# Remote Patient Monitoring: Telehealth for management of postpartum hypertension

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Clinical Trial Protocol

NCT03111095

## Abstract

**Aim 1:** Conduct an initial phase study for postpartum women at risk for severe hypertension to estimate the rates of willingness to participate in and utilize remote mobile health applications to monitor home blood pressures and weights, medication adherence after hospital discharge, to inform a trial to decrease postpartum maternal morbidity and readmission.

> **Sub Aim 1:** Conduct a survey regarding patient satisfaction using mobile health technology

***Hypothesis*:** We hypothesize that the mobile health application will be implemented with strong fidelity, have positive patient acceptability, and demonstrate a meaningful reduction in home blood pressures and postpartum hospital readmission.

**Aim 2:** Obtain prospective daily monitoring of blood pressures in the Peripartum period (initial hospital admission through 6 weeks postpartum) to understand natural history of development and resolution of postpartum hypertension using all patients utilizing the mobile health program over year 1. Specifically, this data will be used to estimate standard deviations of SBP and DBP in the intrapartum compared to 24-96 hours postpartum to inform a future trial regarding the threshold blood pressure to prevent development of severe hypertension or hospital readmission.

***Hypothesis*:** We hypothesize women with severe intrapartum hypertension will predict development of severe hypertension within 7 days of delivery more often than blood pressures obtained in the first 24-96 hours after delivery.

**Aim 3:** Compare the maternal outcomes in the cohort utilizing remote patient monitoring to the cohort of patients with hypertension related disorders discharged with routine care. This would include all patients from Aim 1 as well as the remaining from the entire 1-year experimental period.

***Hypothesis:*** We hypothesize women utilizing the mobile health program will have less hospital readmission and a lower incidence of reported severe hypertension compared to the control group utilizing standard of care.

**Aim 4:** Perform a cost effectiveness modeling will be performed to determine whether it is cost-effective to use remote patient modeling for women with postpartum hypertension in comparison to standard outpatient care in women with hypertension-related disorders of pregnancy.

***Hypothesis***: Patient care utilizing mobile health surveillance postpartum will demonstrate a significant cost savings compared to routine care in patients with postpartum hypertension.

**Aim 5:** Compare the maternal outcomes in the cohort utilizing remote patient monitoring to the cohort of patients with hypertension related disorders discharged with routine care. This would include all patients from Aim 1 as well as the remaining from the entire 1-year experimental period.

***Hypothesis***: We hypothesize that women utilizing the mobile health program will have less hospital readmission and a lower incidence of reported severe hypertension compared to the control group utilizing standard of care.

**Sub-Aim 5A:** Graph the weight loss trajectory of the cohort utilizing remote patient monitoring with daily weights over 6 weeks.

***Hypothesis*:** This is a descriptive sub-aim. We hypothesize that the majority of fluid-related weight loss will occur within the first week postpartum.

**Sub-Aim 5B**: Compare the 6 week postpartum weight loss of the cohort utilizing remote patient monitoring with daily weights to the net 6 week postpartum weight loss of the cohort of patients with hypertension related disorders discharged with routine care who attended their 6 week postpartum visit.

***Hypothesis**:* We hypothesize that women utilizing remote patient monitoring with daily weights will lose more weight in the immediate 6 week postpartum period than women with hypertension related disorders discharged with routine care.

**Sub-Aim 5C**: Compare the 6 week postpartum breastfeeding rates of the cohort utilizing remote patient monitoring to the cohort of patients with hypertension related disorders discharged with routine care.

***Hypothesis**:* We hypothesize that women utilizing remote patient monitoring will have higher rates of ongoing breastfeeding than women with hypertension related disorders discharged with routine care.

**Sub-Aim 5D**: Compare the 6 week postpartum depression rates of the cohort utilizing remote patient monitoring to the cohort of patients with hypertension related disorders discharged with routine care.

***Hypothesis**:* We hypothesize that women utilizing remote patient monitoring will have lower rates of depression than women with hypertension related disorders discharged with routine care.

**Sub-Aim 5E**: Correlate the results of the HoneyWell Biometrics Questionnaire question number 42 to the result of the Edinburgh Depression Scale recorded at the 6 week postpartum visit. (Question number 42 is: Has your mood been more depressed this week compared to a normal week? (Rated from 1-7))

***Hypothesis**:* We hypothesize that the HoneyWell Biometrics Questionnaire question number 42 will capture more postpartum depression than the 6 week Edinburgh Depression Scale, but that it will correlate well.

**Sub-Aim 5F:** Graph the blood pressure trajectory of the cohort utilizing remote patient monitoring with daily weights over 6 weeks.

***Hypothesis*:** This is a descriptive sub-aim. We hypothesize that the postpartum blood pressure will peak at 5-7 days postpartum.

**Sub-Aim 5G**: Compare the 6 week postpartum blood pressure of the cohort utilizing remote patient monitoring to the cohort of patients with hypertension related disorders discharged with routine care who attended their 6 week postpartum visit.

***Hypothesis**:* We hypothesize that women utilizing remote patient monitoring will have lower blood pressures at their 6 week postpartum visit than women with hypertension related disorders discharged with routine care.

**Specific Aim 6**: Conduct a follow-up satisfaction from a medical provider perspective in having their patients cared through this study, as well as the betterment of the telehealth monitoring system for future clinical use. This will be collected anonymously from providers.

***Hypothesis:*** We hypothesize that providers of patients enrolled in this study will have had a positive experience while caring for their subject.

**Specific Aim 7**: Descriptive analysis of exactly what happens to women who end up with developing a hypertensive disorder in pregnancy and blood pressure trend from baseline pregnancy through 6 weeks postpartum. Baseline BP refers to the first blood pressure measurement during the subject's pregnancy.

***Hypotheses:***
1) Baseline BP is lower than the 6 week postpartum after having a hypertension problem in pregnancy.
2) Postpartum blood pressure is highest in labor and then normalizes through 3days postpartum with an abrupt increase 3-7days postpartum.
3) Woman who normalize their blood pressure will do so by 14 days postpartum.

Specific Aim 8: Descriptive comparison of TeleHealth screening for depression, based on change of screening test from single question to Patient Health Questionnaire-9 (PHQ-9) in April 2019.

*Hypothesis*: We hypothesize that the change of screening test for depression from a single question to the PHQ-9 will be a more objective predictor of depression in TeleHealth patients.

Aim 1: A total of 55 subjects will be enrolled.

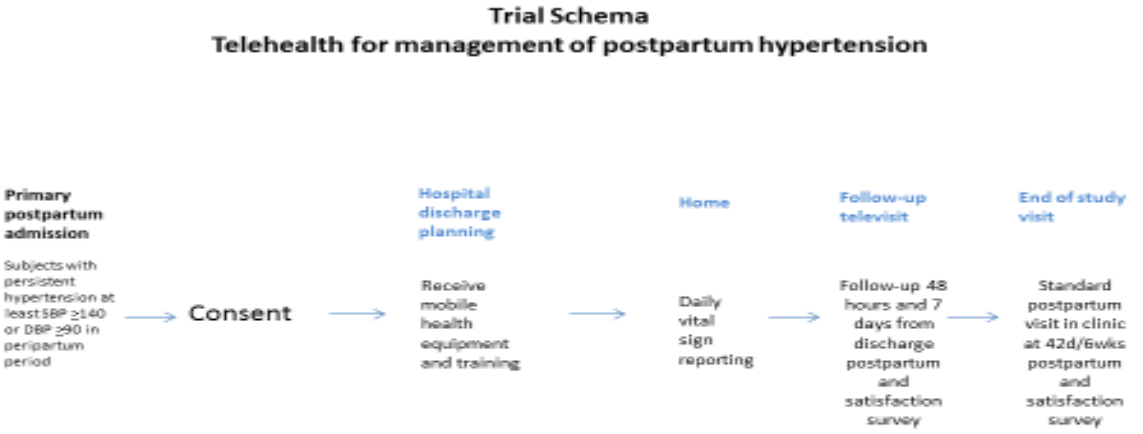
Aim 2-5: A maximum total of 440 patients will potentially be enrolled through the 1-year experimental period (220 experimental and 220 matched controls for chart review)

Aim 7-8: The original study is closed to accrual, with a total of 214 subjects enrolled, along with 214 matched controls. With the success of the study, UPH-Meriter decided to incorporate the home monitoring program into its standard clinical services as of January 1, 2019. Through UPH-Meriter, 358 patients received services through this clinical program.

