Study Protocol

Minding the gap: improving women's health through coordinated postpartum planning

Protocol Date: December 4, 2024

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PROTOCOL TITLE: Minding the gap: improving women's health through coordinated postpartum planning

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VERSION: 14 (4-DEC-2024)

Revision #	Version Date	Summary of Changes
1	10/1/2020	Updated and added in methods and timing of follow-up for control group participants, for survey reminders and re-engagement purposes.
2	11/16/2020	Added additional information to be abstracted from the electronic medical record prior to qualitative interviews (Aim 1).
3	12/18/2020	Added a Community Advisory Board component; included FaceTime and Google Duo as alternate modalities for conducting in-depth interviews; changed incentive for in-depth interview from $25 to $50 and increased interview duration from 60 minutes to 90 minutes; corrected an inconsistency in the protocol (incorrectly stated that verbal consent would be used for the in-depth interviews)
4	10/21/2021	Added a pilot phase for the RCT and EPIC SmartForm
5	5/11/2022	Changed the language to reflect study coordinator instead of nurse coordinator. Updated subject compensation to reflect enrollment and study visits. Added additional information on randomization methods. Removed assent process and will use Under 18 ICF instead for consent. Added in-person option for revoking authorization and replaced with an email option.
6	07/11/2022	Clarified how participants will be contacted for survey

		reminders and remote visit scheduling. Removed 2-month control group outreach for re-engagement.
7	10/03/2022	Added that postpartum planning visits can occur during any type of prenatal care visit (fetal monitoring, ultrasound, routine) or an inpatient antenatal hospitalization. Expanded the modalities through which recruitment can occur, adding phone contact prior to or following prenatal care visits for eligible patients and early contact (at 18-19 weeks) for patients who will become eligible at 20 weeks. Changed the details of the delivery hospitalization visit to allow the visit to be completed prior to delivery, if needed.
8	02/20/2023	Added the option for the delivery admission visit to be conducted via phone for participants with a Covid + diagnosis during their delivery hospitalization.
9	03/14/2023	Added pre-pregnancy obesity as an eligible diagnosis for RCT enrollment
10	05/03/2023	Added the option to obtain electronic consent, via REDCap, during phone recruitment for RCT enrollment
11	08/08/2023	Updated Principal Investigator and updated page info for Table of Contents section
12	11/16/2023	Updated details for blinding, abstraction, and blinded review of internal and external postpartum visits; Added phone visit for completion of delivery admission visit for intervention participants delivering outside of Grady hospital; updated table of contents page info
13	12/4/2024	Updated additional funding source (AMETHIST@PENN) that supports more detailed analysis of already collected data (for implementation assessment). Updated analysis section to reflect more detailed analysis of data for

		implementation assessment in relation to primary and secondary outcomes.

FUNDING SOURCE: National Institutes of Health; AMETHIST@PENN Pilot Grant

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1. Study Summary

Study Title	Minding the gap: improving women's health through coordinated postpartum planning
Study Design	Sequential mixed methods design. Aim 1 will involve in-depth interviews; Aim 2 is a pragmatic randomized trial. The RCT Pilot will include medical record review and abstraction only.
Primary Objective	To develop and evaluate a culturally tailored, comprehensive postpartum care system for pregnant women who deliver at Grady Memorial Hospital and are at increased risk for SMM due to cardiovascular risk factors.
Secondary Objective(s)	
Research Intervention(s)/Interactions	Comprehensive postpartum care system vs standard of care
Study Population	**Aim 1**: Women who attended prenatal care and delivered a live-born infant at Grady Memorial Hospital for a pregnancy complicated by chronic diabetes, chronic hypertension, gestational diabetes, or hypertensive disorder of pregnancy. **Aim 2**: Women who received 1 or more prenatal care visits in at Grady Memorial Hospital, intend to deliver at Grady, have a documented diagnosis of chronic diabetes, chronic hypertension, pre-pregnancy obesity, gestational diabetes, or hypertensive disorder of pregnancy (gestational hypertension or preeclampsia). **RCT Pilot:** Medical records of pregnant patients who would be eligible for Aim 2 (enrolled in prenatal care with eligible diagnosis)
Sample Size	**Aim 1**: Up to 30 women

	Aim 2: 320 women **RCT Pilot:** Up to 10
Study Duration for individual participants	**Aim 1**: 30 minutes **Aim 2**: Approximately 20 months (enrolled during prenatal care and followed 14 months after delivery) **RCT Pilot:** NA (no participant interaction)
Study Specific Abbreviations/ Definitions	EMR, electronic medical record; HDP, hypertensive disorders of pregnancy
Funding Source (if any)	National Institutes of Health; AMETHIST@PENN Pilot Grant

2. Objectives

The purpose of the study is to design, implement, and evaluate a holistic postpartum women's health care system within Grady Memorial Hospital for women who have cardiovascular risk factors for SMM including chronic hypertension, chronic diabetes, pre-pregnancy obesity, gestational diabetes, or a hypertensive disorder of pregnancy (HDP, includes gestational hypertension or preeclampsia). We will use a sequential mixed methods design. First, we will conduct in-depth interviews with women who have given birth in the prior year to characterize barriers and facilitators to accessing postpartum care. The information from these interviews will be used to inform the design of a postpartum care system. Next, we will conduct a pragmatic randomized trial to test the effectiveness of the system on postpartum care engagement (versus standard of care).

Aim 1: Conduct in-depth interviews with women who gave birth at Grady in the previous year to better understand barriers (individual, social, structural) to accessing and engaging in postpartum care.

Aim 2: Conduct a pragmatic randomized trial with 320 high-risk pregnant women who will receive either the enhanced postpartum system or standard of care. We will collect and analyze qualitative and quantitative data on process and outcome measures including adherence with recommended care visits and screenings, contraception initiation and use, use of medications for chronic conditions, and participant opinions about the system of care through 12 months postpartum. We hypothesize that women in the postpartum care system arm will have better rates of care engagement, utilization, and satisfaction compared with the control arm.

RCT Pilot: To design and test data collection instruments and processes for the randomized trial (Aim 2) using electronic medical record data from potentially eligible patients.

3. Background

The US maternal mortality ratio is the highest among developed nations at 26.4 maternal deaths per 100,000 livebirths.[1] Among the states, Georgia has the second highest maternal mortality (66.3 per 100,000), with a 60% higher rate for black vs white women (95.6 vs 59.7 per 100,000).[2] Nearly 100 times more common than maternal mortality is severe maternal morbidity (SMM), defined as unexpected outcomes of labor and delivery that result in short- and long-term deleterious health consequences. Maternal mortality and SMM are highest among women who are black, publicly insured or uninsured, and deliver in safety-net hospitals.[3,4] In Georgia, 66% of maternal deaths occur to women insured by Medicaid at delivery and the majority of deaths and SMM occur postpartum, a time during which healthcare visits are poorly attended and oftentimes inaccessible.[5] The Georgia Maternal Mortality Review Committee concluded that two-thirds of maternal deaths are preventable, with chronic health conditions, obesity, delays in accessing and fragmentation of care as key contributors.[5] As solutions, it recommends improved prenatal and postpartum follow-up and case management, control of chronic health conditions, and extension of Medicaid coverage beyond 60 days postpartum.

