Official Title: Monitoring and Testing of Blood Pressure in Postpartum Women

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Study Title: Systematic Monitoring and Remote Testing of Blood Pressure in Postpartum Women

Short Title: SMART-BP Study

Principal Investigator: Elizabeth Jensen, MPH PhD

Co-investigators: Emily Bunce, MD, David Stamilio, MD MS, Padageshwar Sunkara, MD, Caroline Cochrane, MD, and Karen Gerancher, MD

Study Team Members: Darlene Gold, MSN, RN, Pamela Gammons, Robin Glenn, M. Angie Almond, MEd, RD, LDN, FAND, and Kellyn McKee

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Background, Rationale, and Context

Despite advances in perinatal care in the U.S., maternal mortality has more than doubled over the past two decades, with substantial racial and socioeconomic disparities observed.[1] Hypertensive disorders of pregnancy (HDP) are a leading cause of perinatal morbidity and mortality, with up to 20% of maternal deaths attributed to preeclampsia.[2] In the traditional postpartum care model, many women are not seen for follow-up until six weeks postpartum, with the highest risk women typically scheduled for follow-up three to seven days after discharge. Thus, the postpartum period is a time of particular susceptibility for maternal morbidity and mortality resulting from undiagnosed or inadequately managed HDP.[3] Women from lower socioeconomic status (SES) groups, as well as racial and ethnic minority groups, disproportionately experience an increased risk for adverse consequences from HDP.[4] To mitigate this risk, the American College of Obstetrics and Gynecology (ACOG) recommends blood pressure monitoring (BPM) at 72 hours and through 7-10 days postpartum for women with HDP.[5]

Postpartum readmission for HDP is not limited to antenatally diagnosed HDP; women at "low-risk" account for a significant proportion of readmissions for HDP.[6] ACOG guidelines for postpartum care in lower-risk women recommend an initial postpartum visit by three weeks and a final comprehensive visit by 12 weeks postpartum.[7] However, the majority of readmissions for postpartum HDP occur prior to three weeks, suggesting that this care model is likely inadequate for many women and may contribute to missed or delayed diagnosis and treatment of HDP. In our own, highly diverse patient population, with nearly two-thirds of pregnancies covered by Medicaid or without insurance, compliance with recommended in-person, postpartum visits through this period, among women with higher and lower risk, is less than 50% (internal data).

Given the postpartum risks, women with known HDP experience increased length of stay during their initial postpartum admission.[8] While the increased length of stay has been associated with decreased readmission for HDP, it has also been associated with a significant increase in delivery hospitalization charges.[8] Remote BPM in the postpartum period has been proposed as an intervention to achieve increased monitoring without extending inpatient length of stay.[9]

Several, smaller prospective studies have shown that remote blood pressure monitoring in the postpartum period appears feasible and acceptable in various patient populations, although no studies to date have specifically evaluated feasibility, adherence, and outcomes in lower-income populations. In an RCT

(n=206), Hirshberg et al. demonstrated that remote blood pressure monitoring, coupled with a text-based app providing patient education and real-time provider communication of blood pressure data, resulted in 84% of women receiving recommended blood pressure monitoring.[9] This intervention also reduced racial disparities in receiving recommended follow-up by 50%.[11] Hoppe et al. conducted an experimental study (non-randomized) (n=428) of telehealth with remote blood pressure monitoring that demonstrated a decrease in readmission compared to standard outpatient care.[12] No studies to date have evaluated cost-effectiveness or lower-income populations specifically. In summary, studies have shown the postpartum remote BPM care model to be both feasible and acceptable to patients, with promising evidence from smaller studies for improved patient health outcomes. However, robust, large-scale studies evaluating acceptability and adherence in lower SES populations, clinical outcomes, as well as health care costs are needed to establish the sustainability of this care model.

Objectives

This study is planned to be conducted for a period of 36 months (with an enrollment period of 30 months); however, if it is determined that the following objectives have not been met, the study may be extended based on available funding support.

