Research Protocol for

Use of Reproductive Life Planning Tool At the Pediatric Well-baby Visit with Postpartum Women

Background

Unintended pregnancy is a persistent public health challenge in the U.S. In 2011, 45% of the 6.1 million pregnancies were unintended.[1] Women who have had a recent pregnancy are at increased risk of unintended pregnancy compared to other women of reproductive age not using contraception,[2] with rates up to 44% in the first postpartum (PP) year.[3] In addition, adequate birth spacing in the postpartum period is important for the health of mother and infant. Pregnancies with a short interpregnancy interval (within 18 months of delivery) have been associated with increased risk of preeclampsia, preterm birth, and low birth weight.[4] Low-income women of color are at increased risk of unintended pregnancy and suboptimal birth spacing which in turn increases their risk of adverse pregnancy outcomes.[5] Improved access to postpartum contraception is needed to reduce unintended pregnancies and help women achieve desired birth spacing.[6,7] While the obstetric postpartum visit has historically provided the opportunity for women to receive contraception, many women, particularly low-income women, do not attend this visit.[8] Uptake of family planning is an ongoing process throughout the postpartum period and new approaches are needed to ensure women receive the care they need when they desire it.[9]

Over the last decade, there has been an increased focused on preconception and interconception care as an approach to improve women's and infant's health.[10] The growing interest in the continuum of reproductive health care has gained momentum and a focus by health professionals on the **well-woman primary care visit** is likely to continue.[11] In this context, postpartum care has emerged as the pivotal link between prenatal care and well-woman health care. The fact that a large number of vulnerable women, including low-income women and women of color, fail to seek care during the postpartum period is a major concern, particularly because they are at higher risk of chronic health issues and unintended pregnancy.[12,13] On the other hand, women are very likely to bring their newborns in for care during this same time period in accordance with the well-baby visit (WBV) schedule.[14]

One recent approach to assist women to reflect on their reproductive health as well as contraceptive options to support pregnancy planning, is the integration of a Reproductive Life Planning Tool (RLPT) by health care providers into routine practice.[15] To date, reproductive life planning has typically been discussed in the context of a woman's primary care or family planning visit; as such, little is known about the potential use of a RLPT as a prompt for referral to care in the context of the WBV, particularly for women who may not receive routine postpartum care.[16-21] Research has shown that pediatric providers are open to referring PP mothers for health care; however, little is known about whether those referrals result in care.[22] The objective of the proposed pilot study is to test an innovative system-level intervention in which postpartum women complete a self-administered (RLPT) during their infants' 2-month WBV, which is

reviewed by the pediatrician and prompts a referral for care as needed. This feasibility study focuses on implementing a systems change to improve the accessibility of well-woman primary care including reproductive health care for low-income minority postpartum women.

Women experience a substantial amount of morbidity during pregnancy which often continues into the postpartum (PP) period.[23] In turn, women's PP health status affects their lifelong health status as well as their health during a subsequent pregnancy.[24] Receiving appropriate health care during the PP period, and continued care during the interconception period, can help to ameliorate these risks and improve health for women and children. While few studies examine women's utilization of the PP visit, estimates for non-attendance vary (11%-40%).[8,25-28] Among low-income Medicaid-insured women in Illinois, fewer than 53.7% received a PP visit in 2013; this is also true for the Medicaid population served by the University of Illinois Health system (UIH).[29]

Postpartum women are at particularly high risk of unintended pregnancy.[3] While some women have access to contraception in the hospital after delivery, provision varies and typically women do not receive contraception until the 6-week postpartum visit. Unfortunately, the timing of the 6-week visit is not based on current evidence about women's sexual activity after pregnancy or the need for timely PP contraception; thus, over half of women are at risk for a rapid repeat pregnancy.[30] Glazer and colleagues found 29% of women were using no contraceptive method at 4-6 months postpartum despite the fact they had resumed sexual intercourse and 32% percent of the study population were relying on less effective methods.[30]

