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ABBREVIATIONS AND DEFINITIONS OF TERMS

AE	Adverse event
SAE	Serious Adverse Event
EHR	Electronic Health Record
CoC	Certificate of Confidentiality
MI	Motivational Interviewing

ABSTRACT

Context:

Preterm births occur in 10% of US births, cause 36% of infant mortality, and cost $26 billion each year. Repeat preterm births represent approximately 20% of total prematurity. Preventive care that effectively addresses modifiable risks (e.g. tobacco use, weight status, interpregnancy interval) among women with a prior preterm birth could plausibly reduce overall preterm birth rates by 10% or more. Leveraging existing contact between pediatric health systems and new mothers, this research proposes a pediatric-based intervention as a novel strategy to reduce prematurity.

Objectives:

The primary objective of this study is to determine whether the behavioral intervention Care Coordination After Preterm Birth is feasible and acceptable to women following preterm birth.

Study Design:

This is a preliminary pilot non-randomized open trial of Care Coordination after Preterm Birth with baseline and post-intervention assessments.

Setting/Participants:

The setting for this study is the CHOP primary care network. Women who intend to seek pediatric care for their new infants at CHOP primary care sites (Karabots, Cobbs Creek) will be enrolled from the Hospital of the University of Pennsylvania postpartum unit / newborn care units before hospital discharge or by phone within 4 weeks of a preterm birth. A maximum of 106 women will participate in this preliminary pilot trial. Enrollment will stop once feasibility is established.

Study Interventions and Measures:

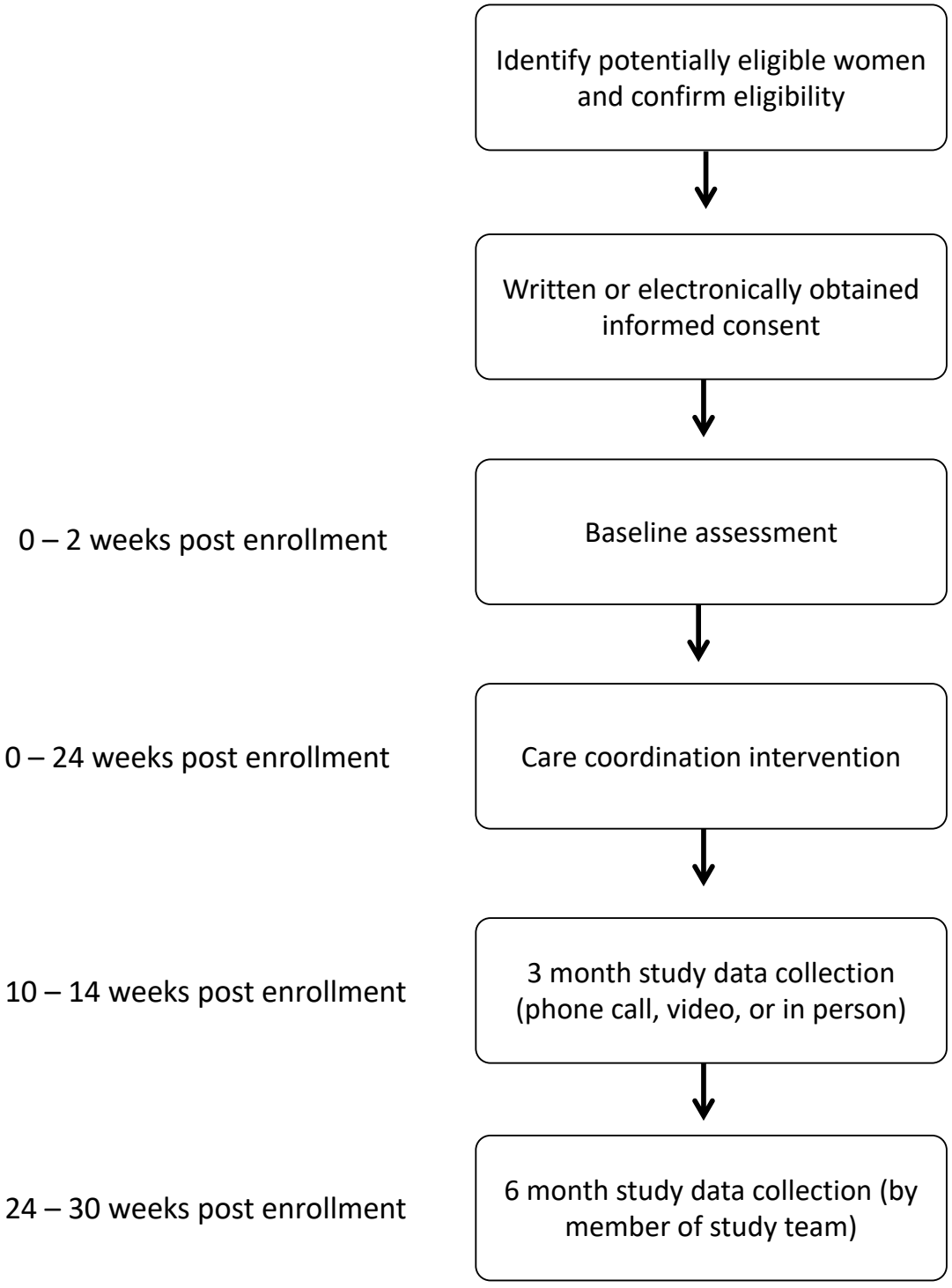
Care Coordination after Preterm Birth is a behavioral intervention for women following preterm birth. Interventionists will provide health education, health care navigation, and motivational interviewing to ensure health care needs are met, positive health behaviors are adopted or sustained, and barriers to health are addressed.