Primary Objective

Evaluating remote BP monitoring (rBPM) in a highly diverse patient population for:

- Feasibility and acceptability (patient adherence and satisfaction)
- Increased adherence to ACOG guidelines particularly to evaluate the impact of rBPM on the proportion of women with antepartum/delivery hypertensive disorder with blood pressure measures obtained within 72 hours and seven days of discharge and for all women within three weeks postpartum Reduced delivery admission length of stay (LOS)
- Reduced utilization of emergency/acute care services (Emergency Department, OB Triage, Urgent Care)
- Reduced incidence of readmission and readmission LOS
- Assess impact of a rBPM intervention on total health care costs to the patient during the first eight weeks postpartum.

Comparisons:

- rBPM relative to usual standard of care (SOC)
- Performance within racial and socioeconomic subgroups

Secondary Objective

Evaluate the performance of a recently developed risk stratification algorithm for predicting postpartum readmission due to complications of high BP [13]. With the rBPM measures, we can examine patient demographic factors associated with developing abnormal BP readings postpartum, and not just those that were recognized because of being readmitted.

- Improve risk stratification
- Inform sustainability planning

Methods and Measures

This is a randomized control trial (RCT). All women, 18 years of age and older, who have delivered or are planning to deliver an infant(s) at The Birth Center at Atrium Health Wake Forest Baptist (AHWFB) and reside in Forsyth County will be eligible for enrollment and invited to participate in the SMART- BP study. We will enroll women during the prenatal period as well as after delivery. A member of the study staff will review the daily OB prenatal clinic schedules at all 3 AHWFB locations (Downtown Health

Plaza, Clemmons Plaza, and Shepherd Street) to screen patients for eligibility. The study staff member will then notify the designated clinic staff of eligible patients that should be offered the opportunity to watch the SMART-BP informational video (with Spanish language closed captioning available-*Appendix 10)* at some point during a clinic visit occurring at >/= 24-weeks gestation. A clinic staff member will provide an iPad that the patient can watch the video on, if the patient is in agreement. The video is approximately 8 minutes in length. After viewing the video, the patient will then be offered an opportunity to contact a study staff member (via email) to answer any questions they may have, to decline enrollment, or they can choose to review the electronic consent form via REDCap and sign if they wish to enroll in the study. A copy of the consent form will be sent to them via email at the time of enrollment.

If an eligible patient received postpartum care in The Birth Center and was not previously provided the opportunity to view the SMART-BP informational video at a prenatal clinic visit, she will be offered the opportunity to view the video in her hospital room prior to discharge from the postpartum unit. After viewing the video, the patient will then proceed through the same enrollment process that is provided to women at their prenatal visit. A Nurse Education and Support Team (NEST) Coordinator would then be able to randomize the subject using REDCap and then inform the subject which study arm they had been assigned. In the event a subject was enrolled in a prenatal clinic, randomized to the rBPM arm and was discharged from the hospital following delivery without receiving a BP cuff/monitor and instructions from a NEST coordinator (on weekends, and designated holidays), a BP cuff/monitor and printed instructions would be delivered to the subject by a courier service (Delivery On Time). A NEST coordinator would then contact mom via phone as soon as feasible (within 48 hours) to review instructions and ensure the subject was able to download the BabyScripts app and was able to record a BP measurement.

Patients who were not offered the opportunity to enroll in the study at a prenatal clinic visit, delivered an infant(s) at The Birth Center, and were discharged or were otherwise not approached for an initial visit by a NEST Coordinator will not be included in this study.

After obtaining electronic consent via REDCap, the subject will be asked to complete a baseline demographic questionnaire *(Appendix 1a and 1b*). After this brief questionnaire is completed, the subject will then be randomized into one of two study arms; either rBPM or SOC. Study ID numbers will be assigned to each subject. Randomization assignment will be completed by a study staff member using the REDCap randomization tool after enrollment and after the subject has completed the baseline questionnaire in REDCap or in real time if the subject is enrolled in the hospital after delivery. All subjects have an equal chance of being assigned to either the rBPM or SOC study arm. The study arm assignment will be documented in the subject's EMR The subjects that were enrolled during a prenatal clinic visit will not be aware of their study arm assignment until after they have delivered their infant(s) at The Birth Center. Logistically, it is not feasible to complete the randomization in real-time in the outpatient setting, and there are no study activities that occur between the time of the subject's outpatient prenatal clinic visit and their delivery at The Birth Center.