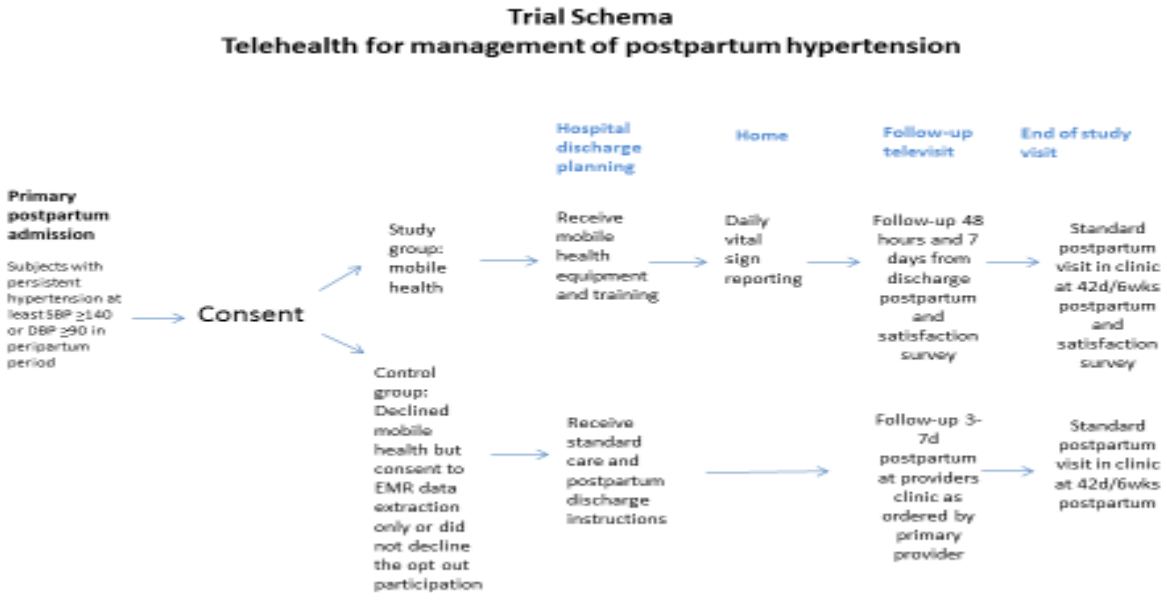
We would like to retrospectively review the patient data in Peridata for these 358 patients. We will collect home vital sign data to assess blood pressure trends from early pregnancy through pregnancy and postpartum. This additional data would help to increase our sample size in this evaluation. The same data would be collected from the clinical patients.

## Trial Schema

## Aim 1




## ***Aim2-5***



***Strategic plan***

| Year 1 (2017) | Jan | Feb | Mar | April | May | June | July | Aug | Sept | Oct | Nov | Dec |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Submit IRB | X | X | | | | | | | | | | |
| Meriter foundation grant funding cycle begins | | X | | | | | | | | | | |
| Construction of Database | | X | X | | | | | | | | | |
| Staff training | | X | X | | | | | | | | | |
| Patient enrollment: Aim1 | | | X | X | X | X | X | X | X | X | X | X |
| Patient enrollment: Aim 2-5 | | | X | X | X | X | X | X | X | X | X | X |
| Patient satisfaction assessment survey | | | | | X | X | X | X | X | X | X | X |
| Data analysis: aim 1 | | | | | | | X | X | X | X | X | X |

| Year 2 (2018-2019) | Jan | Feb | Mar | April | May | June | July | Aug | Sept | Oct | Nov | Dec |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Patient enrollment Aim 2-5 | X | X | | | | | | | | | | |
| Patient satisfaction assessment survey | X | X | X | X | | | | | | | | |
| Data analysis : aim 2-8 | | | | | X | X | X | X | | | | |
| SMFM abstract submission | | | | | | | | | | | | X |
| Manuscript development | | | | | | | | | X | X | X | X |
| Submission of ICTR pilot grant | | | | | | | X | | | | | |

## 1. Introduction
### 1.1 Background

Almost 10% of pregnancies are affected by hypertension related disorders.[1] Hypertension in the postpartum period is one of the leading indications for hospital readmission. Data from Wisconsin demonstrate hypertensive disorders affect approximately 22% of pregnancies.[2] Furthermore, hypertension is the most common cause for readmission within the University of Wisconsin-Madison/Unity Point-Meriter Obstetric unit. There is no reliable data regarding prevention or treatment of postpartum hypertension.[3]

There is limited data regarding the natural history of postpartum hypertension. Many patients discharged from the hospital with mildly elevated blood pressures (SBP) of ≤150 or diastolic blood pressure (DBP) of ≤100 will not be seen by their obstetrical providers until 6 weeks postpartum. Furthermore, only those who develop symptoms of hypertension such as headache or blurred vision will be seen more urgently in an emergency or triage department rather than with routine outpatient care. It is known in women with hypertension related disorders of pregnancy will have a decrease in their blood pressure in the first 48 hours postpartum, however the blood pressure will then start increasing between days 3-6 postpartum. [5] Podymow and August published on the postpartum course of gestational hypertension and preeclampsia and demonstrated the mean time for blood pressure normalization in the postpartum period for those who normalized was 5.4 ± 3.7 weeks post-delivery.[6] An additional study, by Ferrazzani, demonstrated that the majority of patients with hypertension related disorders of pregnancy normalized by 6-16 days postpartum. [7]

The current ACOG guidelines recommend treating postpartum hypertension at a systolic blood pressure of ≥150 mmHg or diastolic blood pressure of ≥100 mmHg. [1] There have been three small trials that treated patients with mild to moderate hypertension. Out of a total of 189 participants, they did not demonstrate any adverse events with treatment. However, other outcomes amongst the studies were not consistent.[8,9,10,11] There is retrospective data demonstrating postpartum readmissions were less likely in those treated for mild hypertension upon discharge. [12] The significance of understanding the natural time course of development and resolution of pregnancy related hypertension and identifying the optimum blood pressure threshold for treating postpartum hypertension is important. Furthermore, identifying a low-cost and highly effective mechanism for tracking postpartum blood pressures outpatient during the period that a new mother is at high risk of not being able to comply with medical care or follow-up due to child care responsibilities, may support the development of new management strategies.

Recent ACOG guidelines recommend blood pressure monitoring via routine follow-up office visits within 72 hours of discharge and again at seven to ten days after childbirth.[1] However, non-compliance is high in the postpartum period, and many do not attend these first follow-up appointments. Subsequently, the only other routine visit is 6 weeks postpartum. Home blood pressure monitoring has been demonstrated to be useful in the long-term follow-up and treatment of hypertension in non-obstetrical populations.[5] There is less experience regarding the optimal application for tracking home blood pressure monitoring and cost-effectiveness of this intervention.[5] There is limited experience with home blood pressure monitoring in pregnancy, in particular with postpartum patients.[6,7,8]

In addition, postpartum weight loss is a significant challenge and impacts the well-being of the mother. There is limited and conflicting research the most effective strategy for weight loss in the general population. Some lower intensity interventions, such as daily self-

weighing, have been found to be an effective strategy for weight loss in the non-obstetric population using either regular or “smart” scales in the non-obstetric population.[17-19] However, such interventions have not yet been studied in the postpartum population. There has also been interest in using technology to promote postpartum weight loss which have demonstrated some success.[20-22] Furthermore, several studies have demonstrated that breastfeeding is associated with lower postpartum weight retention in women.[23-25] Breastfeeding has also been associated with cardiovascular health benefits, but has not specifically been investigated in the immediate postpartum period.[26]

The development of the maternal/infant bonding and breastfeeding is very important and likely one of the most important barriers for new mothers to seek care. Furthermore, most women have access to a mobile device with capabilities allowing for direct communication with the medical community. This proposed project would provide robust data to understand blood pressure values that best predict development of severe hypertension after discharge from the hospital, optimal outcomes to evaluate in future studies, and precise development of a mobile application that patient’s find user friendly and effective in managing their care. The ultimate goal is to improve patient compliance, surveillance, medication initiation or management while the patient remains outpatient to decrease severe maternal morbidity and avoids the need for a readmission that disrupts maternal/infant bonding. Our prospective feasibility will assess a novel approach to outpatient maternal postpartum hypertension surveillance and treatment in the first 6 weeks postpartum and support the development of a future study testing new strategies.

### 1.2 Innovation

Postpartum hypertension has been a recent area of interest and target for quality improvement projects nationwide. Home blood pressure surveillance has been demonstrated as an effective strategy in hypertension management in non-obstetric patients. Utilizing remote patient monitoring and the Honeywell mobile application device to assist with postpartum hypertension surveillance is a novel concept. The ability to work with the UnityPoint Health- Meriter Foundation will support the development of the infrastructure needed for the use of this technology to enhance patient care and overall outcomes.