While the postpartum period represents a crucial window of opportunity for promoting women's current and future health, up to 40% of US women do not attend postpartum visits,[6,7] due to structural barriers (e.g., lack of insurance, transportation or childcare),[8,9] social barriers (e.g., medical mistrust and poor patient-provider relationships),[10,11] or low perceived utility of postpartum care.[12-14] Moreover, the lowest rates of postpartum care utilization are concentrated among women with the highest rates of pregnancy complications and chronic conditions (e.g., women who are uninsured or Medicaid-insured, low-income, and non-Hispanic black).[15.16] Timely and adequate use of postpartum care is especially important for women with diabetes, hypertensive disease, or pre-pregnancy obesity as these conditions are associated with increased risk for postpartum morbidity and mortality and cardiovascular disease later in life.[17]

We plan to conduct an intervention study to assess the effect of a woman-centered, comprehensive postpartum care system on postpartum visit attendance and follow-up care among medically underserved women with chronic diabetes, chronic hypertension, pre-pregnancy obesity, gestational diabetes, or hypertensive disorder of pregnancy (HDP). Because

implementing and sustaining a comprehensive postpartum care system in a health disparities population requires a thorough understanding of patient preferences regarding the structural and process elements of care, methods of provider-patient communication, and strategies for addressing social and contextual barriers to care,[18,19] we will use in-depth interviews to inform the intervention design and then assess health outcomes and satisfaction. The intervention will include the integration of a postpartum care planning tool in the electronic medical record (EPIC) and separate REDCap data collection instruments. In order to finalize intervention protocols and data collection forms, we will pilot the instruments using medical record data from patients not enrolled in the trial prior to beginning the trial.

4. Study Endpoints

Aim 1: The study endpoint for Aim 1 is completion of the in-depth interview, which will be used to inform the design of the intervention tested in Aim 2.

Aim 2: The primary outcome for the randomized trial is attendance at the postpartum visit (between 4-12 weeks), as engaging women in care is critical to addressing needs and reducing SMM risk. Secondary outcomes include receipt of recommended early postpartum screenings for diabetes and hypertension (e.g., glucose testing or blood pressure checks), contraceptive initiation and use, use of medication for chronic conditions, pregnancy complications (including SMM), hospital readmissions, mental health status, perceived risks for SMM and cardiovascular disease, plans and use of care, and satisfaction with care (**Table 1**). Secondary outcomes will be assessed at 2 time points – 12 weeks after delivery and 14 months after delivery (to allow for approximately 12 months of follow-up after attending the 4–12-week postpartum visit).

RCT Pilot: Once study instruments are finalized, all entered data will be deleted.

Table 1. Study outcomes and timing of assessment

12-week survey	14-month survey
Postpartum visit attendance (primary outcome)	Contraceptive use
Receipt of recommended testing	Medication use
Contraceptive use	Pregnancy complications
Medication use	Hospital readmissions
Pregnancy complications	Perceived risks (CVD)
Hospital readmissions	Use of primary & specialty care
Perceived risks (SMM, CVD)	Mental health
Plans for primary & specialty care	Self-rated health
Mental health	
Satisfaction with postpartum care	

5. Study Intervention/Investigational Agent

Aim 1: No intervention strategies will be delivered or evaluated as part of Aim 1, and the usual standard of obstetrical or other clinical care will not be altered in any way for women who participate in this research study.

Aim 2: Women who choose to participate in the pragmatic trial will be randomized to the control or intervention arm using minimization, a covariate-adaptive randomization method to achieve balance in the proportion of participants with each of the diagnoses (chronic diabetes, chronic hypertension, pre-pregnancy obesity, gestational diabetes, and/or HDP) across the two study arms. The intervention will consist of a comprehensive postpartum care system that integrates American College of Obstetrician and Gynecologist's (ACOG) postpartum care guidelines[17] together with American College of Cardiology and American Heart Association (ACC/AHA) guidelines[20] for the prevention of cardiovascular disease in women and patient preferences for care coordination and communication (from Aim 1). The system will consist of: 1) a tailored postpartum care plan that is collaboratively developed with patient and provider input and addresses both social and medical needs; 2) an electronic medical record (EMR) based tool for documenting the plan and monitoring postpartum care; and 3) a postpartum follow-up phone call at 1 week postpartum. To provide continuity of care for women in the intervention group and to prevent spillover effects for women in the standard care group, a trained, dedicated healthcare professional located in the OB/GYN clinic will deliver the postpartum intervention.

RCT Pilot: No intervention strategies will be delivered.

6. Procedures Involved

Aim 1: A member of the research team will contact eligible women by phone using contact information given in the electronic medical record and, if interested, schedule a time for a remote in-depth interview conducted via phone, Zoom, FaceTime, or Google Duo (per participant preference) The research team member will attempt to reach a participant up to 3 times, leaving a voicemail if unavailable. Prior to the interview, a member of the research team will abstract information on the postpartum visit, pregnancy, and delivery characteristics from the medical record using a standardized abstraction form. Prior to performing the qualitative interviews over the telephone, the research team member will obtain written consent using REDCap. We will use interview guides, and women will be asked to participate only once. We do not anticipate that informants will be stressed from this study, nor will they be deceived. The purpose of this study is to learn more about patient preferences for postpartum care.

