Comprehensive Postpartum Management for Women with Hypertensive Disorders of Pregnancy: A Randomized Controlled Trial Protocol

Updated 4/4/2023

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Funding:
R21NR020857-01

ClinicalTrials.gov number: NCT05849103

BACKGROUND

Hypertension complicates 10% of pregnancies in the U.S.,[1] directly accounting for 7% of pregnancy-related deaths[2] and 38% of severe maternal morbidity.[3,4] Hypertensive disorders of pregnancy (HDP) include chronic hypertension, gestational hypertension, preeclampsia, hemolysis-elevated-liver enzymes-low platelets (HELLP), and eclampsia, and occur 2.5 times more frequently among Black compared to non-Black patients.[5] The weeks after delivery are crucial for maternal health, severe maternal morbidity, and hypertension-associated morbidity.[6,7] Half of all pregnancy-related deaths occur in this time[8] and Black patients are impacted disproportionally by these morbidities including pulmonary edema, stroke, and renal failure.[9,10]

The American College of Obstetricians and Gynecologists (ACOG) recently redefined postpartum care to encompass 12 months after birth and stressed the importance of connecting postpartum patients to primary care clinicians to manage chronic conditions.[11] This handoff is critical as 50% of patients with HDP develop chronic hypertension, and patients affected by HDP have twice the risk of later cardiovascular-related death.[12,13] Recently, Tennessee expanded Medicaid coverage to 12 months postpartum.[14] Given that most obstetric clinicians do not provide comprehensive primary care, we urgently need models for bridging gaps in care after pregnancy. While interventions such as telemedicine and peer navigation demonstrate promise to improve patient engagement in care and reduce postpartum racial disparities,[15–18] no randomized trials address system-level initiatives to improve postpartum care for patients with HDP.[19,20]

Another area of active investigation relates to establishing appropriate blood pressure targets for patients in and around the time of pregnancy. Recent findings from the Chronic Hypertension and Pregnancy Trial suggest that stricter control of antepartum blood pressure is beneficial in reducing the incidence of a composite adverse perinatal outcome which included preeclampsia with severe features, medically indicated preterm birth at less than 35 weeks of gestation, placental abruption, and fetal or neonatal death. This trial has been practice-changing, lowering the historic antepartum blood pressure target from 160/110mmHg to less than 140/90mmHg. However, this trial did not contemplate management of maternal blood pressure in the postpartum period. ACOG presently endorses a postpartum goal of less than 150/100mmHg which, notably, is higher than the newly established antepartum goal. Furthermore, the blood pressure target set for non-pregnant adults by the American College of Cardiology and American Heart Association is even lower, at less than 120/80mmHg to minimize the cardiovascular disease risk associated with chronic hypertension.

We propose a comprehensive management program for postpartum patients with HDP who are at risk for severe maternal morbidity and mortality. Our program will emphasize three key components: 1) self-monitoring of blood pressures with app-based reporting connected to our electronic health record, 2) blood pressure management directed by a program navigator with guideline and physician support and 3) facilitated transitions of care to primary care clinicians for hypertension management. We will randomize 1400 patents with HDP on postpartum day one with follow up through 3 months postpartum. Primary outcome will be blood pressure control at 2 weeks postpartum. Secondary outcomes include identification and treatment of severe blood pressures, severe maternal morbidity, postpartum and primary care visit attendance, and multiple patient-reported outcome measures. All outcomes will be stratified by race (Black and non-Black) to evaluate disparities and by tight versus usual blood pressure control to evaluate the impact of strict postpartum blood pressure control on outcomes. We hypothesize that a comprehensive postpartum HDP management program will improve hypertension control for all patients and reduce disparities that affect Black patients, and that stricter blood pressure control will be associated with fewer adverse outcomes.

OBJECTIVE

Specific Aim 1: To assess whether augmented remote blood pressure monitoring and tight blood pressure control, both individually and in combination, improve blood pressure control and the frequency of severe hypertension in the first 2 weeks postpartum.

Specific Aim 2: To test whether these interventions narrow the existing Black/non-Black inequity in postpartum outcomes such as blood pressure control and severe hypertension.

ELIGIBILITY CRITERIA

Inclusion Criteria

1. Age ≥18 years
2. Diagnosed with a Hypertensive Disorder of Pregnancy (HDP), which includes chronic hypertension, preeclampsia, gestational hypertension, HELLP Syndrome (Hemolysis, Elevated Liver enzymes, Low Platelets), or eclampsia (O10, O11, O13, O14, O15, O16)

Exclusion Criteria

1. Not able or willing to receive electronic surveys
2. Deemed inappropriate for study enrollment by bedside nurse
3. Non-English speaking
4. Discharge on postpartum day 6 or greater
5. Contraindication to ACOG-recommended hypertension control (i.e. chronic kidney disease, stroke)

SCREENING

An Epic Dashboard will be used to screen eligibly patients using the following criteria:

- Admitted to the following units: 4 North, 4 South, 4 East, 4 Med Center East
- Age ≥18 years
- Problem list containing the following ICD10 codes: O10, O11, O12, O13, O14, O15, O16
- Preferred language is English

ENROLLMENT

Patients will be approached for enrollment in the study in their private hospital rooms. Research personnel will discuss potentially eligible patients with either the bedside nurse or charge nurse prior to approaching patients to determine any concerns about enrollment.

Recruiting Script: “Hello Ms. [Patient Last Name]. I am [Research Assistant Name] and I am a research assistant at Vanderbilt. I was hoping to talk to you about a study we are doing among patients who have had high blood pressure issues during pregnancy or postpartum.”

Patients Who Express Interest: “We want to learn how to better help patients who have high blood pressure in pregnancy. All women who have high blood pressure in pregnancy should see their obstetric provider within one week of leaving the hospital to watch blood pressure closely. We want to learn the best way to provide blood pressure care. If you join the study, you would be placed randomly into a group. You would either see your OB as usual for blood pressure help or manage your blood pressure electronically with help from a special team. You would still see your OB for regular postpartum follow up and questions. You would also be grouped by different blood pressure goals. As part of the study, we will look at your health record to learn about your delivery and any health issues. We only share this information with the research team and not your OB. You will get $50 if you finish all 3 months of the study. Risks of the study are small but could include over-treatment, meaning that medication to control blood pressure may be given without added benefit to you, and sharing of health information by accident.”

Once a patient expresses interest in participating, they will be given the informed consent document electronically delivered (via text web-link or email link to RedCap) and their e-signature will be obtained if they consent to participation.

STUDY PROCEDURES

- **Enrollment:** After consenting to the study, participants will receive the initial survey via text web-link or email link. **Survey 1** asks questions about the participant's hypertension history, experience with prenatal care and care at delivery, and socio-demographic questions not reliably obtained from the electronic health record. We estimate that this survey will take 15 minutes to complete. Participants will receive a $10 gift card for completion.
- **Randomization and Procedures before Hospital Discharge:** All participants will receive an Omron validated blood pressure monitor with appropriately sized cuff (Appendix A) following measurement of their arm circumference. Many of our patients do not obtain blood pressure cuffs postpartum, and they infrequently are covered by insurance providers. Instructions for blood pressure measurements and discharge instructions will be discussed with the patient and sent via MyHealth messaging with the script described in Appendix B. Participants will be instructed to measure blood pressure after being seated for 10 minutes with legs uncrossed and back supported with their arm positioned at the level of their heart. They will be instructed to avoid caffeine and tobacco for 30 minutes prior to measuring blood pressure. If blood pressures reach a predefined target threshold (Interventions C and D), they should wait 15 minutes and repeat the blood pressure measurement. Participants will be instructed to bring their blood pressure cuff to their first follow up appointment for calibration and clinical correlation. At hospital discharge, participants will receive information regarding follow up after HDP: a) seeking care for sustained severe blood pressures (≥160/110 mmHg at least 15 minutes apart), b) preeclampsia alert symptoms (headache, confusion, or visual changes), and c) scheduling an appointment with a primary care clinician at 3 months postpartum. All patients will receive a written letter explaining the study (Appendix C) that they can take to clinician visits outside the VUMC system. At discharge, a follow up in-person visit for a blood pressure check within 7-10 days postpartum will be requested by the inpatient team, which is our routine practice. Our specific research interventions are:
- **Interventions:** Participants will be randomized in a 1:1:1:1 ratio in permuted blocks of 4-12 to one of four interventions as summarized in **Table 1** and described in detail below. Randomization will be generated through sealedenvelope.com and allocation through REDCap. Randomization will be stratified by race.

