A Prospective Observational Study of the Implementation of Telehealth-Supported LARC Provision in School-Based Health Centers

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1. Study Purpose and Rationale

Study Purpose

In this proposed prospective observational study, we will describe in detail the implementation of a **hybrid model of telehealth-supported long-acting reversible contraception (LARC) service provision in a network of 6 school-based health centers (SBHCs**) in New York City that serve adolescents and young adult high school students age 13-22 years (hereafter referred to as "adolescents"). We will use quantitative and qualitative data, leveraging surveys combined with electronic health record data, to assess satisfaction with telehealth-supported LARC care, and uptake and continuation of LARC methods following introduction of telehealth-supported LARC service delivery in SBHCs. The findings from this study, given the SBHC setting, have the potential to inform and improve LARC service delivery for adolescents far beyond New York City and the SBHC setting.

Specific Aims:

Aim 1. Quantify uptake of LARC (contraceptive implant, IUD) within the SBHC network following implementation of telehealth-supported LARC provision.

Aim 1.1 Among all patients who had a telehealth visit for contraceptive counseling, quantify the number and rate of telehealth LARC consultations and LARC initiations overall, and compare by LARC type (contraceptive implant vs. IUD).

Aim 1.2 Subgroup analyses of LARC initiation (overall and by type) by patient characteristics (e.g. age group, race/ethnicity, sexual activity in last 90 days).

Aim 2: **Describe the implementation of telehealth-supported long-acting reversible contraception (LARC) service provision in school-based health centers (SBHCs) using mixed methods.**

Aim 2.1 Assess, through quantitative surveys among LARC initiators, patients' experience and satisfaction with telehealth-supported care.

Aim 2.2 Explore, through qualitative surveys with a purposive-sampled subset of LARC initiators, adolescents' experience with the telehealth-supported care and perceived benefits and drawbacks of telehealth care overall and for supporting LARC services (Ambresin et al., 2013).

Aim 3: Quantify LARC continuation over a 6-18 month follow-up period among LARC initiators within the SBHC network following implementation of telehealth-supported LARC provision. Using EHR data for all patients who initiated LARC, we will use Kaplan-Meier survival curves to assess LARC discontinuation overall, and Cox proportional hazard models to compare LARC continuation by LARC type.

Aim 3.1 (Primary Efficacy Outcome): 12-month continuation of LARC using telehealth-supported care among SBHC patients compared to LARC continuation rates among adolescents age 25 years and under as documented in a recent meta-analysis. Continuation rates will be expressed both as rates at 6 months and 12 months post-initiation, and using Kaplan-Meier curves to model discontinuation. Continuation rates in this setting will be compared to rates from a recent meta-analysis among adolescents and young adults that found 12-month continuation rates of 85.3% (primary efficacy outcome) for contraceptive implants and IUDs in the US-based studies (Usinger, Gola, Weis & Smaldone, 2016).

Aim 3.2 (Exploratory, pending feasibility) Continuation compared to pre-Telehealth. Compare 12-month continuation rate following introduction of telehealth to 12-month continuation among LARC initiators seen during the 18 month period prior to introduction of telehealth (June 2018-December 2019) *pending ability to export data from the prior electronic health record.*

Hypothesis:

We hypothesize that, in this sample of adolescents receiving telehealth-supported LARC services in a network of SBHCs, the LARC continuation rate at 12 months will be non-inferior to the 12-month continuation rate among adolescents and young adults age <25 (85.3%) as documented in a meta-analysis

comparing contraceptive implants and IUDs, in the absence of telehealth. The non-inferiority margin is chosen to be 10 percentage points less than that of the current standard of care (SOC) in US as such difference represents the maximum tolerable margin for inferiority while clinically important impact of proposed intervention can still be preserved.

Background/ Rationale

Long acting reversible contraceptives (LARCs) are safe and effective for adolescents, but low rates of use among this population and early discontinuation due to method dissatisfaction limits their potential to reduce unintended pregnancy. LARCs have been recognized as safe and appropriate first line contraceptive methods for adolescents by ACOG, American Academy of Pediatrics (AAP), and other expert bodies. Large studies have shown that adolescents are no more likely than adults to discontinue LARC methods early (Danielle et al., 2013). Side effects (e.g. unscheduled or unpredictable bleeding) are the primary reasons for discontinuation of contraceptive implants and IUDs among adolescents (Teal & Sheeder, 2012; McNicholas & Peipert, 2012; Hoggart et al., 2013).