The primary outcome of this study is acceptability and feasibility of the intervention. In addition, this preliminary trial will monitor postpartum visit attendance and other modifiable risk factors for recurrent adverse pregnancy outcomes.

Table 1: Schedule of Study Procedures

	Procedure	Screening & eligibility	Pre-intervention	Intervention	3 mon	6 mon
Measures to determine eligibility						
Screening eligibility	Health records review	X				
Measures of treatment feasibility and acceptability						
Recruitment rates	Study-team documented		X			
Reasons for non-participation	Study team documented (if available)		X			
Intervention fidelity	Study team documented			X		
Retention rate	Study team recorded				X	X
Treatment acceptability interview	Participant reported					X
Demographics, health utilization, and modifiable health behavior						
Participant demographics	Health record review and participant report			X		
Health care receipt	Health record review and participant report				X	X
Autonomy Support (Health Care Climate Questionnaire)	Participant reported		X			X
Autonomous Motivation (Treatment self-regulation questionnaire)	Participant reported		X			X
Contraceptive use	Health record review and participant report		X		X	X
Participant weight	Measured on scale or heath record review or participant report		X			X
Tobacco use (30 days any versus none)	Participant reported		X		X	X
Mental health symptoms (Edinburgh Postnatal Depression Scale, Perceived Stress Scale)	Participant reported		X		X	X
Barriers to care	Participant reported		X		X	X
Sleep-related Impairment scale			X		X	X
Intervention Acceptability	Participant report					X
Intervention						
Care Coordination	Care navigation, health education, screening, care planning, addressing barriers			X		
Motivational Interviewing				X		

1 FIGURE 1: STUDY DIAGRAM



2 BACKGROUND INFORMATION AND RATIONALE

2.1 Introduction

In the United States (US) in 2017, prematurity occurred with 10% of births[1] and was associated with 36% of infant deaths. Due to short- and long-term medical and developmental morbidities, prematurity costs $26.2 billion annually in the US.[2–5] Early preterm births carry particularly high burdens, but late preterm births are also associated with morbidities and with infant costs double those of term births.[6–10] We propose testing an intervention for women at high-risk for preterm birth with a goal of increasing receipt of preventive health care and supporting positive health behaviors.

Among women with a prior preterm birth, more than 20% of second births are also preterm.[11–15] Most of these women have modifiable risks influencing birth outcomes.[16] Both prenatal and population-wide interventions addressing modifiable risks have yielded reductions in preterm birth, demonstrating that many preterm births are preventable.[17–20] For women with a prior preterm birth, addressing risks before pregnancy could reduce individual risk of preterm birth by approximately 30% and overall preterm birth rates by approximately 10%.[12,14,16,21] This proposal focuses on modifiable risks that are universally relevant to women with a history of preterm birth including health care receipt, interpregnancy interval, and postpartum weight retention.[4,18,22,23] The intervention may also address tobacco use and mental health for subgroups experiencing these additional modifiable risks.[19,24]

2.2 Name and Description of Investigational Product or Intervention

Care Coordination after Preterm Birth is a behavioral intervention for women following preterm birth. The program combines strategies of health education, care navigation, and motivational interviewing to improve receipt of recommended preventive health care and to support positive health behavior change. The intervention is based in the pediatric primary care setting, in recognition that this is the health care setting with which women most frequently interact following a preterm birth.[25] However the intervention is designed to address the needs of mothers directly.

2.3 Relevant Literature and Data

Interconception preventive health care is recommended by NICHD, the Centers for Disease Control and Prevention, and the National Academy of Medicine as a strategy to prevent preterm birth and decrease health disparities.[3,4,26–28] Yet many women receive no preventive care between pregnancies and we lack effective approaches to increase care receipt.[29–31] Though many **women lack preventive care, most infants do receive preventive care in the IC period.** Our preliminary work with Medicaid claims found that 43% of women received no preventive care in the first year following a preterm birth.[25] For approximately half of these women, their infants competed pediatric preventive care at or above median levels.

Pediatric preventive care provides an opportunity to identify maternal health risks, but traditional health care models do not fully address risks. A Family Medicine collaborative demonstrated the feasibility of using infant preventive visits to implement universal maternal risk screening.[32] Pediatricians, who provide preventive care to 80% of infants in the US, also consider maternal interconception risks within their scope of

practice.[33–36] However, without strategies to ensure evidence-based care, screening alone will not improve outcomes.[37–40]

Care coordination can improve receipt of recommended care. Care coordination is defined as "the deliberate organization of patient care activities between two or more participants (including the patient)… to facilitate the appropriate delivery of health care services."[41] In pediatric settings, including CHOP, care coordination has addressed needs of children with medical complexity, increasing receipt of recommended preventive care.[42–47] While models vary, defining features include proactive enrollment of children with complexity, comprehensive screening, health care navigation, education, and addressing barriers to care. The care coordination model has been articulated through recent reviews and reports of successful programs.[42–46,48,49]

Motivational Interviewing (MI) can address modifiable behavioral risks. MI is a patient-centered approach that uses strategies such as reflective listening, agenda setting, articulating ambivalence, and eliciting "change talk" to promote positive behavior change.[50] MI values patient autonomy, including the autonomy not to change, but typically functions where there is a clear desired outcome.[50] It has been implemented in a range of health care settings, including primary care, and has yielded benefits for behaviors that pose a risk in the interconception period, including physical activity, diet, contraceptive access, and tobacco use.[51–57] MI can be carried out by practitioners with a variety of professional backgrounds.[58,59] The supportive approach of MI may be particularly well suited to new mothers, who have high rates of depression and anxiety, and frequently face trade-offs when accessing health care or changing behaviors.[60] When maternal screening identifies a modifiable behavioral risk (e.g. poor diet), this intervention will use MI as an approach to address these risks.