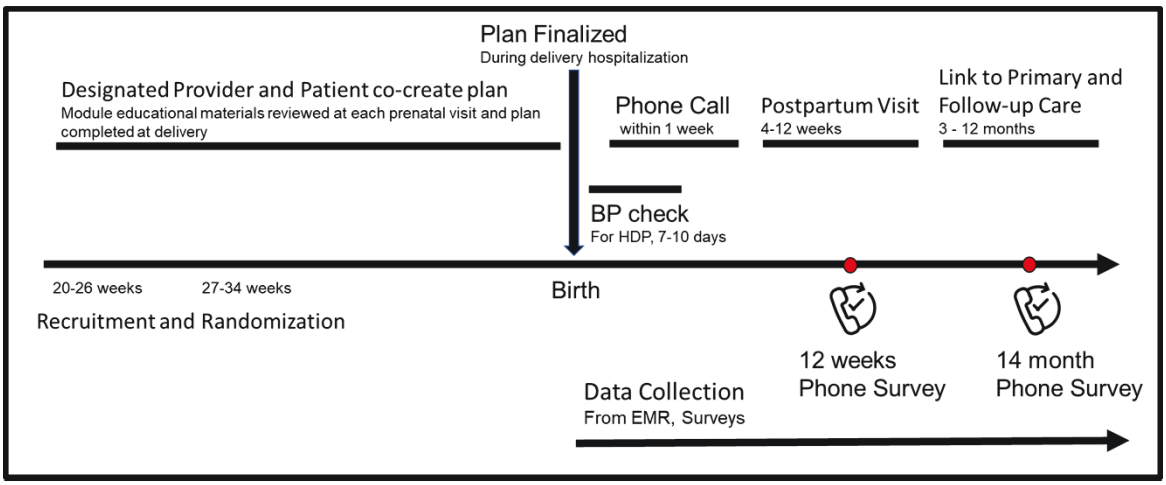
All interviews will be audio-recorded with the consent of the patients and transcribed verbatim. Once transcribed and checked, audio-recordings will be deleted. Transcripts will not be linked

to participant name's or identifying information. However, we will retain information on participant age, diagnosis, postpartum visit attendance, and parity for analytic purposes.

Aim 2:

Control: If randomized to the control study arm, participants will receive usual care, which includes regular prenatal care visits and discussions on infant feeding plans and contraception at provider discretion. In usual care, participants will schedule a 4–12-week postpartum visit during their delivery hospitalization. If signed up for the service, participants will receive a Grady initiated text message reminder for their scheduled postpartum visit. In addition, all patients with a HDP are automatically scheduled to receive a mobile integrated health home visit for a blood pressure check 7-10 days after delivery. We will provide outreach to the control and intervention participants at 12 months after delivery, to re-engage them and remind them about the 14-month survey.

Figure 1. Postpartum care system and data collection schematic



Intervention: If randomized to the intervention arm, participants will receive usual care (as described above) plus the postpartum planning intervention (**Figure 1**). Postpartum Planning study visits will occur during prenatal care visits including fetal monitoring visits, ultrasound visits and other care visits prior to delivery, including any antenatal hospitalizations. During study visits the participants will engage in a 30–45-minute visit with the study coordinator to create a tailored postpartum plan, and if the patient is hospitalized prior to delivery, postpartum planning visits may be held, and modules completed during the hospitalization.

The plan is intended to: 1) document all recommended postpartum screenings and follow-up in the Epic EMR system (via a postpartum planning Epic SmartForm) and 2) actively engage women in their care, thereby reinforcing the importance of postpartum follow-up and the transition to primary care. The plan will include, at minimum, recommended postpartum check-

ups and evidence-based screenings based on risk factors derived from both ACOG and ACC/AHA guidelines (e.g., 1-week blood pressure check for those with HDP), participant preferences for breastfeeding and contraception, tailored referrals for postpartum visits and supports (e.g., providers in the women's zip code, transportation vouchers), and contact information for the patient's postpartum care team (OB/GYN, primary care provider, any specialty care provider, patient's partner, or other social support network). The planning discussions will be guided by 20 topic-specific modules and will be tailored to address specific risk conditions (e.g., hypertension) as appropriate. **Table 2** depicts the topics covered in the postpartum care planning modules. Each module consists of a structured discussion, supported by a short (1-2 page) information sheet on the topic, of which participants will receive both physical and electronic copies (see patient education modules 1-20).

Table 2. Postpartum care plan module topics

Care team	Maternal support team
Postpartum visit	Returning to work
Pregnancy complications	Tobacco use
Immunizations	Substance use
Postpartum problems	Healthy weight
Mental health	Food security and housing
Sexual health and function	Infant feeding
Reproductive life planning	Chronic disease and specialty care
STIs	Heart disease prevention
Healthy relationships	Transition to primary care

Receipt of the educational modules will be documented in REDCap (see REDCap data collection instruments). The study coordinators will be responsible for conducting all planning discussions, providing continuity of care, and creating the postpartum care plan. At each prenatal visit, the study coordinator and participant will complete the postpartum planning modules, and the postpartum plan will be documented and updated (if needed) in the participant's EMR. The plan will also be made available to participants via MyChart (a secure patient portal through Epic that gives patients online access to their medical record), allowing them to review it from their phone or home computer. For participants without an active MyChart account, the plan will be printed and provided to them. During the participant's delivery hospitalization, a study coordinator will visit the participant to finalize the postpartum plan and provide a printed copy of the plan for the participant to take home and review. For participants with a Covid + diagnosis during the delivery hospitalization, the delivery admission visit will be conducted via phone. If an intervention participant delivers outside of Grady hospital, the delivery admission visit will be conducted via phone. Within 1 week of discharge, the study coordinator will call the

participant to check in and address any postpartum concerns. The intervention ends at the time of the 1-week check-in phone call.

Follow-up (Intervention and Control): After the first week postpartum, all participants, whether in the control or intervention arm, are treated the same. Consistent with standard care protocols at Grady, intervention participants with a HDP will have a mobile integrated health visit with blood pressure check at 7-10 days postpartum. Consistent with ACOG guidelines,[17] all participants will be encouraged to attend a comprehensive visit between 4-12 weeks postpartum, which will include a full assessment of physical, social, and psychological well-being, including chronic condition surveillance and management, and a plan to transition to primary and specialty care as needed.

Data collection

For women in both the control and intervention arms of the study, we will collect research data using REDCap surveys, remote survey follow-up, and abstraction of the medical record.

12-week and 14-month survey: A REDCap link for the 12-week and 14-month surveys in English or Spanish, according to the participant's primary language, will be sent to the participant's email on file to collect supplemental information on primary and secondary outcomes and patient experiences. Participants will be asked to complete the surveys on their own, using either their phone or a computer. The study coordinator will then conduct a remote follow-up session with each participant via phone, Zoom, Facetime, or Google Duo to review and discuss the surveys, including any missing responses. Each survey and remote follow-up session will last 20-30 minutes. The week prior to each survey, a research team member will contact the participant to provide a reminder about the upcoming survey, schedule the remote visit to review survey responses and send the survey link. The research team member will offer participants the option to reschedule the remote follow-up session for a time that is more convenient. If we cannot reach a participant by phone, we will try each contact method at three different times (e.g., daytime, evening, weekend), leaving messages as appropriate. In addition, we will check the Grady EMR for any updates to patient contact information that were ascertained through clinical encounters during the follow-up period, and we will ask participants to confirm their preferred contact information upon completing the 12-week survey. For participants who report health care encounters that are not documented in the Grady EMR (including the Care Everywhere function in Epic), we will ask where they received care, and ask for permission to request medical records from that location; this may require participant signing additional consent form specific to the facility where they received health care.

