IRB Protocol

A text message intervention to improve the reproductive health of adolescent females in the emergency department.

Part 2: Reducing Teen Pregnancy in the Emergency Department (ERICA)

Lauren S. Chernick MD MSc
Department of Pediatrics
Division of Pediatric Emergency Medicine

Study purpose and rationale

Over the past 25 years, teen pregnancy rates in the US have dropped primarily due to increased contraception use.[1] Despite this progress, pregnancy risk remains high among adolescent females who use the ED.[2,3] This risk is largely due to non-use of contraception.[3] Since many of these females lack a primary care provider, the ED is an important place to identify adolescents at highest risk of pregnancy and intervene.[4] However, such an intervention must work efficiently in the busy ED setting, extend the teachable moment between patient and provider, and prolong the motivation for change caused by the ED visit.[5]

In the outpatient setting, text messaging interventions have positively changed health behaviors.[6–8] In a 2015 systemic review, text messaging interventions were found to be effective when addressing diabetes self-management, weight loss, physical activity, smoking cessation, and medication adherence.[6] For example, texting interventions increased long-term smoking cessation rates compared to controls (Relative Risk=1.7, 95%CI=[1.5-2.0]).[9] Additionally, receivers of text messages promoting weight reduction lost 7 times more weight than controls (-2.6 kg [-3.5,-1.7] vs -0.4 kg [-1.2 to 0.5]).[10]

There is a growing body of evidence that the specific characteristics of text messages influence their effectiveness.[7,11–13] In a 2013 meta-analysis, text messaging interventions for health promotion had an overall positive effect size (standardized mean difference (d)=0.33 [0.27, 0.39]); studies that employed both text message *tailoring* and *targeting* had the largest effect (d=0.44 [0.36, 0.52]).[8] Moreover, interventions that applied *personalization* (d=0.44 [0.34, 0.50]) were particularly efficacious.[8] In a separate meta-analysis, texting interventions that included *bidirectionality, personalization,* and *tailoring* significantly improved adherence to anti-retroviral therapy (odds ratio (OR)=1.4, [1.2, 1.6]).[14] Lastly, in a 2014 meta-analysis, medication adherence improved in all studies that applied *tailored* or *personalized* messages.[15]

The incorporation of text messaging into health interventions has shown promise in the ED, although few RCTs have been published.[11,16–18] In an ED-based RCT, adults who received automated behavioral feedback with texting were 2.4 times (95%CI=1.4, 4.1) more likely to not report any binge drinking in the last 30 days than the control participants.[17] In a small ED-based pilot RCT, young adult females receiving a texting intervention that included feedback increased condom use compared to those who received standard care (53% compared to 20%).[18] A personalized texting program also improved attendance to post-ED follow-up (72.6% vs 62.1%; p=0.045).[11]

There is little data on the use of personalized and interactive text messaging to promote health behaviors among adolescents.[19,20] However, young women are particularly amenable to text messaging to promote sexual health, perceiving texting as convenient, of minimal cost, and providing a sense of privacy that other forms of health communication do not.[21–24] In addition, tailored messages are more likely to be read, understood, recalled, rated highly, and perceived as credible.[25] Providing short bursts of information throughout the day, text messaging can provide adolescents with support and in-the-moment, automated advice to assist in smart decision-making.[26]

The specific aim of this study is to test a pregnancy prevention text message program to assess feasibility, acceptability, and effectiveness among sexually active adolescent females in a pediatric emergency department. **This study has two parts.**

Part 1 is to measure the feasibility, acceptability and potential efficacy of the texting program among a <u>cohort</u> of female adolescent ED patients.

Part 2 is to conduct a <u>RCT</u> to test the feasibility, acceptability, and efficacy of the intervention to increase contraception initiation among high risk, adolescent females.

APPROACH

<u>Preliminary Studies</u>

Proving high rates of teen pregnancy in the ED setting and poor follow up to reproductive preventive services: In 2012, we found that 20% of our adolescent females (aged 14-19) were expected to become pregnant in the following year, a risk three times the national pregnancy rate and mainly due to non-contraceptive use.[2] Higher risk was associated with frequent ED use and lack of a primary provider. Fifty percent of respondents were receptive to ED-based pregnancy prevention interventions and 25% were interested in starting

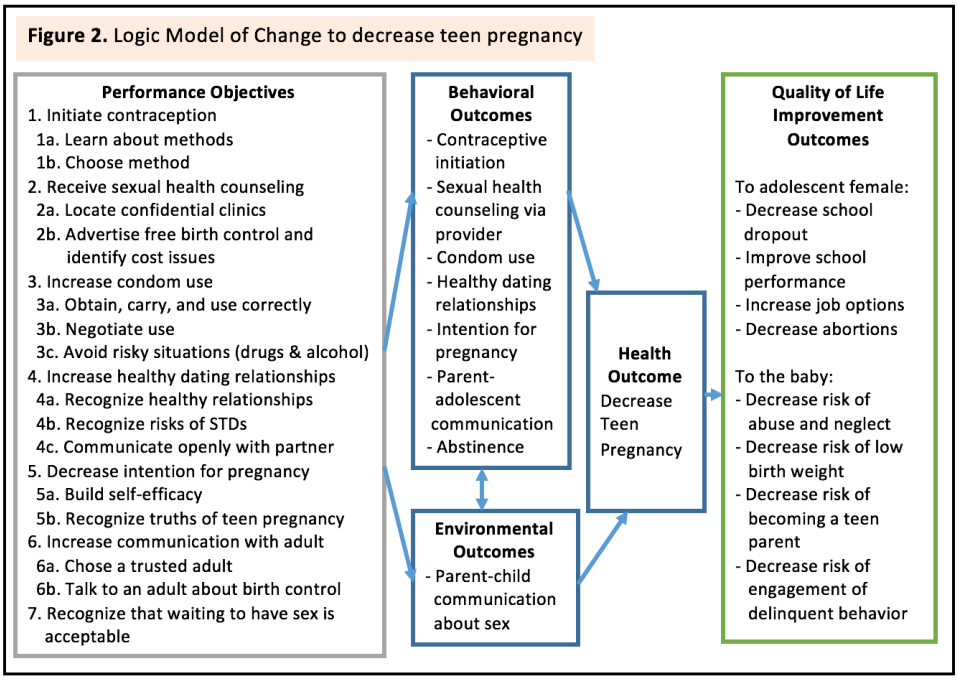
contraceptives. In a study published in 2015, we implemented an enhanced method to refer sexually active females from the ED to family planning but found no substantial improvement in follow up.[27]