In contrast to the PP visit, the Well-Baby Visit (WBV) is highly utilized. In 2011-2012, 90.9% of U.S. infants received visits during the first year of life.[14] Because women are more likely to obtain care for their infants, compared to their own PP care, they are likely to attend multiple visits in the pediatric setting during the PP period. In addition, the WBV is increasingly acknowledged as a site of care where maternal health issues can be addressed. AAP Bright Futures guidelines for health supervision encourage providers to assess maternal well-being as part of routine care of infants.[31] This approach is particularly salient for the many women who do not attend a routine PP visit or who do not select a method of contraception during their PP visit. While a similar model may exist for women who seek care from a family physician who can provide care to both the mother and her infant, for most families, adult care is separate from pediatric care. Family physicians provide 17% of primary care visits for children ages 0-4, while pediatricians provide the remainder.[32]

To both improve the delivery of interconception care to women of reproductive age and to facilitate discussion of contraceptive needs as part of this care, the Centers for Disease Control and Prevention (CDC) recommends use of a **Reproductive Life Plan Tool**.[10] To date, literature on RLPTs has mostly focused on their use in women-focused primary care settings or in family planning settings.[16,17,19-21,33] This study seeks to test the use of a streamlined self-administered RLPT (attachment) with all PP women attending a 2-month WBV with their infant. Pediatricians will then use the RLPT to

assess women's need for well-woman primary care, then refer and provide an appointment for care for women who desire one.

Specific Aims

Aim I. To determine if introducing a self-administered Reproductive Life Planning Tool (RLPT) with postpartum mothers during the 2-month WBV will increase the proportion of women receiving a well-woman primary care health visit by 6 months postpartum.

Aim Ia. To determine if introducing a self-administered Reproductive Life Planning Tool (RLPT) with postpartum mothers during the 2-month WBV will increase utilization rates of contraception by 6 months postpartum.

Aim II: To assess the extent of system adoption as well as patient-, provider-, and systems-level barriers and facilitators to integrating a self-administered Reproductive Life Planning Tool designed to facilitate referral of postpartum women for primary well-woman care within the context of a pediatric clinic.

Study Design and Intervention

This is a single-site system-level pilot study to measure the impact of a self-administered RLPT (attachment) during the 2-month WBV on PP women's subsequent receipt of primary health care and contraception, compared to usual care. To facilitate women's uptake of a referral for well-woman primary care, women will be offered the opportunity to schedule a visit for herself on the same day as her infant's next WBV or the first available visit if she needs more immediate care. This study will have two phases: **phase 1** is enrollment of a control or baseline group, followed by a washout period; **phase 2** is enrollment of the intervention group (intervention).

During phase 2 (intervention), the self-administered RLPT will be implemented in the Child and Youth Center (CYC, the general pediatric clinic) and the Primary Care Adolescent and Child Clinic (PCAC) at UIH with all PP women bringing infants for the 2-month WBV. The intervention leverages an existing system designed to screen all PP women (through 6-months) for depression. Currently, when a mother checks-in her infant for a visit she is provided an Edinburgh Postpartum Depression Screening tool with instructions to complete and return the tool to the infant's physician during the visit. On a daily basis, completed tools are scanned and saved on a secure server (required for billing purposes). This system has been successful for universal PP depression screening and referral. An audit found that in 91% of all WBVs with a child 0-16 wks., the infant's mother was present and eligible to have an Edinburgh tool completed; of these, 90% had a completed Edinburgh tool provided to the physician. We will pair the RLPT with the Edinburgh tool (back to back on the same piece of paper); women of 2-month olds will be instructed to complete both sides. To test the feasibility of this approach, we briefly tested locating a general women's health screening survey on the back of the Edinburgh tool. During the pilot, 37 infants 0-16 wks. of age had a WBV; 89% of these had a complete Edinburgh. Of those who completed the Edinburgh, 100%

completed the survey on the opposite side, suggesting women are willing to complete another brief questionnaire.

During the WBV, physicians will review the information provided by the woman on the RLPT about general health, reproductive plans, and use of contraception. The pediatrician will use the RLPT to initiate a brief conversation with mothers about the need for a referral for well-woman primary care. We expect this conversation to take less than 3 minutes based on previous studies.[22] We will create a referral process to the UIH Primary Care Plus clinic (internal medicine) through our electronic medical record. At the close of the WBV, if the mother desires a referral the pediatrician can request the referral during the infant's check-out process. Research staff will routinely review all referral needs and initiate scheduling based on the mother's preference. Women will be asked if they prefer the **next available** appointment or an appointment on the **same day as their infant's next WBV**. For women who desire their health care visit on the same day as their infant's next WBV (the 4-month visit), we will schedule both visits on the same day. To the extent possible, the mother's appointment will be earlier the same day (ideally 2 hours before) of the infant's scheduled visit, to promote attendance. We expect that by offering women the opportunity for a primary care visit on the same day as their infants' next WBV, the likelihood of adherence will be much greater than just offering a referral. Among women scheduled for care, if by the date of their infant's next WBV the woman has not attended her visit (she cancels or does not show), the research staff will contact her to reschedule, offering either the first available appointment or co-scheduling with the infant's next WBV.