In summary, many women with a prior preterm birth have modifiable risk factors for repeat preterm birth and experience gaps in preventive care. Addressing modifiable risks and gaps in care could reduce overall preterm births by 10% or more. Care coordination for children with medical complexity serves as the initial model for this intervention. **This study will adapt existing care coordination models to meet the needs of women following a preterm birth and integration of MI with care coordination to better address modifiable behavioral risks.**

2.4 Compliance Statement

This study will be conducted in full accordance all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46 and the Good Clinical Practice: Consolidated Guideline approved by the International Conference on Harmonisation (ICH). All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent, and will report unanticipated problems involving risks to subjects or others in accordance with The Children's Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

3 STUDY OBJECTIVES

3.1 Primary Objective (or Aim)

The primary objective of this study is to determine the whether the Care Coordination after Preterm Birth intervention is feasible and acceptable to women following a preterm birth.

3.2 Secondary Objectives (or Aim)

The secondary objectives of this study are to examine the changes in health care utilization, behavioral constructs of autonomy support and autonomous motivation, and modifiable risks from pre- to post-intervention.

4 INVESTIGATIONAL PLAN

4.1 General Schema of Study Design

4.1.1 Screening Phase

First, Potential subjects will be identified from the postpartum unit and from the newborn nursery and Neonatal Intensive Care Unit for the Hospital of the University of Pennsylvania. Potential subjects will first be identified based on key criteria such as age, described in greater depth below. For the screening methods we are requesting a waiver of HIPAA authorization to screen the health records to ensure that potential participants meet the basic eligibility criteria for the study.

4.1.2 Study Intervention Phase

This is a preliminary single arm open trial of Care Coordination after Preterm Birth, a multicomponent behavioral intervention that will last up to 24 weeks post enrollment. This intervention includes screening and care planning, focused health education, health care navigation, addressing barriers to care and MI. Fidelity will be assessed by proportion of planned tasks (proactive enrollment, screening, navigation, education, addressing barriers) that are attempted and completed with a goal of 80% completed. **We will test these components separately or together to optimize:**

- Activities prior to hospital discharge:

Shortly following enrollment (within 4 weeks and potentially much sooner) the care coordinator will engage participants in screening for unmet health needs, knowledge deficits, modifiable risks, and goals for care. In addition, care coordinators will assess sources of social support for participants as well as potential barriers to care. This process will involve chart review, participant report, and eliciting input from the participant's clinical care teams. This process will conclude with development of a care plan designed to summarize goals for health care and behavior change in the postpartum period. The participant will be actively involved in determining priorities for the care plan. This plan will be communicated to the clinical teams working with the participant and her infant, as well as other services involved with the family, as appropriate and as approved by the participant (e.g. home visiting services).

- Supporting completion of health care:

Next the care coordinator will follow-up with the participant by phone, video, or during infant office visits in primary care. These contacts will assess for progress on goals of care, provide health education and health care navigation as needed, and continually reassess barriers to care and help participants identify and access resources to remove barriers. Health education will focus on optimizing reproductive health and will utilize materials already in use at the clinical sites utilized by participants, or from sources recommended by the clinical care team.

- Incorporation of Motivational Interviewing:

Concurrently with care navigation, the Care Coordinator will engage women in 2 – 4 sessions of MI focused on one modifiable behavior selected by the participant and the care coordinator during the goal setting process. Timing of MI sessions may vary somewhat by participant preference and other needs, but we expect they will start 4 – 8 weeks postpartum and occur over a period of approximately 4 – 8 weeks. MI sessions may occur in-person, by phone, or by video and are expected to last 10 – 30 minutes each.

The intervention will conclude when the participant and the care coordinator have met the goals of care and completed the recommended health care visits outlined on the plan of care, or at six months post enrollment. Participants will be informed from the start of the intervention that this is a time-limited intervention. Any outstanding needs at the time of program completion will be summarized in an updated plan of care and communicated to the participant's clinical care team.

Details such as timing of intervention components, mode of delivery, communication with participants may be modified over the course of this preliminary pilot intervention.

Subjects may not complete all study procedures that are outlined, it may depend on when they enroll in the study and the feasibility measures that are being assessed at the time. Women will be informed at enrollment about which components we are currently testing.

4.1.3 Follow-up Phase

Study data will be collected at enrollment, and at 3 months and 6 months after enrollment. For some participants the intervention may conclude several weeks prior to the 6-month data collection period, however all participants will be included in the 3-month and 6-month data collection assessments.

4.2 Allocation to Treatment Groups and Blinding

This is a preliminary, open, non-randomized trial of the Care Coordination after Preterm Birth intervention. All women who consent will receive the intervention. Blinding is not applicable.

4.3 Study Duration, Enrollment and Number of Sites

4.3.1 Duration of Study Participation

The study duration is 6 months.

4.3.2 Total Number of Study Sites/Total Number of Subjects Projected

This study will occur at two sites within the CHOP Primary Care Network (Karabots and Cobbs Creek). In addition, research activities will occur at UPenn (Hospital of the University of Pennsylvania). Recruitment will stop when feasibility and acceptability have been established. We plan to enroll a maximum of 106 participants.

4.4 Study Population

4.4.1 Inclusion Criteria

1) Females age 14 – 45.

2) History of preterm birth at < 34 weeks gestation OR history of preterm birth at 34 – 36 weeks gestation with risk factors for recurrent preterm birth including: low preventive care utilization, tobacco use, obesity, depression or anxiety, history of unmet contraceptive needs.

3) Intention to seek infant pediatric primary care at one of the two study sites (Karabots and Cobbs Creek).

4) Medicaid insurance.

4.4.2 Exclusion Criteria

1) History of sterilization procedure.

2) Plan to move away from the area or transfer pediatric primary care within six months of enrollment.