The 12-week survey will measure depressive symptoms[21] and functional social support[22], perceptions of risk for SMM or cardiovascular disease[23] and need for preventative measures,

plans and actions for well-woman, primary and/or specialty care, and implementation outcomes, including opinions of and satisfaction with postpartum care and the planning process. The 14-month survey will assess well-woman, primary and specialty care use, contraceptive use, perceived cardiovascular risks, mental well-being (depression[21] and social support[22]), and self-rated health.[25] (See the 12-week survey and 14-month survey documents for more information.) The survey will also validate EMR information on hospital readmission, SMM, and medication adherence.

To promote retention of participants over the 14-month follow-up period, we will ask participants to provide at least three ways to contact them (e.g., email addresses, own phone number, or phone number of a partner or family member). Upon completing the 12-week survey, the research team will confirm the preferred contact information for the 14-month survey.

Medical chart review will be used to ascertain health care utilization (postpartum visit, primary care or specialty care utilization, hospital admissions), diagnoses, and medical prescriptions in the 12 months postpartum. A standardized medical abstraction form will be used by research team members who have trained in data abstraction from the medical record. If additional medical records are available from care obtained outside of Grady, that information will also be reviewed and abstracted. The primary outcome of interest (4–12-week postpartum visit attendance) will be identified using data from the medical record. Information on all outpatient visits occurring between delivery discharge and 12 weeks postpartum will be abstracted and blinded for review. Two independent physicians will review the blinded information and determine whether the visit meets the criteria for a comprehensive postpartum visit. ER and urgent care visits external to Grady that fall within the 4 – 12-week postpartum period and through 14 months postpartum will be abstracted but not blinded for review by the blinded reviewers. Information for these visit types occurring within Grady Health System during these time periods will be obtained from the "GOGO" data warehouse (IRB00103211). Mobile integrated health visits, triage visits, and nurse visits occurring during these time periods will not be abstracted or blinded.
Questionnaires and medical chart review will involve collection of identifiable information as names, medical record numbers, telephone numbers, and dates are required for the follow-up of the individuals at subsequent study visits and for ascertainment of outcomes via the EMR.

RCT Pilot: EMR review will be used to create, design, and finalize the Epic and REDCap data collection instruments. By piloting the form via medical records, we will ensure efficient and feasible data collection processes during the intervention.

7. Data and Specimen Banking

Aim 1: All interviews will be transcribed verbatim. Audio-recordings and transcripts will be housed in password protected computer systems secured by Emory University. The transcripts will be cleaned and identified prior to analysis. A transcript key will be maintained that links the informant to their de-identified file and audio-recording. Deidentified transcripts will be stored on REDCap and OneDrive, both of which are compliant with Emory University's HIPAA security policies and procedures.

Aim 2: All study data will be kept on a password-protected Emory OneDrive folder or REDCap database, accessible only to a limited number of research team members. No one will have access to the data or the identifying information other than the Investigators or their designee. All data entry will be done on password-protected and encrypted tablet computers with REDCap software, which allows for the transfer of data to the Emory server over the internet in a HIPAA-compliant, encrypted manner. Upon study completion, de-identified study data will be kept in HIPPA-compliant databases until they are fully analyzed and are no longer needed.

RCT Pilot: All data entry for the pilot will be done on password-protected and encrypted tablet computers with REDCap software, which allows for the transfer of data to the Emory server over the internet in a HIPAA-compliant, encrypted manner. First, we will test a paper version of the postpartum care plan to inform the design of the Epic EMR tool (SmartForm). Once the SmartForm has been developed and deployed in Epic, we will also use patient records to test its functionality prior to the start of the RCT.

8. Sharing of Results with Participants

Once the study results are publicly disseminated, we will inform the study participants via text, email, or telephone, depending on their preferred means of contact. Aim 2 participants with an active account will be able to view the postpartum plan via MyChart. For participants without an active MyChart account, the postpartum plan will be printed for them. We will work with the Community Advisory Board for this study to disseminate results broadly to the communities served by Grady.

9. Study Timelines

Aim 1: Each in-depth interview is expected to last approximately 30 minutes. Each participant will be interviewed only once. We anticipate that it will take approximately one month to enroll all interview participants. We estimate that the qualitative data will be analyzed by the end of Year 1.

Aim 2: Individuals will participate in the study for approximately 18 months (starting during prenatal care and continuing 14 months after delivery). There are approximately 200 deliveries per month at Grady. Assuming that 40% of women will be eligible (data

from our study suggests that 38% of women at Grady have hypertensive disorders[26]) and about 15% of women will not receive any prenatal care, and 50% will agree to participate in the study, we expect recruitment to take about 9 months. We estimate that data from the randomized trial will be analyzed during Year 5.

RCT Pilot: The piloting will be iterative and will occur between May and July 2022.

Study Timeline

	Year 1				Year 2				Year 3				Year 4				Year 5			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Project launch																				
1 Develop questions for interviews																				
1 Conduct interviews																				
1 Analyze qualitative data																				
2 Develop content for care system																				
2 Design and test EMR tool																				
2 Study start up																				
2 Enroll women																				
2 Follow women for 14 months																				
2 Conduct follow-up surveys																				
Analyze/disseminate RCT results																				
Prepare manuscripts																				

10. Inclusion and Exclusion Criteria

Aim 1: We will use EMR data to identify eligible women. Women will be eligible if >18 years of age, had one of the eligible diagnoses (chronic diabetes, chronic hypertension, gestational diabetes, or HDP), and attended at least one prenatal visit and delivered at Grady Memorial Hospital for a pregnancy in the prior year. We will recruit a purposive sample made up of approximately equal proportions of women who were primiparous and multiparous and women who did and did not attend the postpartum visit. For this Aim, we will only recruit English-speaking patients to maximize interview/patient rapport and streamline analysis.

Aim 2: We will use the EMR to identify pregnant women (all ages) between 20-34 weeks of gestation who have received 1 or more prenatal care visits at Grady Memorial Hospital, intend to deliver at Grady, speak English or Spanish, and have a diagnosis of chronic diabetes, chronic hypertension, gestational diabetes, pre-pregnancy obesity, and/or HDP (gestational hypertension or preeclampsia) documented in the EMR.

RCT Pilot: We will use EMR data to identify eligible women (records) between 20-34 weeks of gestation who have received 1 or more prenatal care visits at Grady Memorial Hospital, intend to deliver at Grady, speak English or Spanish, and have a diagnosis of chronic diabetes, chronic hypertension, gestational diabetes, and/or HDP documented in the EMR.

Adults unable to consent, infants, and prisoners will be excluded from all Aims. We will include pregnant persons < 18 in Aim 2; specific protections and procedures for that group are detailed below.