Standard of Care (SOC) Arm

Subjects randomized to SOC arm are provided with the appropriate standard of care depending upon their risk level (as determined by their individual provider or AHWFB Maternal-Fetal Medicine provider)

- High-risk women:
    - Scheduled in-person visit 1 week postpartum with their OB
    - Scheduled in-person visit 4-6 weeks postpartum with their OB
    - Additional visits as clinically indicated determined by the patient's provider(s).
    - Patients with high blood pressure may be instructed to check home blood pressures at the discretion of their primary provider
    - Blood pressure cuffs are not routinely provided by primary provider
- Low-risk women:
    - Typically scheduled in-person visit 4-6 weeks postpartum with their OB
    - Additional visits at patient/provider discretion

The individual subject's provider will perform all follow-up postpartum OB visits. The study team will not initiate the scheduling of any follow-up postpartum OB visits for either study arm (this is the responsibility of the individual subject). However, the study team members may encourage subjects to make and keep their 4-6 week postpartum visit. All physician/health care provider visits will be at the expense of the individual subject.

Remote Blood Pressure Monitoring (rBPM) Arm

Subjects randomized to rBPM arm receive the appropriate standard of care depending upon their risk level, as well as the remote BP monitoring app (BabyScripts) and Bluetooth enabled BP cuff/monitor, and will receive the following equipment and monitoring:

- High-risk women:
    - Scheduled in-person visit 1 week postpartum with their OB
    - Scheduled in-person visit 4-6 weeks postpartum with their OB
    - Additional visits as clinically indicated determined by the patient's provider(s).
- Low-risk women:
    - Typically scheduled in-person visit 4-6 weeks postpartum with their OB
    - Additional visits at patient/provider discretion

- Provided with a specialized, Bluetooth enabled BP monitoring cuff (Clinically Validated, A&D Medical Wireless Blood Pressure Monitor-Upper Arm (*Appendix 2*)
    - The standard BP cuff is designed to fit a wide-range of arm circumferences (8.6-16.5 inches) and can accommodate an individual with a BMI up to 45-50 kg/m2.
    - An extra-large BP cuff will be available for women with larger arm circumferences (16.5-23.6 inches), or BMI >50 kg/m2. The extra-large BP cuff is not Bluetooth enabled and the subject will need to manually enter BP data from the BP monitor into the BabyScripts app. We expect that this extra-large BP cuff will be needed for <10% of our subjects (based on historical data from other facilities utilizing BabyScripts app)
- Assistance with downloading BP monitoring smart phone app, BabyScripts™ (*Appendix 3a and 3b)*
- Verbal and written instructions, to conduct BP checks at home (with reminder notifications sent via the BabyScripts app): (*Appendix 4)*
    - Twice daily on days #1 through #16 (day #1 = day after hospital discharge)
    - At least once daily on days #17 through # 21
    - Due to the customization limitations of the Babyscripts app, subjects will receive twice daily reminder notifications for the duration of the study enrollment period (21 days); however, the NEST coordinators will remind the subjects that we are only asking them to check their BP once daily on days #17 through #21.
    - Subjects will be asked to demonstrate the accurate use of the BP cuff/monitor and the BabyScripts app for a study team member, prior to being discharged from the hospital. This is to evaluate their level of understanding, to confirm the BP cuff is the correct size, and that the equipment is working properly.
    - All BP measures and any alerts will be sent in real-time to a secure cloud-based portal, DIANA. This portal will be accessible only to designated staff members. Clinically-relevant readings and symptoms initiate an alert to BabyScripts call center and then are communicated directly to AHWFB Maternal-Fetal Medicine staff
    - AHWFB Maternal-Fetal Medicine on-call staff are available for response 24/7/365
    - Acceptability and user experience data will be collected via on-line REDCap survey between 21-28 days after enrollment (*Appendix 5a and 5b)*

