Using Bluetooth Home Blood Pressure Monitors with Pharmacist Interventions to Manage Uncontrolled Hypertension in the Community Setting – A Pilot Study

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1. RATIONALE

What We Know:

- Hypertension (HTN) is a major public health concern in the United States as there is wide prevalence, high cost, and poor rates of control
- Self-monitoring of blood pressure (BP) can be helpful for both treatment decisions and evaluating response to treatment
- Hand transmitted BP logs are often inaccurate, with large under-reporting of BP
- White-coat HTN and masked HTN are frequent, and are associated with adverse cardiovascular outcomes
- Evidence that telemonitoring interventions can be effective
- Team-based care including pharmacists can improve BP management
- Home BP monitoring, mobile health interventions and referrals to clinical pharmacists for BP management have all shown potential to be effective intervention strategies

What We Don't Know:

- Available evidence suggests a potential for added benefit with community pharmacists' intervention in HTN, but the true effect is uncertain due to poor study quality, inconsistent results and potential for publication bias (systematic review 2015)
- The impact of pharmacists interventions on cardiovascular disease (CVD) is not quantitatively and qualitatively known
- The impact of pharmacist counseling of adult patients with out-of-control HTN, with managing their telemonitoring blood pressure readings

2. BACKGROUND

Hypertension (HTN) places a significant burden on the health care system in the United States. Over thirty percent of adults over the age of 20 are either taking an antihypertensive agent and/or have hypertensive blood pressure (BP).[1] It is well-known that the risk of cardiovascular disease (CVD) is increased in patients with high blood pressure. Additionally, in 2015, the number of deaths from essential hypertension and hypertensive renal disease was 32,200 or 10 of every 100,000 people in the general population and physicians saw over 42.7 million patients with diagnosed hypertension.[2,3]

In 2017, the American College of Cardiology (ACC) and the American Heart Association (AHA) Task Force on Clinical Practice Guidelines released a guideline that calls for tighter blood pressure control in hypertensive patients. By this guideline, blood pressure above 130/80 mmHg requires treatment with medications for patients who are at high risk for cardiovascular disease.[4] However, the guideline also heavily focuses on non-pharmacological interventions, which play an important role in blood pressure reduction. Recommendations include weight loss for those who are overweight or obese, adopting a heart-healthy diet, sodium reduction, potassium supplementation for those who have increased blood pressure or hypertension, increased physical activity, and limitation of alcohol consumption.

Besides lifestyle modifications, the guideline also places an increased emphasis on self-monitoring of blood pressure. Although there is currently limited evidence to show blood pressure reduction for patients who measure blood pressure at home, the authors of the guideline comment on its benefit because of inconsistencies between home and in-office readings. Home blood pressure monitoring also provides immediate feedback to patients on control.[5] In a systematic review regarding self-monitoring of blood pressure, it was found that self-monitoring of BP worked best when combined with more intensive interventions, such as lifestyle counseling.[6]

Telemonitoring, also known as telemedicine, is defined as the use of health informatics, disease management, and home telehealth technologies to enhance the health of individuals and populations. Results with using remote blood pressure monitors are mixed, however the 2017 ACC/AHA guideline recommends telehealth strategies as useful adjuncts for blood pressure control.[7,8] It is surmised that the mixed results for telemonitoring may be dependent on the extent of patient education and involvement in using the devices.

Pharmacists, working alongside other healthcare providers can help reduce blood pressure in patients with hypertension.[9] Clinical pharmacists can instruct patients on lifestyle modifications, proper blood pressure measurement techniques and medication management. Several studies have shown the benefit of web-based pharmacist care with home blood pressure monitoring for improvement of blood pressure in a clinic setting.[5,10,11] Pharmacists providing lifestyle counseling to patients with hypertension have also helped patients lower their blood pressure more than patients without pharmacist's counseling, as well as improving patient quality of life.[12,13] Because of the strong evidence showing improvement in blood pressure with interventions by both ambulatory care and community pharmacists, collaboration between pharmacists across practice settings may also be beneficial, however further research is needed to demonstrate this.[14]