Access to information and counseling prior to initiation of the method may increase satisfaction with and continuation of LARC methods (Davie et al.), particularly for adolescents (Wilson et al.). Our prior work showed that young people who received method-specific health education prior to IUD insertion were half as likely to discontinue within 6 months (Garbers et al. 2013); this comports with prior research of the positive impact of counseling on continuation of contraceptive implants (Davie et al.). LARC-related side effects improve between 6-12 months post-insertion, with corresponding increases in satisfaction (Hubacher & Park, 2009) suggesting that information on managing side effects prior to initiation may be critical.

Reducing barriers for obtaining LARCs by adolescents who want to use them is key in reducing risk of unintended pregnancy. Same-day provision of LARC has been proposed as a way to reduce the barriers to LARC initiation, as evidence has shown that requiring multiple visits to a clinical practice reduces uptake. One study with Medicaid-insured women found that almost half of women who were ordered an IUD at the first visit did not return for IUD insertion (Bergin et al., 2012). At the same time, other large-scale studies of same-day LARC provision in networks have shown that multiple visits are required to support patient decision-making (Biggs et al., 2013).

The rapid initiation of telehealth services, precipitated by the COVID-19 emergency, represents a **novel opportunity** to assess a “hybrid” care model that eliminates the need for two in-person visits to the office setting, while also providing sufficient time to support patient education, decision-making, and screening prior to the LARC insertion visit, specifically among adolescents. This work can inform **youth-friendly reproductive health care** (Ambresin et al., 2013) more broadly, building on our prior work on providing youth-friendly contraceptive care in SBHCs (Sangraula et al., 2017). Providing youth-friendly reproductive health care to adolescents via telehealth is a field that is in its infancy (Barney et al., 2020; Williams, Meredith, Ott 2018), and the field has called for national organizations to develop guidance on **best practices in using telehealth** to deliver sensitive care to adolescents (World Health Organization, 2020).

School-based health centers (SBHCs) -- of which there are more than 2,580 in urban (46%), rural (36%) and suburban (18%) areas in the United States (Love, Schlitt, et al., 2019) reaching more than 6 million school-aged youth -- represent a unique opportunity to assess the promise of a hybrid model of reducing barriers to initiation of LARC among adolescents to **inform broader replication in other clinical settings**. SBHCs provide a wide range of reproductive health services, including pregnancy testing (80%) and contraceptive counseling (70%) (Love, Suleimanpour, et al., 2019).[1] And, almost half of SBHCs used some telehealth in 2017 (Love, Panchal, et al., 2019), so the networks are well-positioned to integrate telehealth-supported LARC services. This implementation model, therefore, has the potential for replication and scale-up with wide reach. Analyses of continuation by telehealth experience (Aim 4), coupled with the findings from the mixed methods surveys and interviews (Aim 2) will **inform modifications to the telehealth model** before replication.

2. Study Design and Statistical Procedures

This is a prospective observational cohort study that will include all enrolled SBHC patients at the 6 participating SBHCs who receive a telehealth reproductive health visit in the 12-month period following IRB-approved study initiation date, and will follow over a 6-18-month period all patients who initiate a LARC method during the study period.

This two-year study will have three phases: 1) a 4-month study initiation phase; 2) a 12-month enrollment and surveying phase; 3) and a 6-month follow-up observation phase. Continuation analyses will rely on person-time, so that study participants will contribute a minimum of 6 to a maximum of 19 months observation time, depending on their time of enrollment.

Statistical Procedures. Dr. Garbers will have lead responsibility for conducting statistical analyses, supervising data cleaning, and logic checks conducted by the Research Coordinator, and working with the Biostatistician on model building. As this is a prospective observational study that seeks to enroll all patients who receive telehealth-supported LARC services over a 12-month period, the sample size will be determined by patient flow and participation rates.

Aim 1 (Secondary Outcome): Quantify uptake of LARC (contraceptive implant, IUD) within the SBHC network following implementation of telehealth-supported LARC provision

Aim 1.1 Making use of a newly-implemented electronic health record (EHR) system, Epic, we will assess uptake of contraception, quantifying the number and proportion of contraceptive method initiation (uptake), assessing each month:

1) absolute number of contraceptive counseling visits via telehealth;

2) absolute number of LARC telehealth consultations (a LARC consultation being defined as a visit in which an insertion is scheduled);

3) absolute number of LARC initiations by type (contraceptive implant, IUD);

4) LARC initiation visits as a proportion of contraceptive counseling visits (overall, and by LARC type [contraceptive implant, IUD]);

[1] The current SBHA Census does not provide data on how many SBHCs dispense contraception; the most recent data on this are from the 2007-08 census and are not presented here.

5) LARC initiation visits as a proportion of all contraceptive method initiation visits (overall, and by LARC type);

6) LARC initiation visits as a proportion of LARC telehealth consultations (defined as a visit in which a LARC initiation was scheduled; overall and by LARC type;

and 7) relative share of initiations of contraceptive implant and IUD, among LARC initiators.