Understanding barriers to contraceptive use and interest in a mobile health ED-based pregnancy prevention intervention: (PI: Chernick; Funding: *2013 Columbia University Irving Institute CTSA Pilot Grant* and *Society of Family Planning Pilot Award*) In order to build upon our understanding of our target population and how to increase contraceptive use, we conducted a two-part qualitative analysis of females at high pregnancy risk. First, using qualitative data, we developed and published a conceptual model exploring those barriers and enablers affecting their contraceptive use.[23] Subsequently, we determined adolescents' preferences for a pregnancy prevention text messaging intervention, exploring the content, frequency, and timing of conventional (unidirectional and non-interactive) texts.[28] Based on this qualitative data, texts were categorized into three domains: contraceptive education, information about preventive services, and self-efficacy.

Evaluating a conventional pregnancy prevention text messaging intervention: We then conducted an ED-based pilot RCT of sexually active females aged 14–19, randomizing patients to receive 3 months of conventional pregnancy prevention texts versus standardized discharge instructions **(IRB #AAAM3457**).[29] Of the 100 enrolled, feasibility and acceptability were high, with follow-up rates of 88%, 1172/1654 (70.9%) texts successfully delivered, and most (36/41; 87.7%) in the intervention arm wanting future health messages. While there was no signal to suggest a meaningful effect of the intervention for all ages, we identified age group as an effect modifier (p=0.02). Overall, younger adolescents (age 14-17 years) initiated contraception more often than older adolescents (age 18-19 years) [34.8% (8/23) versus 11.8% (9/76); p=0.01].

Developing a user-informed, theory-based, personalized, interactive pregnancy prevention texting intervention: (PI: Chernick; Funding: *Columbia University KL2 Career Development Grant*) In January 2017, we were awarded a 2-year KL2 grant to design and program a personalized and interactive (two-way) pregnancy prevention texting intervention, targeting adolescents at high pregnancy risk using the ED for medical care. There is evidence to suggest that dynamic two-way text messaging interventions, such as those involving alcohol reduction and depression, can guide participants through the process of behavior change.[26,30–32] Individually tailored messaging programs provide a sense of personalization and increases personal relevance, which is particularly important for adolescent behavior change.[33,34]

Over the past year, to design the personalized and interactive texting platform, we have followed the program-planning framework called Intervention Mapping, which is step-wise process of using evidence and theory as a foundation for taking an ecological approach to assessing and intervening in health problems.[35] As seen in Figure 2, we created a Logic Model of Change. This includes our health outcome (to decrease teen pregnancy), the behavioral and environmental outcomes affecting teen pregnancy, and associated performance objectives to change outcomes. Data for this model came from: (1) key stakeholders (e.g. health educators at local high and middle schools and family planning clinics and social workers); (2) our formative quantitative and qualitative work; (3) national and New York State sexual health curricula; (4) evidence-based sexual education guidelines; and (5) an extensive literature review, including logic models from effective teen pregnancy interventions.[36–38] For the theoretical perspective of our intervention, we chose aspects of the Social Cognitive Theory (SCT), the Unified Theory of Behavior (UTB), and Motivational



Interviewing (MI).[34,39,40] These models are: (1) frequently associated with successful contraception promotion interventions (SCT and MI); (2) specifically address the determinants affecting intention to prevent pregnancy and use birth control (UTB), and (3) augment engagement and a sense of independence (MI).[34,41,42] Using these theories and our Logic Model of Change, we developed a curricula of over 20 options for text message algorithms for the present proposal's intervention. (See Attachments for Texting algorithms)

To revise the text message algorithms, we conducted semi-structured interviews with 30 sexually active adolescent female ED patients. (**IRB #AAAQ8814**) We used key themes to write new and revise existing text messages.

Finally, we also conducted a separate survey of sexually active adolescent female ED patients to inform the design of sexual health comic strips. As part of the intervention, the comic strips include local vernacular to affect personal relevance and social norms. Survey participants were presented with cartoon scenarios and asked to write text messages for the main character. (**IRB #AAAR4009**) These messages became the text of each comic strip. In an attachment, you will find 5 cartoons that we plan to use in the intervention.

Part 1: Cohort Study

Study Design

We will conduct a prospective cohort study on 50 participants recruited in the pediatric ED to assess if the 10-week pregnancy prevention text message program is feasible, acceptable, and potentially effective.

