Linking Inter-professional Newborn and Contraception Care (LINCC) Trial: A Novel Approach to Postpartum Contraception Provision at the Well-Baby Visit

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Study Location(s):

Seven community health centers (CHCs) - six urban and one rural from AllianceChicago's network

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1.0 Project Summary/Abstract

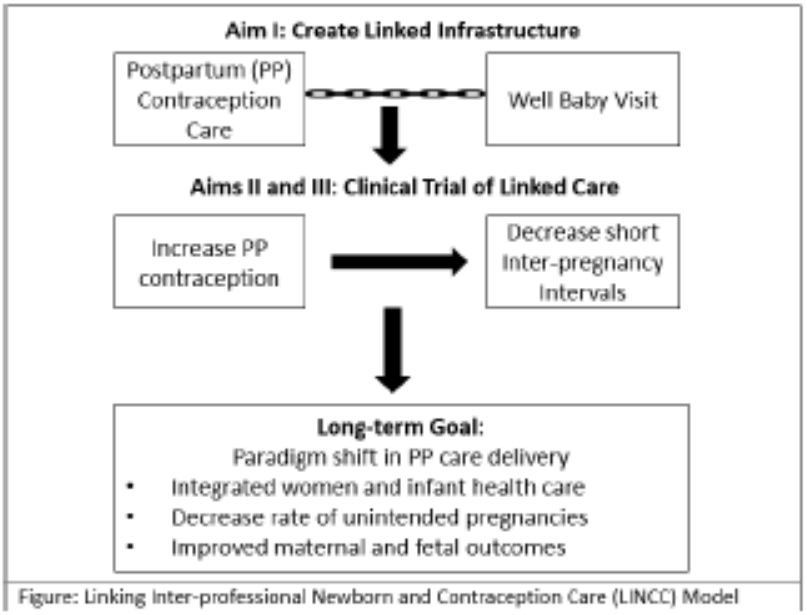
Background: Pregnancies conceived within 18 months of a prior delivery (termed short inter-pregnancy interval [IPI]) place mothers and infants at high risk for poor health outcomes including pre-eclampsia, anemia, and preterm birth.[1,2,3-7] Despite these negative health consequences, nearly one third of women experience a short IPI, highlighting a significant public health problem in the U.S.[9] A critical approach to preventing short IPIs is to provide postpartum (PP) women with timely access to contraception. The current standard clinical practice is to have women return six weeks after delivery for a postpartum visit, at which time contraceptive needs are addressed. However, many women resume sexual activity prior to six weeks PP, and many women, particularly low-income minority women, do not present for this visit. Low rates of postpartum contraception uptake leave women vulnerable to an unplanned pregnancy and significant negative health consequences. Thus, there is an urgent need for alternative approaches to increase timely access to PP contraception to improve outcomes for women and children.

Objectives: The study aims to: (1) develop a comprehensive implementation plan to link PP contraception and newborn care through co-scheduling visits in community health centers (CHC) and (2) use an effectiveness- implementation hybrid design to evaluate this novel system-level approach to linking maternal and newborn care at CHCs served by our partner organization, AllianceChicago. Lastly, we aim to: (3) assess implementation of linked PP contraception and newborn care and report on key barriers and facilitators related to successful implementation of the intervention.

Methods: Using a novel approach, we will test a patient-oriented alternative delivery system for PP contraception that will fill a gap in our current system resulting in improved contraceptive access for women. We will use a cluster randomized cross-sectional stepped wedge design to test the novel linked contraception and WBV model's impact on increasing PP contraception uptake in urban and rural CHCs, compared to usual care.

Outcomes: It is expected that the intervention will increase the proportion of women using contraception and 2 and 6 months postpartum. Increasing access to timely contraception is a promising strategy to help women plan their families and, in turn, reduce the poor health sequela associated with short IPI pregnancies. The long-term impact of this study is to reduce negative health outcomes among PP women and infants by increasing access to patient-oriented PP contraceptive care. Findings may provide evidence supporting a paradigm shift for linked PP care and identify important insights to facilitate successful implementation of this model of care in CHCs across the nation.

Figure 1: Hypothesis—Linking contraception with newborn care will decrease unintended pregnancies and improve maternal and child health outcomes



2.0 Background/Scientific Rationale

Pregnancies conceived within 18 months of a prior delivery (termed short inter-pregnancy interval) place mothers and infants at high risk for poor health outcomes including pre-eclampsia, anemia, and preterm birth.[1,2,3-7] Additionally, among women who experience a short IPI, 74.4% report the pregnancy was unintended.[8] Despite these negative health consequences, nearly one third of women experience a short inter-pregnancy interval, highlighting a significant public health problem in the U.S.[9]

Consistent contraception use is the most effective way to prevent unintended pregnancies.[10] Unfortunately, rates of postpartum (PP) contraception use remain low leading to high rates of unintended pregnancy and short IPIs.[11] Few women receive contraception prior to the standard six-week PP visit, and many do not receive contraception until *after* six-weeks PP.[11] Among a group of low-income publicly-insured women in California (N= 117,664) followed for 18 months PP, only 42% received contraception at *any* time between delivery and 90 days PP, and as few as 13% received contraception at their *first* PP visit.[11] Additionally, over a third (36%) of these women had a short IPI pregnancy.[11] Low rates of PP contraception uptake leave women vulnerable to an unplanned pregnancy and significant negative health consequences. Reducing the national level of unintended pregnancies is important for women and families, and is an important reproductive health goal identified by the United States Department of Health and Human Services (DHHS).[12] Increasing access to timely PP contraception is a promising strategy to help women plan their families and, in turn, reduce the poor health sequela associated with short IPI.

Low-income women are most at-risk for unintended pregnancies and least likely to receive timely contraception. More than 19 million U.S. women need publicly supported contraceptive services, and of those in need, 5.8 million (30%) are uninsured.[10] While overall rates of unintended pregnancies have been decreasing since the 1980s, the decrease has been primarily among higher-income women. A recent study reported significant disparities in unintended pregnancy rates by income, with low- income women significantly more likely to experience an unintended pregnancy underscoring the importance of testing approaches to meet these women's contraceptive needs.[13]

Reproductive health services are limited in many rural areas, contributing to less access to health care and poorer maternal and infant health outcomes.[14] A telephone survey of reproductive age women in Central Pennsylvania in 2004-2005 found rurality impacted contraceptive counseling, with women in rural areas significantly less likely than urban women to receive counseling related to birth control.[15] Sexually active women living in rural areas are also less likely to receive reproductive health services compared to women in urban areas, with approximately 16.9% and 83.1% receiving family planning services in the past 12 months, respectively.[14,16] Given this unmet need for reproductive health services in rural areas, efforts should also focus on strategies to increase access to and provision of contraception for rural women.

Community Health Centers (CHCs) serve as a safety net for low income underserved urban and rural residents.[17] Research has shown that 83% of individuals who receive care at CHCs have a form of public insurance or no insurance, while only 39% of patients who seek care at private physician offices are uninsured or have public forms of insurance.[18] Overall, CHCs serve an estimated 24% of all low- income women of childbearing age in the U.S.[19] Despite the varying scope and delivery of family planning services across CHCs, virtually all CHCs have reported that they provide at least one contraceptive method (99.8%) at one or more clinical sites.[19] Most CHCs are adequately equipped to provide comprehensive contraception counseling and provision of a broad range of contraceptive methods to medically underserved communities. Therefore, CHCs serve as an ideal setting for a program intended to reach the women most in need of improved contraception services in the PP period.