Statistical Methods (Aim 1.1)

1) Descriptive analyses (frequency tables) will present, by month, the absolute numbers of contraceptive counseling visits, LARC consultations (with a scheduled insertion) (overall, and by LARC type [contraceptive implant, IUD]); and initiations (overall, and by LARC type [items 1-3 above].

2) Descriptive analyses will present the proportion of LARC initiations out of the number of contraceptive counseling visits [item 4], contraceptive initiations for all methods [item 5], and telehealth-based LARC consultations [item 6]. A consultation is defined as a visit for which a LARC initiation was

scheduled. These analyses will be presented in frequency tables.

3) For each of the uptake outcomes listed above [items 4-7], bivariate statistical analyses will compare the outcome proportions for contraceptive implant vs. IUD, using Chi-square tests.

Aim 1.2 Bivariate analyses will assess the uptake of LARC methods (overall, and contraceptive implant vs. IUD) by patient subgroup, examining LARC initiation (in absolute numbers, and as a proportion of telehealth consultations) by patient characteristics (age, race/ethnicity, gender identity, sexual orientation, sexual activity in last 90 days, gravidity, parity).

Statistical Methods (Aim 1.2)
Bivariate Chi-square tests will compare the proportion who initiated out of those who had 1) a telehealth contraceptive counseling consultation and 2) a LARC consultation for which an insertion was scheduled across subgroups defined by age group (using age categories consistent with the CDC's Youth Behavior Risk Surveillance System, ages 13-14, 15-17, 18-19, 20 and older); race/ethnicity (Hispanic + Black, Black non-Hispanic, Hispanic of any other race, non-Hispanic race other than Black); gender identity (female, male, transmale, gender non-conforming); sexual orientation (straight/heterosexual, gay/lesbian, bisexual, asexual); sexual activity (any/no sexual activity in last 90 days); gravidity (any/no pregnancy history); parity (any/no live birth).

Aim 2: **Describe the implementation of telehealth-supported long-acting reversible contraception (LARC) service provision in school-based health centers (SBHCs) using mixed methods.**

Aim 2.1 For all patients who initiate a LARC method over the 12 month enrollment period (estimated n=102), we will conduct online follow-up quantitative surveys with all adolescent patients who completed their in-person visit to initiate LARC method (contraceptive implant, IUD) to assess their experience with telehealth-supported care, including: when, where, and using what device they participated in the telehealth video session (e.g. laptop, smartphone, or tablet; with or without headphones); satisfaction with telehealth session (comfort in using telehealth, perceived privacy, extent to which questions were answered); how prepared they felt for the insertion visit; self-efficacy to manage side effects; time (in days) from telehealth visit to method initiation visit; whether attended scheduled follow-up telehealth visit (yes/no); and time (in days) between initiation and follow-up telehealth visit. These surveys will also collect data on interaction with health educators and/or peer health educators. We conservatively estimate a survey sample size of 87 for these surveys (85% participation).

Statistical Methods (Aim 2.1)
Descriptive analyses (frequency tables, means with standard deviations) will describe the telehealth experiences for all survey respondents. Bivariate statistical analyses will compare experiences between contraceptive implant and IUD initiators. We will use Chi-square for dichotomous outcomes, t-tests for means, and Wilcoxon Mann Whitney tests for medians (e.g. time in days between visits).

Aim 2.2 Qualitative interviews with 30 patients, using purposive sampling to ensure a range of perspectives (e.g. age, LARC method, health educator engagement). These qualitative surveys will expand on the aspects covered in the quantitative surveys and will explore, in greater detail, adolescents' experience with the telehealth-supported care from the SBHC, including prior experience with telehealth, perceived benefits and drawbacks of telehealth care overall and for supporting LARC services, specific domains of questions or concerns about side effects and maintenance of their LARC method, and dimensions of youth-friendly care (Ambresin et al., 2013).

Statistical Methods (Aim 2.2)
Thematic analysis will be used to describe the qualitative data generated from the interviews. Using an inductive approach, two coders will scan a random selection of transcripts to generate initial codes; working from these, we will generate a code-book that lists major themes, specifies categories

emerging from the data, and descriptions of each theme. The first 10 transcribed interviews will be jointly coded using Dedoose; then, inter-rater coding agreement will be assessed. The entire study team will: resolve discrepancies in coding, clarify theme definitions, and collapse or expand themes as needed.

Primary efficacy outcome (Aim 3): Continuation post-LARC initiation

The primary outcome for this study (3.1) will be absolute continuation rate 12 months post-initiation (dichotomous yes/no continuation), with analyses also examining continuation at 6 months (yes/no).

