Protocol Title: Text BP: Comparing standard office based follow up versus text-based remote monitoring in the management of postpartum hypertension.

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Short title: Remote surveillance of postpartum hypertension

Brief description of protocol:
Women with hypertensive disorders of pregnancy need postpartum blood pressure (BP) surveillance to detect persistent hypertension. Various barriers result in only 30% attendance at postpartum BP visits. A more effective strategy is needed. Women with hypertension of pregnancy will be randomized to either text-based monitoring or office visits. Those randomized to the intervention will receive a BP cuff and text in their BP to an automated, clinician derived, HIPAA compliant text-based algorithm.

Abstract:
Hypertension is a leading cause of maternal morbidity, mortality and obstetrical readmissions. Peak blood pressure usually occurs 3-6 days postpartum, and is typically unaccompanied by warning symptoms. Although there is a clear need for effective and reliable blood pressure surveillance after delivery, there are significant obstacles to in-person visits in the immediate postpartum period, including sleep deprivation, newborn care, and transportation needs. These barriers have proven real as we observed only 30-50% attendance to office blood pressure visits following delivery. This proposal will investigate whether text-based communication between patients and providers is an effective alternative method for monitoring postpartum hypertension in at risk women.
Women with hypertensive disorders of pregnancy with access to a cell phone with unlimited text message capabilities will be randomized to either office visit blood pressure checks after discharge or receive a blood pressure cuff and text in blood pressures for two weeks postpartum using a standardized, HIPAA compliant, physician derived automated platform.

Objectives
Overall objectives:
The objective of this study is to compare office based blood pressure visits (standard of care) to remote surveillance using a text-messaging system for monitoring postpartum hypertension. The goal of this study is to determine if text messaging is an effective, patient centered way to monitor blood pressure in the postpartum period. By supporting patient self-care and using health information technology, we hope to adopt a method that can achieve best outcomes in our current patient, largely underserved minority population.
Primary outcome variables:
The primary outcome is the percentage of patients in which a single blood pressure is obtained in the first 10 days following discharge. Within the texting group, the percentage of patients in whom blood pressures values are obtained at 72 hours and 7-10 days postpartum, in accordance with ACOG recommendations, will be assessed as well.
Secondary outcome variables:
Secondary outcomes will include ability of providers to initiate antihypertensive medication, number of postpartum emergency room visits for hypertension and readmissions for persistent postpartum hypertension, patient satisfaction with blood pressure surveillance, and future health awareness/patient engagement by assessing number of patients with a primary care/cardiology appointment scheduled by two weeks postpartum. Additionally, cost data will be compared between the two arms.

Background:
Hypertensive disease is a leading cause of maternal morbidity and mortality and obstetrical readmissions in the US, accounting for 27% of the obstetric readmissions in 2009. The majority of patients readmitted with hypertension are diagnosed with a hypertensive disorder of pregnancy on initial admission for delivery, indicating that these readmissions result from disease progression in contrast to new onset disease, and are plausibly preventable. Given the risk of strokes and seizures from persistent or worsening disease, early recognition of progression and aggressive treatment is critical in the postpartum period. For these reasons, identifying patients who are at risk for persistent disease and being proactive in their postpartum care can decrease maternal morbidity.

Current evidence suggests that delayed mobilization of interstitial and extravascular fluid into the intravascular space predisposes women with preeclampsia to sustained hypertension, explaining the increase in blood pressure 3-6 days postpartum. This peak blood pressure postpartum usually occurs after obstetric discharge. Therefore, identification of patients at the optimal time, early enough that intervention can prevent readmission and maternal morbidity and mortality but not too early where intervention may be unnecessary, is critical. As such, the recent ACOG Hypertension in Pregnancy guidelines recommend monitoring blood pressure at 72 hours postpartum and again in 7 to 10 days in women diagnosed with a hypertensive disease of pregnancy. However, there are no recommendations on how to accomplish this.

Currently, all patients with known hypertension or a diagnosis of hypertensive disorder of pregnancy receive 1:1 nursing education about preeclampsia using an approved patient education sheet prior to discharge. Anti-hypertensive agents are initiated as needed based on a standard blood pressure based algorithm. All patients are then instructed to follow up in the office where they received prenatal care 4-6 days postpartum for a blood pressure visit. Given the difference in average length of stay, this equates to post discharge days 3-5 for patients who underwent vaginal delivery and days 2-4 for patients who underwent a cesarean delivery.

