Multi-level Intervention to Reduce Pregnancy Risk Among Adolescents: A Feasibility Trial in the Emergency Department

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PROTOCOL TITLE:

Multi-level Intervention to Reduce Pregnancy Risk Among Adolescents: A Feasibility Trial in the Emergency Department

PRINCIPAL INVESTIGATOR:

Melissa Miller, MD., MS-Cr, Associate Professor of Pediatrics
Department of Emergency Care
816-234-3665
mmiller@cmh.edu

CMH Co-Investigators:

Kathy Goggin, PhD
Vincent Staggs, PhD
Stephani Stancil, PhD

Other Co-Investigators:
Cynthia Mollen, MD (CHOP)
Elizabeth Miller MD, PhD (Pittsburgh)

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Version 8 April, 2022

REVISION HISTORY.

Revision #	Version Date	Summary of Changes	Consent Change?
1	11-3-20	Removal of Phase 1- Addition of APPs to study, consent updates, REDCap screening tools, and medication listed	yes
2	4-2-21	Allow the option is in-person or remote recruiting, allow pediatricians to participate as intervention providers, removal of employment time period criteria, update to wards of the state verbiage and inclusion/exclusion criteria	no
3	07-02-21	Removal of Provider Limit, updated verbiage for training payment for providers,	yes
4	12-06-21	Clarifying adolescent exclusion criteria to include teens on contraception for medical purposes.	no
5	01-17-22	Compensation updates: 1. Adolescents: Increase two gift card amounts: • Post-intervention/enrollment: $25 to $75 • 30 days: $30 to $50	Yes

		This would increase the total amount possible for teens in group 1 to $225 and those in group 2 to $195. 2. Study clinicians: Addition of gift cards: • Site 1: Provide training materials and $15 gift card to clinicians for participating in a short, self-paced session to cover additional counseling tips. This is in lieu of hosting in-person session where refreshments would be provided • Site 2: Provide $10 gift card to study clinician each time they deliver a study counseling session as gratitude for the extra time and effort to perform study-related tasks during the pandemic.	
6	04-08-22	Compensation Update: For both sites (CMH and CHOP), the providers who provide counseling will be offered a $25 gift card payment if they choose to participate in a "semi structured interview," about how their thoughts/comments about the feasibility study. This language has been added to the end of both the CMH and CHOP verbal consent for the providers. All providers who are currently on the study or who were at any point of the study will be notified of these changes, as we would love any feedback about the study, if they choose to complete the semi-structured interview. These providers will be notified either in person or via a Microsoft Teams meeting if needed (to accommodate their schedules).	Yes (For OPP verbal consent only)

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1.0 Study Summary

Study Title	Multi-level Intervention to Reduce Pregnancy Risk Among Adolescents: A Feasibility Trial in the Emergency Department
Study Design	Randomized Clinical Trial This project will involve human subjects in a clinical trial conducted at Children's Mercy (CM) and the Children's Hospital of Philadelphia (CHOP). We will train advanced practice practitioners to deliver the contraception intervention to adolescents and both practitioners and adolescents will complete surveys after the intervention. After recruitment for the intervention is completed, we will conduct interviews with key stakeholders at each institution. CM will be the primary site and CHOP will ultimately seek reliance on our IRB.
Primary Objective	Conduct a randomized clinical trial to evaluate intervention feasibility constructs: acceptability, demand, implementation, practicality, adaptation, integration, expansion, and limited-efficacy.
Secondary Objective(s)	NA
Research Intervention(s)/ Investigational Agent(s)	We will evaluate our novel approach to increase access to contraception comparing our multi-level intervention (MLI) to enhanced standard of care (eSOC). All adolescents receive the MI-enhanced counseling and clinic referral. Those randomized to MLI will be offered immediate, ED-based contraception (i.e., oral pill, transdermal patch, vaginal ring, injection, subdermal implant) in addition to receive a warm referral (provider helping to schedule follow-up appointment) to follow-up on selected method (or to initiate in clinic, if preferred). Per usual care, eSOC participants may obtain contraception only at the referral.
IND/IDE #	NA
Study Population	Adolescents: Females (assigned at birth) aged 15-18 years who report past/anticipated intercourse with a male, do not desire pregnancy, and are not using hormonal contraception/copper IUD. Personnel: Study providers including advanced practice practitioners (APPs) and pediatricians, adolescent medicine specialists, and nursing/administrative leaders.
Sample Size	Adolescents: 98 (49 CMH/49 CHOP) Personnel: study providers = 30 (15 CMH/15 CHOP); other organizational personnel (OOP) = 30 (15 CMH/15CHOP)

Study Duration for Individual Participants	Adolescents: 6 months Personnel: Study providers will participate for the duration of training and adolescent recruitment; other personnel are involved only once in the study (about 60-90 minutes).
Study Specific Abbreviations/ Definitions	MLI = multi-level intervention eSOC = enhanced standard of care IUD = intrauterine device ED = emergency department APP = advanced practice practitioner OOP = other organizational personnel EMR = electronic medical record CHOP=Children's Hospital of Philadelphia CM= Children's Mercy

2.0 Objectives

Evaluate intervention feasibility constructs: acceptability, demand implementation, practicality, adaptation, integration, expansion, and limited-efficacy. We will conduct a small randomized trial to assess feasibility and use mixed-methodology to explore contextual factors at the patient, provider, and system levels. In evaluating limited-efficacy, we compare two arms (MLI vs. eSOC) to determine size of effect rates on contraception initiation.

Hypothesis 1.1: The intervention will be deemed feasible by stakeholders: adolescents and organizational personnel (i.e., study providers, adolescent medicine specialists, hospital nursing and administrative leaders).

