Pregnancy-Related **H**ypertension: **A**dherence to a **N**ew **T**ype **O**f **M**onitoring (PHANTOM)

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A. Objective

To compare standard in-office postpartum blood pressure monitoring to at-home monitoring for patient diagnosed with hypertensive disorders of pregnancy (gestational hypertension, pre-eclampsia with or without severe features, and chronic hypertension with superimposed pre-eclampsia) with regard to identification of elevated blood pressures, adherence to ACOG guidelines for blood pressure monitoring, timing of the identification and treatment of elevated blood pressures, readmission, and patient satisfaction

B. Background

A large segment of our patient population is diagnosed with hypertensive disorders of pregnancy, including gestational hypertension and pre-eclampsia. New ACOG guidelines recommend postpartum monitoring of blood pressures via blood pressure checks on day 3 postpartum and between days 7-10 postpartum. Our purpose is to compare the effectiveness of using a Bluetooth-enabled home blood pressure monitoring platform to the standard postpartum office-based blood pressure monitoring in performing the recommended postpartum follow-up for patients with hypertensive disorders of pregnancy.

C. Study Methodology

1. Study Design

Randomized controlled trial

2. Comparison Groups:

1: Control group:

A. Standard monitoring: Postpartum blood pressure checks in the outpatient setting on postpartum days 7-10

2: Intervention group:

B. At-home monitoring: Postpartum blood pressure checks twice a day for 16 days using supplies and phone app provided by Babyscripts

3. Procedures:

Identification of Potentially Eligible Patients

1. Potentially eligible patients identified in the postpartum period at GMH and MUSC based on documented diagnosis of pregnancy-related hypertension in the antepartum, intrapartum, or postpartum period

Study Enrollment

2. The patient is approached for study participation by a member of the study staff
3. The enrollment process involves a face-to-face interview with study staff for verification of study eligibility and counseling regarding study procedures, potential benefits and risks, prior to obtaining written consent.
4. Enrollment will occur on the post partum unit in the hospitals

Treatment Allocation

5. Patients will be randomized to group 1 or group 2
6. Subjects allocated to group 1
    A. Undergo counseling regarding standard postpartum blood pressure monitoring with outpatient blood pressure checks on days 7-10 postpartum. They will receive appointments for this at the time of discharge from the hospital.

7. Subjects allocated to group 2
    A. Undergo teaching of how to use Babyscripts app and blood pressure cuff
    B. Explanation of timing and frequency of blood pressure checks and explanation of when to expect call/text from a provider
    C. Assurance that mobile phone number listed in the chart is correct
    D. See flowsheet at the end of this document for decision tree regarding patient contact and treatment of blood pressures

4. Outcomes:

1. Primary: percentage of patients with blood pressure ascertainment within the first 10 days following discharge
2. Secondary outcomes:
    A. Adherence to ACOG guidelines for postpartum blood pressure monitoring
        - Defined as blood pressure ascertainment at 72 hours and between 7-10 post delivery
    B. Rates of initiation of anti-hypertensive medication
    C. Rates of readmission and postpartum triage utilization
    D. Timing of the identification and treatment of severe blood pressures (>/= 160/100). See flow diagram for further details
    E. Patient satisfaction with question scored by a 5 point Likert scale
    F. Subgroup analysis of primary outcome stratified by White and Non-White race

5. Study Population:

All postpartum women at GMH and MUSC with a diagnosis of gestational hypertension, pre-eclampsia with or without severe features which also includes chronic hypertension with superimposed preeclampsia

6. Inclusion Criteria:

1. Age >18
2. English is primary language
3. Ability to receive calls and unlimited texts
4. Unlimited texting on cell phone
5. Can receive phone calls on cell phone
6. Arm can accommodate BP cuff

7. Exclusion Criteria:

1. BMI >50
2. English not primary language
3. Unable to receive phone calls on cell phone
4. Does not have unlimited texting capability on cell phone

8. Allocation Method

Randomization will be done after consent is obtained by block randomization in REDCap

9. Withdrawals, Losses and Deviations

As the primary outcome is ascertainment of blood pressure within 10 days of discharge, we will be observing if patients do not participate in their group's allocated care; they will not be removed from their study group

10. Data Collection/Outcome Measurement

Baseline patient characteristics will be obtained on enrollment. Subject outcomes will be catalogued by the research staff via chart review. REDCap will be utilized for data collection.

11. Study Size and Power

Our sample size calculation for this study is based upon a prior published study investigating postpartum blood pressure ascertainment in a similar population of women with hypertensive disorders of pregnancy by Hirshberg et al. In their cohort, a blood pressure was obtained in 43.7% of patients in the usual care group versus 92.2% in the text-based blood pressure monitoring group. We will assume a slightly more conservative estimate of 50% blood pressure ascertainment in the usual care group and 70% in the text-based group. With a two-sided alpha of 0.05% and 80% power, we would need to enroll 93 patients in each arm for a total population of 186.

12. Analytic Plan

- Intention to treat analysis
- No exclusions for protocol violations or post-randomization exclusions
- Calculation of RR and 95% CI for primary outcome
- Univariate analysis of independent variables

D. Possible Risks

Minimal risk to the patient is associated with this study. The most likely risk to the patient would be loss of confidentially. If a patient is started on antihypertensive therapy, it is possible that side effects from the chosen medicine may be experienced. However, the medications used for treatment are standard of care for patients outside of the study as well.