A novel approach to treat postpartum hypertension first requires well-defined threshold values for blood pressure. Tracking and recording daily blood pressures, weight measurements and medication use, at home after discharge serves multiple purposes. The prospectively collected data will also allow for further understanding of the natural time course of postpartum hypertension serving as preliminary data for future studies. If this management strategy is found to be feasible and effective it will have large impacts on improving the quality of maternal care not only at our institution, but also on a national level.

### 1.3 Motivation for this study

Hospital readmission was more common in patients with mild hypertension prior to their primary delivery discharge. In addition, Hirshberg, et al discovered postpartum patients were less likely to be readmitted due to hypertension related complications if they were discharged on antihypertensive medication therapy. Treatment or surveillance strategies have been understudied for postpartum patients with hypertension. Demonstration of a decrease in hospital readmission with a novel mobile application may provide an effective method of preventing severe maternal postpartum hypertension related hospital readmission and associated maternal morbidities.

## 2. Objectives

**Aim 1:** Conduct an initial phase study for postpartum women at risk for severe hypertension to estimate the rates of willingness to participate in and utilize remote mobile health applications to monitor home blood pressures and weights, medication adherence after hospital discharge, to inform a trial to decrease postpartum maternal morbidity and readmission.
**Sub Aim 1:** Conduct a survey regarding patient satisfaction using mobile health technology

***Hypothesis:*** We hypothesize that the mobile health application will be implemented with strong fidelity, have positive patient acceptability, and demonstrate a meaningful reduction in home blood pressures and postpartum hospital readmission.

**Aim 2:** Obtain prospective daily monitoring of blood pressures in the Peripartum period (initial hospital admission through 6 weeks postpartum) to understand natural history of development and resolution of postpartum hypertension using all patients utilizing the mobile health program over year 1. Specifically, this data will be used to estimate standard deviations of SBP and DBP in the intrapartum compared to 24-96 hours postpartum to inform a future trial regarding the threshold blood pressure to prevent development of severe hypertension or hospital readmission.

***Hypothesis:*** We hypothesize women with severe intrapartum hypertension will predict development of severe hypertension within 7 days of delivery more often than blood pressures obtained in the first 24-96 hours after delivery.

**Aim 3:** Compare the maternal outcomes in the cohort utilizing remote patient monitoring to the cohort of patients with hypertension related disorders discharged with routine care. This would include all patients from Aim 1 as well as the remaining from the entire 1-year experimental period.

***Hypothesis***: We hypothesize women utilizing the mobile health program will have less hospital readmission and a lower incidence of reported severe hypertension compared to the control group utilizing standard of care.

**Aim 4:** Perform a cost effectiveness modeling will be performed to determine whether it is cost-effective to use remote patient modeling for women with postpartum hypertension in comparison to standard outpatient care in women with hypertension-related disorders of pregnancy.

***Hypothesis***: Patient care utilizing mobile health surveillance postpartum will demonstrate a significant cost savings compared to routine care in patients with postpartum hypertension.

**Aim 5:** Compare the maternal outcomes in the cohort utilizing remote patient monitoring to the cohort of patients with hypertension related disorders discharged with routine care. This would include all patients from Aim 1 as well as the remaining from the entire 1-year experimental period.

***Hypothesis***: We hypothesize that women utilizing the mobile health program will have less hospital readmission and a lower incidence of reported severe hypertension compared to the control group utilizing standard of care.

**Sub-Aim 5A:** Graph the weight loss trajectory of the cohort utilizing remote patient monitoring with daily weights over 6 weeks.

***Hypothesis*:** This is a descriptive sub-aim. We hypothesize that the majority of fluid-related weight loss will occur within the first week postpartum.

**Sub-Aim 5B**: Compare the 6 week postpartum weight loss of the cohort utilizing remote patient monitoring with daily weights to the net 6 week postpartum weight loss of the cohort of patients with hypertension related disorders discharged with routine care who attended their 6 week postpartum visit.

***Hypothesis**:* We hypothesize that women utilizing remote patient monitoring with daily weights will lose more weight in the immediate 6 week postpartum period than women with hypertension related disorders discharged with routine care.

**Sub-Aim 5C**: Compare the 6 week postpartum breastfeeding rates of the cohort utilizing remote patient monitoring to the cohort of patients with hypertension related disorders discharged with routine care.

***Hypothesis**:* We hypothesize that women utilizing remote patient monitoring will have higher rates of ongoing breastfeeding than women with hypertension related disorders discharged with routine care.

**Sub-Aim 5D**: Compare the 6 week postpartum depression rates of the cohort utilizing remote patient monitoring to the cohort of patients with hypertension related disorders discharged with routine care.

***Hypothesis**:* We hypothesize that women utilizing remote patient monitoring will have lower rates of depression than women with hypertension related disorders discharged with routine care.

**Sub-Aim 5E**: Correlate the results of the HoneyWell Biometrics Questionnaire question number 42 to the result of the Edinburgh Depression Scale recorded at the 6 week postpartum visit. (Question number 42 is: Has your mood been more depressed this week compared to a normal week? (Rated from 1-7))

***Hypothesis**:* We hypothesize that the HoneyWell Biometrics Questionnaire question number 42 will capture more postpartum depression than the 6 week Edinburgh Depression Scale, but that it will correlate well.

**Sub-Aim 5F:** Graph the blood pressure trajectory of the cohort utilizing remote patient monitoring with daily weights over 6 weeks.

***Hypothesis*:** This is a descriptive sub-aim. We hypothesize that the postpartum blood pressure will peak at 5-7 days postpartum.

**Sub-Aim 5G**: Compare the 6 week postpartum blood pressure of the cohort utilizing remote patient monitoring to the cohort of patients with hypertension related disorders discharged with routine care who attended their 6 week postpartum visit.

***Hypothesis**:* We hypothesize that women utilizing remote patient monitoring will have lower blood pressures at their 6 week postpartum visit than women with hypertension related disorders discharged with routine care.

**Specific Aim 6**: Conduct a follow-up satisfaction from a medical provider perspective in having their patients cared through this study, as well as the betterment of the telehealth monitoring system for future clinical use. This will be collected anonymously from providers.

***Hypothesis:*** We hypothesize that providers of patients enrolled in this study will have had a positive experience while caring for their subject.

**Specific Aim 7**: Descriptive analysis of exactly what happens to women who end up with developing a hypertensive disorder in pregnancy and blood pressure trend from baseline pregnancy through 6 weeks postpartum.

The original study closed to accrual, with a total of 214 subjects enrolled, on June 11, 2018. With the success of the study, UPH-Meriter decided to incorporate the home monitoring program into its standard clinical services as of January 1, 2019. Through UPH-Meriter, 358 patients received services through this clinical program.

We would like to retrospectively review the patient data in Peridata for these 358 patients. We will collect home vital sign data to assess blood pressure trends from early pregnancy through pregnancy and postpartum. This additional data would help to increase our sample size in this evaluation. The same data would be collected from the clinical patients.

***Hypotheses:***
1) Baseline BP is lower than the 6 week postpartum after having a hypertension problem in pregnancy.
2) Postpartum blood pressure is highest in labor and then normalizes through 3 days postpartum with an abrupt increase 3-7 days postpartum.
3) Woman who normalize their blood pressure will do so by 14 days postpartum.

**Specific Aim 8:** Descriptive comparison of TeleHealth screening for depression, based on change of screening test from single question to Patient Health Questionnaire-9 (PHQ-9) in April 2019.

*Hypothesis:* We hypothesize that the change of screening test for depression from a single question to the PHQ-9 will be a more objective predictor of depression in TeleHealth patients.

**ENDPOINTS**:
**Aim 1 primary endpoint:** The primary endpoint is enrollment of 55 patients using the mobile health program each for a total 42 days postpartum.

**Aim 2-5 primary endpoint:** The primary endpoint is enrollment of up to 40 patients at all times (for a total of 42 days) over one year (220 experimental and 220 matched controls for chart review) **of the funded period for this project utilizing the proposed mobile health program as an option for postpartum hypertension surveillance.**

**3. Selection criteria**

**3.1. Treatment Center Inclusion**

Subjects will be enrolled in from Unity Point Health-Meriter Hospital Labor & Delivery. Patients will be approached for recruitment in the postpartum period.