3) Limited English proficiency

We are excluding younger women and women with Limited English proficiency from this pilot work because we expect that their health care navigation and education needs, patterns of health care utilization, and barriers to health will be distinct from those of older women and women with English proficiency, and would not be well represented in this small pilot study. Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

5 STUDY PROCEDURES

5.1 Screening phase

Procedures for screening are described above in greater detail (section 3.1.1). The screening phase will include the following activities. Details of data collection tools and definitions are included below in section 5.

- Health record review by study team member to assess gestational age.
- Phone, in person, or video confirmation of eligibility and scheduling of informed consent and baseline assessment.

5.2 Baseline assessment

During the baseline assessment we will collect data on participant demographics, behavioral constructs related to motivational interviewing, modifiable health behaviors, and potential barriers to health care and health behavior. This data will be collected in person, by phone, or by video, with the exception of participant weight which will be measured with a scale in a health care setting. This assessment is intended to be completed prior to participant discharge from the hospital following birth, but may occur after that time. Details of data collection tools and definitions are included below in section 5.

- Informed consent
- Demographic characteristics (age, race, gender, ethnicity, residential address, educational attainment, insurance, household income, marital status)
- Timing of first prenatal visit / prenatal visit count
- Autonomy support
- Autonomous motivation
- Contraceptive use prior to pregnancy
- Weight, height
- Tobacco use
- Mental health symptoms
- Barriers to care / health behavior

5.3 Intervention phase

The Care Coordination After Preterm Birth Intervention will be provided over 4 – 6 months. We will (e.g. reproductive health education topics). Fidelity will be assessed by proportion of follow existing institutional protocols in which experienced peers model and then certify competence in tasks. The study team will supplement training for procedures that differ from existing protocols planned tasks (proactive enrollment, screening, navigation, education, addressing barriers) that are attempted and completed with a goal of 80% completed. The goal of this phase is to test the intervention protocol for feasibility with the proposed population and setting and refine focus on tasks most likely to benefit participants. We will test the following components of the intervention separately or together

- Activities prior to hospital discharge:

Shortly following enrollment (within 4 weeks and potentially much sooner) the care coordinator will engage participants in screening for unmet health needs, knowledge deficits, modifiable risks, and goals for care. In addition, care coordinators will assess sources of social support for participants as well as potential barriers to care. This process will involve chart review, participant report, and eliciting input from the participant's clinical care teams. This process will conclude with development of a care plan designed to summarize goals for health care and behavior change in the postpartum period. The participant will be actively involved in determining priorities for the care plan. This plan will be communicated to the clinical teams working with the participant and her infant, as well as other services involved with the family, as appropriate and as approved by the participant (e.g. home visiting services).

- Supporting completion of health care:

Next the care coordinator will follow-up with the participant by phone, video, or during infant office visits in primary care. These contacts will assess for progress on goals of care, provide health education and health care navigation as needed, and continually reassess barriers to care and help participants identify and access resources to remove barriers. Health education will focus on optimizing reproductive health and will utilize materials already in use at the clinical sites utilized by participants, or from sources recommended by the clinical care team.

- Incorporating Motivational Interviewing:

Concurrently with care navigation, the Care Coordinator will engage women in 2 – 4 sessions of MI focused on one modifiable behavior selected by the participant and the care coordinator during the goal setting process. Timing of MI sessions may vary somewhat by participant preference and other needs, but we expect they will start 4 – 8 weeks postpartum and occur over a period of approximately 4 – 8 weeks. MI sessions may occur in-person, by phone, or by video and are expected to last 10 – 30 minutes each.

The intervention will conclude when the participant and the care coordinator have met the goals of care and completed the recommended health care visits outlined on the plan of care, or at six months post enrollment. Participants will be informed from the start of the intervention that this is a time-limited intervention. Any outstanding needs at the time of program completion will be summarized in an updated plan of care and communicated to the participant's clinical care team.

Details such as timing of intervention components, mode of delivery, communication with participants may be modified over the course of this preliminary pilot intervention.

Subjects may not complete all study procedures that are outlined, it may depend on when they enroll in the study and the feasibility measures that are being assessed at the time. Women will be informed at enrollment about which components we are currently testing.

5.3.1 3-month assessment

The study team will conduct chart review and a telephone call or video call 10 – 14 weeks post-enrollment to assess the following. Details of data collection tools and definitions are included below in section 5.

- Health care utilization
- Autonomy support
- Autonomous motivation
- Contraceptive use
- Tobacco use
- Mental health symptoms (EDPS and PSS)
- Barriers to health care or to positive health behavior
- Sleep related impairment

5.3.2 6-month assessment (end of study)

The study team will conduct chart review and an in-person visit, telephone call, or video call at 24 – 30 weeks post-enrollment to assess the following. Details of data collection tools and definitions are included below in section 5.

- Health care utilization
- Autonomy support
- Autonomous motivation
- Contraceptive use
- Tobacco use
- Mental health symptoms (EPDS and PSS)
- Barriers to health care or to positive health behavior
- Sleep related impairment
- Participant weight (the study team will accept either data recorded in the health record during this window during a clinical visit, measured by the study team in a clinical setting, or if neither of those are available participant report.

5.4 Subject Completion/Withdrawal

Participants may withdraw from the study at any time without prejudice to their care. They may also be discontinued from the study at the discretion of the Investigator for lack of adherence to the study treatment or visit schedule, because of emergence of exclusion criteria, or to protect the subjects for reasons of safety or for administrative purposes.

Participants who do not receive all components of the intervention will still be included in the 3-month and 6-month assessments. Because the primary aim of this study is to determine feasibility and acceptability, efforts will be made to retain participants and to assess reasons for non-completion or withdrawal from the study.