E. Possible Benefits

This research study is not expected to directly benefit individual subjects, but is likely to yield generalizable knowledge which contributes to the field. It may benefit individual patients by identifying an elevated blood pressure earlier than standard of care.

F. Special Precautions

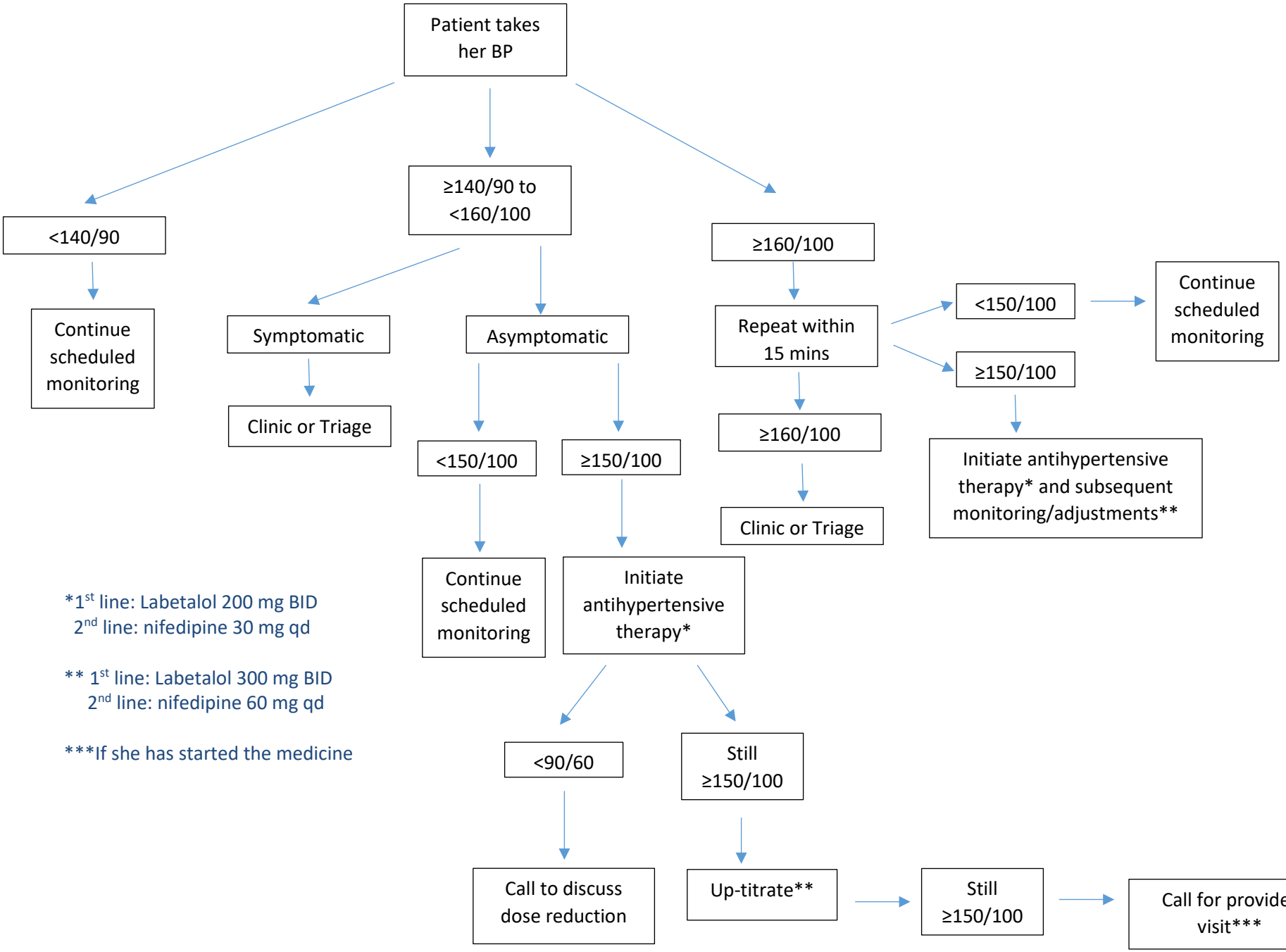
Patients will be given adequate time to review the consent form after being counseled on the study, and will be given adequate time to have questions and concerns answered.

Research staff will be trained in protection of patient confidentially. Captured data will be maintained on password protected electronic files, accessed through password protected computers that are housed behind locked office doors.

The study protocol has been reviewed with other medical centers who have already deployed this process. Their experience has shown this to be safe and feasible

G. Procedures to Maintain Confidentiality

Individual patient data collected as part of this investigation will remain confidential. Composite results from this investigation, however, will be disseminated to the scientific community. The data sheet will contain the patient's name and medical record number for later chart review. Actual data collection will only be performed by the investigators for their study or their designated research personnel. Once the data is collected, each patient will be assigned an alpha-numeric identifier which will allow entry of de-identified data in a computer database. The original data sheets will be stored in a secure location in the Department of Obstetrics and Gynecology.



*1st line: Labetalol 200 mg BID
2nd line: nifedipine 30 mg qd

** 1st line: Labetalol 300 mg BID
2nd line: nifedipine 60 mg qd

***If she has started the medicine