Table 1: Summary of blood pressure (BP) interventions and factorial design

		Postpartum BP Goals	
	Interventions	(C) Standard control BP <150/100	(D) Tight control BP <140/90
BP monitoring	(A) OB Provider Monitoring	(#1) Standard control Provider Monitoring	(#2) Tight control Provider Monitoring
	(B) Augmented Remote Monitoring	(#3) Standard control Remote monitoring	(#4) Tight control Remote monitoring

Blood Pressure Care Navigation

(A) *Obstetric Provider Monitoring (In-Person)*: Participants will be instructed to check their blood pressures twice a day for two weeks and daily for weeks 3-6 after delivery and report abnormal blood pressures or symptoms to their obstetric clinicians. Additional postpartum visits beyond the blood pressure check will be directed by their obstetric clinician.

(B) *Augmented Remote Blood Pressure Monitoring*: A physician investigator (fellow or attending) will place an order for "MyHealth BP Flowsheet" in the participant's chart, which triggers the Track My Health feature on MyHealth. The research assistant will demonstrate to the participant how to track blood pressures through the Track My Health feature on the MyHealth smartphone app. Blood pressure monitoring and management plan outlined below. Among women on antihypertensive medication, blood pressure tracking, monitoring, and feedback will continue until care has been transferred to a clinician who can provide long-term care.

Participant and Hypertension Program Manager responsibilities described in detail below:

Table 2. Participant and Hypertension Program Manager Responsibilities

Blood Pressure Monitoring	Participants Responsibilities	Hypertension Program Manager Responsibilities
Weeks 1-2 after delivery	▸Check blood pressures **twice daily** ▸Record BPs every day in MyHealth ▸Seek urgent care (triage, ED) for sustained severe HTN or symptoms	▸Receive BPs notifications **daily M-F** ▸Call patients who do not send BPs ▸Adjust antihypertensive medications based on sections (C) and (D) below
Weeks 3-6 after delivery	▸Check blood pressures **once daily** ▸Record BPs daily in MyHealth ▸Seek urgent care (triage, ED) for sustained severe HTN or symptoms	▸Receive BPs notifications **weekly** ▸Adjust antihypertensive medications based on sections (C) and (D) below
Communication with obstetric clinicians		▸Send updates on HTN management at weeks 2, 4, and 6 ▸Document medication changes in EStar ▸Send updates to non-VUMC obstetric clinicians with any antihypertensive medication changes
Care Handoffs	▸Schedule postpartum visit at 4-6 weeks ▸Schedule a visit with a primary care clinician or cardiologist at month 3	▸Ensure that postpartum visits are scheduled by 4-6 weeks ▸Ensure that primary care or cardiology visits are scheduled at month 3 ▸Remind patients about all visits

Blood pressure Control

(C) *Standard Blood Pressure Control*: Blood pressure targets will be <150 mmHg systolic and <100 mmHg diastolic consistent with current postpartum recommendations from ACOG. Blood pressure notifications for the HTN program navigator will reflect these parameters and medications will be initiated or titrated to meet these goals. See Appendix J for specifics on management and Appendix L for recommended medication regimens

(D) *Tight Blood Pressure Control*: Blood pressure targets will be <140 mmHg systolic and <90 mmHg diastolic. Blood pressure notifications for the HTN program navigator will reflect these parameters and medications will be initiated or titrated to meet these goals. See Appendix K for specifics on management and Appendix L for recommended medication regimens.

- **Survey 2** (6-weeks after delivery): Participants will receive the survey via text web-link or email link. Survey 2 asks questions about the participant's experience managing hypertension after delivery, the Mothers On Respect Index (MORI) and the Communication Assessment Tool geared towards postpartum care, the PROMIS Bank v1.0 Anxiety (adaptive) survey, the PROMIS Bank v1.0 Depression (adaptive) survey, the PROMIS Bank v2.0 Instrumental Support (adaptive) survey, We estimate that this survey will take 20 minutes to complete. Participants will receive a $20 gift card for completion of this survey.
- **Survey 3**: (12-weeks after delivery): Participants will be contacted via SMS text or email to ask about follow up with a primary care physician and chronic hypertension. Participants will receive a $20 gift card for completion of this survey.

OUTCOMES

Primary Outcomes: The outcome for the R21 and listed on ClinicalTrials.gov is the proportion of patients with a blood pressure recorded in the office at 7-10 days postpartum (**`BPinperson`**). It is not hypothesized that the primary outcome varies by the blood pressure control intervention but will vary by the blood pressure management intervention.

Secondary Outcomes: We will examine three categories of secondary outcomes (**Table 3**). *Hypertension control and adverse events* includes measures of blood pressure control and events potentially associated with poor blood pressure control such as severe maternal morbidity (SMM) and hospital readmission. Given that our intervention tests different models of care, we will assess *health care utilization* associated with these models including adherence to in-person and remote blood pressure monitoring, medication use, attendance at scheduled visits, and unscheduled visits to an urgent care or emergency room.

We will also examine a variety of *patient-reported outcome measures* especially satisfaction with care. HDP carries not only a risk of long-term health sequelae, but also post-traumatic stress disorder, depression, and anxiety.[92,93] In a review of patients' experiences with HDP, the potential for worsening or chronic hypertension was associated increased feelings of anxiety and loss of agency.[94] We hypothesize that augmented remote monitoring and tighter blood pressure control, both individually and in combination, will improve postpartum blood pressure control within the first six weeks postpartum. We also hypothesize that participants, especially Black participants, will find the results of these interventions satisfying and acceptable as they provide a nexus of agency during otherwise stressful life events. Observed reductions in blood pressure provide more frequent and immediate feedback to participants relative to other meaningful outcomes such as SMM or hospital readmission. We also acknowledge the possibility that patients also could find frequent observation of blood pressures and tighter parameters to be burdensome or increase anxiety about health status.

While postpartum patient-reported outcome measures have been developed and validated to study inpatient recovery, lack of consensus exists regarding optimal measures of outpatient recovery.[95] In a recent systematic review of validated measures used to assess three domains or more of outpatient postpartum recovery, three measures were identified but all had significant limitations.[96] The authors conclude that assessment may be better achieved using existing methods such as those endorsed by the Patient-Reported Outcomes Measurement Information System initiative (PROMIS).[96] Therefore, we selected validated PROMIS and NIH Toolbox measures related to depression, anxiety, and social support. Because experience of being listened to or being ignored and dismissed are central drivers of Black women's pregnancy and postpartum experience and health outcomes,[38,39] we emphasize outcomes related to communication during and satisfaction with clinical encounters such as the Communication Assessment Tool -Team (CAT-T) and the Mothers on Respect index (MORi), a scale developed to assess the nature of respectful patient-provider interactions and their impact on a person's sense of comfort, behavior, and perceptions of racism or discrimination.