If any adverse events occur that require clinical intervention during the course of participation, the PI or a co-investigator who is a licensed clinician will conduct a risk and safety assessment and make appropriate clinical referrals. If the investigators become aware of any serious, related, adverse events after study completion or withdrawal, the event will be recorded in a separate, coded REDCap database used to track attrition and adverse events.

5.4.1 Early Termination Study Visit

For subjects who withdraw before the end of the study, we will request that they indicate why they have chosen to withdraw and whether any study modifications would have made participation more valuable for them.

6 STUDY EVALUATIONS AND MEASUREMENTS

6.1 Screening Measures

6.1.1 Medical Record Review

Medical record review will assess initial eligibility criteria for women in the postpartum period.

- Age (years)
- Gestational age at recent delivery
- Insurance
- History of sterilization procedure
- Timing of first prenatal visit
- Number of prenatal visits
- Tobacco use prior to or during pregnancy
- Gestational Diabetes
- Pregnancy Induced Hypertension
- Treatment for depression or anxiety during pregnancy
- Weight and height
- Planned site of infant pediatric care
- Plans to move out of the area during the upcoming six months

The last two items listed above (planned site of infant pediatric care and plans to move out of the area during the upcoming six months) may not be consistently documented in the health record. Potential participants will be informed that we are seeking these characteristics in study participants.

6.2 Measures of Treatment Feasibility and Acceptability (Primary Outcome)

The primary outcome of this study is to assess feasibility and acceptability of the Care Coordination After Preterm Birth intervention. We will assess feasibility and acceptability using the following measures.

- *Screening rate (feasibility):* The study team will compare the number of potentially eligible participants to those who complete screening questionnaires. The number of potentially eligible participants will be considered the number or preterm births with Medicaid insurance in a given month.
- *Recruitment rate (feasibility):* The study team will track the proportion of eligible women screened who enroll in the study.
- *Reasons for non-participation (acceptability):* For women who decline screening or enrollment we will ask them, if they are willing, to provide reasons for non-participation and potential study modifications that might have encouraged them to participate. Responses will be tabulated and reviewed for potential themes.
- *Retention rate (feasibility):* The study team will track the proportion of enrolled participants who complete the intervention and the study assessments.
- *Assessment process (feasibility):* The study team will track the proportion of the baseline, 3-month, and 6-month assessments that are completed.

- *Intervention usability (feasibility):* Study interventionists will keep records of barriers and facilitators of the intervention content and procedures.
- *Family engagement and adherence (feasibility):* Study interventionists will keep track of the proportion of contacts initiated that are completed, contacts initiated by participants, and participant use of resources and strategies discussed during the intervention, based on participant feedback.
- *Intervention fidelity (feasibility)*
    - *Care coordination fidelity:* We will quantify interventionist completion of screening tools, as well as other tasks outlined in the care plan, including focused education, navigation, and addressing barriers to care, screening.
    - *Motivational interviewing fidelity:* OnePass is a validated tool used to evaluate MI practice and assess fidelity based on review of a single session, using 23 items to assess MI components.[61] This tool yields a global score while also identifying specific areas for additional practice and training. Scores range from 1 – 7 with 5 considered a minimum for competence. Interventionists will complete at least one OnePass within a month of starting MI sessions with participants.
- *Intervention acceptability (participants):* Care givers will complete a brief (10 – 15 minutes) audio-recorded, open-ended qualitative interview with questions related to acceptability domains such as attitude towards intervention, intervention burdens, perceived effectiveness of the intervention, willingness to participate again or recommend intervention to a friend, and satisfaction with the intervention.
- *Intervention acceptability (participants):* We will use an adapated version of the validated Acceptability of the Intervention Measure to measure acceptability quantitatively.

6.3 Measures of Modifiable Health Behaviors and Sociodemographic characteristics

6.3.1 Modifiable health behaviors

Modifiable health behaviors will be measured at baseline, 3-months, and 6-months as described here. We will also measure autonomous motivation and autonomy support as outcomes related to the motivational interviewing component of the project. Details are provided here.

- **Care utilization** will be abstracted from the medical record whenever possible. Available data will include all data from the CHOP and Penn health records. In addition, participants will be asked to report on all health care.
- **Tobacco use** will be assessed as any tobacco use in the past 30 days, a meaningful measure of continuous abstinence.[62]
- **Contraceptive use** will be assessed by asking about any current contraceptive methods.
- **Mental health symptoms** will be measured with the Edinburgh Postnatal Depression Scale – This 10 item rating scale has been validated in diverse populations (range 0 – 30, Cronbach alpha 0.87). and widely used in both clinical

practice and research settings. In clinical settings, a cutoff of 10 is typically considered concerning for potentially meaningful clinical symptoms of depression.[63]

- **Perceived stress** will be measured using the Perceived Stress scaled. This 10-item scale has been validated in diverse populations (range 0 – 40, Cronbach alpha 0.80).
- **Participant weight** will be measured at baseline and 6 months. All efforts will be made to obtain a weight in a clinical setting (either during a pediatric visit or from the participants own health record). If these efforts are not successful, we will record participant reported weight.
- **Autonomy support** reflects individuals' perception of the degree to which the health care team understands individuals' perspectives and trusts they will make the best decisions for themselves. Autonomy support will be measured with the short form of the Health Care Climate Questionnaire (6 items, range 6 – 42, Cronbach alpha 0.82).[64]
- **Autonomous motivation** reflects the degree to which individuals are driven by concerns consistent with their own values or identity. Validated tools exist to measure autonomy support and autonomous motivation.[64,65] Autonomous motivation will be measured using the Autonomous Motivation and External Regulation scales of the Treatment Self-Regulation Questionnaire (10 items, range 7 – 70, Cronbach alpha 0.90).[65]
- **Sleep-related impairment** will be measured using the PROMIS Item Bank 8-item measure (range 8 – 40, Cronbach alpha 0.89).