**3.2. Patient inclusion and exclusion**

- **Aim 1:**

**3.2.1.1 Inclusion**

- Hypertensive disorders of pregnancy including gestational, chronic, or preeclampsia diagnosed in the antenatal (primary admission for delivery of the baby (planned or due to hypertension) or postpartum period as determined by SBP ≥140 or DBP ≥90 on two occasions ≥4 hours apart. (Refer to section 3.3 for diagnosis criteria).
- Gestational age at time of delivery ≥ 23 weeks gestation
- Primary hospital admission for the delivery of the neonate(s).
- Age ≥18 years.

**3.2.1.2 Exclusion**

- Inability to obtain informed consent

- **Aim2-5:**

**3.2.1.3 Experimental**

**3.2.1.3.1 Inclusion**

- Hypertensive disorders of pregnancy including gestational, chronic, or preeclampsia diagnosed in the antenatal (primary admission for delivery of the baby (planned or due to hypertension) or postpartum period as determined by SBP ≥140 or DBP ≥90 on two occasions ≥4 hours apart. (Refer to section 3.3 for diagnosis criteria).
- Gestational age at time of delivery ≥23 weeks gestation
- Primary hospital admission for the delivery of the neonate(s).
- Age ≥18years.

**3.2.1.3.2 Exclusion**

- Inability to obtain informed consent

**3.2.1.4 Control group:**

**3.2.1.4.1 Inclusion: we will have an opt out policy (see 4.4.1 below) to maximize all patients to be included to provide an adequate 1:1 comparison control group (see form).**

**3.2.1.4.2 The same inclusion criteria from 3.2.1.3 will be used to define the control group subjects included.**

- Hypertensive disorders of pregnancy including gestational, chronic, or preeclampsia diagnosed in the antenatal (primary admission for delivery of the baby (planned or due to hypertension) or postpartum period as determined by SBP ≥140 or DBP ≥90 on two occasions ≥4 hours apart. (Refer to section 3.3 for diagnosis criteria).
- Gestational age at time of delivery ≥23 weeks gestation
- Primary hospital admission for the delivery of the neonate(s).
- Age ≥18years.

**3.2.1.5 Exclusion**

- Inability to obtain informed consent

### 3.3. Classification/diagnosis of hypertension related disorders in pregnancy

| | |
|---|---|
| **CHRONIC HYPERTENSION** | • **SBP ≥140 mmHg or DBP ≥90 mm Hg**<br>• **Pre-pregnancy or before 20 weeks** |

| | |
|---|---|
| **GESTATIONAL HYPERTENSION** | • SBP ≥140 mm Hg or DBP ≥90 mm Hg<br>• Occurs after 20 weeks<br>• Absence of proteinuria or systemic signs/symptoms consistent with preeclampsia |
| **PRE-ECLAMPSIA** | • New onset BP after 20 weeks<br>• Two BPs SBP≥140 or DBP ≥90 on two occasions at least 4 hours apart<br>• AND Proteinuria with or without signs/symptoms*<br>• OR in the absence of proteinuria new onset of any systemic finding:<br>-Thrombocytopenia (platelets <100,000K)<br>-Renal insufficiency (serum creatinine >1.1 mg/dL)<br>-Impaired liver function (↑LFT 2x normal) |
| **Eclampsia** | • New onset grand mal seizures in woman with preeclampsia<br>• New onset seizures 48-72 hours postpartum |
| **Chronic Hypertension + SUPERIMPOSED PREECLAMPSIA** | • Chronic hypertension in association with preeclampsia |
| **PREECLAMPSIA WITH SEVERE FEATURES (one or more of the listed criteria)** | • SBP ≥160 mm Hg or ≥110 mm Hg on at least 2 occasions at least 4 hours apart<br>-Thrombocytopenia (platelets <100,000K)<br>-Renal insufficiency (serum creatinine >1.1 mg/dL)<br>-Impaired liver function (↑LFT 2x normal)<br>- Pulmonary edema<br>- New-onset cerebral or visual disturbances<br>*Proteinuria >5g is no longer considered for diagnosis nor is IUGR for 'severe' |

**3.4. Outcome variables: see attached data dictionary (Appendix I). I will plan to work with my prior IRB application request (IRB number** 2016-006**) using Peridata and Meriter for variables and have a prospective report built to extract patient data from for patients enrolled in this study.**

## 4. Study procedures

### 4.1. Training and certification of staff and centers

Training of staff and pilot testing of procedures are crucial to standardized study procedures including BP measurement, quality control and data quality. We will provide central training for study staff. Additionally, any staff members consenting patients will undergo training specific to the current consenting procedures. Refresher courses will be provided through webinar technology on a yearly basis or as needed. All training related to the study will be logged in the study's regulatory binder.

Clinical site initiation to enroll and randomize participants is dependent upon completion of preliminary tasks. These tasks include completion of appropriate regulatory approvals

(IRB) and letters of agreement. Site training receipt of study equipment and development of a recruitment plan will be necessary.

### 4.2. Screening for eligibility and consent

For aims 1-5

**Inpatient**

We will screen for subjects on a daily basis by reviewing the patients admitted to postpartum unit. Patients will be approached if the electronic medical record indicates a diagnosis of hypertension or the patient meets the blood pressure criteria for enrollment. This screening will be performed by the mobile health nurse providing support for this program or the research coordinator as needed. If a patient is identified, the patient's nurse or care provider will be contacted to ask the patient if they are interested in learning more about the study.

**Outpatient**

I have also met with the providers providing obstetrical care to patients (midwives and physicians who practice at UW Health- 20 S Park, UW Health- Fitchburg. UW Health- West, UW Health- West Towne, UW Health- Union Corners, Associated Physicians) who express interest in providing this experimental clinical program for their patients. Providers may discuss this project with their patients who have hypertension affecting their pregnancy. They will also have access to the patient brochure and can give this to the patients they believe meet criteria for the study. If they identify a patient who is interested in participating they will directly contact a member of the research team to further discuss enrollment with the patient. In addition, the floor nurses will know the inclusion criteria and may contact a member of the research team for recruitment, however this is not expected.

Finally, a patient can inquire and express interest in participating the program and contact the research coordinator directly with the phone number contact provided in the study flier. The patient inclusion and exclusion criteria will be verified as well as the participant's interest in the study. The informed consent process will be conducted by trained research staff and will include all aspects of the study and full disclosure of the risks, benefits, and alternatives. The study consent and HIPPA authorization form (see appendix) will be signed after all questions have been discussed and answered.

### 4.3. Data management:

Data variables will be stored in REDCap. REDCap (Research Electronic Data Capture) is a browser-based, metadata-driven software solution and workflow methodology for designing clinical and translational research databases. It is a HIPAA compliant system exclusively used for investigator initiated studies and has wide use in the academic research community. You can learn more about REDCap at:
https://en.wikipedia.org/wiki/Redcap_(Research_Electronic_Data_Capture)

Study management will be maintained using Oncore. OnCore is a centralized clinical research management software program that allows researchers to use one program to manage all components of clinical research while maintaining consistency, data integrity and compliance across the institution.

### 4.4. Recruitment and retention

- **Staff**

4.4.1. Staff training and education prior to initiation of the trial for active members of the study team.
4.4.2. General education regarding the trial to all staff providers (physicians, nurses, medical assistants to enhance support of the trial).
4.4.3. Staff education on a 6-month schedule for new staff and further training as needed.
4.4.4. Interval reports back to participating faculty/nurses to share stories of success or patient feedback to encourage continued participation.

- **Study subjects**

4.4.1. We will place a study information sheet titled "The UnityPoint Health-Meriter Hypertensive Study" in the patient enrollment paperwork for all patients admitted to Labor and Delivery. This will sheet will allow research staff to collect data on all patients with respect to their hypertension diagnosis in the Peripartum period. We will be using this data primarily for the control group for aims 2-3.
4.4.2. Once a patient is identified and agrees to participate we will give them a separate patient brochure to further detail the study. This will be directly given to the patients by their nurse once admitted to the postpartum unit.
4.4.3. A member of the research team trained in consenting procedures will then meet with the subject to review the informed consent document. After the researcher reviews the document, the subject will be allowed to ask questions and given sufficient time to contemplate participation. If the patient chooses to participate, they will sign the informed consent document.
4.4.4. Incentives: Subjects will be given a pack of diapers at enrollments and a $15 gift card at completion of the study (6 weeks PP visit) to encourage completion of the trial endpoint.
4.4.5. Care reminders will be sent via the Honeywell Genesis Device by the UnityPoint at Home telehealth nurse. The purpose of this is to remind and encourage daily vital reporting.
4.4.6. Patient surveys for understanding how to improve the system

**5. Pre-enrollment evaluation**

**5.1.** Prior to enrollment, the mobile health nurse or research staff will confirm diagnoses utilizing the table above.
**5.2.** If the subject agrees to participate, the research coordinator will obtain informed consent.
**5.3.** To review eligibility, the patient will have a general physical exam, review of their vital signs, and pertinent laboratory assessments (hematocrit, platelet count, creatinine, urine protein volume, liver function tests) performed as standard of care and will be reviewed in the electronic medical record.
**5.4.** This baseline information will be obtained and entered into the study database and if the subject meets inclusion criteria the subject will be considered on study.
**5.5.** Enrollment is expected to occur over a 1-year time period.