VARIABLE NAME	DESCRIPTION	DERIVATION	VALUE
7-10 Day Outcomes			
BPinperson710	BP recorded in person	None	1=yes 0=no
BPremote710	Any BP recorded remotely	A systolic BP (d710sbp_remote) or a diastolic BP (d710dbp_remote) value is is present	1=yes 0=no
BPany710	Any BP recorded in person or remotely	If BPinperson710 = 1 or BPremote710=1	1=yes 0=no
SBP710	SBP value Selected by the following hierarchy: 1) in person SBP, 2) remote SBP - If multiple remote BP values were submitted, selected the SBP from day 8 and average the values.	SBP710 = d710sbp_inperson if d710sbp_inperson is present. If d710sbp_inperson is absent, then use d710sbp_remote.	Continuous
DBP710	DBP value Selected by the following hierarchy: 1) in person DBP, 2) remote DBP - If multiple remote BP	DBP710 = d710dbp_inperson if d710dbp_inperson is present. If	Continuous

	values were submitted, selected the DBP from day 8 and average the values.	d710dbp_inperson is absent, then use d710dbp_remote.	
SBP710_bin	SBP value >= 140	SBP710 >=140	1=yes 0=no
DBP710_bin	DBP value >= 90	DBP710 >=90	1=yes 0=no
ANYhigh_bin	Any BP value >=140/90	SBP710>= 140 OR DBP710>= 90	1=yes 0=no
SBPsevere710_bin	SBP value >= 160	SBP710 >=160	1=yes 0=no
DBPsevere710_bin	DBP value >= 110	DBP710 >=110	1=yes 0=no
ANYsevere_bin	Any BP value >=160/110	SBP710>= 160 OR DBP710>= 90	1=yes 0=no
dcp_medstart	Any medication started between discharge through week 6 after delivery	n/a	1=yes 0=no
dcpp_medstart	Days postpartum that medication was started	n/a	Continuous
readmit	Hospital readmission	n/a	1=yes 0=no

The two co-primary outcomes are mean systolic blood pressure (SBP) and diastolic blood pressure (DBP) recorded in-office (**Table 3**). In a secondary analysis, we will also include mean blood pressure measurements reported via augmented remote monitoring among women who do not attend in-office visits. The third co-

primary outcome is proportion of participants with sustained severe hypertension during the first 6 weeks postpartum defined as a SBP ≥160 or a DBP ≥110 on two occasions at least 15 minutes apart.

Secondary Outcomes

We will examine three categories of secondary outcomes (**Table 3**). *Hypertension control and adverse events* includes measures of blood pressure control and events potentially associated with poor blood pressure control such as severe maternal morbidity (SMM) and hospital readmission. Given that our intervention tests different models of care, we will assess *health care utilization* associated with these models including adherence to in-person and remote blood pressure monitoring, medication use, attendance at scheduled visits, and unscheduled visits to an urgent care or emergency room.

Table 3: Study outcomes and time frame for assessment

Hypertension Outcomes		
Blood pressure control (**Primary Outcome**)	Mean SBP assessed in-office and through all methods	7-10 days
Blood pressure control (**Primary Outcome**)	Mean DBP assessed in-office and through all methods	7-10 days
Severe hypertension (**Primary Outcome**)	SBP ≥160 or DBP ≥110 on two occasions 15 minutes apart and less than 4 hours apart	6 weeks
Hospital readmission	Readmission for hypertension management after delivery discharge	3 weeks
Severe maternal morbidity	Center for Disease Control criteria	6 weeks
Health Care Utilization		
Blood pressure assessment	Proportion who report at least one BP reading post delivery	7-10 days
Medication use	Proportion requiring and/or initiating antihypertensive medications	6 weeks
Urgent care visit	Visit to obstetric triage or an emergency department for hypertension	3 weeks
Postpartum visit attendance	Visit with an obstetric clinician postpartum (excludes acute care visit)	6 weeks
Primary care visit	Visit with a primary care clinician (excludes acute care visit)	12 week
Patient-Reported Outcome Measures		
Satisfaction	How satisfied have you been with your postpartum care since discharge? (1-10)	6 weeks
Remote BP monitoring satisfaction	Overall, I am satisfied with my experience with remote blood pressure monitoring	6 weeks
Feeling voice is heard	Overall, my questions and concerns have been listened to since delivery	6 weeks
Mothers on Respect index (MORi)	Assessment of respectful patient-provider interactions and their impact on a person's sense of comfort, behavior, and perceptions of racism or discrimination	6 weeks
PROMIS Emotional Support	16 questions regarding availability to talk to others and feel appreciated by others	6 weeks
PROMIS Self-Efficacy	4 questions about perceived ability to manage difficult or unexpected events	6 weeks
PROMIS depression	Computer adaptive test measuring depression symptoms	6 weeks
Communication Assessment Tool (CAT)	15 questions measuring patient perceptions of clinician interpersonal and communication skills	6 & 15 weeks

SBP=systolic blood pressure | DBP=diastolic blood pressure

We will also examine a variety of *patient-reported outcome measures* especially satisfaction with care. HDP carries not only a risk of long-term health sequelae, but also post-traumatic stress disorder, depression, and anxiety.[92,93] In a review of patients' experiences with HDP, the potential for worsening or chronic hypertension was associated increased feelings of anxiety and loss of agency.[94] We hypothesize that augmented remote monitoring and tighter blood pressure control, both individually and in combination, will improve postpartum blood pressure control within the first six weeks postpartum. We also hypothesize that participants, especially Black participants, will find the results of these interventions satisfying and acceptable as they provide a nexus of agency during otherwise stressful life events. Observed reductions in blood pressure provide more frequent and immediate feedback to participants relative to other meaningful outcomes such as SMM or hospital readmission. We also acknowledge the possibility that patients also could find frequent observation of blood pressures and tighter parameters to be burdensome or increase anxiety about health status.

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index (MORi), a scale developed to assess the nature of respectful patient-provider interactions and their impact on a person's sense of comfort, behavior, and perceptions of racism or discrimination.

ENROLLMENT AND FEASIBILITY

During 2021, 22% (n=1120) of patients delivering at VUMC had a diagnosis of HDP, most commonly gestational hypertension, preeclampsia, and chronic hypertension and 22% of these patients were Black. We have used the eligibility, enrollment, and follow up estimates in **Table 5** With an aim for 50% of our participants to self-identify as Black, we estimate that we can enroll a total sample size of 1000 patients with 6-week follow data after 4-years. Enrollment and follow up estimates are based on prior observational and intervention studies performed among postpartum patients.[100–102]

Table 5 : Estimated Enrollment Numbers

	Black patients *annually*	Black patients *4 years*	Total sample size *4 years*
Total deliveries with HDP	246	986	1971
Eligible for study (95%)	234	936	1873
Agree to enroll (75%)	176	702	1404
Retained to 6 weeks (75%)	132	527	1053

ANALYTIC APPROACH

Specific Aim 1: To assess whether augmented remote blood pressure monitoring and tight blood pressure control, both individually and in combination, improve blood pressure control and the frequency of severe hypertension in the first 2 weeks postpartum.

Aim 1 Analytic Approach: Our primary analysis will examine the independent effect of the interventions (blood pressure goals and monitoring approach) on the primary outcomes. While randomized trials greatly reduce confounding, they do not eliminate it, and covariate adjustment enhances statistical power. Balance in participant's demographic and clinical characteristics across the four groups (control + 3 interventions) will be compared using the Mann-Whitney *U* test for continuous variables and Chi squared test for categorical variables. Characteristics that exhibit differences across groups and potential confounding variables such as race, socioeconomic status, and medical comorbidities will be considered as adjusting covariates in the subsequent regression analysis. Multiple linear regression with ordinary least square estimates (OLS) will be used to compare the SBP and DBP primary outcomes across four interventions with a binary variable for the monitoring intervention (standard vs augmented), a binary variable for the blood pressure goal intervention (standard 150/100 and tight 140/90) and an interaction term between the two binary variables for the combined interventions. A negative value for two main effects of interventions indicates better blood pressure control using individual interventions alone than the standard of care. A negative value for the interaction effect indicates better blood pressure control using combined intervention than individual intervention alone. Post hoc analysis of variance (ANOVA) can be conducted to assess the overall effect of each individual interventions (with 2 degree of freedom) and the overall intervention effects (with 3 degree of freedom). Although OLS does not require normality assumption for outcomes and residuals, extreme outliers might result in potential bias. In this case, a non-parametric model (e.g. proportional odds model) will be considered. This analysis will be repeated allowing the primary outcome to include mean blood pressures reported via augmented remote monitoring among women who do not attend in-office visits. Multiple logistic regression will be conducted for binary outcomes including the severe hypertension primary outcome, hypertension secondary outcomes and healthcare utilization secondary outcomes. The same main effects and interaction effects for interventions specified for the linear regression model will be included with negative values for the log-odds ratio indicating improved outcomes in the intervention groups. Linear regression with OLS will be used for patient-reported secondary outcome measures in a similar fashion as SBP and DBP primary outcomes. Given the prospective design and dedicated personnel, we anticipate little missing covariate data. In case there are more than 1% participants with missing data in the analysis, multiple imputation will be conducted as sensitivity analysis. All outcomes will be analyzed as intent-to-treat.