Community Participation: Aim 1 seeks to understand the needs of the community that is being targeted by the study (women who received prenatal care and delivered at Grady). This information will directly inform the design of the postpartum care system that will be tested in Aim 2. Once the study results are publicly disseminated, we will inform the study participants via text, email, or telephone, depending on their preferred means of contact.

The study team will convene a Community Advisory Board (CAB) that will meet 3 times a year until study completion. The CAB will be composed of members of local, state, and national community organizations dedicated to and experienced with improving women's health, health care providers who are experts in the fields of obstetrics and gynecology, maternal fetal medicine, women's primary health care, and public health and women from the community who have experience accessing reproductive health services in Georgia and can serve as patient advocates. The CAB will provide guidance on strategies for reducing maternal health disparities, advise the study team regarding essential components of and barriers to postpartum care, and provide input regarding study design, implementation, interpretation, and dissemination of findings. The CAB members will be provided a $100 VISA gift card per meeting as compensation.

11. Vulnerable Populations

Aim 2 involves pregnant women, a vulnerable population. Participants assigned to the control arm will receive standard prenatal and postpartum care. Participants assigned to the intervention will meet with a study coordinator during routine prenatal care visits, develop a postpartum plan, and receive follow-up phone calls or texts after delivery. The risks associated with participating in this study are minimal since the probability and magnitude of harm or discomfort anticipated in the study are not greater in and of themselves than those ordinarily encountered in routine care delivered at the clinic. There are no physical risks presented by participating in the study. The postpartum care system could benefit participants by enhancing their engagement with care and promoting the early detection and treatment of postpartum complications. Participation in the study will be voluntary and will in no way modify the clinical care the participants receive during and after their pregnancy.

Although we anticipate that relatively few women <18 years of age will meet the eligibility criteria (have a diagnosis of chronic diabetes or hypertension, pre-pregnancy obesity, gestational diabetes, and/or HDP), these women represent a high-risk group in terms of adverse pregnancy outcomes and inadequate postpartum care utilization and

therefore warrant inclusion in the study. We are requesting a waiver of parental consent for pregnant women <18 years of age. Requesting a parental waiver will not adversely affect the rights and welfare of the participants as teens will already be visiting the clinic for prenatal care. Also, requiring parental consent offers no additional protection to the participant. Participants <18 years of age will receive the same information about the study as participants 18 years of age and over. We will use an under 18 informed consent form in the place of the assent process for participants >18 years, since these participants will be in the upper age group for minor subjects. If the participant does not appear to comprehend the consent form or the research, they will not be enrolled. If a participant < 18 years turns 18 during the study period, they will be invited to complete the full informed consent at that time.

RCT Pilot: The pilot involves medical records for pregnant women (same eligibility criteria for Aim 2). Review of patient medical records will in no way modify the clinical care the participants receive during and after their pregnancy.

12. Local Number of Participants

Aim 1: We will recruit up to 30 women.

Aim 2: We will recruit 320 women. Based on prior studies at Grady, we assume a recruitment rate of 50% and expect to approach approximately 640 women.

RCT Pilot: We will review the minimum number of records to finalize instruments, likely between 5-10 records.

13. Recruitment Methods

Aim 1: We will recruit up to 30 women who attended prenatal care at Grady Memorial Hospital for a pregnancy complicated by the presence of chronic hypertension or diabetes, pre-pregnancy obesity, or the occurrence of cardiometabolic complications of pregnancy (gestational diabetes or HDP) in the past year. We will identify potential participants using the electronic medical record, purposively selecting a range of parity (primiparous and multiparous) and postpartum visit attendance (attended and did not attend). A member of the research team will contact women by phone using contact information given in the electronic medical record and, if interested, schedule a time for a phone-based in-depth interview. The research team member will attempt to reach a participant up to 3 times, leaving a voicemail if unavailable. Prior to performing the qualitative interviews over the telephone, the research team member will secure written consent. Participants will be given a $25 VISA gift card for participation in the in-depth interviews.

Aim 2: We will recruit 320 women during scheduled prenatal care visits at Grady Memorial Hospital. We will identify potentially eligible women using the EMR. The study coordinator or

designee will either contact potentially eligible patients prior to the scheduled prenatal care visit, via the phone number listed in the patient's EMR, to provide information about the study and obtain the patient's interest in participating, and if the patient is interested the study team will arrange for consent during a scheduled prenatal care visit, or obtain written, electronic consent via REDCap, during phone recruiting; Or the study coordinator or designee will approach potentially eligible patients before or during scheduled prenatal care visits. If the study team is unable to recruit a potentially eligible patient during a scheduled prenatal care visit, a member of the study team will follow-up with the patient after the scheduled prenatal care visit, via the phone number listed in the patient's EMR, to provide information about the study and obtain the patient's interest in participating, and if the patient is interested the study team will arrange for consent during a scheduled prenatal care visit, or arrange written, electronic consent. If obtaining electronic consent, a member of the research team will contact eligible patients by phone via the patient's contact information in the electronic medical record. The research team member will attempt to reach the eligible patient up to 3 times, leaving a voicemail if unavailable. If the patient is interested in participating the research team member will send the informed consent form to the patient's preferred email via REDCap, or text the REDCap informed consent form survey link to the patient's phone number on file. During the call, the research team member will review the informed consent form with the participant and obtain written consent via REDCap.

In an effort to increase recruiting efforts, we will also approach potentially eligible patients identified in the EMR to have a gestation of 18 weeks or 19 weeks to provide information about the study and obtain the patient's interest in participating when they reach 20 weeks gestation. If the patient agrees to participate in the study, the study coordinator or designee will arrange for the patient to be consented during a scheduled prenatal visit, or arrange written, electronic consent when the patient reaches gestation of 20 to 34 weeks. The study coordinator or designee will either conduct the informed consent process in-person during a scheduled prenatal visit or provide written, electronic consent for all potentially eligible patients interested in participating. All potentially eligible participants will receive information on the purpose of the study, the procedures, expected risks and benefits, and a copy of the informed consent form to review. If a patient is approached during a prenatal care visit and is interested in participating, they will have the option of scheduling the informed consent process the same day or another day. The study coordinator (or member of the study team) will review the informed consent form with the participant and ensure comprehension through an oral review of key points.

The consent form will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation. An explanation will be provided about the use of PHI for research purposes and how confidentiality will be maintained as far as possible under the

Federal Health Insurance Portability and Accounting Act (HIPAA). Written informed consent will be obtained from women who agree to participate in the study. A copy of the signed consent form will be given to the participant and documented in the participant's research record. No PHI will be retained for potential participants that do not qualify for the study or for those who elect not to participate in the study.