**6. Intervention and Follow-up**

Patients will be identified for potential enrollment starting in the antepartum period (time of admission for delivery of baby) if they meet criteria for a hypertensive related disorder of pregnancy as deemed by the minimum criteria of SBP $\geq$140 or DBP $\geq$90 on two occasions

at least 4 hours apart. The planned consent can occur on admission prior to delivery or postpartum, however will not occur if the patient has any evidence of labor. The preference will be consenting postpartum. The exception may be for patients with known chronic hypertension or a diagnosis of preeclampsia and they are admitted with this diagnosis. Patients may be given the program brochure to read and would have adequate time to express interest or hear more about the project if they desire. If the patients then meet criteria for treatment of hypertension postpartum as deemed by the threshold inclusion criteria for this study, SBP $\geq$140 or DBP $\geq$90 or standard of care (SBP $\geq$150 or DBP $\geq$100) on two occasions at least 4 hours apart then medication will be initiated prior to discharge from the hospital.
Devices and instructions will be provided by UnityPoint at Home. They will be given instructions on proper techniques for blood pressure by the labor & delivery nurses, the mobile health nurse or research coordinator if needed. It will be expected if the teaching cannot be performed by one of the nurses they will contact the research coordinator to provide this training. All individuals will have had training for proper blood pressure measurement technique prior to providing this training. The patients will be required to take the blood pressures in a seated position with their arm at heart level. Three values should be obtained and an average of these values will be used in our assessment of daily blood pressure. The patient will also be given instructions on warning signs of preeclampsia or severe hypertension and blood pressure thresholds to call the mobile health nurse or their primary obstetric clinical provider or nurse.

Once discharged from the hospital the patient will initiate their home blood pressure/weight measurements. They will be asked to take a total of three blood pressures everyday (spread out no more than five minutes apart) to validate there are not erroneous values submitted. The blood pressures and weight values will be submitted via the Honeywell device and these values will be delivered to the mobile health nurse platform. These values will need to be manually uploaded into the study database program in REDCap. The values and patient concerns will be reviewed daily by the mobile health nurse with a flowsheet algorithm that directs them when to continue with current care plan or the need to contact the physician for the patient. The patient will be contacted by a mobile health nurse on days 2 and 7 post discharge. Additionally the patient may be contacted by the mobile health nurse based on the flowsheet algorithms and patient concerns (if applicable). A telehealth note will be put into EPIC when contact with the patient is had by phone or video teleconferencing. This note will be cc'd to the primary provider for review. Daily vital signs will eventually be an automated process into EPIC, however until this is possible it will be a manual entry performed daily by the mobile nurse.

**Follow Up Procedures for Patients**
Patients will receive continued care surveillance whether they are on or off medication if their blood pressures remain (SBP $\leq$150 or DBP $\leq$100) and they are not having any concerning symptoms. If they are on treatment with antihypertensive medication at discharge from the hospital the goal is for patients to remain with normal to mild range blood pressures and they will require the medication be titrated upwards to achieve adequate control (SBP $\leq$140 -150 or DBP $\leq$ 90-100) as needed. If severe hypertension develops after discharge, and the blood pressures are SBP $\geq$150 or DBP $\geq$100 and the patient is not on medication we will recommend initiating medication as an outpatient. Alternatively, the medication may need to be titrated downward or discontinued if indicated due to the patient development of hypotension (SBP $\leq$90 or DBP $\leq$ 60).
The mobile health nurse will be reviewing the incoming blood pressures daily. Options for the enrolled patients care management are to report the concerning vital signs to the

patients primary provider or the primary provider can agree to have the Perinatal Service providers manage the abnormal vital signs. All providers for the enrolled patients are contacted and informed of enrollment and then typically they plan for the patients to be followed and managed with the mobile health team and any concerning vitals are addressed by the Perinatal Service and then communicated regarding any management decisions by EPIC-electronic medical charting.
Concerning vital signs are SBP $\geq$150 or DBP $\geq$100 or SBP $\leq$90 or DBP $\leq$ 60, which is the same as prior to discharge from the hospital. After the program began using the above paragraph which outlines need for medication initiation or management – it was acknowledged patients were requiring the initiation and management of their vital signs or medications often, i.e. approximately 40-50% of the patients. Therefore, the mobile health nurses needed a written document with the standard practice to determine the thresholds patients would need to initiate or titrate medications up or down. Therefore we developed algorithms as proposed in this modification that would help manage this care. In addition, as needed the patient will be instructed to call their provider as needed for any concerning vital signs or symptoms if the nurses are not available or as needed. If the patient does not have any concerning symptoms the abnormal vital signs will be discussed with the patient by the patient's provider or the nurse. If the patient is asymptomatic then there is the ability to refer to the management algorithm and then initiate medication or increase/decrease the dose of the medication per the algorithm. The algorithm is based off the standard of care – it is just to ease the communication and care coordination of the patients. The mobile health nurse will notify a doctor with initiation of medication.

It is expected that the patients with gestational hypertension or preeclampsia diagnoses will be able to titrate off of the antihypertensive medication between 14 -42 days postpartum. The recommendation to discontinue the antihypertensive medication can be performed if the patient has (SBP $\leq$120 or DBP $\leq$ 80) by the 14-day follow-up visit. If they are unable to do so by the 42-day follow-up visit they will likely be diagnosed with chronic hypertension (persistent elevation of blood pressure SBP $\geq$140 or DBP $\geq$90 by 12 weeks postpartum. It is expected that patients with chronic hypertension may need to continue this therapy beyond the study endpoint of 42 days.

Due to current ACOG recommendations, the patients will be recommended to remain in the hospital for 3 days postpartum when they have a diagnosis of hypertensive related disorders in pregnancy. If the patient is discharged prior to 3 days they will have an outpatient office visit for a blood pressure evaluation at day 3. If they are discharged on day 3 they will then have planned outpatient clinic blood pressure evaluations on days 5-7 and at 14 days postpartum. As long as the patient is normotensive and clinically stable then the patient will have the last scheduled follow-up exam at approximately 6 weeks (42days) postpartum.

A planned **patient satisfaction survey** will be administered at 6 weeks (42) post-discharge using email or in person at their clinic visit. This may be sent electronically through the mobile app system if possible to allow for best patient access if they are following up at numerous different clinics, vs at the actual clinic visit. We will assure all participating clinics have the survey and a sealed box to protect the patient's identity.

The patients will be instructed to call their primary provider once discharged from the hospital if they do not achieve adequate continued blood pressure control after discharge or they have concerns of developing severe symptoms concerning for worsening disease-listed below-if not addressed through the surveillance as discussed above through the mobile health surveillance and management algorithm. Hospital readmission will be

dependent on provider discretion, however indications would depend on evaluation of patients' clinical symptoms of severe hypertension with SBP ≥160 or DBP ≥110, with the addition of end-organ effects (cerebral or vision disturbances, neurologic symptoms, pulmonary edema, or lab abnormalities as defined in table 4.3) that cannot be explained by medication non-compliance or inability to increase the dose of the medication to achieve adequate control.

If the situation dictates another antihypertensive due to other medical comorbidities (such as asthma) then another antihypertensive medication can be considered. Our recommendation would be to consider use of a calcium channel blocker (specifically Nifedipine).

**Provider Survey:**
The Office Supervisor for the Perinatal Administration at UPH - Meriter hospital will generate a list of providers with delivery privileges for the research team. Each provider will be invited by email to complete the survey. We are requesting a Waiver of Consent and an Exemption from HIPAA as a completed survey implies consent, and there is no private health information involved in this part of the research.

A Provider survey (uploaded in iRIS) will be linked within an email (script attached as separate study document). This email will be sent by UPH-Meriter staff, to their identified list of providers (those who have delivery privileges at UPH-Meriter). They will complete the survey in Qualtrics in which no identifying information will be collected. The email will be sent a total of 3 times.