Specific Aim 2: To test whether these interventions narrow the existing Black/non-Black inequity in postpartum outcomes such as blood pressure control and severe hypertension.

Aim 2 Analytic Approach: Given racial disparities in postpartum outcomes and hypothesized heterogeneity of intervention effect, we plan for two pre-specified subgroup analysis in (1) standard care only (N=250) (2) Black participants only (N=500). The first subgroup analysis aims to assess racial disparities in postpartum outcomes without intervention where Black/non-Black will be the main effect of interests. The second subgroup analysis aims to reassess intervention effects observed in Aim 1 but within Black participants. To test the hypothesis of the interventions narrowing racial inequity, we will use the overall cohort (N=1000) and additionally include the interaction between Black/Non-Black and the intervention effects (two main effects + one interaction effects) on top of all models in Aim 1. Missing data will be handled in the similar fashion as Aim 1. **Power and Sample Size Considerations (All Aims):** For Aim 1, power consideration is conducted in the setting of two group comparisons with sample size of N=250 (N=75 for Aim 3) in the standard care group and N=500 (N=150 for Aim 3) for each individual intervention instead of in the setting of 2x2 factorial design with N=1000 (N=300 for Aim 3) because the effect size of F-statistics for continuous outcomes and chi-square statistics for binary outcomes is not clinically interpretable. Review of institutional data found that 10.2% of patients with HDP at delivery experience sustained severe hypertension within the first 6 weeks postpartum and these patients have a mean SBP of 138 (SD 17.2) and mean DBP of 83 (SD 11.9). We will have 80% power to detect a minimum of 0.22 standardized reduction in SBP and DBP (a small effect by Cohen's nomenclature[103]) which corresponds to reduction in SBP from 138 to 134 mmHg and DBP from 83 to 80 mmHg. Additionally, we will have 80% power to detect 57% reduction in sustained severe hypertension. Minimum detectable effect sizes for selected secondary outcomes in Aim 1 and the primary outcome for Aim 3 are provided (Table 6). For Aim 3, we will have 80% power to detect a minimum of 0.4 standardized difference in cardiovascular outcomes (a medium effect by Cohen's nomenclature), which corresponds to an increase of lateral e' from 11.7 to 13.1. For Aim 2, power justification is conducted based on N=300 using analysis of variance (ANOVA) for the interaction terms between race and interventions effects (with 3 degree of freedom) for the SBP and DBP primary outcomes. The minimum detectable F-statistics for the overall interaction term is 0.19 which is small-to-medium effect by Cohen's nomenclature. The power consideration does not consider adjusting covariates and thus is conservative since inclusion of adjusting covariates will improve the power of the study.

Table 6: Minimum detectable Relative Risk (alpha=0.05, 80% power, N=1000)

Outcome	Baseline	Minimum Detectable RR or Effect Size
Mean systolic blood pressure (SD)	138 (17.2)	4
Mean diastolic blood pressure (SD)	83 (11.9)	3
Sustained severe blood pressure (%)	10%	43%
Postpartum visit attendance (%)	40%	63%
Primary care visit attendance (%)	10%	43%
Diastolic dysfunction: Mean early diastolic filling or e' (SD)	11.7 (3.1)	1.24

DATA AND SAFETY MONITORING

Data will be entered directly into the Research Electronic Data Capture (REDCap) site, a secure web platform for building and managing online databases and surveys with flexible design of electronic CRFs. REDCap is compliant with the Health Insurance Portability and Accountability Act and includes password protection. REDCap maintains records of all changes made to databases so that investigators can identify deleted data and changes made. Each person accessing REDCap has an individual ID for security tracking and to prevent unauthorized access to data. Data can be exported to common statistical analysis packages (e.g., SAS, R, and Stata) and protected health information removed. Several internal quality checks are available in REDCap including: automatic range checks for numeric variables and creation of automatic data reports that help identify data that appears inconsistent, incomplete, or inaccurate. Every two weeks, a separate clinical trials associate assigned to support the study will audit 3 randomly selected charts to ensure that data have been entered correctly and for continuous process improvement. After obtaining informed consent, a copy of the consent form will be sent to participants via email or text and all information retained in the REDCap database. The REDCap database is encrypted and can only be accessed by research personnel with appropriate clearance.

For this study, an adverse event (AE) is defined as any untoward medical occurrence associated with the study, whether or not considered intervention- or procedure-related. An AE can therefore be any undesirable or unintended sign, symptom, laboratory testing or diagnostic imaging finding, or disease temporally associated with participation in the study, without any judgement about causality. The determination of the relationship between the AE and the study procedures must be made by the PI or their designee. This definition will also include changes in the participant medical status that may be related to the study procedures. Maternal medical conditions that are present prior to consent can be considered as baseline and not reported as AEs. However, if the participant's condition deteriorates at any time during the study, it will be recorded as an AE.

The PI will monitor protocol adherence and the progress of the trial on an ongoing basis by reviewing all data collected and monitoring enrollment and follow up. For participants who indicate a high degree of dissatisfaction with the study, the PI will contact the participant to assess the source of the dissatisfaction and whether any postpartum complications have arisen. If complications are uncovered and the participant requires medical care, we will facilitate obtaining care with our providers at Vanderbilt. The PI will notify the Vanderbilt University's Institutional Review Board (IRB) of any AEs promptly and at most within 7 days of the event. If the adverse event is thought to be due to the study, the PI will draft a safety report and send a copy to the IRB who serves as an objective review mechanism. This policy/procedure means that any potential conflict of interest inherent in the PI being the sole reviewer of serious adverse advents is avoided. In addition, all research personnel will be asked to contact the PI within 24 hours to report serious adverse advents. All SAEs occur during the study defined by the given protocol, regardless of the relation to the research, will be reported to the IRB by telephone, e-mail or fax within 24 hours of the investigator's awareness of the occurrence of the event. All expected non-serious adverse events (i.e. patient dissatisfaction) that occur at a greater frequency or severity than anticipated and all unexpected non-serious adverse events will be reported to the IRB within 15 working days of the investigator becoming aware of the event. Adverse events will be summarized annually in the IRB application for continuation or termination of the research.

APPENDIX A

Blood pressure cuff fitting

Arm circumference to be measured and recorded in REDCap along with size of cuff provided

1. AC 17-22cm: small size cuff
2. AC 23-42cm: wide range size cuff
3. AC 43-50cm: extra large adult size cuff

APPENDIX B: Epic MyHealth Message for **Intervention #1** (Standard Control / In-Office Monitoring)

Dear Ms. [last name],

Thank you for being part of the Vanderbilt Fourth Trimester (V4) study. The V4 study will help us learn how to better care for women with high blood pressure in pregnancy.

You have been assigned to the following interventions:

1. **Blood pressure goal: <150/100**
   From discharge through 6 weeks postpartum, we recommend that your blood pressure be less than 150 mmHg systolic (top number) and less than 100 mmHg diastolic (bottom number). If either the top or the bottom blood pressure is higher than the target, your obstetric provider may consider starting or changing medications.

