Postpartum Pregnancy App

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1.0 Background

Short Interpregnancy Intervals have Adverse Consequences for Adolescents. Healthy People 2020 identifies short interpregnancy intervals (IPIs), i.e., pregnancies within 18 months of a previous birth, as an issue of national importance [1]. Short IPIs pose risks for mothers and newborns alike [2] including preterm birth, low birth weight, small for gestational age, and placental abruption [3-5]. IPIs less than 12 months increase risk of neonatal death [6]. One in three American women ages 15-44 have short IPIs [7] Short IPIs disproportionately affect low income, undereducated, women of color [8] accounting for an estimated 8% of low birth weight and preterm infants among African American and Hispanic mothers [9]. However, adolescents (ages 15-25) bear the greatest burden [3, 10]. With one in five births to adolescents a repeat birth [7], over two thirds following short IPIs [11-13] leaving young mothers to care for multiple babies. Postpartum contraception significantly, and perhaps uniquely, lengthens IPIs [14-16]. Injectables reduce short IPIs, with only 14.2% of postpartum adolescent depot medroxyprogesterone acetate (DMPA) users with short IPIs [17]. Women using long acting reversible contraception (LARC), implants and intrauterine devices (IUDs), have optimal IPIs compared to users of oral contraceptive pills and condoms [18]. Initiation of contraception prior to hospital discharge is a crucial strategy, as 10-40% of women do not attend a postpartum visit [19]; 50% of women resume sexual activity before the standard postpartum visit [20, 21] and ovulation can return by postpartum day 25 [22].

A.2. Research and New Policies Support Immediate Postpartum Contraception. All contraceptive methods, save combined hormonal contraception, are safe for use within 48 hours of delivery. Immediate postpartum implant use independently predicts longer IPIs in adolescents [25] as well as general study populations [18]. Significant research demonstrates adolescent interest in immediate postpartum LARC [26], as well as its cost effectiveness in both adolescent and general populations of women [27-29]. Immediate postpartum IUD placement, despite expulsion risk, was found effective in randomized control trials of immediate versus delayed placement, with equal rates of use at six months post vaginal and post cesarean delivery [30, 31]. However, our team has identified several barriers to receiving IUDs for adolescents after hospital discharge, including outdated IUD eligibility requirements and lack of insurance coverage [23]. Hitherto, Medicaid reimbursement policy bundles payment within a global delivery fee, significantly hindering immediate LARC placement [32, 33]. Now, seventeen states, including Illinois, and the District of Columbia allow providers to bill for immediate LARC placement.

A.3. A History of Coercive Contraceptive Practices Calls for Patient-Centered Postpartum Contraceptive Care. Yet, caution is needed given a long history of contraceptive coercion of low-income communities. In 2001, the Institute of Medicine (IOM) published Crossing the Quality Chasm, highlighting patient-centered care as a model for improving quality of care [34]. Within this model, care is respectful and responsive to individual patient preferences, needs, and values. Patients are actively engaged in making decisions about their health care and continuously informed and educated on all the care options [35, 36]. Significant research shows the benefits of "patient activation" and "engagement". Actively engaged patients have lower healthcare utilization [37], greater satisfaction [38, 39], and better health outcomes [40-42]. Patient-centered approaches have been advocated for within contraception counseling and delivery [43, 44] and positively influences adolescent contraceptive use [45].

A.4. Current Provider Practices May Limit Patient-Centered Postpartum Care. Provider practices can limit patient-centered care through contraceptive underuse and overuse. Only 50% of obstetrician gynecologists offer implants at all due to lack of patient interest and provider training [46]. Despite research to the contrary [47], progestin-only methods such as DMPA have been denied due to concerns about lactogenesis or hormones in breast milk [30]. Surveys of obstetrician gynecologists and family physicians show lack of knowledge of LARC placement [48]. Despite endorsement by major professional organizations such as the American College of Obstetricians and Gynecologists (ACOG) and the CDC, many clinicians deny adolescents LARC [49]. Yet, as barriers to contraception decrease there is also a risk of contraceptive overuse. Many providers have adopted directive or first-line counseling approaches in which LARC is recommended above all others [50][51].

A.5. Tailored Patient Approaches are Needed to "Activate" Patients. Racial and ethnic minorities in general are less willing to participate in health care decision-making [52]. Latinos and African Americans report worse patient-provider relationships and communication [53]. These patients also receive less information regarding treatment and are less likely to be asked about their preferences [54]. Populations with low activation are likely to benefit from improved activation [55]. There is a need for interventions designed for the characteristics of the population (e.g., demographic, culture, literacy, age) [56].

A.6. Technological Interventions Can Support Health Care. Interactive, computer-based programs provide a novel platform for delivering health interventions [57]. Tailored, theory-based interventions have been effective for assisting with smoking cessation [58], community counseling interventions for repeat births among low-income African American adolescent mothers [59], promoting adherence to antiretroviral medications [60], and increasing awareness of diabetes complications [61]. Touchscreen computer and tablet interventions have increased likelihood of choosing highly effective contraception [62, 63]. Young women are willing to receive sexual health information via digital media, perceiving these delivery routes as private and accessible [64, 65].