Hypothesis 1.2: Adolescents in the MLI arm will have greater contraception initiation rates relative to the eSOC arm at 30 days after the index ED visit.

3.0 Background

Unintended adolescent pregnancy is a major public health problem linked to pregnancy-induced hypertension, low birthweight, and prematurity.[1-2] In addition, adolescent pregnancies cost an estimated $9.4 billion annually.[3-4] Though declining, U.S. rates remain among the highest in the developed world.[5-7] Highly effective methods exist, but adolescents face unique, multi-level barriers to contraceptive access and use. [3-4] Thus, the vast majority of pregnancies are due to contraceptive non-use or incorrect use.[5] Many, especially minority and uninsured youth, do not attend health maintenance visits;[6] among those who do, 36 seconds is spent discussing sexuality and contraceptive use is not routinely assessed.[6] Multi-level interventions to increase access to contraceptive counseling and all contraceptive types are desperately needed.[7]

As adolescent access to affordable, confidential contraceptive care has worsened in recent years, one approach to increase access is to utilize non-traditional settings, such as Emergency Departments (EDs).[7] The Society for Academic Medicine recognizes the ED as an "effective site for preventive care," evidenced by organizational conferences, consensus statements, and specialized training opportunities to reduce disparities stemming from social determinants of health.[8-11] Adolescents make 19 million ED visits annually, commonly for non-urgent or reproductive complaints; for many, this may be their only contact with a provider.[12-14] Adolescents in the ED frequently report unprotected intercourse.[25,40] The pregnancy risk index (PRI), an estimate of pregnancy risk in the subsequent 12 months, for adolescent females in two EDs was more than three times greater than the national average.[15-16] Lacking a primary provider was associated with higher PRI scores. While the need for reproductive care is evident,[17,18] the majority of ED-based studies have focused on screening for sexually transmitted infections (STIs) including HIV[19-20] and a few, primarily single-site studies have reported on acceptability of hypothetical reproductive care.[21,22-26] Among the few addressing pregnancy prevention, most focused on emergency contraception or increasing clinic referral, with mixed results.[27,28-31] A small open trial provided counseling and clinic referral for those wanting to initiate contraception. Only 22% completed the referral and one was found to be pregnant at her first clinic visit.[32] Lack of transportation was the most common reason for not completing referral. Because interventions to address multi-level barriers and

increase contraception access are sorely needed, we aim to evaluate the feasibility of a novel ED-based intervention, utilizing a mixed methods approach.

Scientific Premise: Many adolescents in the ED are at high-risk of pregnancy yet accepting of reproductive intervention; however, no work describes best practices for ED-based contraceptive provision. Thus, we propose a randomized trial to evaluate MLI, which includes ED-based contraceptive initiation (i.e., oral pill, transdermal patch, vaginal ring, injection, or subdermal implant) vs. eSOC, for adolescents in two EDs utilizing medical providers in a collaborative care model. Thus, we use a rigorous framework from Bowen et al. to evaluate feasibility constructs (see Table 1 for construct definitions) among adolescents and organizational personnel (i.e., medical providers, adolescent medicine specialists, ED nursing and administrative leaders) in two unique EDs.[33]

4.0 Study Endpoints

The primary endpoint will be the determination of feasibility. Methods for establishing feasibility vary and include levels of acceptability, satisfaction, or usefulness. Drawing on similar published criteria, the intervention will be deemed feasible if the average score across all items is ≥ 3 on closed-ended survey items for adolescents, providers, and OOPs (Table 1).

Secondary endpoints will include the following:

- The completion of a referral for any contraceptive care as assessed through EMR review or follow-up phone calls.
- The initiation of contraception as assessed through EMR review or follow-up phone calls.
- Saturation of themes from qualitative interviews that have been coded and analyzed.

Hypotheses 1.1 and 1.2**:** To establish feasibility, we assess multiple constructs via survey items among all stakeholders (Table 1).

Hypotheses 1.2**:** We will determine referral completion and date for contraception initiation (Time 0) via participant contact and review of study/medical records at thirty days after the index visit.

Table 1: Mixed-Methodology Feasibility Assessment with Adolescent and Personnel Stakeholders

Construct	Source	Index Visit: Post-intervention	Time from Index Visit	Time from Initiation (Time 0)	
			30 Days*	3 mos*	6 mos*
Acceptability - How do stakeholders react to the intervention?	Adolescent	S	S	S	S
	Providers	S			SSI
	Other personnel				S, SSI
Demand - To what extent is the innovation likely to be used?	Providers				S, SSI
	Other personnel				S, SSI

	Study/Medical Record*				SMRR
Implementation - To what extent can the intervention be implemented as planned (including intervention fidelity)?	Providers	S			SSI
	Other personnel				S, SSI
	Study/Medical Record*	SMRR	SMRR		
Practicality - What factors make intervention delivery challenging or facilitate delivery?	Providers	S			S, SSI
	Other personnel				S, SSI
	Study/Medical Record*				SMRR
Adaptation – How does model perform in new setting?	Providers				SSI
	Study/Medical Record*				SMRR
Integration - To what extent can model be integrated within the system?	Providers				S, SSI
	Other personnel				S, SSI
Expansion - To what extent can model be expanded to provide service?	Providers				S, SSI
	Other personnel				S, SSI
	Study/Medical Record*				SMRR
Limited efficacy testing - What are rates of contraception initiation/continuation and referral completion?	Adolescent		S	S	S
	Study/Medical Record*	SMRR			SMRR

