted infections, we will set the age of recruitment to **16 years** (the age of consent to sexual activity in the state of Maryland) as there is no close in age exemption in the state of Maryland. Further, the research team will comply with Maryland law and notify local or state authorities related to the mandated reporting of suspected abuse or neglect of a child or dependent adult for disclosures that occur in the course of communication with enrolled participants during counseling sessions. Additional language will be added to the consent form to ensure that potential participants are aware of this obligation set forth in Maryland law for their protection and a separate sign-off for this provision will be added to the consent form using a change in research addendum to ensure that participants understand the requirement and supports available to them should a report be made in the context of disclosures to research staff. All research staff will complete the required institutional human subjects training and additional study-specific training on this topic for effective communication with key contacts to facilitate notifications and referrals to mobilize support services for optimal outcomes. *http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/reporting_obligations.html*

Only members of our clinical care and evaluation team will have access to the patient chart and data extraction forms to document STI results. Involved personnel will be trained and committed to confidentiality and protection of patient rights and have received formal training through the institution. Additional training on delivery of the interventions and group debriefing will be provided to staff. No identifying patient data will be included in any of the presentations or publications that may be generated as a consequence of this study. Our analytic database will not contain any patient identifiers, as all participants will be assigned unique identifiers. Due to cost constraints, the study cannot have a dedicated data manager. The principal investigator will not access the database except download the collected data for use by contracted data analyst through the Institutional Center for Translational Research (ICTR) for interim analyses required to generate reports for data safety monitoring committee.

There is no added risk with the COVID-19 Survey. However, as with our other contacts with participants, they can be referred to the institutional resources for follow-up for health concerns raised during the call. The Adolescent Health/Young Adult Clinic has access to a range of additional services including social work and the Johns Hopkins Healthy Community Connections program which offers a range of support services including job placement, ride-share services, legal referral, and food pantry. Research staff who have additional questions related to where patients can receive services will contact core outreach staff, community health nursing staff, or the principal investigator for advice and support to facilitate referral. All referrals will be documented in the research record.

Data Safety Monitoring Plan: The study will employ a data safety-monitoring plan consistent with NIH guidelines. The research team will meet regularly to communicate about ethical issues related to the study. As a small randomized pilot trial, a data-safety and monitoring committee [DSMC] will be created. DSMC members will not have any formal association with the study and will be selected based on their expertise in AYA clinical interventions, SRH service delivery, and biostatistics. The following faculty members have been identified to serve in this role: Dr. Cynthia Rand (Professor of Pediatrics, Johns Hopkins Medicine), Dr. Sharon Ghazarian (Centers for

Disease Control and Prevention/Johns Hopkins Medicine), Dr. Peter Rowe (Professor of Pediatric, Johns Hopkins Medicine, and Dr. Lydia Shirer, MD, MPH (Adolescent Medicine, Harvard Medical School) The DSMC will develop a charter to govern DSMC activities and develop a communication plan with the research team. Annual data reports will be submitted to the DSMC for review prior to the annual continuing IRB review as a part of ongoing study and subject monitoring. Online tracking of patient data will be managed via the clinical research monitoring system (CRMS) and Biostatistical consultation and support will be obtained through the Johns Hopkins Biostatistics Center in conjunction with the Johns Hopkins Institute for Clinical and Translational Research. Dr. Trent has budgeted for and will submit a consultation request upon grant approval. Dr. Trent has effectively utilized this service for prior research. Use of this service for data analytic support will also allow for the study to remain single blinded to the principal investigator.

c. Plan for reporting unanticipated problems or study deviations.
Any unanticipated problems or adverse events will be reported to the IRB immediately. Deviations from the original study protocol will be requested through a change in research request.

d. Legal risks such as the risks that would be associated with breach of confidentiality.

There are no anticipated legal risks associated with study participation. We have been following girls in the community for many years and in their homes without consequence as we have put safeguards in place to protect confidentiality as outlined above.

e. Financial risks to the participants.

There are no anticipated financial risks to participations that are unaccounted for in the support and remuneration plan.

9. Benefits

There are no direct benefits to participants in this study. The proposed research is the first to measure the feasibility and acceptability of an intervention designed to change [STI] outcomes by understanding partners and the learning environment related to sex. If successful, this study will support adoption of an alternative cost conscious, but effective strategy for engaging dyads in their sexual health. Additionally, data gathered from the in-depth interviews will serve to inform any future iterations or interventions involving dyads. Partners may also receive free STI/HIV testing through the Title X program and treated accordingly, that they may not have sought without the infrastructure of the study.

10. Payment and Remuneration

Study incentives are: $50 for the intervention visit and $50 for the follow-up interview for each participant, both patient and partner. Those participants who elect to complete the in-depth interview will receive $50.

Participants who agree to participate for the 2 COVID-19 calls will receive a total of $50. After each completed call, a $25 gift card will be sent via mail.

11. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

There are no anticipated costs to participants that are unaccounted for in the support and remuneration plan for the study and/or usual care