Subjects selection criteria

Inclusion Criteria

- Women that received prenatal care at one of the AHWFB OB/MFM outpatient clinic locations (Downtown Health Plaza, Clemmons Plaza, and Shepherd Street)
- Women that delivered an infant(s) at The Birth Center at AHWFB
- Women that delivered an infant(s) at home or outside facility, and were transported to AHWFB and received postpartum care in The Birth Center
- Currently resides in Forsyth County, NC
- 18 years of age or older
- Able to read and understand either English or Spanish
- Owns or has daily access to a smartphone (iOS or Android operating system) and Wi-Fi or monthly mobile data plan

Exclusion Criteria

- Women that delivered an infant(s) at any location other than The Birth Center at AHWFB
- Women that did not receive postpartum care at The Birth Center at AHWFB
- Resides outside of Forsyth County, NC
- Under 18 years of age
- Unable to read or understand either English or Spanish
- Does not own or have daily access to a smartphone (iOS or Android operating system)
- Owns a smartphone but does not have Wi-Fi or monthly mobile data plan

Sample Size

It is estimated that approximately 5,000 women will deliver in Forsyth County over a 30 month time period. Of these, we anticipate that approximately 2000 women will be randomized equally (1000 in each study arm) during this time period.

Interventions and Interactions

After obtaining informed consent electronically via REDCap, all subjects will be asked to complete a questionnaire using REDCap in order to collect baseline demographic data. Collecting this demographic data directly from the subject is to ensure accuracy. It has been reported that race, ethnicity, and even preferred language data may be missing from a subject's EMR or may have been previously entered into the EMR incorrectly (internal report). Additionally, collecting data on the subject's education level and marital status may help inform health disparities among various subject groups.

The subject will be directed to the demographic questionnaire after signing the electronic consent form via REDCap. The questionnaire must be completed in order to randomize the subject to a study arm. It is estimated that it will take </= 5 minutes to complete the baseline questionnaire. The baseline questionnaire will be available in both English and Spanish.

The subjects randomized to the rBPM study arm will receive a specialized Bluetooth enabled BP cuff/monitor from a NEST Coordinator in the hospital after delivery and before they are discharged home. The subject will receive both verbal and written education (in the subject's primary language) on the correct use of the specialized BP cuff/monitor. *(Appendix 7a and 7b).* The BabyScripts app will be downloaded on the subject's personal smartphone utilizing either an iOS or Android operating system. Instructions on the use of the BabyScripts app will be provided verbally and in writing (in the subject's primary language). The data entered into the BabyScripts app by the subject includes the following: name, email, DOB, cell phone number, pre-pregnancy weight, height, and date of (actual or expected) hospital discharge following delivery. The subject's pre-pregnancy weight and height are utilized by the app to calculate the subject's BMI, which will then help to identify the correct size of BP cuff that the

subject should be using for this study. Using an oversized or undersized BP cuff can result in erroneous BP measurements. The BabyScripts app is downloaded at no cost to the subject. Per the Master Agreement with BabyScripts, BabyScripts does not sell or share any personal data collected through the app.

The subject's education/training for participating in this research study is expected to take approximately 10 - 15 minutes, but the amount of time needed may vary based on the individual subject's level of understanding. After completing the training, a NEST Coordinator must observe a successful subject-directed trial of the rBPM equipment and app. The NEST Coordinator will document any identified barriers that may limit the subject's successful participation in the study.

The subject will use the specialized BP cuff/monitor to measure their BP twice-daily beginning on the morning of the day following hospital discharge. This day will be noted as "Day 1". Twice daily BP monitoring will continue through Day 16. Then, starting on Day 17, the subject will need to obtain their blood pressure only once daily in the morning, and continuing daily through Day 21. Subject's BP measurements will no longer be transmitted via BabyScripts app beginning on Day 22. The subject will receive a reminder text via the BabyScripts app when it is time to obtain their BP. Due to the limitations for customization, the Babyscripts reminder notifications will be sent twice daily (one in the morning and once in the evening) for the entire 21 day study period. . It is expected that it will take the subject less than 5 minutes (after a 5-10 minute rest period that is recommended to for the most accurate reading) to obtain each BP measurement. The subject's BP measurements, and any alerts are sent in real-time to a secure cloud-based portal. If the subject's BP falls within the normal range (</= 140/90), they will receive notification via the BabyScripts app, that their BP reading is normal. Any clinically relevant BP readings (defined below) will initiate an alert to the BabyScripts call center staff, who then communicates directly with a member of AHWFB Maternal-Fetal Medicine (MFM) staff. An assigned (or on-call) MFM staff member is available for response 24/7/365. While BabyScripts acts in real-time to alert the provider, any issues with wait time, unanswered phone lines, etc. may lead to delays to when the subject can expect to hear from the provider. Alert calls received from BabyScripts are documented in the subject's EMR.