The current standard of care is to address women's PP contraceptive needs at the six-week PP visit. However, this model of care is ineffective for many reasons, particularly for low-income women. First, many women resume sexual intercourse before six-weeks PP and prior to initiation of contraception.[20,21] Second, many women do not attend the six-week PP visit.[22] Prior analyses of Illinois Medicaid data by our team, and an analysis of California Medi-Cal data, found PP visit rates to be 56% and 49.4% (respectively).[22,23] In addition, health disparities exist resulting in African-American women and women living in high poverty communities experiencing the lowest rates of PP care.[22] Third, few women who return for PP care receive contraception at this time due to a provider barrier (i.e., inadequate time to address contraception at the visit, less skilled providers with lack of knowledge about medically appropriate PP contraception or requiring return visit for placement of long-acting methods).[11] Fourth, the timing of the six-week PP visit is based on tradition rather than evidence supporting improved patient outcomes.[24,25] Finally, efforts to date such as antenatal discussion of the importance of the PP visit, use of discharge planners to encourage PP follow-up, and email and text reminders have had limited impact on increasing attendance at PP visits or contraception use.[26,27] This has led to testing alternative strategies to improve uptake of PP contraception, such as providing contraception prior to hospital discharge after delivery.[28,29] Unfortunately, efforts to increase immediate PP contraception provision have also faced significant implementation challenges due to lack of knowledge among providers of appropriate immediate PP contraception options, financial concerns regarding billing and reimbursement, and competing clinical and administrative priorities.[30] **Thus, there is an urgent need for new approaches to improve timely access to contraception for PP women.**

A highly promising opportunity to reach PP women is to counsel and provide contraception at the newborn care visit. Nearly all mothers routinely bring their infants in for newborn care during the first six months of life.[31,32] In 2009-2010, 93.2% of women reported that their infant had a well-baby visit (WBV) within one week of birth, and in 2011-2012, 90.9% of U.S. infants attended WBV visits during the first year of life.[32] The American Academy of Pediatrics recommends normal infants have WBVs at 3-5 days post hospital discharge and by one month of age (both of which are prior to the standard

PP visit) and four more visits before one year (i.e., two, four, six, and nine months).[32] **Hence, the newborn care visit is an opportunity to reach more women than are reached through the current standard PP visit model of care and there is precedent for linking maternal health care to infant care.** Addressing maternal health needs during a pediatric visit is now standard practice for pediatricians with respect to screening for PP depression. Evidence supports findings that PP depression screening is reliable and feasible in the pediatric setting, which led to national systematic changes to include PP depression screening at the WBV.[33] Furthermore, research efforts are beginning to study the feasibility of management of PP depression within pediatric care.[34] Routine infant health care visits represent the most regular contact new mothers have with the health care system, making it an ideal venue for implementing timely PP contraception care.[35]

This study will use a novel patient-oriented approach to link (co-schedule) PP contraception care with newborn WBV care (Figure 1). Though this model of co-scheduling care for mothers and newborns may appear intuitive, the current model of health care in the U.S. is *individual-patient* focused. Even in clinical environments where care is provided to both mothers and infants (i.e., family medicine clinic), the care is rarely coordinated. Continuity of care for families with the same primary care clinician or practice has been associated with improved outcomes, including increased use of preventive services, better adherence to clinician recommendations, and lower total costs, although this model of care has not been well studied in the context of maternal and child care delivery.[36] Our relatively small system-level change in scheduling practice linking maternal contraceptive care with newborn care could have a very large impact on women's receipt of care and contraception. In addition, by offering co-scheduled care to all PP women the model explicitly acknowledges the importance of PP care directly to new mothers. If successful, the model of care could be implemented broadly in a variety of health care settings. This project will contribute to national efforts to improve maternal health and decrease unintended pregnancies and short IPI pregnancies specifically addressing the *Healthy People 2020* goal to decrease unintended pregnancy by ten percent.[12,37] **Finally, results from this project will take the next step in informing the science to improve care delivery strategies to provide comprehensive PP care for women.**

Based on our findings, **we hypothesize that providing PP women contraception care linked with newborn care through co-scheduling these visits will increase the number of women offered contraception prior to two and six months PP and reduce the number of short interval pregnancies.** We will use an effectiveness-implementation hybrid design guided by two implementation science frameworks (CFIR and RE- AIM) to evaluate this novel system-level approach linking maternal and newborn care at community health centers served by AllianceChicago, our partner organization. AllianceChicago focuses on improving clinical care for vulnerable populations, and has significant experience in community-based research.

The long-term impact of this study is to reduce negative health outcomes among PP women and infants by increasing access to patient-oriented PP contraceptive care.

Findings may provide evidence supporting a paradigm shift for linked PP care and identify important insights to facilitate successful implementation of this model of care in community health centers across the nation.

3.0 Objectives/Aims

Aim 1: Develop a comprehensive implementation plan to link PP contraception and newborn care through co-scheduling in community health centers. We will work with AllianceChicago to assess community health center fit and readiness. Guided by the *Consolidated Framework for Implementation Research (CFIR)*, we will interview administrators, staff, providers, and patients from each site with the goal of identifying factors that may facilitate or impede the development of an implementation plan for linked care.

All study activities for Aim 1 have been completed.

Aim 2: Implement linked PP contraception and newborn care in seven geographically diverse community health centers (six urban and one rural) and evaluate the effect on provision of PP contraception and rates of short-interval pregnancy. We will roll out the intervention across sites with a stepped-wedge, cluster-randomized design and use AllianceChicago's common electronic health record to evaluate effectiveness by comparing pre- and post-intervention outcomes including clinic-level provision of all methods of contraception at two and six months PP and clinic-level rates of short inter-pregnancy intervals.

> Hypothesis: we hypothesize that providing PP women contraception care linked with newborn care through co-scheduling these visits will increase the number of women offered contraception prior to two and six months PP and reduce the number of short interval pregnancies.

All participating CHC's have been randomized for the intervention. All sites entered the control period April 1, 2021 and the first site will enter the intervention period August 1, 2021.

Aim 3: Assess implementation of linked PP contraception and newborn care and report on key barriers and facilitators related to successful implementation of the intervention. A mixed methods approach will be utilized to assess and document the implementation process using the *RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance)* and CFIR frameworks.

4.0 Study Design Background

Implementation science methods can be used to test the impact of linking maternal care with infant care in CHCs and used to enhance the utility of findings. From a design standpoint, hybrid trials are increasingly being utilized in implementation research

to simultaneously assess the clinical and implementation outcomes resulting from the introduction of a clinical intervention in a new context.[38] Traditional trial designs that focus only on clinical patient outcomes often fail to capture complex details of the implementation of the intervention and what factors impact implementation across different settings.[39] As a result, the public health impact of clinical studies is too often not fully realized because evidence is lacking for how interventions can successfully be brought to scale or translated to other settings. **Hybrid trials can speed the pace of translation by generating evidence about both the clinical effectiveness of an intervention and factors influencing successful implementation in a given setting.**

Implementation science also provides relevant conceptual and measurement frameworks to guide a hybrid trial of clinical outcomes and implementation factors. For instance, the **Consolidated Framework for Implementation Research (CFIR)**, which has been used to guide the implementation and evaluation of numerous evidence-based health programs, synthesizes the concepts of several available models into five inter-related domains: intervention characteristics, outer setting, inner setting, characteristics of individuals involved, and the process of implementation, with several constructs in each domain.[40] CFIR accounts for the non-linear process of implementation and incorporates consideration of the adaptation that is required for different contexts, making it a useful framework for studying the implementation of linked maternal and infant care in CHCs. CFIR also describes several constructs particularly relevant to this intervention, a sample of which is provided in Table 1 (see approach).