Aim 3.1 (Primary Efficacy Outcome): Overall 12-month continuation of LARC using telehealth-supported care compared to LARC continuation rates among adolescents age 25 and under as documented in a meta-analysis of US studies.

The primary outcome will be the proportion of patients continuing their initiated LARC method at 12 months post-initiation. Hypothesis: We hypothesize that, with the non-inferiority margin of 10 percentage point difference, in this sample of adolescents receiving telehealth-supported LARC services in a network of SBHCs, the LARC continuation rate at 12 months will be non-inferior to the reported 12-month continuation rate among adolescents and young adults age under 25 years (85.3%) in the US who initiated contraceptive implants or IUDs the absence of telehealth (Usinger, Gola, Weist & Smaldone, 2016).

Statistical Methods (Aim 3.1):

Continuation rates will be expressed as rates at both 6 months and 12 months post initiation, and time to discontinuation will be visualized using Kaplan-Meier curves.

We will test the primary null hypothesis H_0: $p \leq 0.753$ (i.e., 10 percentage points less than the reference rate of 0.853) using one-sample, one-tailed Z-test, where p is the LARC continuation rate at 12 months for participants who receive telehealth-supported LARC services in a network of SBHCs, and the reference the proportion (of 0.853) was chosen from the finding of the meta-analysis mentioned above.

Additionally, we will use Chi-squared tests to compare continuation (yes, continued/no, discontinued) between LARC types (contraceptive implant vs. IUD) at two time points: 6 months and 12 months post-initiation. Adjusted analyses using logistic regression will be conducted to compare the continuation at 6 and12 months (yes or no) separately between contraceptive implant and IUD patients, adjusting for covariates (age, race/ethnicity, gender identity, sexual orientation, sexual activity in last 90 days, gravidity, parity). Operationalization of these covariates is outlined in Aim 1.

Power/Sample Size (Aim 3.1):

The study anticipates enrolling 113 patients, with 102 patients included in the continuation analyses for Aim 3 (primary outcome). Our sample size estimates are based on conservative SBHC clinical data from 2018-2019 and from the first seven months of 2019-20 (which was disrupted by both the transition to a new EHR Epic system and school and SBHC closures due to COVID-19); during the July 2018 to January 2020 time period, there were, respectively, 129 LARC initiations (86 contraceptive implant, 43 IUD), and 44 LARC initiations (41 implant, 3 IUD). These sample size estimates are conservative, as the SBHCs have three newly-hired and trained medical providers since the 2019-20 disrupted year.

We anticipate having complete data for the continuation analyses sample size (n=102). Using the new Epic EHR, at each visit within the NYP clinical network – the participating study sites in the SBHCs, as well as the emergency department, inpatient and outpatient clinics – the health care provider is required to conduct reconciliation of medications and document it in the Epic EHR. The medical providers ask every patient at every visit what their current contraceptive method is – confirming the presence of the method, and documenting in two places in the EHR (in the contraception and in medications sections). These analyses will be able to assess continuation (presence of the device at a visit) and censoring

(device removal, device removal with re-insertion).

With a sample size of 102 and the margin of non-inferiority of 10 percentage points, the proposed study has 80% power to declare the non-inferiority of the telehealth-supported LARC services in a network of SBHCs in a one sample, one-sided Z test. This power analysis is for the primary efficacy outcome of interest, i.e., LARC continuation rate at 12 months. The reference LARC continuation rate at 12 months of 0.853 was obtained from the meta analysis conducted by Usinger, Gola, Weis & Smaldone in 2016. The studies included in their meta-analysis collected sample in the US with participants in those studies being young women aged 25 years and younger using a range of contraceptive methods. Therefore, if the true LARC continuation rate at 12 months is 0.753 or higher, the study is adequately powered to establish the non-inferiority of telehealth-supported approach. In the CHOICE Project, 12-month continuation of Copper IUDs among participants age 14-19 was 75.6% (Rosenstock et al., 2012).

Aim 3.2 (Exploratory, pending feasibility) Continuation compared to pre-Telehealth. Pending examination of the feasibility of constructing a pre-telehealth research database using the prior EHR system, compared to continuation rates within the same network prior to the implementation of telehealth-supported care, we will compare 12-month continuation (yes/no) following introduction of telehealth to 12-month continuation among LARC initiators seen the 18 month period prior to introduction of telehealth (June 2018-December 2019) *pending ability to export data from the prior electronic health record.*

3. Study Procedures

AIM 1

Participant enrollment – Aim 1: All patients who receive care at the SBHC provide informed consent for care, as well as record review for quality assurance purposes. Analyses for Aim 1 will include all female patients who have a “reproductive health visit,” which includes contraceptive counseling, contraceptive management, or contraceptive method initiation, during the study period. All patients who have a telehealth consultation with a SBHC medical provider for LARC services (conservatively estimated n=113) will be considered enrolled patients once the data are extracted from the EHR, and these will inform uptake analyses for Aim 1.