If BP mildly elevated (>/=140/90)

- Alert is generated through the BabyScripts app for both or either diastolic alone or systolic alone readings above the threshold
- Subject receives an immediate text and an email message via BabyScripts letting the subject know they have a mildly elevated BP reading and asking the subject to complete a symptom checklist (headache, vision changes, severe abdominal pain, swelling of hands and face, shortness of breath/anxiety) directly in the app. If they have no symptoms, the "no symptoms" icon must be checked in the app.*(Appendix 8a and 8b)*
- Subject is instructed via BabyScripts app to recheck BP in 10 minutes
- The MFM staff member or provider is alerted by the BabyScripts call center within 4 hours
- MFM staff member or provider calls subject for further evaluation and instructions:
    - If this is new onset and subject has no symptoms, then subject will be scheduled for an office visit in 1-3 days.
    - If has chronic or known history of hypertension and subject has no symptoms, then they will continue monitoring BP per study protocol.
    - If subject has symptoms, she will be referred to OB triage

If BP critically elevated (>/=160/110)

- Alert is generated through the BabyScripts app for either diastolic alone or systolic alone readings or if both readings are above the threshold

- Subject receives an immediate text and email message via BabyScripts letting subject know they have a critically elevated BP reading and asking the subject to complete a symptom checklist directly in the app. If they have no symptoms, the "no symptoms" icon must be checked in the app.
- On-call MFM staff is alerted by BabyScripts call center within 60 minutes [14-19].
- Provider (or nurse – see 2nd bullet below) calls subject for further evaluation and instructions within 45 minutes:
    - If this is new onset hypertension irrespective of symptoms, the subject is referred to OB triage and instructed to present without delay.
    - If subject also has a chronic or known history of high BP, but no other symptoms, then a RN reviews the BP measurements, discusses with the clinic or on-call MFM physician, and contacts the subject with the provider's recommended instructions.

For the subjects in the rBPM study arm, acceptability and user experience data will be collected via on-line REDCap questionnaire ~ 21 – 28 days after study enrollment, or within one week of the subject's completion of the study. A unique link to the REDCap questionnaire will be sent via email to the subject. If the questionnaire is not completed within 1 week of being sent, a reminder email to complete the survey will be sent weekly for a maximum of 3 weeks. Completion of this on-line survey is expected to take </= 5 minutes.

Per standard of care, the rBPM study arm subject's initial postpartum OB provider visit will be scheduled either at ~1 week after delivery for high risk subjects and at ~4-6 weeks after delivery for subjects with a low risk of postpartum complications. Additional follow-up medical care visits may be scheduled at the discretion of the provider and the subject. All follow-up medical care, regardless of the study arm, will be at the expense of the individual subject.

The subjects randomized to the experimental study arm will be provided with a specialized BP cuff/monitor at no cost. The subject will be able to keep the BP cuff/monitor for personal use after they have completed the study. The subject does not need to return the monitor.

The subjects randomized to the SOC study arm will not be provided with specialized BP cuffs and monitors, and will not download the BabyScripts app. For subjects that are considered to be high risk within this study arm, with high blood pressure or a history of high blood pressure during or before pregnancy, they may be instructed to check home blood pressures at the discretion of their primary provider. The subject's postpartum OB provider visit will be scheduled either at ~1 week after delivery for high risk subjects and at ~4-6 weeks after delivery for subjects with a low risk of postpartum complications. Additional follow-up visits may be scheduled at the discretion of the provider and the subject.

Study subjects will not receive any financial compensation for participating in this research study.