The **Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework** is an evaluation and reporting scheme commonly used to examine the potential public health impact of an intervention.[41] *Reach* represents the number and representativeness of patients who participate out of the eligible patient population. *Effectiveness* is the impact of the intervention on participant outcomes. *Adoption* is the number and representativeness of eligible staff/settings that agree to deliver the intervention out of all eligible staff/settings. *Implementation* is the fidelity to the intervention. *Maintenance* is the degree to which the intervention is sustained over time. RE-AIM provides a useful measurement framework for capturing both clinical and implementation outcomes within the same study. **Integrating CFIR and RE-AIM within a hybrid clinical effectiveness and implementation trial will generate the evidence needed to rapidly translate the findings from a clinical trial of linked care maternal and infant care to standard practice.**

5.0 Aim 1 Research Design, Methods, and Data Analysis

Aim 1 is to develop a comprehensive implementation plan to link PP contraception and newborn care through co-scheduling in community health centers. Our research team has demonstrated that, despite favorable patient attitudes towards linked care, delivery needs to consider physician, clinic and patient factors, which may influence implementation in the CHC setting. To that end and guided by CFIR, Aim 1 will assess clinic, staff and patient factors that may affect successful implementation of linked care.

A CFIR (Table 1) construct important for successful implementation within the inner setting (CHC-level) domain is readiness for implementation.[40] We partnered with AllianceChicago to engage the CHC sites identified as eligible and introduced the intervention to find out which sites are interested in participating in the study. We will recruited seven CHCs total (six urban and one rural) from AllianceChicago's network.

5.2 Aim 1a: Staff and Clinic Structure Assessment

Participating CHCs were asked to select 4-6 staff to participate with representation from administration, physicians providing pediatric or PP services, nurses and ancillary staff including schedulers. **Key informant interviews** were conducted with selected CHCs by Drs. Caskey and Haider and their investigative team to identify features of the individual CHCs and the overall network that are potential barriers and facilitators to implementation of the intervention. Semi-structured interview guides were developed to ensure consistency of qualitative data collected while allowing for open-ended responses. Questions and prompts were developed to solicit information about the CFIR constructs, which will be closely reviewed by both PIs before conducting interviews (see Table 1 for a sample of relevant constructs).

Table 1: Consolidation Framework for Implementation Research Constructs for *Linking Postpartum and Newborn Care*

Construct	Description
INTERVENTION CHARACTERISTICS	
Adaptability	The degree to which the intervention can be adapted or reinvented to meet patient and CHC needs. (SA1)
Complexity	Perceived difficulty of implementation. (SA1, SA3)
Relative Advantage	Postpartum women and CHC's perception of the advantage of implementing the intervention. (SA1)
OUTER SETTING	
Patient Needs & Resources	The extent to which postpartum women's needs and preferences are accurately known and prioritized by CHCs. (SA1)
INNER SETTING	
Readiness for Implementation	Tangible and immediate indicators of CHCs commitment to implement the intervention. (SA1)
CHARACTERISTICS OF INDIVIDUALS IN CHCs	
Personal Attributes	Traits of physicians and staff in CHCs. (SA1)
PROCESS	
Planning	Tasks for implementation are developed in advance, and the quality of the methods. (SA1)
Champions	CHC staff (clinical and administrative) who drive the implementation of the intervention. (SA1)
Executing	Carrying out or accomplishing the implementation according to plan. (SA 2, SA 3)
Reflecting & Evaluating	Quantitative and qualitative feedback from physicians and staff about the progress and quality of implementation. (SA3)

Adapted from the Damschroder et al. 2009

5.3 Aim 1b: Patient Assessment

PP women (<9 months PP) who are attending a WBV were asked for voluntary participation in an interview by phone. Interviews were conducted by Drs. Caskey and Haider and their investigative team with 3 patients per site. **Key informant interviews** were conducted to identify women's preferences and needs regarding PP contraception as well as obtain feedback on the intervention. Semi-structured interview guides were developed by the PIs to ensure consistency of qualitative data collected while allowing for open-ended responses. Questions and prompts were developed to solicit information about the CFIR constructs relevant to patient experience (Table 1).

5.4 Data Analysis

All interviews were audio-recorded and transcribed. Qualitative data was coded according to CFIR constructs. Emerging themes were identified and categorized as adaptable components of the intervention (barriers or facilitators) then compared across the urban and rural sites. All interviews were reviewed carefully by both PIs to determine clinically relevant aspects particular to ensuring successful implementation development. Themes as well as data from the readiness for implementation instrument were used to develop an implementation plan for the adapted clinical intervention that includes strategies to address potential barriers.

All study activities for Aim 1a and 1b have been completed.

6.0 Aim 2 Research Design, Methods, and Data Analysis

Aim 2 is to implement linked PP contraception and newborn care in 7 CHCs and evaluate the effect on provision of PP contraception and rates of short-interval pregnancy. We hypothesize that a linked PP contraception care with newborn care model can be implemented successfully in urban and rural CHC settings. PP women offered contraceptive care linked with newborn care would be more likely to receive any form of contraception at two months PP and by six months PP. Additionally, we hypothesize that CHCs will have a lower rate of short IPIs among incoming prenatal patients after implementing the linked contraception care with newborn care model compared with their rate prior to implementation.

Using a novel approach, we will test a patient-oriented alternative delivery system for PP contraception that will fill a gap in our current system resulting in improved contraceptive access for women. We will use a cluster randomized cross-sectional stepped wedge design to test the novel linked contraception and WBV model's impact on increasing PP contraception uptake in urban and rural CHCs, compared to usual care. We will include the 7 CHCs (six urban, one rural) recruited through Aim 1 of this project.

During the intervention period, staff will capture women during the first WBV (typically 3-5 days after delivery) and offer to have the next visit co-scheduled for infant and contraception care. Current practice at all AllianceChicago CHCs is to ensure all newborn infants leave the clinic with the next visit already scheduled. Appointments are scheduled during the discharge process at the end of each visit. During the discharge process all women 0-6 months postpartum who are established patients will be identified by an electronic prompt in the infant's electronic medical record. The prompt will instruct staff to offer the mother a co-scheduled visit for newborn and contraceptive care at the time of the next newborn visit.

Those who agree will be co-scheduled and those who are not in need of care, or do not wish for co-scheduled care, can decline. Women will be excluded if they had a tubal ligation or a long acting reversible contraception planed immediately after delivery. Women will be offered this co-scheduling option at each WBV through six months PP. Repeat opportunities for co-scheduled care are important as women's needs and

preferences change over time. Prior to initiation of the scheduling change, the PIs with Dr. Mohanty and the site clinical champions, will conduct several training sessions of the clerical staff, support staff, and clinicians. Training for clinicians will emphasize appropriate medical knowledge about PP women's overall care needs including contraception needs. We will brief clinicians on the linked model of care. Training with staff will focus on the need for a linked model of care and logistical considerations.

A key element of the research infrastructure will be AllianceChicago's uniform electronic health record system (EHRS), which is distinguished by the integration of evidence-based practice recommendations into the end user interface to provide decision support at the point of care. AllianceChicago's information technology (IT) team will build custom templates to match PP women and their infant's records. They will create a study-specific field in the EHR during well-baby visits for infants 0-6 months to prompt and record the offering of a co-scheduled appointment for the mother during the discharge process. The prompt will be rolled-out consistently among all sites based on the step-wedge design (below).