2.0 Rationale and Specific Aims

The proposed study seeks to evaluate a post-partum app. Using a pre-post survey design the following hypotheses will be tested:

H1: Do end users (pregnant women age 15-25) find the app usable, feasible, and acceptable and recommend continued development?
H2: After using the app, users will have increased information about IPIs.
H3: After using the app, users will have increased intention to communicate about IPIs with their provider.
H4: After using the app, users will have increased Patient Activation Measures.

3.0 Inclusion/Exclusion Criteria

Inclusion criteria are:

(1) Being 18-25 years old
(2) Currently pregnant.
(3) Identify as African American/Black

Exclusion criteria are:

Being male
Being over age 25.
Not identifying as African American/Black

The rationale for exclusion criteria is to focus on adolescent and young adult pregnancy and pregnancy prevention among this group.

4.0 Recruitment and Enrollment

We will recruit up to 40 young pregnant women who are between 15-25 to evaluate our app. Participants will be paid $35 upon completion of study activities. Participants will be recruited from ACCESS prenatal care or maternity community clinic waiting rooms.

Prenatal case management teams will inform patients there is a research study they may be eligible for. If potential participants are interested they will be told to contact a research team member in the waiting room. Research team members will administer a short screener survey on an iPad to ensure eligibility. The survey will inform potential participants if they are eligible or not. If participants are eligible they will be taken through informed consent/assent.

Additionally flyers will be posted directing interested potential participants to contact an ACCESS staff member or text a number (that will be a study phone, that is a Ci3 phone used only for study purposes) to enroll in the study. ACCESS team members will refer potential participants to the research team member in the waiting room. The same screener and informed consent/assent procedure will be performed.

5.0 Study Procedures

Participants will be given a consent/assent form to read. A researcher will ask the participant if they have any questions. Once all questions have been resolved, or if there are no questions, the participant will sign the consent/assent form. Consent/assent forms will be stored in a locked filing cabinet in a locked University of Chicago office.

All participants will be given an iPad tablet containing a brief pre survey to fill out. This survey will include questions on demographics, contraception knowledge, contraception use, and patient activation measures (readiness of patients to take charge of their own healthcare). This survey will take 20-30 minutes to complete.

Next participants will use the app on the iPad for 5-10 minutes. Participants will be instructed to go through all parts of the app.

Lastly, participants will complete a brief post survey on the iPad. The survey will include questions on usability, feasibility, and acceptability of the app, patient activation measures, and contraception knowledge. This survey will take 20-30 minutes to complete.

All study activities will take between 40-70 minutes to complete. All study activities will take place in the waiting room.

At the conclusion of the post surveys, participants will be paid and participation in the study will end.

Participants will be paid $35 in visa gift card or cash equivalent after completion of the post survey.

6.0 Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

Participants are exposed to few risks in this study. The informed consent/assent will assure participants complete confidentiality throughout the study. Possible adverse events that are unanticipated will be brought to the attention of the Principal Investigators and Co-investigator, and reported immediately to the IRB. The IRB will determine whether it is appropriate to stop the study protocol temporarily or will provide suggestions/modifications to the study procedures. Possible modifications include adding these possible adverse events to the consent/assent form and re-consenting all study participants. The PI will be responsible for monitoring participant safety on a monthly basis at regularly scheduled research meetings. They will keep a written log of all adverse events and ensure that the IRB is contacted immediately. They will also keep a log of the outcome of IRB decisions regarding adverse events and apprise the research team of any changes that need to be made as a result of IRB decisions. If a participant discloses suicidal ideation, any type of violence, or homicidal intent, the Research Team will assess the level of risk and determine the best course of action (e.g., sending the participant to the emergency room, notifying the police).

7.0 Privacy/Confidentiality Issues

Study records that identify the participant will be kept confidential. All participants will be assigned a unique study identifier. Informed consents/assents with the subjects' names will be stored at the UC and only accessible to designated research staff. Printed consent/assent forms will be stored in a locked filing cabinet in a locked University of Chicago office and they will only be available to the research team described in the proposal. All reports, manuscripts, and presentations will omit identifying information. Participants are informed of these protections in the consent/assent form.

8.0 Record Retention

All data will be stored on a secure, password- protected computer or iPad tablet and printed consent/assent forms will be stored in a locked filing cabinet in a locked University of Chicago office. They will only be available to the research team.

9.0 Statistical Analysis Plan

Descriptive statistics will be used to describe the study sample and the feasibility, usability, and acceptability of the app. Appropriate parametric and nonparametric paired statistics will be used for outcomes assessed at pre- and post-test based on data normality and how well assumptions are met.

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