AIM 2

Participant enrollment – Aim 2: For the surveys (Aim 2), participant enrollment will take place after the in-person LARC initiation procedure at the SBHC, to avoid having the decision-making around survey participation influence contraceptive decision-making. At the visit, the medical provider (nurse practitioner) will pre-screen the patient for eligibility, describe the study, and ask for the patient’s permission to be contacted via text, email, or telephone by the Research Coordinator to conduct a survey. If the patient agrees to be contacted, the nurse practitioner will:

1. Send the chart by secure message in Epic to Melanie Gold, DO (the Medical Director of NYP School-Based Health Centers), as part of the usual chart review that Dr. Gold conducts per SBHC protocol, with documentation in the message that patient has been given permission to be contacted by the Research Coordinator.

2. Dr. Gold will send the patient name, contact information, and DOB to the Research Coordinator, as two points of identification are needed for Step 5.
3. The Research Coordinator will contact the patient via text or email with more information.
4. The Research Coordinator will create a study ID in RedCap and send a link to a REDCap or Qualtrics survey site that includes study info, information sheet, and the full survey. Full informed consent will be solicited and documented in the survey site.
5. Once the survey is completed, the Research Coordinator will provide the Grant Reporting Manager for the Center for Community Health & Education (via encrypted communication) patient name, DOB, and study ID, which can then be linked (by Grant Reporting Manager) to the Epic record.
6. The Grant Reporting Manager identifies patient within the larger exported file and adds study ID provided by the Research Coordinator.

Each week, as a supplement to this process and as part of reviewing the completed charts for any LARC insertions, Dr. Gold will send a "SmartText" (included in *SBHC Provider Scripts*) to any LARC patient who does not have documentation of declining or accepting to be contacted by the Research Coordinator. Dr. Gold will send a secure message to the patient asking permission to be contacted by the Research Coordinator. The message will also include the Research Coordinator's contact information if the patient wants to learn more about the survey.

This model of enrollment has been successfully used by Dr. Gold in prior studies among SBHC patients receiving LARC services (Sangraula et al., 2017).

Quantitative surveys: The quantitative surveys will be programmed into CUIMC-hosted REDCap or Qualtrics, which are HIPAA-compliant. The link to the Initial Survey, with an average of 30-40 questions about the patient's LARC counseling and insertion appointments, will be sent via text message or email to each participant who provided consent to be contacted. The link to the Follow-Up Survey, with 25-30 questions about the follow-up appointment post-insertion, will be sent via text or email once after the date of their follow-up visit (indicated by the patient in the Initial Survey). Participants who have had their follow-up visit at the time of completing the Initial Survey will be directed to complete the Follow-Up Survey in tandem.

The surveys, survey invitations and reminders, and informed consent forms will be in both English and Spanish; patients can choose which language they prefer to complete the survey. Participants will be sent up to 4 reminders at different times of the day to remind them to complete the survey (over 8 weeks). The English surveys will include, at the end, the option of consenting to be contacted for a follow-up qualitative interview if selected.

Qualitative interviews: Each month, in a phase of 5 per month, a total subset of up to 30 participants will be purposively sampled from the sample who responded to the quantitative survey and provided consent to be contacted for a follow-up telephone or Zoom interview. Given the small sample size, these interviews will be conducted among English-speaking patients (identified by the language in which they completed the survey). Participants will be purposively sampled (using quota sampling) to ensure distribution of respondents across LARC type, age, and race/ethnicity. Interviews will be audio recorded (with the voice print and study number being the only voice data recorded) and transcribed, using only the study ID number.

EHR abstraction and data completion tracking: The Grant Reporting Manager for the Center for Community Health & Education (CCHE), Division of Community and Population Health, (Ryan Levy) will construct a patient management database that maintains a linkage between the consent status, EHR number, and the study number, which will be linked to the survey. All data for export will be de-identified (maintaining only the study number) before sharing with the analytic team. The Research Coordinator will work with the Grant Reporting Manager to facilitate the export of linked, de-identified data for analyses. The fields that will be exported from the EHR are fields that would be used to monitor patient satisfaction outcomes consistent with quality assurance activities (see *Wish List of Data Points* in documents).

Linkage of survey data with EHR data: The Grant Reporting Manager will be the only person to maintain a link between the participant's EHR number and a study number. The Research Coordinator will program each survey to be individually linked to the unique study ID code; the survey data can then later be linked to the patient's electronic health record by the Grant Reporting Manager. The data can be linked using the study ID; the surveys will not include the EHR number.