We will conduct a cluster randomized, cross-sectional stepped wedge study to roll out the intervention across sites and assess the change in clinical and implementation outcomes from before to after the adapted intervention is introduced into clinics. The cluster, or unit of analysis, is the clinic (not individual), which is critical for a system-level intervention. In a stepped wedge study, the design is extended so that every cluster provides before and after observations and every cluster switches from the control (usual care) to the intervention condition (linked care) at regular intervals ("steps"), at different points in time. The order in which a cluster switches from control to intervention is randomized. The advantages of the stepped wedge design are that it provides a pragmatic and robust approach to testing the effectiveness of health service delivery interventions (53). The stepped wedge design is pragmatic because the intervention can be rolled out over time. Additionally, no individual patient consent is required for this system-level health service delivery intervention, and therefore outcomes may be obtained through routinely collected de-identified data from the common AllianceChicago EHR. It is a robust design because each cluster provides data under both the control and intervention condition and therefore may serve as its own control, improving the precision of the study. A limitation of the stepped wedge design is the confounding effect of time given that clusters switch over to the intervention at different times. To help control for the effect of time, 4 additional clusters will be randomized to either the control or the intervention for the entire study period, as in a traditional parallel cluster randomized trial.

One urban and one rural CHC site will be randomized to each step occurring at 3-month intervals. Each step includes a 3-month transition period when the individual clinics will prepare to implement linked care. The design is cross-sectional because outcomes are obtained from the subset of patients seen during each time period at each clinic rather than following individually recruited patients over time.

6.1 Eligibility

Eligible participants include women presenting with their infants at one of the 7 chosen CHC sites for their first WBV (typically 3-5 days after delivery).

6.1.1 Inclusion Criteria

- Women bringing infant for their first WBV at chosen CHC

6.1.2 Exclusion Criteria

- PP tubal ligation
- Emergency hysterectomy due to life threatening bleeding during the delivery

6.1.3 Excluded or Vulnerable Populations

Any males will be excluded from the study because the study outcomes of contraceptive method use and pregnancy status are not applicable to males.

6.2 Outcome Variables

Primary outcome*:*

- **Receipt of all methods of contraception by two months PP.** Using de-identified patient-level EHRS data for eligible women at each clinic within each time interval, we will create a dichotomous variable for receiving any contraception by two months PP. We will work with AllianceChicago's IT team to restrict the data pull to eligible women who attended an infant 3-5 day WBV after the study period began.

Secondary outcome**:**

- **Receipt of all methods of contraception by six months PP.** This outcome will be calculated similar to the primary outcome with the exception of time-period.
- **Short IPI pregnancies.** During the baseline period (control condition) and 18 months after the introduction of the intervention in each CHC, we will use EHRS data to estimate the clinic-level rate of incoming prenatal patients presenting with a short IPI.

6.3 Data Collection

AllianceChicago's information technology (IT) team will build custom templates to match

PP women and their infant's records. They will create a study-specific field in the EHRS during WBV to prompt and record whether a co-scheduled appointment is **offered** to the mother. Similarly, a unique field will be created to record that a PP appointment is **co-scheduled** with a WBV appointment. The IT team will build custom reports in their data warehouse for the investigators to access and validate data in real-time. Reports will be built to pull data (ICD, CPT, and HCPCS codes) from the medical record and billing claims. In addition to real-time data, reports will be pulled monthly and reviewed closely by Drs. Caskey and Haider and their investigative team. Findings from the reports will be used to determine the primary and secondary outcomes.

6.4 Data Analysis

Drs. Rankin and Campbell, our epidemiology and biostatistics experts will conduct all analysis. They will compare the distribution of patient characteristics between the unexposed observations from the control period and the exposed observations during the intervention period, which are analogous to distributions across arms in a parallel cluster randomized trial. Then, they will plot rates of our outcomes over each three- month time period, comparing how rates differ from the control period to the intervention period overall, within each clinic, and between urban and rural clinics to examine the effects of the intervention, time and level of urbanicity on the outcomes. To examine treatment effects for our primary and secondary outcomes related to receipt of all methods of contraception, we will use a generalized linear mixed model, adjusting for the confounding effect of time with the random effect for CHC site and fixed effect for each time interval.[53]

6.5 Expected Outcomes

Intervention: After the intervention period begins, postpartum women within the selected CHC sites will be more likely to receive any contraceptive method by two and six months postpartum. We anticipate a minimum absolute increase in contraception use of 15% (from 45% to 60%) and a decrease in short IPI pregnancies from approximately 35% to 20% from before to after the intervention, both of which would have a clinically meaningful impact on the population.

Implementation Process: By the end of Aim 2, we expect the intervention will be implemented successfully at all sites. However, important clinic-level and system-level barriers will be identified at each site. For example, the discharge process likely occurs in slightly different ways in each clinic, which may impact who responds to the alert in the EHR and the efficiency in which the co-scheduling can be accomplished.

All modifications (i.e. custom fields, prompts) within EHR and scheduling software have been built. Participating CHC's have been randomized for the intervention. All sites entered the control period April 1, 2021 and the first site will enter the intervention period August 1, 2021.

7.0 Aim 3 Research Design, Methods, and Data Analysis

Aim 3 is to assess implementation of linked PP contraception and newborn care and report on key barriers and facilitators related to successful implementation of the intervention.

7.1 Outcome Variables

We will utilize the RE-AIM framework to evaluate outcomes of the effectiveness-implementation hybrid trial throughout the trial. Table 3 describes the data collected per RE-AIM construct.

Table 3: RE-AIM Evaluation of Implementation of Linked Care

RE-AIM Construct	Data Source	Outcome
Reach	EHR	• Percentage of eligible women identified for a co-scheduled appointment
Effectiveness	EHR	• Percentage of eligible women receiving any form of contraception at 2 and 6 months PP
Adoption	EHR	• Percentage of eligible women offered co-scheduled appointments
Implementation	EHR field created for study Key informant interviews	• Work flow process to identify eligible women in EHR and offer co-scheduled appointments • Acceptability and feasibility of the intervention as reported by PP women and clinic staff • Barriers or facilitators of implementation that impact fidelity to the intervention as reported by CHC staff and PP women (i.e., length of visits, no shows)
Maintenance	EHR	• Reach and Implementation outcomes measured at years 4 and 5 of grant

(Adapted from Glasgow et al. 2007)

7.2 Data Collection

AllianceChicago's information technology (IT) team will build custom reports in their data warehouse to access and validate data in real-time. Reports will be built to pull data (ICD, CPT and HCPCS codes) from the medical record and billing claims; which will be used to determine implementation success. Reports will be built to monitor: 1) EHR alert consistency; 2) if co-scheduled care is offered; 3) if co-scheduled care is accepted or declined by women; 4) among those who accept, if both the co-scheduled appointments are completed

At approximately the midpoint of each site's intervention period, key informant interviews will be conducted with staff, physicians and PP women to assess implementation

outcomes such as acceptability, feasibility, and fidelity over time. Semi- structured interview guides will be developed around CFIR constructs (similar to Aim 1) to elicit information related to barriers and facilitators encountered during the implementation of linked care and the RE-AIM implementation outcomes listed in Table 3. Interviews will be audio-recorded and transcribed and carefully reviewed by both PIs. If the subject declines to have their interview recorded, they will be asked to complete the interview in person and notes will be taken in lieu of audio-recording.