Study Subjects

The eligibility criteria identify females at high risk of pregnancy who will receive the intervention. Inclusion: (1) age 14-19 years and (2) sexually active with males in the past 3 months. Exclusion: (1) currently using any "effective" form of contraception (as defined by the World Health Organization and includes the Shot, intrauterine device, ring, implantable device, Patch, birth control pills, or sterilization), (2) do not own a mobile phone with text messaging, (3) are pregnant, (4) are too ill for participation per the attending physician, (5) are cognitively impaired, (6) do not live locally (Manhattan or Bronx), (7) do not speak English or (8) does not want to become pregnant in the next year. We will purposively sample 14-17 year old and 18-19 year old patients. Although our population is predominantly Hispanic, we will only enroll English-speaking participants. In our prior work, when we offered English and Spanish text messages, 94% of participants chose English.[43]

Recruitment

A member of the research team will identify potentially eligible patients using the electronic medical record (EMR) in the pediatric Emergency Department at New York-Presbyterian Children's Hospital of New York. Our EMR reveals the age of each patient. The research team member will ask the medical provider caring the patient to confirm eligibility criteria. If a patient is eligible, that provider will privately introduce the study and ask if a research team member can explain it further.

A member of the research team will then privately explain the study in full to the eligible patient in a private location by reviewing the informational form and answering all questions. We used Columbia University IRB-suggested language to design the informational sheet. As part of our information sheet, we will include the language of HIPAA Form B that will include the nature and scope of the PHI to which access is sought and certifications to be made by the researcher.

To ensure the protection or the rights and welfare of the minor, we will put a substitute process in place to verify the minor's willingness to participate. This will be in the form of a two-person verification (as suggested in IRB correspondence). These 2 people will be the research investigator/ coordinator consenting the patient and the medical provider caring for the patient in the ED (who is involving in the screening process).

Eligible patients will have a choice if they want to sign the informational sheet or verify verbally their agreement to participation. All participants will receive a copy of the informational sheet.

We will explain that we are not responsible for the costs of the texts but do compensate with a gift card. Based on our prior work, the vast majority of our ED adolescent population has unlimited texting on their phones.[29]

We have experience enrolling adolescents into sexual health studies when their parents are present and are able to maintain confidentiality. By explaining the study as a sexual health study aiming to educate adolescents in our community, we are able to discuss the study to both the parent and adolescent. We then talk to the adolescent in private, explain that she was selected because she is at risk of getting pregnant.

Why should adolescents be enrolled in research studies?

There are several reasons why minors should be enrolled in research studies. The following reasons are paraphrased excerpts from the Society of Adolescent Health Position Paper, *Guidelines for Adolescent Health Research,* and a World Health Organization (WHO) policy on *Sexual and Reproductive Health* by their Ethical and Scientific Review Group.

A. Participation by specific populations, such as adolescents, in health research is critical in order for those populations to receive the full benefits of research. Adolescents as a class have often been excluded from participation in clinical trials, studies in public health prevention, and other critical research efforts from which this age group would benefit. The result is that treatment options and the design of interventions for adolescents must often be extrapolated from studies involving either children or adults.
B. Numerous national commissions, panels, and reports have articulated their great concern about adolescent health and the urgent need for research that can guide interventions and inform public policy. Unintended pregnancy poses continuing and serious challenges to the health and well being of youth in communities across the country.
C. Research with adolescents has produced important benefits for this population in recent years, with significant insights emerging about the ways in which adolescents differ from both children and adults.
D. **Laws have evolved over time to try to include adolescents in research**. Beginning in the 1960s, laws in many states began to accord minors the right to consent to emergency care and to medical treatment of conditions such as pregnancy, STDs, and drug, alcohol, and mental health problems. Similarly, state laws have recognized the right of minors with a certain status, such as "mature" or emancipated minors to consent to their own care. Other minors authorized to consent may include those who are parents, are living independently of their own parents, have graduated from high school, or have reached a specific age. In addition to the explicit state statutes, minors' autonomy in health care decision-making and privacy has been protected in federal law. In Planned Parenthood of Missouri v. Danforth, 1976, Carey v. Population Services International, 1977, and Belloti v. Baird, 1979, and a long line of other cases, the United States Supreme Court recognized that the constitutional right of privacy protects minors as well as adults, particularly for reproductive health care, including contraceptives.
E. Research on cognition and capacity suggests that both adolescents and younger children show significant ability to provide informed consent. **For mid- and late adolescents (aged 14 years old or older), understanding of research and the cognitive ability to make decisions about research participation are similar to these abilities in adults.**
F. Lastly, the justification for conducting research on reproductive health in adolescents is the same as that for any biomedical or behavioural research: only by carrying out well-designed studies can adequate information be gained that will enable delivery of appropriate preventive and therapeutic services to this population group. Therefore, research on reproductive health involving adolescents should be undertaken in order to enhance scientific knowledge specific to these individuals. The omission of such research can perpetuate inadequate understanding of the particular reproductive health needs of adolescents and result in failure to deliver adequate services to this group.