2. **Blood pressure monitoring: Obstetric Provider**
   - *You will be given an appointment to have your blood pressure checked in the office within 10 days of delivery. Usually you receive a MyHealth message about the appointment.*
   - *For the first 2 weeks after delivery, you should check your blood pressure twice a day*
   - *For weeks 3 to 6, you should check your blood pressure once a day*
   - *If your blood pressures are over the goal above, contact your obstetric provider*

3. **Preeclampsia Danger Signs**
   Seek medical attention within an hour if you have any of the following:
   - *Blood pressure of 160 mmHg systolic (top number) or 110 mmHg diastolic (bottom number) after two blood pressure checks at least 15 minutes or more apart and within 4 hours*
   - *A persistent headache that does not go away with rest, eating, or Tylenol*
   - *Spots in your vision or difficulty seeing*
   - *Difficulty breathing*
   - *Persistent and worsening pain in your belly especially in the mid-upper or right-upper areas*

4. **Long-term Care**
   High blood pressure in pregnancy often goes away after delivery, but in some people it stays. Even if it goes away, having high blood pressure in pregnancy can make you higher risk for high blood pressure or heart disease later in life. You should see a primary care provider or cardiologist within 3 months after delivery to discuss ways to improve your heart health and to monitor your blood pressure. Be sure to tell your provider that you had high blood pressure in pregnancy.

Instructions for checking your blood pressure
1. Wait at least 30 minutes after smoking, eating, drinking caffeine (coffee, tea, soda), or exercising.
2. Sit comfortably at a table with both feet on the floor and your arm resting on the table, palm up.
3. Wrap the cuff around your arm, just above your elbow and not over clothing.
4. Push the button to inflate the cuff and record the blood pressure reading.
5. If the reading is above your goal blood pressure, wait 15 minutes and recheck it

If you have any questions or concerns about the study, please contact Dr. Alexandra Phelps at alexandra.j.phelps@vumc.org

APPENDIX C: Epic MyHealth Message for **Intervention #2** (Tight Control / OB Provider Monitoring)

Dear Ms. [last name],

Thank you for being part of the Vanderbilt Fourth Trimester (V4) study. The V4 study will help us learn how to better care for women with high blood pressure in pregnancy.

You have been assigned to the following interventions:

1. **Blood pressure goal: <140/90**
   From discharge through 6 weeks postpartum, we recommend that your blood pressure be less than 140 mmHg systolic (top number) and less than 90 mmHg diastolic (bottom number). If either the top or the bottom blood pressure is higher than the target, your obstetric provider may consider starting medications or changing your dose of medication.

2. **Blood pressure monitoring: Obstetric Provider**
   - *You will be given an appointment to have your blood pressure checked in the office within 10 days of delivery. Usually, you receive a MyHealth message about the appointment.*
   - *For the first 2 weeks after delivery, you should check your blood pressure twice a day*
   - *For weeks 3 to 6, you should check your blood pressure once a day*
   - *If your blood pressures are over the goal above, contact your obstetric provider*

3. **Preeclampsia Danger Signs**
   Seek medical attention within an hour if you have any of the following:
   - *Blood pressure of 160 mmHg systolic (top number) or 110 mmHg diastolic (bottom number) after two blood pressure checks at least 15 minutes or more apart and within 4 hours*
   - *A persistent headache that does not go away with rest, eating, or Tylenol*
   - *Spots in your vision or difficulty seeing*
   - *Difficulty breathing*
   - *Persistent and worsening pain in your belly especially in the mid-upper or right-upper areas*

4. **Long-term Care**
   High blood pressure in pregnancy often goes away after delivery, but in some people it stays. Even if it goes away, having high blood pressure in pregnancy can make you higher risk for high blood pressure or heart disease later in life. You should see a primary care provider or cardiologist within 3 months after delivery to discuss ways to improve your heart health and to monitor your blood pressure. Be sure to tell your provider that you had high blood pressure in pregnancy.

Instructions for checking your blood pressure
1. Wait at least 30 minutes after smoking, eating, drinking caffeine (coffee, tea, soda), or exercising.
2. Sit comfortably at a table with both feet on the floor and your arm resting on the table, palm up.
3. Wrap the cuff around your arm, just above your elbow and not over clothing.
4. Push the button to inflate the cuff and record the blood pressure reading.
5. If the reading is above your goal blood pressure, wait 15 minutes and recheck it

If you have any questions or concerns about the study, please contact Dr. Alexandra Phelps at alexandra.j.phelps@vumc.org

APPENDIX D: Epic MyHealth Message for **Intervention #3** (Standard Control / Augmented Remote Blood Pressure Monitoring)

Dear Ms. [last name],

Thank you for being part of the Vanderbilt Fourth Trimester (V4) study. The V4 study will help us learn how to better care for women with high blood pressure in pregnancy.

You have been assigned to the following interventions:

1. **Blood pressure goal: <150/100**
   From discharge through 6 weeks postpartum, we recommend that your blood pressure be less than 150 mmHg systolic (top number) and less than 100 mmHg diastolic (bottom number). If either the top or the bottom blood pressure is higher than target, your obstetric provider may start or change medications.

2. **Blood pressure monitoring: Remote Blood Pressure Monitoring**
   - *Our Hypertension Nurse Navigator [Name] will be the primary contact for all issues related to blood pressure until 6 weeks after delivery. She will contact you through MyHealth.*
   - *You will be given an appointment to have your blood pressure checked in the office within 10 days of delivery. Usually, you receive a MyHealth message about the appointment.*
   - *For the first 2 weeks after delivery, you should check your blood pressure twice a day. Record your blood pressures every day in the Track My Health feature on your MyHealth app. The Hypertension Nurse Navigator will contact you every weekday to comment on your blood pressures.*
   - *For weeks 3 to 6, you should check your blood pressure once a day unless otherwise instructed. Record your blood pressures every day in the Track My Health feature on your MyHealth app. The Hypertension Nurse Navigator will contact you at least weekly to comment on your blood pressures.*
   - *If your blood pressures are over the goal above, you may be recommended to start medications or change your dose of medication*
   - *The Hypertension Nurse Navigator will update your obstetric provider on your blood pressure management*

3. **Preeclampsia Danger Signs**
   Seek medical attention within an hour if you have any of the following:
   - *Blood pressure of 160 mmHg systolic (top number) or 110 mmHg diastolic (bottom number) after two blood pressure checks at least 15 minutes or more apart and within 4 hours*
   - *A persistent headache that does not go away with rest, eating, or Tylenol*
   - *Spots in your vision or difficulty seeing*
   - *Difficulty breathing*
   - *Persistent and worsening pain in your belly especially in the mid-upper or right-upper areas*

4. **Long-term Care**
   High blood pressure in pregnancy often goes away after delivery, but in some people it stays. Even if it goes away, having high blood pressure in pregnancy can make you higher risk for high blood pressure or heart disease later in life. You should see a primary care provider or cardiologist within 3 months after delivery to discuss ways to improve your heart health and to monitor your blood pressure. Be sure to tell your provider that you had high blood pressure in pregnancy

Instructions for checking your blood pressure
1. Wait at least 30 minutes after smoking, eating, drinking caffeine (coffee, tea, soda), or exercising.
2. Sit comfortably at a table with both feet on the floor and your arm resting on the table, palm up.
3. Wrap the cuff around your arm, just above your elbow and not over clothing.
4. Push the button to inflate the cuff and record the blood pressure reading.
5. If the reading is above your goal blood pressure, wait 15 minutes and recheck it

If you have any questions or concerns about the study, please contact Dr. Alexandra Phelps at alexandra.j.phelps@vumc.org

APPENDIX E: Epic MyHealth Message for **Intervention #4** (Tight Control / Augmented Remote Blood Pressure Monitoring)

Dear Ms. [last name],

Thank you for being part of the Vanderbilt Fourth Trimester (V4) study. The V4 study will help us learn how to better care for women with high blood pressure in pregnancy.

You have been assigned to the following interventions:

1. **Blood pressure goal: <140/90**
   From discharge through 6 weeks postpartum, we recommend that your blood pressure be less than 140 mmHg systolic (top number) and less than 90 mmHg diastolic (bottom number). If either the top or the bottom blood pressure is higher than the target, your obstetric provider may start or change medications.