7.3 Data Analysis

Reach and implementation outcomes from the EHR will be assessed at the midpoint and endpoint of the intervention period for each step. Qualitative data will be coded according to CFIR constructs. Data will be coded independently by two coders and then discussed to resolve coding discrepancies. Emerging themes will be identified and categorized by CFIR construct and/or implementation outcome: acceptability, feasibility, and fidelity. Mixed methods will be used to elaborate on quantitative RE-AIM findings with themes from qualitative data.[56]

7.4 Expected Outcomes

We expect to identify important barriers and facilitators as a continuum during the implementation process at the clinician-level, clinic-level and system-level. Understanding those factors could help not only to improve the intervention at the local CHCs, but also will could increase understanding of similar interventions in the CHC setting. Findings will also result in understanding factors that may differ between urban and rural settings. Determining how implementation in CHCs vary over levels of urbanicity will be a valuable contribution to the literature. The process and results of this aim will be disseminated to contribute to the implementation science literature.

8.0 Expected Risks/Benefits

Potential risks consist of potential breaches of confidentiality. However, participants will be allowed to opt out of the study at any time and to not respond to questions they are uncomfortable with, without any penalty. Study records that identify the participant will be kept confidential; however there is a risk of loss of confidentiality. Participants will be informed of these risks, protections against loss of confidentiality, and their rights to skip any question and to withdraw from the study at any time in the consent forms and all relevant study documents. We will take the utmost caution to protect the confidentiality of responses.

The potential benefits of this research far outweigh the risks. Pregnancies conceived within 18 months of a prior delivery (termed short inter-pregnancy interval) place mothers and infants at high risk for poor health outcomes including pre-eclampsia, anemia, and

preterm birth. Despite these negative health consequences, nearly one third of women experience a short inter-pregnancy interval highlighting a significant public health problem in the U.S. A critical approach to preventing short inter-pregnancy intervals is to provide postpartum women with timely access to contraception. The current standard clinical practice is to have women return six weeks after delivery for a PP visit at which time contraceptive needs are addressed. However, many women resume sexual activity prior to six weeks PP, and many women, particularly low-income minority women do not present for this visit. Thus, there is an urgent need for patient-centered approaches to improve timely access to PP contraception to improve outcomes for women and children. This study has the potential to address these unmet contraceptive needs of postpartum women using a patient-centered approach to contraception care.

The key informant interviews will allow us to effectively develop and implement a linked postpartum and newborn care in CHCs and in turn, compare clinic-level provision of all methods of contraception and clinic- level rates of short inter-pregnancy intervals. The intervention and assessments will allow us to understand how well this intervention works and provide critical feedback in a real-world setting. The possible risks (i.e. potential confidentiality breaches) are outweighed by the new knowledge gained regarding how to implement this patient-centered model intervention in both urban and rural CHC settings. We have adequate safeguards to protect against these risks and will alert the RUMC IRB of any problems.

9.0 Data Collection and Management Procedures

We will collect qualitative and quantitative data from participants via audio-recorded and transcribed key informant interviews administered via laptop computer, telephone, and/or paper-and-pencil evaluations. Additionally, clinic-level EHR data will be collected pre- and post-implementation of the intervention.

Subjects will be assigned a study ID during the course of the study. All data collected will use the participant's study number in place of identified information. Participant information will be de-identified and will not be linked to any specific subject. The consent forms will be the only remaining link to the subjects. They will be available only to the IRB-approved research team. Given reliance agreement between collaborating institutions, consent forms for the subjects will be securely stored in a locked filing cabinet in a locked office within a PI's institution (i.e. Rush University Medical Center [RUMC], University of Illinois at Chicago [UIC]). All data will be stored on a secure, password- protected computer accessible only to the study team.

A reliance request on behalf of UIC and AllianceChicago was approved in July 2021. This reliance agreement is being submitted to RUMC's Institutional Review Board (IRB) and once approved, the RUMC's IRB will be the IRB of Record. Additionally, data from this study will be shared between collaborating sites (i.e., RUMC, UIC, AllianceChicago). A confidentiality agreements are in place and a data sharing agreement will be submitted and approved prior to any data being shared between sites.

10.0 Quality Control and Quality Assurance

Analysis of each phase will help to ensure adherence to the protocol as well as informing the next phase of the research project. The co-investigators are all responsible for ensuring the quality of the data and how the analysis will inform the next phase of the research study.

11.0 Data and Safety Monitoring

The PIs and Co-Is are responsible for monitoring the data, assuring protocol compliance, and conducting safety reviews regularly. The research staff will oversee day-to-day compliance. This protocol presents minimal risks to the subjects and adverse events or other problems are not anticipated. The PIs, Co-Is, and research staff will be responsible for monitoring the data, assuring protocol compliance, and conducting safety reviews at regular intervals, which must be conducted at a minimum of every 6 months (including when re-approval of the protocol is sought). During the review process, the PIs, Co-Is and research staff will evaluate whether the study should continue unchanged, require modification/amendment, or to close enrollment. The PIs, Co-Is, IRB, and research staff will ensure that any deviations from the protocol or safety concerns are reported according to institutional guidelines. Data and study risk will be assessed throughout the study.

12.0 Regulatory Requirements

12.1 Informed Consent

A qualified member of the study team will conduct eligibility screening to ensure participant eligibility. Eligible participants will be consented and enrolled. Recruitment will take place at the participating CHC sites. The informed consent process will inform the participant that participation in the study is completely voluntary.

12.2 Subject Confidentiality

Confidentiality will be maintained by following the data collection and management plans described previously in the protocol. Additionally, we will provide each participant with a study ID number that will be used to code all collected data. Participant information will be de-identified and will not be linked to any specific subject. Only key research personnel will have access to all collected data. All identifiers will be destroyed upon completion of the study.

12.3 Unanticipated Problems

Any unanticipated problems experienced by study personnel will be reported to the PI and co-PI. The PI and co-PI will then report any problems to the IRB, and National Institutes of Health, as necessary.

Improving Health by Linking Postpartum and Well-Baby Visits: Administrative Supplement to LINCC Trial

Project Summary/Abstract

Severe maternal morbidity (SMM) and maternal mortality (MM) remain a public health crisis in the United States despite efforts to improve maternal health. Most pregnancy-related deaths in the U.S. occur in the postpartum (PP) period, thus, timely access to high quality comprehensive care during the transition period from prenatal to PP period is critical to reduce SMM and MM.

High quality longitudinal health care improves outcomes for women before, during and after pregnancy; and decreases morbidity and mortality related to pregnancy. The "Linking Inter-professional Newborn and Contraception Care (LINCC) Trial" was funded in 2019 to test a novel, patient-centered approach to providing contraception care, in conjunction with an infant's well baby visit (WBV), for PP women. The LINCC trial aims to remove barriers to accessing PP care by co-scheduling the PP contraception visit with WBVs. The LINCC trial provides an ideal foundation upon which to develop a reproducible model to identify women at risk for MM and SMM, and link them into care, among a national sample of predominantly low-income women receiving care at Community Health Centers (CHCs).

The specific aims of this study are to: (1) build a population-health interface to identify pregnant and PP women at risk for SMM or MM using standard clinical health data from electronic medical records and (2) Validate the registry (i.e., LINK MOMS) using data from CHCs across the country. Lastly, we aim to: (3) design an implementation plan for the LINK MOMS registry in CHCs across the country.

Increasing access to timely comprehensive care is a promising strategy to prevent pregnancy-related morbidity and mortality. The long-term impact of this study is to reduce adverse health outcomes among PP women by increasing access to patient-oriented care before, during, and after pregnancy. Findings may provide evidence supporting a paradigm shift for linked PP care and identify important insights to facilitate successful implementation of this registry in health care systems across the nation.