Waiver of assent with a substitute of an information sheet

Our study requests a waiver of assent with a substitute of an information sheet (**as suggested by the IRB**) to be provided to enrolled minors. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds (based on 45 CFR 46.117(c)(1)):

- Principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research
    - *This study collects behavioral information about the participant, such as sexual behaviors. This is sensitive information. The principal risk to the participant is confidentiality.*

AND

- Consent document is the only record linking the subject with the research.
    - *This study does NOT collect dates of birth or HIV status. This study does collect medical record numbers and phone numbers. The only record linking the subject's name with the research would be her consent form. (We have omitted the release of medical information form to comply with this term). All patients will receive a unique identifier. Only at the time of follow-up will her name as read from the medical record; however, researchers will be blinded to any behavioral information already provided in the study by that participant.*

AND

- Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participants wishes will govern.
    - *We will ask each participant if she wants to sign the consent form. If so, we will also collect written consent from the consenting researcher and medical provider verifying her willingness to consent.*

In addition, we believe that our study presents **MINIMAL risk**. Participants will not be exposed to the possibility of harm -- physical, psychological, social, legal, or other -- as a consequence of participation as a human subject in this research activity. This study should not increase the probability or magnitude of risks ordinarily encountered in daily life. We believe this to be true for the following reasons:

- The sexual health information we will send via mobile phone is similar to the sexual health education received in schools, which is approved by state and federal initiatives.
- The principal threats to adolescent health and well-being are social and behavioral: personal behavior and the behavior of peers. Behavioral research includes intervention programs to reduce harmful behaviors and increase protective behaviors as well as projects designed to improve understanding of the factors influencing adolescent behavior. Behavioral research generally presents little risk to the individual adolescent. Research on the prevention of HIV and teen pregnancy has resulted in more effective prevention programs to reduce sexual risk behavior.
- The primary risks to the adolescent participant from behavioral research, particularly survey research, are potential embarrassment and disclosure of sensitive information to others. This is true for survey research involving adults as well. However, disclosure resulting from survey research is a rare phenomenon.

*Additional reasons that support our request for a waiver of assent with a substitute of an information sheet AND **a waiver of a parental consent** are the following:*

A. The definition of children in the federal regulations recognizes the legal status of mature and emancipated minors under state law and the ability of adolescents to consent for specific health services. These state minor consent laws implicitly recognize that under certain circumstances minors are capable of making independent judgments and that this emerging decision-making capacity should be respected. Parental permission is not required under the federal regulations, where adolescents do not fit the regulatory definition of children.

B. Patients who are younger than 18 years old and present to the ED for a reproductive health care concern can legally provide their own consent. New York Public Health Law (Title 1, #2305 (2)) states that a person under the age of 21 years may receive reproductive health care without the consent or knowledge of parents or guardians of said person, when said person has been infected or exposed to a sexually transmitted disease.

C. New York Consolidated Law, Social Service Law 350(e). Family planning services and supplies shall be offered and promptly furnished to eligible persons of childbearing age, including children who can be considered sexually active, who desire such services and supplies, in accordance with the regulations of the department.

D. Using the US federal definition of children, teenagers presenting for reproductive complaints are not considered children and are considered adults for research purposes. The federal Title X legislation requires that confidential services be available to adolescents in Title X-funded family planning clinics, such as the Columbia family planning clinic, and the US Supreme Court has extended privacy rights in matters related to the use of contraception to minors.

E. Under the federal regulations governing research, the IRB may waive the requirement for parental permission for research involving children (including minor adolescents) if parental permission is deemed not reasonable or ethically problematic. The National Commission noted that IRBs may determine that parental permission may not be appropriate, for example, regarding health care for contraception. Adolescents' rights to both clinical care and research may be compromised if parental permission is required for research participation. We strongly believe that adolescent confidentiality is RISKED in this study if there is parental consent.

Study Procedures

Eligible enrolled patients will either text message in the ED will confirm intervention receipt (manual enrollment) or will text RipRoad for enrollment (technological enrollment). This will ensure texting capabilities.

10 participants will receive the 2 month intervention as a beta test.[26] They will receive weekly follow-up calls to qualitatively assess real-life occurrences, such as current sexual activity, change in pregnancy intentions, and perspectives of the messages. Questions will include, "*What about the program is least or most engaging?"* and *"How have your contraceptive choices change because of the texts?".*

Other probes may include questions about message frequency and time of day. Texts will then be refined and finalized. 40 participants will receive the complete intervention to assess feasibility and acceptability, and potential effectiveness. These participants will not be assessed weekly but rather 3 months after enrollment (week 12).

We expect that approximately 10 of the 50 participants will have technological issues with their phones such as phone disconnections. That is why we have a target accrual of 50 but an actual accrual of 40.

Sources of material

Similar to our prior texting trial (**IRB #AAAM3457**), we will collect data from the EMR, a baseline survey, telephone follow-up, and mobile platform provider.

- The EMR tracking board in the ED will be used by research coordinators and investigators to identify potentially eligible patients. The EMR will also be used to collect follow-up information. (See Documents)
- A baseline survey will collect information regarding
    - Demographics (such as age and grade in school),
    - Reproductive and sexual history (such as prior use of birth control methods, age at first intercourse, and number of sexual partners),
    - Prior medical care (such as last time to a primary care provider and history of contraceptive counseling by a provider),
    - Contraceptive knowledge,
    - Decisional conflict with choosing a contraceptive method,
    - Psychosocial mediators of behavior change (self-efficacy, self-esteem, social support)
    - and pregnancy intentions (such as wanting and timing of future pregnancies).