6.3.2 Sociodemographic factors

The following sociodemographic factors will be assessed at baseline only:

- Maternal age (years) (Health record review)
- Race (participant self-report)
- Ethnicity (Participant self-report)
- Educational attainment (Participant self-report)
- Estimated household income (Participant self-report)
- Prior pregnancies (Health record review)
- Complications of pregnancy including gestational diabetes or pregnancy-induced hypertension (Health record review)
- Chronic conditions including diabetes, asthma, hypertension, depression, or anxiety (Health record review)

The following demographic factors will be assessed at baseline and at 6-month follow-up and will both be collected via participant self-report:

- Household composition
- Relationship with other biological parent of child (if applicable) including married, cohabitating, not cohabitating but still in a relationship, no longer in a relationship but other parent actively involved in parenting

The following potential barriers to positive health behaviors will be assessed at baseline and at 3-month and 6-month follow-up and will all be collected via participant self-report:

- Health insurance will be assessed using item structure used in the Behavioral Risk Factors Surveillance Survey (at time of enrollment all participants should have Medicaid, however this may vary over time).[66]
- Transportation needs will be assessed using items from the WellRx screening, which was developed in a Family Medicine setting and has been widely used.[67]
- Child care will be assessed using items from the WellRx screening, which was developed in a Family Medicine setting and has been widely used.[67]
- Food insecurity will be assessed with a two item screen that has been previously validated with families in pediatric settings. The two items are "within the past 12 months we worried whether our food would run out before we got money to buy more" and "within the past 12 month the food we bought just didn't last and we didn't have money to get more."[68]
- Employment status will be assessed using item structure used in the Behavioral Risk Factors Surveillance Survey and the Pregnancy Risk Assessment Monitoring System.[66,69]

6.4 Safety Evaluation

Participant safety will be monitored by adverse events throughout the study. Please see the Data Safety and Monitoring Plan (Section 8.4.1) for further information.

7 STATISTICAL CONSIDERATIONS

7.1 Primary Endpoint

The primary endpoints are overall rating of intervention feasibility and acceptability of the intervention.

7.2 Secondary Endpoints

As secondary endpoints we will assess modifiable behaviors and will include the following:

- Health care utilization over the study period
- Change in Autonomous Motivation over the study period
- Change in Autonomy Support over the study period

7.3 Control of Bias and Confounding

This is a single arm feasibility study. Our participants may differ in important ways from those who choose not to participate in the study, which will limit generalizability of our findings. We will mention this as a limitation in any study data dissemination. In addition, we well compare demographic and utilization characteristics of enrolled participants to available summary data on women delivering at the enrollment sites.

7.4 Statistical Methods

7.4.1 Primary outcome: Feasibility data

We will examine the following quantitative feasibility and acceptability outcomes through the use of descriptive statistics, which include means for continuous variables and proportions for categorical variables. In some cases, we will compare them to a priori goals for feasibility. See above (Section 5) for more detail about measurement of these outcomes.

- Screening rate: Proportion of potentially eligible participants screened.
- Recruitment rate: Proportion of screened women who enroll.
- Retention rate: Proportion of enrolled participants who complete the intervention and the study assessments.
- Assessment process: Proportion of the baseline, 3-month, and 6-month assessments that are completed.
- Family engagement and adherence: Proportion of contacts initiated that are completed within 3 days will be compared to an a priori threshold of 80%, # of contacts initiated by participants, # of recommended resources utilized.
- Intervention fidelity
    - Care coordination fidelity: # of screenings completed, # of care plan goals achieved
    - Motivational interviewing fidelity: OnePass score will be compared to an a priori threshold of 5, considered a minimum threshold for competence.

7.4.2 Quantitative secondary outcomes

We will also examine the following quantitative secondary outcomes through the use of descriptive statistics, which include means for continuous variables and proportions for categorical variables.

- Count of preventive care visits
- Proportion of preventive care recommended in care plan that is completed
- Change in autonomy support
- Change in autonomous motivation

7.4.3 Qualitative data

Qualitative data (itemized below) will be reviewed and assessed for themes using a priori codes related to theories of acceptability and feasibility,[70] as well as a grounded theory approach where we allow themes to emerge from data. (For more details on how these data will be defined and collected, see Section 5 above.)

- Reasons for non-participation
- Intervention usability
- Family engagement and adherence (participant feedback)
- Intervention acceptability

7.4.4 Safety Analysis

This is a minimal risk study and therefore we do not anticipate any adverse events related to study participation. However, for all subjects who consent to participation we will track and describe any adverse events that occur during the study.

7.5 Sample Size and Power

This open single arm study is not designed to have power to test the efficacy or significance of the intervention effects. A power analysis was thus not appropriate. The sample size for this study was identified through review of the literature on testing preliminary interventions.

8 SAFETY MANAGEMENT

8.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

8.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

9 STUDY ADMINISTRATION

9.1 Treatment Assignment Methods

There will be no randomization and no blinding in this study.

9.2 Data Collection and Management

Here we describe a data collection and management plan that is consistent with CHOP Policy A-3-6: Acceptable Use of Technology Resources that defines the requirements for encryption and security of computer systems

Confidentiality: All study data (with the exception of qualitative audio recordings, see below) will be maintained on in a password-protected RedCap database that will only be available to members of the study team. This database will contain Protected Health Information. At the conclusion of data collection (i.e. after completing the 6-month study assessment), study staff will convert each record to a "Coded" record through two steps. First, we will create creating a separate RedCap database (the Master List) that includes only the study identification number, subject name, and subject date of birth. Second, we will remove all PHI from the main study database but removing identifying information and converting dates into times from most recent birth. Data entry into RedCap will involve a combination of direct participant entry, study team entry from participant report, and study team entry from health record review. Only coded data will be downloaded from RedCap for analysis. When coded data is downloaded, it will be stored in password protected folders on the CHOP network drives.