**UPH-Meriter Telehealth Clinical Program:**
We will retrospectively review the patient data in Peridata for these 358 patients. We will collect home vital sign data to assess blood pressure trends from early pregnancy through pregnancy and postpartum. No new data fields will be added to the data collection.

**Subject withdrawal policy**
Withdrawals are considered subjects that have been enrolled but are deliberately omitted from the analysis. This study will be analyzed on the intention-to-treat principle, so that all subjects who were enrolled will be included in the analysis. To minimize the amount of missing data, subjects will only be randomized after they have undergone appropriate diagnostic tests, eligibility has been confirmed by the research coordinators. If a subject is randomized but later decides to discontinue study participation, they are asked in the consent form to allow follow-up via medical record review. For further information on subjects who discontinue participation, see Section 9.2. Every effort will be made to follow all patient outcomes via medical records.

## 7. Statistical considerations

### 7.1. Sample size calculation

Aim1:
Our sample size calculation is based on numerous assumptions.
To estimate rates of participation and retention a sample size of 50 subjects we will be able to estimate a participation rate of 80% to within a 95% confidence interval of +/- 10% and a retention rate of 60% to within a 95% confidence interval of +/- 13%. [13,14,15,16] Adjusting for up to a 10% drop out rate we increased the sample size to 55 subjects.

Aims 2-5; are not powered as they are exploratory outcomes that will be used for future study planning. However, there may be up to 440 subjects available to include in this analysis. This was determined knowing there are 30 mobile units available at all times. The endpoint is at 6 weeks. So, this would allow for 30 patients in the first month and then on a rolling basis approximately 20 patients could be recruited per month at max enrollment. This would total 220 patients using mobile health for the 1-year experimental period. The control group would be subjects matched within the same month of experimental subjects and be a 1:1 matching. So the control group would consist of up to 220 patients. The numbers may be less due to lower rates of recruitment/participation.

Aim 7-8:
The original study is closed to accrual, with a total of 214 subjects enrolled. With the success of the study, UPH-Meriter decided to incorporate the home monitoring program into its standard clinical services as of January 1, 2019. Through UPH-Meriter, 358 patients received services through this clinical program.

We would like to retrospectively review the patient data in Peridata for these 358 patients. We will collect home vital sign data to assess blood pressure trends from early pregnancy through pregnancy and postpartum. This additional data would help to increase our sample size in this evaluation. The same data would be collected from the clinical patients.

Therefore, our sample size would increase. We enrolled 214 subjects in the original Telehealth study, with 214 matched controls. 358 patients received remote monitoring services from the UPH-Meriter program. 100 providers with delivery privileges at UPH-Meriter were offered the opportunity to complete a survey regarding the research. The new sample size is 886 patients. We do have prior IRB approval to collect data from Peridata for our original study patients.

**1. Non-compliance policies**

**9.1 Dropout**

A subject is considered to have “dropped out” of the study if they are randomized but later decide to discontinue participation. Because of the potential compliance issues in postpartum patients and possible side effects of the drugs, we anticipate a dropout of 10%. Participants will be asked in the consent form to allow follow-up via medical records after they drop out. Every effort will be made to ask subjects to complete a withdrawal form, which will allow us to learn more about why the subject chose to leave this study. As with crossover patients, all patients who drop out of the study will be included in the analysis on an intention to treat principle.

## 7.2 Analysis plan

**Aim 1:** Analysis of the primary outcome will be performed assessing rates of willingness to participate and patient retention in the study for 42 days postpartum. Secondary outcome measures will be attrition rate and compliance rates to both care and medication.

**Aim 2:** We will be developing an ROC curve with Youden’s index to predict the optimum SBP and DBP from intrapartum and postpartum to target for postpartum blood pressure thresholds for blood pressure management to prevent postpartum readmission due to severe hypertension.

**Aim2-8:** Baseline demographic and descriptive statistics will be compared to assess comparability of the study groups. Continuous variables will be assessed with student t-test and categorical data will be analyzed using ANOVA.

**Aim 4:** Analyses were performed to determine whether it is cost-effective to use Bluetooth-enabled tablets for postpartum blood pressure monitoring in comparison to standard monitoring in women with hypertension-related disorders of pregnancy. The data for the analyses will be derived from a prospective study at UnityPoint Health- Meriter Hospital where patients with hypertensive-related disorders of pregnancy will be enrolled in either standard management of blood pressure (routine nurse blood pressure visit 3-5 days from discharge) or monitoring with a Honeywell Genesis Android Touch Bluetooth remote patient monitoring system. Primary outcomes examined will include cost and readmissions.

## 8. Feasibility

**Table #. UnityPoint Health-Meriter Data 2015. Total deliveries: 3873**

| Hypertensive disorder | Maternal (n=476) | Neonatal (n=147) |
|---|---|---|
| Chronic | 87 (18%) | 30 (20%) |
| Gestational, preeclampsia and SIPE | 387 (81%) | 115 (78%) |
| Eclampsia | 2 (0.4%) | 2 (1.4%) |

** We anticipate that we will have approximately 40 patients with a hypertension related disorder for potential enrollment each month. At the beginning of the study, we only had 30 mobile health units that could have been used at any time. Effective 10/01/2017, an additional 10 mobile health units were acquired, making 40 mobile health units to available for study use at any time. We would strive to include all in the future as routine care if possible. We believe this project will be very successful in improving the quality of care for postpartum women at risk of developing severe complications associated with hypertension.

** The initial phase study is reasonable to complete in 1 year. Estimating a total of 400 patients annually with a hypertensive related disorder. Only 14% of the hypertensive patients would be required to participate.

**We had access to 30 mobile health units at the beginning of the study, and in 1 year that would allow for participation from 220 patients if we were using all units on a rolling basis (20 new recruits per month). Effective 10/01/2017, we now have access to 40 mobile health kits, in which we will not change the sample size, but will achieve 220 participants more quickly.

** To maximize patients eligible for recruitment I am reaching out to all obstetrical providers. I have approval to recruit patients who receive their primary obstetrical care from the Perinatal Center and the UW Health General Obstetrics clinics. I will be meeting with the private practitioner groups to assess their willingness to utilize this program with their patients prior to approaching their patients for enrollment.

**9. Cost determination**

**9.1 Personnel**

**Kara Hoppe, MD (1.2 cal months - 10%, salary/fringe not requested)** is Principle Investigator of this application. Dr. Hoppe will be developing the protocol, IRB with the assistance of the research coordinator, data storage development and coordination of the mobile application data from patients, as well as monitoring data imports, quality and patient satisfaction. Dr. Hoppe will also be monitoring direct needs for patient care and coordination of medical management for the patients.

**Mobile Health Nurse (6 cal months-50%)-** A mobile health nurse will be employed as a member to the Perinatal Clinic. He/she will be directly supervised by Sue Ellen Dolan, Clinical Nurse Manager. This nurse will be responsible for daily review of telehealth data, patient concerns, and telehealth video conferencing visits, and will interface with providers as needed to optimize patient care.

**Research Coordinator (3.6 cal months – 30%)** who will be responsible for IRB submission and coordination, patient consent, and patient contact/follow-up.

**10. Materials and Supplies**

**Android Touch full Bluetooth Kit Hardware-** Per Honeywell, Android Touch tablets with full Bluetooth hardware are quoted at $1,800 each. The 40 units are requested to be utilized each month of the proposed project, with the potential for a long-term cost-sharing agreement.

**Patient reimbursement:**

An18 pack of diapers would be provided to each participant at enrollment. A gift card at the end of the 6-week participation.

**11. Other fees**

- **UW Survey Center ($2,000)** The University of Wisconsin Survey Center will be providing validated questions to adequately assess our patient satisfaction, compliance, and feedback on improvements for utilization of mobile health and telemedicine in their postpartum care to optimize the future use of this platform.
- **Connectivity, Verizon, and hotspot fees ($26,400)** Connectivity fees, Verizon connection fees, and hotspot fees will be required monthly per participant. As discussed with Lisa Urban, the monthly fee is $80. Except for the first month of the project, where 20 participants are anticipated, and the last month where 10 active participants are expected, the remaining months are expected to have 30 active participants necessitate the monthly fee. We anticipate that our participants will be followed-up until 42 days post-partum and will return the equipment at that time.