Questions for the survey were adapted from the Youth Risk Behavioral Survey, National Survey of Family Growth, The Fog Zone (Guttmacher validated survey set) and others written *de* novo based on investigator expertise. (See Documents)

- Telephone follow-up phone calls will be completed to determine outcomes, including contraceptive initiation. (See Documents)
- Two-way text messages will be delivered and received by RipRoad, a HIPAA-compliant mobile provider. This company has been used by Columbia University researchers in the past (see studies by Dr. Melissa Stockwell) and has a Business Agreement with Columbia.
- Upon enrollment into the study, participants will watch two short videos and receive a link to the website, www.dr-erica.com.
    - The first video is a short explanation of how pregnancy occurs that was created by StayTeen, a reliable, adolescent-friendly educational website. The video can be found at http://stayteen.org/videos and is called Birth Control 101: Pregnancy. We think this is important for all females to watch so they understand how pregnancy occurs.
    - The second video is a compilation of 6 1-minute videos of 6 birth control methods. Many adolescents know very little about birth control methods, and the acquisition of knowledge is

important to making healthy decisions. These videos are also on Stay Teen (http://stayteen.org/videos) and are on the shot, ring, pill, patch, IUD, and Implant.

- In our prior qualitative interviews, we learned that adolescents receive their health information from unreliable sources, especially on the Internet. We created www.dr-erica.com as a one-stop website that contains reliable, medically accurate links to websites such as StayTeen.org and Bedsider.org. Topics include birth control options, local clinics, testimonials, and an introduction to who Dr.Erica is. Many of the links we sent to teens in our texts are on this site. This site contains NO Columbia identifiers, collects NO patient identifiers, and is approved by Columbia University Information Technology.

- All text messages are attached under Documents.

Statistical Analysis

For the first 10 participants, we will measure acceptability of the program via weekly follow-up phone calls. (See Documents) Questions include which messages the participants liked the best, the least, and why.

For the following 90 participants, we will summarize data using standard descriptive statistics.

Feasibility of the program will be determined by measuring the proportion of those eligible who are enrolled, the lost to follow up and opt out rates, and the texting response rates (as an indicator of engagement). We will summarize technological problems such as bounced back messages by proportions.

Acceptability will be determined after the intervention via web-based surveys (assessing satisfaction using a 5 point Likert scale and free-text responses) and telephone follow-up (including open ended questions regarding message satisfaction).

Outcomes will be measured at month 3, which is 2 weeks after the completion of the 10-week intervention. We will assess the primary patient-oriented outcome of whether the participant initiated effective contraception based on EMR review and self-report. We will consider “effective contraception initiated” if (1) patient self-reports initiation or (2) there is EMR documentation of initiation. We define “effective contraception not initiated” if noted by self-report to not have initiated, or lost to follow-up and no evidence of initiation in EMR.

Another outcome is decisional conflict. This measures a participant’s level of commitment to choosing a birth control method and has been used in other contraceptive studies and is a validated scale. We are using the low literacy version to meet the needs of our adolescent population.

We will also conduct exploratory analyses to identify characteristics of participants who appear more likely to opt out of the study (allowing us to develop further retention strategies). Finally, we will examine texting response rates over time and how this relates to contraception initiation. Secondary outcomes include follow-up to reproductive care clinics, pregnancy rates, an increase in condom use, talking to an adult about birth control, and psychosocial mediators of behavior change.

Part 2: The pilot randomized control trial

Strategy: We will conduct a pilot RCT of 250 adolescent females at high risk of unintended pregnancy to receive either the 10-week texting program, Dr. Erica, or standard discharge instructions. *We hypothesize that the texting program will be feasible, acceptable, and increase contraceptive initiation rates (our primary outcome).*

Setting: We will recruit patients from the pediatric ED at New York-Presbyterian Children's Hospital, which cares for over 50,000 patients per year. Patients are predominantly Hispanic, insured, and of low socioeconomic status.

Subjects: The eligibility criteria is the same as Study Part #1. Inclusion: (1) age 14-19 years and (2) sexually active with males in the past 3 months. Exclusion: (1) currently using any "effective" form of contraception (as defined by the World Health Organization and includes the Shot, intrauterine device, ring, implantable device, Patch, birth control pills, or sterilization), (2) do not own a mobile phone with texting, (3) are pregnant, (4) are too ill for participation per the attending physician, (5) are cognitively impaired, (6) do not live locally within the 5 boroughs, Westchester, Rockland, Nassau or Suffolk counties, (7) do not speak English or (8) want to "become pregnant in the next year."[50,51]

Recruitment (same as Part 1)

A member of the research team will identify potentially eligible patients using the electronic medical record (EMR) in the pediatric Emergency Department at New York-Presbyterian Children's Hospital of New York. Our EMR reveals the age of each patient. The research team member will ask the medical provider caring the patient to confirm eligibility criteria. If a patient is eligible, that provider will privately introduce the study and ask if a research team member can explain it further.