3. STUDY OBJECTIVES

Primary Objective

- To produce preliminary data to design a larger, funded study

Secondary Objectives

- To assess patient comfort in using home telemonitoring for blood pressure combined with pharmacist counseling and monitoring using a survey instrument with a Likert scale
- To assess the ability to collect and monitor hypertension data using Bluetooth enabled mobile health technology
- To determine if blood pressure readings improve with pharmacist interventions

4. STUDY DESIGN

This is a pragmatic before and after trial with the patient serving as their own control

5. STUDY POPULATION

We are aiming to enroll 20 patient participants for this pilot study. To be eligible for participation, enrollees must be ≥ 18 years old, have a smartphone compatible with the mobile intervention, have been previously diagnosed with hypertension, have uncontrolled hypertension (SBP > 130 mmHg and/or DBP > 80 mmHg), be under the care of a primary care physician in the Family Medicine

Department of the USF Morsani Center for Advanced Care, have had at least one prescription filled at Pharmacy Plus within the last six months, and speak English fluently.

Patients will be excluded if they are already under the care of a clinical pharmacist in the Family Medicine department, are pregnant, or have a serious existing medical condition(s) that may affect their ability to self-monitor their blood pressure (for example, stroke, dementia).

Recruitment

A list of potential patients (Family Medicine patients with diagnosis of hypertension who have had at least one prescription filled at Pharmacy Plus within the last 6 months) will be generated by the Epic support team and identified through the electronic medical records system as well as the pharmacy prescription database. The pharmacists from Pharmacy Plus on this study or 4th year pharmacy students on their Ambulatory Care or Community Pharmacy Rotation will call patients on this list and will discover if the patient meets the final qualification for the study (has a smart phone or other smart device) and is interested in being a part of the study. This is not cold calling, as this list includes eligible patients who have had a prescription filled at Pharmacy Plus within the last 6 months. Each patient on this list has interacted with the pharmacists at Pharmacy Plus when the medication was dispensed. The pharmacists have an established relationship with these patients, as they are involved with the care of these patients. They are involved with the treatment of these patients as they provide pharmacy services when dispensing medications and counseling the patients, as well as some medical services such as vaccine administration.. Dr. Karim Hanna, who practices in the Family Medicine department, is the physician on this study and is aware that these patients will be contacted via phone. We will not be obtaining verbal consent to participate during this phone call.

Enrollment

Patients interested in participating in the study will be scheduled for a one-hour in-person appointment at the clinic site, where they will be asked for consent for participation in the study. The informed consent process will be completed by the study coordinator or a study pharmacist, (all who have successfully passed CITI training) in a face-to-face session with the patient. The pharmacist will explain the consent form in detail, with opportunities along the way for the patient to ask questions. The pharmacist will check, at proper points, for confirmation of understanding.

6. INTERVENTIONS

Devices

- Smart Phones with Apple Health Software will be used to monitor blood pressure once a day, and results will be sent automatically to the patients EHR (Epic)
- The Omron 10 Series Wireless Upper Arm Blood Pressure Device will be given to the patient to monitor blood pressure at home daily

Pre- and Post-surveys

- A pre- and post-survey will be given at the initial and final in-person appointments, respectively
- These surveys will collect basic patient demographics, knowledge of blood pressure, comfort with checking blood pressure at home, and previous experience working with a pharmacist

Pharmacist Management

- Review of evidence-based therapy and recommendations for improvement if needed
- Educate the patients on how to monitor their blood pressure with their Bluetooth enabled home blood pressure monitor and smart phones

- Patients will be scheduled for a one-hour in-person appointment for the initial study visit where informed consent will be obtained, and for the final study visit
    - At the final study visit, the patients will complete a post-study survey and be given a $25 gift card upon return of the blood pressure device
- Review results once per week
    - If any patient has an SBP reading > 160 mmHg or DBP > 100 mmHg, they will be instructed to wait five minutes and then recheck their BP. If the BP readings exceed these thresholds for three days in a row, the patients should contact their primary care provider in the clinic for further management.
    - If SBP > 180 mmHg and/or DBP > 120 mmHg, patients will be instructed to call 911 or have someone drive them to the ER immediately
    - There will not be alerts sent to the study pharmacists if the blood pressure readings are above these thresholds
- Follow-up with patients once per week for six (6) weeks via scheduled 20-minute telehealth appointment with each patient via the HIPAA secure and compliant platform, VSee
    - During this telehealth appointment, the study pharmacists will counsel the patients on their blood pressure readings for that week and provide lifestyle education focusing on patient-specific diet and exercise recommendations
- The total duration of the study will be eight (8) weeks