AIM 3

Follow-up observation (Continuation Analyses, Aim 3): Follow-up observation will continue for 6 months after the enrollment phase has completed; therefore, participants enrolled in the first month will have 18 total months observation, while those enrolled in the last month will have 6 months. In 2018-19, in the network of 6 SBHCs, 2,425 unique female patients had a total of 12,398 visits (for any purpose), representing an average of 5 SBHC visits per female patient in the academic year.[2] At each visit to the SBHC, regardless of visit type, all female patients have their medications, including contraceptive method, reconciled and confirmed in the medical record. With the new Epic EHR system, export of all LARC-related procedure codes (insertions, removals, removal with replacement) and device codes (e.g. Nexplanon, Liletta, Paragard) *in addition to all* visits (with corresponding data on current contraceptive method) will enable us to identify person-time events including censoring. At all New York Presbyterian (NYP) sites, the health care provider is required to conduct reconciliation of medications and document it in the EHR at every visit. The SBHC medical providers ask every SBHC patient at every visit what their current contraceptive method is – confirming the presence of the method, and documenting this in two places in the EHR (in the contraception history section, and in the medications section).

Compensation.
All Aim 2 survey and interview participants will receive compensation for their time and effort in the form of an Amazon electronic gift card, purchased through the Mailman School of Public Health. Compensation is as follows:

> **Quantitative survey participants** will receive, as compensation for their time and effort, an Amazon gift card valued at $10 at the conclusion of the survey. The card will be sent to participants electronically.
>
> **Qualitative interview participants will receive,** as compensation for their time and effort, an Amazon gift card valued at $25. The card will be sent to participants electronically.

4. Study Subjects

Subject Population Justification:
Adolescents and young adult high school students are the primary study participants. This study will describe in detail the implementation of a hybrid model of telehealth-supported LARC service provision in a network of 6 SBHCs in New York City that serve students who are between the ages of 13 and 22 years. The specific age range of the students was selected because it reflects the age range of students served by the 6 SBHCs. We are limiting our enrollment to high school students because the study is based in SBHCs. We have used the enrollment and retention strategies proposed in this application in our past research.

Patient population. Based on SBHC clinical data from the full academic year (2018-19), we estimate that, over the 12 month cohort there will be 113 telehealth consultations, defined as a visit in which an appointment is scheduled to initiate a LARC methods (Aim 1), and 102 LARC insertions (Aim 2). The SBHC

[2] This figure represents total number of visits for all patients, including patients receiving mental health care, who have regularly scheduled repeat visits. The average number of visits per year per unique female patient among LARC users is anticipated to be lower.

patient population, as a whole, is 69% Hispanic and 26% Black (not mutually exclusive), with an average age of 16 years. The majority of patients have their visits covered by Medicaid.

Participants will be eligible to participate in the study if they are: 1) an enrolled patient at the participating SBHC; 2) age 13-22 years; 3) female; 4) had a visit at the SBHC during the study period that is coded as a "reproductive health visit" including contraceptive counseling, contraceptive management, and contraceptive method initiation.

For Aims 2 and 3, individuals will be excluded if they: 1) are younger than age 13 years; 2) are older than age 22; 3) are not an enrolled patient of the participating SBHCs; 4) did not initiate a LARC method; 5) are a person without a uterus; 6) are unable to read, speak, and understand either English or Spanish**.**

5. Recruitment

Aim 2.1: Adolescent Survey Participants:
Adolescent participants will be recruited by the treating clinician (SBHC providers, including Dr. Gold) following in-person LARC initiation procedures. Flyers and scripts will be provided to SBHC providers to share with patients in person or via secure message through EPIC, the SBHCs' electronic health record system. Adolescents who are interested in participating in the survey will either provide permission to be contacted by the Research Coordinator, or will be provided with the Research Coordinator's CUIMC email address and cell phone number to learn more about the study.

> **Eligibility Screening – Survey Participants.** The Research Coordinator will initially screen potential survey participants for eligibility by asking 1) if they would like to determine their eligibility to participate in a study; 2) if so, their age.

Aim 2.2: Adolescent Interview Participants (n=30):
A purposive sampling method will be used to recruit participants who gave consent in the survey to be re-contacted for an interview. All eligible adolescent participants will be sent (via REDCap) a detailed Study Information sheet (included in documents) which will explicitly convey who is conducting the study, the purpose of the study, the procedures (e.g., time needed, study risks and benefits, a discussion of compensation, and a statement that participation is voluntary and will not affect their care at the SBHCs). E-consent will be solicited and documented in REDCap. All informed consent processes for Zoom or telephone interviews will be conducted prior to the interview with the trained study staff. Recording will start only after the participant has been consented.