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J. **Laws have evolved over time to try to include adolescents in research**. Beginning in the 1960s, laws in many states began to accord minors the right to consent to emergency care and to medical treatment of conditions such as pregnancy, STDs, and drug, alcohol, and mental health problems. Similarly, state laws have recognized the right of minors with a certain status, such as "mature" or emancipated minors to consent to their own care. Other minors authorized to consent may include those who are parents, are living independently of their own parents, have graduated from high school, or have reached a specific age. In addition to the explicit state statutes, minors' autonomy in health care decision-making and privacy has been protected in federal law. In Planned Parenthood of Missouri v. Danforth, 1976, Carey v. Population Services International, 1977, and Belloti v. Baird, 1979, and a long line of other cases, the United States Supreme Court recognized that the constitutional right of privacy protects minors as well as adults, particularly for reproductive health care, including contraceptives.
K. Research on cognition and capacity suggests that both adolescents and younger children show significant ability to provide informed consent. **For mid- and late adolescents (aged 14 years old or older), understanding of research and the cognitive ability to make decisions about research participation are similar to these abilities in adults.**
L. Lastly, the justification for conducting research on reproductive health in adolescents is the same as that for any biomedical or behavioural research: only by carrying out well-designed studies can adequate information be gained that will enable delivery of appropriate preventive and therapeutic services to this population group. Therefore, research on reproductive health involving adolescents should be undertaken in order to enhance scientific knowledge specific to these individuals. The omission of such research can perpetuate inadequate understanding of the particular reproductive health needs of adolescents and result in failure to deliver adequate services to this group.

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Additional reasons that support our request for a waiver of assent with a substitute of an information sheet AND ***a waiver of a parental consent*** *are the following:*

F. The definition of children in the federal regulations recognizes the legal status of mature and emancipated minors under state law and the ability of adolescents to consent for specific health services. These state minor consent laws implicitly recognize that under certain circumstances minors are capable of making independent judgments and that this emerging decision-making capacity should be respected. Parental permission is not required under the federal regulations, where adolescents do not fit the regulatory definition of children.

G. Patients who are younger than 18 years old and present to the ED for a reproductive health care concern can legally provide their own consent. New York Public Health Law (Title 1, #2305 (2)) states that a person under the age of 21 years may receive reproductive health care without the consent or knowledge of parents or guardians of said person, when said person has been infected or exposed to a sexually transmitted disease.

H. New York Consolidated Law, Social Service Law 350(e). Family planning services and supplies shall be offered and promptly furnished to eligible persons of childbearing age, including children who can be considered sexually active, who desire such services and supplies, in accordance with the regulations of the department.

I. Using the US federal definition of children, teenagers presenting for reproductive complaints are not considered children and are considered adults for research purposes. The federal Title X legislation requires that confidential services be available to adolescents in Title X-funded family planning clinics, such as the Columbia family planning clinic, and the US Supreme Court has extended privacy rights in matters related to the use of contraception to minors.

J. Under the federal regulations governing research, the IRB may waive the requirement for parental permission for research involving children (including minor adolescents) if parental permission is deemed not reasonable or ethically problematic. The National Commission noted that IRBs may determine that parental permission may not be appropriate, for example, regarding health care for contraception. Adolescents' rights to both clinical care and research may be compromised if parental permission is required for research participation. We strongly believe that adolescent confidentiality is RISKED in this study if there is parental consent.

Study Procedures: (different than Part 1)

After a patient provides informed consent, participants will complete a baseline questionnaire (new version attached as a Document, which is a shorter version of Part 1 baseline questionnaire).

Participants will then be block-randomized into one of two arms, Text Messaging (TM) or Standard Referral (SR). Participants will receive a $10 gift card.

After randomization, participants in the TM arm will receive the texting intervention. The server will store all libraries of branched-logic messages and responses. All ingoing and outgoing texts will be time-stamped, recorded, and accessible to investigators.

Patients randomized to the SR arm will receive a welcome text message and then standard medical care as decided by their emergency medicine physician.

Sources of material (same as Part 1 except for when mentioned as unique to Part 2)

Similar to our prior texting trial (**IRB #AAAM3457**), we will collect data from the EMR, a baseline survey, telephone follow-up, and mobile platform provider.

- The EMR tracking board in the ED will be used by research coordinators and investigators to identify potentially eligible patients. The EMR will also be used to collect follow-up information. (See Documents)
- A baseline survey will collect information regarding
    - Demographics (such as age and grade in school),
    - Reproductive and sexual history (such as prior use of birth control methods, age at first intercourse, and number of sexual partners),
    - Prior medical care (such as last time to a primary care provider and history of contraceptive counseling by a provider),
    - Contraceptive knowledge,
    - Decisional conflict with choosing a contraceptive method,
    - Psychosocial mediators of behavior change (self-efficacy, self-esteem, social support)
    - and pregnancy intentions (such as wanting and timing of future pregnancies).

Questions for the survey were adapted from the Youth Risk Behavioral Survey, National Survey of Family Growth, The Fog Zone (Guttmacher validated survey set) and others written *de* novo based on investigator expertise. (See Documents)

- Telephone follow-up phone calls will be completed to determine outcomes, including contraceptive initiation. (See Documents)
- Two-way text messages will be delivered and received by RipRoad, a HIPAA-compliant mobile provider. This company has been used by Columbia University researchers in the past (see studies by Dr. Melissa Stockwell) and has a Business Agreement with Columbia.
- Upon enrollment into the study, participants will watch two short videos and receive a link to the website, www.dr-erica.com.
    - The first video is a short explanation of our program which can be viewed at www.dr-erica.com/introductory.video.
    - The second video a video about birth control options which can be viewed at https://vimeo.com/271757026.
    - In our prior qualitative interviews, we learned that adolescents receive their health information from unreliable sources, especially on the Internet. We created www.dr-erica.com as a one-stop website that contains reliable, medically accurate links to websites such as StayTeen.org and Bedsider.org. Topics include birth control options, local clinics, testimonials, and an introduction to who Dr.Erica is. Many of the links we sent to teens in our texts are on this site. This site contains NO Columbia identifiers, collects NO patient identifiers, and is approved by Columbia University Information Technology.