- **REDCap Annual Fee ($200).** 50 hours for REDCap database setup and data management to help with data and study management, based on past database set-up requirements and an intention to create an entry page.
- IRB fees: IRB will be submitted through Meriter and will thus have no cost to this project.
- 60 hours for data analysis

### 11.1 Cost savings

Based on data from the National Perinatal information center the estimated average loss per hospital for obstetrical readmissions are $200,000. With 30-50% of hospital readmissions being related to hypertension there would be a large potential for cost savings with identifying effective strategies to avoid readmission. In addition to financial cost there would be an emotional cost to readmission and potential interruption of maternal-neonatal bonding and breastfeeding.

## 12. Investigators and research staff

**Kara Hoppe, DO, (PI**) is an Assistant Professor in the School of Medicine and Public Health, Department of Obstetrics & Gynecology, Division of Maternal Fetal Medicine. This proposed work builds on prior experience historical and prospective research with the goal to develop an expertise in prospective clinical trials. She is currently enrolled in the capstone certificate program for clinical investigation through the Institute for Clinical and Translational Research.

**Makeba Williams, MD (co-I**) is a Clinical Assistant Professor in the School of Medicine and Public Health has extensive experience caring for women of all ages. She has a particular interest in caring for women with high risk pregnancies and will be directly involved in supporting the program from the General Obstetric service.

**Deborah Ehrenthal, MD, MPH, (collaborator)** is Associate Professor in the School of Medicine and Public Health with experience conducting historical and prospective cohort studies, using administrative and clinical data, examining predictors of adverse birth and child outcomes including hypertension related disorders in pregnancy. She serves as one of my research mentors and has dedicated her time to participate as a co-investigator in this project.

**Dinesh Shah, MD (collaborator)** is a Professor in the School of Medicine and Public Health, Department of Obstetrics & Gynecology, Division of Maternal-Fetal Medicine. He has a long standing research and clinical interest as well as expertise in the pathogenesis of hypertension related disorders in pregnancy. His experience will be instrumental in including basic physiology and mechanisms of disease in the translation of bench to clinical research. He is also dedicated to serving as a primary mentor in my endeavors to pursue and advance clinical research within our department.

**David VanNess, PhD (collaborator)** is an Associate Professor of Population Health Sciences (with tenure) at the University of Wisconsin School of Medicine and Public Health and an affiliate of the La Follette School of Public Affairs, the Department of Industrial and Systems Engineering, the Center for Demography and Ecology, and the UW Carbone Cancer Center at UW-Madison. His current research focuses on developing and applying innovative empirical and simulation methods for comparative effectiveness and cost-effectiveness analysis, with a special focus on Bayesian evidence synthesis.

**Jennifer Dykema, PhD (collaborator)** a senior survey methodologist at the UW Survey Center regarding development of a survey application that would be appropriate to utilize for postpartum women using mobile health applications.

**Mobile health nurse:** A mobile health nurse will be employed as a member to the Perinatal Clinic. He/she will be directly supervised by Sue Ellen Dolan, Clinical Nurse Manager. This nurse will be responsible for daily review of telehealth data, patient concerns, and telehealth video conferencing visits, and will interface with providers as needed to optimize patient care.

**Several other collaborators and trainees** will provide scientific input and guidance to this project, including the faculty members of the Maternal Fetal Medicine Division. There is a wide interest and dedication from the Unity Point-Meriter Obstetric Unit. Key institutional members identified to support this work on a nursing and administrative level are: Kathy Kostrivas who is the Executive Director of the Mother-Baby Care, Carla Griffin, MSN, RNC, NE-BC who is the Director of Perinatal Services, and Sue Ellen Dolan, RN, BSN, Manager of the Women's Health Outpatient Services at Unity Point Health-Meriter.

## 13. Contingency plans

### 13.1. Poor recruitment

- May need to increase patient incentives
- May need to adjust the follow-up time as patients may lose interest by 42 days postpartum
- May need to increase patient and provider education

### 13.2. High drop-out or failure to complete required daily vital sign collection

- Set reminders on tablet
- Call patients for direct reminders

### 13.3. Technology failure

- Will have 24-hour tech support that is covered by the company and UnityPoint Health

### 13.4. Staff failure/retention

- May need to hire more assistance due to need for 7 days per week surveillance. Will plan to have 2 staff coverage immediately. Also, require patients to submit data by noon daily to avoid need for 24-hour coverage of mobile health nurse.

### 13.5. Loss of equipment

- Will need to have contact information and plan to maintain and retain equipment return.

## 14. Conclusion

We propose a feasibility clinical trial of the effectiveness of a mobile application for tracking patients at risk of developing severe postpartum hypertension. The primary outcome variable is hypertension related hospital readmission by 42 days postpartum.

This trial is scheduled to last for approximately 1 years and enroll up to a total of 55 patients in aim 1 and up to 440 patients in the aims 2-5 depending on patient enrollment and patient willingness to participate 220(mobile health) 220(controls not participating in mobile health).

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**APPENDIX I**

Data variables to extract from EPIC Electronic Medical Records/Peridata

1. Medical record number for mother
2. Date of birth
3. Link baby to mother (Medical record number)
4. Date of birth

Demographics Maternal

5. Maternal age
6. Tobacco use
    a. Yes
    b. No
7. Date of first prenatal care visit
8. Body mass index at first prenatal care visit
9. Body mass index at delivery or with initial admission
10. Body mass index at second admission
11. Body mass index >30 at delivery
    a. Yes
    b. No
12. Maternal weight in kilograms with first prenatal care visit
13. Maternal weight in kilograms on initial admission
14. Maternal weight in kilograms within 24 hours of delivery
15. Maternal weight in kilograms within 24-48 hours of delivery
16. Maternal weight in kilograms within 48-72 hours of delivery
17. Maternal weight in kilograms within 72-96 hours of delivery
18. Maternal weight in kilograms within 24 hours of initial admission discharge
19. Maternal weight in kilograms on readmission
20. Maternal weight in kilograms on discharge from readmission
21. Maternal diabetes
    a. Gestational
    b. Type 1
    c. Type 2
22. Marital status
    a. Married
    b. Single
    c. Unknown
23. Insurance
    a. Commercial
    b. Medicaid
    c. HMO
    d. Uninsured
    e. Other
    f. Unknown
24. Race

    a. Caucasian
    b. Hispanic
    c. African American
    d. American Indian/Alaskan Native
    e. African
    f. Asian American
    g. Other
    h. Unknown
25. Ethnicity
    a. Hispanic
26. Gravidity
27. Parity (live children)
28. Gestational age rounded in weeks at delivery
29. Estimated date of delivery
30. Singleton pregnancy
    a. Yes
    b. No
31. Multiple pregnancy
    a. Twins
    b. Triplets
32. Mode of delivery
    a. Normal spontaneous vaginal delivery
    b. Operative delivery
        i. Forceps
        ii. Vacuum
    c. Cesarean section
33. Indication for cesarean section
    a. First stage arrest
    b. Second stage arrest
    c. Fetal intolerance of labor
    d. Fetal distress
    e. Repeat cesarean section
    f. Failed trial of labor after prior cesarean section
    g. Elective primary cesarean section
    h. Vaginal bleeding/abruption
    i. Placentation
    j. Fetal malpresentation
    k. Maternal illness
    l. Other
34. Hypertension related disorder was diagnosed in pregnancy
    a. Prior to initial admission
    b. Prior to delivery of baby (intrapartum)
    c. After delivery of baby (postpartum)
    d. Only upon readmission to hospital after initial admission discharge

35. Specific hypertension related disorder diagnosed in pregnancy
    a. Chronic
    b. Gestational
    c. Preeclampsia
        i. Mild
        ii. Severe features
    d. Eclampsia

Demographics Neonatal

36. Birth weight in grams
37. Apgar score <7 at 5 minutes after birth
38. Oxygen required after 24 hours of delivery
    a. CPAP
    b. Nasal cannula
    c. Intubation
39. Disposition
    a. Mother baby unit
    b. Progressive care nursery
    c. Neonatal intensive care unit

Outcomes Maternal

40. Date and time of primary of admission for delivery
41. Date and time of secondary of admission for delivery
42. Date and time of emergency room visit for hypertension
43. Date and time of triage room visit for hypertension
44. Date and time of primary of discharge after delivery
45. Date and time of secondary of discharge after delivery
46. Number of initial admission days for length of stay
47. Number of secondary admission days for length of stay
48. Systolic blood pressure on admission with date and time
49. Diastolic blood pressure on admission with date and time
50. Date of postpartum visit
    a. Date
51. Maternal weight in kilograms at 6 week postpartum visit (via Meriter Epic or UW Epic/ HealthLink)
    a. Continuous variable
52. Breastfeeding status at the time of postpartum hospital discharge (via Meriter Epic)
    a. Exclusive breastfeeding
    b. Both breast and bottle feeding
    c. Exclusively bottle feeding
53. Breastfeeding status at 6 week postpartum visit (via Meriter Epic or UW Epic/ HealthLink)
    a. Exclusive breastfeeding
    b. Both breast and bottle feeding
    c. Exclusively bottle feeding