7. EXPECTED RESULTS

The Hypotheses – It is expected that:

- The study will be able to produce data in order to design a larger, funded study
- Patients will express comfort in using home telemonitoring
- The pharmacists will be able to collect and monitor hypertension data using mobile health technology
- A statistically significant ($p < 0.05$) greater proportion of patients in the after study period will be in proper control of their hypertension (< 130/80 mmHg) than in the before study period

8. STUDY INVESTIGATORS

- Principal Investigator and Project Coordinator
    - Wendy Updike, Pharm.D., BCPS, Assistant Professor, College of Pharmacy
- Co-Investigators
    - Olivia Pane, Pharm.D., Assistant Professor, College of Pharmacy
    - Mariam Gendi, Pharm.D., Pharmacy Manager, Pharmacy Plus, USF Morsani Center
    - Rossina Chevasco, PharmD, Assistant Pharmacy Manager, Pharmacy Plus, USF Morsani Center
    - William Kelly, Pharm.D., FISPE, Professor, College of Pharmacy
    - Kevin Sneed, Pharm.D, Dean and Professor, College of Pharmacy
    - Karim Hanna, M.D., Assistant Professor, College of Medicine

9. POTENTIAL RISKS TO PATIENTS

We anticipate minimal risk for patients. In fact, our study seeks to improve safety for patients through the use of a home monitoring device with integration to the electronic health record. Participation in this study is voluntary and refusal to participate will not result in penalties or loss of care.

Although measures will be in place to minimize risk, it is possible that health information could be improperly disclosed. We will gather only essential information necessary to complete the study.

10. BENEFITS/OUTCOMES

Potential benefits may include:

- Patients may have better knowledge and control of their BP
- Pharmacists may feel good about helping patients improve their BP
- Patients may have a more trusting relationship with their pharmacist
- The Family Medicine Department might improve BP outcomes and quality of care
- There may be less morbidity and mortality from out-of-control BP
- Patients may be satisfied with home telemedicine

11. DATA MANAGEMENT AND ANALYSIS

- Primary Objective: Preliminary data to design a larger, funded study
    - Captured data and information will be collected in such a way as to make it useful for putting forth a cogent argument for a larger effort.
- BP readings will be captured automatically in Epic
- Mean BP readings will be calculated and compared for the pre- and post-periods, as will the number of patients in and out of blood pressure control
- Pre- and post-study data will be analyzed using a comparison of means (2-tail t-test) and chi-square for comparing low compliant patients (for using the devices) with high compliant patients. The post-study patient satisfaction data will be analyzed using descriptive statistics.

12. HUMAN SUBJECT CONSIDERATIONS

The study does not include any vulnerable populations needing added protection beyond the routine. The study population age range (≥ 18 years) will be considered by making sure all study patients understand the study purpose, their role, and our expectations. We will take time to make sure consenting patients want to use telemonitoring and understand how to use the devices. Pharmacists will call patients to answer any questions once they start using the devices, and when they have not monitored their blood pressure in the last 48 hours.

Privacy and confidentially, based on the Pharmacist Oath, will be maintained always. Informed consent documents will be kept in a locked drawer within a locked office in the Primary Investigator's office for 5 years. After 5 years, these documents will be destroyed through the University shredder. Pharmacists will be conscious to not expose patient information on computer monitors with patient information showing when unattended.

13. SAFETY MONITORING PLAN

<u>Data Capture</u>

- Survey data will be captured through Qualtrics and then stored in RedCAP
- Blood pressure results will be transmitted through a secure portal within Apple Health from the patient's mobile device to the EHR system, Epic. This process has already been approved and released through USF Health IT.

- The safety of the patient will be our primary concern. All procedures, including patient consent will be carefully performed and double checked by the study coordinator. We will encourage and answer all question from patients.

14. REFERENCES

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