Legend: S=Survey, SSI= Semi-Structured Interview, SMRR= Study/Medical Record Review *=+/- 10 days
*Additional assessments include proportion enrolled, drug interaction or contraindications, intervention fidelity and duration, length of stay (participants vs. non-participants), rates of contraception initiation/continuation/referral completion, cost estimates

Data Sources: Sources include: surveys (via Research Electronic Data Capture – REDCap), semi-structured interviews, medical records, and study records (i.e., recruitment logs, interview transcripts, Providers/investigator field notes) (Table 1)

5.0 Study Intervention/Investigational Agent

5.1 The study intervention is the implementation of Emergency Department-based contraceptive counseling. A provider will provide this confidential, comprehensive, 10-15-minute counseling. The counseling will assess patients' preferences regarding different methods, knowledge about methods, personal motivations, and environmental factors that may influence contraceptive use, such as partner preference. After counseling is complete, enrolled subjects that have been randomized into the MLI group will have the opportunity to accept birth control and a referral for follow-up care.

For Emergency Contraception

Plan B (also called levonorgestrel) is taken by mouth by a woman to prevent pregnancy after she has already had unprotected sex. It is available over-the-counter for any person to buy. Plan B has no serious or lasting side-effects and leaves the body within a few days. Some women (fewer than one in five) have mild and short-term side-effects, including irregular bleeding from the vagina, belly pain, being tired, nausea (feeling like you might throw up).

For hormonal contraception

Many formulations of hormonal contraception exist including those with estrogen and progesterone combined (e.g., Sprintec, Ortho-Evra, Yaz). The most common side effects from combination hormonal contraception are mild and include: irregular vaginal bleeding, breast tenderness, nausea, and mood changes. Serious adverse events may occur. Older women who smoke are at increased risk of myocardial infarction or stroke. There is no increased risk of myocardial infarction or stroke among healthy nonsmoking women who use the pill. Blood clots in the legs and elsewhere are slightly more frequent with contraceptive use, but the risk is very low, and lower than the increased risk of clotting that occurs with pregnancy. There is no increased risk of birth defects in babies born to women who have taken hormonal contraception while pregnant, but a woman should not use hormonal contraception if she is pregnant.

Medroxyprogesterone acetate: The most common side effects from DMPA are mild and include: irregular menstrual cycles, cessation of menstrual periods, headache, and weight gain. Serious adverse events may occur. Use of DMPA may cause loss of bone mineral density, which may lead to an increased risk of developing osteoporosis. The decrease in bone calcium is most concerning if the patient has bone disease, family history of osteoporosis, or anorexia nervosa. Older women who smoke are at increased risk of myocardial infarction or stroke. There is no increased risk of myocardial infarction or stroke among healthy nonsmoking women who use the pill. Blood clots in the legs and elsewhere are slightly more frequent with contraceptives, but the risk is very low, and lower than the increased risk of clotting that occurs with pregnancy. There is no increased risk of birth defects in babies born to women who have taken hormonal contraception while pregnant, but a woman should not use hormonal contraception if she is pregnant.

Ortho Evra and Xulane (Norelgestromin/ethinyl estradiol) is birth control patch that works by stopping ovulation. It may also change cervical mucus to prevent the sperm from reaching the egg and change the lining of the uterus to prevent a fertilized egg from implanting in the uterus. Side effects can include: breast tenderness or enlargement; headache; menstrual cramps; mild fluid retention or weight gain; mild skin irritation at the application site; nausea; stomach pain, cramps, or bloating; vaginal spotting or breakthrough bleeding; vomiting.

NuvaRing (ethinyl estradiol and etonogestrel) is a birth control vaginal ring that contains female hormones that stop ovulation (the release of an egg from an ovary). This medicine also causes changes in the cervical mucus and uterine lining, making it harder for sperm to reach the uterus and harder for a fertilized egg to attach to the uterus. Side effects may include: headache; vaginal irritation or discharge, cervical pain; menstrual cramps; mood changes, decreased sex drive; nausea, vomiting, stomach pain; breast pain or tenderness; acne; or weight gain.

The most common side effects from subdermal implants include changes in menstrual bleeding patterns; headaches; vaginitis; weight gain; acne; breast pain; viral infection such as sore throats or flu-like symptoms; stomach pain; painful periods; mood swings, nervousness, or depressed mood; back pain; nausea; dizziness; pain and pain at the site of insertion.

For Non-Hormonal Contraception

Common side effects for non-hormonal contraception (Copper IUD, Phexxi) include irritation, dryness and/or allergic reactions.

Risk of emotional distress: Participants may experience increased stress over the sensitive survey questions. However, we feel this risk is minimal and we have included information in the consent process that reminds participants that they are not required to answer questions that make them feel uncomfortable. In the emergency department, there are always advocates available for patients and families, if needed, including health care providers, social workers, and patient advocates. In this study setting, if a participant expresses a concern or need that is outside of the scope of this project (e.g., sexual assault), we will refer those participants back to their ED treating team, as is our standard practice. During the consent process, we will inform participants that most of the information they share during the study will be kept confidential except in rare cases where their safety is at risk or mandated reporting is in effect

5.2 To decrease risk of serious adverse events, we will follow regulations and recommendations in accordance with the Food and Drug Administration. We will prescribe the dosage regimen which contains the least amount of estrogen and progesterone that is compatible with a low failure rate and the needs of the individual patient. We will screen participants for predisposing conditions and duration of previous DMPA use. Women with these conditions should not use hormonal contraceptives: women with stroke or blood clot, circulation problems (especially if caused by diabetes), a hormone-related cancer such as breast or uterine cancer, abnormal vaginal bleeding, liver disease or liver cancer, severe high blood pressure, migraine headaches, or a heart valve disorder. Further, DMPA should not be used as a long-term method (i.e., longer than 2 years) unless other methods are considered inadequate.