During the consent process, we will make it clear that participation is voluntary, and that there are no adverse consequences to choosing not to participate or to terminating participation at any time. The study coordinator will review the informed consent document with potential participants and explain in detail the purpose of the study, procedures, and risks.

In addition, we will prioritize recruitment of a bilingual, Spanish-speaking study coordinator and research assistants as Spanish is the most common non-English language among pregnant patients at Grady. If a patient agrees to participate, they will be randomized to an intervention/control study arm. All participants will receive an incentive of $25 for enrolling in the study, $25 after completing the 12- week survey, and $25 after completing the 14-month survey. If randomized to the intervention arm, these participants will receive $10 after each completed study visit. The number of study visits offered will depend on how far along a participant is in their pregnancy at enrollment. Participants will be offered up to (8) study visits and, if needed, 4 supplemental visits for a total of up to $195 total compensation. If participants miss visits or do not finish the study, they will be compensated only for the visits and surveys they complete. Compensation will be provided via an e-gift card. Intervention arm participants will also be gifted a "Grady onesie" for their newborn during the delivery admission.

RCT Pilot: There will be no recruitment for the pilot.

14. Withdrawal of Participants

We do not anticipate any circumstances under which participants in Aim 1 or Aim 2 would be withdrawn without their consent. If participants choose to withdraw from the intervention study (Aim 2), the study coordinator will note this information, along with the reason, if known, in the study records. Medical record abstraction for this participant will be conducted for the period of time during which they were enrolled.

Participants in the RCT pilot will not be withdrawn.

15. Risks to Participants

There are potential (yet minimal) risks related to the conduct of this research study, including risks of breach of confidentiality and risk of some participants experiencing distress or revealing depression or intention for self-harm during the questionnaire and

interview data collection, as the postpartum period is emotional and questions about social support or depressive symptoms may feel invasive.

16. Potential Benefits to Participants

Participants in this research study may not receive any benefit. However, participants in the intervention arm of the study may benefit from better continuity of care, more one on one time with a provider during prenatal care, and enhanced follow-up postpartum. In addition, the potential benefits of this research may extend to future postpartum patients at Grady Memorial Hospital or in other communities as these data are incorporated into the design of an EMR-integrated, culturally appropriate postpartum planning system.

17. Data Management and Confidentiality

Aim 1: All qualitative data will be professionally transcribed. These transcripts will be cleaned and de-identified prior to analysis. Once cleaned, we will use a team-based approach to systematically code each transcript using a qualitative software program called MaxQDA2020. Two researchers will review and code the transcripts with a lead analyst to identify emerging themes. We will use a directed approach to content analysis whereby the research theory will be used as guidance for data coding.

Aim 2: For Aim 2, we will conduct a randomized controlled trial to test the effectiveness of the comprehensive postpartum care system on postpartum care use and engagement. The primary outcome will be attendance at the postpartum visit occurring between 4-12 weeks after delivery. Secondary outcomes include receipt of early postpartum screenings for diabetes and hypertension (e.g., glucose testing or blood pressure checks), contraceptive initiation and use, use of medication for chronic conditions, pregnancy complications (including severe maternal morbidity), hospital readmissions, mental health status, perceived risks for SMM and cardiovascular disease, care plans and use, and satisfaction with care.

We will recruit 320 pregnant women between 20-34 weeks of gestation who receive 1 or more prenatal care visits in the Grady OB/GYN clinic, intend to deliver at Grady Memorial Hospital, have a documented diagnosis of chronic diabetes, chronic hypertension, pre-pregnancy obesity, gestational diabetes, and/or HDP and speak English or Spanish. We will assign participants to intervention or control arm using simple randomization. Participants will be randomized (1:1) to receive the postpartum care system (175) or standard of care (175) and will be followed for up to 14 months to allow ample time for attending the 4–12-week postpartum visit and to connect to primary and specialty care.

Power. Preliminary data suggest that 55% of women with HDP return for a postpartum follow-up visit in the absence of the intervention. Based on this, we should have 80% power to detect

a risk ratio of 1.5 (or greater) with a sample of 292 women (146 in each arm), stratified evenly by chronic or new onset disease. To achieve this, 78% of women in the intervention arm would need to attend the postpartum visit, which is conservative. Assuming some (up to 15%) loss to follow-up, we should aim to recruit a sample of 320 women.

Analysis.

Primary outcome (Attendance at 4–12-week postpartum visit): We will compare the probability of attending the 4–12-week postpartum visit between intervention and control groups. We will fit log binomial models to estimate the effect (risk difference and relative risk) of the intervention on attendance at the 4–12-week visit, adjusting for diagnosis (chronic hypertension, chronic diabetes, pre-pregnancy obesity, gestational diabetes, or hypertensive disorder of pregnancy). If sample size permits, we will include relevant confounders, as appropriate.

Secondary outcomes: Secondary outcomes include receipt of recommended early postpartum screenings for diabetes and hypertension (e.g., glucose testing or blood pressure checks), contraceptive initiation and use, use of medication for chronic conditions, pregnancy complications (including SMM), hospital readmissions, mental health status, perceived risks for SMM and cardiovascular disease, plans for and use of primary and specialty care, and satisfaction with postpartum care. We will analyze these outcomes using log-binomial models to estimate relative risks and risk differences and 95% confidence intervals, adjusting diagnosis.

Implementation Analysis of existing RCT data: We will also conduct implementation analysis of intervention records and patient outcomes data to assess intervention fidelity and influences on equity in participation and primary and secondary outcomes. These data include study records in RedCap documenting number and timing of educational sessions, referrals and resources provided. We will also use data from two patient surveys implemented at 12 weeks and 14 months postpartum. We will compute descriptive statistics to determine the number of patients having received the full intervention. A preliminary definition for "receipt of full intervention" is if individuals received all 20 modules, had a complete postpartum care plan logged in Epic, received referrals for care, and appointment reminders. We will also analyze education module logs and will categorize patients as having received the content in the intended duration (over 8 study visits) or in a shortened time frame (e.g., in 2-3 visits). We will assess the extent to which the intended primary (receipt of a comprehensive postpartum visit) and secondary intervention outcomes (occurrence of SMM, primary care use, contraceptive use, and patient satisfactory with care) differ by level of implementation fidelity (dose and duration) using chi-square tests for association. We will also analyze quantitative study record data to describe the number of social service needs (e.g. housing, food, violence, etc.) and health needs (e.g. mental health) participants reported during the perinatal and postpartum

period. We will assess the relationship between patients' social needs and barriers to meeting those needs with primary and secondary outcomes. We will assess the extent to which the intended primary (receipt of a comprehensive postpartum visit) and secondary intervention outcomes (occurrence of SMM, primary care use, contraceptive use, and patient satisfactory with care) differ by level of social needs and experiences of barriers to completing referrals using chi-square tests for association. We will compute descriptive statistics and tests of significance using SAS 9.4.