While surveillance during this time period is critical, a standard visit based approach has not proven effective in this population of newly delivered women. There are significant obstacles to in-person visits in the immediate postpartum period, including sleep deprivation, care of a newborn, difficulty with transportation, and discomforts due to post-delivery recovery. These barriers have proven real as we observed only 30-50% attendance to in-person, office based blood pressure visits scheduled immediately postpartum over the last 2 years. Utilizing text messaging for surveillance plausibly addresses some of the barriers unique to this population.

Given the significant morbidity and mortality attributable to preeclampsia and persistent and progressive postpartum disease coupled with 1) the observation that postpartum hypertension is the leading cause of obstetrical readmissions (over 45% of all readmissions within 7 days in Fiscal Year 14) and 2) our current surveillance is inadequate and generally reaches fewer than half of all women at risk, we sought to test an innovative approach to surveillance using sms-text messaging as an alternative to in-person follow up.

With support and partnership through the Penn Medicine Center for Health Care Innovation, we previously performed a small pilot study of 32 women with hypertensive disorders of pregnancy. The goal of this initial pilot was to determine if we could engage patients in remote postpartum hypertension surveillance and obtain important and necessary preparatory patient feedback to develop this proposal. Patients were provided with a home blood pressure cuff and were instructed on its use.

They were asked to send in blood pressures on the seven days following discharge from the hospital after their delivery. We found that 84% of the patients engaged in the study and texted at least one blood pressure in the 7 days and nearly 65% of patients sent in blood pressures on 5 of the 7 days requested. Of the 32 patients in the pilot, only six (19%) returned for their scheduled office blood pressure check (routine care). Patients reported that text messaging was an active way for them to participate in their care and increased their awareness of postpartum hypertension.

While we found remote surveillance of blood pressure with mobile phone texting to be a feasible, convenient, affordable, and patient-centered way for patients and providers to monitor blood pressure in the postpartum period, further testing is needed prior to widespread adoption. We have since developed a bidirectional, HIPAA compliant, clinician derived, automated text based hypertension algorithm that provides reminders to patients to text in blood pressures, timely automated responses to patient texts based on a preset clinical blood pressure algorithm, and alerts clinicians to preset high blood pressure values that require response. We have already tested this with seven patients and received feedback ensuring its functionality.

Using this two-way text based clinician derived automated hypertension algorithm, we will perform a randomized controlled trial comparing the effectiveness of these two strategies usual visit based care to this text based innovative strategy. Our overall goal is to improve postpartum blood pressure monitoring in women with a previously diagnosed hypertensive disorder of pregnancy. If, in fact, text message surveillance decreases maternal morbidity and readmissions, this would have large implications for patient care and enhance the way we perform postpartum blood pressure monitoring. Additionally, this has potential generalizability to other populations that require frequent blood pressure monitoring (adult cardiovascular, heart failure, etc.) as well as possible use in monitoring other postpartum conditions (depression, breastfeeding).

Study design
Design:
The study will be an un-blinded randomized, two arm trial. Patient will be randomized to usual one time office visit based blood pressure check or to text-message based remote surveillance for two weeks. Randomization will be performed using a computer generated sequence using REDCAP. Demographic information will be collected from those who decline randomization or are ineligible in order to assess patient characteristics of those willing to be randomized and who meet eligibility.

Study duration:
Estimated length of time is 12 months. We believe it will take no more than 9 months to enroll all of the patients and allow three months for data analysis. This is based on our previous ability to enroll patients in a pilot study investigating remote surveillance. The subjects will participate in the study for two weeks (14 days) following discharge if they are randomized to the text-message arm.