5.3 Participants will be advised of all potential adverse events and instructed to seek care if symptoms develop or they have concern about such an event. In the case of illness or injury resulting from this study, treatment is available at CM or CHOP, and can be provided at the usual charge. Participants may also see care at the hospital-affiliated Title X Clinic, which provides reproductive care at reduced cost.

6.0 Procedures Involved

We propose a randomized trial of our contraceptive counseling intervention (MLI vs. eSOC) with mixed methods feasibility evaluation at patient, provider, and system levels. Feasibility constructs are: acceptability, demand, implementation, practicality, adaptation, integration, expansion, and limited-efficacy.

Using an electronic board that tracks patient data in real time, the research study staff will identify and enroll adolescent participants (N=98) before they meet with a provider. Due to possible COVID precautions, research staff will have the capability of recruiting patients remotely. Consenting and the study visit will take place on the same day of enrollment during the patients ED visit. If necessary, a member of the research team may call into the patient room via Microsoft Teams or CMH office phones to contact the patient up to five times. Follow up surveys at thirty-days, three months, and six months are administered via REDCap and may be sent through Twilio or e-mail. Members of the research team may also call participants up to five times to administer the surveys verbally using either Microsoft Teams or CMH phones.

We will use a care model demonstrated as best practice in clinic-based settings[36] and train providers using adapted materials publicly available (e.g., slide decks, written materials).[37-40] Adaptations are needed for vulnerable adolescent populations that are mindful of coercion and will include use of brief Motivational Interviewing (MI) strategies to facilitate autonomy and focus on patient preference. MI training for providers will focus on these skills: open questions, reflective listening, and pulling for change talk.[41-45] Providers will receive nine hours of training (e.g., prescribing, adolescent-centered counseling, technology) and demonstrate competency (mean fidelity score ≥3, appendix 1) prior to continued recruitment.

As adolescents mature along different trajectories, we plan open-ended questions to ask about intention, experiences (self/referents), and contraceptive qualities. Given that many in our ED reported relationship abuse, we will use a trauma-informed approach (i.e., realize, recognize, respond, resist re-traumatization) to foster collaboration, explore safety, and offer harm reduction strategies.[48-49] We will help participants 1) map information onto values and lifestyle, and 2) anticipate and solve problems, including identification of a trusted adult. We will address risk misperceptions use visual aids, and counsel dual protection with condoms. Based on our work and others, providers will provide 10-15 minutes for counseling; this is easily integrated into most ED visits. Counseling sessions will occur after patients have completed triaging, without interrupting the evaluation of standard of care services.

Providers will also have access to educational material, which can be distributed to adolescents randomized in MLI arm. These documents include the following: FDA Approved factsheets (Ring, Pill, Patch, Mini Pill, Progestin IUD, Implant, Non-Hormonal Gel, Emergency Contraception, and Depo), Switching Birth

Control, IUD Facts, Implant Facts, Contraception Choices, and CMH Clinic Hours and Locations. The contraception handouts that are being provided will help to provide further clarifications regarding medication effectiveness, adherence instructions, as well as medication side effects.

C6eii. Adolescent Randomization and Treatment: Randomization will be in a 1:1 ratio. Due to potential influence of previous contraception use on uptake, we will use block randomization with randomly selected blocks of 4 or 8 to balance allocation of those with previous use equally between arms.[48] Dr. Staggs will create the master randomization list for both Children's Mercy and Children's Hospital of Philadelphia, placing each assignment in a sealed envelope numbered sequentially from 001.[54] Participant IDs will be assigned beginning with 001. After consent, a research assistant will open the corresponding envelope to carry out the arm assignment, notifying the providers before counseling is completed.

All participants receive contraceptive counseling. Per evidence-based guidelines,[52-53] MLI participants can receive contraception (one injection, three-month supply of pill/patch/ring, or subdermal implant) in the ED, or prescription for another method if desired. If a patient in this group desires another method that is not being covered by the study, patient will be made aware of their responsibility to cover the cost of the medication either out of pocket, or by using their own insurance. Due to credentialing and staffing constraints, intrauterine devices will only be available at referral clinics. MLI participants who want to initiate contraception must complete a urine pregnancy test, which must be negative. MLI participants who initiate contraception will be given a take home pregnancy test that is to be completed two weeks after enrollment. eSOC participants will have the opportunity of being referred to a follow-up appointment to discuss and begin contraception. Subjects in this group will not begin contraception in the Emergency Department or given a prescription. All participants will be referred to an adolescent gynecologist, hospital-affiliated adolescent clinic, or Title X clinic for additional care and to initiate or follow-up on contraception.

MLI participants will have a "warm transfer" to follow-up on or initiate, if preferred, selected method. Warm transfers occur with the assistance of a provider scheduling the follow-up appointment. Doing this in such a way should help to minimize barriers with navigating the healthcare system. The provider will share detailed clinic information including hours of operation and contact the receiving site. We will assist with scheduling (sending multiple reminders) and transportation. eSOC participants will be given printed information on clinics.

C6eiii. Intervention Fidelity: Counseling sessions will be audio-recorded and reviewed periodically to ensure for fidelity to content and use of MI strategies using a tool adapted from our previous work and the CHOICE Project, a clinic-based intervention efficacious for increasing contraception uptake in family-planning clinics.[54-55] We will provide feedback to individual APPs if mean fidelity score ≤ 3.

6.1

Prior to adolescent patients being enrolled, providers will be enrolled to participate in the study. Providers will be trained on motivational interviewing practices, contraception methods, as well as medication ordering practices.