Background/Scientific Rationale

Maternal Morbidity and Mortality in the United States: Severe maternal morbidity (SMM) and maternal mortality (MM) in the U.S. remains a public health crisis despite efforts to improve maternal health. Given most pregnancy-related deaths in the U.S. occur in the postpartum (PP) period[1], a critical preventive measure to SMM and MM is timely access to quality health care during the transition between the prenatal period to one year PP.

Importance of Continuum of Care for PP Women: Standard clinical practice, i.e. a single PP visit approximately six weeks after delivery, fails to provide adequate care for women, particularly for those at risk for SMM or MM. Indeed, many women, particularly low-income minority women, do not present for the traditional PP visit [3]. In fact, prior analyses of Illinois Medicaid data by our team, and an analysis of California Medi-Cal data, found PP visit rates to be 56% and 49.4% (respectively) [4, 5]. Because the majority of maternal deaths occur between 6-weeks to 12-months after delivery, the need for a continuum of care that extends beyond the traditional 6-week period is essential to improve outcomes for new mothers [6]. In May 2019, The American College of Obstetricians and Gynecologists' (ACOG) reported that PP care should be an on-going process with the timing of visits scheduled to address woman's individual needs, including recovery from birth, newborn care, psychosocial and sexual well-being, contraception, chronic disease management, and transition to ongoing well-woman care[7]. Unfortunately, this proposed continuum of PP care has not yet been adopted broadly across the U.S.

Disparities in Access to Quality Maternity Care: Access to quality maternity care is a critical component of positive maternal health outcomes, especially within the PP period as most complications occur within this period. However, research has indicated that access to reproductive health care and health insurance continues to be a barrier for women [8]. Although disparities in the rates of uninsured have narrowed among some populations [9], gaps do remain, particularly for low-income and minority women [10]. For instance, while an average of 13% of adult women in the U.S. are uninsured, the percentages are greater for Black (15%), Latina (24%), and low-income women (26%)[10]. In addition, uninsured women use fewer preventative services (e.g., mammograms, well-woman visits) and are more likely to delay care due to cost [11]. Thus, increasing prevalence of chronic disease risk factors [12], coupled with inadequate care due to cost or delays, puts low-income and minority women at an high risk for adverse maternal health outcomes.

Other key factors contributing to poor access to care include geographic disparities (e.g., distance to care, transportation needs) [6, 13]. Compared to those living in urban areas, women living in rural areas experience disparities in obstetric care access and outcomes [14]. In fact, maternal and infant mortality rates in most rural areas of the U.S. are measurably higher than those in large metropolitan areas [15]. Furthermore, research suggests that risk factors for related chronic diseases such as diabetes, high cholesterol,

and cardiovascular disease are becoming more prevalent in women of reproductive age [12], with the burden of these conditions disproportionality falling on women in rural or low-income communities [16]. Given more than 18 million women of reproductive age live in rural counties of the U.S., and nearly half a million women give birth each year in rural hospitals [17, 18], ensuring access to maternity care for all women has the potential to reduce preventable maternal mortality and morbidity across the U.S. and improve maternal outcomes overall.

Community Health Centers (CHCs) serve as a safety net for underserved urban and rural residents [19]. Research has shown that 83% of individuals who receive care at CHCs have a form of public insurance or no insurance, while only 39% of patients who seek care at private physician offices are uninsured or have public forms of insurance [20] Overall, CHCs serve an estimated 24% of all low-income women of childbearing age in the U.S. [24]. Therefore, CHCs can serve as an ideal setting to identify women at risk for poor pregnancy-related outcomes.

Optimize Linkage to Continued Care – Leveraging the "Linking Inter-professional Newborn and Contraception Care (LINCC)" Trial: A crucial approach to preventing pregnancy-related morbidity and mortality is to provide women-centered approaches to improve timely access to comprehensive care before, during and after pregnancy. The LINCC Trial was funded in 2019 to test a novel, woman-centered approach to providing contraception in conjunction with an infant's well baby visit (WBV) to PP women. This intervention aims to remove barriers to accessing PP care by co-scheduling the PP care with WBVs. The LINCC model allows women greater opportunity to receive timely PP contraception, space pregnancies, and decrease the risk of a rapid repeat pregnancy within a short inter-pregnancy interval which is associated with poor maternal and infant outcomes. The LINCC Trial provides an ideal platform for a larger paradigm shift in PP care: ensuring a continuum of care throughout the pregnancy and interception period. Comprehensive women's health care, including PP care, preventive care, chronic disease management and mental health care, is desperately needed to address rising SMM and MM, especially among underserved vulnerable women. By leveraging our existing community partnership with AllianceChicago as well as our clinical champions at participating CHCs engaged in the ongoing LINCC Trial, we will build a population-health approach to identify women at highest risk for maternal morbidity and mortality.

Impact of the Research: Most pregnancy-related deaths in the U.S. occur in the PP period [1], however the traditional model for PP care is inadequate in identifying women at risk for SMM and MM; and inadequate in addressing maternal health needs in the inter-conception period [3]. The fragmentation of the current healthcare system leads to inadequate linkage between health care services, specifically for women at highest risk for adverse health outcomes [21, 22]. Early identification of women who are at risk for SMM or MM will lead to earlier management of chronic conditions and prevention of pregnancy-related complications.

Study Design Background

The “Improving Health by Linking Postpartum and Well-Baby Visits (LINCC Trial)” was funded in 2019 to test a novel, patient-centered approach to providing contraception care, in conjunction with an infant’s well baby visit (WBV), for postpartum (PP) women. The impetus for the LINCC Trial was to improve outcomes for women at greatest risk for poor pregnancy-related outcomes: low-income and minority women. The LINCC Trial is reducing barriers to receipt of PP contraception care by linking women’s care with newborn care. The LINCC model allows women greater opportunity to receive timely PP contraception, space pregnancies, and decrease the risk of a rapid repeat pregnancy within a short interpregnancy interval which is associated with poor maternal and infant outcomes. Thus, the LINCC Trial is an ideal foundation upon which to further develop a reproducible model to identify pregnant and postpartum women at risk for severe maternal morbidity (SMM) and maternal mortality (MM) among a national sample of federally qualified health centers and respond to the goals of the administrative supplement.

The specific aims of this study are to:

1) Build a population-health interface to identify pregnant and PP women at risk for severe maternal morbidity or mortality using standard clinical health data from electronic health records and create a LINK MOMS registry;
2) Validate the LINK MOMS registry using data from Community Health Centers (CHCs) across the country;
3) Design an implementation plan for the LINK MOMS registry in CHCs across the country. This supplement aims to bridge the gap in care during a critical time, the PP period, by identifying women at increased risk of SMM and MM.

The LINCC Trial provides an ideal platform for a larger paradigm shift in PP care: ensuring a continuum of care throughout the pregnancy and interception period. By leveraging our existing community partnership with AllianceChicago, as well as our clinical champions engaged in at participating CHCs, from the ongoing LINCC Trial, we will build a population-health approach to identify women at highest risk for maternal morbidity and mortality with the long-term goal of providing improved linkage to care.

The following text will outline the study activities for Aims 1, 2, and 3 of this Administrative Supplement.

Aim 1: Build a population-health interface to identify pregnant and PP women at risk for severe maternal morbidity or mortality using standard clinical health data from electronic health records (EHR).

In partnership with AllianceChicago, we will use Health Catalyst's Population Builder™ to build a registry to identify pregnant and PP women at risk for SMM or MM. Though many women do not receive timely or adequate PP care, nearly all women receive at least some medical care during pregnancy [23]. We hypothesize that medical record data, even if limited, can be used for early identification of women at highest risk for SMM and MM and will result in earlier intervention and improved health outcomes.