Reproductive Life Planning Tool: We have created a RLPT (in English and Spanish) based on detailed feedback from physicians and women regarding how best to operationalize a RLPT in the pediatric setting (previous research studies).

Study site: The CYC and PCAC are comprehensive pediatric clinics; patients can be seen by a pediatric faculty member (faculty practice) or by a pediatric resident physician with direct supervision by a faculty member. The clinics serves a predominantly low-income Medicaid-insured population.

Participant Eligibility: Postpartum women 15-49 years presenting with their infants to the CYC or PCAC for a 2-month WBV, and who also receive their own care at UIC (needed for chart abstraction purposes), are eligible to participate in the study. Women must be English and Spanish speakers.

Participant Exclusion: Women who are currently pregnant, less than 15 years or older than 49 years of age, or do not speak English or Spanish.

Participant Recruitment into the Research Study: The intervention is planned as a system-level intervention, thus, all women whose infants are scheduled for a 2-month WBV during the intervention period will have the opportunity to be exposed to the RLPT intervention. On study recruitment days (randomly selected half-days during phase 2), women whose infants are scheduled for a 2-month WBV will be approached by a

research assistant (RA) who will screen for eligibility. Recruitment into the study will occur before, during or after the WBV, baseline surveys will be completed during or after the WBV to avoid biasing women's responses on the RLPT, which is administered *prior* to the WBV. If a woman is eligible and interested in participating, she will be consented and asked if she has time to complete a baseline survey. The baseline survey will include the domains listed in Table 1. To the extent possible, the baseline survey will be self-administered using a tablet computer linked to the RedCap database. A study RA will be available to provide assistance or administer the survey if necessary. When possible, the surveys will be completed immediately after the WBV in a private room. We are sensitive to the fact that women may not have the time to stay after the WBV, in which case we will request permission to conduct the survey by phone at a convenient time. Our research team has extensive experience recruiting PP participants and we have found this to be an effective strategy. Because this is a system-level intervention, women who decline participation in the study will still receive the intervention but will not participate in any research data collection. For example, a woman who does not agree to participate in the study would still have been given the RLPT prior to the infant's visit and, if desired, she will receive a referral and appointment for care though she will not be included in the study.

Though this is a system-level intervention, the intervention is targeting only the 2-month WBV, thus we do not expect a RLPT will be offered to a woman more than once. After consent is obtained, the RA will cross-check the participant list using a secure network on a tablet device to ensure that the woman is not already enrolled. Each RLPT will be linked to the infant by medical record number and date of birth. Limited physician characteristics (male/female, trainee/faculty) will be recorded; no physician names will be collected. The RLPTs for women who are consented and enrolled in the study will remain intact and all data will be collected from the tool and linked to the enrolled mother. The RLPTs for women who are *not* enrolled into the study will be de-identified after the Edinburgh tool is scanned by removing and shredding the patient sticker so no identifying information remains on the form. This will allow us to calculate clinic-specific adoption rates and examine the extent to which provider and system characteristics, such as the type of physician (e.g., attending versus resident), demographic characteristics of the physician (e.g., sex), and clinic operational factors (e.g., morning versus afternoon clinic; day of the week), influences adoption of the intervention (Table 1).

Consent for Intervention Group: Informed consent will be obtained for: 1) a baseline survey; 2) a phone survey at 6 months PP; and 3) access to a woman's medical records to document receipt of health care services. Women will be will reimbursed for their time with gift cards [$10 at baseline and $10 at 6 months]. The RA will log the recruitment process, including number of women approached and if women accepted or refused, participation.