Research team staff will screen potential study candidates via electronic tracking board. The research team will approach patients to ensure that they meet qualifications for the study. If qualifications are meet, the research team will provide consent/assent to the patient, conduct a pre-counseling survey, then notify a study provider of study status. Once the subject has been enrolled, the study provider will provide contraception counseling, while incorporating motivational interviewing techniques. Counseling sessions will be audio recorded and analyzed periodically for fidelity. At the completion of counseling, the study provider will offer the participant various contraception options and incorporate warm-referral practices to encourage follow-up at a local health clinic. The subject and provider will complete the Adolescent Post-Counseling Survey via REDCap at the end of their initial enrollment .

Immediately after the initial enrollment and at thirty-days post intervention, the research team staff will conduct a medical chart review. At thirty days, three months and six months post-intervention, a follow-up survey will be sent to the participant. OOP and provider staff will participate in semi-structured interviews that can be completed either in-person, virtually, or via telephone at 6-months to evaluate the feasibility of the study.

6.2

To help ensure the safety and validity of this study, we will ensure that provider staff are properly trained prior to enrollment. Training sessions will cover interviewing techniques, contraception, and ordering practices.

Members of the study team will also review audio recordings periodically for intervention fidelity.

6.3

Prior to approaching an adolescent participant, research team members will view the medical chart to ensure eligibility. Team members will look for the following, date of birth, custody status, and current contraception usage. In the post-intervention medical chart review, team members will look to see if a follow-up visit had been completed, and it so, if any services were obtained.

Surveys from adolescent participants will assess attitudes towards contraception, pregnancy prevention methods, perceived risk of contraception, and barriers to follow-up care.

6.4

Enrolled adolescents will receive follow-up surveys at 30-days, 3-months, and 6-months after their initial enrollment at their ED visit. The questions asked will assess subjects' attitudes towards contraception methods, access to care, and contraception efficacy. Enrolled patients may complete the survey over the phone with a member of the research team. A link may also be sent via text messaging using Twilio or other approved messaging system or to their email address.

7.0 Data and Specimen Banking

No data or specimens will be retained or banked used for future use.

8.0 Genetic Analysis Information NA

9.0 Sharing of Results with Subjects NA

10.0 Study Timelines

Timeline

	Year 1				**Year 2**			
Prepare study materials	X							
Provide all Provider training and booster		X		X				
Recruit adolescents			X	X	X			
Complete adolescent follow-up (electronic medical record/surveys)				X	X	X	X	
Conduct semi-structured interviews					X	X		
Perform data analysis and write manuscripts					X	X	X	X

We will conduct training for our study providers. We anticipate that adolescent recruitment will begin around month 6. We anticipate reaching our enrollment goals within 6 months, as described in the recruitment plan. We plan for adolescent follow-up into year 2. Semi-structured interviews will begin after all adolescents have been enrolled and qualitative data analysis begins as soon as the first interviews are completed.

Duration of individual subject's participation
Adolescents: 6 months
Personnel: Study providers will participate for the duration of training and adolescent recruitment; other personnel are involved only once in the study (about 60-90 minutes).

11.0 Inclusion and Exclusion Criteria

Study APPs

Inclusion Criteria

1. Work in the Emergency Department
2. Are interested in participating in study procedures

Exclusion Criteria

1. Because they often lack organizational familiarity and may be temporarily working in the ED, providers in training will be excluded.
2. AP provider who were otherwise eligible, but have declined to participate in training activities.

Adolescents

Inclusion Criteria

1. Females aged 15-18 years who are at risk of pregnancy, defined as those who 1) report previous sexual activity or intent to be sexually active with a male partner in the next few months, 2) do not desire pregnancy within the next year, and 3) are not currently using hormonal contraception or copper IUD.

2. Eligible individuals must be comfortable speaking in English

Exclusion Criteria

1. Females who are currently using hormonal contraception or the copper intrauterine device
2. Females who report current pregnancy or have positive urine pregnancy test
3. Patient has a developmental delay limiting participation
4. Patients is presenting in the ED after sexual assault
5. Patient is too ill to be screened
6. Minor adolescent who is ward of the state is eligible to enroll for the study but may not be eligible for Nexplanon insertion (if desired) unless proper parental or legal guardian permission is obtained (Nexplanon insertion is not available without parental or legal guardian permission due to hospital guidelines. Without the proper consent, wards of the state may opt for another form of contraception)
7. Patients who receive contraceptive medications as part of their Emergency Department clinical care (e.g., treatment for heavy menses).

Other Organizational Personnel

Inclusion Criteria

1. Employed at CM or CHOP with experience or expertise in hospital administration, adolescent medicine, or clinical care

2. Are interested in participating in study procedures

Exclusion Criteria

1 . Provider/staff who were otherwise eligible, but have declined to participate in training activities.

12.0 Vulnerable Populations

We will make it clear during the Provider consent process that participation is entirely voluntary. The decision to participate or not will not affect their current or future relationship with CM or CHOP. If a provider decides to participate, they may withdraw from the study at any time without affecting their employment status. They may skip any questions they do not feel comfortable answering. Drs. Miller and Mollen have established relationships with ED Providers and have collaborated on similar projects in the past.

To participate in this research study, adolescent participants must be between the ages of 15-18 years of age. Local state contraception laws enables adolescents to have capabilities to make decisions regarding their own contraception care. Because of this, the research team is requesting a waiver of parental permission in order to help maintain confidentiality for patients. Adolescents will be provided as much time as they want to make their decision.

13.0 Local Number of Subjects

13.1 There will be up to 98 total adolescent participants we expect to enroll between each site. 49 subject participants will enroll from CM and CHOP.