Health Catalyst Population Builder™ is a tool designed to interface with large datasets, including medical records, to develop robust registries based on pre-specified criteria. Importantly, Population Builder™ is end-user friendly through the use of visually-oriented data, a drag-and-drop interface, rapid identification of desired populations and flexibility to be used in many domains (clinical, financial, and geographic). Nontechnical individuals can easily learn to use the tool, which allows for rapid access to desired data by clinical staff.

Population Builder™ can interface with standard EHR data and create populations based on defined criteria. We will build a registry, LINK MOMS, to identify pregnant and PP women at risk for SMM or MM. To ensure accurate identification of women at risk, our team will convene subject matter experts (SMEs) from AllianceChicago, and affiliated CHCs, to refine the data used to build the LINK MOMS registry. LINK MOMS will include a combination of International Classification of Diseases, Tenth Revision (ICD-10) codes, Common Procedural Technology (CPT) codes, lab results, demographics, and clinic visit data. For example, we anticipate using CPT codes to identify women who are pregnant or PP; well established ICD-10 codes to identify women at risk for SMM or MM (gestational diabetes, hypertension, depression, substance use, etc.) or women who have SMM [24]; and identifiers of social determinants of health (housing instability, financial limitations, violence, etc.).

Focus Group Sessions

Approximately 15 subject matter experts (SMEs) from the collaborating LINCC Trial sites will be convened twice to participate in two focus group sessions:

1. First to provide guidance on potential data to include in the registry;
2. And second to review the registry build.

Inclusion Criteria

- English-speaking staff member at AllianceChicago or affiliated CHC collaborating on the LINCC Trial
- Ages 18 and above

Exclusion Criteria

- Not a staff member at AllianceChicago or affiliated CHC

- Under 18 years old

Subject enrollment:
Subject matter experts from AllianceChicago and affiliated Community Health Centers (CHC) of any age were recruited to refine the data used to build the LINK MOMS registry. Dr. Mohanty will coordinate with the CHC's and facilitate recruitment of eligible participants for the two focus groups. The RUMC and UIC study team will then conduct these focus groups. Trained research assistants from RUMC and UIC will consent SMEs prior to participating in the focus groups. Those interested and eligible will complete an oral informed consent form and be enrolled in the study. All participants will have their participation and all risks and benefits to participation explained to them.

Data Collection and Management Procedures

We will collect data from participants via audio-recorded and transcribed focus group sessions administered virtually. All focus group session data will be stored on a secure, password- protected computer accessible only to the study team.

Focus group subjects will be assigned a study ID during the course of the study. All data collected will use the participant's study number in place of identified information. Participant information will be de-identified and will not be linked to any specific subject. The consent forms will be the only remaining link to the subjects. They will be available only to the research team. Consent forms for the subjects will be securely stored in a locked filing cabinet in a locked RUMC office. All data will be stored on a secure, password- protected computer accessible only to the study team.

Both focus group sessions will take place virtually over the Zoom platform and be audio-recorded and transcribed. Qualitative data will be coded independently by two coders and then discussed to resolve coding discrepancies. Emerging themes will be identified and categorized as components of the registry. All sessions will be reviewed carefully by the PIs to determine clinically relevant aspects particular to ensuring successful registry development.

- Each focus group session is expected to take approximately 1 hour
- Each participant will receive $100 gift card after participating in each session for a total of $200. (Per benchmark standard for clinicians [hourly rate = $100])

Retrospective Chart Review

In addition, once the LINK MOMS metrics are defined and built; the registry will be tested nationally using 32 CHCs affiliated with AllianceChicago. During the test phase the registry will be limited to electronic health record (EHR) data from 2017-2019. This time frame allows for the validation process to include review of care after delivery. This retrospective chart review will be conducted to test the registry. Data will be collected on all pregnant or postpartum women attending the 32 CHCs affiliated with AllianceChicago.

The chart will be reviewed to ensure the registry is accurately identifying women at risk of adverse health outcomes during pregnancy and the postpartum period.

Retrospective Chart Review Criteria
Approximately 1000 charts will be included in the retrospective chart review period from 2017-2019.

Inclusion Criteria

- Pregnant or postpartum women of reproductive age attending an appointment at an AllianceChicago affiliated CHC between 2017-2019.

Exclusion Criteria

- Pregnant or postpartum women of reproductive age attending an appointment at a health clinic not affiliated with AllianceChicago
- Pregnant or postpartum women of reproductive age attending an appointment at an AllianceChicago affiliated CHC outside of the 2017-2019 date range

Data Collection and Management Procedures

The AllianceChicago study team and SMEs will test the LINK MOMS registry using data from CHCs within AllianceChicago's network. Data from this retrospective chart review process will be securely stored at AllianceChicago Office. The RUMC and UIC teams will oversee the testing process and provide insight where applicable. De-identified data may be shared between sights for this aim of the study.

A reliance request on behalf of AllianceChicago and UIC has been approved and is being submitted via amendment to RUMC's IRB for final approval. Once approved, the RUMC IRB will be the IRB of Record. Additionally, de-identified data from this study will be shared between collaborating sites (i.e., RUMC, UIC, AllianceChicago). Confidentiality agreements and a data sharing agreement will be submitted and approved prior to any data being shared between sites.

The first focus group session for Aim 1 has been completed. The second focus group will be conducted in Fall 2021. The variables and metrics for the registry are currently being defined and built by the study team. The registry is on track to be built and ready for testing and validation in September 2021.

Aim 2: Validate the LINK MOMS registry using data from CHCs across the country.

To ensure the registry accurately identifies women at risk for SMM and MM, AllianceChicago SMEs in conjunction with SMEs across a sub-set of clinical sites will validate the national LINK MOMS registry through a manual review of patient-level EHR data (i.e., retrospective chart review). A random sample of 15% of women from the LINK MOMS registry will be pulled for validation. The validation process will include a manual review of each patient's chart and discussion with treating clinicians if appropriate. The

chart review will include all clinical data 2017-2019, which will include the timeframe during and after pregnancy. A structured chart abstraction tool will be used to standardize the review process; and each abstraction will result in one of three outcomes: Appropriate, Inappropriate, Unknown. Our team will meet with the validation team weekly during the validation process to review findings and refine the validation methodology as needed.

Retrospective Chart Review Criteria
Approximately 15% of the 1000 charts (Aim 1) will be included in the retrospective chart review period from 2017-2019.

Inclusion Criteria

- Pregnant or postpartum women of reproductive age attending an appointment at an AllianceChicago affiliated CHC between 2017-2019.

Exclusion Criteria

- Pregnant or postpartum women of reproductive age attending an appointment at a health clinic not affiliated with AllianceChicago
- Pregnant or postpartum women of reproductive age attending an appointment at an AllianceChicago affiliated CHC outside of the 2017-2019 date range.

Data Collection Analysis

The chart abstraction process will include documentation of details supporting the final outcome (Appropriate, Inappropriate, Unknown). For example, the registry identifies a chart with a one-time use of ICD-10 code 013.9 (gestational hypertension). However, upon chart review the documented blood pressure measurements were found to be normal during pregnancy. Thus, the team concludes the use of the code was likely an error and the chart is labelled as an inappropriate identification of risk. Similarly, the team may find conflicting data in the EHR and the chart is labelled as an unknown identification of risk.

All charts found to be unknown or inappropriate will be reviewed by the validation team and PIs (Haider, Caskey) and the group will reach consensus on the final determination (Appropriate, Inappropriate or Unknown). If needed, the team will engage the woman's care providers to accrue additional information. All findings will be compiled and used to continually refine the LINK MOMS registry. An example of such a registry refinement process would be if the team determines, based on the chart abstraction, that certain ICD codes need to be documented more than once for the chart to be pulled into the registry.