Resources necessary for human research protections:
The research staff will include Maternal Fetal Medicine fellows and attendings and the Maternal and Child Health Research inpatient clinical research team. We have a Maternal and Child Health Research program in our OBGYN department with an established track record of successful recruitment in the antepartum, intrapartum, and postpartum periods. Patients will be recruited by Maternal Fetal Medicine fellows (primarily Dr. Hirshberg), with assistance from the postpartum nursing leadership and inpatient clinical research coordinators within MCHRP. Recruitment for the pilot mentioned above occurred with assistance from the womens health postpartum nursing leadership. The research

coordinators will enroll into the WaytoHealth Texting Platform. Data collection will be performed by Dr. Hirshberg.

The population will be approached on the postpartum recovery floor prior to discharge. The blood pressure cuffs will be stored on the postpartum unit and patients will be instructed on use if they are randomized to the text-message arm.

A Maternal Fetal Medicine nurse, with assistance from Dr. Hirshberg, will respond to elevated blood pressures that are sent in the text message arm and clinical staff at the practices will check office blood pressures as currently designed for those in the standard of care arm. All research staff and those involved in responding to blood pressures will receive education regarding the protocol and their duties prior to the start of the study.

Target population:
Postpartum women with a diagnosis of chronic hypertension, gestational hypertension, or preeclampsia will be eligible for the study.

Subjects enrolled by Penn Researchers:
206

Accrual:
This study will take place at the Hospital of the University of Pennsylvania (HUP). We perform approximately 4200 deliveries annually. Our patient population is primarily from the surrounding urban region. The majority receives prenatal care at our institution and 10% are unregistered at our hospital. Based on fiscal year 2014 at HUP, 68% of patients were African American, and 10% of patients had preeclampsia and would be potentially eligible. Therefore, about 420 women annually have a hypertensive disorder and would be eligible for this proposed study.

Our sample size calculation is based on the show rate for office blood pressure visits since initiation of this standard of care and the results from our pilot study. The range of show rates in these office visits is 30-50% and our preliminary data suggests that approximately 80% of patients text at least one blood pressure in the 7 days post discharge. Using a more conservative usual care show rate of 50%, with an alpha of 0.05, 80% power and using a 2-sided t-test, we would require 103 patients in each arm to detect this 1.4 fold increase blood pressure ascertainment.

Key inclusion criteria:
Women with chronic hypertension, gestational hypertension, or preeclampsia who deliver at HUP will be eligible. All patients must be 18 years old, able to speak and read English, have a hypertension diagnosis listed above, and have access to a cell phone with unlimited text message capabilities.
Key exclusion criteria:

Women without access to a cell phone with unlimited text message capabilities will be excluded from the study in order to eliminate barriers to participate in remote surveillance. However, we will track the number of women not eligible for this reason in order to understand generalizability in an urban population. Women who cannot read or speak English or are younger than 18 years of age will be ineligible.

Populations vulnerable to undue influence or coercion:

Patients will specifically be told what arm they are in following randomization. Those not randomized to text-messaging and those electing not to participate will receive the current standard of care (office based visit).

Subject recruitment:
Eligibility will be determined in the postpartum period on the postpartum recovery unit by the research team which will include the Maternal Fetal Medicine fellows, the MCHRP inpatient clinical research coordinator team, and postpartum nursing leadership (see eligibility algorithm). Women will be approached at time of their routine hypertension education, prior to discharge, by the research coordinators. Enrollment in the study will take place at this time if they agree, and entry into the automated platform will occur prior to discharge for those randomized to this arm. Those randomized to usual care will receive their office visit date/time prior to discharge.

Subject compensation:
None

Procedures:
The study will be performed as a pilot randomized control trial. Patients will be randomized to either having routine office based blood pressure check visit or to remote text-message based surveillance using a previously developed automated algorithm (WaytoHealth). Study flow chart is attached. Postpartum patients with a hypertensive disorder of pregnancy will be approached for enrollment by trained study personnel on the recovery unit. Participates will be randomized 1:1 using a computer generated random number table of permuted blocks. Recruitment will occur prior to discharge at time of hypertension education and randomization will occur once consent is obtained.
Those randomized to the standard protocol for blood pressure monitoring will be scheduled for an office based nursing blood pressure visits 4-6 days postpartum. The date and time of the office appointment is specified in the discharge document and reviewed with the patient prior to discharge. Care at this visit is based on a physician derived algorithm. Women randomized to the text-based surveillance arm will be given an automatic Omron© blood pressure cuff and instructed on its use by research team members prior to discharge. Patients will be enrolled into the texting program platform developed through Way to Health. A starting introductory text message is sent by the Way to Health platform to the phone number provided on day of discharge. Patients receive reminders to text message their blood pressures twice daily for two weeks postpartum, starting on the day after discharge. Immediate feedback is provided to the patient based on a preprogrammed automated algorithm. The primary investigator is alerted with pre-specified severe range blood pressure values (systolic blood pressure > 160 mmHg or diastolic > 100 mmHg) via text message or email and care is escalated as needed based on the same outpatient algorithm used in the office. All patients will receive a phone call 3 weeks after delivery for a patient satisfaction survey. All patients will be instructed to return for their usual postpartum visit at 4-6 weeks.