Up to 30 other professional participants will be eligible to enroll in the study.

13.2 Screening for adolescent participants will take place via electronic tracking board. Using that, study staff will have the capability of selecting viable subjects who meets the qualifications of the study. Once approached, potential subjects have the option of refusing to continue participation in the study.

14.0 Screening and Recruitment Methods

Adolescent subjects will be recruited from the Emergency Departments of Children's Mercy Adele Hall and Children's Hospital of Philadelphia Emergency Departments. Research staff will evaluate for potential patients via electronic tracking boards. Recruitment for adolescent subjects will take place while patients are within the Emergency Department. Once a subject is deemed potential eligible, research staff will approach a patient to ensure eligibility, provide informed consent, and continue with study procedures. Patients will be approached after they have become admitted in the Emergency Department from triage. Parents and patients will be told basic information regarding research at Children's Mercy, and parents will be asked to step out of the room

to further discuss details of the study. If any parent refuses to step out of the room, the research team will not be allowed to continue in their recruitment efforts for that patient. Once a patient decides that they would like to continue with screening for the study, they can also decide if they would like to have their parent to participate in the study. If a patient refuses to participate, basic demographics including age and race as well as their reasoning for refusal will be tracked in the REDCap Refusal survey. The research team will also track the participant and language preference. Understanding this information will generate a better understanding a patient needs for future research studies. This information will be used for data analysis purposes.

Study providers and OOP will be recruited via word of mouth, email, workplace OOP Recruitment e-mail and flyer.

A screening log will be used to maintain records for screening and eligibility purposes. The screening log will maintain minimal PHI such as the patients age.

Adolescent subjects will be approached once for recruitment.

Study providers and other personnel may receive more than one communication about study participation as we will use email and workplace announcements and postings to facilitate recruitment.

We are requesting a Waiver of HIPAA Authorization based on the following:

1) Description of the PHI for which use or access is necessary for recruitment: see PHI chart below

2) The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals based upon the following:

   a. Plan to protect PHI from improper use and disclosure: All PHI will be accessible by the study team. All storage units will be password protected (Cerner and REDCap) and devices will be stored in locked cabinets within the research team office.

   b. Plan to destroy PHI at the earliest opportunity, unless there is a health or research justification for retaining the PHI: Study related PHI will be maintained throughout the completion of enrollment and data analysis. Information will later be kept and destroyed in accordance with Children's Mercy records retention requirements.

   c. Assurance that PHI will not be reused or disclosed to any other person or entity: PHI will only be accessed by study team personnel and Good Clinical Practice guidelines will be followed in order to ensure that information will not be disclosed to unauthorized persons.

3) Reason why the research cannot practicably be conducted without the waiver:

   Without the waiver, obtaining parental consent compromises validity of responses from subjects, as well as patient rights to privacy regarding reproductive health services.

4) Reason why the research cannot practicably be conducted without access to and use of the PHI: This study requires the research team to notate and access qualifying information such as age, personal health information, and date of birth.

*PHI chart:

1. Name/Initials	☐ Accessed only	☒ Recorded
2. *All* elements of date (except year) directly related to an individual (e.g., date of birth, admission date, discharge date, date of death)	☐ Accessed only	☒ Recorded
3. Medical record number	☐ Accessed only	☒ Recorded
4. Account number	☐ Accessed only	☒ Recorded
5. Health plan identification number	☒ Accessed only	☐ Recorded
6. Social Security Number	☐ Accessed only	☐ Recorded
7. Device identifiers and serial number	☐ Accessed only	☐ Recorded
8. Certificate/License number	☐ Accessed only	☐ Recorded
9. Telephone number	☐ Accessed only	☒ Recorded
10. Fax number	☐ Accessed only	☐ Recorded
11. Email addresses	☐ Accessed only	☒ Recorded
12. Web addresses (URLs); Internet IP addresses	☐ Accessed only	☐ Recorded
13. Street address, city, county, precinct, zip code or equivalent geographical codes	☐ Accessed only	☒ Recorded
14. Full face photographic images and any comparable images	☐ Accessed only	☐ Recorded
15. Biometric identifiers, including finger and voice print	☐ Accessed only	☐ Recorded
16. Vehicle identifiers and serial numbers, including license plate number	☐ Accessed only	☐ Recorded
17. Any other unique identifying number, characteristic or code that may help identify individual participants including their initials (e.g., student or employee ID number)	☐ Accessed only	☐ Recorded
18. Elements of date, including year, for persons 90 years or older	☐ Accessed only	☐ Recorded

We will be collecting minimal PHI for data collection purposes. This information will be recorded on a screening log and submitted in REDCap at the end of the screening day. REDCap will be used to collect all identifiable information and only accessible to members of the research team. The screening logs will be locked in a secured location only accessible by the research team and destroyed at the end of the study.

Without the waiver, parents/guardians may have access to confidential information with may compromise the integrity of the study. Requesting this, will provide the opportunity to proceed with study procedures, while remaining HIPPA compliant.

15.0 Reimbursement, Payment and Tangible Property provided to subjects

Study providers will be compensated their normal hourly rate for completing study related training activities. A one time electronic gift card of $15.00 would be given to CMH clinicians for participating in a short, self-paced session to cover additional counseling tips. Clinicians at CHOP will be provided a $10 gift card each time they deliver a study counseling session for their effort to perform study specific tasks during the pandemic. Compensation for participation will be considered taxable income. OOPs will not be compensated. For both sites (CMH and CHOP), the providers who provide counseling will be offered a $25 gift card payment if they choose to participate in a "semi structured interview," about how their thoughts/comments about the feasibility study. This language has been added to the end of both the CMH and CHOP verbal consent for the providers.