2. **Blood pressure monitoring: Remote Blood Pressure Monitoring**
   - *Our Hypertension Nurse Navigator [Name] will be the primary contact for all issues related to blood pressure until 6 weeks after delivery. She will contact you through MyHealth.*
   - *You will be given an appointment to have your blood pressure checked in the office within 10 days from delivery. Usually, you receive a MyHealth message about the appointment.*
   - *For the first 2 weeks after delivery, you should check your blood pressure twice a day. Record your blood pressures every day in the Track My Health feature on your MyHealth app. The Hypertension Nurse Navigator will contact you every weekday to comment on your blood pressures.*
   - *For weeks 3 to 6, you should check your blood pressure once a day unless otherwise instructed. Record your blood pressures every day in the Track My Health feature on your MyHealth app. The Hypertension Nurse Navigator will contact you at least weekly to comment on your blood pressures.*
   - *If your blood pressures are over the goal above, you may be recommended to start medications or change your dose*
   - *The Hypertension Nurse Navigator will update your obstetric provider on your blood pressure management*

3. **Preeclampsia Danger Signs**
   Seek medical attention within an hour if you have any of the following:
   - *Blood pressure of 160 mmHg systolic (top number) or 110 mmHg diastolic (bottom number) after two blood pressure checks at least 15 minutes or more apart and within 4 hours*
   - *A persistent headache that does not go away with rest, eating, or Tylenol*
   - *Spots in your vision or difficulty seeing*
   - *Difficulty breathing*
   - *Persistent and worsening pain in your belly especially in the mid-upper or right-upper areas*

4. **Long-term Care**
   High blood pressure in pregnancy often goes away after delivery, but in some people it stays. Even if it goes away, having high blood pressure in pregnancy can make you higher risk for high blood pressure or heart disease later in life. You should see a primary care provider or cardiologist within 3 months after delivery to discuss ways to improve your heart health and to monitor your blood pressure. Be sure to tell your provider that you had high blood pressure in pregnancy

Instructions for checking your blood pressure
1. Wait at least 30 minutes after smoking, eating, drinking caffeine (coffee, tea, soda), or exercising.
2. Sit comfortably at a table with both feet on the floor and your arm resting on the table, palm up.
3. Wrap the cuff around your arm, just above your elbow and not over clothing.
4. Push the button to inflate the cuff and record the blood pressure reading.
5. If the reading is above your goal blood pressure, wait 15 minutes and recheck it

If you have any questions or concerns about the study, please contact Dr. Alexandra Phelps at alexandra.j.phelps@vumc.org

APPENDIX F: Message to Obstetric Providers **Intervention #1** (Standard Control / OB Provider Monitoring)

Dear [provider's name and salutation],

Your patient, [patient's name], recently delivered and her pregnancy was complicated by a hypertensive disorder of pregnancy. She is participating in the Vanderbilt Fourth Trimester (V4) Study, which is a randomized controlled trial examining different blood pressure targets and management styles for postpartum hypertension.

Ms. [patient last name] has been assigned to the standard blood pressure control group in line with current recommendations from ACOG. Her target blood pressure is **<150 mmHg systolic** and **<100 mmHg diastolic.**

As part of the study, your patient will:

- Receive a blood pressure cuff and be taught how to use it properly
- Be scheduled for an in-person blood pressure check within 10 days of delivery
- Be instructed to check blood pressures twice daily for weeks 1-2 after delivery and daily for weeks 3-6
- Contact you if she has blood pressures consistently above this target
- Be advised of preeclampsia danger signs and symptoms
- See you for routine postpartum needs including a postpartum visit
- Be instructed to see a primary care provider or cardiologist within 3 months of delivery

We sincerely appreciate your support for this study. If you have any questions or concerns, please do not hesitate to contact Dr. Alexandra Phelps at alexandra.j.phelps@vumc.org.

Sincerely,

Sarah Osmundson, MD, MS (Primary Investigator)
Maternal-Fetal Medicine

Alexandra Phelps, MD (Co-Primary Investigator)
Maternal-Fetal Medicine Fellow

APPENDIX G: Message to Obstetric Providers **Intervention #2** (Tight Control / OB Provider Monitoring)

Dear [provider's name and salutation],

Your patient, [patient's name], recently delivered and her pregnancy was complicated by a hypertensive disorder of pregnancy. She is participating in the Vanderbilt Fourth Trimester (V4) Study, which is a randomized controlled trial examining different blood pressure targets and management styles for postpartum hypertension.

Ms. [patient last name] has been assigned to the tight blood pressure control group. Her target blood pressure is **<140 mmHg systolic** and **<90 mmHg diastolic**. We recommend initiating or titrating medications to maintain blood pressures less than 140/90.

As part of the study, your patient will:

- Receive a blood pressure cuff and be taught how to use it properly
- Be scheduled for an in-person blood pressure check within 10 days of delivery
- Be instructed to check blood pressures twice daily for weeks 1-2 after delivery and daily for weeks 3-6
- Contact you if she has blood pressures consistently above this target
- Be advised of preeclampsia danger signs and symptoms
- See you for routine postpartum needs including a postpartum visit
- Be instructed to see a primary care provider or cardiologist within 3 months of delivery

We sincerely appreciate your support for this study. If you have any questions or concerns, please do not hesitate to contact Dr. Alexandra Phelps at alexandra.j.phelps@vumc.org.

Sincerely,

Sarah Osmundson, MD, MS (Primary Investigator)
Maternal-Fetal Medicine

Alexandra Phelps, MD (Co-Primary Investigator)
Maternal-Fetal Medicine Fellow

APPENDIX H: Message to Obstetric Providers **Intervention #3** (Standard Control / Augmented Remote Blood Pressure Monitoring)

Dear [provider's name and salutation],

Your patient, [patient's name], recently delivered and her pregnancy was complicated by a hypertensive disorder of pregnancy. She is participating in the Vanderbilt Fourth Trimester (V4) Study, which is a randomized controlled trial examining different blood pressure targets and management styles for postpartum hypertension.

Ms. [patient last name] has been assigned to the standard blood pressure control group in line with current recommendations from ACOG. Her target blood pressure is **<150 mmHg systolic** and **<100 mmHg diastolic**.

As part of the study, your patient will:

- Receive a blood pressure cuff and be taught how to use it properly
- Be scheduled for an in-person blood pressure check within 10 days of delivery
- Record blood pressures and send them to the study Hypertension Nurse Manager
- Have all hypertension related issues including blood pressure medications managed by the study Hypertension Nurse Manager in collaboration with Maternal-Fetal Medicine.
- Be advised of preeclampsia danger signs and symptoms
- See you for routine postpartum needs including a postpartum visit
- See a primary care provider or cardiologist within 3 months of delivery

The Hypertension Nurse Manager will send you periodic updates on your patient's hypertension progress.

We sincerely appreciate your support for this study. If you have any questions or concerns, please do not hesitate to contact Dr. Alexandra Phelps at alexandra.j.phelps@vumc.org.

Sincerely,

Sarah Osmundson, MD, MS (Primary Investigator)
Maternal-Fetal Medicine

Alexandra Phelps, MD (Co-Primary Investigator)
Maternal-Fetal Medicine Fellow

APPENDIX I: Message to Obstetric Providers **Intervention #4** (Tight Control / Augmented Remote Blood Pressure Monitoring)

Dear [provider's name and salutation],

Your patient, [patient's name], recently delivered and her pregnancy was complicated by a hypertensive disorder of pregnancy. She is participating in the Vanderbilt Fourth Trimester (V4) Study, which is a randomized controlled trial examining different blood pressure targets and management styles for postpartum hypertension.

Ms. [patient last name] has been assigned to the tight blood pressure control group. Her target blood pressure is **<140 mmHg systolic** and **<90 mmHg diastolic**.

As part of the study, your patient will:

- Receive a blood pressure cuff and be taught how to use it properly
- Be scheduled for an in-person blood pressure check within 10 days of delivery
- Record blood pressures and send them to the study Hypertension Nurse Manager
- Have all hypertension related issues including blood pressure medications managed by the study Hypertension Nurse Manager in collaboration with Maternal Fetal Medicine.
- Be advised of preeclampsia danger signs and symptoms
- See you for routine postpartum needs including a postpartum visit
- See a primary care provider or cardiologist within 3 months of delivery

The Hypertension Nurse Manager will send you periodic updates on your patient's hypertension progress.