Protection against risks. As a research team, we will protect against risks and potential risks in a number of ways. A primary mechanism for protecting against risks will be ensuring intensive training of the research team. First, the MPI's will require all of the research team members to complete Human Subjects Research Training, as documented through their successful completion of the Human Subjects Collaborative Institutional Training Initiative (CITI) modules, available at: https://www.citiprogram.org/. Second, the investigative team will conduct several in-depth trainings of all research staff prior to the recruitment of any research participants that will include an overview of the entire research plan and protocol and specific trainings to address recruitment, enrollment, and informed consent procedures; questionnaire data collection; and clinical data collection through the electronic medical record; and secure maintenance of confidentiality and security of all data streams and participant confidentiality.

In particular, the research team members having face-to-face interaction and/or telephone interaction with the research participants will be trained in the following potential risks and strategies for protecting against these risks prior to initiation of any participant recruitment.

Confidentiality: Confidentiality will be maintained on several levels. First, all research investigators and staff are fully trained, and required to maintain training, in human research protections, including the most up-to-date strategies for maintaining the confidentiality of research data. Second, all data will be protected from anyone who does not have a staff position in the study. Third, the raw data will be kept in password protected OneDrive files or on a HIPAA compliant database (e.g., REDCap), accessible only to a limited number of the research team. No one will have access to the data or the identifying information other than the study investigators and designated study staff, directly involved. Fourth, all data entry will be done on password-protected and encrypted tablet computers with REDCap, which is a software that allows for the transfer of data to the Emory server over the internet in a HIPAA-compliant, encrypted manner. Deidentified transcripts will be stored on REDCap and OneDrive, both of which are compliant with Emory University's HIPAA security policies and procedures; Fifth, the Emory server is password-protected, encrypted, and backed up to ensure data confidentiality and integrity; Sixth, data for analyses will be stripped of all PHI

identifiers; Seventh, the data will be kept until they are fully analyzed and destroyed when they are no longer needed. Upon completion of the conduct of the protocol, the subject log linking study identifiers to subject identity and PHI will be destroyed.

RCT Pilot: We will use the same data management protocols as in Aim 2. However, data will be destroyed once instruments are finalized. No data will be analyzed.

18. Provisions to Monitor the Data to Ensure the Safety of Participants

Aim 2 is a clinical trial and will have a Data and Safety Monitoring Plan. An individual's participation in the clinical trial aspect of this study meets Federal Regulations defining minimal risk: "minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." [§46.102]. The intervention itself (enhanced postpartum care system) does not pose a risk for adverse events, however, as eligibility criteria for participation in the clinical trial include having chronic hypertension or diabetes or experiencing cardiometabolic complications during pregnancy, it is possible that a non-study related adverse event may occur to enrolled participants. We believe that the enhanced postpartum care system may help in the early identification and prevention of complications, as participants in the intervention arm will receive additional follow-up postpartum. As part of the study, the study coordinator will monitor any readmissions or complications using the EMR and, as reported on the surveys conducted at 12-weeks and 14-months postpartum.

We have constituted a Data Safety Monitoring Board (DSMB) to review safety and study enrollment of participants in this study, which will meet on an annual basis. The DSMB will review in tabular form any and all Adverse Events (AEs); in narrative, any and all Serious Adverse Events (SAEs); enrollment data; attrition data; data quality and completeness; and narrative reports of any issues around loss of participant confidentiality. Serious adverse events will be reported to the IRB within 7 days of the study team becoming aware of the occurrence of the event; any deaths will be reported within 24 hours of the team becoming aware of the event. The report of DSMB's annual review to the Emory University IRB annually.

The DSMB responsibilities are to:

1. Review the research protocol, informed consent documents, and plans for data safety and monitoring prior to beginning enrollment;

2. Evaluate the progress of interventions, including periodic assessments of data quality, participant recruitment, accrual and retention, participant risk versus benefit, performance of the site, and other factors that can affect study outcome;
3. Consider factors external to the study when relevant, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial;
4. Ensure the rights and safety of the study participants are protected;
5. Report on the safety and scientific progress of the trial;
6. Make recommendations to the PI, and research ethics board/institutional review board about any determination, or other modifications of the trial based on the observed beneficial or adverse effects of the treatment under study.

DSMB Membership

1. Members of the DSMB have been invited by PI Jamieson; members will be completely independent of the trial investigators and have no financial or scientific conflict of interest with the study. A potential conflict that develops during a member's tenure on the DSMB must be disclosed and, if significant, will lead to replacement of the DSMB member.
2. Disciplines represented on the DSMB will include health professionals with expertise in obstetrics and gynecology, family medicine, internal medicine, and epidemiology or biostatistics.
3. A Chairperson will be selected prior to the first meeting. The Chair will lead all meetings, coordinate meetings and communications, develop the agenda, and produce meeting minutes and reports.

DSMB Meetings. The first meeting will take place before initiation of the trial to discuss the protocol and to establish guidelines to monitor the study. The Chair, with input from PI Jamieson, will prepare the initial agenda, which should address issues concerning commencement of the trial. The initial tasks of the DSMB are to review the protocol and informed consent forms with regard to subject safety, review this charter and amend it, if necessary, and discuss the plan for monitoring data, subject safety, and compliance. PI Jamieson will distribute the proposed reports to DSMB members prior to each subsequent meeting. Following the initial meeting, the DSMB will convene at least once per year to review accumulated data on safety. Meetings shall be convened face-to-face or by teleconference, at the DSMB members' discretion. If a question of patient safety arises or if a Serious Adverse Event occurs, an emergency meeting of the Board may be

called at any time by the Chairperson. The format for DSMB meetings will consist of two sessions. The first session will be attended by the PIs where the conduct and progress of the study, subject accrual, and subjects' compliance with protocol, general safety issues, and any other problems encountered will be discussed. The second session will be open only to DSMB members. Safety and efficacy data, the general conduct of the trial, outcome results, and adverse events are presented at this session.

19. Provisions to Protect the Privacy Interests of Participants

Aim 1: In-depth interviews will be conducted via phone, Zoom, FaceTime or Google Duo (according to patient preference). Patients will have the ability to decide when and where to take part in the interview. The privacy interests of all participants will be protected during the interviews. We will describe the study procedures at the time of the screening call as well as at the beginning of the interview. This information will detail our procedures for collecting, storing, and de-identifying the qualitative interview data. In addition, we will explain the interview process and identify each staff member (interviewer, note taker) who will be present during the interview. If a participant expresses concerns about his/her privacy or confidentiality, we will respond accordingly. This may include asking the note taker not to participate in the interview or not to record the interview.