- (NEW TO THIS MODIFICATION): We will be asking for email addresses for the following two reasons:
    - Disconnected phone numbers: Adolescents often change phone numbers. If RipRoad reports that a phone number has "undelivered" texts, that is usually due to a disconnected phone number. We will email that participant (using the email template attached in Documents) to ask for an updated phone number.
    - Follow up: If a participant does not complete the follow up survey (sent via text as a link), she will be sent an email with the follow-up survey link (using the email template attached in Documents).
- All text messages are attached under Documents.
- Based on preliminary feedback from Study Part 1, we found that many adolescent text questions into the program such as "Where can I get birth control pills?". Because this program is automated, when questions are received, we send an error message that reads, "Sorry, we do not understand that. If you are answering a question, please reread & try again. If you have general questions, check out www.dr-erica.com." Therefore, these questions are never answered by the program. As a solution to this, we have built in "Dr. Erica Office Hours." This will work in the following manner:
    - Any incoming response (text into the program by a participant) that is 4 or more words will trigger two events:
        - A response text to the participant which reads as follows: "Sorry, I don't understand your text. But we can answer your questions LIVE during our Dr. Erica Office Hours. You can text privately with a confidential health educator who can answer all your questions! Dr. Erica Office Hours are from 7-8pm. I'll have her text you this week and let you both connect. In the meanwhile, check out dr-erica.com."
        - An email to the study PI: All texts received into the RipRoad system will trigger an immediate email to the PI. This will alert to PI who will be texted during the Dr. Erica Office Hours.
    - Dr. Erica Office Hours: These will occur from 7-8:30pm. Dr. Lauren Chernick (the PI and board-certified pediatrician and pediatric emergency provider) will manage the text message interactions. She will follow the Dr. Erica Office Hours Handbook (attached as a document) and dispense no personal medical advice. The email interaction will begin as follows:

1.	**Introduction** Example: "Hi [nickname]! Welcome to Dr. Erica office hours."
2.	**Warm welcome** Example: "We will be open for the next hour and able to answer your questions. I am trained health professional and what you say here is private and confidential."
3.	**Clarifying questions** Example: "I see you asked Dr. Erica a question. You asked [insert question here]. I think I can help you answer that."

        - Dr. Chernick will answer this question using the Dr. Erica Office Hours Handbook. These questions and answers are evidence-based and many borrowed from a Planned Parenthood Program that provides live chat opportunities for women across the US. This program has been in existence for several years and has provided medical information to thousands of women across the USA.
        - If a participant poses a question outside the scope of this handbook, such as medical advice (which we define as anything outside the scope of our guidebook), she will receive the following text:

- "I am sorry but that is outside the scope of what I can answer by text message. I suggest you talk to your medical provider or call the Family Planning Clinic for an appointment. You can also check out dr-erica.com for more information."

Outcomes and Data Sources:

Feasibility will be operationalized as the following dependent variables: (a) rate of refusal to participate (*expected <20%*), (b) opt outs (texted to stop receiving messages; *expected <5%*), (c) loss to follow up (*expected <20%*), (d) technological failures (frequency and proportion of text message "bounce backs"; *expected <20%*), (e) response to texting interactivity, as an indicator of engagement (*expected >80%*), and (f) time to reply to texting interactivity (expected *<15 sec*). Data for these outcomes will come directly from our mobile platform provider.

Acceptability will be based on participant feedback. We expect that participants will *"like"* messages *(>4* on a Likert scale) and find the intervention "*relatable," "helpful," and "engaging*," when asked open-ended questions about the intervention. These outcomes will be determined during month 3, 2 weeks after the 10-week intervention, via phone follow up and web-based survey sent via text message link.

Efficacy The primary outcome is effective contraception initiation, defined as (1) patient self-reports initiation at phone follow up or via text or (2) there is electronic medical review (EMR) documentation of initiation. If there is a discrepancy between self-report and EMR documentation (e.g. received prescription but never started pills), we will prioritize self-report. We define "contraception not initiated" if noted by self-report to not have initiated or if lost to follow up and no evidence of initiation in EMR.

Similar to our cohort study, our second primary outcome is decisional conflict. This measures a participant's level of commitment to choosing a birth control method and has been used in other contraceptive studies and is a validated scale. We are using the low literacy version to meet the needs of our adolescent population.

We will also conduct exploratory analyses to identify characteristics of participants who appear more likely to opt out of the study (allowing us to develop further retention strategies). Finally, we will examine texting response rates over time and how this relates to contraception initiation.

Secondary outcomes include follow-up to reproductive care clinics, pregnancy rates, an increase in condom use, talking to an adult about birth control, and psychosocial mediators of behavior change.

Data for secondary outcomes will also be collected via phone follow up and EMR review during month 3 and interactive text messaging at weeks 3 and 6. A baseline survey will collect information regarding demographics, reproductive and sexual history, prior medical care, and pregnancy intentions. Questions were adapted from the Youth Risk Behavioral Survey, National Survey of Family Growth, and written *de novo*.