54. Maternal Edinburgh Depression Screen Score at 6 week postpartum visit (via Meriter Epic or UW Epic/ HealthLink)
    a. Score 0-30
    b. Positive or Negative
        i. Positive (>=10)
        ii. Negative
    c. Suicidal
55. Contraception method utilized/ implemented at 6 week postpartum visit(via Meriter Epic or UW Epic/ HealthLink)
    a. None
    b. Natural family planning
    c. Condoms
    d. Combined oral contraceptive pills
    e. Progestin-only oral contraceptive pills
    f. Vaginal ring
    g. Depot medroxyprogesterone acetate
    h. Long acting reversible contraceptive
        i. Copper IUD
        ii. Levonorgestrel IUD
        iii. Nexplanon
56. Blood pressure at 6 week postpartum visit (via Meriter Epic or UW Epic/ HealthLink)
    a. SBP
    b. DBP
57. Whether a referral to the primary care provider is discussed in the 6 week postpartum note (via Meriter Epic or UW Epic/ HealthLink)
    a. Yes
    b. No

Please report the top three values for the maximum values below

58. Maximum Systolic blood pressure during labor (top three) with date and time
59. Maximum Diastolic blood pressure during labor (top three) with date and time
60. Maximum Systolic blood pressure within 24 hours of delivery with date and time
61. Maximum Diastolic blood pressure within 24 hours of delivery with date and time
62. Maximum Systolic blood pressure on admission on 24-48 hours of delivery with date and time
63. Maximum Diastolic blood pressure on 24-48 hours of delivery with date and time
64. Maximum Systolic blood pressure on admission on 48-72 hours of delivery with date and time
65. Maximum Diastolic blood pressure on 48-72 hours of delivery with date and time
66. Maximum Systolic blood pressure on admission on 72-96 hours of delivery with date and time
67. Maximum Diastolic blood pressure on 72-96 hours of delivery with date and time
68. Maximum Systolic blood pressure within 24 hours of discharge date and time
69. Maximum Diastolic blood pressure within 24 hours of discharge date and time
70. Minimum Systolic blood pressure during labor (top three) with date and time
71. Minimum Diastolic blood pressure during labor (top three) with date and time
72. Minimum Systolic blood pressure within 24 hours of delivery with date and time
73. Minimum Diastolic blood pressure within 24 hours of delivery with date and time
74. Minimum Systolic blood pressure on admission on 24-48 hours of delivery with date and time

75. Minimum Diastolic blood pressure on 24-48 hours of delivery with date and time
76. Minimum Systolic blood pressure on admission on 48-72 hours of delivery with date and time
77. Minimum Diastolic blood pressure on 48-72 hours of delivery with date and time
78. Minimum Systolic blood pressure on admission on 72-96 hours of delivery with date and time
79. Minimum Diastolic blood pressure on 72-96 hours of delivery with date and time
80. Minimum Systolic blood pressure within 24 hours of discharge date and time
81. Minimum Diastolic blood pressure within 24 hours of discharge date and time
82. Blood pressure medications used prior to delivery of baby (used prior to initial admission due to chronic or gestational hypertension) with date and time of initiation if available.
    a. Atenolol
    b. Hydralazine
    c. Lasix
    d. Clonidine
    e. Labetalol
    f. Nifedipine
    g. Metoprolol
    h. Enalapril
    i. Other medication
    j. No medications

83. Blood pressure medications used prior to delivery of baby (started on admission) with date and time of initiation
    a. Atenolol
    b. Hydralazine
    c. Lasix
    d. Clonidine
    e. Labetalol
    f. Nifedipine
    g. Metoprolol
    h. Enalapril
    i. Other medication
    j. No medications
84. Blood pressure medications used after delivery of baby with date and time of initiation
    a. Atenolol
    b. Hydralazine
    c. Lasix
    d. Clonidine
    e. Labetalol
    f. Nifedipine
    g. Metoprolol
    h. Enalapril
    i. Other medication
    j. No medications

85. Blood pressure meds used at discharge with date and time of initiation
    a. Atenolol
    b. Hydralazine
    c. Lasix
    d. Clonidine
    e. Labetalol
    f. Nifedipine
    g. Metoprolol
    h. Enalapril
    i. Other medication
    j. No medications

86. Blood pressure medications used upon readmission with date and time of initiation
    a. Atenolol
    b. Hydralazine
    c. Lasix
    d. Clonidine
    e. Labetalol
    f. Nifedipine
    g. Metoprolol
    h. Enalapril
    i. Other medication
    j. No medications

87. Number of total antihypertensive medications used with initial admission
88. Number of total antihypertensive medications used with secondary readmission
89. Intravenous route of medication used prior to delivery of baby
90. Intravenous route of medication used after delivery of baby
91. Intravenous route of medication used upon readmission of baby
92. Magnesium sulfate used prior to delivery of baby
93. Magnesium sulfate used after delivery of baby
94. Magnesium sulfate used upon readmission of baby
95. Date and time of postpartum follow-up visit appointment after initial discharge (first)
96. Date and time of postpartum follow-up visit appointment after initial discharge (second)
97. Date and time of postpartum follow-up visit appointment after initial discharge (third)
98. Date and time of postpartum follow-up visit appointment after secondary readmission discharge (first)
99. Date and time of postpartum follow-up visit appointment after secondary readmission discharge(second)
100. Date and time of postpartum follow-up visit appointment after secondary readmission discharge(third)
101. Total Days calculated in-between initial discharge and secondary readmission
102. Total Days calculated for initial admission
103. Total Days calculated for secondary readmission

104. Maternal admission to Intensive care unit
    a. Yes
    b. No

105. Maternal death
    a. Yes
    b. No
106. Labs drawn for preeclampsia
    a. Specific labs (report them out for each day of admission (primary and secondary) – Please give the maximum and minimum due to some individuals may have many values
        i. AST
        ii. ALT
        iii. Hematocrit
        iv. Platelet count
        v. Urine protein total in 24 hours
        vi. Urine protein by protein:creatinine ratio
        vii. Uric acid
107. Reported maternal symptoms related to hypertension
    a. Headache
    b. Visual changes
    c. Shortness of breath
    d. Chest pain
    e. Seizure
    f. Abdominal pain
    g. Vomiting
    h. Nausea
108. Total amount of Intravenous fluids given with initial admission
109. Pulmonary edema
110. Estimated blood loss volume at delivery in (cc)
111. Maternal transfusion
    a. Yes
    b. No
112. Maximum Systolic blood pressure during 1st trimester of pregnancy (top three) with date and time
113. Maximum Diastolic blood pressure during 1st trimester of pregnancy (top three) with date and time
114. Maximum Systolic blood pressure during 2nd trimester of pregnancy (top three) with date and time
115. Maximum Diastolic blood pressure during 2nd trimester of pregnancy (top three) with date and time
116. Maximum Systolic blood pressure during 3rd trimester of pregnancy (top three) with date and time
117. Maximum Diastolic blood pressure during 3rd trimester of pregnancy (top three) with date and time
118. Maximum Heart Rate during 1st trimester of pregnancy (top three) with date and time

119. Maximum Heart Rate during 2nd trimester of pregnancy (top three) with date and time
120. Maximum Heart Rate during 3rd trimester of pregnancy (top three) with date and time
121. Minimum Systolic blood pressure during 1st trimester of pregnancy with date and time
122. Minimum Diastolic blood pressure during 1st trimester of pregnancy with date and time
123. Minimum Systolic blood pressure during 2nd trimester of pregnancy with date and time
124. Minimum Diastolic blood pressure during 2nd trimester of pregnancy with date and time
125. Minimum Systolic blood pressure during 3rd trimester of pregnancy with date and time
126. Minimum Diastolic blood pressure during 3rd trimester of pregnancy with date and time
127. Minimum Heart Rate during 1st trimester of pregnancy with date and time
128. Minimum Heart Rate during 2nd trimester of pregnancy with date and time
129. Minimum Heart Rate during 3rd trimester of pregnancy with date and time

UPH-Meriter Telehealth Screening Test

130. self-reported response to patient's depressed mood (January - March 2019)
    a. Yes
    b. No
131. PHQ-9 score (April 2019 - January 2020)