Pediatrician Training: Pediatricians (faculty and resident physicians) will all receive a 1-hour formal training on using the RLPT prior to the start of the study, offered at three different times to accommodate physician schedules. Research staff will touch-base

with pediatricians weekly during the first 4 weeks of the study, and monthly thereafter, to answer questions and encourage consistent provider use of the tool. We will schedule a 'refresher' training 3 months after the start of the study to reinforce appropriate use of the tool. During the training, physicians will be instructed on how to start a conversation with women, what to document on the tool, and how to initiate a referral if needed. Physicians are *not e*xpected to provide contraceptive counseling to mothers, only to engage women in a discussion about their health care needs. An information sheet about the study will be given to all pediatric providers who are trained.

Selection of control group: The control group will be enrolled during phase 1 (first 4 months) prior to the introduction of the intervention. Similar to the intervention group, women will be recruited by an RA before, during or after the health care visit and screened for eligibility. Informed consent will be obtained for a baseline survey using the same procedure as described for the intervention group (same gift card amounts). Because we are studying health behaviors, we cannot share the specific aims of the study with control group participants as this could bias behavior. The control group participants will be told that this is a study monitoring women's general health care experiences at UIH. After enrollment of the control group, a 6-week washout period prior to phase 2 (intervention) will ensure women are not enrolled into both arms of the study.

Sample: This pilot study will enroll at least 50 women per group. This sample size will provide a stable estimate of the intervention's effect on primary care receipt by 6 months postpartum for power calculations for a larger, subsequent study of intervention effectiveness. There are approximately 200 deliveries per month at UIH, with 57% (114) of these infants having a 2-month WBV at UIH. For the 4-month period of recruitment each for control and intervention groups, we can meet our target enrollment of 50 in each group by recruiting women during four of the ten half-day CYC clinics per week, assuming a conservative participation rate of 40%.

Table 1 Study Variable Table

Variable	Specific Aim	Level of Measurement	Time of Collection	Tool	Variable Type
Demographic Data	I	Women	Enrollment	Baseline survey	Covariate
Physician Characteristics Male/Female, Trainee/Faculty	II	Physicians	Enrollment	Medical record schedule	Covariate
Clinical Operations Visit time and day of week	II	Health System	Enrollment	Medical record schedule	Covariate
Health and Family Planning					
Women's general health status	I	Women	Enrollment	Baseline Survey	Covariate

Women's general health behaviors (smoking, alcohol, nutrition and exercise)	I	Women	Enrollment	Baseline Survey	Covariate
Plans for future pregnancy	I	Women	Enrollment	RLPT	Covariate
Current contraception type and use	I	Women	Enrollment	RLPT	Covariate
Pregnancy status	I	Women	6 months postpartum	Phone survey and Chart review	Dependent
Referral to primary care	I	Women	Enrollment	RLPT	Dependent
Receipt of primary care visit	I	Women	6 months postpartum	Phone survey and Chart review	Dependent
Use contraception, duration and method	I	Women	6 months postpartum	Phone survey and Chart review	Dependent
Feasibility, Acceptability, and Adoption of RLPT					
Ease of use, comfort and satisfaction with tool	II	Physician	Year 2	Focus groups	Acceptability
Ease of use, comfort and satisfaction with tool	II	Women	Enrollment	Baseline survey	Acceptability
Women's need and desire for referral	I and II	Women	Enrollment	RLPT	Acceptability
Women's barriers and facilitators	II	Women	6 months postpartum	Phone survey and Chart review	Feasibility
Physician barriers and facilitators	II	Physician	Completion of study	Focus groups	Feasibility
Completion rate for grey box on RLPT form	II	Health System	Enrollment	RLPT completion rate by women and physicians	Adoption

Data Sources and Collection

Surveys of Women: All participants will complete a baseline survey (English and Spanish) at the time of enrollment in the study (during or after the WBV) and will receive

a phone call at 6 months PP for the follow-up survey (survey and interview questions domains listed in Table 1). During the baseline survey, in addition to demographic information, women will be asked about their general health status and health behaviors, and current contraception type and use. Those in intervention arm will be asked about their experience completing the RLPT during the WBV, referral to well-woman primary care (if applicable). For the follow-up survey we will try to reach each participant as close to 6 months as possible, but no later than 9 months PP. Structured phone interviews with women will include questions from the following domains: 1) use of health care services; 2) use and type(s) of contraception; and 3) known pregnancy status. The intervention group interviews will also include experience completing the RLPT during the WBV; and, the process of getting care (for those who chose to do so) (SA II). To verify RLPT exposure at the individual level, the RLPT tool will be linked to the mother using the patient sticker placed on the tool.