Analysis: We will analyze both an intention-to-treat (ITT) population and per-protocol population. The ITT population will include all enrolled and randomized patients. The per-protocol population will only include participants who completed follow-up and, for those in the intervention group, excludes those who received none of the text messages. *Acceptability and Feasibility:* We will summarize outcomes related to feasibility and acceptability using standard descriptive statistics and conduct exploratory bivariable analyses to identify characteristics of participants who appear more likely to opt out of the study (in order to develop further retention strategies). *Potential efficacy:* We will calculate the absolute risk difference (ARD) between groups with exact test-based 95% confidence intervals. For the ITT analysis, the outcome for those lost to follow-up will be imputed conservatively as contraception not initiated. We will use the chi-square test to determine the potential effect of the intervention on contraception initiation. We will conduct exploratory multivariable logistic regression analyses to test if age group (older (18-19 years) versus younger (17 and younger)), ethnicity, race, prior family planning clinic visits, having a primary care provider, prior pregnancy, and prior use of contraceptives, potentially confound or modify the effect of texting on contraception initiation. We will also examine texting response rates over time and how this relates to contraception initiation. We will also measure changes in contraception knowledge and decisional conflict based on proportions.

Sample size: Using prior ED studies, we expect to enroll approximately 250 patients over 2 years. Accounting for a 20% lost to follow up rate, this would enable us to detect a 17% absolute increase in contraception initiation

(assuming 17% in SR arm, based on prior data) with 80% power (p=0.05, two sided). We readily understand that the effect size is likely not to be this large. As this is a pilot trial (Phase II), our goal is to gather the preliminary data needed for a definitive, multi-center RCT grant application (Phase III). We also plan to enroll equal proportions of younger (aged 14-17) and older (aged 18-19) adolescents to verify our prior findings that age modifies the effect of the intervention, with younger teens more often initiating contraceptives than older teens.[12]

Data and follow-up

Data will remain confidential. Any protected health information (including email addresses) will be stored in an encrypted password-protected database with access granted only to IRB approved study investigators and coordinators. Surveys will be completed using Qualtrics, a password protected internet-based survey tool. We will use a portable tablet such as an iPad to allow the patient to complete the questionnaire in privacy in the ED using the Mercury secure network. This tablet will also be password protected. Texting services will be provided by a HIPAA compliant provider of text message services, RipRoad. All email will be sent from the CUMC Microsoft Outlook server from a CUMC email address (e.g. lc2243@columbia.edu; the PI of this study).

The risk to loss of privacy is low. Qualitative studies suggest that adolescents do not perceive parents reading their texts as threat. Adolescents describe that their phones are usually password protected and parents do not read their texts.[20] Additionally, in our prior studies, we demonstrated that no participant felt unsafe from receiving the text messages.[24,43]

Potential benefits to subjects and others

This study presents few potential risks to its participants. Instead, it presents several potential direct benefits to subjects. The patient may benefit from participation by gaining knowledge about her reproductive health. From previous studies, we know that adolescent females in our ED report not wanting to become pregnant and are interested in starting contraception.[2] Our study connects them to reproductive services, builds self-efficacy, provides reliable factual sexual health information, supports healthy relationships, provides information on how to talk to trusted adults about sex, dispels contraceptive myths, and provides information on where to obtain birth control locally. The intervention also utilizes the psychology of motivational interviewing, which emphasizes the importance of adolescent involvement in their decision making, and incorporates sexual education from evidence-based curriculums.

Importance of knowledge to be gained

The potential risks to subjects are reasonable in relation to the knowledge that will result from the study. We will learn if a user-informed, theory-based texting intervention is feasible, acceptable and potentially efficacious. Data from this study will allow us to decide if we should proceed with the conduct of a larger, multi-center RCT. We will also learn if texting is a useful way to provide adolescent ED patients with information, based on the feedback we receive. This will inform national models for health promotion both inside and outside the ED setting.

This texting intervention is automated, reproducible and scalable. As such, it could be an important vehicle to disseminate reliable sexual health information to adolescents who have unmet health needs and may not have other sources of medical care.

Alternatives

Subjects do not have to participate and their clinical care will not be affected in any way.

Data and Safety Monitoring (as written in our K23 application)

We will create an independent data safety and monitoring board (DSMB) consisting of 4 members not associated with the trial who have expertise in the study content area or the conduct of clinical trials. All members will be from the schools of Columbia University but will not be associated with the trial. We will monitor for any conflicts of interest.

The DSMB will primarily monitor participant safety and the scientific conduct of the trial. No interim analyses for efficacy will be undertaken. We will create a data and safety monitoring plan prior to study initiation.

The DSMB will be responsible for the following:

- Reviewing the research protocol and plans for data and safety monitoring
- Ensuring that the monitoring is timely (at least twice a year) and that those responsible for the monitoring have appropriate expertise to accomplish its mission
- Evaluating the progress of the interventional trial, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of the trial site, and other factors that can affect study outcome
- Conducting ongoing monitoring of the trial, with review of the protocol prior to study initiation and reviews when half of the participants are accrued and at study completion
- Ensuring that the study investigators respond to recommendations emanating from the monitoring activities
- Protecting the confidentiality of the data and the results of monitoring

Meetings will be closed and written summary reports will identify topics discussed by the DSMB and describe their individual findings, overall safety assessment and recommendations. The rationale for recommendations will be included when appropriate. This report will generally not include confidential information. The final summary report will be forwarded to NIH program officer and Principal Investigator.

We consider an Adverse Event to be any loss to confidentiality of patient data. If that occurs, the DSMB will be notified within 24 hours and a DSMB review will ensue. We also define an Adverse Event as an event where a participant feels threatened or is hurt due to the text messages we send her. This is a question we ask on our follow up phone survey. If this occurs, we will contact our DSMB. Changes will be made to the intervention or protocol accordingly.

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