	Study related training activities	Additional Gift Card
Site 1: CMH Clinicians	normal hourly rate	$15 for the additional counseling session (one-time)
Site 2: CHOP Clinicians	normal hourly rate	$10 for each study counseling session delivered

Adolescents: Payment will be received on a gift card. After the completion of each study point, adolescent subjects will receive additional payments as indicated in the table below.

	Post Intervention/ Enrollment	2-wks pregnancy test **(Group 1 only)**	30-Days	3-months	6-months	Maximum compensation
Group 1	$75	$30	$50	$30	$40	$225
Group 2	$75	----	$50	$30	$40	$195

16.0 Withdrawal of Subjects

All subjects may withdraw from the research study at any time. If they would like to withdraw, they are asked to notify any member of the research team immediately.

If an adolescent, study provider, or OOP withdraws from the study, any data collected will be kept and deidentified for analysis purposes.

17.0 Risks to Subjects

Providers/OOP: Risks to study providers/OOPs will likely be minimal as they are receiving contraceptive training and completing brief surveys to share their perceptions. There is minimal risk of loss of confidentiality which will be explained during consent.

Adolescents: Using the various birth control methods can cause minimal side effects that are listed in Section 5 of this document and will be described during the consent process. We will follow best practice guidelines for administering and prescribing medications.

Risks to participants are anticipated to be minimal. ED patients with severe illness or who experienced sexual assault will be excluded from this study to minimize the physical and emotional harm to study participants. Counseling sessions will be administered by trained providers in a confidential setting to avoid emotional discomfort to participants when discussing sensitive matters. There is minor risk of variance of counseling content, but this will be avoided by extensive training that will be provided to the providers by an adolescent family planning expert at each site. Counseling sessions will be continuously reviewed for quality. Additionally, there is minor risk of unauthorized disclosure of confidential information, which will be made known to participants and will be minimized by the research team's efforts to ensure confidentiality. Every effort will be made to keep data coded. All recruitment materials (e.g., signed consent forms) and information linking unique identification numbers to participant names will be stored in password-protected electronic files within REDCap. Only Dr. Miller and designated study staff will have access to these files. Risks are greatly reduced by using secure files, storing data on secure computers, and coding of data. Patients may choose not to participate.

As with any study involving collection of data, there is a possibility of breach of confidentiality of data. There is also a risk to confidentiality when using the internet or a mobile network. Corresponding through email and text messaging is not a secure method of sending information and others may be able to access the information sent. Every precaution will be taken to secure participants' personal information.

18.0 Potential Benefits to Subjects

Study providers may benefit from additional training in contraception counseling.

Adolescent participants may benefit from learning about birth control methods and ways to reduce their risk of unintended pregnancy.

Findings of this study could contribute to a reduction in unintended pregnancies among adolescents. The data obtained through this study may be used to inform new guidelines for adolescent-centered contraceptive services, which could offer benefits for adolescents in the future. The minimal risks of participation are reasonable in relation to these generalizable benefits.

19.0 Investigator Assessment of Risk/Benefits Ratio: (IRB makes the final determination) *Based upon your response in Sections 17.0 and 18.0, please provide your assessment of risk and benefits in below table.*

Select as applicable:	**Pediatric Risk Category:**	
x	Category 1	Research not involving greater than minimal risk (45 CFR §46.404 and 21 CFR §50.51)
Select if applicable:	**Adult Risk Category:**	
☒	Not Greater than Minimal Risk	
☐	Greater than Minimal Risk	

As there is no more than minimal risk to study participation, and potential for minimal direct benefits and significant indirect benefits, we feel that the benefit outweighs the risk of participation.

20.0 Data Management and Confidentiality

Participants will be informed that their participation in all aspects of the proposed study is entirely voluntary, and that they are free to withdraw at any time. Strict measures will be taken to ensure participant privacy and confidentiality. All data will be coded and then stored in the secure REDCap database, and all participants will be assigned a unique identification number. The master list linking identification numbers to identifying information will be stored separately from the study database. All personally identifiable information will be kept strictly confidential and stored in an encrypted document, on a dedicated research server only accessible by Dr. Miller and the designated study staff. Contact information for the study team will be included on consent forms to allow participants to ask questions or raise concerns about the study. Should any specific concerns arise, the study team would intervene to address problems including, if needed, a change or discontinuation of study procedures. The mentor team and site IRB's will be informed of any concerns, and the IRB and NIH will be informed of any adverse events.

Secure Storage of Data
Records to be kept and Secure Storage of Data: Survey development, data collection and handling will be conducted through Children's Mercy's REDCap Research software. The Redcap database is protected by Gazzang's zNcrypt product. zNcrypt transparently encrypts and secures data at rest without any changes to your applications or database and ensures there is minimal performance lag in the encryption or decryption process. Advanced key management and process-based access controls enable organizations to meet compliance regulations and ensure unauthorized parties or malicious actors never

gain access to the encrypted data. zNcrypt meets compliance for HIPAA, PCI-DSS, FISMA, EU Data Protection, and more.
Data will be exported from REDCap to statistical programs for analysis (i.e. SAS, SPSS, Excel.) All data will be securely stored on password-protected servers.

20.1 A Certificate of Confidentiality has been granted for this study because it is funded by the NIH

20.2 Audio data for study provider interviews will be periodically checked to ensure fidelity of the study.

Study data and information will be kept according to CM Record Retention guidelines.