6. Informed Consent Process

All Informed Consent procedures will start with a concise presentation, in lay language, of the key information about the research study. Sufficient information about the study purpose, procedures, risks, and benefits will be provided to all potential subjects.

Adolescent Survey and Interview Participants. We are seeking a waiver of parental permission for participants under the age of 18, as the study meets the following criteria: 1) the research involves no more than minimal risk to the subjects; 2) the waiver will not adversely affect the rights and welfare of the subjects; 3) the research could not practicably be carried out without the waiver or alteration; and 4) the subjects will be provided with additional pertinent information after participation.

All adolescent survey and interview participants are expected to be able to provide consent to participate, as they are currently enrolled students in high school and English or Spanish speaking. A written information sheet will be included on the survey site or sent electronically to interview participants via REDCap prior to the interview date. The REDCap e-consent program will meet all elements of e-consent (per the September 24, 2020 CUIMC e-Consent seminar, which Dr. Garbers attended). The e-consent program is easy to navigate, allowing the user to proceed forward or backward in the system and to stop and continue at a later time. The platform provides standardized tools to obtain consent and store consent documentation with a certification screen and a storage function which automatically generates a 'hard-copy' PDF of the signed form. The 'Auto-Archiver + e-Consent Framework' survey option adds two things to the typical survey taking process: 1) before a participant completes the survey, an extra certification page is added to the end of the survey that displays an in-line PDF copy of the document in which they will be asked to confirm that all information in the document is correct; 2) upon completion of the survey, a static copy of their responses in the form of a consent-specific PDF will be stored in the project's File Repository. HIPAA authorization will be obtained as part of the e-consent. All hyperlinks included on the sheet will be maintained and the information will be accessible until study completion. The process is secure with access restricted to authorized study personnel along with methods to ensure confidentiality of the subject's identity, study participation, and personal information. E-consent will be solicited remotely. The information sheet states that if the subject has any question, they can call Dr. Garbers at 646-494-7163.

The materials will explain that the study is being conducted to improve IUD and contraceptive implant services at the school-based health center, and will include contact information for the study team so participants will be given the opportunity to contact the investigators to have any questions answered or concerns addressed. The informed consent forms provided will explain, in plain language written at no higher than 8th grade reading level, who is conducting the study, the purpose of the study, the procedures (including the length of the survey and interview), study risks and benefits, a discussion of compensation, specific steps that will be taken to protect confidentiality, and a statement that participation is voluntary and their participation will not affect their care at the SBHC. E-consent will be documented in the survey site or in REDCap prior to initiation of the survey or interview. All consent forms will be IRB and HIPAA compliant, and will include mention that the study will be registered with the ClinicalTrials.gov website.

Any adolescent participant who turns 18 during the course of their active participation in the study will be re-consented.

Note: It is a funding requirement by Merck MISP that the study be posted on ClinicalTrials.gov. There will be no prospective assignment to intervention. The study is exploring aspects of quality and satisfaction with services. The study will not be open to enrollment outside existing SBHC patients.

7. Study Instruments

Quantitative Survey. We will use quantitative surveys among LARC initiators to assess patients' experience and satisfaction with telehealth-supported care. The Initial Survey will have on average 30-40 questions about the patient's LARC counseling and insertion appointments, and will be sent via text message or email. The Follow-Up Survey will have 25-30 questions about the patient's follow-up appointment following their LARC insertion. Please see attached *Initial Survey* and *Follow-Up Survey* for an overview of the questions we will ask.

Qualitative Interviews. Using a semi-structured interview guide, trained study staff will interview English-speaking patients to explore adolescents' experience with the telehealth-supported care from the SBHC and inform modifications to the telehealth model before replication. Please see attached *Qualitative Interview Guide* for the semi-structured interview guide.

8. Confidentiality of Study Data

Data collection and storage protocols will minimize the use of identifying information. All EHR data will be de-identified by the Grant Reporting Manager before being shared with the study team for analysis. All research participants will be identified on all research forms and logs (other than the study ID linkage forms) by unique but non-identifying codes. Code linkage files relating ID codes to names will be maintained on RedCap, a password-protected site, accessed only by the lead study staff (Garbers, Gold, and Maier). Zoom and telephone interviews will be recorded only using CUIMC-hosted Zoom accounts, with a password required for entry into the room. Recordings of the interviews will only be recorded onto encrypted, password-protected endpoint computer temporarily. This electronic data will be maintained on the encrypted, password-protected computer files on encrypted devices with limited access to data by staff – different levels of access will depend on the person's specific level on the staff, and server security safeguards that in the aggregate provide a high degree of protection from unauthorized users. Interviews will be transcribed as quickly as possible; once transcribed and checked for accuracy, the recordings will be deleted.