Medical Records: Medical records will be reviewed at baseline and at 6 months PP to determine receipt of health care services and contraception. We recognize that some women may receive additional health care outside the UIC system; for this group, we will not be able to confirm medical visits outside the UIC system.

Focus Groups with Providers: We will conduct two in-depth qualitative focus groups with physicians (residents and faculty) after the intervention is complete during study year 2. The focus group guide will include questions from the following domains: 1) Experience implementing the RLPT; and, 2) barriers and facilitators to implementation of RLPT (SA II). In addition, study investigators will keep a running log of barriers and facilitators experienced throughout the intervention implementation period.

Data Management

All survey data will be directly entered into REDcap web-based data capture screens that will be programmed and tested prior to the study. Data will be imported to SAS for analysis. Variables (Table 1) will be merged across time point by study ID and cleaned and recoded. Focus groups will be recorded, transcribed, and uploaded to DeDoose qualitative analysis software. Completion of the Grey Box (physician section of the tool) will be a measure of provider "adoption" of the intervention; completion rates will be tracked by comparing completed forms with completed clinic visits for 2-month WBVs. Completed clinic visit data are available in our existing medical record scheduling system.

Analysis

Specific Aim I and Ia: Baseline characteristics will be assessed for equivalency across groups using chi-square tests for categorical and t-tests for continuous variables. Unbalanced characteristics will be adjusted for in further analyses. The primary outcome, receipt of primary care services for women by 6 months PP (SA I) will be ascertained both by self-report during the 6-month phone interview and by medical record review, in order to minimize missing data. Evidence of a visit from either source

will be counted as receipt. Utilization, type and duration of contraception (SA Ia) by 6 months PP will be assessed similarly. An intent-to-treat analysis will be performed for SA I and Ia. A crude relative risk (RR) and risk difference (RD) will be calculated with 95% confidence intervals to estimate the effect of the intervention on primary outcomes. If adjustment is needed for covariates, RRs and RDs will be estimated using the average marginal predictions from a fitted logistic regression model with the following form:[41]

$$\text{logit}(y) = \beta_0 + \beta_1 x_1 + \beta_2 x_2 + \ldots + \beta_k x_k \text{, } \textit{where:}$$

y = SA 1: Woman's primary care visit by 6 months (1 = Yes/0 = No)
SA 1a: Use of contraception at 6 months (1 = Yes/0 = No)

x_1 = RLPT Intervention (1 = Intervention/0 = Control)

$x_2 - x_k$ = Unbalanced covariates

Specific Aim II: Patient and physician facilitators, barriers and satisfaction data will be gathered from the RLPT, surveys, and focus groups. System adoption will be defined as the number of completed RLPT forms clinic-wide during the intervention (for enrollees and non-enrollees) divided by the total number of eligible visits during that time period, which will be ascertained through the clinic's scheduling database. Adoption will be compared across provider (e.g., status) and clinic operation factors (e.g., day of week) using chi-square tests. Adoption statistics will be shared with providers prior to focus groups, allowing them to elaborate on these findings. Qualitative focus group data from providers will be coded according to domains and analyzed for emergent themes related to feasibility and acceptability. Women's perceptions of feasibility and acceptability will be derived through the survey data and will be analyzed by other key covariates.

Although the findings of this study will reflect the experiences of low-income women at one large medical center in Chicago, they are likely to be relevant to the experiences of many low-income women. While a hospital outpatient clinic is a unique health care setting, the experience of having a pediatrician discuss new mothers' health needs and refer them for their own care is likely to be similar across pediatric practices. This study will add to the emerging literature related to a dual care focus for mother and infant. If this intervention is successful, it will provide evidence of the feasibility of introducing a system-level intervention related to women's health into pediatric practice. This information can inform changes in payment and policy to support the ability of pediatricians to discuss women's health needs and facilitate referral with mothers at their infants' WBV, with the ultimate goal of increasing women's use of primary care and PP contraception, preventing rapid repeat and unintended pregnancies, and ultimately decreasing adverse pregnancy outcomes.

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