Analysis plan:
Chi square or Fishers exact test will be used to compare categorical data. T-test will be used to compare parametric data. Mann-Whitney U test will be used to compare non-parametric data. Univariate comparisons will be made between exposure and outcome. Multivariable logistic regression models will be created to control for potential confounders. Outcomes will be analyzed by the intention to treat principle.

Subject confidentiality:

Participant's private information will be viewed by study personnel only. All information collected as part of the research study will be placed into a database which will be kept on a password protected computer which can be accessed by the PI and key personnel only. Each study subject will be assigned a study number.

The consent form will include statements informing subjects that privacy of information sent through text messaging cannot be guaranteed and that only blood pressure values should be sent to the platform. Only the minimum information necessary is placed in the text messages to reduce the chance of anyone seeing details about the patient and their health. Patients will be encouraged to put a screen lock on their device.

Subject privacy:
All recruitment, informed consent, and conversations related to study participation will be performed in private work spaces. Patient randomized to the text message arm will sign a waiver stating that privacy of information sent through text messaging cannot be guaranteed and that only blood pressure values should be sent to the platform. Only the minimum information necessary is placed in the text messages to reduce the chance of anyone seeing details about the patient and their health. Patients will be encouraged to put a screen lock on their device.

Consent process
Overview:
Consent will be obtained by the study investigators or assigned research staff when receiving postpartum hypertension education prior to discharge. The study will be explained in lay person terms to each eligible woman by one of the investigators or assigned research staff. The consent form will be given to the patient and she will have ample time to read the consent form on her own. The woman will be asked if she has any questions regarding the study protocol or the consent form. All questions will be answered. The woman will be informed that her care will not be affected if she chooses not to participate in the study and that she may discontinue participation at any time point. She will be made aware of what is needed in the intervention arm including taking her blood pressure and texting the result either once or twice daily for seven days after discharge from the hospital. She will be told a text message will be sent every morning saying "Good morning. Please send us a morning blood pressure reading." and that she will receive a text message back based on the value of her reading. Women will be informed that while the platform is HIPAA compliant, text messaging is not a completely secure means of communication.

Potential study risks:
There is a risk of loss of confidentiality in patients randomized to the intervention arm as texting technology was not built for secure communications. Therefore, privacy of information sent through text messaging cannot be completely guaranteed. However, as texting has the potential to be a more patient-centered, effective means of remote surveillance, we believe the potential benefits outweigh the risks. Additionally, patients will only be texting blood pressure readings and responses in the text messages have minimum information necessary to reduce the chance of someone else seeing any details about their health. The platform includes only the patient's name and cell phone number, each matched to a study ID number. The privacy policy of WaytoHealth ensures that no information shared with the site will be sold or distributed and the site is password protected. Patients will be encouraged to have a security lock on their phones. As only those with unlimited texting services will be included in the study, there is no additional financial cost to receiving or sending text messages.
Potential study benefits:

Potential benefits include improved patients centered means of monitoring blood pressure in the postpartum period. It is unclear whether remote surveillance with text messaging improves blood pressure ascertainment and can reduce morbidity so both arms have the potential benefit of being in the more effective treatment arm.

Alternatives to participation:
Alternatives to participation involves having office based blood pressure checks per usual practice.

Data and safety monitoring: PI

Risk/benefit assessment: There is minimal risk to participation in this study. Women may directly benefit from participation in the study related to improved blood pressure surveillance in the immediate postpartum period.