All paper consent forms will be stored in a locked filing cabinet in the Roberts Center for Pediatric Research. They will also be scanned and stored in password protected files on the CHOP network drive.

Qualitative data will be collected via audio-recording in-person or over the phone or video. All audio files will be stored on the secure CHOP computer network drive in password protected folders accessible only to members of the study team. Transfer of audio files from the audio device to the CHOP network drive will via cable directly from the device to the computer or via an encrypted flash drive. In the password protected file, audio

files will be labeled with only the participants' study ID. Audio files will be transcribed by a professional transcription agency that functions in accordance with all CHOP technology transfer policies. We will contact OTT to ensure that a Business Associate Agreement is in place for the transcription agency. Transcripts will be stored in password protected files on the CHOP network drives and will be de-identified by removing any references to names, dates, or specific addresses. Audio files will be maintained until analysis is complete, to assist with any uncertainties in the analysis of the data.

Security: The CHOP REDCap system operates with back-up recovery systems in place. Consent forms will have a paper back-up system available. Qualitative transcripts will have a back-up stored locally on the CHOP-issued computer of the study PI in a password protected folder.

Anonymization, de-identification, or destruction of data: Plans to de-identify and code data are described above (see "Confidentiality"). All study data will be retained a minimum of 6 years from study start completion, consistent with current CHOP policies on retention and destruction of records for Human Subjects Research with minimal risk. Data files will include instructions about study start date to assist the study team with completing destruction of data.

9.3 Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy. The PI and all members of the study team will not use data and records for any purpose other than conducting the study. All members of the study team will complete training on confidentiality in research. All data will be safeguarded as described above.

No identifiable data will be used for future study without first obtaining IRB approval. The investigator will obtain a data use agreement between the provider (the PI) of the data and any recipient researchers (including others at CHOP) before sharing a limited dataset (PHI limited to dates and zip codes).

9.4 Regulatory and Ethical Considerations

9.4.1 Data and Safety Monitoring Plan

In this minimal risk study, the primary anticipated safety risk relates to disclosure of sensitive information to study team members. This information includes information on mental health symptoms which are explicitly included in study data collection (Edinburgh Postnatal Depression Scale). In addition, though we are not explicitly asking participants to report on or discuss instances of abuse and neglect for either themselves or their infants, these issues may be disclosed. Finally, study team members may directly observe signs of abuse or neglect or signs of mental health deterioration.

We will ensure that all study team members have completed training for identifying abuse and neglect as well as severe mental health symptoms, and are also trained in reporting requirements. In addition, we have developed the following protocol to address any instances of safety concerns.

- **Mild to moderate behavioral health concerns that are not currently being treated**: Research staff will offer a resource sheet (included in IRB application as attachment) for community resources. This intervention will be embedded in two CHOP primary care sites. Therefore, study staff may also remind participants that social workers associated with their child's care site are available to help parents navigate access to behavioral health services for themselves.
- **Severe behavioral health concerns that are not currently being treated:** This includes any mention of current thoughts or acts of self-harm or harm to others. In these situations, staff will notify the Principal Investigator (a licensed pediatrician) who will speak to the participant immediately, if time permits, or by phone as soon as possible. If indicated, suicidality will be assessed using the suicidal thoughts item from the Edinburgh Postnatal Depression Scale, which is currently the standard scale to assess maternal mental health in the Care Network. Item 10 of this scale reads "Over the last two weeks, the thought of harming myself has occurred to me…" response options include "yes, quite often," "sometimes," "hardly ever," and "never." Should there be an imminent risk to caregiver safety, study staff or the Principal Investigator will contact emergency services (911 or Pennsylvania mobile crisis services) for further suicide/homicide/risk assessment. If for some reason the Principal Investigator is not available in an emergency situation, study team members will contact the social work team associated with the child's care site for guidance.
- **Child abuse or neglect:** Should a caregiver spontaneously disclose incidents of abuse or neglect, we will file a report with Department of Human Services.
- **Intimate partner violence:** If a caregiver spontaneously discloses incidents of intimate partner violence, they will be offered a resource sheet (included in the IRB application as an attachment) about IPV resources. If they report ongoing intimate partner violence, they will be connected with the IPV specialist affiliated with the study sites to conduct further assessment and develop a safety plan. If there is concern for an immediate safety issue, study team members will immediately notify the principal investigator or, if she is not available for some reason, the IPV specialist associated with the child's care site.

Any referrals or follow-up activities related to the above safety concerns will ***not*** be documented in patient health records by the study team. In situations where an immediate safety concern was noted in study materials (recordings / transcripts), the transcript will be annotated to indicate any immediate or follow-up actions taken to address those concerns.

Resource sheets were adapted from sheets used for a parenting intervention currently underway in the Care Network with oversite from the CHOP IRB. In addition, this protocol has been in place for CHOP IRB exempt qualitative work preliminary to the current study.

This study is covered by a **Certificate of Confidentiality** to protect identifiable information from forced disclosure. The CoC will allow all individuals who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, the CoC will help achieve the research objectives and promote participation in the study by ensuring confidentiality and privacy.

The PI for this study to review data storage and integrity, safety events, and other adverse events at least once every six month. These will be reported during continuing reviews to the IRB and the study sponsor. Any unanticipated severe events or episodes of reported abuse or neglect will be urgently reviewed by the PI to ensure reporting to the CHOP IRB and the study sponsor and the review protocols to assess for any needed revisions to ensure participant safety.