We sincerely appreciate your support for this study. If you have any questions or concerns, please do not hesitate to contact Dr. Alexandra Phelps at alexandra.j.phelps@vumc.org.

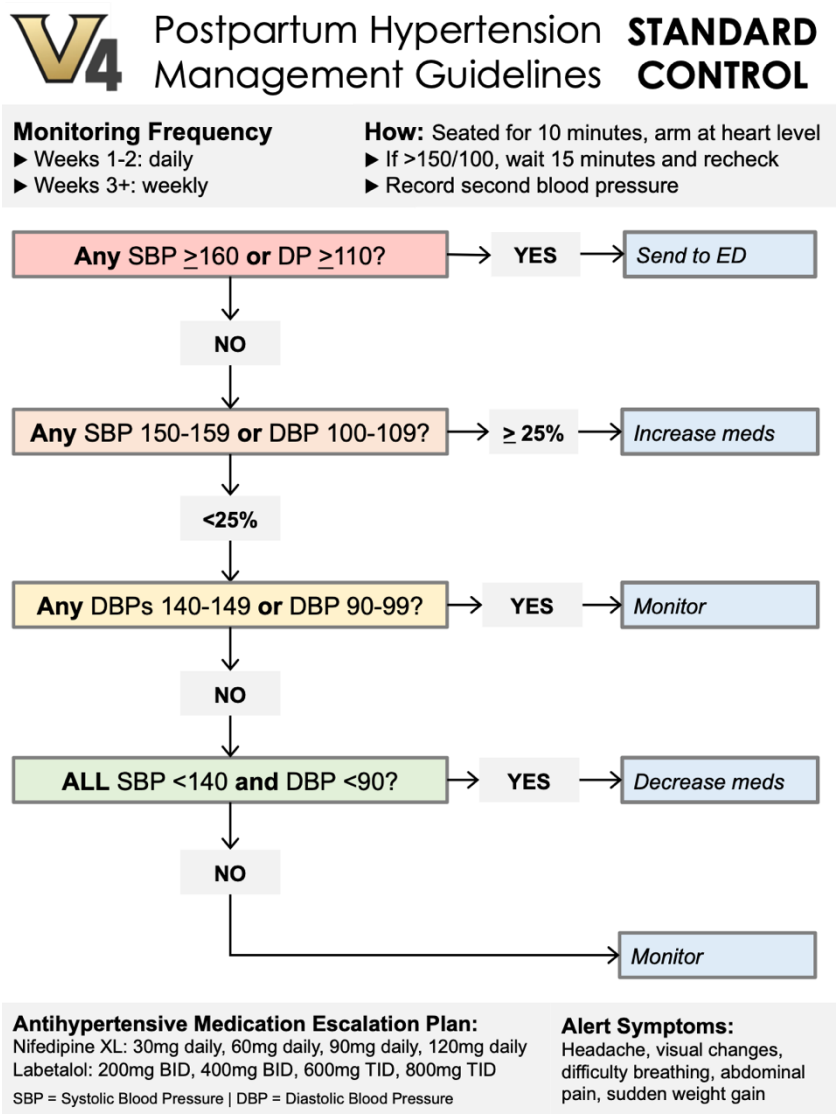
Sincerely,

Sarah Osmundson, MD, MS (Primary Investigator)
Maternal-Fetal Medicine

Alexandra Phelps, MD (Co-Primary Investigator)
Maternal-Fetal Medicine Fellow

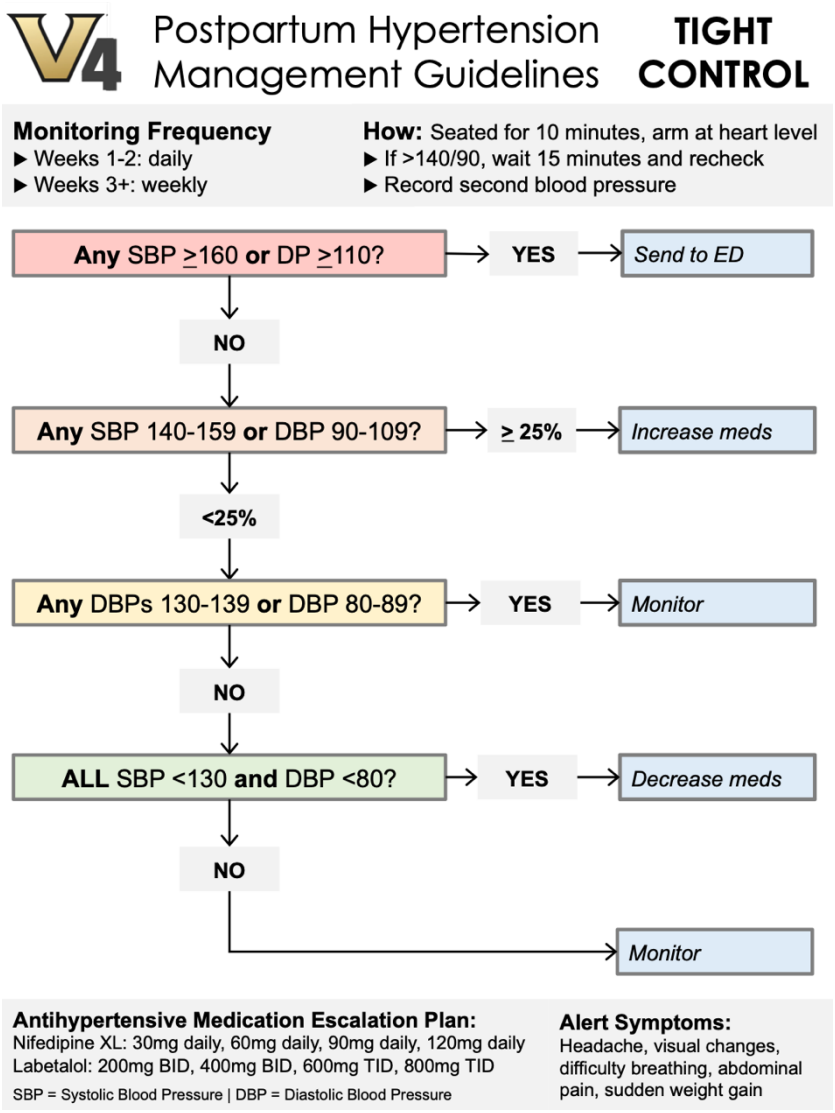
APPENDIX J

STANDARD blood pressure control treatment algorithm:

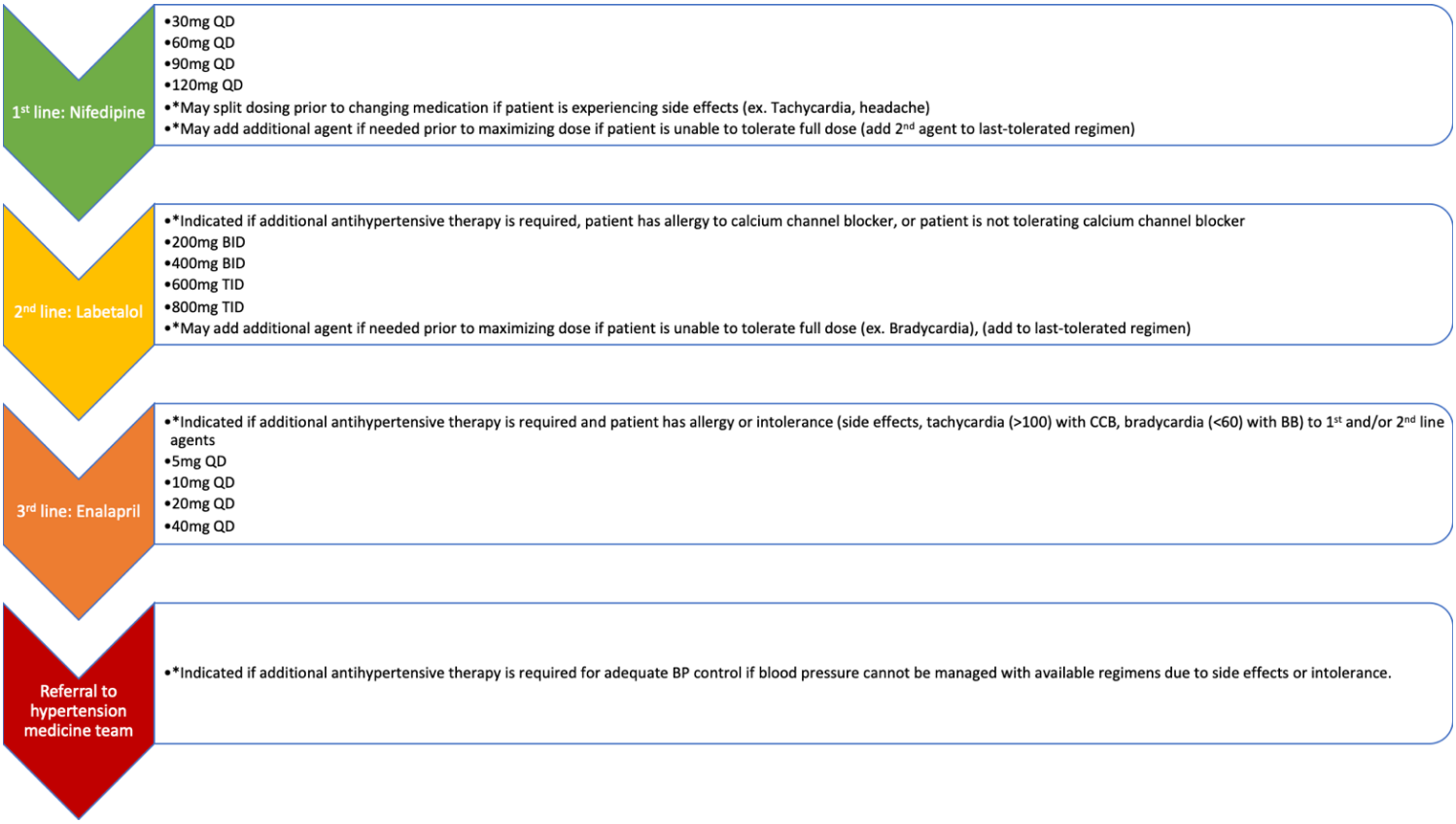


APPENDIX K

TIGHT blood pressure control treatment algorithm:



APPENDIX L


1st line: Nifedipine
•30mg QD
•60mg QD
•90mg QD
•120mg QD
•*May split dosing prior to changing medication if patient is experiencing side effects (ex. Tachycardia, headache)
•*May add additional agent if needed prior to maximizing dose if patient is unable to tolerate full dose (add 2nd agent to last-tolerated regimen)
2nd line: Labetalol
•*Indicated if additional antihypertensive therapy is required, patient has allergy to calcium channel blocker, or patient is not tolerating calcium channel blocker
•200mg BID
•400mg BID
•600mg TID
•800mg TID
•*May add additional agent if needed prior to maximizing dose if patient is unable to tolerate full dose (ex. Bradycardia), (add to last-tolerated regimen)
3rd line: Enalapril
•*Indicated if additional antihypertensive therapy is required and patient has allergy or intolerance (side effects, tachycardia (>100) with CCB, bradycardia (<60) with BB) to 1st and/or 2nd line agents
•5mg QD
•10mg QD
•20mg QD
•40mg QD
Referral to hypertension medicine team
•*Indicated if additional antihypertensive therapy is required for adequate BP control if blood pressure cannot be managed with available regimens due to side effects or intolerance.

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VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Comprehensive Postpartum Management for Women with Hypertensive Disorders of Pregnancy: a Randomized Controlled Trial
Version Date:	4/4/2023
PI:	Sarah Osmundson, MD, MS

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
The purpose of this study is to see if close monitoring of blood pressure postpartum by a dedicated team and using lower blood pressure goals improves blood pressure outcomes. You will randomly be assigned to one of four treatment groups and receive a blood pressure cuff to monitor blood pressures at home. You will be asked to complete three 15-minute surveys during the 3 months after giving birth. You may be asked to communicate with a study member about your blood pressure and aim for lower blood pressure during the study period.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you had high blood pressure during pregnancy and/or postpartum.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:
Risks from participating in the study are minimal but could include accidental disclosure of personal health information. Other risks could include over-treating or over-managing blood pressure without added health benefits.

Good effects that might result from this study:
By taking part in this study, you may receive more attention and assistance managing your blood pressures and have positive feelings from contributing to science. This study may help us better care for women with high blood pressure after pregnancy, reduce complications, and improve long-term health outcomes.

Study Title: Comprehensive Postpartum Management for Women with Hypertensive Disorders of Pregnancy: a Randomized Controlled Trial
Version Date: 4/4/2023
PI: Sarah Osmundson, MD, MS

Procedures to be followed:
You will receive a blood pressure cuff and be assigned to 1 of 4 treatment groups:

1) Blood Pressure Management by your OB Provider **and** Standard Blood Pressure Goals
   You will be asked to check your blood pressure twice a day for the first two weeks and report elevated blood pressures to your obstetric provider. Your goal blood pressure will be less than 150 systolic and less than 100 diastolic.
2) Blood Pressure Management by your OB Provider **and** Lower Blood Pressure Goals
   You will be asked to check your blood pressure twice a day for the first two weeks and report elevated blood pressures to your obstetric provider. Your goal blood pressure will be less than 140 systolic and less than 90 diastolic.
3) Blood Pressure Management by a Study Nurse **and** Standard Blood Pressure Goals
   You will be asked to check your blood pressure twice a day for the first two weeks and report elevated blood pressures daily through MyHealth to the Study Nurse. Your goal blood pressure will be less than 150 systolic and less than 100 diastolic.
4) Blood Pressure Management by a Study Nurse **and** Lower Blood Pressure Goals
   You will be asked to check your blood pressure twice a day for the first two weeks and report elevated blood pressures daily through MyHealth to the Study Nurse. Your goal blood pressure will be less than 140 systolic and less than 90 diastolic

In addition, you will be asked to complete 3 surveys: 1) In the hospital at the time you join the study (10minutes), 2) At 6 weeks postpartum (20 minutes), and 3) at 12 weeks postpartum (5 minutes). You will not be asked to attend any additional visits outside of those routinely recommended for patients with high blood pressure during pregnancy. You may be asked to start medications to keep your blood pressure below the target goal.

Payments for your time spent taking part in this study or expenses:
You will receive $10 for completing the 1st survey in the hospital, $20 for completing a 2nd survey at 6 weeks postpartum, and $20 for completing a 3rd survey at 12 weeks postpartum, for a total of $50 if you complete the entire study.

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

Costs to you if you take part in this study:
There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury.

Study Title: Comprehensive Postpartum Management for Women with Hypertensive Disorders of Pregnancy: a Randomized Controlled Trial
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There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Alexandra Phelps at 615-782-9849 or the Principal Investigator, Dr. Sarah Osmundson at 615-343-7869. If you cannot reach the research staff, please page the study doctor at 615-835-7969.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
If you develop a condition that would require your blood pressure to be managed in a non-routine way or if you cannot complete the surveys or use MyHealth for communicating, you may be taken out of the study.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Clinical Trials Registry:
A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Confidentiality:
You will be assigned a study number and all study information will be collected under this number. All information will be held in a password-protected electronic file and any hardcopies will be kept in a locked file cabinet in the research office. All information published will be de-identified and published as total study numbers.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

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Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:
We will publish our study results, which makes them available to the public. If you would like a copy of the study results, please email Dr. Phelps at alexandra.j.phelps@vumc.org.

Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

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Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Signature of patient	Date
Signature of person obtaining consent	Date and time
Printed name and title	