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

We will convene a Data Safety Monitoring Board comprised of experts in adolescent reproductive health, health services research, and public health that are not connected to this project or to our Institutions. The Board will meet regularly to monitor participant safety and assess study progress and will be available to meet on an ad hoc basis if an immediate safety concern arises.

22.0 Provisions to Protect the Privacy Interests of Subjects

Study staff will take greatest measures to protect the privacy of research subjects. All data collected will be deidentified for data analysis purposes. Participants will be assigned a study number. Surveys will be completed confidentially and will not contain identifying information. Contact information will be recorded separately, via a separate REDCap data collection tool. PHI to be accessed and recorded will include medical record number, date of birth, address, and phone number.

All data will be managed in accordance with hospital institutional review board and HIPAA requirements to ensure confidentiality and protection of research participants. The Investigator and other site personnel will not use such data and records for any purpose other than for conducting the study. Human subject's names will be kept on a password protected database and will be linked only with a study identification number for this research. There are no patient identifiers recorded in the research record. All computer entry and networking programs will be done using study identification only. All data will be entered into a computer that is password protected. Clinical information will not be released without written permission of the subject, except as necessary for monitoring by IRB, the FDA, the OHRP, the Sponsor, or the Sponsor's designee. Data will be stored in a locked office of the investigators and maintained for a minimum of three years after the completion of the study.

The consent for the study will encompass the contraceptive counseling and follow-up call or text and medical record review to assess the primary and secondary outcomes. All participants will be given the opportunity to ask questions and decline participation. Completed consent documentation will be

signed and dated by the designated study staff, and a copy will be provided to the participant.

23.0 Compensation for Research-Related Injury

Provider/OOP: Research-related injury would be highly unlikely and there will be no compensation for research-related injury. If study providers feel they need to receive care, they will need to obtain it on their own.

Adolescents: Being in this study involves no more than minimal risk, therefore we do not require compensation for research-related injuries.

Economic Burden to Subjects

Training for providers will be provided free of cost and there should be no additional economic burden to study providers.

A 3-month supply of non-LARC study related medications, plus 1 etonogrstrel implant for adolescents in the MLI will be provided free of charge. Urine pregnancy testing will be provided free of charge if not already included in usual ED care for adolescents.

Adolescents must provide their own transportation for any medical follow-up visits that may be needed. If an adolescent decides to begin a method of contraception, follow-up care may be sought at a local Title X clinic or any medical facility preferred by the adolescent and adolescents will be responsible for any out-of-pocket expenses which may be incurred.

24.0 Permission/Assent/Consent Process

Providers: A study team member will obtain providers' verbal informed consent for study procedures.

OOP: A study team member will obtain verbal consent for study procedures (i.e., semi-structured interview).

Adolescent: If eligible, a study team member will obtain the adolescent patient's informed consent if they are 18 years of age or assent if they are less than 18 years of age for the study procedures. HIPAA Authorization will be obtained as part of the consent procedures. Study team members will verify with the clinical care team that the patient has the capacity to consent/assent.

For both sites, subjects who are 18 years old will provide written consent and HIPAA authorization for their own participation. For all minors, we will request a waiver of parental permission and waiver of HIPAA authorization and the minor will provide assent for their own participation. Minors may elect to have their

parent or legal guardian involved in the consent process, if desired. All parents of minor patients who are present in the ED will receive an information sheet that is available in English and Spanish about the study and have the opportunity to state that they would not like for their child to participate in the study prior to participant assent procedures. Though the parent information sheet will be available in English or Spanish, only English-Speaking patients will be recruited for the intervention.

A waiver of parental permission is requested for participants under 18 years of age as this study is no more than minimal risk and could not be practicably carried out without a waiver. Finally, the waiver or alteration will not adversely affect the rights and welfare of the subjects. Given that teen subjects may not want to involve their parent in a study about their reproductive health, it would not be reasonable to require permission from a parent or legal guardian to discuss study information with the minor, and mechanisms are in place to protect the children. The adolescents will be asked to provide assent. We will follow best practice guidelines established for adolescent participation in sexual health research. For any adolescent who desires placement of a subdermal contraceptive implant, we will follow established clinical practice at each site and obtain written consent from the procedure from the participant (if aged 18 years) or a guardian (for minor participants).

Process to Document Permission/Assent/Consent

Staff at each site will follow institutional standards for documentation. Documentation will be stored in a secured setting only accessible to study staff.

25.0 Setting

Research will take place within Children's Mercy Adele Hall campus and the Children's Hospital of Philadelphia. Most of the study procedures will be conducted in the emergency department.

26.0 Resources Available

Providers: Study team members and leaders will be readily available by email and in-person to resolve any issues that arise. The leadership teams representing the ED Providers also support this project and are available to provide assistance if needed.

Adolescents: Participants are not required to answer questions that make them feel uncomfortable. In the emergency department, there are always advocates available for patients and families, if needed, including health care providers, social workers, and patient advocates. In this study setting, if a participant expresses a concern or need that is outside of the scope of this project (e.g., sexual assault), we will refer those participants back to their ED treating team, as is our standard practice. During the consent process, we will inform participants that most of the information they share during the study will be kept confidential except in rare cases where their safety is at risk or mandated reporting is in effect.

27.0 Multi-Site Research

Drs. Miller and Mollen have a detailed plan for study oversite that was reviewed and approved by the NIH. Communication between study sites will take place via conference calls and emails. Regular conference calls will take place to discuss study updates, discuss any potential barriers and concerns and discuss other study logistics. Our estimated recruitment plan is detailed in the table below.

	CMH	CHOP	Total
Providers	Approximately 30	Approximately 30	60
Adolescents	49	49	98
Other personnel	15	15	30
Total	74	74	158

28.0 International Research NA

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