Aim 2: The study coordinator will approach potential participants either before or after their prenatal care visit and will invite them to a private clinic room for recruitment. For women in the intervention arm, postpartum planning visits will also take place in a private room before or after prenatal care. After women deliver, the coordinator will schedule a time to meet with participants in their private room and finalize their postpartum care plan.

RCT Pilot: There will be no recruitment or participation during the pilot phase.

20. Economic Burden to Participants

There are no costs to the study participants.

21. Consent Process

Aim 1:

a) We are requesting a partial HIPPA waiver for the purpose of identifying and recruiting prospective research participants for enrollment. We will use the Grady Obstetric and Gynecologic Outcomes database (IRB00103211) to identify women meeting the study criteria who delivered at Grady during the past year.

Review of PHI is necessary to determine whether potential participants are eligible for this study, and it is impracticable to ask all women delivering at GMH to sign an authorization to access their PHI to determine eligibility. Only the PI and study coordinator will have access to PHI. No PHI will be retained for potential participants that do not qualify for the study. If the potential participant does qualify for the study, PHI will be retained for recruitment purposes.

b) We will obtain written consent prior to the start of the remote follow-up session using REDCap. This consent process will take approximately 5 minutes and will allow for the participants to ask questions about the consent process or study purpose.

Aim 2:

a) We are requesting a partial HIPPA waiver for the purpose of identifying and recruiting prospective research participants for enrollment. We will use the daily appointment schedules and medical record data to identify women with prenatal care visits who meet the study criteria. Review of PHI is necessary to determine whether potential participants are eligible for this study, and it is impracticable to ask all women attending a prenatal care visit to sign an authorization to access their PHI to determine eligibility. Only the PI and study coordinator will have access to PHI. No PHI will be retained for potential participants that do not qualify for the study. If the potential participant does qualify for the study, PHI will be retained for recruitment purposes.

b) We will obtain informed consent from all women who agree to participate in the study. The consent process will take place in a private clinic room or office when conducting consent in-person, and in a private space when conducting and obtaining written, electronic consent via REDCap, during phone recruiting and will take approximately 15 minutes. During the consent process, we will make it clear that participation is voluntary, and that there are no adverse consequences to choosing not to participate or to terminating participation at any time. The study coordinator will review the informed consent document with potential participants and explain in detail the purpose of the study, procedures, and risks. A copy of the signed consent form will be given to the participant and documented in the participant's research record. No PHI will be retained for potential participants that do not qualify for the study or for those who elect not to participate in the study.

c) For women who report receiving care outside of Grady in the year postpartum, we will ask women to sign an 'Authorization of Release of Information' allowing the study team to access their medical records at the other provider.

***RCT Pilot*:** We are requesting a *full HIPPA waiver* for this pilot phase, for the purposes of review and abstraction only, of the EMR for patients that meet the criteria for enrollment. These patients will not actually be recruited or consented/enrolled; the purpose of review and abstraction is solely to design and test the REDCap instruments and EMR (Epic) care plan to prepare for implementation and start of the randomized trial (Aim 2).

Non-English-Speaking Participants

Approximately 23% of Grady obstetric patients are non-native English speakers. Spanish is the predominant language of non-English speaking women (76%), followed by Amharic (12%) and French (6%).

Aim 1: Due to budget concerns associated with transcription and translation costs for interviews conducted in languages other than English, will only recruit English-speaking participants for the in-depth interviews. All consents and interviews will be in English.

Aim 2: We will recruit English and Spanish speaking participants. It is not practicable to translate all study material and surveys into multiple languages, and English and Spanish are the most common languages among pregnant Grady patients. We will translate all consent forms, educational materials, and surveys into Spanish and will hire a bilingual study coordinator.

Participants who are not yet adults (infants, children, teenagers)

For Aim 2, we will use EMR data to determine the age of prospective participants. If patients are eligible (have a diagnosis of chronic hypertension or diabetes, gestational diabetes, and/or HDP), we will include pregnant women <18 years of age in Aim 2. As women ages 14-18 years of age are able to receive prenatal care without parental consent in Georgia, we will request a waiver of parental consent for enrolling pregnant minors into the study. For pregnant minors, a member of the study team with experience working with minors will conduct the informed consent process. Minors will receive the same information as women ≥ 18 years of age but will undergo a longer conversation to ensure comprehension. Minors will sign the informed consent form if they agree to participate, and the study team member determines they understand the information on the study.

Cognitively Impaired Adults

We will not include cognitively impaired adults as they may require additional support for postpartum care planning and therefore would not be appropriate candidates for this intervention.

Adults Unable to Consent

We will not include adults unable to consent.

22. Setting

Aim 1: Recruitment and in-depth interviews will take place over the phone or virtually.

Aim 2: Recruitment will take place at the OB/GYN at Grady Memorial Hospital. For participants in the intervention arm, postpartum care planning visits will take place in the Grady clinic and in the postpartum ward (after delivery). All participants will fill out surveys remotely. The study coordinator will be assigned a dedicated space in the Emory Faculty Building, adjacent to Grady.

RCT Pilot: This pilot phase will take place in the OB/GYN clinic at Grady Memorial Hospital.

23. Resources Available

Describe the resources available to conduct the research: The PI for this study, Dr. Jamieson, is the Associate Chief of Service at Grady's OB/GYN clinic, where about 200 women receive prenatal care each month. The research team for this NIH-funded study includes 3 clinicians, Dr. Jamieson, Dr. Franklyn Geary (Morehouse OB/GYN), and Dr. Daniel Wu (Chief Medical Information Officer for the Grady Health System) an epidemiologist (Dr. Boulet), 1-2 post-docs, 2 study coordinators, and 2-4 master's level students. The study takes place in Grady Memorial Hospital, which is a formal affiliate of the Emory Health Sciences Center. It is staffed by Emory School of Medicine (80%) and Morehouse School of Medicine (20%). Faculty, Residents, and Nurse Midwives staff the Women and Infants Center, a center for the provision of prenatal and obstetrical care. Grady Hospital has a bed capacity of 953 and is among the largest in the Southeast, serving a population that is more than 75% African American. The hospital has a regional perinatal center for high-risk mothers and babies, and a state-of-the-art neonatal intensive care unit. Grady has recently completed an approximate $30 million renovation of the Women's and Infants Center, including the outpatient gynecology and obstetrics clinics, as well as the inpatient labor and delivery. These state-of-the-art facilities to support patient-centered reproductive health and obstetrical care for the women and families who access their health services through this system.

A mental health practitioner will be on the hospital premises. In any event that study personnel are concerned about the immediate safety or well-being of the participant (e.g., as a result of psychological stress or injury), a PI will be notified, and emergency care will be arranged.

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