Outcome Measures

1. Assess the feasibility and acceptability (patient adherence and satisfaction) of administering a rBPM intervention in the postpartum period particularly in a predominantly lower socioeconomic status population.

2. Evaluate the impact of rBPM on adherence to ACOG recommendations, the length of postpartum admission, occurrence of readmissions and length of stay for readmissions. The initial hospital admission

stay could be reduced as a result of the provider discharging the patient when they know that the patient will be able to monitor their blood pressure at home (instead of keeping them to conduct additional monitoring in the hospital).

3. Assess the impact of rBPM intervention on emergency and urgent acute care utilization and rate of severe hypertension within first week postpartum and third week postpartum.

4. Assess impact of a rBPM intervention on total health care costs to the patient during the first eight weeks postpartum

4. Validate and calibrate previously developed predictive algorithm for postpartum high blood pressure complications.

Feasibility and acceptability outcomes

Primary:

Among those randomized to the intervention arm, at least 90% will have a smartphone and will be able to have the remote BPM app loaded onto their phone, prior to discharge. We hypothesize an absolute difference of no more than 10% (e.g., 85% vs 95% with a smartphone) according to insurance status (Medicaid or uninsured vs. private insurance).

Remote BPM will be successfully integrated into patient care as evidenced by at least 90% adherence to a median of at least one blood pressure reading/day for three weeks and 70% adherence to obtaining a median of two blood pressure measures for initial 2 weeks postpartum. We hypothesize an absolute difference in adherence, according to patient insurance status of <15%.

Secondary:

A high proportion (>90%) of patients indicating satisfaction with use of the remote BPM tool, with no significant difference in satisfaction according to patient insurance status. Satisfaction to be assessed at 3-4 weeks postpartum through a unique link to a satisfaction survey sent to participant.

Clinical outcomes

Primary:

We anticipate a significant increase in proportion of women having their blood pressure monitored according to ACOG guidelines for obtaining BP measures (obtain BP with 72 hours of discharge and maintain monitoring through 7-10 days for all women with hypertensive disorders of pregnancy (HDP)), with an absolute difference of >30% between those randomized to usual care versus remote BPM for within 72 hours and an absolute difference of 30% for continuous monitoring through 10 days (60% for usual care vs 90% intervention arm in those with higher risk - antepartum/delivery HDM).

Among all women (with and without HDP) we anticipate an absolute difference of 60% between those randomized to usual care versus remote BPM for obtaining blood pressure measures within three weeks of discharge (30% usual care vs 90% intervention arm for low and high risk women combined). We hypothesize that the disparity in obtaining these measures, according to insurance status, will be reduced.

Secondary:

Remote BPM will decrease the duration of stay in the postpartum unit, with women with remote BPM discharged earlier than those with usual care, with a median, absolute decrease of length of stay of >1 day(s), irrespective of insurance status.

Secondary:

Readmissions for HDP, within eight weeks of discharge, occurs in ~2% of the general patient population.[4,8] We hypothesize an absolute decrease of 60% in readmission rates. With earlier intervention, we hypothesize that the median length of stay for the readmission will be significantly reduced in the intervention arm.

Health care costs

Primary:

We hypothesize >50% average total cost reduction (charges and amount paid, examined separately), for the period from discharge through eight weeks postpartum, for the intervention versus usual care arm, irrespective of insurance status.

Analytical Plan

The subject will complete a baseline demographic questionnaire at the time of enrollment. This questionnaire will be completed electronically through a unique link via REDCap. Additionally, subjects in the rBPM study arm will be asked to complete a post-study questionnaire electronically through a unique link via REDCap ~ 1 week after subject has completed the study.