9.4.2 Risk Assessment

This is a minimal risk study. The safety plan described relates primarily to identification of safety risks not related to study procedures (i.e. the study should not increase the risk of mental health symptoms, but may identify these symptoms incidentally). Related to study procedures, it is possible that discussion with the study interventions or study data collection forms will cause psychological distress to participants. There is also some risk that increased monitoring from the health care team will increase utilization of health care services, which may carry some economic cost to participants. We do not anticipate any physical or societal harms. Our study design intends to minimize these harms by ensuring that study interventionists are trained to recognize distress, provide immediate support, and connect families to resources to that may assist with management of mental health symptoms, or with economic barriers to health care receipt.

9.4.3 Potential Benefits of Trial Participation

Benefits may benefit from increased access to preventive health care during the study period, and increased support for positive behaviors. These benefits may improve short-term health and wellbeing, medium range health outcomes such as improved outcomes in subsequent births, and long-term cardiovascular health. In addition, this trial may benefit participant offspring, if increased wellbeing allows greater attention to parenting activities, or if interventionists provide some care navigation relevant to infant health care.

9.4.4 Risk-Benefit Assessment

The risks associated with this study are minimal and generally no greater than the risks of receiving standard of care in the community (e.g. routine postpartum care).

9.5 Recruitment Strategy

Potentially eligible participants will be identified by screening health records in the newborn nursery and the neonatal intensive care unit at the Hospital of the University of Pennsylvania or by identifying women whose infants present for primary care at Karabots or Cobbs Creek. Chart review of women within four weeks of delivering a preterm infant (< 37 weeks) will assess for potential modifiable health risks, as well as other inclusion and exclusion factors. Next, potentially eligible women will be approached for recruitment and informed consent. Two eligibility factors may not be consistently documented in a health record (planned site of pediatric care for infant, any plans to move out of the area in the upcoming six months). These factors will be confirmed verbally before proceeding with other enrollment activities. Women will be approached by study staff via phone or in person during hospitalization following delivery, or when visiting their infant in the hospital. In the event that conditions related to COVID or other unanticipated events prevent the physical presence of study staff in the clinical setting we will develop a flier to be distributed at

discharge, allowing women to call a number to opt out of the study. This flier will be submitted to the IRB for review prior to use. We are requesting a waiver of consent and authorization for screening. Preliminary chart review estimates that approximately 100 eligible women deliver at HUP each year and choose to take their infants for pediatric care at one of the study primary care sites. We therefore expect it will be feasible to enroll 106 participants over two years.

9.6 Informed Consent/Assent and HIPAA Authorization

9.6.1 Waiver of HIPAA Authorization to Screen Medical Records

We are requesting a waiver of HIPAA authorization to screen health records for women following birth to identify potentially eligible participants. This will ensure that women who are contacted appear to be eligible based on chart review.

The use of health record data for eligibility screening involves no more than a minimal risk to the privacy of individuals. Identifiers for potentially eligible participants (name, room number, telephone number) will be stored in a secure REDCap database and will be destroyed within two weeks for any potentially eligible participant who has not been contacted or who has been contacted by declined enrollment. As noted above, screening summary data will be retained (number potentially eligible, number completed screening, number consented to study participation) but these data will not include any protected health information. Individual screening data will not be used for study purposes (beyond screening). Screening data will not be reused or disclosed for any reason.

The research could not practicably be conducted without the waivers. Due to the large number of women delivering at HUP and the frequency of rapid discharges, a requirement to obtain HIPAA authorization for screening could introduce bias into recruitment with women with longer length of stay more likely to be identified as potentially eligible. In addition, the research could not be conducted without access to this data as there would be no practicable way to identify potentially eligible women.

9.6.2 Combined Informed Consent-Authorization of HIPAA for Study Procedures

Members of the study team will be responsible for obtaining informed consent for study participation. For eligible participants, informed consent using a combined consent-HIPAA authorization will occur either in person or electronically, via a secure REDCap portal, pending participant preference and availability. When consent takes place in person, it will take place in the postpartum unit at HUP in a private room or in areas such as waiting areas that are semi-private and far enough away from other patients to maintain confidentiality. If informed consent is obtained electronically, the participant will receive a link to a secure REDCap portal in which they will be asked to enter their name and the date to indicate their consent. The participants name will associate the consent document with the enrolled participant. The REDCap portal will contain the exact same information in the same format as the paper consent form. The study team will email a copy of the completed electronic consent to the participant, with instructions to save a copy of this form.

For all consent procedures, potential participants will be given unlimited time to decide on participant. Potential participants will be informed of the nature of the research, the study procedures, the potential benefits and possible risks. Families will be informed that they are

free to decline to participate or to withdraw from the study, and that this decision will not influence any future medical care.

Though this study may enroll individuals aged 14 – 18, all participants will be considered adults for the purpose of this research. According to 45 CFR 46.402 children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction where the research will be conducted. In Pennsylvania, individuals 14 years of age and older are legally able to consent to treatment related to reproductive health care and to care for their children. Because this research relates to reproductive health, in Pennsylvania women 14 years of age and older will be able to consent for this study independently.

9.7 Payment to Subjects/Families

9.7.1 Payments to parent for time and inconvenience (i.e. compensation)

Compensation for study participation will be provided to participants as described below. All payments will be provided by ClinCard or by gift cards.

- $30 for completion of the baseline assessment
- $30 for completion of the 3-month assessment
- $60 for completion of the 6-month assessment

The total possible payment for completion of all assessments is $120.

9.7.2 Gifts

During the intervention participants may be provided with diapers, infant thermometers, or other items that are sometimes donated to the study sites and provided to new parents.

10 PUBLICATION

We intend to present results of this project at national conferences and to publish project results in peer-reviewed journals.

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