All qualitative and quantitative information will be coded by identification number, so that no full names or other personally identifying information (PII) are associated with any of the data. Identity of participants – including deductive disclosure -- will not be revealed in the presentation or publication of any results from the project. All personnel working on the project will be regularly trained and re-trained about the importance of strictly respecting participants' rights to confidentiality and specific approaches to ensure such protections. The only data for which PII cannot be inextricably separated from the data is a voice print. Special steps will be taken to protect this data.

Confidentiality and privacy for audio/video recording of human subjects
The project will ensure the following steps are followed, and will include these steps in the consent forms for participants:

1. Participants will be informed that the interviews will be recorded. Their voices will be recorded, but no other likenesses will be recorded. Names and likenesses (pictures or live video) will not be recorded. The interviewer will instruct participants to change their screen name on Zoom to their study ID.
2. The recording will not start until the participant has turned off their video camera and changed their screen name to their study ID.
3. The video recording will be recorded and viewed by the Research Coordinator and the Principal Investigators. The recording will be downloaded to extract the transcription of the audio feed. No identifiers will be included in the transcriptions. The Research Coordinator will review the transcript for accuracy, consulting the original audio as needed. As soon as the accuracy of the transcription is confirmed, the recordings will be destroyed from all locations.
4. The video recordings (before destruction) and the transcriptions (without identifiers) will be stored temporarily on an encrypted and password protected computer.
5. There will be no future use of the recordings, once the recordings are transcribed.

Participants will be consented prior to the start of the interview, and all of these points will be reviewed.

9. Privacy Protections

We will ensure confidentiality is protected by taking several steps. Per CUIMC Institutional Review Board (IRB) guidelines, all members of the study staff must complete trainings in human subjects protection and HIPAA requirements, as well as ongoing training by the PIs in all aspects of human subjects protection. The platforms we will use for data collection, Zoom and either REDCap or Qualtrics, will use only the CUIMC-hosted versions, which are HIPAA compliant. For purposes of the research database, each participant will be assigned a unique identifier that bears no systematic relation to the family, or school, or SBHC records. Information to be excluded from the research database includes names of study participants, addresses, telephone numbers, school, clinician, and other information that has the potential to identify individuals. All outcome data will be de-identified by HIPAA standards using the “safe-harbor” method (i.e., all 18 PII elements will be stripped) prior to being stored on a password-protected, encrypted server.

10. Potential Risks

Participation in this research involves minimal risk, defined in the Federal guidelines as "the probability and magnitude of harm anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

(1) It is possible that the adolescent participants will experience some inconvenience, embarrassment, or distress while participating in the interviews or completing surveys.

Survey and interview participants will be reminded of the option to not answer any questions or to stop the survey or interview at any time. Adolescent participants reporting distress to the study team will be referred to onsite mental health providers that are always available at the SBHCs. Adolescent participants have access to primary care through the SBHCs, if parental permission is on file for them to receive primary care.

Since the risks to individual study participants are minimal, the study appears to be readily justifiable.

11. Data and Safety Monitoring

This is a minimal risk study. The PIs (Garbers and Gold) will be responsible for all data safety and monitoring. They will have responsibility for ensuring that the policies outlined above to minimize risk – including staff training, storing identifiers separately from survey and interview data, and storing all data on encrypted, password-protected servers – are followed. The PIs will conduct regular checks of data storage procedures, ensuring, for instance, that: any recordings have been destroyed following transcription; access to electronic data is limited to trained study staff, and the research database does not include any personally identifying information.

In their weekly team meetings, Drs. Garbers and Gold will review with the study staff weekly data reports regarding all study-related activities. This will include the sample size and proportion of approached contacts, eligibility rates (and reasons), consent/refusals, and surveys and interviews completed.

All study personnel will report any study-related adverse events and/or unanticipated problems involving risks to participants to Drs. Garbers and Gold. In the case of any adverse event or unanticipated problem, Drs. Garbers and Gold will notify the CUIMC IRB. Dr. Garbers will, if appropriate, inform the Merck Project Officer in writing of any actions taken by the IRBs as a result of such adverse events.

12. Potential Benefits

Reducing barriers for obtaining LARCs by adolescents who want to use them is key in reducing risk of unintended pregnancy. Access to information and counseling prior to initiation of the method may increase satisfaction with and continuation of LARC methods, particularly for adolescents. A “hybrid” care model involving telehealth eliminates the need for two in-person visits, while also providing sufficient time to support patient education, decision-making, and screening prior to the LARC insertion visit. This work can inform youth-friendly IUD and contraceptive implant services, and the SBHC implementation model has the potential for replication and scale-up in other clinical settings.

13. Alternatives

Participants have the alternative to not participate in this research.

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