The following EHR-based clinical measures will be obtained from each subject:

- Demographics
- History of hypertension or use of blood pressure lowering agents
- Pregnancy-related data (e.g. blood pressure, pre-pregnancy BMI, weight gain, complications, pre-pregnancy diabetes, gestational diabetes, delivery complications)
- Birth outcomes, including gestational age at delivery, cesarean or vaginal delivery, singleton or multiparous delivery, birth weight
- Length of stay of admission and any readmissions through 12 weeks postpartum
- Use of blood pressure lowering agents through 12 weeks postpartum

We will link EHR, BP, baseline demographic questionnaire data, billing, and user satisfaction data to inform study questions as described above. Data will be reviewed for missingness, with multiple imputation performed as appropriate. Initially, data will be analyzed using descriptive statistics. Comparison between groups may be performed using chi square tests for proportions, and t-tests or ANOVA procedures for continuous variables. Crude and adjusted regression analysis will be performed to identify independent outcome predictors. Other inferential statistical analysis will be conducted as appropriate.

Human Subjects Protection

Subject Recruitment Methods

A study staff member will review the daily prenatal clinic schedules at all 3 AHWFB locations (Downtown Health Plaza, Clemmons Plaza, and Shepherd Street) to screen patients for eligibility. The study staff member will then notify the designated clinic staff of the eligible patients that should be offered the opportunity to watch the SMART-BP informational video at some point during a prenatal clinic visit at >/= 24 weeks gestation. Additional study subjects may be identified using daily census reports of the postpartum units in WakeOne (Epic).
Routine inpatient visits by our NEST Coordinators typically occur on the postpartum unit after delivery and before the patient is discharged from the hospital. If a patient is not in her private room at the time of the visit, for example, if she is visiting her baby in the NICU, the NEST Coordinator typically contacts these patients via phone, or may approach them in the NICU (only if appropriate). These efforts are made to ensure a patient that was not enrolled during a prenatal clinic visit is not excluded from the study if they are not physically in their room at the time of the NEST Coordinator's routine postpartum visit. If the patient is interested in participating in the study, the NEST Coordinator will offer the patient the opportunity to view the SMART-BP informational video and review and sign the consent form on an iPad ideally, in the patient's postpartum room. These visits are conducted on weekdays only. The patients that were not enrolled during a prenatal clinic visit and are discharged prior to an inpatient visit by a NEST Coordinator will not be eligible for enrollment in this study.

Any study recruitment advertisements will only be displayed in The Birth Center location on the main campus of Atrium Health Wake Forest Baptist and the prenatal clinics located at Downtown Health Plaza, Clemmons Plaza, and Shepherd Street.

Informed Consent

Informed consent will only be obtained electronically via a secure REDCap platform from each eligible adult (18 years old or older) subject after viewing the SMART-BP informational video. Consent will be obtained in a private area in the outpatient clinic (prenatal enrollment) or in the subject's private hospital room or other private area located in The Birth Center or on the main campus (postpartum enrollment) In the event a private area is not available, the patient can view the SMART-BP informational video using closed captioning prior to reviewing and signing the informed consent in REDCap. The subject will also have an opportunity to select a link to contact a study staff member if they would like additional information about the study and/or to answer any questions they may have about the study or the consent process. An electronic copy of the consent form will sent via email to the subject following enrollment in the study.
Subjects will also have the opportunity to ask the study staff any questions before initiating any study activities

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, a unique study identifier will appear on the data collection report in REDCap. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, stored separately from the data, or maintained in REDCap. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection, subject identifying information will be kept in a secure file indefinitely, to allow for future study of patient outcomes relevant to the identification of elevated blood pressure in the postpartum period. Data access will be limited to designated study staff. Subject data and records will secured and maintained on a password protected, network computer. There will not be any printed copies of reports that contain PHI or identifiable subject

data. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study subjects. The principal investigator will be assisted by co-investigators and other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations, or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and to the research study stakeholders.

Appendices

1 – Baseline demographic questionnaire
- 1a – English
- 1b - Spanish

2 – Bluetooth enabled BP cuff and monitor specifications/manufacturer data

3 – BabyScripts app - directions to download app
- 3a – English
- 3b - Spanish

4 – BabyScripts app reminder to check BP notifications
- 4a – English
- 4b – Spanish

5 – Patient satisfaction survey including email intro to survey
- 5a – English
- 5b – Spanish

7 – Directions on how to use the BP cuff and monitor
- 7a – English
- 7b – Spanish

8 – BabyScripts app symptoms list
- 8a – English
- 8b - Spanish

10 – Video Script

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