The AllianceChicago study team and SMEs will validate the LINK MOMS registry using data from CHCs within AllianceChicago's network. Data from this retrospective chart review and validation process will be securely stored at AllianceChicago Office. The RUMC and UIC team will oversee the validation process and provide insight where applicable. De-identified data may be shared between sights for this aim of the study.

Aim 3: Design an implementation plan for the LINK MOMS registry in CHCs across the country.

Key Informant Interviews

Through in-depth key-informant interviews, we will use the guidance from women and women's health providers to develop a strategy for how best to incorporate LINK MOMS data into practice.

Inclusion Criteria

- **Patients**: Pregnant or postpartum (delivery within last 12 months) women (ages 18 and above) receiving care at an affiliated CHC in AllianceChicago network
- **Providers:** English or Spanish-speaking women's health provider at affiliated CHC (ages 18 and above)

Exclusion Criteria

- **Patient:** Not a pregnant or postpartum women receiving care at an affiliated CHC in AllianceChicago's network (under 18 years old)
- **Providers:** Not a women's health provider at affiliated CHC in AllianceChicago's network (under 18 years old)

Subject enrollment:

The key informant interviews will be conducted by a member of our research team using a semi-structured interview guide to ensure consistency of data collection while allowing for open-ended responses. Questions and prompts will be developed to solicit information; which will be closely reviewed by the PIs before conducting interviews. Participation will be voluntary.

- **Patient:** The study team will coordinate with the CHC's to facilitate recruitment of eligible participants for the key informant interviews. Staff at each CHC will hand out study flyers to recruit patients. Interested patients will reach out to the study team using the contact information on the flyers. A trained research assistant will determine eligibility and coordinate a time with the patient to participate in the interview by phone. The research assistant will consent eligible patients prior to participating in the interview. Those interested and eligible will complete an oral informed consent form and be enrolled in the study. All participants will have their participation and all risks and benefits to participation explained to them.
- **Providers:** The study team will coordinate with the CHC's and facilitate recruitment of eligible participants for the key informant interviews. A trained research assistant will determine eligibility and coordinate a time with the providers to participate in the interview by phone. The research assistant will consent eligible providers prior to participating in the interview. Those interested and eligible will complete an oral informed consent form and be enrolled in the study. All participants will have their participation and all risks and benefits to participation explained to them.

- Each interview (patient and provider) is expected to take approximately 30 minutes.
- Each patient participant will receive $25 gift card after participating in one interview.
- Each provider participant will receive $50 gift card after participating in one interview (Per benchmark standard for clinicians [hourly rate = $100]).

Women's Voices: We will recruit 10 women who are pregnant or PP (delivery within last 12 months) to participate in an interview by phone. Interviews will focus on women's preferences and needs regarding care, feedback on the LINK MOMS registry, suggestions for how the registry should be used to identify and link women to needed care, and concerns regarding privacy.

Provider's Voices: We will recruit 10 women's health providers who provide pregnancy and/or PP care. We aim to recruit a variety of providers with varying backgrounds and perspectives (OB/GYN, Family Medicine, Nurse Midwife and Internal Medicine). Interviews will focus on clinician's preferences regarding how registry data is utilized in clinical practice, barriers and facilitators to utilization of LINK MOMS and any resource considerations.

Aim 3a: Evaluate usability of LINK MOMS registry

Survey
A qualified study team member will disseminate a survey via REDCap to evaluate the usability and usefulness of the LINK MOMS registry. The 8-question deidentified survey will be sent to the 20 emails of health providers who currently use the registry.

Data Analysis
Data analysis: All interviews will be audio-recorded and transcribed. Data will be coded independently by two coders and then discussed to resolve coding discrepancies. Emerging themes will be identified and categorized as important considerations for an implementation plan for the LINK MOMS registry. All interviews will be reviewed carefully by both PIs to determine relevant aspects particular to ensuring successful implementation development.

Data Collection and Management Procedures
We will collect qualitative and quantitative data from participants via audio-recorded and transcribed key informant interviews administered virtually.

Interview subjects will be assigned a study ID during the course of the study. All data collected will use the participant's study number in place of identified information. Participant information will be de-identified and will not be linked to any specific subject. The consent forms will be the only remaining link to the subjects. They will be available only to the research team. Consent forms for the subjects will be securely stored in a locked filing cabinet in a locked RUMC office. All data will be stored on a secure,

password- protected computer accessible only to the study team.

Clinic-level EHR data collected retrospectively as part of the testing process in Aim 1 and validation process in Aim 2 will be stored securely at AllianceChicago Office.

A reliance request on behalf of UIC and AllianceChicago was approved in July 2021. This reliance agreement is being submitted to RUMC's Institutional Review Board (IRB) and once approved, the RUMC's IRB will be the IRB of Record. Additionally, de-identified data from this study will be shared between collaborating sites (i.e., RUMC, UIC, AllianceChicago). Confidentiality agreements are in place and a data sharing agreement will be submitted and approved prior to any data being shared between sites.

Quality Control and Quality Assurance

Analysis of each phase will help to ensure adherence to the protocol as well as informing the next phase of the research project. The co-investigators are all responsible for ensuring the quality of the data and how the analysis will inform the next phase of the research study.

Data and Safety Monitoring

The PIs and Co-I are responsible for monitoring the data, assuring protocol compliance, and conducting safety reviews regularly. The research staff will oversee day-to-day compliance. This protocol presents minimal risks to the subjects and adverse events or other problems are not anticipated. The PIs, Co-I, and research staff will be responsible for monitoring the data, assuring protocol compliance, and conducting safety reviews at regular intervals, which must be conducted at a minimum of every 6 months (including when re-approval of the protocol is sought). During the review process, the PIs, Co-Is and research staff will evaluate whether the study should continue unchanged, require modification/amendment, or to close enrollment. The PIs, Co-I, IRB, and research staff will ensure that any deviations from the protocol or safety concerns are reported according to institutional guidelines. Data and study risk will be assessed throughout the study.

Informed Consent

Focus group sessions (Aim 1): A qualified member of the study team will conduct eligibility screening to ensure participant eligibility in focus group sessions. Eligible participants will be complete oral consent over the phone and be enrolled. Recruitment will take place at AllianceChicago and participating CHC sites. The oral informed consent process will inform the participant that participation in the study is completely voluntary.

Retrospective chart review (Aim 1 and 2): The study team is requesting a waiver of consent process and consent documentation for the retrospective chart reviews in Aims 1 and 2.

Key informant interviews (Aim 3): A qualified member of the study team will conduct eligibility screening to ensure participant is eligible to participate in the key informant interview. Eligible participants (providers and patients) will complete oral consent over the phone and be enrolled. Recruitment will take place at AllianceChicago and participating CHC sites. The oral informed consent process will inform the participant that participation in the study is completely voluntary.

Survey (Aim 3a): No identified data will be obtained. Therefore, a Waiver of Documented Consent will be submitted.

Subject Confidentiality

Confidentiality will be maintained by following the data collection and management plans described previously in the protocol. Additionally, we will provide each participant with a study ID number that will be used to code all collected data. Participant information will be de-identified and will not be linked to any specific subject. Only key research personnel will have access to all collected data. All identifiers will be destroyed upon completion of the study.

Unanticipated Problems

Any unanticipated problems experienced by study personnel will be reported to the PIs. The PIs will then report any problems to the IRB, and National Institutes of Health, as necessary.

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